EC DECLARATIONO F CONFORMITY

Leqal Entitv:
Vitrex Medical AIS
Vaseker 6-8
2730 Herlev
Denmark

Notified Bodv:
LNE/G-MED
1 , rue Gaston Boissier
F-75724P arisC edex' t5
France

VitrexM edicalA ,/Sd eclarest hat their rangeo f steriled isposableb loodl ancetsa re in Conformitwy itht he EssentiaRl equiremenatsn dp roceduresse to uti n AnnexV section3 of the CouncilD irective9 3l42lEEC.

Product Name	REF
Vitrex@S TEELS terileB loodL ancets2. 00 pcs.	350213
Vitrex@S OFTS terileB loodL ancets2, 3G,2 00 pcs.	351213
vitrex@S OFTS terileB loodL ancets2, 8G,2 00 pcs.	352213
Vitrex@S OFTS terileB loodL ancets3. 0G.2 00 Dcs.	354213
Vitrex@S OFTS terileB loodL ancets3, 2G,2 00 pcs.	357213
Vitrex@C OMPACTE JECTI ancinqd evicew ithD ushb uttone iection	369300
Vitrex@S terilanceL ITES terileS afetvL ancets1. 8G- 'l.2mmY ellow,1 00p cs.	38311 3
Vitre)@S terilanceL ITES terileS afetvL ancets2. 6G- 1.8mm- Pink,1 00p cs.	38411 3
Vitrex@S terilanceL ITES terileS afetvL ancets2. 1G- 1.8mm- Blue,1 00p cs.	38511 3
Vitrex@S terifanceL ITES terileS afetyL ancets2, 1G- 2.4mm - Grey,1 00p cs.	38611 3
Vitrex@S terilanceL ITES terileS afetvL ancets2. 1G- 2.8mm- Green.1 00D cs.	387113
Vitrex@S terilanceL ITEl I SterileS afetvL ancets1. 8G- 1-8mm- Green,1 00p cs.	373113
Vitrex@S terilanceL ITEl I SterileS afetyL ancets2, 8G- 1.8m m - Purple,1 00p cs.	374113
Vitre)i@S terilanceL ITEl I SterileS afeUL ancets2, 6G- 1.8m m - Yellow,1 00p cs.	375113
Vitrex@S terilanceL ITEl I SterileS afetvL ancets2, 6G- 2.4 mm- Blue,1 00p cs.	376113
Vitrex@S terilancLel TEl I SterileS afetvL ancets2,1 G- 1.8m m- Orange1, 00p cs.	377113
Vitrex@S terilanceL ITEl I SterileS afetvL ancets2. 1G- 2-4 mm - Pink,1 00p cs.	378113
Vitrex@S terilancPeR ESSS terileS afetvL ancets1. 8G- 1.8mm- Green1, 00p cs-	39311 3
Vitrex@S terilanceP RESSS terileS afetvL ancets2, 6G- 1.8mm- Yellow,1 00 pcs.	39411 3
Vitrex@S terilanceP RESSS terileS afetyL ancets2, 1G- Z2mm - Orange,1 00p cs.	395113
Vitrex@S terilanceP RESSS terileS afetvL ancets2, 1G- 2.8mm- Pink,1 00p cs.	39611 3
Vitrex@S terilanceF LEXS terileS afetvL ancets2. 6G- 1.2- 1. 8 - 2.4mm- Blue,1 00p cs.	399913
Vitrex@S teriheeBl abvc uttinqs afetvl ancet1 .Ommd epthi2,5mmle ngth- vellow,5 0 pcs.	333113
Vitrex@S teriheeBl abvc uttinqs afetvl ancet0 .85mmd epth/1.75mmle nqth- orange,5 0 pcs.	33411 3

The Productsa re classifieda s Classl la, accordingto rule6 of the Directive9 3l42lEEC, and are coveredb y the devicec ategoryo f the CertificateN ' 10349R evision2 , issuedb y LNE/G -MEDo n 15-01-201a0n dv alidu nti0l 7-01-2016.

Date: 06-01-2013
VITREX MEDICAL A/S

Peter Jørgensen
Quality and System Manager

Versta iš anglų kalbos

EB ATITIKTIES DEKLARACIJA

Juridinis Subjektas:
Vitrex Medical A/S
Vasekaer 6-8
2730 Herlev
Danija

Notifikuotoji Įstaiga:
LNE/G-MED
1, rue Gaston Boissier
F-75724 Paris Cedex 15
Prancūzija

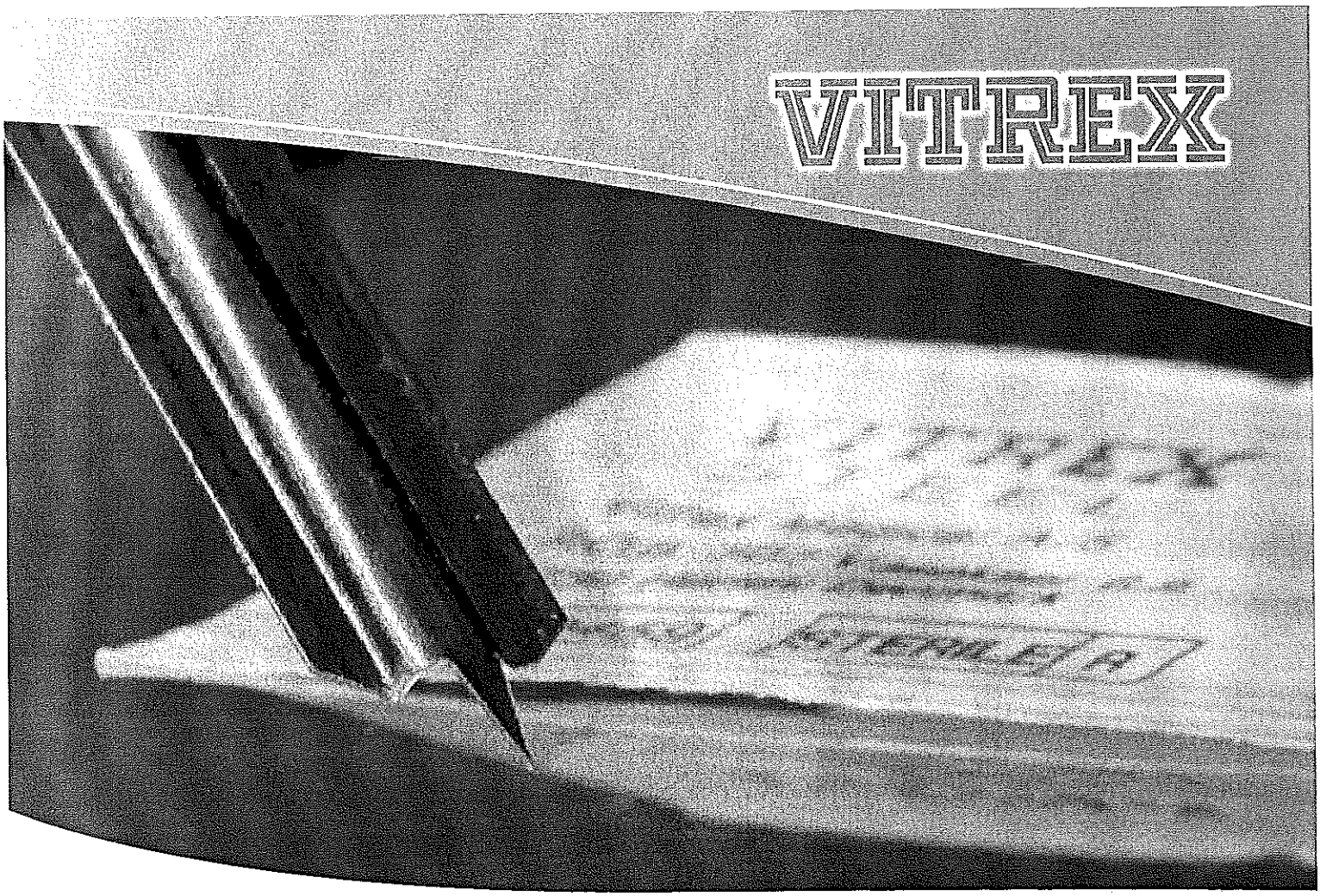
Vitrex Medical A/S pareiškia, kad jų sterilių vienkartinių kraujo lancetų asortimentas atitinka būtinus Tarybos Direktyvos 93/42/EEB reikalavimus ir procedūras, išdėstytus Priede V, skirsnyje 3.

Produkto pavadinimas	Kat. Nr.
Vitrex® STEEL Sterilūs Kraujo Lancetai, 200 vnt.	350213
Vitrex® SOFT Sterilūs Kraujo Lancetai, 23G, 200 vnt.	351213
Vitrex® SOFT Sterilūs Kraujo Lancetai, 28G, 200 vnt.	352213
Vitrex® SOFT Sterilūs Kraujo Lancetai, 30G, 200 vnt.	354213
Vitrex® SOFT Sterilūs Kraujo Lancetai, 32G, 200 vnt.	357213
Vitrex® COMPACT EJECT pradūriklis su paspaudžiamu numetimo mygtuku	369300
Vitrex® Sterilance LITE Sterilūs Saugūs Lancetai, 18G - 1.2mm - Geltoni, 100 vnt.	383113
Vitrex® Sterilance LITE Sterilūs Saugūs Lancetai, 26G - 1.8mm - Rožiniai, 100 vnt.	384113
Vitrex® Sterilance LITE Sterilūs Saugūs Lancetai, 21G - 1.8mm - Mėlyni, 100 vnt.	385113
Vitrex® Sterilance LITE Sterilūs Saugūs Lancetai, 21G - 2.4mm - Pilki, 100 vnt.	386113
Vitrex® Sterilance LITE Sterilūs Saugūs Lancetai, 21G - 2.8mm - Žali, 100 vnt.	387113
Vitrex® Sterilance LITE II Sterilūs Saugūs Lancetai, 18G - 1.8mm - Žali, 100 vnt.	373113
Vitrex® Sterilance LITE II Sterilūs Saugūs Lancetai, 28G - 1.8mm - Violetiniai, 100 vnt.	374113
Vitrex® Sterilance LITE II Sterilūs Saugūs Lancetai, 26G - 1.8mm - Geltoni, 100 vnt.	375113
Vitrex® Sterilance LITE II Sterilūs Saugūs Lancetai, 26G - 2.4mm - Mėlyni, 100 vnt.	376113
Vitrex® Sterilance LITE II Sterilūs Saugūs Lancetai, 21G - 1.8mm - Oranžiniai, 100 vnt.	377113
Vitrex® Sterilance LITE II Sterilūs Saugūs Lancetai, 21G - 2.4mm - Rožiniai, 100 vnt.	378113
Vitrex® Sterilance PRESS Sterilūs Saugūs Lancetai, 18G - 1.8mm - Žali, 100 vnt.	393113
Vitrex® Sterilance PRESS Sterilūs Saugūs Lancetai, 26G - 1.8mm - Geltoni, 100 vnt.	394113
Vitrex® Sterilance PRESS Sterilūs Saugūs Lancetai, 21G - 2.2mm - Oranžiniai, 100 vnt.	395113
Vitrex® Sterilance PRESS Sterilūs Saugūs Lancetai, 21G - 2.8mm - Rožiniai, 100 vnt.	396113
Vitrex® Sterilance FLEX Sterilūs Saugūs Lancetai, 26G - 1.2 – 1.8 – 2.4mm - Mėlyni, 100 vnt.	399913
Vitrex® Steriheel Baby cutting Saugus lancetas 1.0mm gylio/2,5mm ilgio – geltonas, 50 vnt.	333113
Vitrex® Steriheel Baby cutting Saugus lancetas 0.85mm gylio/1.75mm ilgio – oranžinis, 50 vnt.	334113

Produktai klasifikuojami kaip Klasė IIa, pagal Direktyvos 93/42/EEB taisyklę 6, ir jie patenka į prietaiso kategorijos grupę Sertifikate Nr. 10349 Leidimas 2, išduotas LNE/G-MED 2010-01-15 ir galiojantis iki 2016-01-07.

Išversta teisingai
Su LR BK 295 str. susipažinęs
Vertėjas:
Parašas:
Patento numeris:

Data: 2013-01-06
Vitrex Medical A/S
<PARAŠAS>
Peter Jørgensen
Kokybės ir Sistemos Vadovas



Vitrex® Steel

General Purpose Capillary Blood Lancet

LOW COST
Simple, flat, steel lancet.

SAMPLE VOLUME
Excellent blood flow.

HIGH QUALITY
Hardened surgical steel.

MINIMUM DISCOMFORT
Modern asymetric design.

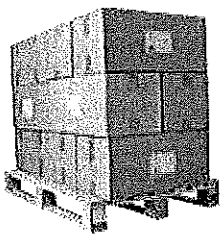
STERILE
Sterilised by gamma radiation to EN 556 and EN ISO 11137.

Technical Specs.

Product	Description	Article No.
Vitrex Steel	Flat blade sterile lancet	350213

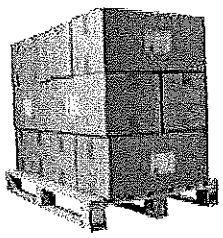
Packaging:

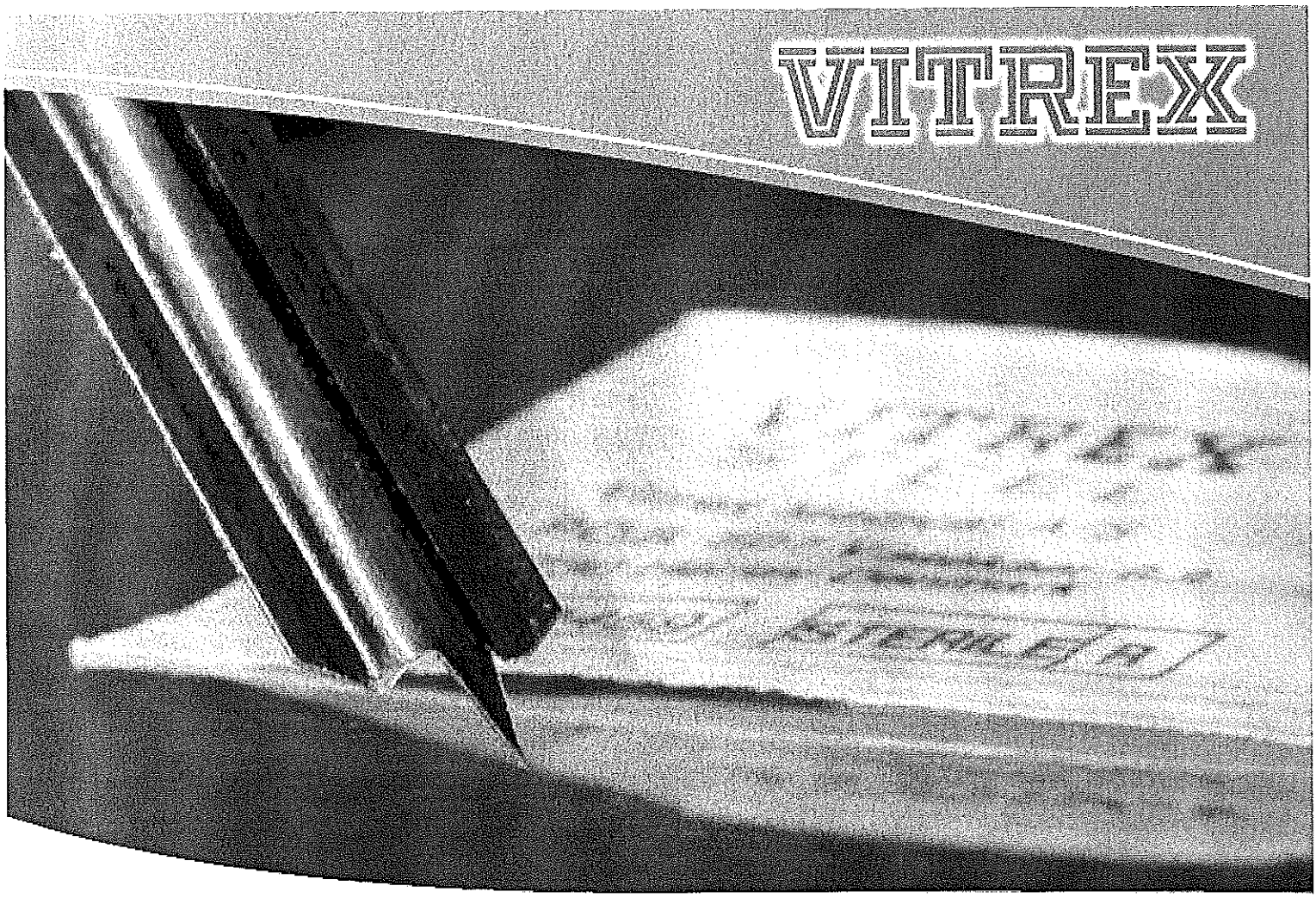
Primary packaging:	200 pcs
Secondary packaging:	10000 pcs
Transit packaging:	40000 pcs
Pallet:	720000 pcs



Transit packaging

Pallet





Vitrex® Steel

Bendros paskirties kapiliarinio kraujo lancetas

MAŽA KAINA
Paprastas plokščias plieninis lancetas.

MĖGINIO KIEKIS
Puiki kraujo tėkmė.

AUKŠTA KOKYBĖ
Sukietintas chirurginis plienas.

MINIMALUS DISKOMFORTAS
Modernus asimetriškas dizainas.

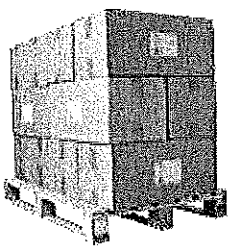
STERILUS
Sterilizuotas gama spinduliais pagal EN 556 ir EN ISO 11137.

Techninės specifikacijos

Produktas	Aprašymas	Produkto nr.
Vitrex Steel	Sterilus lancetas plokščiais ašmenimis	350213

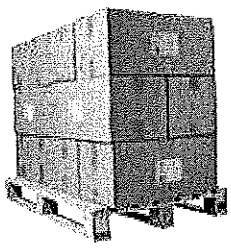
Pakuotė:

Pirminė pakuotė:	200	vnt.
Antrinė pakuotė:	10000	vnt.
Pervežimo pakuotė:	40000	vnt.
Paletė:	720000	vnt.



Pervežimo pakuotė

Paletė



#266

OWEN MUMFORD

Brook Hill, Woodstock, Oxfordshire
OX20 1TU, United Kingdom
T: +44 (0)1993 812021
F: +44 (0)1993 813466
E: info@owenmumford.co.uk
www.owenmumford.com

18th June 2013

POWER OF ATTORNEY

To Whom It May Concern,

Owen Mumford Ltd, Brook Hill, Woodstock, Oxfordshire, U.K., a company established and operating under the laws of the United Kingdom with registered office at Brook Hill Woodstock (the 'Company'), hereby entrust: **Interlux Co. Ltd. Avieciu str. 16, LT-08418 Vilnius, Lithuania,** to represent the Company in connection with all questions that relate to the registration of the medical device as detailed below, submitted in Lithuania by the Company.

- **Unistik 3 Normal**
- **Unistik 3 Extra**
- **Unistik 3 Comfort**
- **Unistik 3 Laboratory & Neonatal**

For such purposes, **Interlux Co. Ltd.** is empowered to submit all necessary documents, to sign on behalf of the Company any documents associated with such registration, to make any necessary changes to such documents – with the prior approval of the Company - and perform all other actions connected with fulfilling these legal acts.

Interlux Co. Ltd., in the name of Owen Mumford Ltd, is entitled to:

1. Undertake any actions necessary to obtain registration of the named Owen Mumford Ltd branded products with the relevant regulatory authorities.
2. Distribute the named products.
3. Act in Lithuania as a responsible body for obligations for the producer concerning the named products.

The present Power of Attorney shall be valid until further notice from the date of execution.

Mr. Richard Thomas
Sales & Marketing Director

For and on behalf of Owen Mumford Ltd.

OWEN MUMFORD

Brook Hill, Woodstock, Oxfordshire
OX20 1TU, Didžioji Britanija
Tel.: +44(0)1993 812021
Faks.: +44(0)1993 813466
El. paštas: info@owenmumford.co.uk
www.owenmumford.com

2013 birželio 18 d.

ĮGALIOJIMAS

Tiems, kam tai gali rūpėti,

Owen Mumford Ltd, Brook Hill, Woodstock, Oxfordshire, D. Britanija, kuri įkurta ir veikia pagal Didžiosios Britanijos įstatymus, turinti būstinę Brook Hill Woodstock(toliau vadinama „Kompanija"), patiki: **UAB „INTERLUX", Aviečių g. 16, LT-08418 Vilnius, Lietuva,** atstovauti KOMPANIJĄ dėl visų iškilusių klausimų susijusių su žemiau pateiktų medicinos prietaisų registracija.

- Unistik 3 normal;
- Unistik 3 extra;
- Unistik 3 comfort;
- Unistik 3 laboratory & neonatal.

Dėl tokių priežasčių, **UAB „INTERLUX"** yra įgaliota tvirtinti visus reikalingus dokumentus, pasirašyti KOMPANIJOS vardu visus dokumentus, kurie susiję su registracija, daryti visus reikalingus pakeitimus dokumentuose – su KOMPANIJOS patvirtinimu – ir atlikti visus kitus veiksmus, kurie reikalingi užpildant atitinkamus teisinius dokumentus.

UAB „INTERLUX", Owen Mumford Ltd vardu, yra įgalioti:

1. Imtis visų reikalingų veiksmų atliekant įvardintų kompanijos Owen Mumford Ltd produktų registraciją;
2. Platinti įvardintus produktus;
3. Lietuvoje būti atsakinga organizacija įsipareigojant gamintojui dėl įvardintų produktų.

Šis įgaliojimas turi galioti iki kito pareiškimo nuo įsigaliojimo datos.

Išversta teisingai
Su LR BK 295 str. susipažinęs
Vertėjas
Parašas
Patento numeris

Ponas Adam Mumford
Pardavimų ir rinkodaros direktorius

Owen Mumford Ltd. Vardu.

OWEN MUMFORD LTD
Brook Hill Woodstock
Oxfordshire OX20 1TU England
Tel: +44 (0) 1993 812021
Fax: +44 (0) 1993 813466
Fax: +44 (0) 1993 813473 - Sales
E-mail: info@owenmumford.co.uk
www.owenmumford.com

EC MEDICAL DEVICE DIRECTIVE

DECLARATION OF CONFORMITY

I hereby declare that the **Unistik 3 PC** family of medical devices as listed below, is in conformity with the essential requirements of the Council Directive 93/42/EEC.

Product Codes:

AT1001CA000/K – Unistik 3 PC Normal – Sample pack of 30.
AT1002CA000/K – Unistik 3 PC Normal - 100 in a dispenser.
AT1003CA000/K – Unistik 3 PC Normal – 1000 in a case.
AT1004CA000/K – Unistik 3 PC Normal – 200 in a dispenser.

AT1011CA000/K – Unistik 3 PC Extra – Sample pack of 30
AT1012CA000/K – Unistik 3 PC Extra – 100 in a dispenser
AT1014CA000/K – Unistik 3 PC Extra – 200 in a dispenser

AT1041CA000/K – Unistik 3 PC Comfort – Sample pack of 30
AT1042CA000/K – Unistik 3 PC Comfort – 100 in a dispenser
AT1043CA000/K – Unistik 3 PC Comfort – 1000 in a case
AT1044CA000/K – Unistik 3 PC Comfort – 200 in a dispenser
AT1046CA000 – Unistik 3 PC Comfort – 4 in a blister pack

AT1051CA000/K – Unistik 3 PC Neonatal – Sample pack of 30
AT1052CA000/K – Unistik 3 PC Neonatal – 100 in a dispenser
AT1056CA000 – Unistik 3 PC Neonatal – 4 in a blister pack

Classification of the device under Annex IX of the directive:

♦ Class:	IIa
♦ Term:	Transient Use
♦ Invasive:	Invasive
♦ Rule:	6
♦ Conformity assessment route:	Annex II (excluding section 4).

The quality system established and maintained by Owen Mumford Limited along with the relevant technical documentation is periodically reviewed by SGS United Kingdom Limited, Unit 202B, Worle Parkway, Weston-Super-Mare, Somerset, BS22 6WA. Notified body number CE 0120.

Signed..... Date 26/04/06

S D Miles
Corporate Quality & Regulatory Manager

For A J Mumford

Managing Director

OWEN MUMFORD LTD
Brook Hill Woodstock Oxfordshire OX20 1TU England Tel: +44 (0) 1993 812021 Faks: +44(0)1993 813466 Faks: +44 (0) 1993 813473 – pardavimų el. pašto adresas: into@owenmumford.co.uk
www.owenmumford.com

Versta iš anglų kalbos

EB MEDICININIŲ PRIETAISŲ DIREKTYVA

ATITIKTIES DEKLARACIJA

Patvirtinu, kad **Unistik 3 PC** šeimos medicininiai prietaisai, išvardinti žemiau, atitinka pagrindinius Tarybos Direktyvos 93/42/EEB reikalavimus.

Produktų Kodai:

AT1001CA000/K - Unistik 3 PC Normal – 30 pakuotėje
AT1002CA000/K - Unistik 3 PC Normal -100 dalytuve.
AT1003CAOOO/K - Unistik 3 PC Normal -1000 dėžutėje.
AT1004CA000/K - Unistik 3 PC Normal - 200 dalytuve.

AT1011CA000/K - Unistik 3 PC Extra - 30 pakuotėje.
AT1012CA000/K - Unistik 3 PC Extra - 100 dalytuve.
AT1014CA000/K - Unistik 3 PC Extra - 200 dalytuve.

AT1041CA000/K - Unistik 3 PC Comfort - 30 pakuotėje.
AT1042CA000/K - Unistik 3 PC Comfort - 100 dalytuve.
AT1043CA000/K - Unistik 3 PC Comfort - 1000 dėžutėje.
AT1044CA000/K - Unistik 3 PC Comfort - 200 dalytuve.
AT1046CA000 - Unistik 3 PC Comfort - 4 lizdinėje plokštelėje.

AT1051CA000/K-Unistik 3 PC Neonatal - 30 pakuotėje.
AT10S2CA000/K - Unistik 3 PC Neonatal -100 dalytuve.
AT1056CA000 - Unistik 3 PC Neonatal - 4 lizdinėje plokštelėje.

Prietaiso klasifikavimas pagal direktyvos IX Skirsnį.

- Klasė: IIa
- Trukmė: Trumpalaikis naudojimas
- Invazinis: Invazinis
- Norma: 6
- Atitikties įvertinimo būdas: Skirsnis **II** (išskyrus 4 skyrių).

Išversta teisingai
Su LR BK 295 str. susipažinęs
Vertėjas:
Parašas:
Patento numeris: 0625 63

Owen Mumford Limited sukurta ir palaikoma kokybės sistema, kartu su atitinkama technine dokumentacija, periodiškai yra peržiūrima SGS United Kingdom Limited, Unit 202B, Worle Parkway, Weston-Super-Mare, Somerset, BS22 6WA. Notifikuotosios įstaigos numeris CE 0120.

Pasirašė .... . ----------

Data 2006/04/26

S D Miles
Kokybės & Reguliavimo Vadybininkas

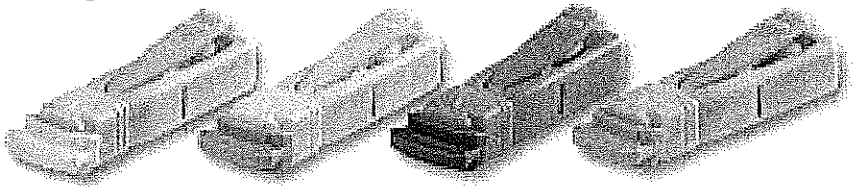
A J Mumfordui

Generaliniam Direktoriui

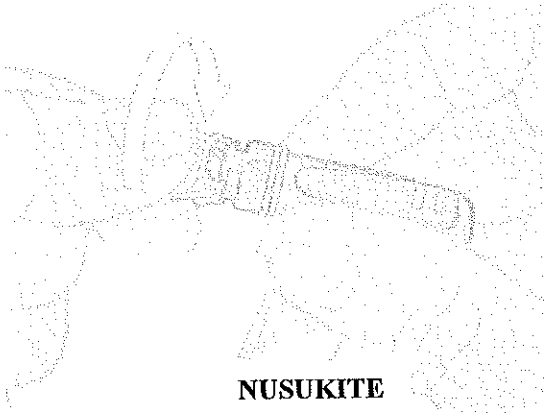
OFICIALUSIS ATSTOVAS LIETUVOJE
interlux
Aviečių 16, LT-08418 VILNIUS
Tel. (8~5) 278 68 50,
Faks. (8~5) 279 67 28
El. paštas: spirit@interlux.lt

unistik 3

saugūs-automatiniai lancetai

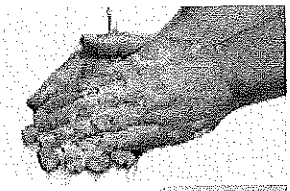


Naudojimas

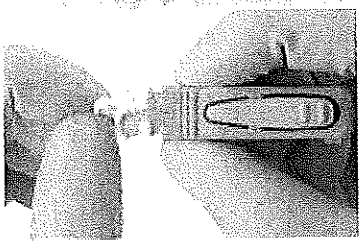


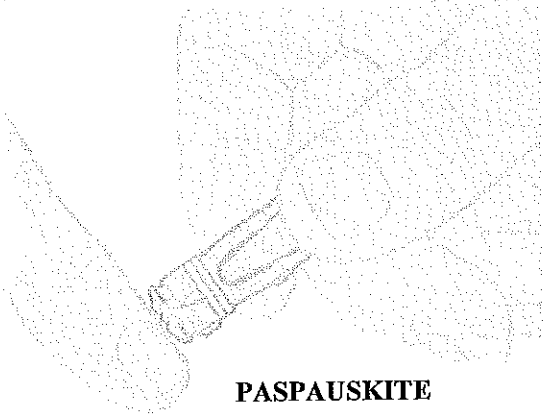
NUSUKITE

1. Nusiplaukite rankas.



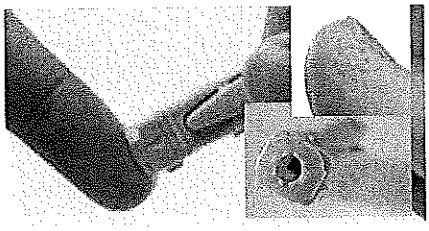
2. Nusukite apsauginį laikiklį.

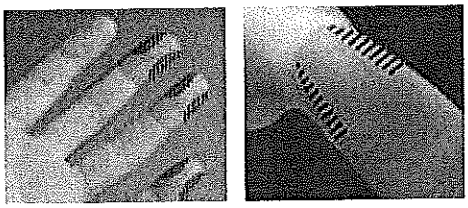


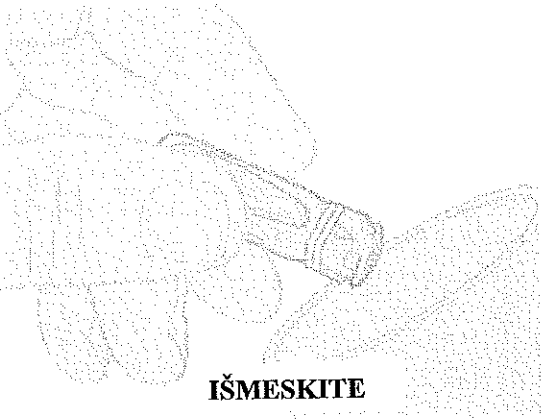


PASPAUSKITE

3. Tvirtai prispauskite lanceto galą prie pirštogaliuko arba kulniuko nurodytose vietose (žr. pav.) ir paspauskite lanceto korpuse esančią auselę.

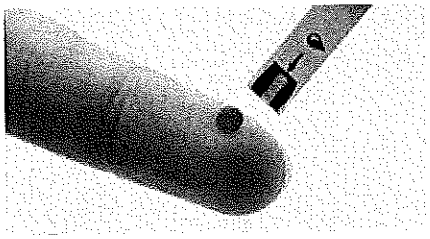




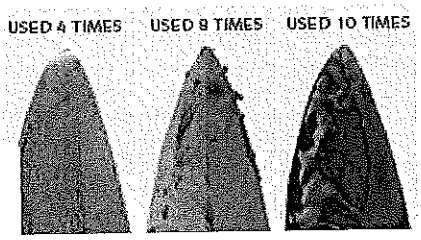


IŠMESKITE

4. Švelniai masažuodami piršto galiuką formuokite reikiamą kraujo mėginio kiekį.



5. Išmeskite panaudotą lancetą į atliekų konteinerį.



6. Lancetai yra vienkartinio naudojimo.

Naudojimo principas: vienkartinio naudojimo, saugu tiek pacientui, tiek personalui, paspaudus mygtuką suveikia spyruoklinis mechanizmas ir išaunama adatėlė, kuri po dūrio sugrįžta į pradinę padėtį.
Lanceto gale esantys 8 iškilę taškeliai stimuliuoja nervų galūnėles, taip maskuojamas ir sumažinamas skausmo jausmas, kurį sukelia lancetas dūrio metu. Galima naudoti tiek pirštui įdurti, tiek vaikams i kulniuką.

CE 0120

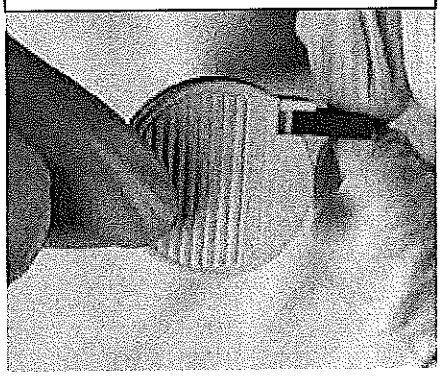
Owen Mumford Ltd.
Oxword OX20 1TU, Jungtinė Karalystė

OFICIALUSIS ATSTOVAS LIETUVOJE
interlux
Aviečių 16, LT-08418 VILNIUS
Tel. (8~5) 278 68 50,
Faks. (8~5) 279 67 28
El. paštas: spirit@interlux.lt

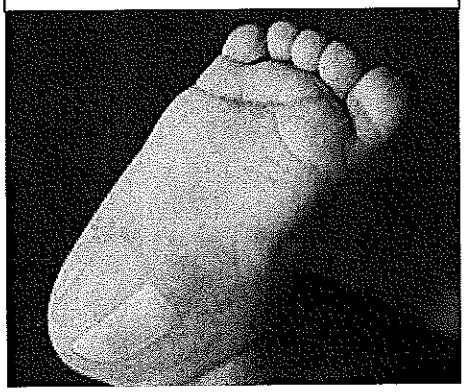
Vitrex Steriheel Baby
saugūs-automatiniai lancetai

Naudojimas

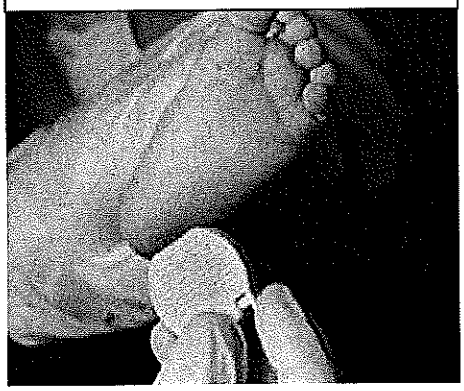
1. Nuimkite apsauginį laikiklį.



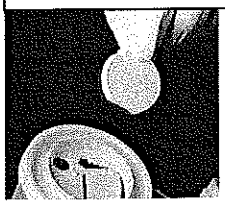
2. Rekomenduojama dūrio vieta naujagimiams nurodyta paveiksliuke.



3. Tvirtai priglauskite lancetą prie dūrio vietos ir paspauskite lanceto paleidimo auselę.



4. Išmeskite lancetą.

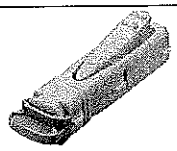
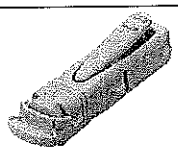
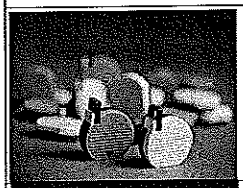
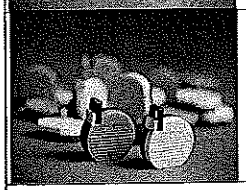
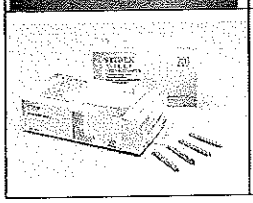


CE 0197
EC REP

Vitrex Medical A/S.
P.O. Box 507, Vasekaer 6-8
2730 Harlev, Danija

SteriLance Medical (Suzhou) Inc., Kinija

Emergo Europe
Molenstraat, 15-2513 BH The Hague, Olandija

	Saugūs-automatiniai poodiniai lancetai	Pakuotė vnt.	Techninės specifikacijos
	**Unistik 3 *Extra*** 21G x 2,00 mm (oranžiniai) Vidutiniškai 75-125 µl kraujo	100 lancetų	Saugūs lancetai, su automatiniu dūrio mechanizmu, 21Gx2,00mm (vidutiniškai 75-125 µl kraujo), adatelė smaigalio formos, dūrio perimetras 0,8mm
	**Unistik 3 *Laboratory&Neonatal*** 18G x 1,8 mm (mėlyni) Vidutiniškai 200 µl+ kraujo	100 lancetų	Saugūs lancetai, su automatiniu dūrio mechanizmu, 18Gx1,8mm (vidutiniškai 200 µl ir daugiau kraujo), adatelė ašmens formos, dūrio perimetras 1,2mm
	**Vitrex Steriheel Baby *** sterilūs, naujagimiams, adatelė ašmens formos gylis 0,85mm x skersmuo 1,75mm	1 lancetas	Saugūs lancetai naujagimiams, su automatiniu dūrio mechanizmu, sterilūs, adatelė ašmens formos gylis 0,85mm x skersmuo 1,75mm
	**Vitrex Steriheel Baby *** sterilūs, naujagimiams, adatelė ašmens formos gylis 1,00mm x skersmuo 2,5mm	1 lancetas	Saugūs lancetai naujagimiams, su automatiniu dūrio mechanizmu, sterilūs, adatelė ašmens formos gylis 0,85mm x skersmuo 1,75mm
	**Vitrex Steel Lancet** (plieniniai skarifikatoriai)	200 lancetų	Skarifikatoriai plieniniai, bendra ilgis ne maziau 49mm, dūrio gylis ne mažiau 3mm, sterilūs DIN EN 552/556, kiekvienas individualiame įpakavime

248

Bio-Rad
Medical Diagnostics GmbH

Industriestr. 1, D-63303 Dreieich,
Germany
Telefon : +49 (0) 6103 3130-0
Telefax :+49 (0) 6103 3130-724

Bio-Rad Medical Diagnostics GmbH · P.O.Box 10 21 50 · 63267 Dreieich

TO WHOM IT MAY CONCERN

Tel.: +49 (0) 6103-3130 743
Fax: +49 (0) 6103-3130 724
michael_bauer@bio-rad.com

12 January 2015

A member of the Bio-Rad Group

Letter of Authorization

We, Bio-Rad Medical Diagnostics GmbH (BMD) hereby confirm that Interlux Ltd., Avieciu Str. 16, LT-08418 Vilnius is our exclusive distributor in the territory of Lithuania for BMD transfusion- and transplantation product line.

This authorization shall expire on December 31st 2015.

Kind regards

Bio-Rad Medical Diagnostics GmbH

i.V.
Martin Demand
Area Manager

i.A.
Michael Bauer
Export & Logistics

Bio-Rad Medical Diagnostics GmbH P.O. Dėžutė 10 21 50 – 63267 Dreieich

-tiems, kuriems svarbu-

Tel: +49 (0) 6103 – 801 138
Faks.: +49 (0) 6103 – 801 724
volker_schwind@bio-rad.com

2015 m. sausio mėn. 12 d.

Bio-Rad grupės narys

Įgaliojimo laiškas

Mes, Bio-Rad Medical Diagnostics GmbH (BMD), patvirtiname, kad UAB „Interlux“, Aviečių g. 16, LT-08418 Vilnius, yra išskirtinis mūsų atstovas Lietuvos teritorijoje BMD transfuzijos ir transplantacijos produktams.

Šis įgaliojimas galioja iki 2015 metų gruodžio 31 dienos.

Pagarbiai,

Bio-Rad Medical Diagnostics GmbH

<PARAŠAS>

i. V Martin Demand
Regiono vadybininkas

<PARAŠAS>

i. A Michael Bauer
Klientų aptarnavimas eksporto klausimais

Vertimo patvirtinimas

Aš, VAIDAS VILMANTAS

vertimų verslo liudijimo nr. MK 478428-1 savininkas patvirtinu, kad patikrinau Lietuvių kalbos vertimą

BIO-RAD atstovavimo sertifikatas
(vertimo pavadinimas)

iš Anglų kalbos dokumento

BIO-RAD Letter of Authorization
(originalaus dokumento pavadinimas)

pagal savo žinias ir įsitikinimus.

Tekstas yra išverstas teisingai ir tiksliai bei be pakeitimų prasmėje.

Aš esu užtikrintas, kad Lietuvių kalbos vertimas atitinka originalų dokumentą.

VILNIUS, LIETUVA 2015-01-12
(Vieta/data) (parašas)

ZERTIFIKAT ◆ CERTIFICATE ◆ 認証書 ◆ СЕРТИФИКАТ ◆ CERTIFICADO ◆ CERTIFICAT

148

Product Service

EC Certificate

Full Quality Assurance System

Directive 98/79/EC on In Vitro Diagnostic Medical Devices (IVDD), Annex IV excluding (4, 6)
(List A and B and devices for self-testing)

No. V1 11 05 40330 107

Manufacturer:
DiaMed GmbH
Pra Rond 23
1785 Cressier FR
SWITZERLAND

Facility(ies):
DiaMed GmbH
Pra Rond 23, 1785 Cressier FR, SWITZERLAND

Product Category(ies):
Products for blood typing
ABO, Rh, Kell, Duffy, Kidd, irregular anti RBC antibodies

Model(s):
- **DiaMed ID Microtyping System (cards, reagents, cells)**
- **DiaMed MP-Test (microplates, sera, cells)**
- **Products for conventional testing (sera, reagents, cells)**

For details on the Annex II List A-products see respective Design-Examination Certificates.
For details on the Annex II List B-products see attachment.

The Certification Body of TÜV SÜD Product Service GmbH declares that the aforementioned manufacturer has implemented a quality assurance system for design, manufacture and final inspection of the respective devices / device families in accordance with IVDD Annex IV. This quality assurance system conforms to the requirements of this Directive and is subject to periodical surveillance. For marketing of List A devices an additional Annex IV (4) certificate is mandatory. See also notes overleaf.

Report no.: 71384748

Valid from: 2011-07-31
Valid until: 2016-07-30

420439

Date, 2011-07-18

Hans-Heiner Junker

TÜV SÜD Product Service GmbH is Notified Body with identification no. 0123

TÜV SÜD Product Service GmbH · Zertifizierstelle · Ridlerstraße 65 · 80339 München · Germany

TÜV®

Product Service

Attachment for Certificate no V1 11 05 40330 107 dated 2011-07-18

Several Annex II List A devices as specified in the corresponding design examination certificates and the following Annex II list B devices:

DiaMed-ID Micro Typing cards:

Ident-No. 50531: ID-LISS/Coombs
Ident-No. 50270: ID-DiaClon Anti-Jk^a
Ident-No. 50280: ID-DiaClon Anti-Jk^b
Ident-No. 51250: ID-DiaClon Anti-Jk^a / -Jk^b
Ident-No. 51270: ID-Card Anti-Fy^a / -Fy^b
Ident-No. 50350: ID-Card Anti-Fy^a
Ident-No. 50360: ID-Card Anti-Fy^b
Ident-No. 50380: ID-Antigen profile II
Ident-No. 50390: ID-Antigen profile III
Ident-No. 50510: ID-Reverse grouping with antibody screening
Ident-No. 50571: ID-DiaScreen
Ident-No. 50581: ID- LISS/Coombs+Enzyme test
Ident-No. 50550: ID- Reverse grouping + Antibody Screening 4/2
Ident-No. 50540: ID- Coombs Anti -IgG
Ident-No. 50549: ID- Coombs Anti -IgG

Reagents and test sera for the DiaMed-ID Micro Typing System:

Ident-No. 09210: ID-Anti Fy^a
Ident-No. 09310: ID-Anti Fy^b
Ident-No. 45140: ID-Testsera Anti-M,-N,-S,-s,-Fya,-Fyb (6x1,4ml)
Ident-No. 45460: ID-Testsera Anti-M,-N,-S,-s,-Fya,-Fyb (6x5,0ml)
Ident-No. 46180: ID-Testsera Anti-Fy^a / Anti-Fy^b

Test cells for the DiaMed-ID Micro Typing System:

Ident-No. 45184: ID-DiaCell I-II-III (3x10ml)
Ident-No. 45404: ID-DiaCell I-II-III (3x5ml)
Ident-No. 45330: ID-DiaCell I-II-III Asia
Ident-No. 45194: ID-DiaCell I-II-III P (3x10ml)
Ident-No. 45414: ID-DiaCell I-II-III P (3x5ml)
Ident-No. 45151: ID-DiaCell I-II
Ident-No. 06070: ID-DiaCell Pool
Ident-No. 45161: ID-DiaPanel
Ident-No. 45171: ID-DiaPanel-P
Ident-No. 05980: ID-Di^a (Diego) positive

TÜV SÜD Product Service GmbH · Zertifizierstelle · Ridlerstraße 65 · 80339 München · Germany

TÜV®

ZERTIFIKAT ◆ CERTIFICATE ◆ 認証書 ◆ СЕРТИФИКАТ ◆ CERTIFICADO ◆ CERTIFICAT

Product Service

Attachment for Certificate no V1 11 05 40330 107
dated 2011-07-18

Ident-No. 06291: ID I- negative cell
Ident-No. 45070: ID-DiaScreen I-VI
Ident-No. 45200: ID-DiaScreen I-IV

Ident-No. 45210: ID-DiaScreen V+VI
Ident-No. 45660 ID-DiaScreen Prophylax
Ident-No. 45670 ID-DiaPanel Plus 6

DiaClon blood grouping reagents:
Ident-No. 17620: DiaClon Anti-Jk^{a}
Ident-No. 17720: DiaClon Anti-Jk^{b}
Ident-No. 14070: DiaClon Coombs-serum uncolored
Ident-No. 14060: DiaClon Coombs-serum green

Polyclonal blood grouping reagents:
Ident-No. 14710: Coombs-serum IgG
Ident-No. 16070: Coombs-control IgG
Ident-No. 17610: Anti-Jk^{a} human
Ident-No. 17710: Anti-Jk^{b} human
Ident-No. 19210: Anti-Fy^{a} human
Ident-No. 19310: Anti-Fy^{b} human

Test cells:
Ident-No. 16080: DiaCell Di^{a+} (Diego) positiv
Ident-No. 45220: DiaCell I+II
Ident-No. 45230: DiaCell I+II+III
Ident-No. 45241: DiaPanel
Ident-No. 06060: ID-DiaCell SF

Munich, CRT-2, 2011-07-18

Hans-Heiner Junker

MÜNCHEN TÜV SÜD PRODUCT SERVICE

TÜV SÜD Product Service GmbH · Zertifizierstelle · Ridlerstraße 65 · 80339 München · Germany

TÜV®

A1 / 12.09

Product Service

EB Sertifikatas

Visiška kokybės užtikrinimo sistema

98/79/EC direktyva in vitro diagnostiniams medicinos prietaisams (IVDD), IV priedas
Išskyrus (4, 6)
(A ir B sąrašas ir prietaisai skirti savęs tikrinimui)

Nr. V1 11 05 40330 107

Gamintojas:	**DiaMed GmbH** Pra Rond 23 1785 Cressier FR Šveicarija
Infrastruktūra:	DiaMed GmbH Pra Rond 23, 1785 Cressier FR, Šveicarija
Produktų Kategorija(os):	**Produktai kraujo tipo nustatymui** **ABO, Rh Kell, Duffy, Kidd, nevienodi anti RBC antikūnai**
Modelis(iai):	**-DiaMed ID Mikrotipavimo sistema** **(kortelės, reagentai, ląstelės)** **-DiaMed MP-Test** **(mikroplokštelės, serumas, ląstelės)** **-Produktai, skirti įprastiniams testams** **(serumas, reagentai, ląstelės)** **Detali informacija, skirta II priedo A sąrašo produktams, pateikta atitinkamuose dizaino-tyrimo sertifikatuose.** **Detali informacija, skirta II priedo B sąrašo produktas pateikta prisegtame dokumente.**

Notifikuotoji įstaiga TÜV SÜD Product Service GmbH patvirtina, kad aukščiau minėtas gamintojas įdiegė atitinkamų prietaisų/prietaisų kategorijų kūrimo, gamybos ir galutinio įvertinimo kokybės užtikrinimo sistemą pagal MPD Priedo II reikalavimus. Ši kokybės užtikrinimo sistema atitinka šios Direktyvos reikalavimus ir turi būti periodiškai prižiūrima. Prekybai III klasės prietaisai papildomai būtinas Priedo II (4) sertifikatas. Žiūrėkite pastabas kitame lape.

Ataskaitos nr.:	71384748
Galioja nuo:	2011-07-31
Galioja iki:	2016-07-30

420439

Data, 2011-07-18

TUV SUD Product Service GmbH yra patvirtinimo agentūra su identifikacijos nr.: 0123

Product Service

Priedas prie sertifikato nr.: V1 11 05 40330 107
datuoto 2011-07-18

Keletas II priedo A sąrašo įrenginių, kaip apibūdinama atitinkame dizaino tyrime, sertifikuoja ir kitos II priedo B sąrašo įrenginius.

Diamed-ID Mikro tipavimo kortelės:

Identifikacinis nr.: 50531:	ID-LISS/Coombs
Identifikacinis nr.: 50270:	ID-DiaClon Anti-Jk^a
Identifikacinis nr.: 50280:	ID-DiaClon Anti-Jk^b
Identifikacinis nr.: 51250:	ID-DiaClon Anti-Jk^a/- Jk^b
Identifikacinis nr.: 51270:	ID-Card Anti-Fy^a/- Fy^b
Identifikacinis nr.: 50350:	ID-Card Anti-Fy^a
Identifikacinis nr.: 50360:	ID-Card Anti-Fy^b
Identifikacinis nr.: 50380:	ID-Antigne Profile II
Identifikacinis nr.: 50390:	ID-Antigne Profile III
Identifikacinis nr.: 50510:	ID-Atvirkštinis grupavimas su antikūnių atvaizdavimu
Identifikacinis nr.: 50571:	ID-DiaScreen
Identifikacinis nr.: 50581:	ID-LISS/Coombs+Enzimų testas
Identifikacinis nr.: 50550:	ID-Atvirkštinis grupavimas + Antikūnių atvaizdavimas 4/2
Identifikacinis nr.: 50540:	ID-Coombs Anti-IgG
Identifikacinis nr.: 50549:	ID-Coombs Anti-IgG

Reagentai ir testų serumas, skirtas DiaMed-ID mikro tipavimo sistemai:

Identifikacinis nr.: 09210:	ID-Anti Fy^a
Identifikacinis nr.: 09310:	ID-Anti Fy^b
Identifikacinis nr.: 45140:	ID-Testsera Anti-M,-N,-S,-s,-Fya,-Fyb (6x1,4ml)
Identifikacinis nr.: 45460:	ID-Testsera Anti-M,-N,-S,-s,-Fya,-Fyb (6x5,0ml)
Identifikacinis nr.: 46180:	ID-Testsera Anti-Fy^a/- Fy^b

Testų ląstelės, skirtos DiaMed-ID Mikro tipavimo sistemai:

Identifikacinis nr.: 45184:	ID-DiaCell I-II-III (3x10ml)
Identifikacinis nr.: 45404:	ID-DiaCell I-II-III (3x5ml)
Identifikacinis nr.: 45330:	ID-DiaCell I-II-III Asia
Identifikacinis nr.: 45194:	ID-DiaCell I-II-III P (3x10ml)
Identifikacinis nr.: 45414:	ID-DiaCell I-II-III P (3x5ml)
Identifikacinis nr.: 45151:	ID-DiaCell I-II
Identifikacinis nr.: 06070:	ID-DiaCell Pool
Identifikacinis nr.: 45161:	ID-DiaPanel
Identifikacinis nr.: 45171:	ID-DiaPanel-P
Identifikacinis nr.: 05980:	ID-Di^a (Diego) teigiamas

Product Service

Priedas prie sertifikato nr.: V1 11 05 40330 107 datuoto 2011-07-18

Identifikacinis nr.: 06291:	ID I-neigiamos ląstelės
Identifikacinis nr.: 45070:	ID-DiaScreen I-VI
Identifikacinis nr.: 45200:	ID-DiaScreen I-IV
Identifikacinis nr.: 45210:	ID-DiaScreen V+VI
Identifikacinis nr.: 45660:	ID-DiaSceen Prophylax
Identifikacinis nr.: 45670:	ID-DiaPanel Plus 6

DiaClon kraujo grupavimo reagentai:

Identifikacinis nr.: 17620:	DiaClon Anti-Jk^a
Identifikacinis nr.: 17720:	DiaClon Anti-Jk^b
Identifikacinis nr.: 14070:	DiaClon Coombs-nespalvotas serumas
Identifikacinis nr.: 14060:	DiaClon Coombs-žalias serumas

Poliklonaliniai kraujo grupavimo reagentai:

Identifikacinis nr.: 14710:	Coombs-serumas IgG
Identifikacinis nr.: 16070:	Coombs-kontrolė IgG
Identifikacinis nr.: 17610:	Anti-Jk^a žmogus
Identifikacinis nr.: 17710:	Anti-Jk^b žmogus
Identifikacinis nr.: 19210:	Anti-Fy^a žmogus
Identifikacinis nr.: 19310:	Anti-Fy^b žmogus

Testų ląstelės:

Identifikacinis nr.: 16080:	DiaCell Di^{a+} (Diego) teigiamas
Identifikacinis nr.: 45220:	DiaCell I+II
Identifikacinis nr.: 45230:	DiaCell I+II+III
Identifikacinis nr.: 45241:	DiaPanel
Identifikacinis nr.: 06060:	ID-DiaCell SF

Išversta teisingai
Su LR BK 295 str. susipažinęs
Vertėjas:
Parašas:
Patento numeris: 000250

Miunchenas, CRT-2, 2011-07-18

LISS/Coombs

ID-Card

English B004014 05.10

Indirect and direct antiglobulin test

Product-Identification: 50531

INTRODUCTION

Polyspecific anti-human globulin (AHG) reagents are used for routine alloantibody detection and identification, compatibility tests and the direct antiglobulin test (DAT).

The most important function of the polyspecific AHG reagent is to detect the presence of IgG. The importance of anticomplement in the AHG reagent is debatable since antibodies detectable only by their ability to bind complement are rather rare. However, anti-C3d activity is important for the DAT in the investigation of autoimmune haemolytic anaemia (AIHA) [4]. A positive DAT generally indicates that the red cells are coated in vivo with immunoglobulin and/or complement.

The microtubes of the ID-Card "LISS/Coombs" contain polyspecific AHG, to be used for antibody screening, antibody identification, crossmatch and the DAT. For the indirect antiglobulin test (IAT), labour intensive washing procedures are eliminated, due to the fact that the red cell suspension is added to the microtube before the plasma/serum, creating a barrier over the gel suspension, thus avoiding neutralization of the AHG by serum IgG proteins.

The anti-human globulin IgG used in the ID-Card "LISS/Coombs" is not heavy chain specific and thus may also be capable of reacting with the Kappa (k) and Lambda (l) light chains of IgA and IgM molecules.

The ID-Card "LISS/Coombs" is suitable for the DAT, for the compatibility test, for antibody screening and identification with "ID-DiaCell" and "ID-DiaPanel".

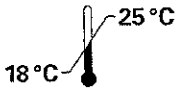
BIO-RAD

English B004014 05.10

REAGENTS

IVD

ID-Card "LISS/Coombs" with 6 microtubes containing polyspecific AHG (rabbit anti-IgG and monoclonal anti-C3d, cell line C139-9) within the gel matrix. Preservative: < 0,1% NaN_3.



Do not store near any heat, air conditioning sources or ventilation outlets.
Stability: see expiry date on label.

ADDITIONAL REAGENTS REQUIRED

- ID-Diluent 2: modified LISS for red cell suspension.
- ID-DiaCell, ID-DiaPanel: Test cell reagents.

(see related package insert)

FURTHER MATERIALS REQUIRED

- ID-Dispenser
- ID-Pipetor
- ID-Tips (pipetor tips)
- Suspension Tubes
- ID-Working table
- ID-Incubator 37 °C
- ID-Centrifuge 6, 12 or 24

#2981

BIO-RAD

SAMPLE MATERIAL

For optimal results, the determination should be performed using a freshly drawn sample, or in accordance with local laboratory procedures for sample acceptance criteria. Preferably, blood samples should be drawn into citrate, EDTA or CPD-A anticoagulant. Samples drawn into plain tubes (no anticoagulant) may also be used.
When the use of serum instead of plasma is required, the serum must be well cleared, by centrifugation at 1500 g for 10 minutes, before use avoid fibrin residues, which may interfere with the reaction pattern.

PREPARATION OF BLOOD SAMPLE

a) Red cell suspension for DAT or autocontrol
Prepare a 0,8% red cell suspension in ID-Diluent 2 as follows:
Allow the diluent to reach room temperature before use.
1. Dispense 1,0 mL of ID-Diluent 2 into a clean tube.
2. Add 10 µL of packed red cells, mix gently.

The cell suspension may be used immediately.

b) Red cell suspension for crossmatch procedures
Prepare a 0,8% red cell suspension in ID-Diluent 2 as above. Where whole blood directly from a segment of the blood bag is used, add 20 µL of blood to the 1,0 mL of ID-Diluent 2.

c) Plasma or serum for indirect antiglobulin test (IAT) procedures
Where samples are not for immediate testing they should be stored at 2-8 °C after separation (see also under "Sample material") for a maximum of 48 hours, thereafter at -20 °C or in accordance with local/national policies/ guidelines.

TEST PROCEDURES

Do not use ID-Cards which show signs of drying, have bubbles, damaged seals, drops of gel or supernatant in the upper part of the microtubes or on the underside of the aluminium foil.

I. Direct antiglobulin test (DAT)
1. Identify the appropriate microtubes of the ID-Card "LISS/Coombs" with the patient's or donor's name or number.
2. Remove the aluminium foil from as many microtubes as required by holding the ID card in the upright position.
3. Pipette 50 µL of the red cell suspension to the appropriate microtube.
4. Centrifuge the ID-Card for 10 minutes in the ID-Centrifuge.
5. Read and record the results.

II. Antibody screening (IAT)
Use ready-to-use test cell reagents "ID-DiaCell".
Allow the test cell reagents and samples to reach room temperature before use.
1. Identify the appropriate microtubes of the ID-Card "LISS/Coombs" with the patient's or donor's name or number.
2. Remove the aluminium foil from as many microtubes as required by holding the ID card in the upright position.
3. Pipette 50 µL of each test cell reagent to the appropriate microtubes (marked with the corresponding test cell).
4. When an autocontrol is to be included, pipette 50 µL of the sample's own red cell suspension to the appropriate microtube.
5. Add 25 µL of the patient's or donor's plasma or serum to each microtube.
6. Incubate the ID-Card for 15 minutes at 37 °C in the ID-Incubator.
7. Centrifuge the ID-Card for 10 minutes in the ID-Centrifuge.
8. Read and record the results.

III. Antibody Identification (IAT)
Use the ready-to-use test cell reagent "ID-DiaPanel".
Allow the test cell reagents and samples to reach room temperature before use.
1. Identify two ID-Cards "LISS/Coombs" with the patient's or donor's name or number.
2. Remove the aluminium foil from as many microtubes as required by holding the ID card in the upright position.
3. Pipette 50 µL of each "ID-DiaPanel" test cell to the appropriate microtube (marked 1 to 11).
4. Pipette 50 µL of the sample's own red cell suspension to the 12th microtube (autocontrol).
5. Add 25 µL of the patient's or donor's plasma or serum to all 12 microtubes.
6. Incubate the ID-Card for 15 minutes at 37 °C in the ID-Incubator.
7. Centrifuge the ID-Card for 10 minutes in the ID-Centrifuge.
8. Read and record the results.

IV. Compatibility test
1. Identify the appropriate microtubes of the ID-Card "LISS/Coombs" with recipient's and donor's name or number.
2. Remove the aluminium foil from as many microtubes as required by holding the ID card in the upright position.
3. Pipette 50 µL of the donor red cell suspensions to the appropriate microtubes.
4. For the autocontrol, pipette 50 µL of the patient's own red cell suspension to the appropriate microtube.
5. Add 25 µL of the patient's plasma or serum to each microtube.
6. Incubate the ID-Card for 15 minutes at 37 °C in the ID-Incubator.
7. Centrifuge the ID-Card for 10 minutes in the ID-Centrifuge.
8. Read and record the results.

INTERPRETATION OF THE RESULTS

A) Principle
Positive: Agglutinated cells forming a red line on the surface of the gel or agglutinates dispersed in the gel.

Negative: Compact button of cells on the bottom of the microtube.

B) Reactions for:
I. Direct antiglobulin test (DAT)
- A negative reaction indicates absence of detectable IgG antibodies or C3d complement component on the red cells.
- A positive reaction (± to ++++) indicates that the patient's red cells are sensitized (red cells coated with IgG antibodies and/or C3d).

II. Antibody screening
- A negative reaction indicates the absence of detectable irregular antibodies in the patient's or donor's serum or plasma.
- A positive reaction indicates the presence of irregular antibodies. Enter the reactions obtained on the antigen table. Verify that the lot number of the test cell reagents "ID-DiaCell I-II" or "ID-DiaCell I-II-III" corresponds to the lot number indicated on the antigen table.
- Following the reaction pattern and the antigen configuration, the type of antibody present may be indicated. Perform the usual further tests to identify the antibody.
- A positive reaction with one or more test cells and a negative autocontrol suggest the presence of a specific antibody (see Remarks).
- A positive reaction with all test cells and a positive autocontrol may be due to non-specific reactions.
- A positive reaction with all test cells and a positive autocontrol but with one or more test cells showing a stronger positive reaction than the autocon-

trol, the patient sample should be submitted for further testing, to investigate the possibility of an underlying allo-antibody.

III. Antibody Identification
- A positive reaction indicates the presence of irregular antibodies. Enter the reactions obtained on the antigen table. Verify that the lot number of the test cell reagents "ID-DiaPanel" corresponds to the lot number indicated on the antigen table.
- Following the reaction pattern and the antigen configuration, the type of antibody present can, in most cases, be identified (autocontrol must be negative).
- A positive reaction with all "ID-DiaPanel" test cells and a negative autocontrol may be due to non-specific reactions or may indicate the presence of an alloantibody directed against a high frequency antigen.
- A positive reaction with all "ID-DiaPanel" test cells and a positive autocontrol may be due to non-specific reactions.
- A positive reaction with all "ID-DiaPanel" test cells and the autocontrol but with one or more test cells showing stronger reactions than the autocontrol, may indicate an underlying allo-antibody and further investigation should be undertaken.

IV. Compatibility test
- A negative reaction indicates compatibility of the donor blood with the recipient.
- A positive reaction indicates incompatibility of the donor blood with the recipient, due to presence of antibodies directed against antigens on the donor red cells. Further investigation to identify the antibody specificity should be performed.

REMARKS

As for all procedures covered by GLP rules, the sensitivity of the above procedures should be validated using antibodies of known potency. The DiaMed Anti-D reference reagent provides the means to regularly perform controls for all antibody detection procedures (see related package insert).

LIMITATIONS

a) ID cards which show air bubbles or gel drops in the upper part of the microtubes and/or the seal, must be centrifuged before use.
b) Certain drugs are known to cause positive reactions in anti-human globulin procedures.
c) Some pathological conditions are also reported as causing positive reactions in anti-human globulin procedures.
d) Cells that have become polyagglutinable, due to cryptantigen exposure e.g. T antigen, either in vivo or in vitro may react with all human sera. Further investigation of such reactions is required.
e) Bacterial or other contamination of materials used can cause false positive or false negative results.
f) Fibrin residues in the red cell suspension may trap non-agglutinated cells presenting a fine pink line on top of the gel while most of the cells are on the bottom of the microtube after centrifugation.
g) Strict adherence to the procedures and recommended equipment is essential. The equipment should be checked regularly according to GLP procedures.
h) Use of suspension solutions other than ID-Diluent 2 may modify the reactions.
i) The use of other test cell reagents than "ID-DiaCell" or "ID-DiaPanel" may modify the reaction patterns.
j) Too heavy or too weak red cell suspensions can cause aberrant results.

BIBLIOGRAPHY

1. Coombs, R.R.A., Mourant, A.E. and Race, R.R.: Lancet 1945; 2: 15.
2. Coombs, R.R.A., Mourant, A.E. and Race, R.R.: Brit. J. Exp. Path 1945; 26: 255.
3. Lapierre, Y., Rigal, D., Adam, J. et al.: The gel test; A new way to detect red cell antigen-antibody reactions. Transfusion 1990; 30: 109-113.
4. Technical Manual; R. H. Walker (ed.); 11th ed. 1993; American Association of Blood Banks.

PRODUCTS

ID-Card "LISS/Coombs"

4 x 12 . . . . . REF 004014
24 x 12 . . . . . REF 004017
60 x 12 . . . . . REF 004016
112 x 12 . . . . . REF 004015

These products are guaranteed to perform as described on the label and in the instruction sheet. The manufacturer declines all responsibility arising out of the use or sale of these products in any way or for any purpose other than those described therein.

DiaMed GmbH
1785 Cressier FR
Switzerland

CE
0123

BIO-RAD

Nr. 004015

Tiesioginio ir netiesioginio antiglobulino tyrimo atlikimas naudojant ID - korteles " LISS / Coombs "

1. ĮVADAS

Polispecifinis antiglobulininis serumas (AS, angliškai : AHG) naudojamas rutininiam alloantikūnų nustatymui ir identifikavimui, suderinamumo mėginio atlikimui ir tiesioginiam Kumbso mėginio atlikimui (TKM angliškai DAT).

Svarbiausia AS funkcija yra nustatyti IgG buvimą. Antikomplemento buvimo antiglobuline svarbumas yra ginčytinas, kadangi antikūnai, kurie nustatomi tiktai pagal jų sugebėjimą surišti komplementą yra ganėtinai reti. Tačiau anti - C3d aktyvumas yra labai svarbus atliekant tiesioginius Kumbso mėginius, tiriant autoimuninių hemolitinių anemijų priežastis.Teigiamas tiesioginis mėginys paprastai rodo, kad raudonieji kraujo kūneliai padengti in vivo imunoglobulinu arba/ir komplementu.

ID - kortelės " LISS/Coombs " mikromėgintuvėliai užpildyti polispecifiniu AS skirti antikūnų skryningui, antikūnų identifikavimui, tapatumo mėginiui ir tiesioginio Kumbso mėginio atlikimui. Atliekant netiesioginį Kumbso mėginį nenaudojama varginanti nuplovimo procedūra, kadangi raudonųjų kraujo kūnelių suspensija , kuri pirmiausia pridedama į mikromėgintuvėlį, sudaro virš gelio barjerą ir tokiu būdu išvengiama AS neutralizacijos serumo proteinais (IgG).

Kortelė ID-Card "LISS/Coombs" yra tinkama tiesioginio Kumbso mėginio atlikimui, tapatumo mėginiui, antikūnų skryningui ir identifikavimui su "ID-DiaCell" ir " ID-DiaPanel".

2. REAGENTAI

ID-kortelės **" LISS / Coombs "** **Nr.004015.**

Šiose kortelėse naudojami paruošti ir suspenduoti gelyje polispecifiniai (triušio anti - IgG ir monokloninis C3d) antižmogaus globulino serumai.

Priedai: < 0,1%NaN3.

Saugoti kambario temperatūroje prie 18 - 25^0 C.

Nelaikyti prie bet kokio šilumos šaltinio, oro kondicionavimo sistemų ar ventiliacijos angų.

Eritrocitų reagentai

" ID - Dia Cell " **Nr.003613, 004310**
Nr.005310, 005311

" ID - DiaPanel " **Nr.004114, 004114**

Tai paruošti naudojimui standartiniai tipuoti eritrocitai, skirti netiesioginio Kumbso atlikimui ieškant antikūnų ir nustatant jų specifiškumą (pridedame pase nurodomas kiekvienos serijos specifiškumą).

Paruošimo tirpalas **" ID - Diluent - 2 "** **Nr. 009280.**

Modifikuotas LISS tirpalas, skirtas eritrocitų suspensijos pagaminimui.

Pavyzdžio medžiaga. Tyrimas turi būti atliekamas su krauju, nevėliau kaip 24 val po paėmimo, maks. 1 savaitė, laikant prie 2 - 8^0 C. Kraujo pavyzdžiai turi būti stabilizuoti konservantais: citratu, EDTA arba CPD-A.

3. KRAUJO (ERITROCITŲ) PAVYZDŽIO PARUOŠIMAS

a) Eritrocitų suspensija tiesioginiam antiglobulino tyrimui arba autokontrolei.

Paruoškite 0,8% eritrocitų suspensiją ID - Diluent - 2 tirpale :

- ID - Diluent - 2 tirpalas turi sušilti iki kambario temperatūros.
- pridėkite 1 ml ID - Diluent - 2 į švarų mėgintuvėlį.
- pridėkite 10 µl kraujo arba eritrocitų koncentrato, lengvai sumaišykite.
- eritrocitų suspensija gali būti naudojama tuoj pat.

b) Plazma arba serumas netiesioginio antiglobulino tyrimo procedūroms.

Jei pavyzdžiai nenaudojami tuoj pat, juos laikyti po atskyrimo prie 2 - 8^0 C (žiūr. taip pat "Pavyzdžio madžiaga") maksimum 48 val, po to laikyti prie -20^{0}C.

4. TYRIMO PROCEDŪROS ATLIKIMAS

Nenaudokite kortelių, kuriose matosi išdžiuvę reagentai, yra burbuliukų ar pažeista apsauga.

4.1. *Tiesioginis antiglobulino tyrimas*

- pažymėkite atitinkamai ID - kortelę ir mikromėgintuvėlį pagal paciento pavardę ar numerį. Nuo naudojamų tyrimui mikromėgintuvėlių nuplėškite aliumininę folijos apsaugą.
- pridėkite 50 µl tiriamų eritrocitų suspensijos į atatinkamą mikromėgintuvėlį.
- įdėkite ID - kortelę į ID - Centrifugą ir centrifuguokite 10 min.
- vertinkite gautą rezultatą.

4.2. *Antikūnų skryningas*

Naudokite paruoštus tyrimui standartinius eritrocitus "ID-DiaCell"

- standartiniai eritrocitai ir tiriami pavyzdžiai turi sušilti iki kambario temperatūros.
- atitinkamus ID - kortelės mikromėgintuvėlius pažymėkite pagal paciento pavardę ar numerį. Nuo naudojamų tyrimui mikromėgintuvėlių nuimkite aliumininę folijos apsaugą.
- pridėkite po 50 µl ID - DiaCell į atitinkamai pažymėtus mikromėgintuvėlius (pažymėtus pagal atitinkamus standartinius eritrocitus).
- tuo atveju, kai atliekama autokontrolė, pridėkite 50 µl eritrocitų suspensijos į atitinkamai pažymėtą mikromėgintuvėlį.
- pridėkite po 25 µl paciento ar donoro plazmos arba serumo į kiekvieną mikromėgintuvėlį.
- patalpinkite ID - korteles 15 minučių į inkubatorių t = 37^0 C.
- įdėkite ID - korteles į ID - Centrifugą ir centrifuguokite 10 min.
- vertinkite gautą rezultatą.

4.3. *Antikūnų identifikavimas*

Naudokite paruoštus tyrimui standartinius eritrocitus "ID-Dia Panel" .

- tiriama plazma arba serumas prieš vartojimą turi sušilti iki kambario temperatūros.
- paimkite dvi ID - korteles " LISS / Coombs " ir pažymėkite paciento ar donoro pavardę arba numerį. Nuo kortelių nuimkite aliumininę foliją.
- pridėkite po 50 µl kiekvienos ID - DiaPanel į atitinkamus mikromėgintuvėlius (pažymėtus 1 - 11)
- pridėkite 50µl paruošto pavyzdžio eritrocitų suspensijos į 12 - tą mikromėgintvėlį, skirtą autokontrolei.
- pridėkite po 25 µl paciento ar donoro plazmos arba serumo į visus 12 mikromėgintuvėlių.
- patalpinkite ID - korteles 15 min. į inkubatorių t = 37^0 C.
- įdėkite ID - korteles į ID - Centrifugą ir centrifuguokite 10min.
- vertinkite gautą rezultatą.

4.4. *Tapatumo mėginys (Crossmatch test)*

- pažymėkite atitinkamus kortelės ID-Card "LISS/Coombs" mikromėgintuvėlius pagal paciento ar donoro pavardę ar numerį. Nuo naudojamų tyrimui mikromėgintuvėlių nuimkite aliumininę folijos apsaugą.
- pridėkite po 50 µl donoro eritrocitų suspensijos į atitinkamus mikromėgintuvėlius.
-autokontrolei pridėkite į atitinkamą mikromėgintuvėlį 50 µl paciento eritrocitų suspensijos.
- pridėkite po 25 µl paciento plazmos arba serumo į visus mikromėgintuvėlius.
- patalpinkite ID - korteles 15 min. į inkubatorių t = 37^0 C.
- įdėkite ID - korteles į ID - Centrifugą ir centrifuguokite 10 min.
- vertinkite gautą rezultatą.

5. REZULTATŲ VERTINIMAS

A) Principas

TEIGIAMA: agliutinatai suformuoja raudoną liniją gelio paviršiuje arba prasiskverbia į jo gilumą.
NEIGIAMA: visos ląstelės mikromėgintuvėlio dugne.

5.1. *Tiesioginis antiglobulino tyrimas*

- neigiama reakcija rodo, kad ant eritrocitų paviršiaus nėra ieškomų IgG antikūnų ar C3d komplemento komponentų.
- teigiama reakcija (nuo ± iki ++++) rodo, kad paciento eritrocitai yra sensitizuoti (padengti antikūnais ir/arba C3d).

5.2. *Antikūnų skryningas*

- neigiama reakcija rodo, kad paciento ar donoro serume ar plazmoje nėra ieškomų nepastovių antikūnų.
- teigiama reakcija rodo pastovių antikūnų buvimą.
įveskite gautos reakcijos duomenis į antigenų lentelę. Patikrinkite, kad standartinių eritrocitų ID - DiaCell I,II, arba ID-DiaCell I-II-III serijos numeris sutaptų su numeriu, esančiu antigenų lentelėje.
- pagal reakcijos aprašymą ir antigeno konfigūraciją galima nustatyti antikūno tipą.Antikūnų patvirtinimui toliau atlikite antikūnų identifikavimo procedūrą.
- teigiama agliutinacijos reakcija su vienu ar daugiau standartinių eritrocitų ir neigiama autokontrolė nurodo specifinio antikūno buvimą (žiūr. Pastabas)
- teigiama agliutinacijos reakcija su visais standartinais eritrocitais ir teigiama agliutinacijos reakcija autokontrolėje greičiausiai rodo nespecifinę agliutinaciją.
- kai yra teigiama agliutinacijos reakcija su visais standartiniais eritrocitais ir teigiama agliutinacijos reakcija autokontrolėje, bet su vienu ar keliais standartiniais eritrocitais agliutinacijai esant stipresnei nei autokontrolėje, paciento tyrimo pavyzdys turi būti pateiktas tolimesniam tyrimui tam kad ištirti alloantikūnų buvimo galimybę.

5.3 *Antikūnų identifikavimas*

- teigiama reakcija rodo nepastovių antikūnų buvimą. Įveskite gautus rezultatus į antigenų lentel. Patikrinkite, kad ID - DiaPanel serijos numeris sutaptų su antigenų serijos numeriu, esančiu lentelėje.
- daugeliu atvejų, pagal reakcijos šabloną ir antigeno konfigūraciją galima nustatyt esančio antikūno tipą (autokontrolė turi būti neigiama).
- teigiama reakcija su visais ID - DiaPanel standartiniais eritrocitais ir neigiama agliutinacijos reakcija autokontrolėje tikriausiai yra nespecifinių reakcijų rezultatas, arba gali rodyti alloantikūno prieš gana dažnai sutinkamą antigeną buvimą.
- teigiama reakcija su visais ID-DiaPanel standartiniais eritrocitais ir teigiam agliutinacijos reakcija autokontrolėje gali būti dėl nespecifinės reakcijos
- teigiama reakcija su visais ID-DiaPanel standartiniais eritrocitais ir teigiama agliutinacijos reakcija autokontrolėje, bet su vienu ar kelias standartiniais eritrocitais agliutinacijai esant stipresnei nei autokontrolėje gali rodyti alloantikūnų buvimą ir turi būti atliekamas tolimesnis tyrimas.

5.4. *Tapatumo tyrimas*

- neigiama agliutinacijos reakcija rodo donoro ir recipiento kraujo suderinamumą.
- teigiama agliutinacijos reakcija rodo donoro kraujo nesuderinamumą su recipiento kraują, dėl antikūnų, nukreiptų prieš antigenus, esančius ant donoro eritrocitų, buvimo. Reikia atlikti tolimesnius tyrimus ir identifikuoti antikūnų specifiškumą.

Pastaba Pagal visas GLP procedūras, aukščiau išvardintų procedūrų jautrumas turi būti pagrįstas žinomo stiprumo antikūnų naudojimu.
DiaMed Anti-D referens reagentas gaminamas pastoviai atliekant kontrolę visoms antikūnų nustatymo procedūroms (žiūr. įpokavimo įdėklą)

6. APRIBOJIMAI

- žinoma, kad kai kurie vaistai gali iššaukti teigiamą reakciją atliekant anti-žmogaus globulino tyrimo procedūras .
- yra nuomonių, kad kai kurios patologinės būklės gali būti teigiamos anti-žmogaus globulino reakcijos priežastimi.
- eritrocitai kurie gali tapti poliagliutinabiliais dėl kryptantigeno išryškinimo t.y. T antigenas, ar *in vivo* ar *in vitro* gali reaguoti su žmogaus serumu. Esant tokiai reakcija, reikia atlikti tolimesnius tyrimus.
- bakterinis ir kitoks naudojamų medžiagų užteršimas gali duoti klaidingai teigiamus ar neigiamus rezultatus.
- fibrino siūlų priemaišos eritrocitų suspensijoje gali pagauti neagliutinuotus eritrocitus ir gelio paviršius atrodo kaip rožinė linija, tuo tarpu likę eritrocitai po centrifugavimo lokalizuojasi mikromėgintuvėlio dugne.
- būtina griežtai prisilaikyti procedūros, reagentų ir įrangos naudojimo rekomendacijų. Įrangą būtina reguliariai tikrinti pagal GLP ir šalies standartizacijos ir metrologijos procedūras.
- naudojimas kitų, **išskyrus ID Diluent suspenduojanèiø tirpalø,** gali iškreipti reakcijos rezultatus.
- naudojimas kitų, **išskyrus ID - DiaCell , ID - DiaScreen arba ID - DiaPanel standartinių eritrocitø reagentø** ,gali pakeisti reakcijų eigą.
- labai koncentruotos eritrocitų suspensijos gali duoti klaidingai teigiamos reakcijos rezultatus.

#248.2

DiaClon ABO/D + Reverse Grouping for Patients ID-Card

English B001228 05.10

A, B, DVI-, ctl/A_1, B

Determination of the ABO/Rh blood groups combined with reverse grouping

Product-Identification: 50092

INTRODUCTION

ABO blood group typing, using anti-A and anti-B test sera, is known as direct or forward grouping test.

Reverse grouping uses red cell reagents of known ABO antigen specificity to indicate the presence or absence of anti-A and anti-B isoagglutinins, the results of which determine the reverse group. Discrepancies between forward and reverse grouping require further investigation [1].

Classification of blood groups must be based on both forward and reverse grouping.

The ID-Card "DiaClon ABO/D + Reverse Grouping for Patients" allows combined testing of forward and reverse grouping as well as RhD determination.

REAGENTS

IVD

ID-Card "DiaClon ABO/D + Reverse Grouping for Patients" contains monoclonal anti-A [cell line A5], anti-B [cell line GY2] and anti-D [cell lines LHM 59 / 20 (LDM3) + 175-2] within the gel matrix. The microtube ctl is the negative control. Two microtubes with "neutral" gel serve for reverse grouping with A_1 and B cells.
Preservative: < 0,1% NaN_3.

Caution: All reagents should be treated as potentially infectious.

18 °C – 25 °C *Do not store near any heat, air conditioning sources or ventilation outlets.*

Stability: see expiry date on label.

ADDITIONAL REAGENTS REQUIRED

- ID-Diluent 2: modified LISS for red cell suspensions.
- Test cell Reagents: ID-DiaCell A_1 and B in a 0,8% suspension, in 10 mL vials, ready-to-use

(see related package insert)

FURTHER MATERIALS REQUIRED

- ID-Dispenser
- ID-Pipetor
- ID-Tips (pipetor tips)
- Tubes for suspensions
- ID-Working table
- ID-Centrifuge 6, 12 or 24

SAMPLE MATERIAL

For optimal results, the determination should be performed using a freshly drawn sample, or in accordance with local laboratory procedures for sample acceptance criteria. Preferably, blood samples should be drawn into citrate, EDTA or CPD-A anticoagulant. Samples drawn into plain tubes (no anticoagulant) may also be used.

When the use of serum instead of plasma is required, the serum must be well cleared, by centrifugation at 1500 g for 10 minutes, before use avoid fibrin residues, which may interfere with the reaction pattern.

PREPARATION OF BLOOD SAMPLE

a) Red cell suspension (for ABO/D determination)

Prepare a 5% red cell suspension in ID-Diluent 2 as follows:
Allow the diluent to reach room temperature before use.

1. Dispense 0,5 mL of ID-Diluent 2 into a clean tube.
2. Add 50 µL of whole blood or 25 µL of packed cells, mix gently.

The cell suspension may be used immediately.

b) Plasma or Serum for reverse grouping

Where samples are not for immediate testing they should be stored at 2-8 °C after separation for a maximum of 48 hours, thereafter at -20 °C, or in accordance with local / national policies / guidelines.

CONTROLS

Known positive and negative samples should be included in accordance with the relevant guidelines of quality assurance.

TEST PROCEDURE

Do not use ID-Cards which show signs of drying, have bubbles, damaged seals, drops of gel or supernatant in the upper part of the microtubes or on the underside of the aluminium foil.

Allow the test cell reagent to reach room temperature before use.

1. Identify the ID-Card with the unique patient or donor number / details as appropriate.
2. Remove the aluminium foil from as many microtubes as required by holding the ID card in the upright position.
3. Pipette 50 µL of "ID-DiaCell A_1" to microtube 5 (A_1).
4. Pipette 50 µL of "ID-DiaCell B" to microtube 6 (B).
5. Pipette 50 µL of the patient serum or plasma to both microtubes 5 and 6. An incubation for 10 minutes at room temperature is recommended (see remarks, point 4).
6. Pipette 10 or 12,5 µL of the patient's red cell suspension to the microtubes 1–4 (A, B, D, ctl).
7. Centrifuge the ID-Cards for 10 minutes in the ID-Centrifuge.
8. Read and record the reactions.

BIO-RAD

DiaClon ABO/D + Reverse Grouping for Patients — ID-Card

English — B001228 05.10

INTERPRETATION OF THE RESULTS

A) Principle [2]

Positive: Agglutinated cells forming a red line on the surface of the gel or agglutinates dispersed in the gel.
Negative: Compact button of cells on the bottom of the microtube.

B) Reactions for blood groups ABO

Anti-A	Anti-B	Blood group
+++ to ++++	negative	A
negative	+++ to ++++	B
+++ to ++++	+++ to ++++	AB
negative	negative	O

Weaker reactions than +++ may indicate A or B subgroups. For correct interpretation, a complete grouping test should be performed (anti-A, anti-B, anti-AB). In the presence of weak or very weakly expressed antigens the reaction can be negative. The anti-B of monoclonal origin does not react with the acquired B antigen.

Important: The microtube ctl must show a negative reaction. If the ctl is positive, the ABO determination is not valid. Repeat the test as described under "Remarks 1.".

C) Reactions for reverse grouping

A1	B	Blood group
+ to ++++	negative	B
negative	+ to ++++	A
+ to ++++	+ to ++++	O
negative	negative	AB

If questionable reactions are obtained, repeat reverse grouping with 4 red cell reagents (A_1, A_2, B and O).

D) Reactions for RhD

+++ to ++++	± to ++*	negative
RhD positive	RhD weak positive	RhD negative

* ±, trace or weak reactions should be subject to further investigations to distinguish between weak and partial D types as appropriate for the category of sample being tested.

The anti-D used has been selected so as not to react with DVI variants.

Weak D may give a negative reaction. If all weak / partial D's are required to be detected, all D negative results must be retested. Note that most guidelines do not recommend further testing for weak or partial-D in patients.

Important: The microtube ctl must show a negative reaction. If the ctl is positive, the RhD determination is not valid. Repeat the test as described under "Remarks 1.".

REMARKS

1. The negative control must always show a negative reaction.
   - If the negative control is positive, wash the red cells first in warm isotonic saline solution or ID-Diluent 2, before preparing the red cell suspension.
   - Then proceed as under "Preparation of blood sample" and "Test procedure".
   - If the negative control subsequently shows a negative result, the reactions can be interpreted as described in sections B, C and D.
   - If the negative control remains positive, the results of the ABO/Rh determination should be considered invalid and further investigations following recommended techniques should be undertaken to ascertain the reason, before valid antigen typing can be assured.
2. Where a discrepancy occurs between the results of ABO typing and reverse grouping, consult the 'DiaMed ABO discrepancy chart' for appropriate information.
3. Full forward and reverse grouping requires the use of anti-A, -B, -AB, and A_1, A_2, B and O cells. The ID-Card 'DiaClon ABO/D + Reverse Grouping for Patients' does not contain anti-AB and allows the use of A_1 and B cells only. It should be used only for confirmation of previously fully tested samples with established blood group status or in accordance with local or national guidelines / recommendations for blood grouping.
4. For reverse grouping, an incubation of at least 10 minutes at 18-25 °C prior to centrifugation will enhance the reactions and minimise repeat testing due to weak isoagglutinins.

LIMITATIONS

a) ID-Cards which show air bubbles in the gel or drops in the upper part of the microtubes and / or the seal, must be centrifuged before use.
b) Bacterial or other contamination of materials used can cause false positive or false negative results.
c) Fibrin residues in the serum or the red cell suspension may trap non-agglutinated cells presenting a fine pink line on top of the gel while most of the cells are on the bottom of the microtube after centrifugation.
d) Strict adherence to the procedures and recommended equipment is essential. The equipment should be checked regularly according to GLP procedures.
e) Use of suspension solutions other than ID-Diluent 2 may modify the reactions.
f) Too heavy or too weak red cell suspensions can cause aberrant results.

BIBLIOGRAPHY

1. Mollison, P.L., Engelfriet, C.P. and Contreras, M.: Blood Transfusion in Clinical Medicine, 10th ed. 1997; Blackwell Scientific Publications, Oxford.
2. Lapierre, Y., Rigal, D., Adam, J. et al.: The gel test; A new way to detect red cell antigen-antibody reactions. Transfusion 1990; 30: 109-113.

PRODUCTS

ID-Card "DiaClon ABO/D + Reverse Grouping for Patients"

4 x 12	REF 001234
24 x 12	REF 001237
60 x 12	REF 001236
112 x 12	REF 001235

These products are guaranteed to perform as described on the label and in the instruction sheet. The manufacturer declines all responsibility arising out of the use or sale of these products in any way or for any purpose other than those described therein.

DiaMed GmbH
1785 Cressier FR
Switzerland

CE 0123

BIO-RAD

ID - kortelė "DiaClon ABO/D + Reverse group "
A – B - D (VI-) – ctl / A_1 - B
Kraujo grupių ABO / Rh nustatymui kartu su atvirkštiniu grupavimu

ĮVADAS

ABO sistemos eritrocitų antigenų tipavimas naudojant anti - A, anti - B serumus yra žinomas kaip tiesioginė reakcija.

Atvirkštiniam grupavimui naudojami žinomų ABO antigenų eritrocitai, kuriais nustatomas buvimas arba nebuvimas anti - A ir anti – B izoagliutininų. Rezultatas parodo atvirkštinę grupę. Nesutapimas tarp tiesioginio ir atvirkštinio grupavimų reikalauja tolimesnių tyrimų.

Kraujo grupės įvertinimas turi remtis šiomis abiejomis reakcijomis.

ID - kortelė " DiaClon ABO/D + Reverse grouping " leidžia suderinti tiesioginės ir netiesioginės reakcijos atlikimą ir nustatyti Rh D priklausomybę.

2. REAGENTAI

ID-kortelė " DiaClon ABO/D + Reverse grouping". Šiose kortelėse naudojami suspenduoti gelyje monoklonaliniai anti – A [ląstelių linija A-5],, anti - B [ląstelių linija G ½] ir anti - D [ląstelių linijos LHM 59/20 (LDM3) + 175 - 2]. Mikromėgintuvėlyje ctl yra neigiama kontrolė. Du mikromėgintuvėliai su neutraliu geliu atvirkštiniam grupavimui su A_1 B ląstelėmis.
Konservantas: <0.1% NaN_3.

Įspėjimas: *Su visais reagentais elgtis kaip su galimai infekuotais.*
Nelaikyti prie bet kokio šilumos šaltinio, oro kondicionavimo sistemų ar ventiliacinių angų.
Stabilumas: žiūrėti galiojimo datą ant įpakavimo.

PAPILDOMAI REIKALINGI REAGENTAI

- ID - Diluent – 2: modifikuotas LISS tirpalas eritrocitų suspensijos paruošimui.
- Eritrocitų reagentai: ID - DiaCell A_1 ir B 0.8 % suspensijoje, supakuoti po 10 ml buteliukuose. Paruošti naudojimui

(žiūr. atitinkamo įpakavimo įdėklą)

TOLIAU REIKALINGI REIKMENYS

ID-Dispenseris
ID-Pipetorius
ID-Antgaliai (pipečių antgaliai)
ID-Darbo stalas
Suspensijų mėgintuvėliai
ID-Centrifuga 6, 12 ar 24

TIRIAMO PAVYZDŽIO MEDŽIAGA

Prieš paimant kraują paciento specialiai tam paruošti nereikia. Kraują paimti naudojant žinomas kraujo paėmimo technologijas. Geriau, jei kraujas bus stabilizuotas konservantais, pvz.: EDTA, citratas, CPD-A antikoaguliantas.
Patikimiems rezultatams gauti geriau naudoti tuoj pat paimtą dar nesukrėšėjusį kraują.

KRAUJO PAVYZDŽIO PARUOŠIMAS

a) eritrocitų suspensijos paruošimas (ABO/D nustatymui)
Paruoškite 5 % eritrocitų suspensiją ID-Diluent 2 tirpale:
ID-Diluent - 2 tirpalas turi sušilti iki kambario temperatūros prieš naudojimą.

1.Įlašinkite 0.5 ml ID-Diluent – 2 į švarų mėgintuvėlį.
2.Įlašinkite 50 µl kraujo arba 25 µl eritrocitų koncentrato, atsargiai sumaišykite.
- *Ląstelių suspensiją galima naudoti tuoj pat.*

b) Plazmos arba serumo paruošimas atvirkštiniam grupavimui
Jei mėginiai netiriami nedelsiant, juos reikia laikyti 2-8 °C temperatūroje maksimaliai 48 valandas po atskyrimo, po to –20 °C.

KONTROLĖS

Kokybės užtikrinimui reikėtų įtraukti žinomus teigiamos ir neigiamos kontrolės mėginius.

TYRIMO PROCEDŪROS ATLIKIMAS

Nenaudokite kortelių, kuriose matosi išdžiuvę reagentai, yra burbuliukų ar pažeista apsauga.
Leiskite sušilti reagentams iki kambario temperatūros.
1.Pažymėkite atitinkamai ID-kortelės " DiaClon ABO/D + Reverse group " mikromėgintuvėlį pagal paciento pavardę ir/ar numerį. Nuo naudojamų tyrimui mikromėgintuvėlių nuimkite aliumininę foliją.
2. Pridėkite "ID - DiaCell A_1" 50µl į mikromėgintuvėlį 5 (A_1).
3. Pridėkite "ID - DiaCell B" 50 µl į mikromėgintuvėlį 6 (B).
4. Į tuos pačius mikromėgintuvėlius 5 ir 6 pridėkite po 50µl paciento serumo arba plazmos. Inkubuokite kambario temperatūroje (18-25 °C) 10 minučių.
5. Pridėkite po 10 ar 12,5µl tiriamų paciento eritrocitų suspensijos į mikromėgintuvėlius 1-4 (A – B – D - ctl).
6. Įdėkite ID - kortelę į ID - Centrifugą ir centrifuguokite 10 min.
7. Vertinkite reakciją.

REZULTATŲ VERTINIMAS

A) Principas [2]

Teigiama: agliutinatai suformavę raudoną liniją gelio paviršiuje arba prasiskverbę į jo gilumą.
Neigiama: visos ląstelės mikromėgintuvėlio dugne.

B) Kraujo grupių reakcijų vertinimas

	Anti-A	Anti-B
A	+++/++++	neigiama
B	neigiama	+++/++++
AB	+++/++++	+++/++++
O	neigiama	neigiama

Reakcijos, silpnesnės nei +++ gali rodyti A ir B antigenų pogrupių buvimą. Atsakymą galima duoti tik atlikus pilną ištyrimą pagal ABO (anti-A, anti-B, anti-AB).

Svarbu: Kontrolės mikromėgintuvėlis (ctl) turi rodyti neigiamą reakciją. Jeigu kontrolė teigiama ABO nustatymas nepagrįstas. Reikia pakartoti tyrimą kaip aprašyta "Pastabose-1".

C) Atvirkštinių grupių reakcijų vertinimas

A_1	B	Kraujo grupė
+ iki ++++	neigiama	B
neigiama	+ iki ++++	A
+ iki ++++	+ iki ++++	O
neigiama	neigiama	AB

Jei nustatomos abejotinos reakcijos, pakartokite atvirkštinį grupavimą su 4 eritrocitų reagentais (A_1, A_2, B ir O).

D) Rh D reakcijų vertinimas

+++/++++	+/++	neigiamas
Rh D teigiamas	Rh D silpnai teigiamas	Rh D neigiamas

Silpnas D gali duoti neigiamą reakciją. Jeigu reikia nustatyti D silną, visus D neigiamus rezultatus reikia pertikrinti. Pilnam ištyrimui žiūrėkite įdėklą ID-kortelių "ABO/Rh" arba "Anti-D" su žmogaus kilmės poliklonineis reagentais.

Svarbu: Kontrolės mikromėgintuvėlis (ctl) turi rodyti neigiamą reakciją. Jeigu kontrolė teigiama ABO nustatymas nepagrįstas. Reikia pakartoti tyrimą kaip aprašyta "Pastabose-1".

PASTABOS

1. Neigiama kontrolė visada turi rodyti neigiamą rezultatą.
- Jeigu kontrolės mikromėgintuvėlyje reakcija teigiama, tai veiksmai sekantys: nuplaukite tiriamus eritrocitus šiltu 0,9% NaCl tirpalu arba ID - Diluent - 2 tirpalu, prieš ruošdami eritrocitųsuspensiją.
- Tada paruoškite 5% eritrocitų suspensiją ir tęskite procedūrą kaip aprašyta anksčiau "Kraujo pavyzdžio paruošimas" ir "Tyrimo procedūros atlikimas".
- Jeigu neigiama kontrolė rodo neigiamą rezultatą, reakcijų rezultatus vertinkite, kaip aprašyta B, C, D skirsniuose.
- Jeigu neigiamos kontrolės rezultatas išlieka teigiamas, ABO/Rh grupių rezultatų vertinti negalima, reikia atlikti tolimesnius tyrimus pagal rekomenduojamas technologijas ir surasti priežastį.
2. Nesutapus tiesioginės ir atvirkštinės ABO tipavimo reakcijos rezultatams, naudokite DiaMed schemą ABO nesutapimams.
3. **Anti - D parinktas taip, kad nereaguotų su D^{VI} variantais.**
4. Kraujo grupės korektiškas nustatymas naudojant dvigubą reakciją reikalauja naudoti anti - A, anti - B, anti - AB antikūnus ir A_1, A_2, B, 0 eritrocitus. Kadangi ID - kortelė "DiaClon ABO/D + Reverse grouping " neturi anti - AB antikūnų ir sudaro galimybę

naudoti tiktai A_1 ir B eritrocitus, todėl juos naudoti reikia tiktai dėl jau žinomų kraujo grupių patvirtinimo.

6. APRIBOJIMAI

- bakterinis ir kitoks naudojamų medžiagų užteršimas gali duoti klaidingai teigiamus ar neigiamus rezultatus.
- fibrino siūlų priemaišos eritrocitų suspensijoje gali pagauti neagliutinuotus eritrocitus ir gelio paviršius atrodo kaip rožinė linija, kai tuo tarpu likę eritrocitai po centrifugavimo lokalizuojasi mikromėgintuvėlio dugne.
- būtina griežtai prisilaikyti procedūros, reagentų ir įrangos naudojimo rekomendacijų. Įrangą būtina reguliariai tikrinti pagal GLP ir šalies standartizacijos ir metrologijos procedūras.
- naudojimas kitų, išskyrus ID Diluent - 2 suspenduojančių tirpalų, gali iškreipti reakcijos rezultatus.
- labai koncentruotos eritrocitų suspensijos gali duoti klaidingai teigiamos reakcijos rezultatus.

REAGENTAI

ID-kortelė "DiaClon ABO/D + Reverse grouping"	4×12.....REF 001234
	24 ×12.....REF 001237
	60×12.....REF 001236
	112×12.....REF 001235

Šių priduktų kokybė garantuojama, kai tyrimas atliekamas pagal aprašymą. Gamintojas neprisiima atsakomybės jei produktas naudojamas ar parduodamas kitais būdais ar tikslais, skirtingai negu šioje instrukcijoje aprašyta.

Nr.001236

Eritrocitų antigenų sistemos ABO ir RH(D) ir antikūnų anti - A, anti B nustatymas naudojant ID - korteles "DiaClon ABO/D + reverse group "

1. ĮVADAS

ABO sistemos eritrocitų antigenų tipavimas naudojant anti - A, anti - B serumus yra žinomas kaip tiesioginė reakcija. Serumo tipavimas naudojant A1 ir B eritrocitus, siekiant išaiškinti anti - A, anti - B, anti - AB antikūnų buvimą arba nebuvimą vadinama atvirkštine reakcija.

ABO tipavimo įvertinimas turi remtis šiomis abiejomis reakcijomis.

ID - kortelė " DiaClon ABO/D + reverse grouping " leidžia suderinti tiesioginės ir netiesioginės reakcijos atlikimą ir nustatyti RH(D) priklausomybę.

2. REAGENTAI

ID-kortelės **" DiaClon ABO/D + reverse group"** **Nr.001236.**

Šiose kortelėse naudojami suspenduoti gelyje monoklonaliniai anti - A, anti - B ir anti - D serumai- antikūnai, turintys neigiamą kontrolę autokontrolės (ctl) mėgintuvėlis, du mikromėgintuvėliai su neutraliu geliu.

Paruošimo tirpalas	**" ID - Diluent - 2**	**Nr. 009280.**
Eritrocitų reagentai	**" ID - DiaCell A1 "**	**Nr. 003624**
	" ID - DiaCell B "	**Nr. 003624**

3. KRAUJO (ERITROCITŲ) PAVYZDŽIO PARUOŠIMAS

3.1. Tyrimui galima naudoti tuoj pat paimtą dar nesukrešėjusį be stabilizatoriaus kraują arba kraują, stabilizuotą konservantais, pvz.: EDTA, citratas,. heparinas, CPDA.
Nustatant anti - A ir anti - B antikūnus naudokite tiriamą plazmą arba serumą.
3.2. Atitinkamai pažymėtame laboratoriniame mėgintuvėlyje iš tiriamo kraujo paruoškite 5% eritrocitų suspensiją "ID-Diluent - 2" tirpale:

- "ID-Diluent - 2" tirpalas turi sušilti iki kambario temperatūros;
- 50 µl kraujo arba 25µl eritrocitų koncentrato sumaišykite mėgintuvėlyje su 0,5 ml "ID -Diluent - 2";
- rūpestingai sumaišykite eritrocitų suspensiją;
- gautą suspensiją galima naudoti tuoj pat.

4. TYRIMO PROCEDŪROS ATLIKIMAS

4.1.Pažymėkite atitinkamai ID-kortelę pagal paciento pavardę ar numerį.
4.2. Pridėkite ID - DiaCell A1 50µl (standartinių eritrocitų) į mikromėgintuvėlį 5 (A1) ir ID - DiaCell B 50 µl į mikromėgintuvėlį 6 (B).
4.3. Į tuos pačius mikromėgintuvėlius pridėkite po 50µl paciento serumo arba plazmos.
4.4. Pridėkite po 10µl tiriamų eritrocitų suspensijos į mikromėgintuvėlius 1-4 (A, B, D, ctl).
4.5. Įdėkite ID - korteles į ID - Centrifugą ir centrifuguokite 10 min.
4.6. Vertinkite reakcijas.

5. REZULTATŲ VERTINIMAS

5.1. TEIGIAMA : agliutinatai suformuoja raudoną liniją gelio paviršiuje arba prasiskverbia į jo gilumą (nuo 4+ iki 1 +).

NEIGIAMA: visos ląstelės mikromėgintuvėlio dugne.

Reakcijos, silpnesnės nei ++++ gali nurodyti, kad yra A arba B pogrupiai. Norint gauti teisingą atsakymą, būtina atlikti pilną tipavimą (anti - A, anti - B, anti - AB, ir A1, A2, B ir 0 ląstelės).

S v a r b u !!!

Kontrolės mikromėgintuvėlis (ctl) turi rodyti neigiamą reakciją.Jeigu kontrolė teigiama, tęskite tyrimą pagal p. 5.2.

5.2. PASTABOS (PAPILDYMAI)

Jeigu kontrolės mikromėgintuvėlyje reakcija teigiama, tai veiksmai sekantys:
- nuplaukite tiriamus eritrocitus 0,9% NaCl arba ID - Diluent - 2 tirpalu, paruoškite 5% eritrocitų suspensiją ir tęskite procedūrą kaip aprašyta anksčiau p.3, p.4.
- ID - kortelėse naudojami monoklonaliniai anti - B reaguoja tiktai su pažįstamu B antigenu.
- nesutapus tiesioginės ir atvirkštinės ABO tipavimo reakcijos rezultatams, naudokite DiaMed schemą ABO nesutapimams, parinkę atitinkamą procedūrą.
- anti - D parinkti taip, kad eritrocitų suspensija paruošta naudojant ID Diluent - 2 reaguotų ir su D^{VI} variantais.
- kraujo grupės korektiškas nustatymas naudojant dvigubą reakciją reikalauja naudoti anti - A, anti - B, anti - AB antikūnus ir A1, A2, B, 0 eritrocitus.
- kadangi ID - kortelė " DiaClon ABO/D + reverse grouping " neturi anti - AB antikūnų ir sudaro galimybę naudoti tiktai A1 ir B eritrocitus, todėl juos naudoti reikia tiktai dėl jau žinomų kraujo grupių patvirtinimo.

6. APRIBOJIMAI

- bakterinis ir kitoks naudojamų medžiagų užteršimas gali duoti klaidingai teigiamą ar neigiamą reakcijas.
- fibrino siūlų priemaišos eritrocitų suspensijoje gali pagauti neagliutinuotus eritrocitus ir gelio paviršius atrodo kaip rožinė linija, tuo tarpu likę eritrocitai po centrifugavimo lokalizuojasi mikromėgintuvėlio dugne.
- būtina griežtai prisilaikyti procedūros, reagentų ir įrangos naudojimo rekomendacijų. Įrangą būtina reguliariai tikrinti pagal GLP ir šalies standartizacijos ir metrologijos procedūras.
- naudojimas kitų, **išskyrus ID- Diluent - 2 suspenduojančių tirpalų,** gali pakeisti reakcijos rezultatus.
- labai koncentruotos eritrocitų suspensijos gali duoti klaidingai teigiamos reakcijos rezultatus.

ID-Diluent 2

English B009254 05.10 #248.3

Modified LISS for red cell suspensions

Product-Identification: 05761

INTRODUCTION

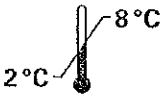
Low ionic strength solution (LISS) increases the rate of antibody association and thus enhances antigen/antibody reactions.

"ID-Diluent 2" is a modified low ionic strength solution made for the Bio-Rad ID-Card System, for preparing 5% red cell suspensions for blood grouping as well as 0,8% red cell suspensions for crossmatching, autocontrol, direct anti-human globulin test, blood grouping of newborns and test cells prepared in the laboratory.

REAGENTS

IVD

- ID-Diluent 2: modified LISS for red cell suspension, in 100 and 500 mL bottles.
  Preservatives: the antibiotics trimethoprim and sulfamethoxazole.



Stability: see expiry date on label.

FURTHER MATERIALS REQUIRED

- ID-Dispenser
- Pipette for 10, 25 and 50 µL
- ID-Tips (pipetor tips)
- Tubes for suspensions
- ID-Working table

SAMPLE MATERIAL

For optimal results, the determination should be performed using a freshly drawn sample, or in accordance with local laboratory procedures for sample acceptance criteria. Preferably, blood samples should be drawn into citrate, EDTA or CPD-A anticoagulant. Samples drawn into plain tubes (no anticoagulant) may also be used.
When the use of serum instead of plasma is required, the serum must be well cleared, by centrifugation at 1500 g for 10 minutes, before use avoid fibrin residues, which may interfere with the reaction pattern.

PREPARATION OF BLOOD SAMPLE

A) For blood group determinations

Prepare a 5% red cell suspension of the patient's red cells in "ID-Diluent 2" as follows:
Allow the diluent to reach room temperature before use.
1. Dispense 0,5 mL of "ID-Diluent 2" into a clean tube
2. Add 50 µL of whole blood or 25 µL of packed cells, mix gently.
The cell suspension may be used immediately.

Important: consult the relevant instruction sheet of the ID-Cards for precise working procedures.

B) For crossmatching, direct anti-human globulin test, autocontrol in antibody screening and other tests as specified in the relevant box inserts

Prepare a 0,8% red cell suspension in "ID-Diluent 2" as follows:
Allow the diluent to reach room temperature before use.
1. Dispense 1,0 mL of "ID-Diluent 2" into a clean tube.
2. Add 10 µL of packed red cells, mix gently.
The cell suspension may be used immediately.

Important: consult the relevant instruction sheet of the ID-Cards for precise working procedures.

C) For preparation of test cell reagents in the laboratory

1. Wash the red cells with isotonic saline solution or with "ID-Diluent 2" three times or more, until the supernatant is clear.
2. Decant the supernatant and resuspend the packed cells to a 0,8% suspension with "ID-Diluent 2".
3. Under aseptic conditions place the suspension into sterile glass vials or tubes, close with sterile caps.
   Red cell reagents thus prepared and stored at 2-8 °C are stable for one day.

LIMITATIONS

a) Bacterial or other contamination of materials used can cause false positive or false negative results.
b) Strict adherence to the procedures and recommended equipment is essential. The equipment should be checked regularly according to GLP procedures.
c) "ID-Diluent 2" has been formulated in order to reduce the incidence of detection of nonsignificant red cell bound complement components.
d) Some antibodies in the Kell system may react more weakly in LISS techniques.
e) LISS solutions may enhance autoantibody activity and therefore may cause problems with certain samples.

BIBLIOGRAPHY

1. Technical Manual; 11th ed. 1993; American Association of Blood Banks.
2. Löw, B. and Messeter, L.: Vox Sang 1974; 26: 53.
3. Hughes-Jones, N.C., Polley, M. J., Telford R., Gardner, B. and Kleinschmidt, G.: Optimal conditions for detecting blood group antibodies by the antiglobulin test. Vox Sang 1964; 9: 385–395.
4. Lapierre, Y., Rigal, D., Adam, J. et al.: The gel test; A new way to detect red cell antigen-antibody reactions. Transfusion 1990; 30: 109–113.

PRODUCTS

ID-Diluent 2	2 x 100 mL ..... REF 009260
	1 x 500 mL ..... REF 009280

These products are guaranteed to perform as described on the label and in the instruction sheet. The manufacturer declines all responsibility arising out of the use or sale of these products in any way or for any purpose other than those described therein.

DiaMed GmbH
1785 Cressier FR
Switzerland

CE

BIO-RAD

ID – Diluent 2
Modifikuotas LISS eritrocitų suspensijoms
500 ml

Produkto identifikacija: 05761

ĮVADAS

Žemos jonų koncentracijos tirpalas (LISS) padidina antikūnų susijungimo dažnį ir taip sustiprina antigeno/antikūno reakciją.

" ID-Diluent 2 " yra modifikuotas žemos jonų koncentracijos tirpalas, skirtas DiaMed – ID Micro Typing Sistemai. " ID – Diluent 2 " naudojamas ruošiant 5% eritrocitų suspensijas kraujo grupių nustatymui ir 0.8% eritrocitų suspensijas kryžminiam suderinamumui, autokontrolei, tiesioginiam anti-žmogaus globulino testui, naujagimių kraujo grupių nustatymui ir tyrimo ląstelių paruošimui laboratorijose.

REAGENTAI

ID – Diluent 2: modifikuotas LISS, skirtas eritrocitų suspensijos paruošimui. 100 ir 500 ml buteliukuose.
Konservantaai: antibiotikai trimetoprimas ir sulfametoksazolas.

Stabilumas: žiūrėti galiojimo datą ant įpakavimo.
Laikyti 2-8 °C temperatūroje.

TOLIAU REIKALINGI REIKMENYS

ID-Dispenseris
ID-Antgaliai (pipečių antgaliai)
ID-Darbo stalas
Pipetės 25 ir 50 µl
Suspensijų mėgintuvėliai

TIRIAMO PAVYZDŽIO MEDŽIAGA

Prieš paimant kraują paciento specialiai tam paruošti nereikia. Kraują paimti naudojant žinomas kraujo paėmimo technologijas. Geriau, jei kraujas bus stabilizuotas konservantais, pvz.: EDTA, citratas, CPD-A antikoaguliantas. Patikimiems rezultatams gauti geriau naudoti tuoj pat paimtą dar nesukrešėjusį kraują (be antikoaguliantų).

KRAUJO PAVYZDŽIO PARUOŠIMAS

A) Kraujo grupių nustatymui:

Paruoškite 5% eritrocitų suspensiją iš paciento eritrocitų "ID-Diluent 2" tirpale:
ID-Diluent - 2 tirpalas turi sušilti iki kambario temperatūros
1.Įlašinkite 0.5 ml "ID-Diluent – 2" į švarų mėgintuvėlį.
2.Įlašinkite 50 µl kraujo arba 25 µl eritrocitų koncentrato, atsargiai sumaišykite.
- *Eritrocitų suspensiją galima naudoti tuoj pat.*

Svarbu: Kad preciziškai atliktumėte darbo procedūrą visada atsižvelkite į susijusios ID - kortelės instrukciją.

B) Naudojant kryžminiam suderinamumui, tiesioginiam žmogaus antiglobulino testui, autokontrolei antikūnų skryninge ir kitiems tyrimams, specifiškai tinkantiems pagal atitinkamų dėžučių įdėklus:

Paruoškite 0.8% eritrocitų suspensiją "ID-Diluent 2" tirpale:
ID-Diluent - 2 tirpalas turi sušilti iki kambario temperatūros
1.Įlašinkite 1.0 ml "ID-Diluent – 2" į švarų mėgintuvėlį.
2.Įlašinkite 10 µl eritrocitų koncentrato, atsargiai sumaišykite.
- *Eritrocitų suspensiją galima naudoti tuoj pat.*

Svarbu: Kad preciziškai atliktumėte darbo procedūrą visada atsižvelkite į susijusios ID - kortelės instrukciją.

C) Tyrimo ląstelių paruošimui laboratorijoje:

1. Nuplaukite eritrocitus izotoniniu fiziologiniu tirpalu ar " ID – Diluent 2 " tris kartus ar daugiau, kol supernatantas taps švarus.
2. Nufiltruokite supernatantą ir vėl gražinti į 0.8% suspensiją su " ID – Diluent 2".
3. Aseptinėmis sąlygomis įdėkite suspensiją į sterilų stiklinį buteliuką ar mėgintuvėlį, uždarykite steriliu dangteliu.

- *Taip pagaminti eritrocitai laikomi 2-8 °C yra stabilūs vieną dieną.*

APRIBOJIMAI
- bakterinis ir kitoks naudojamų medžiagų užteršimas gali duoti klaidingai teigiamus ar neigiamus rezultatus.
- būtina griežtai prisilaikyti procedūros, reagentų ir įrangos naudojimo rekomendacijų. Įrangą būtina reguliariai tikrinti pagal GLP procedūras.
- " ID – Diluent 2" sukurtas, siekiant sumažinti nereikšmingų atvejų, kai eritrocitai sujungiami su komplemento komponentais.
- Kai kurie Kell sistemos antikūnai gali reaguoti silpniau LISS tirpale.
- LISS tirpalas gali sustiprinti autoantikūnų aktyvumą ir taip sukelti problemų su tikrais mėginiais.

REAGENTAI

ID – Diluent 2	2×100 ml.....REF 009260
	1×500 ml.....REF 009280

Šių priduktų kokybė garantuojama, kai tyrimas atliekamas pagal aprašymą. Gamintojas neprisiima atsakomybės jei produktas naudojamas ar parduodamas kitais būdais ar tikslais, skirtingai negu šioje instrukcijoje aprašyta.

Test cell reagents for the ID-System

English B004350 05.10

Test cell reagents for antibody screening: ID-DiaCell I-II, ID-DiaCell I-II-III, ID-DiaCell I-II-III P (papainized), ID-DiaCell I-II-III Asia, ID-DiaCell Pool; for antibody identification: ID-Panel, ID-Panel P; special antigens: ID-Di^a (Diego) positive, ID-I negative cell

INTRODUCTION

The reliability of antibody detection is largely dependent on the availability of test cells with appropriate antigens and on the sensitivity of the test methods used.

The requirements for antigen configuration are stringent: it must allow the safe detection of all clinically significant antibodies. For the Rh system, MNSs, Duffy and Kidd, the antigens must be in homozygous form. The Lewis antigens must be present, as should the rare antigen Kp^a.

It is generally considered most effective to perform screening tests by both anti-human globulin (AHG) and enzyme test procedures. Due to higher sensitivity of the indirect antiglobulin test (IAT) with new procedures such as the Bio-Rad ID-System, some scientists in various countries have formed the opinion that the enzyme test has become somewhat less important.

However, enzyme techniques are useful when increased sensitivity in antibody screening is desired or where more than one antibody may be present. They enhance the reactions of certain antibodies, notably in the Rh, Kell and Kidd systems, whereas antibodies to enzyme-sensitive antigens may not be detected, notably in the Duffy and MNS Systems.

The test cell reagents are specially designed for the ID-System.

REAGENTS

IVD

All test cell reagents are of human origin, in a buffered suspension medium at 0.89% (± 0,1%).
Preservatives: the antibiotics trimethoprim and sulfamethoxazole.

For antibody screening, single donors, blood group O:

ID-DiaCell I-II	$R_1^wR_1$-R_2R_2 for IAT and NaCl test
ID-DiaCell I-II-III	$R_1^wR_1$-R_2R_2-rr for IAT and NaCl test
ID-DiaCell I-II-III P	papainized, for enzyme technique
ID-DiaCell Pool	R_1R_1-R_2R_2 (2 pooled cells for donor screening)
ID-DiaCell I-II-III Asia	R_1R_1-R_2R_2-cell of the GPMUR phenotype, for IAT and NaCl test

For antibody identification, single donors, blood group O:

ID-DiaPanel	11 test cells for IAT and NaCl test
ID-DiaPanel P	11 test cells papainized, for enzyme technique

Special antigens:

These cells are for use as an adjunct with other routine antibody screening cell sets.

ID-Di^a (Diego) positive
ID-I negative cell

Shipment on standing order, every 4 weeks.

Caution: The source materials from which these products were manufactured, were found non-reactive for HBsAg, HCV and HIV (1+2) when tested with licensed reagents. However, no known test method can assure that infectious agents are absent. Products from human blood should be considered potentially infectious.

Stability: see expiry date on label.

ADDITIONAL REAGENTS REQUIRED

- ID-Card "LISS Coombs + Enzyme Test" 3 microtubes with polyspecific anti-human globulin AHG) serum and 3 microtubes containing neutral gel (id-no: 50581).
- ID-Card "LISS/Coombs" 6 microtubes with polyspecific AHG serum (id-no: 50531).
- ID-Card "Coombs Anti-IgG" 6 microtubes containing rabbit anti-IgG (id-no: 50540).
- ID-Card "NaCl, Enzyme test and cold agglutinins" 6 microtubes containing neutral gel (id-no: 50520).
- ID-Card "Reverse Grouping with Antibody Screening" 3 microtubes containing neutral gel and 3 microtubes containing polyspecific anti-human globulin (AHG) serum (id-no: 50510).
- ID-Diluent 2: modified LISS for red cell suspensions (id-no: 05761).

(see related package insert)

FURTHER MATERIALS REQUIRED

- ID-Dispensar
- ID-Pipetor
- ID-Tips (pipetor tips)
- ID-Working Table
- Suspension Tubes
- ID-Incubator 37 °C
- ID-Centrifuge 8, 12 or 24

SAMPLE MATERIAL

For optimal results, the determination should be performed using a freshly drawn sample, or in accordance with local laboratory procedures for sample acceptance criteria. Preferably, blood samples should be drawn into citrate, EDTA or CPD-A anticoagulant. Samples drawn into plain tubes (no anticoagulant) may also be used.

BIO-RAD

Test cell reagents for the ID-System

English B004350 05.10

CONTROLS

Controls should be included in accordance with the relevant guidelines of quality assurance.

USE OF THE ID-TEST CELL REAGENTS

- All test cell reagents are for use with the ID-Cards of the Bio-Rad ID-System only.
- Strictly follow the test procedures as described in the specific package inserts of the ID-Cards to be used.
- Always gently resuspend the red cells, by inverting the vial several times before use and also before placing the vials into a pipetting automate.
- Make sure that the test cells are at room temperature (18-25 °C) when in use.
- During the working procedures, check that the test cell reagents remain in suspension. If there is settling of the cells, resuspend again.
- For the ID-System, precise pipetting is of importance. Use the ID-Pipetors for serial pipetting.
- Avoid contamination of the test cell reagents.
- When recording the reactions, ensure that the lot number of the antigen table corresponds with the lot number of the reagent vials.
- After use, close the vials and replace them in the refrigerator.

INTERPRETATION OF THE RESULTS

A) Principle [2]

Positive: Agglutinated cells forming a red line on the surface of the gel or agglutinates dispersed in the gel.

Negative: Compact button of cells on the bottom of the microtube.

Note: Test cell reagents for antibody screening containing pooled cells can show a double cell population appearance depending on the antibody present. This is considered to be a positive result.

B) Reactions

see package inserts of the corresponding ID-Cards

LIMITATIONS

a) Bacterial or other contamination of materials used can cause false positive or false negative results.
b) Strict adherence to the procedures and recommended equipment is essential. The equipment should be checked regularly according to GLP procedures.

BIBLIOGRAPHY

1. Technical Manual of the American Association of Blood Banks, 13th edition, 1999.
2. Laplerre, Y., Rigal, D., Adam, J. et al.: The gel test: A new way to detect red cell antigen-antibody reaction. Transfusion 1990;30:109-113.

PRODUCTS

ID-DiaCell I-II-III (id-no: 45104)	Set of 3 vials ($R_1^wR_1$-R_2R_2-rr)	3 x 10 mL ..... REF 004310
ID-DiaCell I-II-III (id-no: 45404)	Set of 3 vials ($R_1^wR_1$-R_2R_2-rr)	3 x 5 mL ..... REF 004304
ID-DiaCell I-II-III Asia (id-no: 45330)	Set of 3 vials (R_1R_1-R_2R_2-GPMUR)	3 x 10 mL ..... REF 003614
ID-DiaCell I-II-III P (id-no: 45104)	Set of 3 vials ($R_1^wR_1$-R_2R_2-rr papainized)	3 x 10 mL ..... REF 005310
ID-DiaCell I-II-III P (id-no: 45414)	Set of 3 vials ($R_1^wR_1$-R_2R_2-rr papainized)	3 x 5 mL ..... REF 005304
ID-DiaCell I-II (id-no: 45151)	Set of 2 vials ($R_1^wR_1$-R_2R_2)	2 x 10 mL ..... REF 003613
ID-DiaCell Pool (id-no: 06070)	2 pooled cells (R_1R_1-R_2R_2)	1 x 10 mL ..... REF 003630
ID-DiaCell Pool (id-no: 06070)	2 pooled cells (R_1R_1-R_2R_2)	3 x 10 mL ..... REF 003601
ID-DiaPanel (id-no: 45161)	Set of 11 vials	11 x 4 mL ..... REF 004114
ID-DiaPanel P (id-no: 45171)	Set of 11 vials	11 x 4 mL ..... REF 004214
ID-Di^a (Diego) positive (id-no: 05980)		1 x 10 mL ..... REF 004154
ID-I negative cell (id-no: 06291)		1 x 1,6 mL ..... REF 004111

These products are guaranteed to perform as described on the label and in the instruction sheet. The manufacturer declines all responsibility arising out of the use or sale of these products in any way or for any purpose other than those described therein.

DiaMed GmbH
1785 Cressier FR
Switzerland

CE 0123

BIO-RAD

Tyrimo ląstelės, skirtos ID-Micro Typing sistemai
Antikūnių skryningui: ID-DiaCell I-II, ID-DiaCell I-II-III, ID-DiaCell I-II-III P (papainizuotas), ID-DiaCell I-II-III Azija, ID-DiaCell Pool;
Antikūnių identifikavimui: ID-Panel, ID-Panel P;
Specialūs antigenai:ID-Di^a (Diego) teigiama, ID-I negatyve cell

ĮVADAS

Antikūnių nustatymas labai priklauso nuo tyrimo ląstelių su atitinkamais antigenais ir nuo naudojamo tyrimo metodo jautrumo.
Antigeno nustatymo reikalavimai: visi kliniškai svarbūs antikūnai turi būti nustatomi saugiai. Nustatant Rh, MNSs, Duffy ir Kidd, antigenai turi būti homozigotiniai. Turi būti Lewis antigenų ir retai sutinkamas Kp^a.
Paprastai manoma, kad efektyviausia skryningą atlikti su antiglobulininiu žmogaus serumu (AHG) ir enzimo tyrimu. Dėl aukšto netiesioginio antiglobulininio tyrimo (IAT) jautrumo ir naujų metodų, tokių kaip DiaMed-ID Micro Typing System, kai kurių šalių mokslininkai mano, kad enzimo tyrimas nebėra toks svarbus.
Tačiau enzimo tyrimas yra naudingas, kai reikia padidinto jautrumo antikūnių skryninge arba kai numanomas daugiau nei vienas antikūnis. Jie sustiprina tam tikrų antikūnių reakcijas, ypač Rh, Kell ir Kidd sistemos, tačiau galima nenustatyti antikūnių prieš enzimui jautrius antigenus, ypač Duffy ir MNS sistemas.
Tyrimo ląstelės skirtos darbui su ID-Micro Typing sistema.

REAGENTAI

Visos tyrimo ląstelės yra žmogaus kilmės, buferio suspensijoje vidutiniškai 0,8% (±0,1%).
Konservantai: antibiotikai trimetoprimas ir sulfametoksazolis.

Antikūnių skryningui, vienas donoras, kraujo grupė O:

ID-DiaCell I-II	$R_1^wR_1+R_2R_2$, skirtos IAT ir NaCl tyrimams
ID-DiaCell I-II-III	$R_1^wR_1+R_2R_2$+rr, skirtos IAT ir NaCl tyrimams
ID-DiaCell I-II-III P	papainizuotas, skirtas enzimo metodikai
ID-DiaCell Pool	$R_1R_1+R_2R_2$ (2 suriktos eritrocitų grupės, skirtos donorų skryningui)
ID-DiaCell I-II-III Azija	$R_1R_1+R_2R_2$+GP.MUR fenotipo ląstelės, skirtos IAT ir NaCl tyrimams

Antikūnių identifikavimui, vienas donoras, kraujo grupė O

ID-DiaPanel	11 tyrimo ląstelių grupių, skirtų IAT ir NaCl tyrimams
ID-DiaPanel P	11 papainizuotų tyrimo ląstelių grupių, skirtų enzimo metodikai

Specialūs antigenai
Šios tyrimo ląstelės naudojamos kartu su kitais rutiniškai atliekamais tyrimais atliekant antikūnių skryningą.
ID-Di^a (Diego) teigiamas
ID-I negatyve cell

Pristatoma kas 4 savaitės.

Įspėjimas: *Šios medžiagos yra ištirtos ir nereaktyvios su HBsAg, HCV ir ŽIV (1+2) reagentais. Tačiau nei vienas žinomas metodas neužtikrina, kad infekcijos nėra. Visi produktai iš žmogaus kraujo turi būti laikomi galimai infekuotais.*

Stabilumas: žiūr. galiojimo datą ant įpakavimo.
Laikymas: saugoti 2°C-8°C.

PAPILDOMAI REIKALINGI REAGENTAI

- ID-kortelė „LISS Coombs + enzime test" 3 mikromėgintuvėliai su polispecifiniu žmogaus anti-globulino (AHG) serumu ir 3 mikromėgintuvėliai su neutraliu geliu (ID-nr: 50581).
- ID-kortelė „LISS Coombs" 6 mikromėgintuvėliai su polispecifiniu AHG serumu (ID-nr: 50531).
- ID-kortelė „Coombs Anti-IgG" 6 mikromėgintuvėliai su triušio anti-IgG (ID-nr: 50540).
- ID-kortelė „NaCl, enzime test and cold agglutinins" 6 mikromėgintuvėliai, užpildyti neutraliu geliu (ID-nr: 50520).
- ID-kortelė „Reverse grouping with antibody screening" 3 mikromėgintuvėliai su neutraliu geliu ir 3 mikromėgintuvėliai su polispecifiniu žmogaus anti-globulino (AHG) serumu (ID-nr: 50510).
- ID-Diluent 2: modifikuotas LISS tirpalas, skirtas eritrocitų suspensijai (ID-nr: 05761).
  (papildomai žiūrėkite įdėtą informaciją)

TOLIAU REIKALINGI REIKMENYS

ID-Dispenseris
ID-Pipetorius
ID-Antgaliai (pipečių antgaliai)
Suspensijų mėgintuvėliai
ID-Darbo stalas
ID-Inkubatorius 37°C
ID-Centrifuga 6, 12 ar 24

TIRIAMO PAVYZDŽIO MEDŽIAGA

Norint gauti optimalus rezultatus, reikia tirti šviežią kraują arba pagal vietinės laboratorijos nuostatus. Geriau jei kraujas stabilizuojamas antikoaguliantais: citratu, EDTA, CPD-A.Taip pat galima naudoti ką tik paimtą kraują be antikoagulianto.

KONTROLĖS

Kokybės užtikrinimui reikėtų įtraukti žinomus teigiamos ir neigiamos kontrolės mėginius.

ID-TYRIMO LĄSTELIŲ PANAUDOJIMAS

- Visos tyrimo ląstelės naudojamos tik su DiaMed-ID Micro Typing sistemos kortelėmis.
- **Griežtai laikykitės prie ID-kortelių esančių specifinių instrukcijų.**
- Visada kruopščiai sumaišykite eritrocitus, apversdami buteliukus kelis kartus prieš naudojimą ir prieš įdėdami į pipetavimo automatą.
- Įsitikinkite, kad tyrimo ląstelės prieš naudojimą sušilo iki kambario temperatūros (18-25°C).

- Tyrimo metu patikrinkite, kad ląstelės būtų suspensijoje. Jei yra nusėdusių ląstelių, sumaišykite iš naujo.
- **ID-Sistemai labai svarbus preciziškas pipetavimas.** Jei pipetuojama daug kartų iš eilės, naudokitės ID-Pipetoriumi. Jei atliekate skubų vieną tyrimą, nenaudokite pipečių, esančių prie buteliukų, nes lašinamas kiekis gali būti netikslus.
- Venkite tyrimo ląstelių užteršimo.
- Po naudojimo, buteliukus uždarykite ir padėkite į šaldytuvą.

REZULTATŲ INTERPRETAVIMAS

A) Principas
Teigiamas: agliutinatai suformavę raudoną liniją gelio paviršiuje arba prasiskverbę į jo gilumą.
Neigiamas: visos ląstelės mikromėgintuvėlio dugne.
Pastaba: atliekant antikūnių skryningą galima gauti dvigubą populiaciją, priklausomai nuo esančių antikūnių. Tai laikoma teigiama reakcija.

B) Reakcijos
Žiūrėkite atitinkamų ID-kortelių instrukcijas

APRIBOJIMAI

a) Bakterinis ir kitoks naudojamų medžiagų užteršimas gali duoti klaidingai teigiamus ar neigiamus rezultatus.
b) Būtina griežtai prisilaikyti procedūros, reagentų ir įrangos naudojimo rekomendacijų. Įrangą būtina reguliariai tikrinti pagal GLP ir šalies standartizacijos ir metrologijos procedūras.

LITERATŪRA

1. Technical Manual of the American Association of Blood Blanks, 13th edition, 1999.
2. Lapierre, Y.,Rigal, D.,Adam, J. et al.: The gel test; A new way to detect red cell antigen-antibodyreaction. Transfusion 1990; 30:109-113.

PRODUKTAI

ID-DiaCell I-II-III (ID-nr: 45184)	3 buteliukų rinkinys ($R_1^wR_1$- R_2R_2-rr)	3×10ml.....REF 004310
ID-DiaCell I-II-III (ID-nr: 45404)	3 buteliukų rinkinys ($R_1^wR_1$- R_2R_2-rr)	3×5ml.....REF 004304
ID-DiaCell I-II-III Azijos (ID-nr: 45330)	3 buteliukų rinkinys (R_1R_1- R_2R_2-GP.MUR)	3×10ml.....REF 003614
ID-DiaCell I-II-III P (ID-nr: 45194)	3 buteliukų rinkinys ($R_1^wR_1$- R_2R_2-rr papainizuotas)	3×10ml.....REF 005310
ID-DiaCell I-II-III P (ID-nr: 45414)	3 buteliukų rinkinys ($R_1^wR_1$- R_2R_2-rr papainizuotas)	3×5ml.....REF 005304
ID-DiaCell I-II (ID-nr: 45151)	2 buteliukų rinkinys ($R_1^wR_1$+R_2R_2)	2×10ml.....REF 003613
ID-DiaCell I-II Pool	2 rinkinių buteliukas (R_1R_1+R_2R_2)	1×10ml.....REF 003630

(ID-nr: 06070)		
ID-DiaCell I-II Pool (ID-nr: 06070)	2 rinkinių buteliukas (R_1R_1+R_2R_2)	3×10ml.....REF 003631
ID-DiaPanel (ID-nr: 45161)	11 buteliukų rinkinys	11×4ml.....REF 004114
ID-DiaPanel P (ID-nr: 45171)	11 buteliukų rinkinys	11×4ml.....REF 004214
ID-Di^a (Diego) (ID-nr: 45161)		1×10ml.....REF 004134
ID-I negatyve cell (ID-nr: 06291)		1×1,6ml.....REF 004111

Šių produktų kokybė garantuojama, kai tyrimas atliekamas pagal aprašymą. Gamintojas neprisiima atsakomybės jei produktas naudojamas ar parduodamas kitais būdais ar tikslais, skirtingai negu šioje instrukcijoje aprašyta.

DiaCell ABO

English B109411 08.10

human

Red cell reagents for reverse grouping

INTRODUCTION

Blood group test results obtained with anti-A, anti-B and anti-AB test sera should be considered valid only if the natural occuring blood group antibodies (isoagglutinins) are tested at the same time, by reverse grouping method.

DiaCell ABO red cell reagents are prepared from selected donors' blood and are suitable for reverse grouping, the detection of hemolysins, immune A and B antibodies and for the control of ABO test sera in conventional techniques.

REAGENTS

IVD

All test cell reagents are of human origin, in a buffered suspension at 3% ±1.
Preservatives: the antibiotics trimethoprim and sulfamethoxazole.

DiaCell ABO: A_1, A_2, B, O
A_2, B
A_1 coddee
A_2 coddee
B coddee
O CcD,Ee

Shipment on standing order every 4 weeks

Caution: The source materials from which these products were manufactured, were found non reactive for HBsAg, HCV and HIV (1+2) when tested with licensed reagents. However, no known test method can assure that infectious agents are absent. Products from human blood should be considered potentially infectious.

Stability: see expiry date on label

FURTHER MATERIALS REQUIRED

- Suspension tubes
- Tube rack
- Pipette
- Immunhaematological Centrifuge

SAMPLE MATERIAL

For optimal results, the determination should be performed using a freshly drawn sample, or in accordance with local laboratory procedures for sample acceptance criteria. Preferably, blood samples should be drawn into citrate, EDTA or CPD-A anticoagulant. Samples drawn into plain tubes (no anticoagulant) may also be used.

When the use of serum instead of plasma is required, the serum must be well cleared, by centrifugation at 1500 g for 10 minutes, before use to avoid fibrin residues, which may interfere with the reaction pattern.

CONTROLS

Controls should be included in accordance with the relevant guidelines of quality assurance.

USE OF THE TEST CELL REAGENTS

- Always gently resuspend the red cells by inverting the vial several times before use.
- Make sure that the cells are at room temperature (18-25 °C) when in use.
- During the working procedures, check that the test cell reagents remain in suspension.
- Avoid contamination of the test cell reagents.
- After use, close the vials and replace them in the refrigator.

TEST PROCEDURE

Tube Test

1. Identify test tubes with A_1, A_2, B and O.
2. Add into each tube 2 drops (100 µL) of the serum or plasma to be tested.
3. Add 1 drop (50 µL) of the corresponding red cell reagent.
4. Mix well by shaking gently and centrifuge for 20 seconds at 1000 g (3400 rpm) or 1 minute at 125 g (1000 rpm).
5. Gently resuspend the cells and, over an indirect light source, observe macroscopically for agglutination.

DiaCell ABO

English B109411 08.10

INTERPRETATION OF THE RESULTS

A) Principle

- Agglutination indicates the presence of antibodies.
- Haemolysis also indicates the presence of antibodies (see remark 3).
- No agglutination (or haemolysis) indicates the absence of ABO antibodies.

B) Reaction with DiaCell ABO

A_1	A_2	B	O	Isoagglutinins	Blood group
-	-	+	-	anti-B	A
+	+	-	-	anti-a	B
-	-	-	-	none	AB
+	+	+	-	anti-B and anti-B	O

Note: The results of the reverse grouping must agree with the blood group observed from forward (antigen) typing. Discrepant results should be subjected to further investigation, preferably with a new sample.

REMARKS

1. The optimal reaction temperature for isoagglutinins is 4 °C. If weak or doubtful reactions are observed in the normal test procedure repeat the test with an incubation at 2-8 °C for 15 minutes.
2. Atypical reactions require further studies.
3. If the sample shows no haemolysis, but haemolysis is observed after testing, repeat the test after inactivation of the serum to be tested (10 minutes incubation at 56 °C). Haemolysis of the "A" and "B" cells may indicate the presence of high titers of isoagglutinins and of immune anti-A and immune anti-B. Such immune antibodies may cause haemolytic disease of the newborn due to ABO incompatibility.
4. In general, anti-A and anti-B iso-antibodies are not detectable in newborns and infants. Older people and patients with agammaglobulinaemia may also lack these iso-antibodies.

LIMITATIONS

a) Bacterial or other contamination of materials used can cause false positive or false negative results.
b) Strict adherence to the procedures and recommended equipment is essential. The equipment should be checked regularly according to GLP procedures.

BIBLIOGRAPHY

1. Technical Manual of the American Association of Blood Banks, 13th edition, 1999.
2. Human Blood Groups, second edition, Geoff Daniels, Blackwell Science LTD, 2002.

PRODUCTS

DiaCell ABO A_1, A_2, B, O (Id-n°: 45111)	Set of 4 vials	4 x 5 mL ..... REF 109445
DiaCell ABO A_1, A_2, B, O (Id-n°: 45061)	Set of 4 vials	4 x 10 mL ..... REF 109414
DiaCell ABO A_1, B (Id-n°: 45101)	Set of 2 vials	2 x 10 mL ..... REF 109416
DiaCell ABO A_1 (Id-n°: 16011)	single vial	1 x 5 mL ..... REF 109405 1 x 10 mL ..... REF 109410
DiaCell ABO A_2 (Id-n°: 16021)	single vial	1 x 5 mL ..... REF 109406 1 x 10 mL ..... REF 109411
DiaCell ABO B (Id-n°: 16031)	single vial	1 x 5 mL ..... REF 109407 1 x 10 mL ..... REF 109412
DiaCell ABO O (Id-n°: 16041)	single vial	1 x 5 mL ..... REF 109408 1 x 10 mL ..... REF 109413

These products are guaranteed to perform as described on the label and in the instruction sheet. The manufacturer declines all responsibility arising out of the use or sale of these products in any way or for any purpose other than those described therein.

ID-DiaCell ABO
Tyrimo ląstelės atvirkštiniam grupavimui

ĮVADAS

Tyrimo ląstelės rutiniškai naudojamos kraujo grupių serologijoje, jų pagalba nustatomi esantys arba nesantys anti-A ir anti-B izoagliutininai (atvirkštiniam grupavimui).
Atvirkštiniam grupavimui pagal įvairius reikalavimus ir nuorodas naudojamos tokių grupių ląstelės: A_1 ir B/A_1 , A_2 ir B/A_1, B ir B/A_1, B ir O ar A_1, A_2, B ir O.
Tyrimo ląstelės skirtos darbui su ID-Micro Typing sistema.

REAGENTAI

Visos tyrimo ląstelės yra žmogaus kilmės, buferio suspensijoje vidutiniškai 0,8% (±0,1%).
Konservantai: antibiotikai trimetoprimas ir sulfametoksazolis.
ID-DiaCell ABO: A_1, A_2, B, O/A_1, A_2, B/A_1, B, O/A_1, $B/A_1/A_2/B/O$
Pristatoma kas 4 savaitės.

Įspėjimas: *Šios medžiagos yra ištirtos ir nereaktyvios su HBsAg, HCV ir ŽIV (1+2) reagentais. Tačiau nei vienas žinomas metodas neužtikrina, kad infekcijos nėra. Visi produktai iš žmogaus kraujo turi būti laikomi galimai infekuotais.*

Stabilumas: žiūr. galiojimo datą ant įpakavimo.
Laikymas: saugoti 2°C-8°C.

PAPILDOMAI REIKALINGI REAGENTAI

- ID-kortelė „NaCl, enzime test and cold agglutinins" su 6 mikromėgintuvėliais, užpildytais neutraliu geliu (ID-nr: 50520).
- ID-kortelė „Reverse grouping žith antibody screening" su 3 mikromėgintuvėliais, užpildytais neutraliu geliu ir 3 mikromėgintuvėliais, užpildytais polispecifiniu anti-globulino (AHG) serumu (ID-nr: 50510).
- ID-kortelė „ABO/D+ reverse grouping", A-B-D-ctl/A_1-B (ID-nr: 50080).
- ID-kortelė „DiaClon ABO/D + reverse grouping", A-B-$D^{(VI-)}$-ctl/A_1-B (ID-nr: 50091).

(papildomai žiūrėkite informaciją įpakavimuose)

TOLIAU REIKALINGI REIKMENYS

ID-Dispenseris
ID-Pipetorius
ID-Antgaliai (pipečių antgaliai)
Suspensijų mėgintuvėliai
ID-Darbo stalas
ID-Inkubatorius 37°C
ID-Centrifuga 6, 12 ar 24

Norint gauti optimalus rezultatus, reikia tirti šviežią kraują arba pagal vietinės laboratorijos nuostatus. Geriau jei kraujas stabilizuojamas antikoaguliantais: citratu, EDTA, CPD-A.Taip pat galima naudoti ką tik paimtą kraują be antikoagulianto.
Kai naudojamas serumas vietoj plazmos, serumą reikia tinkamai paruošti nucentrifuguojant prie 1500g per 10min, kad neliktų fibrino likučių, kurie gali pakeisti rezultatą.

KONTROLĖS

Kokybės užtikrinimui reikėtų įtraukti žinomus teigiamos ir neigiamos kontrolės mėginius.

ID-TYRIMO LĄSTELIŲ PANAUDOJIMAS

- Visos tyrimo ląstelės naudojamos tik su DiaMed-ID Micro Typing sistemos kortelėmis.
- **Griežtai laikykitės prie ID-kortelių esančių specifinių instrukcijų.**
- Visada kruopščiai sumaišykite eritrocitus, apversdami buteliukus kelis kartus prieš naudojimą ir prieš įdėdami į pipetavimo automatą.
- Įsitikinkite, kad tyrimo ląstelės prieš naudojimą sušilo iki kambario temperatūros (18-25°C).
- Tyrimo metu patikrinkite, kad ląstelės būtų suspensijoje. Jei yra nusėdusių ląstelių, sumaišykite iš naujo.
- **ID-Sistemai labai svarbus preciziškas pipetavimas.** Jei pipetuojama daug kartų iš eilės, naudokitės ID-Pipetoriumi. Jei atliekate skubų vieną tyrimą, nenaudokite pipečių, esančių prie buteliukų, nes lašinamas kiekis gali būti netikslus.
- Venkite tyrimo ląstelių užteršimo.
- Po naudojimo, buteliukus uždarykite ir padėkite į šaldytuvą.

REZULTATŲ INTERPRETAVIMAS

A) Principas
- Agliutinacija parodo, kad agliutininų yra.
- Jei agliutinacijos nėra, agliutininų irgi nėra.

B) Reakcija su ID-DiaCell ABO

A_1	A_2	B	O	Izoagliutininai	Kraujo grupė
-	-	+	-	Anti-B	**A**
+	+	-	-	Anti-A	**B**
-	-	-	-	nėra	**AB**
+	+	+	-	Anti-A ir anti-B	**O**

Pastaba: *Atvirkštinio grupavimo rezultatai turi sutapti su grupe iš antigenų tipavimo. Prieštaringus rezultatus reikia pakartotinai tirti, geriau su nauju mėginiu.*

PASTABOS

1. Optimali reakcijos temperatūra izoagliutininų nustatymui yra 4°C. Jei stebimos silpnos ar abejotinos reakcijos, tyrimą reikia pakartoti inkubuojant 2-8°C 15 min.
2. Atipines reakcijas reikia toliau tirti.
3. Bendrai, anti-A ir anti-B izoagliutininai nenustatomi naujagimiams ir kūdikiams. Šių izoagliutininų gali trūkti ir senyvo amžiaus žmonėms bei asmenims su agamaglobulinemija.

a) Bakterinis ir kitoks naudojamų medžiagų užteršimas gali duoti klaidingai teigiamus ar neigiamus rezultatus.
b) Būtina griežtai prisilaikyti procedūros, reagentų ir įrangos naudojimo rekomendacijų. Įrangą būtina reguliariai tikrinti pagal GLP ir šalies standartizacijos ir metrologijos procedūras.

LITERATŪRA

1. Technical Manual of the American Association of Blood Blanks, 13th edition, 1999.
2. Lapierre, Y.,Rigal, D.,Adam, J. et al.: The gel test; A new way to detect red cell antigen-antibodyreaction. Transfusion 1990; 30:109-113.

PRODUKTAI

ID-DiaCell ABO (ID-nr: 45022)	4 buteliukų rinkinys (A_1-A_2-B-O)	4×10ml.....REF 003619
ID-DiaCell ABO (ID-nr: 45082)	3 buteliukų rinkinys (A_1-A_2-B)	3×10ml.....REF 003617
ID-DiaCell ABO (ID-nr: 45352)	3 buteliukų rinkinys (A_1-B-O)	3×10ml.....REF 003615
ID-DiaCell ABO (ID-nr: 45092)	2 buteliukų rinkinys (A_1-B)	2×10ml.....REF 003624
ID-DiaCell ABO (ID-nr: 06012)	vienas buteliukas A_1	1×10ml.....REF 003620
ID-DiaCell ABO (ID-nr: 06022)	vienas buteliukas A_2	1×10ml.....REF 003621
ID-DiaCell ABO (ID-nr: 06032)	vienas buteliukas B	1×10ml.....REF 003622
ID-DiaCell ABO (ID-nr: 06042)	vienas buteliukas O	1×10ml.....REF 003623

Šių produktų kokybė garantuojama, kai tyrimas atliekamas pagal aprašymą. Gamintojas nepriisiima atsakomybės jei produktas naudojamas ar parduodamas kitais būdais ar tikslais, skirtingai negu šioje instrukcijoje aprašyta.

BIO-RAD

Safety data sheet

according to 1907/2006/EC, Article 31

Printing date 03.07.2013 Version number 1 Revision: 28.05.2013

1 Identification of the substance/mixture and of the company/ undertaking

· **Product identifier**

· **Trade name:** NACL, LISS/Coombs, DAT, Coombs Anti-IgG and Screening

· **Bio-Rad MSDS Number:** 2008M

· **References and packagings (Id-N°):**

50520 NaCl, Enzyme Test and Cold Aggluzinins
50531 LISS/Coombs
50830 DC-Screening I
50560 DC-Screening II
50540 Coombs Anti-IgG
50450 Anti-IgG Coombs
50870 DAT Igg-Dilution
50890 DAT IgG1/IgG3
50571 DiaScreen
50581 LISS/Coombs + Enzyme Test
50549 Coombs Anti-IgG
50530 ID-Liss/Coombs
50682 DiaClon Type + Screen
50683 DiaClon Type + Screen
50591 Complete Crossmatch
50601 DiaClon Complete Crossmatch
50771 DiaClon BAS-Test
51190 DiaClon BAS-Test IgG
50510 Reverse Grouping with Antibody Screening

· **Relevant identified uses of the substance or mixture and uses advised against**
No further relevant information available.

· **Application of the substance / the preparation**
In vitro diagnostic medical device or component.

· **Details of the supplier of the safety data sheet**

· **Manufacturer/Supplier:**
DiaMed GmbH
Pra Rond 23
CH-1785 Cressier FR
(Switzerland/Schweiz/Suisse/Swizzera)
Tel: +41 (0)26 674 51 11
Fax: +41 (0)26 674 51 45

· **Further information obtainable from:** fds-msds.ch@bio-rad.com

· **Emergency telephone number:** Tel.: 145 oder/or/ou +41 442 51 51 51

2 Hazards identification

· **Classification of the substance or mixture**
The product is not classified according to the Globally Harmonized System (GHS).

· **Classification according to Directive 67/548/EEC or Directive 1999/45/EC**
Not applicable.

(Contd. on page 2)

BIO-RAD

Safety data sheet
according to 1907/2006/EC, Article 31

Printing date 03.07.2013 Version number 1 Revision: 28.05.2013

(Contd. of page 1)

· **Information concerning particular hazards for human and environment:**
The product does not have to be labelled due to the calculation procedure of the "General Classification guideline for preparations of the EU" in the latest valid version.

· **Classification system:**
The classification is according to the latest editions of the EU-lists, and extended by company and literature data.

· **Label elements**

· **Labelling according to EU guidelines:**
Observe the general safety regulations when handling chemicals.
The product is not subject to identification regulations under EU Directives and the Ordinance on Hazardous Materials (German GefStoffV).

· **Other hazards**

· **Results of PBT and vPvB assessment**

· **PBT:** Not applicable.

· **vPvB:** Not applicable.

3 Composition/information on ingredients

· **Chemical characterization: Mixtures**

· **Description:**
Mixture of substances listed below with nonhazardous additions.

· **Additional information:**
For the wording of the listed risk phrases refer to section 16.

4 First aid measures

· **Description of first aid measures**

· **General information:** No special measures required.

· **After inhalation:**
Supply fresh air; consult doctor in case of complaints.

· **After skin contact:** Generally the product does not irritate the skin.

· **After eye contact:**
Rinse opened eye for several minutes under running water.

· **After swallowing:** If symptoms persist consult doctor.

· **Information for doctor:**

· **Most important symptoms and effects, both acute and delayed**
No further relevant information available.

· **Indication of any immediate medical attention and special treatment needed**
No further relevant information available.

5 Firefighting measures

· **Extinguishing media**

· **Suitable extinguishing agents:**
CO2, powder or water spray. Fight larger fires with water spray or alcohol resistant foam.
Use fire extinguishing methods suitable to surrounding conditions.

· **Special hazards arising from the substance or mixture**
No further relevant information available.

(Contd. on page 3)

1.248#

BIO-RAD

Safety data sheet
according to 1907/2006/EC, Article 31

Printing date 03.07.2013 Version number 1 Revision: 28.05.2013

(Contd. of page 2)

· **Advice for firefighters**
· **Protective equipment:** No special measures required.

6 Accidental release measures

· **Personal precautions, protective equipment and emergency procedures**
Not required.
· **Environmental precautions:**
Dilute with plenty of water.
Do not allow to enter sewers/ surface or ground water.
· **Methods and material for containment and cleaning up:**
Absorb with liquid-binding material (sand, diatomite, acid binders, universal binders, sawdust).
· **Reference to other sections**
No dangerous substances are released.
See Section 7 for information on safe handling.
See Section 8 for information on personal protection equipment.
See Section 13 for disposal information.

7 Handling and storage

· **Handling:**
· **Precautions for safe handling** No special measures required.
· **Information about fire - and explosion protection:**
No special measures required.

· **Conditions for safe storage, including any incompatibilities**
· **Storage:**
· **Requirements to be met by storerooms and receptacles:**
No special requirements.
· **Information about storage in one common storage facility:**
Not required.
· **Further information about storage conditions:**
see related package insert
The substance / preparation must be stored between 18 °C and 25 °C
· **Specific end use(s)** No further relevant information available.

8 Exposure controls/personal protection

· **Additional information about design of technical facilities:**
No further data; see item 7.

· **Control parameters**
· **Additional information:**
The lists valid during the making were used as basis.

· **Exposure controls**
· **Personal protective equipment:**
· **General protective and hygienic measures:**
The usual precautionary measures are to be adhered to when handling chemicals.
· **Respiratory protection:** Not required.

(Contd. on page 4)

BIO-RAD

Safety data sheet
according to 1907/2006/EC, Article 31

Printing date 03.07.2013 Version number 1 Revision: 28.05.2013

(Contd. of page 3)

· **Protection of hands:**

Protective gloves

The glove material has to be impermeable and resistant to the product/ the substance/ the preparation.
· **Penetration time of glove material**
The exact break through time has to be found out by the manufacturer of the protective gloves and has to be observed.
· **Eye protection:** Safety glasses
· **Body protection:** Protective work clothing

9 Physical and chemical properties

· **Information on basic physical and chemical properties**	
· **General Information**	
· **Appearance:**	
· **Form:**	Liquid on inert carrier material
· **Colour:**	Different according to colouring
· **Odour:**	Odourless
· **Odour threshold:**	Not determined.
· **pH-value:**	Not determined.
· **Change in condition**	
· **Melting point/Melting range:**	Undetermined.
· **Boiling point/Boiling range:**	Undetermined.
· **Flash point:**	Not applicable.
· **Flammability (solid, gaseous):**	Not applicable.
· **Ignition temperature:**	
· **Decomposition temperature:**	Not determined.
· **Self-igniting:**	Product is not selfigniting.
· **Danger of explosion:**	Product does not present an explosion hazard.
· **Explosion limits:**	
· **Lower:**	Not determined.
· **Upper:**	Not determined.
· **Vapour pressure:**	Not determined.
· **Density:**	Not determined.
· **Relative density**	Not determined.
· **Vapour density**	Not determined.
· **Evaporation rate**	Not determined.
· **Solubility in / Miscibility with**	
· **water:**	Fully miscible.

(Contd. on page 5)

BIO-RAD

Safety data sheet
according to 1907/2006/EC, Article 31

Printing date 03.07.2013 Version number 1 Revision: 28.05.2013

(Contd. of page 4)

· **Partition coefficient (n-octanol/ water):**	Not determined.
· **Viscosity:**	
· **Dynamic:**	Not determined.
· **Kinematic:**	Not determined.
· **Solvent content:**	
· **Organic solvents:**	0,0 %
· **Water:**	8,6 %
· **Other information**	No further relevant information available.

10 Stability and reactivity

· **Reactivity**
· **Chemical stability**
· **Thermal decomposition / conditions to be avoided:**
No decomposition if used according to specifications.
· **Possibility of hazardous reactions** No dangerous reactions known.
· **Conditions to avoid** No further relevant information available.
· **Incompatible materials:** No further relevant information available.
· **Hazardous decomposition products:**
No dangerous decomposition products known.

11 Toxicological information

· **Information on toxicological effects**
· **Acute toxicity:**
· **LD/LC50 values relevant for classification:**
Sodium Azid is used as a preservative. (Concentration < 0.1%)

26628-22-8 Sodium Azide		
Oral	LD50	27 mg/kg (rat)
Dermal	LD50	20 mg/kg (rabbit)

· **Primary irritant effect:**
· **on the skin:** No irritant effect.
· **on the eye:** No irritating effect.
· **Sensitization:** No sensitizing effects known.
· **Additional toxicological information:**
The product is not subject to classification according to the calculation method of the General EU Classification Guidelines for Preparations as issued in the latest version.
When used and handled according to specifications, the product does not have any harmful effects to our experience and the information provided to us.

12 Ecological information

· **Toxicity**
· **Aquatic toxicity:** No further relevant information available.
· **Persistence and degradability** No further relevant information available.

(Contd. on page 6)

BIO-RAD

Safety data sheet
according to 1907/2006/EC, Article 31

Printing date 03.07.2013 Version number 1 Revision: 28.05.2013

(Contd. of page 5)

· **Behaviour in environmental systems:**
· **Bioaccumulative potential** No further relevant information available.
· **Mobility in soil** No further relevant information available.
· **Additional ecological information:**
· **General notes:**
Water hazard class 1 (German Regulation) (Self-assessment): slightly hazardous for water
Do not allow undiluted product or large quantities of it to reach ground water, water course or sewage system.
· **Results of PBT and vPvB assessment**
· **PBT:** Not applicable.
· **vPvB:** Not applicable.
· **Other adverse effects** No further relevant information available.

13 Disposal considerations

· **Waste treatment methods**
· **Recommendation**
Smaller quantities can be disposed of with household waste.
· **Uncleaned packaging:**
· **Recommendation:**
Disposal must be made according to official regulations.
· **Recommended cleansing agents:**
Water, if necessary together with cleansing agents.

14 Transport information

· **UN-Number**	
· **ADR, ADN, IMDG, IATA**	Void
· **UN proper shipping name**	
· **ADR, ADN, IMDG, IATA**	Void
· **Transport hazard class(es)**	
· **ADR, ADN, IMDG, IATA**	
· **Class**	Void
· **Packing group**	
· **ADR, IMDG, IATA**	Void
· **Environmental hazards:**	
· **Marine pollutant:**	No
· **Special precautions for user**	Not applicable.
· **Transport in bulk according to Annex II of MARPOL73/78 and the IBC Code**	Not applicable.
· **Transport/Additional information:**	Not dangerous according to the above specifications.
· **UN "Model Regulation":**	-

(Contd. on page 7)

BIO-RAD

Safety data sheet
according to 1907/2006/EC, Article 31

Printing date 03.07.2013 Version number 1 Revision: 28.05.2013

(Contd. of page 6)

15 Regulatory information

· **Safety, health and environmental regulations/legislation specific for the substance or mixture**

· **Labelling according to EU guidelines:**
Observe the general safety regulations when handling chemicals.
The product is not subject to identification regulations under EU Directives and the Ordinance on Hazardous Materials (German GefStoffV).

· **Chemical safety assessment:**
A Chemical Safety Assessment has not been carried out.

16 Other information

This information is based on our present knowledge. However, this shall not constitute a guarantee for any specific product features and shall not establish a legally valid contractual relationship.

· **Department issuing MSDS:**
DiaMed GmbH
Pra Rond 23
CH-1785 Cressier FR
(Switzerland/Schweiz/Suisse/Svizzera)

· **Abbreviations and acronyms:**
ADR: Accord européen sur le transport des marchandises dangereuses par Route (European Agreement concerning the International Carriage of Dangerous Goods by Road)
IMDG: International Maritime Code for Dangerous Goods
IATA: International Air Transport Association
GefStoffV: Gefahrstoffverordnung (Ordinance on Hazardous Substances, Germany)
LC50: Lethal concentration, 50 percent
LD50: Lethal dose, 50 percent

· *** Data compared to the previous version altered.**

BIO-RAD

Safety data sheet
according to 1907/2006/EC, Article 31

Printing date 03.07.2013 Version number 2 Revision: 03.07.2013

1 Identification of the substance/mixture and of the company/ undertaking

· **Product identifier**

· **Trade name:** ID Blood Groups, Rh & Reverse Grouping with Human Antibodies

· **Bio-Rad MSDS Number:** 2001M

· **References and packagings (Id-N°):**

50001 ABO/Rh
50061 ABO/Rh for Newborns
50081 ABO/D + Reverese Grouping
50041 ABD/Confirmation
50031 ABO/RhD
50140 Anti-A1 Absorbed

· **Relevant identified uses of the substance or mixture and uses advised against**
No further relevant information available.

· **Application of the substance / the preparation**
In vitro diagnostic medical device or component.

· **Details of the supplier of the safety data sheet**

· **Manufacturer/Supplier:**
DiaMed GmbH
Pra Rond 23
CH-1785 Cressier FR
(Switzerland/Schweiz/Suisse/Swizzera)
Tel: +41 (0)26 674 51 11
Fax: +41 (0)26 674 51 45

· **Further information obtainable from:** fds-msds.ch@bio-rad.com

· **Emergency telephone number:** Tel.: 145 oder/or/ou +41 442 51 51 51

2 Hazards identification

· **Classification of the substance or mixture**
The product is not classified according to the Globally Harmonized System (GHS).

· **Classification according to Directive 67/548/EEC or Directive 1999/45/EC**
Not applicable.

· **Information concerning particular hazards for human and environment:**
The product does not have to be labelled due to the calculation procedure of the "General Classification guideline for preparations of the EU" in the latest valid version.

· **Classification system:**
The classification is according to the latest editions of the EU-lists, and extended by company and literature data.

· **Label elements**

· **Labelling according to EU guidelines:**
Observe the general safety regulations when handling chemicals.
The product is not subject to identification regulations under EU Directives and the Ordinance on Hazardous Materials (German GefStoffV).

(Contd. on page 2)

BIO-RAD

Safety data sheet
according to 1907/2006/EC, Article 31

Printing date 03.07.2013 Version number 2 Revision: 03.07.2013

(Contd. of page 1)

· **Other hazards**

· **Results of PBT and vPvB assessment**

· **PBT:** Not applicable.

· **vPvB:** Not applicable.

3 Composition/information on ingredients

· **Chemical characterization: Mixtures**

· **Description:**
Mixture of substances listed below with nonhazardous additions.

· **Additional information:**
Caution: The source materials from which these products were manufactured, were found non reactive for HBsAg, HCV and HIV (1+2) when tested with licensed reagents. However, no known test method can assure that infectious agents are absent. Products from human blood should be considered potentially infectious.
Caution: All reagents should be treated as potentially infectious.
For the wording of the listed risk phrases refer to section 16.

4 First aid measures

· **Description of first aid measures**

· **General information:** No special measures required.

· **After inhalation:**
Supply fresh air; consult doctor in case of complaints.

· **After skin contact:** Generally the product does not irritate the skin.

· **After eye contact:**
Rinse opened eye for several minutes under running water.

· **After swallowing:** If symptoms persist consult doctor.

· **Information for doctor:**

· **Most important symptoms and effects, both acute and delayed**
No further relevant information available.

· **Indication of any immediate medical attention and special treatment needed**
No further relevant information available.

5 Firefighting measures

· **Extinguishing media**

· **Suitable extinguishing agents:**
CO2, powder or water spray. Fight larger fires with water spray or alcohol resistant foam.
Use fire extinguishing methods suitable to surrounding conditions.

· **Special hazards arising from the substance or mixture**
No further relevant information available.

· **Advice for firefighters**

· **Protective equipment:** No special measures required.

6 Accidental release measures

· **Personal precautions, protective equipment and emergency procedures**
Not required.

(Contd. on page 3)

#648.2

BIO-RAD

Safety data sheet
according to 1907/2006/EC, Article 31

Printing date 03.07.2013 Version number 2 Revision: 03.07.2013

(Contd. of page 2)

· **Environmental precautions:**
Dilute with plenty of water.
Do not allow to enter sewers/ surface or ground water.
· **Methods and material for containment and cleaning up:**
Absorb with liquid-binding material (sand, diatomite, acid binders, universal binders, sawdust).
· **Reference to other sections**
No dangerous substances are released.
See Section 7 for information on safe handling.
See Section 8 for information on personal protection equipment.
See Section 13 for disposal information.

*
7 Handling and storage

· **Handling:**
· **Precautions for safe handling** No special measures required.
· **Information about fire - and explosion protection:**
No special measures required.

· **Conditions for safe storage, including any incompatibilities**
· **Storage:**
· **Requirements to be met by storerooms and receptacles:**
No special requirements.
· **Information about storage in one common storage facility:**
Not required.
· **Further information about storage conditions:**
see related package insert
· **Specific end use(s)** No further relevant information available.

*
8 Exposure controls/personal protection

· **Additional information about design of technical facilities:**
No further data; see item 7.

· **Control parameters**
· **Additional information:**
The lists valid during the making were used as basis.

· **Exposure controls**
· **Personal protective equipment:**
· **General protective and hygienic measures:**
The usual precautionary measures are to be adhered to when handling chemicals.
· **Respiratory protection:**
Not necessary if room is well-ventilated.
· **Protection of hands:**

Protective gloves

The glove material has to be impermeable and resistant to the product/ the substance/ the preparation.
· **Material of gloves**
The selection of the suitable gloves does not only depend on the material, but also on further marks of quality and varies from manufacturer to manufacturer. As the product is a preparation of several substances, the resistance of the

(Contd. on page 4)

BIO-RAD

Safety data sheet
according to 1907/2006/EC, Article 31

Printing date 03.07.2013 Version number 2 Revision: 03.07.2013

(Contd. of page 3)

glove material can not be calculated in advance and has therefore to be checked prior to the application.
· **Penetration time of glove material**
The exact break through time has to be found out by the manufacturer of the protective gloves and has to be observed.
· **Eye protection:** Safety glasses
· **Body protection:** Protective work clothing

9 Physical and chemical properties

· **Information on basic physical and chemical properties**	
· **General Information**	
· **Appearance:**	
· **Form:**	Liquid
· **Colour:**	Various colours
· **Odour:**	Characteristic
· **Odour threshold:**	Not determined.
· **pH-value at 20 °C:**	7,1
· **Change in condition**	
· **Melting point/Melting range:**	Undetermined.
· **Boiling point/Boiling range:**	Undetermined.
· **Flash point:**	Not applicable.
· **Flammability (solid, gaseous):**	Not applicable.
· **Ignition temperature:**	
· **Decomposition temperature:**	Not determined.
· **Self-igniting:**	Product is not selfigniting.
· **Danger of explosion:**	Product does not present an explosion hazard.
· **Explosion limits:**	
· **Lower:**	Not determined.
· **Upper:**	Not determined.
· **Vapour pressure at 20 °C:**	23 hPa
· **Density at 20 °C:**	1,1 g/cm³
· **Relative density**	Not determined.
· **Vapour density**	Not determined.
· **Evaporation rate**	Not determined.
· **Solubility in / Miscibility with**	
· **water:**	Fully miscible.
· **Partition coefficient (n-octanol/ water):**	Not determined.
· **Viscosity:**	
· **Dynamic:**	Not determined.
· **Kinematic:**	Not determined.
· **Solvent content:**	
· **Organic solvents:**	0,0 %

(Contd. on page 5)

BIO-RAD

Safety data sheet
according to 1907/2006/EC, Article 31

Printing date 03.07.2013 Version number 2 Revision: 03.07.2013

(Contd. of page 4)

· Water:	13,5 %
· Other information	No further relevant information available.

10 Stability and reactivity

· **Reactivity**
· **Chemical stability**
· **Thermal decomposition / conditions to be avoided:**
No decomposition if used according to specifications.
· **Possibility of hazardous reactions** No dangerous reactions known.
· **Conditions to avoid** No further relevant information available.
· **Incompatible materials:** No further relevant information available.
· **Hazardous decomposition products:**
No dangerous decomposition products known.

*
11 Toxicological information

· **Information on toxicological effects**
· **Acute toxicity:**
· **LD/LC50 values relevant for classification:**
Sodium Azid is used as a preservative. (Concentration < 0.1%)

26628-22-8 Sodium Azide		
Oral	LD50	27 mg/kg (rat)
Dermal	LD50	20 mg/kg (rabbit)

· **Primary irritant effect:**
· **on the skin:** No irritant effect.
· **on the eye:** No irritating effect.
· **Sensitization:** No sensitizing effects known.
· **Additional toxicological information:**
The product is not subject to classification according to the calculation method of the General EU Classification Guidelines for Preparations as issued in the latest version.
When used and handled according to specifications, the product does not have any harmful effects to our experience and the information provided to us.

12 Ecological information

· **Toxicity**
· **Aquatic toxicity:** No further relevant information available.
· **Persistence and degradability** No further relevant information available.
· **Behaviour in environmental systems:**
· **Bioaccumulative potential** No further relevant information available.
· **Mobility in soil** No further relevant information available.
· **Additional ecological information:**
· **General notes:**
Water hazard class 1 (German Regulation) (Self-assessment): slightly hazardous for water
Do not allow undiluted product or large quantities of it to reach ground water, water course or sewage system.

(Contd. on page 6)

BIO-RAD

Safety data sheet
according to 1907/2006/EC, Article 31

Printing date 03.07.2013 Version number 2 Revision: 03.07.2013

(Contd. of page 5)

· **Results of PBT and vPvB assessment**
· **PBT:** Not applicable.
· **vPvB:** Not applicable.
· **Other adverse effects** No further relevant information available.

*
13 Disposal considerations

· **Waste treatment methods**
· **Recommendation**
Smaller quantities can be disposed of with household waste.
· **Uncleaned packaging:**
· **Recommendation:**
Disposal must be made according to official regulations.
· **Recommended cleansing agents:**
Water, if necessary together with cleansing agents.

14 Transport information

· UN-Number · ADR, ADN, IMDG, IATA	Void
· UN proper shipping name · ADR, ADN, IMDG, IATA	Void
· Transport hazard class(es) · ADR, ADN, IMDG, IATA · Class	Void
· Packing group · ADR, IMDG, IATA	Void
· Environmental hazards: · Marine pollutant:	No
· Special precautions for user	Not applicable.
· Transport in bulk according to Annex II of MARPOL73/78 and the IBC Code	Not applicable.
· Transport/Additional information:	Not dangerous according to the above specifications.
· UN "Model Regulation":	-

*
15 Regulatory information

· **Safety, health and environmental regulations/legislation specific for the substance or mixture**
· **Labelling according to EU guidelines:**
Observe the general safety regulations when handling chemicals.
The product is not subject to identification regulations under EU Directives and the Ordinance on Hazardous Materials (German GefStoffV).

(Contd. on page 7)

BIO-RAD

Safety data sheet
according to 1907/2006/EC, Article 31

Printing date 03.07.2013 Version number 2 Revision: 03.07.2013

(Contd. of page 6)

- **Chemical safety assessment:**
A Chemical Safety Assessment has not been carried out.

16 Other information

This information is based on our present knowledge. However, this shall not constitute a guarantee for any specific product features and shall not establish a legally valid contractual relationship.

- **Department issuing MSDS:**
DiaMed GmbH
Pra Rond 23
CH-1785 Cressier FR
(Switzerland/Schweiz/Suisse/Svizzera)
  - **Abbreviations and acronyms:**
ADR: Accord européen sur le transport des marchandises dangereuses par Route (European Agreement concerning the International Carriage of Dangerous Goods by Road)
IMDG: International Maritime Code for Dangerous Goods
IATA: International Air Transport Association
GefStoffV: Gefahrstoffverordnung (Ordinance on Hazardous Substances, Germany)
LC50: Lethal concentration, 50 percent
LD50: Lethal dose, 50 percent
  - *** Data compared to the previous version altered.**

BIO-RAD

Safety data sheet
according to 1907/2006/EC, Article 31

Printing date 11.09.2014 Version number 1 Revision: 19.03.2014

1 Identification of the substance/mixture and of the company/undertaking

· **Product identifier**

· **Trade name:** Solutions for Red Cells and Reagents

· **Bio-Rad MSDS Number:** 2044M

· **References and packagings (Id-N°):**

05751 ID-Diluent 1
05761 ID-Diluent 2
05740 ID-CellStab
05710 ID-CellWash-P
06311 ID-Papain
12140 DiaBrom
20100 Diluent N.A.
40560 Ec-Stabilizing Solution
40230 DiaMed CellFreeze
40240 DiaMed CellThaw

· **Relevant identified uses of the substance or mixture and uses advised against**
No further relevant information available.

· **Application of the substance / the mixture** In vitro diagnostic medical device or component.

· **Details of the supplier of the safety data sheet**

· **Manufacturer/Supplier:**
DiaMed GmbH
Pra Rond 23
CH-1785 Cressier FR
(Switzerland/Schweiz/Suisse/Swizzera)
Tel: +41 (0)26 674 51 11
Fax: +41 (0)26 674 51 45

· **Further information obtainable from:** fds-msds.ch@bio-rad.com

· **Emergency telephone number:** Tel.: 145 oder/or/ou +41 442 51 51 51

2 Hazards identification

· **Classification of the substance or mixture**
The product is not classified according to the Globally Harmonized System (GHS).

· **Label elements**

· **GHS label elements** Void

· **Hazard pictograms** Void

· **Signal word** Void

· **Hazard statements** Void

· **Other hazards**

· **Results of PBT and vPvB assessment**

· **PBT:** Not applicable.

· **vPvB:** Not applicable.

3 Composition/information on ingredients

· **Chemical characterization: Mixtures**

· **Description:** Mixture of substances listed below with nonhazardous additions.

(Contd. on page 2)

EN

BIO-RAD

Safety data sheet
according to 1907/2006/EC, Article 31

Printing date 11.09.2014 Version number 1 Revision: 19.03.2014

(Contd. of page 1)

· **Dangerous components:** Void

4 First aid measures

· **Description of first aid measures**

· **General information:** No special measures required.

· **After inhalation:** Supply fresh air; consult doctor in case of complaints.

· **After skin contact:** Generally the product does not irritate the skin.

· **After eye contact:** Rinse opened eye for several minutes under running water.

· **After swallowing:** If symptoms persist consult doctor.

· **Most important symptoms and effects, both acute and delayed**
No further relevant information available.

· **Indication of any immediate medical attention and special treatment needed**
No further relevant information available.

5 Firefighting measures

· **Extinguishing media**

· **Suitable extinguishing agents:**
CO2, powder or water spray. Fight larger fires with water spray or alcohol resistant foam.
Use fire extinguishing methods suitable to surrounding conditions.

· **Special hazards arising from the substance or mixture** No further relevant information available.

· **Advice for firefighters**

· **Protective equipment:** No special measures required.

6 Accidental release measures

· **Personal precautions, protective equipment and emergency procedures** Not required.

· **Environmental precautions:** Dilute with plenty of water.

· **Methods and material for containment and cleaning up:**
Absorb with liquid-binding material (sand, diatomite, acid binders, universal binders, sawdust).

· **Reference to other sections**
See Section 7 for information on safe handling.
See Section 8 for information on personal protection equipment.
See Section 13 for disposal information.

7 Handling and storage

· **Precautions for safe handling** No special measures required.

· **Information about fire - and explosion protection:** No special measures required.

· **Conditions for safe storage, including any incompatibilities**

· **Storage:**

· **Requirements to be met by storerooms and receptacles:** No special requirements.

· **Information about storage in one common storage facility:** Not required.

· **Further information about storage conditions:** see related package insert.

· **Specific end use(s)** No further relevant information available.

EN

(Contd. on page 3)

#248.3

BIO-RAD

Safety data sheet
according to 1907/2006/EC, Article 31

Printing date 11.09.2014 Version number 1 Revision: 19.03.2014

(Contd. of page 2)

8 Exposure controls/personal protection

· **Additional information about design of technical facilities:** No further data; see item 7.

· **Control parameters**
· **Additional information:** The lists valid during the making were used as basis.

· **Exposure controls**
· **Personal protective equipment:**
· **General protective and hygienic measures:**
The usual precautionary measures are to be adhered to when handling chemicals.
· **Respiratory protection:** Not necessary if room is well-ventilated.
· **Protection of hands:**

Protective gloves

The glove material has to be impermeable and resistant to the product/ the substance/ the preparation.
· **Material of gloves**
The selection of the suitable gloves does not only depend on the material, but also on further marks of quality and varies from manufacturer to manufacturer.
The selection of the suitable gloves does not only depend on the material, but also on further marks of quality and varies from manufacturer to manufacturer. As the product is a preparation of several substances, the resistance of the glove material can not be calculated in advance and has therefore to be checked prior to the application.
· **Penetration time of glove material**
The exact break through time has to be found out by the manufacturer of the protective gloves and has to be observed.
· **Eye protection:** Safety glasses
· **Body protection:** Protective work clothing

9 Physical and chemical properties

· **Information on basic physical and chemical properties**	
· **General Information**	
· **Appearance:**	
· **Form:**	Fluid
· **Colour:**	Various colours
· **Odour:**	Odourless
· **Odour threshold:**	Not determined.
· **pH-value:**	Not determined.
· **Change in condition**	
· **Melting point/Melting range:**	Undetermined.
· **Boiling point/Boiling range:**	100 °C
· **Flash point:**	Not applicable.
· **Flammability (solid, gaseous):**	Not applicable.

(Contd. on page 4)

BIO-RAD

Safety data sheet
according to 1907/2006/EC, Article 31

Printing date 11.09.2014 Version number 1 Revision: 19.03.2014

(Contd. of page 3)

· **Ignition temperature:**	
· **Decomposition temperature:**	Not determined.
· **Self-igniting:**	Product is not selfigniting.
· **Danger of explosion:**	Product does not present an explosion hazard.
· **Explosion limits:**	
· **Lower:**	Not determined.
· **Upper:**	Not determined.
· **Vapour pressure:**	Not determined.
· **Density:**	Not determined.
· **Relative density**	Not determined.
· **Vapour density**	Not determined.
· **Evaporation rate**	Not determined.
· **Solubility in / Miscibility with**	
· **water:**	Fully miscible.
· **Partition coefficient (n-octanol/water):**	Not determined.
· **Viscosity:**	
· **Dynamic:**	Not determined.
· **Kinematic:**	Not determined.
· **Solvent content:**	
· **Organic solvents:**	0,0 %
· **Other information**	No further relevant information available.

10 Stability and reactivity

· **Reactivity**
· **Chemical stability**
· **Thermal decomposition / conditions to be avoided:**
No decomposition if used according to specifications.
· **Possibility of hazardous reactions** No dangerous reactions known.
· **Conditions to avoid** No further relevant information available.
· **Incompatible materials:** No further relevant information available.
· **Hazardous decomposition products:** No dangerous decomposition products known.

11 Toxicological information

· **Information on toxicological effects**
· **Acute toxicity:**
· **Primary irritant effect:**
· **on the skin:** No irritant effect.
· **on the eye:** No irritating effect.
· **Sensitization:** No sensitizing effects known.
· **Additional toxicological information:**
The product is not subject to classification according to the calculation method of the General EU Classification Guidelines for Preparations as issued in the latest version.

(Contd. on page 5)

BIO-RAD

Safety data sheet
according to 1907/2006/EC, Article 31

Printing date 11.09.2014 Version number 1 Revision: 19.03.2014

(Contd. of page 4)

When used and handled according to specifications, the product does not have any harmful effects to our experience and the information provided to us.

12 Ecological information

· **Toxicity**
· **Aquatic toxicity:** No further relevant information available.
· **Persistence and degradability** No further relevant information available.
· **Bioaccumulative potential** No further relevant information available.
· **Mobility in soil** No further relevant information available.
· **Additional ecological information:**
· **General notes:** Generally not hazardous for water
· **Results of PBT and vPvB assessment**
· **PBT:** Not applicable.
· **vPvB:** Not applicable.
· **Other adverse effects** No further relevant information available.

13 Disposal considerations

· **Waste treatment methods**
· **Recommendation** Smaller quantities can be disposed of with household waste.

· **Uncleaned packaging:**
· **Recommendation:** Disposal must be made according to official regulations.
· **Recommended cleansing agents:** Water, if necessary together with cleansing agents.

14 Transport information

· **UN-Number** · **ADR, ADN, IMDG, IATA**	Void
· **UN proper shipping name** · **ADR, ADN, IMDG, IATA**	Void
· **Transport hazard class(es)** · **ADR, ADN, IMDG, IATA** · **Class**	Void
· **Packing group** · **ADR, IMDG, IATA**	Void
· **Environmental hazards:** · **Marine pollutant:**	No
· **Special precautions for user**	Not applicable.
· **Transport in bulk according to Annex II of MARPOL73/78 and the IBC Code**	Not applicable.
· **Transport/Additional information:**	Not dangerous according to the above specifications.

(Contd. on page 6)

BIO-RAD

Safety data sheet
according to 1907/2006/EC, Article 31

Printing date 11.09.2014 Version number 1 Revision: 19.03.2014

(Contd. of page 5)

· **UN "Model Regulation":** -

15 Regulatory information

· **Safety, health and environmental regulations/legislation specific for the substance or mixture**
· **GHS label elements** Void
· **Hazard pictograms** Void
· **Signal word** Void
· **Hazard statements** Void
· **Chemical safety assessment:** A Chemical Safety Assessment has not been carried out.

16 Other information

This information is based on our present knowledge. However, this shall not constitute a guarantee for any specific product features and shall not establish a legally valid contractual relationship.

· **Department issuing MSDS:**
DiaMed GmbH
Pra Rond 23
CH-1785 Cressier FR
(Switzerland/Schweiz/Suisse/Svizzera)
· **Abbreviations and acronyms:**
ADR: Accord européen sur le transport des marchandises dangereuses par Route (European Agreement concerning the International Carriage of Dangerous Goods by Road)
IMDG: International Maritime Code for Dangerous Goods
IATA: International Air Transport Association
EINECS: European Inventory of Existing Commercial Chemical Substances
ELINCS: European List of Notified Chemical Substances
CAS: Chemical Abstracts Service (division of the American Chemical Society)
· * **Data compared to the previous version altered.**

BIO-RAD

Safety data sheet
according to 1907/2006/EC, Article 31

Printing date 07.08.2013 Version number 1 Revision: 12.06.2013

1 Identification of the substance/mixture and of the company/ undertaking

· **Product identifier**

· **Trade name:** ID Screening, Identification and Quality Control Testcells

· **Bio-Rad MSDS Number:** 2012M

· **References and packagings (Id-N°):**

45022 ID-DiaCell ABO A1, A2, B, O
45082 ID-DiaCell ABO A1, A2, B
45352 ID-DiaCell ABO A1, B, O
45092 ID-DiaCell ABO A1, B
06012 ID-DiaCell A1
06022 ID-DiaCell A2
06032 ID-DiaCell B
06042 ID-DiaCell O
45012 ID-DiaCell ABO/I-II-III
45002 ID-DiaCell ABO/I-II
45070 ID-DiaScreen I-VI
45200 ID-DiaScreen I-II-III-IV
45210 ID-DiaScreen VP-VIP
45660 ID-DiaScreen Prophylax
45184 ID-DiaCell I-II-III
45404 ID-DiaCell I-II-III
45194 ID-DiaCell IP-IIP-IIIP
45414 ID-DiaCell IP-IIP-IIIP
45151 ID-DiaCell I-II
45330 ID-DiaCell I-II-III Asia (Mia+)
05980 ID-Dia (Diego) Positive
06291 ID-I Negative Cell
06060 ID DiaCell SF
06070 ID-DiaCell Pool
45161 ID-DiaPanel
45670 ID-DiaPanel Plus 6
45171 ID-DiaPanel-P
45341 ID-Internal Quality Control
45840 DiaMed Basic Q.C.
45950 DiaMed Q.C. System
45530 DiaMed Quality Control Survey Basic
45650 DiaMed Quality Control Survey Advanced

· **Relevant identified uses of the substance or mixture and uses advised against**
No further relevant information available.
· **Application of the substance / the preparation**
In vitro diagnostic medical device or component.

· **Details of the supplier of the safety data sheet**
· **Manufacturer/Supplier:**
DiaMed GmbH
Pra Rond 23
CH-1785 Cressier FR
(Switzerland/Schweiz/Suisse/Swizzera)
Tel: +41 (0)26 674 51 11
Fax: +41 (0)26 674 51 45

· **Further information obtainable from:** fds-msds.ch@bio-rad.com

(Contd. on page 2)

BIO-RAD

Safety data sheet
according to 1907/2006/EC, Article 31

Printing date 07.08.2013 Version number 1 Revision: 12.06.2013

(Contd. of page 1)

· **Emergency telephone number:** Tel.: 145 oder/or/ou +41 442 51 51 51

2 Hazards identification

· **Classification of the substance or mixture**
The product is not classified according to the Globally Harmonized System (GHS).

· **Classification according to Directive 67/548/EEC or Directive 1999/45/EC**
Not applicable.
· **Information concerning particular hazards for human and environment:**
The product does not have to be labelled due to the calculation procedure of the "General Classification guideline for preparations of the EU" in the latest valid version.
· **Classification system:**
The classification is according to the latest editions of the EU-lists, and extended by company and literature data.

· **Label elements**

· **Labelling according to EU guidelines:**
Observe the general safety regulations when handling chemicals.
The product is not subject to identification regulations under EU Directives and the Ordinance on Hazardous Materials (German GefStoffV).

· **Other hazards**
· **Results of PBT and vPvB assessment**
· **PBT:** Not applicable.
· **vPvB:** Not applicable.

3 Composition/information on ingredients

· **Chemical characterization: Mixtures**
· **Description:**
Mixture of substances listed below with nonhazardous additions.
· **Additional information:**
For the wording of the listed risk phrases refer to section 16.

4 First aid measures

· **Description of first aid measures**
· **General information:** No special measures required.
· **After inhalation:**
Supply fresh air; consult doctor in case of complaints.
· **After skin contact:** Generally the product does not irritate the skin.
· **After eye contact:**
Rinse opened eye for several minutes under running water.
· **After swallowing:** If symptoms persist consult doctor.
· **Information for doctor:**
· **Most important symptoms and effects, both acute and delayed**
No further relevant information available.

(Contd. on page 3)

2089-2982

BIO-RAD

Safety data sheet
according to 1907/2006/EC, Article 31

Printing date 07.08.2013 Version number 1 Revised: 12.06.2013

(Contd. of page 2)

· **Indication of any immediate medical attention and special treatment needed**
No further relevant information available.

5 Firefighting measures

· **Extinguishing media**
· **Suitable extinguishing agents:**
CO2, powder or water spray. Fight larger fires with water spray or alcohol resistant foam.
Use fire extinguishing methods suitable to surrounding conditions.
· **Special hazards arising from the substance or mixture**
No further relevant information available.
· **Advice for firefighters**
· **Protective equipment:** No special measures required.

6 Accidental release measures

· **Personal precautions, protective equipment and emergency procedures**
Not required.
· **Environmental precautions:**
Dilute with plenty of water.
Do not allow to enter sewers/ surface or ground water.
· **Methods and material for containment and cleaning up:**
Absorb with liquid-binding material (sand, diatomite, acid binders, universal binders, sawdust).
· **Reference to other sections**
No dangerous substances are released.
See Section 7 for information on safe handling.
See Section 8 for information on personal protection equipment.
See Section 13 for disposal information.

* 7 Handling and storage

· **Handling:**
· **Precautions for safe handling** No special measures required.
· **Information about fire - and explosion protection:**
No special measures required.
· **Conditions for safe storage, including any incompatibilities**
· **Storage:**
· **Requirements to be met by storerooms and receptacles:**
No special requirements.
· **Information about storage in one common storage facility:**
Not required.
· **Further information about storage conditions:**
see related package insert
· **Specific end use(s)** No further relevant information available.

8 Exposure controls/personal protection

· **Additional information about design of technical facilities:**
No further data; see item 7.

(Contd. on page 4)

BIO-RAD

Safety data sheet
according to 1907/2006/EC, Article 31

Printing date 07.08.2013 Version number 1 Revision: 12.06.2013

(Contd. of page 3)

· **Control parameters**
· **Additional information:**
The lists valid during the making were used as basis.
· **Exposure controls**
· **Personal protective equipment:**
· **General protective and hygienic measures:**
The usual precautionary measures are to be adhered to when handling chemicals.
· **Respiratory protection:**
Not necessary if room is well-ventilated.
· **Protection of hands:**

Protective gloves

The glove material has to be impermeable and resistant to the product/ the substance/ the preparation.
· **Material of gloves**
The selection of the suitable gloves does not only depend on the material, but also on further marks of quality and varies from manufacturer to manufacturer. As the product is a preparation of several substances, the resistance of the glove material can not be calculated in advance and has therefore to be checked prior to the application.
· **Penetration time of glove material**
The exact break through time has to be found out by the manufacturer of the protective gloves and has to be observed.
· **Eye protection:** Safety glasses
· **Body protection:** Protective work clothing

9 Physical and chemical properties

· **Information on basic physical and chemical properties**	
· **General Information**	
· **Appearance:**	
· **Form:**	Fluid
· **Colour:**	Red
· **Odour:**	Characteristic
· **Odour threshold:**	Not determined.
· **pH-value at 20 °C:**	7,4
· **Change in condition**	
· **Melting point/Melting range:**	Undetermined.
· **Boiling point/Boiling range:**	Undetermined.
· **Flash point:**	Not applicable.
· **Flammability (solid, gaseous):**	Not applicable.
· **Ignition temperature:**	
· **Decomposition temperature:**	Not determined.

(Contd. on page 5)

BIO-RAD

Safety data sheet
according to 1907/2006/EC, Article 31

Printing date 07.08.2013 Version number 1 Revision: 12.06.2013

(Contd. of page 4)

· **Self-igniting:**	Product is not selfigniting.
· **Danger of explosion:**	Product does not present an explosion hazard.
· **Explosion limits:**	
· **Lower:**	Not determined.
· **Upper:**	Not determined.
· **Vapour pressure at 20 °C:**	23 hPa
· **Density at 20 °C:**	1,2 g/cm³
· **Relative density**	Not determined.
· **Vapour density**	Not determined.
· **Evaporation rate**	Not determined.
· **Solubility in / Miscibility with**	
· **water:**	Fully miscible.
· **Partition coefficient (n-octanol/ water):**	Not determined.
· **Viscosity:**	
· **Dynamic:**	Not determined.
· **Kinematic:**	Not determined.
· **Solvent content:**	
· **Organic solvents:**	0,0 %
· **Water:**	26,7 %
· **Other information**	No further relevant information available.

10 Stability and reactivity

· **Reactivity**
· **Chemical stability**
· **Thermal decomposition / conditions to be avoided:**
No decomposition if used according to specifications.
· **Possibility of hazardous reactions** No dangerous reactions known.
· **Conditions to avoid** No further relevant information available.
· **Incompatible materials:** No further relevant information available.
· **Hazardous decomposition products:**
No dangerous decomposition products known.

11 Toxicological information

· **Information on toxicological effects**
· **Acute toxicity:**
· **LD/LC50 values relevant for classification:**
Sodium Azid is used as a preservative. (Concentration < 0.1%)

26628-22-8 Sodium Azide		
Oral	LD50	27 mg/kg (rat)
Dermal	LD50	20 mg/kg (rabbit)

· **Primary irritant effect:**
· **on the skin:** No irritant effect.
· **on the eye:** No irritating effect.

(Contd. on page 6)

BIO-RAD

Safety data sheet
according to 1907/2006/EC, Article 31

Printing date 07.08.2013 Version number 1 Revision: 12.06.2013

(Contd. of page 5)

· **Sensitization:** No sensitizing effects known.
· **Additional toxicological information:**
The product is not subject to classification according to the calculation method of the General EU Classification Guidelines for Preparations as issued in the latest version.
When used and handled according to specifications, the product does not have any harmful effects to our experience and the information provided to us.

12 Ecological information

· **Toxicity**
· **Aquatic toxicity:** No further relevant information available.
· **Persistence and degradability** No further relevant information available.
· **Behaviour in environmental systems:**
· **Bioaccumulative potential** No further relevant information available.
· **Mobility in soil** No further relevant information available.
· **Additional ecological information:**
· **General notes:**
Water hazard class 1 (German Regulation) (Self-assessment): slightly hazardous for water
Do not allow undiluted product or large quantities of it to reach ground water, water course or sewage system.
· **Results of PBT and vPvB assessment**
· **PBT:** Not applicable.
· **vPvB:** Not applicable.
· **Other adverse effects** No further relevant information available.

13 Disposal considerations

· **Waste treatment methods**
· **Recommendation**
Smaller quantities can be disposed of with household waste.
· **Uncleaned packaging:**
· **Recommendation:**
Disposal must be made according to official regulations.
· **Recommended cleansing agents:**
Water, if necessary together with cleansing agents.

14 Transport information

· **UN-Number**	
· **ADR, ADN, IMDG, IATA**	Void
· **UN proper shipping name**	
· **ADR, ADN, IMDG, IATA**	Void
· **Transport hazard class(es)**	
· **ADR, ADN, IMDG, IATA**	
· **Class**	Void
· **Packing group**	
· **ADR, IMDG, IATA**	Void

(Contd. on page 7)

BIO-RAD

Safety data sheet
according to 1907/2006/EC, Article 31

Printing date 07.08.2013 Version number 1 Revision: 12.06.2013

(Contd. of page 6)

· **Environmental hazards:**	
· **Marine pollutant:**	No
· **Special precautions for user**	Not applicable.
· **Transport in bulk according to Annex II of MARPOL73/78 and the IBC Code**	Not applicable.
· **Transport/Additional information:**	Not dangerous according to the above specifications.
· **UN "Model Regulation":**	–

15 Regulatory information

· **Safety, health and environmental regulations/legislation specific for the substance or mixture**

· **Labelling according to EU guidelines:**
Observe the general safety regulations when handling chemicals.
The product is not subject to identification regulations under EU Directives and the Ordinance on Hazardous Materials (German GefStoffV).

· **Chemical safety assessment:**
A Chemical Safety Assessment has not been carried out.

16 Other information

This information is based on our present knowledge. However, this shall not constitute a guarantee for any specific product features and shall not establish a legally valid contractual relationship.

· **Department issuing MSDS:**
DiaMed GmbH
Pra Rond 23
CH-1785 Cressier FR
(Switzerland/Schweiz/Suisse/Svizzera)

· **Abbreviations and acronyms:**
ADR: Accord européen sur le transport des marchandises dangereuses par Route (European Agreement concerning the International Carriage of Dangerous Goods by Road)
IMDG: International Maritime Code for Dangerous Goods
IATA: International Air Transport Association
GefStoffV: Gefahrstoffverordnung (Ordinance on Hazardous Substances, Germany)
LC50: Lethal concentration, 50 percent
LD50: Lethal dose, 50 percent

· *** Data compared to the previous version altered.**

#, 248.6-248.10

TÜVRheinland®

EC Design-Examination Certificate
Directive 98/79/EC Annex IV, Section 4
In Vitro Diagnostic Medical Devices

Registration No.: IL 60088992 0001

Report No.: 21100610 002

Manufacturer:

Bio-Rad Medical Diagnostics GmbH
Industriestr. 1
63303 Dreieich
Deutschland

Product Identification:

Monoclonal liquid reagents for blood group determination for the ABO System, Rhesus (C , c, D, E, e) and Kell System; Control reagents for ABO and Rh reagents

(see attachment for products included)
Replaces Certificate, Registration No.: IL 60030153 0001

The Notified Body hereby declares that an examination of the design dossier relating to the listed products has been performed according to Annex IV, section 4 of the directive 98/79/EC and that the design of the devices conforms to the requirements of the abovementioned directive.

Expiry Date: 2018-10-01

Effective Date: 2013-10-02

Date: 2013-10-02

Notified Body

TÜV Rheinland LGA Products GmbH Zertifizierungsstelle TÜVRheinland®

Dr. H. Lüdemann

TÜV Rheinland LGA Products GmbH - Tillystraße 2 - 90431 Nürnberg

TÜV Rheinland LGA Products GmbH is a Notified Body according to Directive 98/79/EC concerning in vitro diagnostic medical devices with the identification number 0197.

TÜVRheinland®

Doc. 1/1, Rev. 0

TÜV Rheinland
LGA Products GmbH
Tillystraße 2, 90431 Nürnberg

Attachment to Certificate
Registration No.: IL 60088992 0001
Report No.: 21100610 002

Manufacturer: Bio-Rad Medical Diagnostics GmbH
Industriestr. 1
63303 Dreieich
Deutschland

Products included:

Seraclone® Anti-A
Seraclone® Anti-B
Seraclone® Anti-AB
Seraclone® Anti-D (RH1) 226
Seraclone® Anti D (RH1) 232
Seraclone® Anti-D (RH1) Blend
Seraclone® Anti-CDE (RH1,2,3)
Rh(D) IgM Blood Grouping Kit (Monoclonal Antibody)
Solidscreen II Anti-D Blend
Seraclone® Anti-C (RH2), Seraclone® Anti-c (RH4)
Seraclone® Anti-E (RH3), Seraclone® Anti-e (RH5)
Seraclone®(2) Anti-C (RH2), Seraclone®(2) Anti-c (RH4)
Seraclone®(2) Anti-E (RH3), Seraclone®(2) Anti-e (RH5)
Seraclone® Anti-K (KEL1)
Seraclone® Control ABO + Rh

TÜV Rheinland LGA Products GmbH Zertifizierungsstelle TÜVRheinland®

Notified Body

Date: 2013-10-02

Dr. H. Lüdemann

EC dizaino apžiūros sertifikatas
Pagal ES direktyvą 98/79/EC IV priedą, 4 skirsnį
In vitro diagnostikos prietaisams

Registracijos Nr.: IL 60088992 0001
Raporto Nr.: 21100610 002

Gamintojas:
Bio-Rad Medical Diagnostics GmbH
Industriestr. 1
63303 Dreieich
Vokietija

Produktai: In vitro medicinos diagnostikos prietaisai
Monoklonioniai ABO kraujo grupių nustatymo reagentai

Identifikavimas: Skysti monokloniniai ABO, Rezus (C, c, D, E, e) ir Kell sistemų kraujo grupių nustatymo reagentai; kontrolės reagentai ABO ir Rh reagentams

Produktai: žr. priedą

Pakeičia sertifikatą, registracijos Nr.: IL 60030153 0001

Notifikuota įstaiga šiuo raštu pažymi, kad aukščiau nurodytoje įmonėje įdiegta ir palaikoma kokybės vadybos sistema. IV priedo, 4 skirsnio reikalavimai išpildyti. Aprobuojamas objektas yra subjektas priežiūrai pagal aukščiau paminėtos direktyvos IV priedo 5 skirsnį. Gamintojui suteikiama teisė naudoti šį pažymėjimą kartu su gamintojo atitikties deklaracija.

Galioja iki: 2018-10-01

Galiojimo pradžios data:2013-10-02

Data, 2013-10-02

Notifikuota įstaiga
<PARAŠAS>
Dr. H. Lüdemann

TÜV Rheinland LGA Products GmbH-Tillystraße 2- 90431 Nürnberg

TÜV Rheinland LGA Products GmbH yra notifikavimo įstaiga pagal 98/79/EC direktyvą dėl in vitro medicinos diagnostikos prietaisų su identifikavimo Nr. 0197.

CE ženklas gali būti naudojamas, jei buvo laikomasi visų atitinkamų ES direktyvų reikalavimų.

Dok. 1/1, Rev.0

TÜV Rheinland
LGA Products GmbH
Tillystraße 2, 90431 Nürnberg

Priedas prie sertifikato
Registracijos Nr.: IL 60088992 0001
Ataskaitos Nr.: 21100610 002

Gamintojas
Bio-Rad Medical Diagnostics GmbH
Industriestr. 1
63303 Dreieich
Vokietija

Sritis:

Produktai:
Seraclone® Anti-A
Seraclone® Anti-B
Seraclone® Anti-AB
Seraclone® Anti-D (RH1) 226
Seraclone® Anti-D (RH1) 232
Seraclone® Anti-D (RH1) Blend
Seraclone® Anti-CDE (RH1, 2, 3)
Rh (D) IgM kraujo grupavimo rinkinys (monokloniniai antikūnai)
Solidscreen II Anti-D Blend
Seraclone® Anti-C (RH2), Seraclone® Anti-c (RH4)
Seraclone® Anti-E (RH3), Seraclone® Anti-e (RH5)
Seraclone® (2) Anti-C (RH2), Seraclone® (2) Anti-c (RH4)
Seraclone® (2) Anti-E (RH3), Seraclone® (2) Anti-e (RH5)
Seraclone® Anti-K (KEL1)
Seraclone® Kontrolė ABO+Rh

Sertifikavimo įstaiga

<PARAŠAS>

Data 2013-10-02

Dr. H. Lüdemann

Vertimo patvirtinimas

Aš, VAIDAS VILMANTAS

vertimų verslo liudijimo nr. MK 478428-1 savininkas patvirtinu, kad patikrinau Lietuvių kalbos vertimą

BIO-RAD CE sertifikatas
(vertimo pavadinimas)

iš Anglų kalbos dokumento

BIO-RAD Design-Examination Certificate
(originalaus dokumento pavadinimas)

pagal savo žinias ir įsitikinimus.

Tekstas yra išverstas teisingai ir tiksliai bei be pakeitimų prasmėje.

Aš esu užtikrintas, kad Lietuvių kalbos vertimas atitinka originalų dokumentą.

VILNIUS, LIETUVA 2014-01-22
(Vieta/data)

(parašas)

#248.6

Haltbarkeit
Nach Öffnung des Reagenzes ist das Produkt bei sachgemäßer Lagerung (2-8°C) bis zum Ende der angegebenen Laufzeit haltbar. Die Laufzeit ist dem Reagenzienetikett zu entnehmen.
Bei beschädigten Fläschchen darf das Produkt nicht mehr verwendet werden.

Hinweis
Manuelle Techniken sind nach den Vorgaben des Herstellers anzuwenden. Für den Einsatz des Reagenzes in Automaten kann eine Verdünnung des Reagenzes erforderlich sein. Die Anwendung ist dann vom Anwender und in Verantwortung des Anwenders zu validieren. Die Verantwortung des Anwenders gilt auch für jede sonstige Veränderung des Fertigreagenzes, z.B. Einfrieren auf Mikrotiterplatten.
Abgearbeitete Tests müssen entsprechend der jeweiligen nationalen Richtlinien, z.B. in Deutschland als Abfall der Gruppe B wie beschrieben im „Merkblatt über die Vermeidung und die Entsorgung von Abfällen aus öffentlichen und privaten Einrichtungen des Gesundheitsdienstes" und der „Richtlinie für Krankenhaushygiene und Infektionsprävention", entsorgt werden.
Durch die biotechnologische Herstellung der humanen monoklonalen Antikörper ist das Risiko einer Kontamination durch infektiöse Krankheitserreger nahezu ausgeschlossen. Trotzdem sollten alle Testreagenzien als potentiell infektiös gehandhabt und die entsprechenden Vorsichtsmaßnahmen getroffen werden.
Das bei der Herstellung der Reagenzien verwendete Rinderalbumin wird nur aus BSE-freien Beständen bezogen.
Der Anwender muss eine regelmäßige interne Qualitätskontrolle durchführen. Dazu werden die Antiseren mit Testerythrozyten, die das korrespondierende Antigen in heterozygoter Ausprägung tragen, geprüft. Es gelten die jeweiligen nationalen Richtlinien z. B. (1).

Seraclone® Anti-D (RH1) 226
Seraclone® Anti-D (RH1) 232

For the detection of the red cell antigen D

Diagnostic reagent for in vitro use only
To be used by trained laboratory personnel only. The ACT is printed on the vial label. Symbols are used according to regulation EN 980. Symbols not contained in regulation EN 980 are described.

Test purpose
Seraclone® Anti-D (RH1) 226, -D (RH1) 232 is used for the detection of the blood group characteristic D (rhesus system).

Test principle
The test principle is hemagglutination to detect red cell antigens. The rhesus characteristic D is defined by its presence or absence on red cells. The antigens D reacts specifically with the corresponding antibodies contained in Seraclone® Anti-D (RH1) 226 and Seraclone® Anti-D (RH1) 232.

Reagent
As reactive components Seraclone® Anti-D (RH1) 226, -D (RH1) 232 contain human monoclonal antibodies of the immunoglobulin and are thus not suited for an indirect antiglobulin test. They are derived from cell culture supernatant and demonstrate the consistent specificity and reproducability characteristic for monoclonal antibodies.

Seraclone® Anti-D (RH1) 226	clone BS226
Seraclone® AntiD (RH1) 232	clone BS232

Additional reagents and material
- Slides, tiles, Bioplate
- Pipettes (drop volume 40-50µl)
- Isotonic saline solution
- Glass tubes
- Laboratory Centrifuge

Sample material
Blood samples should be taken following general blood sampling guidelines. Fresh, non-hemolytic samples (native, EDTA, or citrate blood) should be used. If needed prepare a red cell suspension from a centrifugated blood sample (e.g. 2 min. at 1000 x g) in isotonic saline solution as suspension medium. We recommend to wash the red cells to be tested prior to preparing the cell suspension at least 2 times or until the supernatant is clear. Strongly lipemic, icteric or microbiologically contaminated samples may lead to false results.

Test procedure
Tile and slide test
A. Rapid test
The test is performed on a viewbox with a surface temperature of 40 - 50°C.
1. Place 1 drop reagent on tile or slide.
2. Add 1 drop whole blood and mix well.
3. Gently rock plate or slide back and forth and observe for agglutination. Reading of results should not exceed 2 minutes because drying out may falsely be interpreted as a positive reaction.

In case of negative, weak or unclear results, a tube test should be performed.

B. Incubation test
1. Suspend red cells to be tested 5-10% in isotonic saline solution or use whole blood.
2. On a slide or tile mix 1 drop reagent and 1 drop red cell suspension or whole blood.
3. Incubate 30 minutes at room temperature or 37°C (cover to prevent drying out).
4. Gently rock slide or tile and observe for agglutination.

In case of negative, weak or unclear results, a tube test should be performed.

Tube Test
1. Prepare a 3-5 % suspension in isotonic saline of the red cells.
2. In a properly marked tube mix 1 drop reagent with 1 drop of the red cell suspension.
3. Centrifuge for 2 minutes at 1000 rpm (150 x g) or 20 seconds at 3000 rpm (1000 x g).
4. Gently dislodge the cell button and observe for agglutination.
5. In case of a negative, weak or unclear result, incubate the tube 15 min. at room temperature.
6. Centrifuge for 2 minutes at 1000 rpm (150 x g) or 20 seconds at 3000 rpm (1000 x g).
7. Gently dislodge the cell button and observe for agglutination.

A positive and a negative control should be performed in parallel (1).

Interpretation of results
Evaluation of the reaction strength is carried out according to the Technical Manual, 12th edition, Section 1, American Association of Blood Banks:

Reaction strength	Agglutination
4+	One single agglutinine. No free red cells.
3+	Strong reaction. Some large agglutinines
2+	Large agglutinines within numerous small lumps, no free red cells
1+	Numerous small agglutinines against a background of free red cells
+/-	Just a few macroscopically detectable agglutinines within red cell suspension. Numerous microscopically detectable agglutinines
-	Homogenous red cell suspension without detectable agglutinines

If agglutinates can be resuspended by gentle shaking, the reaction is to read as negative.

Test limits
If the reaction with Seraclone® Anti-D (RH1) 226 and Seraclone® Anti-D (RH1) 232 is negative a test for weak D characteristics (D^{weak} or $D^{variant}$) should be performed with suitable reagents (Seraclone® Anti-D (RH1) Blend) in an indirect antiglobulin test. Generally, tube tests are recommended for the detection of weak antigens.
Seraclone® Anti-D (RH1) 226 and Seraclone® Anti-D (RH1) 232 do not detect category VI cells.
Turbidity or other visible changes may indicate a bacterial contamination. In this case the reagent must be discarded. The cause for turbidity must be examined by the manufacturer.
In case of unclear results with unknown causes, our Biotest Service (phone: +49-6103-801470) will assist you.

Shelf life
After opening the reagent the product can be stored until its expiry date under proper storage conditions (2-8°C). The expiry date is printed on the label. Do not use damaged vials.

Note
Manual techniques are to be performed according to the manufacturer's instructions. The use in automated systems may require dilution of the reagent. The use in automated systems is to be validated by the user. The user's responsibility extents to all changes in the reagent, i.e. freezing on microtiterplates.
Used test material must be discarded as hazardous material. Waste management according to national guidelines. Because of biotechnological manufacturing of non-human monoclonal antibodies, a contamination with infectious diseases can be considered impossible. Nevertheless, all test reagents of biological origin must be regarded as potential transmitters of infectious agents. Appropriate safety precautions are recommended. The bovine albumin used for the production of this reagent is purchased from BSE-free sources. The user must perform regular in-house quality control procedures . For a quality control test antisera are examined with test red cells carrying the corresponding expressed heterozygous antigen. National guidelines apply e.g. (1).

Seraclone® Anti-D (RH1) 226
Seraclone® Anti-D (RH1) 232

Pour la détection de l'antigène érythrocytaire D

Réactif pour usage diagnostique in vitro
Le test ne doit être utilisé que par le personnel de laboratoire formé à cet effet. Le ACT figure sur l'étiquette du flacon. Les symboles sont utilisés conformément à la norme EN 980. Les symboles non visés dans la norme EN 980 sont expliqués dans le texte.

Seraclone® Anti-D (RH1) 226
Seraclone® Anti-D (RH1) 232

Eritrocitų D antigeno nustatymui

Diagnostiniai reagentai tik tyrimams *in vitro*.
Turi būti naudojamas tik apmokyto laboratorijos personalo. ACT užrašytas ant buteliuko etiketės.. Naudojami simboliai pagal EN 980 reikalavimus. EN 980 reikalavimuose nenurodyti simboliai yra paaiškinami.

Tyrimo paskirtis
Seraclone® Anti-D (RH1) 226, -D (RH1) 232 naudojamas D kraujo grupės nustatymui (rezus sistema).

Testo principas
Tyrimo principas pagrįstas hemagliutinacija eritrocitų antigenų nustatymui. Rezus charakteristikos apibūdinamos pagal D antigeno buvimą ar nebuvimą ant eritrocitų. D antigenas reaguoja su atitinkamais antikūnais, esančiais Seraclone® Anti-D (RH1) 226 ir Seraclone®-D (RH1) 232.

Reagentai
Seraclone® Anti-D (RH1) 226, -D (RH1) 232 reagentuose reaktyvus komponentas yra monokloniniai antikūnai imunoglobulinai, todėl netinkami netiesioginiams antiglobulino testui. Jie gaunami iš ląstelių kultūros supernatanto, pasižymi pastoviomis specifiškumo ir atkartojamumo charakteristikomis monokloniniams antikūnams.
Seraclone® Anti-D (RH1) 226 – klonas BS226
Seraclone® Anti-D (RH1) 232 – klonas BS232

Papildomi reagentai ir medžiagos
Plokštelės, bioplokštlės
Pipetės, kurių lašo turis 40-50 µl
Izotoninis NaCl tirpalas
Stikliniai mėgintuvėliai
Laboratorinė centrifuga

Mėginiai
Kraujo mėginiai turi būti gaunami pagal standartines procedūras. Turi būti naudojamas šviežias, nehemolizuotas (natyvinis, EDTA ar citratinis) kraujas. Jei reikalinga, kraujo suspensiją galima pagaminti iš centrifuguoto (pvz. 2 min x 1000 g) kraujo mėginio, resuspenduojant fiziologiniame tirpale. Prieš paruošiant suspensiją, mes rekomenduojame išplauti eritrocitus bent du kartus, kol supernatantas pasidaro skaidrus. Labai lipemiški, hemolizuoti ar mikrobiologiškai užteršti mėginiai gali duoti klaidingus rezultatus.

Tyrimo procedūra
Tyrimas ant objektinio stiklelio ar plokštelės

A. Greitas metodas:
1. Užlašinkite 1 lašą Seraclone reagento ant objektinio stiklelio ar plokštelės. (Nešildykite!)
2. Įlašinkite 1 lašą kraujo ir gerai išmaišykite.
3. Atsargiai pavartykite plokštelę pirmyn ir atgal ir įvertinkite agliutinaciją. Rezultatus reikėtų skaityti ne vėliau kaip po 2 min, nes džiūstant galima gauti klaidingai teigiamą reakciją.

Jei gaunami neigiama, silpna ar neaiški reakcija, reikėtų atlikti tyrimą mėgintuvėlyje.

B. Inkubacinis metodas:
1. Tyrimui paruoškite 5-10% paciento eritrocitų suspensiją fiziologiniame NaCl tirpale arba naudokite natyvinį kraują.
2. Sumaišykite 1 lašą reagento ir 1 lašą suspensijos arba paciento kraujo ant objektinio stiklelio ar plokštelės.
3. Inkubuokite 30 minučių 37°C temperatūroje (tinkamai uždenkite, kad neišgaruotų).
4. Švelniai sukratykite objektinį stiklelį ir įvertinkite agliutinaciją.

Jei gaunami neigiama, silpna ar neaiški reakcija, reikėtų atlikti tyrimą mėgintuvėlyje.

Tyrimas mėgintuvėlyje
1. Paruoškite 3-5% tiriamų eritrocitų suspensiją fiziologiniame NaCl tirpale.
2. Į atitinkamai pažymėtus mėgintuvėlius įlašinkite 1 lašą reagento ir 1 lašą eritrocitų suspensijos.
3. Centrifuguokite 2 min prie 1000 aps./min (150 g) arba 20 sekundžių prie 3000 aps./min (1000 g) arba inkubuokite 30 minučių kambario arba 37°C temperatūroje.
4. Švelniai išformuokite ląstelių centrifugatą ir įvertinkite agliutinaciją.
5. Jei gaunami neigiama, silpna ar neaiški reakcija, inkubuokite mėgintuvėlį 15 min kambario temperatūroje.
6. Centrifuguokite 2 min prie 1000 aps./min (150 g) arba 20 sekundžių prie 3000 aps./min (1000 g).
7. Švelniai išformuokite ląstelių centrifugatą ir įvertinkite agliutinaciją.

Rezultatų interpretavimas
Agliutinacijos reakcijos stiprumas vertinamas pagal Amerikos kraujo bankų asociacijos Techninio vadovo 12 leidimą:

Reakcijos stiprumas	Agliutinacija
4+	Vienas agliutinatas. Nėra laisvų eritrocitų.
3+	Stipri reakcija. Keli dideli agliutinatai.
2	Dideli agliutinatai su daug mažų grupelių, nėra laisvų eritrocitų.
1+	Daug mažų agliutinatų laisvų eritrocitų fone.
+/-	Tik keli makroskopiškai nustatomi agliutinatai eritrocitų suspensijoje. Daug mikroskopiškai nustatomų agliutinatų.
-	Homogeniška eritrocitų suspensija be agliutinatų.

Jei agliutinatą galima resuspenduoti nestipriai pakračius, reakcija turi būti vertinama kaip neigiama.

Procedūros apribojimai
Jei yra stebima neigiama ar silpnai teigiama reakcija su Seraclone Anti-D (RH1) 226 ir Seraclone Anti-D (RH1) 232, Dweak (D silpnas) ir Dvariant (D variantai) turi būti patikrinti su reagentais (pvz. Seraclone Anti-D (RH1) Blend), kurie yra tinkami antiglobulininiam tyrimui. Paprastai, silpnų antigenų nustatymui rekomenduojami tyrimai mėgintuvėliuose.
Seraclone Anti-D (RH1) 226 ir Seraclone Anti-D (RH1) 232 neaptinka VI kategorijos ląstelių.
Drumstumas ar kiti matomi pokyčiai rodo bakterinį užterštumą. Šiuo atveju reagento naudoti negalima. Drumstumo priežastį turi nustatyti gamintojas.
Gavus neaiškius rezultatus, gali padėti Biotest Servisas (+49 6103-801470)

Galiojimo laikas
Atidarius reagentą, jis išlieka galiojantis iki ant etiketės nurodytos galiojimo datos 2-8°C temperatūroje. Nepažeiskite buteliukų.

Pastabos
Rankiniai tyrimai turi būti atliekami pagal gamintojo instrukcijas.
Už nukrypimus nuo procedūros atsakingas vartotojas. Naudojant automatinėse sistemose, gali būti reikalingas reagento praskiedimas. Automatines sistemas turi validuoti vartotojas. Vartotojas atsako už visus reagento pakeitimus, pvz. Šaldymas mikroplokštelėse.
Medžiagos po tyrimų turi būti šalinamos kaip pavojingos. Atliekos tvarkomos pagal nacionalinius reikalavimus.
Šiems Seraclone® antiserumams pagaminti nebuvo naudotos jokios žmogiškos kilmės medžiagos. Praktiškai nėra galimybės užsikrėsti Hepatito, HIV-1/2 virusais ar kitom krauju plintančiomis ligomis. Nepaisant to, visi biologinės kilmės reagentai turi būti laikomi potencialiais hepatito, ŽIV ar kitų infekcinių ligų pernešėjais. Rekomenduojama laikytis tinkamų saugumo priemonių.
Albuminas, naudojamas reagento gamyboje, gautas iš šaltinių be BSE.
Vartotojas turėtų reguliariai atlikti vidinę kokybės kontrolę. Kokybės kontrolei reagentų antiserumai tiriami su atitinkamus heterozigotinius antigenus ekspresuojančiais eritrocitais.

Išversta teisingai
Su LR BK 295 str. susipažinęs
Vertėjas:
Parašas:
Patento numeris: U00250.33

248.7 -248.9

Die Bewertung der Reaktionsstärken erfolgt analog den Vorgaben des Technical Manual, 12th ed., Sect. 1, American Association of Blood Banks:

Reaktions-stärke	Agglutinationsbild
4+	Ein einziges Agglutinat. Keine freien Erythrozyten.
3+	Starke Reaktion. Einige große Agglutinate.
2+	Große Agglutinate innerhalb vieler kleinerer Verklumpungen, keine freien Erythrozyten.
1+	Viele kleine Agglutinate innerhalb eines Hintergrunds freier Erythrozyten.
+/-	Wenige makroskopisch erkennbare Agglutinate innerhalb der Erythrozytensuspension. Zahlreiche mikroskopisch erkennbare Agglutinate.
-	Homogene Erythrozytensuspension ohne erkennbare Agglutinate.

Grenzen des Verfahrens
Eine Trübung des Produktes kann ein Hinweis auf bakterielle Verunreinigung sein. In diesem Fall darf das Produkt nicht eingesetzt werden, da die Ursache der Trübung durch den Hersteller geklärt werden muss. Bei zweifelhaften Ergebnissen unklarer Ursache steht der Biotest-Service (Tel. 06103-801470) für Rückfragen zur Verfügung.

Haltbarkeit
Nach Öffnung des Reagenzes ist das Produkt bei sachgemäßer Lagerung (2-8°C) bis zum Ende der angegebenen Laufzeit haltbar. Die Laufzeit ist dem Reagenzienetikett zu entnehmen. Bei beschädigten Fläschchen darf das Produkt nicht mehr verwendet werden.

Hinweis
Manuelle Techniken sind nach den Vorgaben des Herstellers anzuwenden. Jede Abweichung von den Vorgaben des Herstellers liegt in der Verantwortung des Anwenders. Seraclone® Anti-A, -B, -AB sind für den Einsatz im Automaten geeignet. Die Anwendung im Automaten ist vom Anwender und in Verantwortung des Anwenders zu validieren. Für den Einsatz des Reagenzes in Automaten kann eine Verdünnung des Reagenzes erforderlich sein. Die Verantwortung des Anwenders gilt auch für jede sonstige Veränderung des Fertigreagenzes, wie z.B. Einfrieren auf Mikrotiterplatten. Abgearbeitete Tests müssen entsprechend der jeweiligen nationalen Richtlinien, z.B. in Deutschland als Abfall der Gruppe B wie beschrieben im „Merkblatt über die Vermeidung und die Entsorgung von Abfällen aus öffentlichen und privaten Einrichtungen des Gesundheitsdienstes" und der „Richtlinie für Krankenhaushygiene und Infektionsprävention", entsorgt werden. Durch die biotechnologische Herstellung der nicht humanen monoklonalen Antikörper ist das Risiko einer Infektion mit Hepatitis, HIV 1/2 oder anderen Erregern nahezu ausgeschlossen. Dennoch sollten alle Testreagenzien als potentielle Überträger von Hepatitis, HIV oder anderen infektiösen Krankheitserregern behandelt werden. Angemessene Sicherheitsvorkehrungen werden empfohlen. Das bei der Herstellung der Reagenzien verwendete Rinderalbumin wird nur aus BSE-freien Beständen bezogen. Der Anwender muss eine regelmäßige interne Qualitätskontrolle durchführen. Dazu werden die Antiseren mit Testerythrozyten, die das korrespondierende Antigen in heterozygoter Ausprägung tragen, geprüft. Es gelten die jeweiligen nationalen Richtlinien, z. B. (1).

Seraclone®
Anti-A (AB01), -B (AB02), -AB (AB03)

For typing of AB0 blood characteristics

Diagnostic reagent for in vitro use only
To be used by trained laboratory personnel only. The ACT is printed on the vial label. Symbols are used according to regulation EN 980. Symbols not contained in regulation EN 980 are described.

Test purpose
AB0 blood type characteristics are determined with the monoclonal reagents Anti-A, Anti-B and Anti-AB. They are verified by serum characteristics determination. Blood typing is considered valid if both red cell and serum characteristics were examined.

Test principle
The test principle is a hemagglutination test for the detection of red cell antigens. The antibodies in Seraclone® Anti-A, -B, -AB bind to the corresponding antigen on red cells and cause an antigen-antibody-reaction visible as red cell agglutination. The four AB0 blood types A, B, AB and 0 are defined by the presence or absence of A and B characteristics on red cells. The absence of both A and B characteristics defines blood type 0. The antigens (characteristics) A and B react with the corresponding antibody in Seraclone® Anti-A, -B, -AB.
Seraclone® Anti-A, -B, -AB can be used for slide, tile or tube testing.

Reagent
Seraclone® Anti-A, -B, -AB contain as reactive components monoclonal antibodies of the immunoglobulin class IgM. They are derived from hybridoma cell lines which are created by fusing mouse antibody producing B lymphocytes with mouse myeloma cells and demonstrate consistent specificity and reproducability characteristic for monoclonal antibodies. Both antibodies derived from a single clone (sister cells of one hybridoma cell) and a mixture of different antibodies derived from several clones are called monoclonal.

Seraclone® Anti-A	Clone A003
Seraclone® Anti-B	Clone B005
Seraclone® Anti-AB	Clones BS 63/BS 85

Materials required but not supplied
- Slides, Bioplate
- Pipettes (drop volume 40-50µl)
- Isotonic saline solution
- Glass tubes
- Laboratory centrifuge

Sample material
Blood samples should be taken according to common extraction procedures. Fresh, non-hemolytic samples (native, EDTA or citrate blood) should be used. If needed prepare a red cell suspension from a centrifugated blood sample (e. g. 2 min. at 1000 x g) in isontonic saline solution as suspension medium. We recommend to wash the red cells to be tested prior to preparing the cell suspension at least 2 times or until the supernatant is clear. Strongly lipemic, icteric or microbiologically contaminated samples may lead to false results.

Test procedure
For the detection of AB0 blood types the red cells to be tested are treated with Seraclone® Anti-A, Anti-B, Anti-AB. The serum to be tested is treated with test red cells, such as Biotestcell®-A1, -A2, -B, -0 (reverse typing).

Slide test
A. Rapid test
1. Place 1 drop reagent to slide (do not pre-heat!).
2. Add 1 small drop whole blood and mix well.
3. Agglutination will occur within 30 to 60 seconds. In order not to overlook weak A reactions, the agglutination should be read only after 2 minutes of careful rotation.

B. Incubation test
1. Suspend red cells to be tested 5-10% in isotonic saline solution or use whole blood.
2. On a slide mix 1 drop reagent and 1 drop red cell suspension or whole blood.
3. Incubate 15-30 minutes at room temperature (cover adequately to prevent drying out)
4. Gently rock slide and observe for agglutination.

Tube test
1. Suspend red cells to be tested in 3-5% isotonic saline solution.
2. In a properly marked tube mix 1 drop reagent and 1 drop red cell suspension.
3. Centrifugate 2 minutes at 1000 rpm (150 x g) or 20 seconds at 3000 rpm (1000 x g) or incubate 20 minutes at room temperature.
4. Gently dislodge cell button and observe for agglutination.

Test of serum characteristics (reverse typing)
The serum to be tested should be examined with known A1-, A2, -B and 0-cells or Biotestcell®-A1, -A2, -B, -0 with the above described procedures in slide or tube testing. Since serum characteristics may react in different strength, an incubation for 15-30 minutes at room temperature should be performed. Generally, newborns and young babies do not show test reaction due to missing isoagglutinines. Isoagglutinines may also be absent in elderly patients.

Interpretation of results
Reaction patterns red cell characteristics and isoagglutinines

Test sera + Patient red cells			Test red cells + serum/plasma				Blood-group
Anti-A	Anti-B	Anti-AB	A1	A2	B	O	
+	-	+	-	-	+	-	A
-	+	+	+	+	-	-	B
-	-	-	+	+	+	-	0
+	+	+	-	-	-	-	AB

+ = agglutination - = no agglutination

Reactions of Seraclone® Anti-A, Anti-B and Anti-AB with AB0 variations
Seraclone® test reagents do not react with cryptoantigens (T-, Tn-, Tk-activated cells).
Seraclone® Anti-B reacts correctly negative with acquired B characteristics.

Seraclone®	Anti-A	Anti-B	Anti-AB
A_2	++++	-	++++
A_2B	++++	++++	++++
A_3	+++(+)	-	++(+)
A_3B	+++(+)	++++	++++
A_x	++(+)	-	+(+)
A_xB	++(+)	++++	++++
B_{weak}	-	++(+)	++(+)
AB_{weak}	++++	++(+)	++++

Evaluation of the reaction strength is carried out according to the Technical Manual, 12th edition, Section 1, American Association of Blood Banks:

Reaction strength	Agglutination
4+	One single agglutinate. No free red cells.
3+	Strong reaction. Some large agglutinates.
2+	Large agglutinates within numerous small clumps, no free red cells.
1+	Numerous small agglutinates against a background of free red cells.
+/-	Just a few macroscopically detectable agglutinates within red cell suspension. Numerous microscopically detectable agglutinates.
-	Homogenous red cell suspension without detectable agglutinates.

Limits of the procedure
Turbidity or other visible changes may indicate a bacterial contamination. In this case the reagent must be discarded. The cause for turbidity must be examined by the manufacturer. In case of questionable results of unknown origin our Biotest Service will assist you (phone: +49-6103-801470).

Shelf life
After opening the reagent the product can be stored until its expiry date under proper storage conditions (2-8°C). The expiry date is printed on the label. Do not use damaged vials.

Note
Manual techniques are to be performed according to the manufacturer's instructions. Each deviation from these instructions is the sole responsibility of the user. Seraclone® Anti-A, -B, -AB is suited for use in automated systems. The use in automated systems is to be validated by the user. The use of Seraclone® Anti-A, -B, -AB in automated systems may require dilution of the reagent. The user's responsibility extents to all changes in the reagent, e.g. freezing on microtiterplates.
Used tests must be discarded as hazardous material. Waste management according to national guidelines.
Because of biotechnological manufacturing of non-human monoclonal antibodies, an infection with hepatitis, HIV 1/2 or other infectious diseases can be considered impossible. Nevertheless, all test reagents of biological origin must be regarded as potential transmitters of hepatitis, HIV or other infectious agents. Appropriate safety precautions are recommended.
The bovine albumin used for the production of this reagent is purchased from BSE-free sources.
The user must perform internal quality controls regularly. For a quality control test antisera are examined with test red cells carrying the correspondingly expressed heterozygous antigen. National guidelines apply.

Seraclone®
Anti-A (AB01), -B (AB02), -AB (AB03)
Pour l'identification des caractéristiques du groupe sanguin ABO

Réactif pour diagnostic in vitro
Ne doit être utilisé que par le personnel de laboratoire formé à cet effet. Le ACT figure sur l'étiquette du flacon. Les symboles utilisés sont conformes à la norme EN 980. Les symboles non visés dans la norme EN 980 sont expliqués dans le texte.

Application
Les caractéristiques des groupes sanguins ABO sont déterminées à l'aide des réactifs monoclonaux Anti-A, Anti-B et Anti-AB et confirmés par détermination des propriétés sériques. Le groupage sanguin est considéré comme confirmé si non seulement les caractéristiques érythrocytaires, mais aussi les propriétés sériques ont fait l'objet d'une analyse.

Principe du test
Le principe du test est basé sur l'hémagglutination en éprouvette qui décèle les antigènes des érythrocytes correspondants. Les anticorps contenus dans Seraclone® Anti-A, Anti-B et Anti-AB se fixent sur l'érythrocyte avec l'antigène correspondant et provoquent une réaction antigène/anticorps sous forme d'agglutination visible des érythrocytes. Les quatre groupes sanguins A, B, AB et O sont définis par la présence ou l'absence de caractéristiques A et B sur les érythrocytes. L'absence de A et B donne le groupe sanguin O. Les antigènes (caractéristiques) A et B réagissent avec l'anticorps correspondant contenu dans Seraclone® Anti-A, -B et -AB. Seraclone® Anti-A, -B et -AB peut être utilisé pour le test sur lame porte-objets, sur plaque ou en éprouvette.

Réactifs
Seraclone® Anti-A, -B et -AB contiennent comme éléments réactifs des anticorps monoclonaux de la classe des immunglobulines IgM. Ils proviennent d'excédents de culture de lignées d'hybridation cellulaire obtenus par fusion de lymphocytes B de souris, producteurs d'anticorps, avec des cellules de myélomes de souris. Ils présentent la spécificité et la reproductibilité constante caractéristique des anticorps monoclonaux. Les produits d'un clone (cellules filles d'une cellule d'hybridation) ainsi que les mélanges de plusieurs produits de clones individuels sont appelés monoclonaux.

Seraclone® Anti-A	Clone A003
Seraclone® Anti-B	Clone B005
Seraclone® Anti-AB	Clones BS 63/BS 85

Réactifs et matériel supplémentaires
- Lames porte-objets, plaque, bioplate
- Pipettes (volume par goutte: 40-50µl)
- Solution saline isotonique
- Éprouvettes de verre
- Centrifugeuse de laboratoire

Echantillons
Les échantillons sanguins sont prélevés selon des procédés généralement reconnus. Utiliser, par analogie aux méthodes de test citées, des échantillons frais, non hémolytiques (sang natif, EDTA ou citraté).
Dans la mesure où la conduite du mode opératoire nécessite une suspension d'érythrocytes, celle-ci est confectionnée à partir des érythrocytes de l'échantillon de sang centrifugé (par ex. 2 min. à 1000 x g) avec une solution saline isotonique comme milieu de suspension cellulaire.

Avant de préparer la suspension cellulaire, il est conseillé de laver les érythrocytes de test à 2 reprises, voire autant de fois qu'il sera nécessaire pour obtenir la limpidité du surnageant.
Les échantillons fortement lipémiques, ictériques ou présentant une contamination microbienne peuvent conduire à des résultats de tests non fiables.

Mode opératoire
Pour déterminer les groupes sanguins ABO, les érythrocytes des patients sont analysés avec Seraclone® Anti-A, -B et -AB. Le sérum des patients est analysé avec des érythrocytes de test connus, comme par ex. Biotestcell® -A1, -A2, -B, -O (contre-épreuve sérique).

Test sur plaque et sur lame porte-objets
A. Test rapide
1. Déposer sur une lame porte-objets non chauffée une goutte de réactif.
2. Ajouter une goutte de sang total et bien mélanger.
3. L'agglutination apparaît après 30 à 60 sec. Pour éviter de ne pas remarquer une propriété A faiblement exprimée, attendre 2 minutes avant d'évaluer l'agglutination tout en imprimant une légère rotation.

B. Test par incubation
1. Mettre en suspension de 5 à 10% les érythrocytes à analyser dans une solution saline isotonique ou bien utiliser du sang total.
2. Mélanger sur une lame porte-objets ou sur une plaque respectivement une goutte de réactif et une goutte de suspension d'érythrocytes ou une goutte de sang total.
3. Laisser incuber pendant 15 à 30 minutes à température ambiante (recouvrir adéquatement pour éviter l'assèchement).
4. Evaluer l'agglutination en imprimant une légère rotation.

Test en éprouvette
1. Mettre en suspension de 3 à 5% les érythrocytes à examiner dans une solution saline isotonique.
2. Mélanger respectivement dans une éprouvette adéquatement marquée 1 goutte de réactif et 1 goutte de suspension d'érythrocytes.
3. Centrifuger pendant 2 minutes à 1000 rpm (150 x g) ou 20 sec à 3000 rpm (1000 x g) ou bien faire incuber pendant 20 minutes à température ambiante.
4. Observer l'agglutination en secouant doucement.

Analyse des propriétés sériques (contre-épreuve sérique)
Le sérum des patients doit être soumis à une analyse sur plaque, sur lame porte-objets ou en éprouvette, conformément aux méthodes décrites ci-dessus, en utilisant les cellules connues A1, A2, B, 0 ou Biotestcell®-A1,-A2, -B, -0. Etant donné que les propriétés sériques réagissent selon des forces différentes, il convient d'effectuer une incubation de 15 à 30 minutes à température ambiante. En general, dans le cas de nouveau-nés et de nourissons le test n'aboutit pas à un résultat définitif en raison de l'absence d'isoagglutinines. Les isoagglutinines peuvent également faire défaut chez les personnes âgées.

Interprétation des résultats
Tableau de réactivité des caractéristiques des érythrocytes et des isoagglutinines:

Réactif + Erythrocytes des patients			Erythrocytes de test+ Sérum/Plasma				Groupe sanguin
Anti-A	Anti-B	Anti-AB	A1	A2	B	O	
+	-	+	-	-	+	-	A
-	+	+	+	+	-	-	B
-	-	-	+	+	+	-	0
+	+	+	-	-	-	-	AB

\+ = Agglutination - = Aucune agglutination

Réactions de Seraclone® Anti-A, Anti-B & Anti-AB avec les variantes d'ABO:
Les réactifs de test Seraclone® ne réagissent pas avec des cryptantigènes (cellules activées avec T, Tn, Tk). Seraclone® Anti-B réagit de façon nettement négative dans le cas de caractéristiques B acquises.

Seraclone®	Anti-A	Anti-B	Anti-AB
A_2	++++	-	++++
A_2B	++++	++++	++++
A_3	+++(+)	-	++(+)
A_3B	+++(+)	++++	++++
A_x	++(+)	-	+(+)
A_xB	++(+)	++++	++++
B_{weak}	-	++(+)	++(+)
AB_{weak}	++++	++(+)	++++

L'évaluation des forces de réaction s'opère conformément aux dispositions du Technical Manual, 12th ed., Sect. 1, American Assoc. of Blood Banks:

Force de réaction	Agglutination
4+	Un agglutinat unique. Aucun érythrocyte libre
3+	Réaction forte. Quelques agglutinats de grande dimension.
2+	Agglutinats de grande dimension à l'intérieur de nombreux grumeaux plus petits, aucun érythrocyte libre.
1+	Nombreux agglutinats de faible dimension sur un fond d'érythrocytes libres.
+/-	Peu d'agglutinats macroscopiquement reconnaissables à l'intérieur de la suspension d'érythrocytes. Nombreux agglutinats reconnaissables au microscope.
-	Suspension d'érythrocytes homogène sans agglutinats reconnaissables.

Seraclone®
Anti-A (ABO1), -B (ABO2), -AB (ABO3)
Kraujo tipavimui pagal ABO charakteristikas

Diagnostiniai reagentai tik tyrimams *in vitro*.
Turi būti naudojamas tik apmokyto laboratorijos personalo. ACT užrašytas ant buteliuko etiketės.. Naudojami simboliai pagal EN 980 reikalavimus. EN 980 reikalavimuose nenurodyti simboliai yra paaiškinami.

Tyrimo paskirtis
Kraujo ABO charakteristikos nustatomos naudojant monokloninius anti-A, anti-B ir anti-AB reagentus. Jos patikrinamos nustatant kraujo serumo charakteristikas. Kraujo tipavimas laikomas galiojančiu, jei buvo atlikti eritrocitų ir serumo tyrimai.

Testo principas
Tyrimo principas pagrįstas hemagliutinacija eritrocitų antigenų nustatymui. Antikūnai, esantys Seraclone® anti-A, -B ir –AB, susijungia su eritrocitų paviršiuje esančiais atitinkamais antigenais ir sukelia antigeno-antikūno reakciją, matomą kaip agliutinaciją. Keturios ABO kraujo grupės A, B, AB, 0 apibūdinamos pagal A ir B antigeno buvimą ar nebuvimą ant eritrocitų. A ir B nebuvimas būdingas 0 grupei. Antigenai A ir B reaguoja su atitinkamais antikūnais, esančiais Seraclone® anti-A, -B ir –AB.
Seraclone® anti-A, -B ir –AB gali būti naudojami tyrimams ant plokštumos ar mėgintuvėliuose.

Reagentai
Seraclone® anti-A, -B, -AB reagentuose reaktyvus komponentas yra monokloniniai IgM klasės antikūnai. Jie gaunami iš hibridomos ląstelių kultūrų, kurios sukuriamos sumaišius antikūnius produkuojančius B limfocitus su pelių mielominėmis ląstelėmis. Pastarosios gamina pastovių specifiškumo ir atkartojamumo charakteristikų monokloninius antikūnus. Antikūnai gauti iš atskiro ląstelių klono (iš vienos hibridomos ląstelės gautų "seserinių" ląstelių) arba antikūnų mišiniai gauti iš antikūnų klonų, vadinami monokloniniais.
Seraclone® Anti-A – klonas A003
Seraclone® Anti-B – klonas B005
Seraclone® Anti-AB – klonai BS63/BS85.

Reikalingos, bet nepateikiamos medžiagos
Plokštelės, bioplokštlės
Pipetės, kurių lašo turis 40-50 µl
Izotoninis NaCl tirpalas
Stikliniai mėgintuvėliai
Laboratorinė centrifuga

Mėginiai
Kraujo mėginiai turi būti gaunami pagal standartines procedūras. Turi būti naudojamas šviežias, nehemolizuotas (natyvinis, EDTA ar citratinis) kraujas. Jei reikalinga, kraujo suspensiją galima pagaminti iš centrifuguoto (pvz. 2 min x 1000 g) kraujo mėginio, resuspenduojant fiziologiniame tirpale. Prieš paruošiant suspensiją, mes rekomenduojame išplauti eritrocitus bent du kartus, kol supernatantas pasidaro skaidrus. Labai lipemiški, hemolizuoti ar mikrobiologiškai užteršti mėginiai gali duoti klaidingus rezultatus.

Tyrimo procedūra
ABO kraujo grupės nustatymui eritrocitai turi būti ištirti su Seraclone® anti-A, -B, -AB reagentais. Serumas turi būti ištirtas su standartiniais eritrocitais, tokiais kaip Biotestcell®-A1, A2, -B, -0 (atvirkštinis tipavimas).

Tyrimas ant objektinio stiklelio ar plokštelės
A. Greitas metodas:
1. Užlašinkite 1 lašą Seraclone reagento ant objektinio stiklelio ar plokštelės. (Nešildykite!)
2. Įlašinkite 1 lašą kraujo ir gerai išmaišykite.
3. Agliutinacija atsiras maždaug po 30-60 sekundžių. Kad nepraleisti silpnos reakcijos su A antigenu, rezultatai turi būti įvertinti tik praėjus ne mažiau nei 2 minutėm atsargiai sukant.

B. Inkubacinis metodas:
1. Tyrimui paruoškite 5-10% paciento eritrocitų suspensiją fiziologiniame NaCl tirpale arba naudokite natyvinį kraują.
2. Sumaišykite 1 lašą reagento ir 1 lašą suspensijos arba paciento kraujo ant objektinio stiklelio ar plokštelės.
3. Inkubuokite 15-30 minučių kambario temperatūroje (tinkamai uždenkite, kad neišgaruotų).
4. Švelniai sukratykite objektinį stiklelį ir įvertinkite agliutinaciją.

Tyrimas mėgintuvėlyje
1. Paruoškite 3-5% tiriamų eritrocitų suspensiją fiziologiniame NaCl tirpale.
2. Į atitinkamai pažymėtus mėgintuvėlius įlašinkite 1 lašą reagento ir 1 lašą eritrocitų suspensijos.
3. Centrifuguokite 2 min prie 1000 aps./min (150 g) arba 20 sekundžių prie 3000 aps./min (1000 g) arba inkubuokite 20 minučių kambario temperatūroje.
4. Švelniai išformuokite ląstelių centrifugatą ir įvertinkite agliutinaciją.

Netiesioginis grupavimas arba paciento serumo tyrimas
Serumas turi būti ištirtas su standartiniai eritrocitai su žinomais antigenais paviršiuje – A1, A2, B ir 0 ląstelės, arba Biotestcell – A1, A2, B ir 0 pagal aukščiau aprašytas objektinių stiklelių ir mėgintuvėlių metodikas. Kadangi serumas gali reaguoti nevienodai stipriai, reikėtų inkubuoti 15-30 min kambario temperatūroje. Paprastai naujagimiams ir mažiems vaikams reakcijos nebūna dėl izoagliutininų stokos. Izoagliutininų gali neturėti ir vyresni pacientai.

Rezultatų interpretavimas
Izoagliutininų ir eritrocitų reakcijų pavyzdžiai

Monokloniniai serumai + paciento eritrocitai			Standartiniai eritrocitai +serumas/plazma				Kraujo grupė
anti-A	anti-B	anti-AB	A1	A2	B	0	
+	-	+	-	-	+	-	A
-	+	+	+	+	-	-	B
-	-	-	+	+	+	-	0
+	+	+	-	-	-	-	AB

Pastaba: "+" =agliutinacija, "-"=nėra agliutinacijos.

Seraclone® anti-A, anti-B ir anti-AB reakcijos su AB0 sistemos variantais
Seraclone® reagentai nereaguoja su kriptoantigenais (T-, Tn-, Tk- ląstelėmis)
Seraclone® anti-B reaguoja neigiamai su atitinkamomis B charakteristikomis.

Seraclone®	Anti-A	Anti-B	Anti-AB
A2	++++	-	++++
A2B	++++	++++	++++
A3	+++(+)	-	++(+)
A3B	+++(+)	++++	++++
Ax	++(+)	-	+(+)
AxB	++(+)	++++	++++
Bweak (silpnas)	-	++(+)	++(+)
ABweak (silpnas)	++++	++(+)	++++

Agliutinacijos reakcijos stiprumas vertinamas pagal Amerikos kraujo bankų asociacijos Techninio vadovo 12 leidimą:

Reakcijos stiprumas	Agliutinacija
4+	Vienas agliutinatas. Nėra laisvų eritrocitų.
3+	Stipri reakcija. Keli dideli agliutinatai.
2	Dideli agliutinatai su daug mažų grupelių, nėra laisvų eritrocitų.
1+	Daug mažų agliutinatų laisvų eritrocitų fone.
+/-	Tik keli makroskopiškai nustatomi agliutinatai eritrocitų suspensijoje. Daug mikroskopiškai nustatomų agliutinatų.
-	Homogeniška eritrocitų suspensija be agliutinatų.

Procedūros apribojimai
Drumstumas ar kiti matomi pokyčiai rodo bakterinį užterštumą. Šiuo atveju reagento naudoti negalima. Drumstumo priežastį turi nustatyti gamintojas. Gavus neaiškius rezultatus, gali padėti Biotest Sevisas (+49 6103-801470)

Galiojimo laikas
Atidarius reagentą, jis išlieka galiojantis iki ant etiketės nurodytos galiojimo datos 2-8°C temperatūroje. Nepažeiskite buteliukų.

Pastabos
Rankiniai tyrimai turi būti atliekami pagal gamintojo instrukcijas.
Už nukrypimus nuo procedūros atsakingas vartotojas. Seraclone® Anti-A, Anti-B, Anti-AB tinkami ir automatinėms procedūroms. Automatines sistemas turi validuoti vartotojas. Seraclone® Anti-A, Anti-B, Anti-AB naudojant automatinėse sistemose, gali būti reikalingas reagento praskiedimas. Vartotojas atsako už visus reagento pakeitimus, pvz. Šaldymas mikroplokštelėse.
Medžiagos po tyrimų turi būti šalinamos kaip pavojingos. Atliekos tvarkomos pagal nacionalinius reikalavimus.
Šiems Seraclone® antiserumams pagaminti nebuvo naudotos jokios žmogiškos kilmės medžiagos. Praktiškai nėra galimybės užsikrėsti Hepatito, HIV-1/2 virusais ar kitom krauju plintančiomis ligomis. Nepaisant to, visi biologinės kilmės reagentai turi būti laikomi potencialiais hepatito, ŽIV ar kitų infekcinių ligų pernešėjais. Rekomenduojama laikytis tinkamų saugumo priemonių.
Albuminas, naudojamas reagento gamyboje, gautas iš šaltinių be BSE.
Vartotojas turėtų reguliariai atlikti vidinę kokybės kontrolę. Kokybės kontrolei reagentų antiserumai tiriami su atitinkamus heterozigotinius antigenus ekspresuojančiais eritrocitais

#248.10

Haltbarkeit
Nach Öffnung des Reagenzes ist das Produkt bei sachgemäßer Lagerung (2-8°C) bis zum Ende der angegebenen Laufzeit haltbar. Die Laufzeit ist dem Reagenzienetikett zu entnehmen.
Bei beschädigten Fläschchen darf das Produkt nicht mehr verwendet werden.

Hinweis
Manuelle Techniken sind nach den Vorgaben des Herstellers anzuwenden. Für den Einsatz des Reagenzes in Automaten kann eine Verdünnung des Reagenzes erforderlich sein. Die Anwendung ist dann vom Anwender und in Verantwortung des Anwenders zu validieren. Die Verantwortung des Anwenders gilt auch für jede sonstige Veränderung des Fertigreagenzes, z.B. Einfrieren auf Mikrotiterplatten.
Abgearbeitete Tests müssen entsprechend der jeweiligen nationalen Richtlinien, z.B. in Deutschland als Abfall der Gruppe B wie beschrieben im „Merkblatt über die Vermeidung und die Entsorgung von Abfällen aus öffentlichen und privaten Einrichtungen des Gesundheitsdienstes" und der „Richtlinie für Krankenhaushygiene und Infektionsprävention", entsorgt werden.
Seraclone® Control AB0+Rh ist nicht humanen Ursprungs. Das Risiko einer Kontamination durch infektiöse Krankheitserreger ist nahezu ausgeschlossen. Trotzdem sollten alle Testreagenzien als potentiell infektiös gehandhabt und die entsprechenden Vorsichtsmaßnahmen getroffen werden.
Das zugesetzte Rinderalbumin und Casein wird nur aus BSE- und MKS-freien Beständen bezogen.
Der Anwender muss eine regelmäßige interne Qualitätskontrolle durchführen. Dazu werden die Reagenzien mit geeigneten Methoden und Kontrollmaterialien geprüft. Es gelten die jeweiligen nationalen Richtlinien z. B. (1).

Seraclone® Control AB0+Rh

Reagent for the negative control in blood and Rh-typing with Seraclone® AB0- and Rh reagents

Diagnostic reagent for in vitro use only
To be used by trained laboratory personnel only. Symbols are used according to regulation EN 980. Symbols not contained in regulation EN 980 are described.

Test purpose
Seraclone® Control AB0+Rh is used as negative control in AB0-blood group typing and Rh factor determination with Seraclone® AB0- and Rh reagents.

Test principle
The test principle is a hemagglutination test. The antigens (characteristics) of the AB0 as well as the Rh system react with the corresponding antibodies in the Seraclone® AB0- and Rh reagents.
Samples with autoimmune antibodies, cold antibodies or rouleaux formation may show false positive reactions in testing with monoclonal antibodies. Thus a positive and a negative control should be performed with each test. A negative reaction is visible as a homogenous red cell suspension with no agglutinates. Seraclone® Control AB0+Rh can be used for slide, tile or tube testing.

Reagent
Seraclone® Control AB0+Rh is not of human origin. It contains all components of Seraclone® AB0- and Rh-reagents but not the antibodies. Thus it is suited as negative control in blood- and Rh-factor-typing with Rh reagents.

Additional materials needed but not supplied
- Seraclone® Anti-A (AB01), Seraclone® Anti-B (AB02), Seraclone® Anti-AB (AB01,2), Seraclone® Anti-C^w (RH8), Seraclone® Anti-D (Rh1) 226, Seraclone® Anti-D (RH1) 232, Seraclone® Anti-D (RH1) Blend, Seraclone® Anti-CDE (Rh2,1,3), Seraclone® Anti-C (RH2), Seraclone® Anti-c (RH4), Seraclone® Anti-E (RH3), Seraclone® Anti-e (RH5), Seraclone® (2) Anti-C (RH2), Seraclone® (2) Anti-c (RH4), Seraclone® (2) Anti-E (RH3), Seraclone® (2) Anti-e (RH5)
- Pipettes (drop volume 40-50 µl)
- Isotonic saline solution
- Glass slides
- Glass tubes
- Laboratory centrifuge

Sample material
Blood samples should be taken following general blood sampling guidelines. Fresh, non-hemolytic samples (native, EDTA or citrate blood) should be used according to the cited test methods.
If needed prepare a red cell suspension from a centrifuged blood sample (e. g. 2 min. at 1000 x g) in isotonic saline solution as suspension medium.
We recommend to wash the red cells to be tested prior to preparing the cell suspension at least 2 times or until the supernatant is clear.
Strongly lipemic, icteric or microbiologically contaminated samples may lead to false results.

Test procedure
For each blood sample test for AB0- and Rh-determination, a parallel negative control can be performed with Seraclone® Control AB0+Rh. The test has to be performed according to the method chosen for AB0 and Rh testing.

Slide Test
A. Rapid test
1. Place 1 drop reagent to slide (do not pre-heat).
2. Add 1 small drop whole blood and mix well.
3. The result should be read at the same time as the AB0- and Rh-characteristic reading - while cautiously rotating the slide.

B. Incubation test
1. Suspend red cells to be tested 5-10% in isotonic saline solution or use whole blood.
2. Place 1 drop of Seraclone® Control AB0+Rh a slide.
3. Add 1 drop red cell suspension or 1 small drop whole blood and mix well.
4. Incubate 15-30 minutes at room temperature.
5. The result should be read at the same time as the AB0- and Rh-characteristic reading - while cautiously rotating the slide.

Tube test
1. Suspend red cells to be tested 3-5% in isotonic saline solution.
2. In a properly marked tube place 1 drop Seraclone® Control AB0+Rh.
3. Add 1 drop red cell suspension to tube and mix well.
4. Centrifugate 2 minutes at 1000 rpm (150 x g) or 20 seconds at 3000 rpm (1000 x g) or incubate 20-30 minutes at room temperature.
5. Gently dislodge cell button and read result at the same time as the AB0- and Rh-characteristic reading.

Interpretation or results
No agglutination of the red cells to be tested with Seraclone® Control AB0+Rh: the result of the blood typing and Rh-factor determination is valid.
Agglutination of the red cells to be tested with Seraclone® Control AB0+Rh: the result of the blood typing and Rh-factor determination is not valid.
Independent from the negative control with Seraclone® Control AB0+Rh, efficacy and specificity of Seraclone® reagents must be validated.

Evaluation of the reaction strength is carried out according to the Technical Manual, 12th edition, Section 1, American Association of Blood Banks:

Reaction strength	Agglutination
4+	One single agglutinate. No free red cells.
3+	Strong reaction. Some large agglutinates.
2+	Large agglutinates within numerous small clumps, no free red cells.
1+	Numerous small agglutinates against a background of free red cells.
+/-	Just a few macroscopically detectable agglutinates within red cell suspension. Numerous microscopically detectable agglutinates.
-	Homogenous red cell suspension without detectable agglutinates.

Limits of the procedure
In rare cases, turbidity of the product may occur after opening the vial. Turbidity or other visible changes may indicate a bacterial contamination. In this case the reagent must be discarded. The cause for turbidity must be examined by the manufacturer.
In case of unclear results with unknown causes, our Biotest Service (phone: +49-6103-801470) will assist you.

Shelf life
After opening the reagent the product can be stored until its expiry date under proper storage conditions (2-8°C). The expiry date is printed on the label. Do not use damaged vials.

Note
Manual techniques are to be performed according to the manufacturer's instructions. The use of Seraclone® Control AB0+Rh in automated systems may require dilution of the reagent. The use in automated systems is to be validated by the user. The user's responsibility extents to all changes in the reagent, e.g. freezing on microtiterplates.
Used tests must be discarded as hazardous material. Waste management according to national guidelines.
Seraclone® Control AB0+Rh is of non-human origin. The risk of a contamination with infectious diseases can be considered impossible. Nevertheless, all test reagents must be regarded as potentially infectious. Appropriate safety precautions are recommended.
The bovine albumin and casein used for the production of this reagent are purchased from BSE- and MFD-free sources.
The user must perform internal quality controls regularly. For a quality control reagents are examined appropriate test methods and materials. National guidelines apply, e.g. (1).

Seraclone® Control ABO+Rh

Reagentas neigiamai kontrolei tiriant kraujo ABO ir Rh sistemas su Seraclone® ABO- ir Rh reagentais.

Diagnostiniai reagentai tik tyrimams *in vitro*.
Turi būti naudojamas tik apmokyto laboratorijos personalo. ACT užrašytas ant buteliuko etiketės.. Naudojami simboliai pagal EN 980 reikalavimus. EN 980 reikalavimuose nenurodyti simboliai yra paaiškinami.

Tyrimo paskirtis
Seraclone® Control ABO+Rh naudojamas neigiamai kontrolei tiriant kraujo ABO ir Rh sistemas su Seraclone® ABO- ir Rh reagentais.

Testo principas
Tyrimo principas pagrįstas hemagliutinacija. ABO ir D antigenai reaguoja su atitinkamais antikūnais, esančiais Seraclone® ABO ir Rh reagentuose.
Jei tiriamuose kraujo mėginiuose yra autoantikūnių, krioagliutininų ar sulipusių eritrocitų, galima klaidingai teigiama reakcija su monokloniniais antikūnais. Todėl kiekvieną kartą reikėtų atlikti teigiamą ir neigiamą kontrolinį tyrimą. Neigiama reakcija matoma kaip homogeninė eritrocitų suspensija be agliutinatų. Seraclone® ABO+Rh gali būti naudojamas tyrimams ant objektinio stiklelio, plokštelės ar mėgintuvėlyje.

Reagentai
Seraclone® Control ABO+Rh yra ne žmogaus kilmės. Jame yra visi Seraclone ABO- ir Rh reagentų komponentai, bet ne antikūnai. Todėl jis tinkamas kraujo grupių ir Rh faktoriaus tyrimų neigiamai kontrolei.

Papildomi reagentai ir medžiagos
Seraclone® Anti-A (AB01), Seraclone® Anti-B (AB02), Seraclone® Anti-AB (AB01,2), Seraclone® Anti-Cw (RH8), Seraclone ® Anti-D (Rh1) 226, Seraclone® Anti-D (RH1) 232, Seraclone® Anti-D (RH1) Blend, Seraclone® Anti-CDE (Rh2,1,3), Seraclone® Anti-C (RH2), Seraclone® Anti-c (RH4), Seraclone® Anti-E (RH3), Seraclone® Anti-e (RH5), Seraclone® (2) Anti-C (RH2), Seraclone® (2) Anti-c (RH4), Seraclone® (2) Anti-E (RH3), Seraclone® (2) Anti-e (RH5)
Pipetės, kurių lašo turis 40-50 µl
Izotoninis NaCl tirpalas
Plokštelės, bioplokštlės
Stikliniai mėgintuvėliai
Laboratorinė centrifuga

Mėginiai
Kraujo mėginiai turi būti gaunami pagal standartines procedūras. Turi būti naudojamas šviežias, nehemolizuotas (natyvinis, EDTA ar citratinis) kraujas. Jei reikalinga, kraujo suspensiją galima pagaminti iš centrifuguoto (pvz. 2 min x 1000 g) kraujo mėginio, resuspenduojant fiziologiniame tirpale. Prieš paruošiant suspensiją, mes rekomenduojame išplauti eritrocitus bent du kartus, kol supernatantas pasidaro skaidrus. Labai lipemiški, hemolizuoti ar mikrobiologiškai užteršti mėginiai gali duoti klaidingus rezultatus.

Tyrimo procedūra
Kiekvienam ABO ar Rh tyrimui paraleliai gali būti atliekamas neigiamas kontrolinis tyrimas su Seraclone® ABO+Rh. Tyrimas turi būti atliekamas pagal pasirinktą ABO ar Rh metodą.
Tyrimas ant objektinio stiklelio

A. Greitas metodas:
1. Užlašinkite 1 lašą Seraclone reagento ant objektinio stiklelio. (Nešildykite!)
2. Įlašinkite 1 lašą kraujo ir gerai išmaišykite.
3. Rezultatas gali būti vertinamas tuo pat metu kaip ir ABO ar Rh, atsargiai sukiojant stikliuką.

B. Inkubacinis metodas:
1. Tyrimui paruoškite 5-10% paciento eritrocitų suspensiją fiziologiniame NaCl tirpale arba naudokite natyvinį kraują.
2. Užlašinkite 1 lašą Seraclone® ABO+Rh.
3. Įlašinkite 1 lašą suspensijos arba paciento kraujo ir gerai išmaišykite.
4. Inkubuokite 15-30 minučių kambario temperatūroje.
5. Rezultatas gali būti vertinamas tuo pat metu kaip ir ABO ar Rh, atsargiai sukiojant plokštelę.

Tyrimas mėgintuvėlyje
1. Paruoškite 3-5% tiriamų eritrocitų suspensiją fiziologiniame NaCl tirpale.
2. Į atitinkamai pažymėtus mėgintuvėlius įlašinkite 1 lašą Seraclone® ABO+Rh.
3. Į mėgintuvėlį įlašinkite 1 lašą eritrocitų suspensijos.
4. Centrifuguokite 2 min prie 1000 aps./min (150 g) arba 20 sekundžių prie 3000 aps./min (1000 g) arba inkubuokite 20-30 minučių kambario arba 37°C temperatūroje.
5. Švelniai išformuokite ląstelių centrifugatą ir įvertinkite agliutinaciją tuo pat metu kaip ir ABO bei Rh tyrimų.

Rezultatų interpretavimas
Jei agliutinacija su Seraclone Control ABO +Rh neįvyko: gautas rezultatas nustatant kraujo grupes yra teisingas. Jei agliutinacija su Seraclone Control ABO +Rh reagentais įvyko: gautas rezultatas, nustatant kraujo grupes, yra klaidingas. Tokiais atvejais paraleliai turi būti tikrinamas Seraclone reagentų specifiškumas ir efektyvumas, nepriklausomai nuo Seraclone Control ABO ir Rh .

Agliutinacijos reakcijos stiprumas vertinamas pagal Amerikos kraujo bankų asociacijos Techninio vadovo 12 leidimą:

Reakcijos stiprumas	Agliutinacija
4+	Vienas agliutinatas. Nėra laisvų eritrocitų.
3+	Stipri reakcija. Keli dideli agliutinatai.
2	Dideli agliutinatai su daug mažų grupelių, nėra laisvų eritrocitų.
1+	Daug mažų agliutinatų laisvų eritrocitų fone.
+/-	Tik keli makroskopiškai nustatomi agliutinatai eritrocitų suspensijoje. Daug mikroskopiškai nustatomų agliutinatų.
-	Homogeniška eritrocitų suspensija be agliutinatų.

Procedūros apribojimai
Retai, po buteliuko atidarymo gali atsirasti produkto drumstumas.
Drumstumas ar kiti matomi pokyčiai rodo bakterinį užterštumą. Šiuo atveju reagento naudoti negalima. Drumstumo priežastį turi nustatyti gamintojas.
Gavus neaiškius rezultatus, gali padėti Biotest Servisas (+49 6103-801470)

Galiojimo laikas
Atidarius reagentą, jis išlieka galiojantis iki ant etiketės nurodytos galiojimo datos 2-8°C temperatūroje. Nepažeiskite buteliukų.

Pastabos
Rankiniai tyrimai turi būti atliekami pagal gamintojo instrukcijas. Naudojant Seraclone® ABO+Rh automatinėse sistemose, gali būti reikalingas reagento praskiedimas. Automatines sistemas turi validuoti vartotojas. Vartotojas atsako už visus reagento pakeitimus, pvz. šaldymas mikroplokštelėse.
Medžiagos po tyrimų turi būti šalinamos kaip pavojingos. Atliekos tvarkomos pagal nacionalinius reikalavimus.
Šiems Seraclone® ABO+Rh pagaminti nebuvo naudotos jokios žmogiškos kilmės medžiagos. Praktiškai nėra galimybės užsikrėsti infekcinėmis ligomis. Nepaisant to, visi biologinės kilmės reagentai turi būti laikomi potencialiais infekcinių ligų pernešėjais. Rekomenduojama laikytis tinkamų saugumo priemonių.
Jaučio albuminas ir kazeinas naudojamas reagento gamyboje, gautas iš šaltinių be BSE ir MFD.
Vartotojas turėtų reguliariai atlikti vidinę kokybės kontrolę. Kokybės kontrolei reagentų antiserumai tiriami atitinkamais metodais ir medžiagomis pagal nacionalinius reikalavimus.

SECTION 1: Identification of the substance/mixture and of the company/undertaking

1.1 Product identifier

Trade name: Seraclone™

This safety data sheet pertains to the following products:

801136 Seraclone™ Anti-A1 (ABO4), 5 ml
801165 Seraclone™ Anti-H (H1), 5 ml
801370 Seraclone™ Anti-AB (ABO3), 10 ml
801375 Seraclone™ Anti-AB (ABO3), 10x10 ml
802032 Seraclone™ Anti-D (RH1) Blend, 10 ml
802033 Seraclone™ Anti-D (RH1) Blend, 10x10 ml
802155 Seraclone™ Anti-Cw (RH8), 5 ml
802280 Seraclone™ Anti-C (RH2), 5 ml
802282 Seraclone™ Anti-C (RH2), 10 ml
802330 Seraclone™ Anti-E (RH3), 5 ml
802331 Seraclone™ Anti-E (RH3), 10 ml
802346 Seraclone™ Anti-c (RH4), 5 ml
802348 Seraclone™ Anti-c (RH4), 10 ml
805171 Seraclone™ Control ABO+Rh, 10 ml
808090 Seraclone™ Anti-K (KEL1), 5 ml
808158 Seraclone™ Anti-P1 (P1), 2 ml
808179 Seraclone™ Anit-Jka (JK1), 2 ml
808184 Seraclone™ Anti-Jkb (JK2), 2 ml
808227 Seraclone™ Anti-Lub (LU2), 2 ml
808404 Seraclone™ Anti-Lea (LE1), 2 ml
808410 Seraclone™ Anti-M (MNS1), 2 ml
808415 Seraclone™ Anti-N (MNS2), 2 ml
808423 Seraclone™ Anti-Leb (LE2), 2 ml
802356 Seraclone™ (2) Anti-c (RH4), 5 ml
802370 Seraclone™ Anti-e (RH5), 5 ml
802372 Seraclone™Anti-e (RH5), 10 ml
802039 Seraclone™ Anti-D (RH1) 226, 10 ml
802042 Seraclone™ Anti-D (RH1) 226, 10x10 ml
802054 Seraclone™ Anti-D (RH1) 232, 10 ml
802080 Seraclone™ Anti-CDE (RH2,1,3), 10 ml
802288 Seraclone™ (2) Anti-C (RH2), 5ml
802336 Seraclone™ (2) Anti-E (RH3), 5 ml

1.2 Relevant identified uses of the substance or mixture and uses advised against

General use: Use as laboratory reagent.
Only for industrial users.

1.3 Details of the supplier of the safety data sheet

Company name: Bio-Rad Medical Diagnostics GmbH
Street/POB-No.: Industriestr. 1
Postal Code, city: 63303 Dreieich
Germany
WWW: www.medizinische-diagnostik-dreieich.de
E-mail: contact.bmd@bio-rad.com
Telephone: +49 (0)6103-3130-0
Telefax: +49 (0)6103-3130-646
Dept. responsible for information:
Produktmanagement Transfusion
Telephone: 06103 3130-611
Telefax: 06103 3130-724

1.4 Emergency telephone number

GIZ-Nord, Germany, Telephone: +49 (0)551-19240

SECTION 2: Hazards identification

2.1 Classification of the substance or mixture

Classification according to EC regulation 1272/2008 (CLP)

This mixture is classified as not hazardous.

2.2 Label elements

Labelling (CLP)

Hazard statements: not applicable

Precautionary statements: not applicable

2.3 Other hazards

May be harmful if swallowed.

SECTION 3: Composition / information on ingredients

3.1 Substances: not applicable

3.2 Mixtures

Chemical characterisation: Aqueous solution of anorganic salts and organic compounds.
Contains proteine of different origins (human, bovine, murine).

Additional information: Contains sodium azide < 0.1% as preservative.

SECTION 4: First aid measures

4.1 Description of first aid measures

In case of inhalation: Provide fresh air. Seek medical treatment in case of troubles.

Following skin contact: Remove residues with water. Change contaminated clothing. In case of skin reactions, consult a physician.

After eye contact: Immediately flush eyes with plenty of flowing water for 10 to 15 minutes holding eyelids apart. In case of eye irritation consult an ophthalmologist.

After swallowing: Rinse mouth and drink large quantities of water.
Induce vomiting when the affected person is not unconscious. Observe risk of aspiration if vomiting occurs.
Seek medical attention. Never give anything by mouth to an unconscious person.

4.2 Most important symptoms and effects, both acute and delayed

May be harmful if swallowed.

4.3 Indication of any immediate medical attention and special treatment needed

Treat symptomatically.

SECTION 5: Firefighting measures

5.1 Extinguishing media

Suitable extinguishing media:
Product is non-combustible. Extinguishing materials should therefore be selected according to surroundings.

5.2 Special hazards arising from the substance or mixture

Fires in the immediate vicinity may cause the development of dangerous vapours. In the event of a fire, the following may be produced when the water evaporates: Carbon monoxide and carbon dioxide.

5.3 Advice for firefighters

Special protective equipment for firefighters:
Wear self-contained breathing apparatus. Wear protective equipment.

Additional information: Hazchem-Code: -
Do not allow fire water to penetrate into surface or ground water.

SECTION 6: Accidental release measures

6.1 Personal precautions, protective equipment and emergency procedures

Avoid contact with the substance. Provide adequate ventilation. Wear personal protection equipment. Do not breathe vapour/aerosol.

6.2 Environmental precautions

Do not allow to penetrate into soil, waterbodies or drains.

6.3 Methods and material for containment and cleaning up

Soak up with absorbent materials such as sand, siliceus earth, acid- or universal binder.
Store in special closed containers and dispose of according to ordinance. Final cleaning.

6.4 Reference to other sections

Refer additionally to section 8 and 13.

SECTION 7: Handling and storage

7.1 Precautions for safe handling

Advices on safe handling: Avoid contact with skin and eyes. Do not breathe vapours. Wear protective equipment.
Keep all containers, equipment and working place clean.

7.2 Conditions for safe storage, including any incompatibilities

Requirements for storerooms and containers:
Keep containers tightly closed and at a temperature between 2 °C and 8 °C.

Hints on joint storage: Do not store together with acids/alkalies and oxidation agents.

Storage class: 12 = Non-combustible liquids

7.3 Specific end use(s)

No information available.

SECTION 8: Exposure controls/personal protection

8.1 Control parameters

Additional information: Contains no substances with occupational exposure limit values.

8.2 Exposure controls

Provide good ventilation and/or an exhaust system in the work area.

Personal protection equipment

Occupational exposure controls

Respiratory protection: Provide fresh air. If vapours form, use respiratory protection. The filter class must be suitable for the maximum contaminant concentration (gas/vapour/aerosol/particulates) that may arise when handling the product.

Hand protection: Protective gloves according to EN 374.
Glove material: Nitrile rubber - Breakthrough time: >480 min.
Observe glove manufacturer's instructions concerning penetrability and breakthrough time.

Eye protection: Tightly sealed goggles according to EN 166.

Body protection: Wear suitable protective clothing.

General protection and hygiene measures:
Avoid contact with skin and eyes. Change contaminated clothing. After work, wash hands and face.

SECTION 9: Physical and chemical properties

9.1 Information on basic physical and chemical properties

Appearance:	Form: liquid Colour: colourless
Odour:	odourless
Odour threshold:	no data available
pH value:	no data available

Melting point/freezing point:	no data available
Initial boiling point and boiling range:	approx. 100 °C
Flash point/flash point range:	no data available
Evaporation rate:	no data available
Flammability:	non-flammable
Explosion limits:	LEL (Lower Explosion Limit): not applicable UEL (Upper Explosive Limit): not applicable
Vapour pressure:	no data available
Vapour density:	no data available
Density:	no data available
Solubility:	no data available
Partition coefficient: n-octanol/water:	no data available
Auto-ignition temperature:	not applicable
Thermal decomposition:	no data available
Viscosity, kinematic:	no data available
Explosive properties:	not applicable
Oxidizing characteristics:	no data available

9.2 Other information

Additional information: no data available

SECTION 10: Stability and reactivity

10.1 Reactivity

refer to 10.3

10.2 Chemical stability

Stable under recommended storage conditions.

10.3 Possibility of hazardous reactions

No hazardous reactions known.

10.4 Conditions to avoid

Protect against heat /sun rays.

10.5 Incompatible materials

Strong oxidizing agents, strong acids and alkalis.

10.6 Hazardous decomposition products

In the event of a fire, the following may be produced when the water evaporates: Carbon monoxide and carbon dioxide.

Thermal decomposition: no data available

SECTION 11: Toxicological information

11.1 Information on toxicological effects

Toxicological effects: Acute toxicity (oral): Based on available data, the classification criteria are not met. May be harmful if swallowed.

Acute toxicity (dermal): Lack of data.

Acute toxicity (inhalative): Lack of data.

Skin corrosion/irritation: Lack of data.

Eye damage/irritation: Lack of data.

Sensitisation to the respiratory tract: Lack of data.

Skin sensitisation: Lack of data.

Germ cell mutagenicity/Genotoxicity: Lack of data.

Carcinogenicity: Lack of data.

Reproductive toxicity: Lack of data.

Effects on or via lactation: Lack of data.

Specific target organ toxicity (single exposure): Lack of data.

Specific target organ toxicity (repeated exposure): Lack of data.

Aspiration hazard: Lack of data.

SECTION 12: Ecological information

12.1 Toxicity

Aquatic toxicity: Sodium azide: Very toxic to aquatic organisms, may cause long-term adverse effects in the aquatic environment. Even if strongly diluted, toxic water compounds develop.

12.2. Persistence and degradability

Further details: no data available

12.3 Bioaccumulative potential

Partition coefficient: n-octanol/water:
no data available

12.4 Mobility in soil

no data available

12.5 Results of PBT and vPvB assessment

no data available

12.6 Other adverse effects

General information: Do not allow to penetrate into soil, waterbodies or drains.

SECTION 13: Disposal considerations

13.1 Waste treatment methods

Product

Waste key number: 16 10 02 = aqueous liquid wastes other than those mentioned in 16 10 01

Recommendation: Small quantities can be disposed of with the domestic waste or burnt, with due observance of regulations of local authorities. Large quantities are hazardous waste and must be disposed of accordingly.

Contaminated packaging

Recommendation: Dispose of waste according to applicable legislation.
Handle contaminated packages in the same way as the substance itself.
Non-contaminated packages may be recycled.

SECTION 14: Transport information

14.1 UN number

ADR/RID, IMDG, IATA-DGR:
not applicable

14.2 UN proper shipping name

ADR/RID, IMDG, IATA-DGR:
Not restricted

14.3 Transport hazard class(es)

ADR/RID, IMDG, IATA-DGR:
not applicable

14.4 Packing group

ADR/RID, IMDG, IATA-DGR:
not applicable

14.5 Environmental hazards

Marine pollutant: No

14.6 Special precautions for user

No dangerous good in sense of these transport regulations.

14.7 Transport in bulk according to Annex II of MARPOL 73/78 and the IBC Code

no data available

SECTION 15: Regulatory information

15.1 Safety, health and environmental regulations/legislation specific for the substance or mixture

National regulations - Great Britain

Hazchem-Code: -
No data available

BIO-RAD

SAFETY DATA SHEET
according to Regulation (EC) No. 1907/2006 (REACH)
and Regulation (EU) No 2015/830

Seraclone™
Material number 186042

15.2 Chemical Safety Assessment

For this mixture a chemical safety assessment is not required.

SECTION 16: Other information

Further information

Date of first version: 8/6/2015

Department issuing data sheet

Contact person: see section 1: Dept. responsible for information

For abbreviations and acronyms, see: ECHA Guidance on information requirements and chemical safety assessment, chapter R.20 (Table of terms and abbreviations).

The information in this data sheet has been established to our best knowledge and was up-to-date at time of revision. It does not represent a guarantee for the properties of the product described in terms of the legal warranty regulations.

BIO-RAD

Safety data sheet
according to 1907/2006/EC, Article 31

Printing date 03.07.2013 Version number 1 Revision: 28.05.2013

*

1 Identification of the substance/mixture and of the company/ undertaking

· **Product identifier**

· **Trade name:** NACL, LISS/Coombs, DAT, Coombs Anti-IgG and Screening

· **Bio-Rad MSDS Number:** 2008M

· **References and packagings (Id-N°):**

50520 NaCl, Enzyme Test and Cold Aggluzinins
50531 LISS/Coombs
50830 DC-Screening I
50560 DC-Screening II
50540 Coombs Anti-IgG
50450 Anti-IgG Coombs
50870 DAT Igg-Dilution
50890 DAT IgG1/IgG3
50571 DiaScreen
50581 LISS/Coombs + Enzyme Test
50549 Coombs Anti-IgG
50530 ID-Liss/Coombs
50682 DiaClon Type + Screen
50683 DiaClon Type + Screen
50591 Complete Crossmatch
50601 DiaClon Complete Crossmatch
50771 DiaClon BAS-Test
51190 DiaClon BAS-Test IgG
50510 Reverse Grouping with Antibody Screening

· **Relevant identified uses of the substance or mixture and uses advised against**
No further relevant information available.
· **Application of the substance / the preparation**
In vitro diagnostic medical device or component.

· **Details of the supplier of the safety data sheet**
· **Manufacturer/Supplier:**
DiaMed GmbH
Pra Rond 23
CH-1785 Cressier FR
(Switzerland/Schweiz/Suisse/Swizzera)
Tel: +41 (0)26 674 51 11
Fax: +41 (0)26 674 51 45

· **Further information obtainable from:** fds-msds.ch@bio-rad.com
· **Emergency telephone number:** Tel.: 145 oder/or/ou +41 442 51 51 51

2 Hazards identification

· **Classification of the substance or mixture**
The product is not classified according to the Globally Harmonized System (GHS).

· **Classification according to Directive 67/548/EEC or Directive 1999/45/EC**
Not applicable.

(Contd. on page 2)

BIO-RAD

Safety data sheet
according to 1907/2006/EC, Article 31

Printing date 03.07.2013 Version number 1 Revision: 28.05.2013

(Contd. of page 1)

· **Information concerning particular hazards for human and environment:**
The product does not have to be labelled due to the calculation procedure of the "General Classification guideline for preparations of the EU" in the latest valid version.
· **Classification system:**
The classification is according to the latest editions of the EU-lists, and extended by company and literature data.

· **Label elements**

· **Labelling according to EU guidelines:**
Observe the general safety regulations when handling chemicals.
The product is not subject to identification regulations under EU Directives and the Ordinance on Hazardous Materials (German GefStoffV).

· **Other hazards**
· **Results of PBT and vPvB assessment**
· **PBT:** Not applicable.
· **vPvB:** Not applicable.

3 Composition/information on ingredients

· **Chemical characterization: Mixtures**
· **Description:**
Mixture of substances listed below with nonhazardous additions.
· **Additional information:**
For the wording of the listed risk phrases refer to section 16.

4 First aid measures

· **Description of first aid measures**
· **General information:** No special measures required.
· **After inhalation:**
Supply fresh air; consult doctor in case of complaints.
· **After skin contact:** Generally the product does not irritate the skin.
· **After eye contact:**
Rinse opened eye for several minutes under running water.
· **After swallowing:** If symptoms persist consult doctor.
· **Information for doctor:**
· **Most important symptoms and effects, both acute and delayed**
No further relevant information available.
· **Indication of any immediate medical attention and special treatment needed**
No further relevant information available.

5 Firefighting measures

· **Extinguishing media**
· **Suitable extinguishing agents:**
CO2, powder or water spray. Fight larger fires with water spray or alcohol resistant foam.
Use fire extinguishing methods suitable to surrounding conditions.
· **Special hazards arising from the substance or mixture**
No further relevant information available.

(Contd. on page 3)

BIO-RAD

Safety data sheet
according to 1907/2006/EC, Article 31

Printing date 03.07.2013 Version number 1 Revision: 28.05.2013

(Contd. of page 2)

· **Advice for firefighters**
· **Protective equipment:** No special measures required.

6 Accidental release measures

· **Personal precautions, protective equipment and emergency procedures**
Not required.
· **Environmental precautions:**
Dilute with plenty of water.
Do not allow to enter sewers/ surface or ground water.
· **Methods and material for containment and cleaning up:**
Absorb with liquid-binding material (sand, diatomite, acid binders, universal binders, sawdust).
· **Reference to other sections**
No dangerous substances are released.
See Section 7 for information on safe handling.
See Section 8 for information on personal protection equipment.
See Section 13 for disposal information.

7 Handling and storage

· **Handling:**
· **Precautions for safe handling** No special measures required.
· **Information about fire - and explosion protection:**
No special measures required.
· **Conditions for safe storage, including any incompatibilities**
· **Storage:**
· **Requirements to be met by storerooms and receptacles:**
No special requirements.
· **Information about storage in one common storage facility:**
Not required.
· **Further information about storage conditions:**
see related package insert
The substance / preparation must be stored between 18 °C and 25 °C
· **Specific end use(s)** No further relevant information available.

8 Exposure controls/personal protection

· **Additional information about design of technical facilities:**
No further data; see item 7.
· **Control parameters**
· **Additional information:**
The lists valid during the making were used as basis.
· **Exposure controls**
· **Personal protective equipment:**
· **General protective and hygienic measures:**
The usual precautionary measures are to be adhered to when handling chemicals.
· **Respiratory protection:** Not required.

(Contd. on page 4)

BIO-RAD

Safety data sheet
according to 1907/2006/EC, Article 31

Printing date 03.07.2013 Version number 1 Revision: 28.05.2013

(Contd. of page 3)

· **Protection of hands:**

Protective gloves

The glove material has to be impermeable and resistant to the product/ the substance/ the preparation.
· **Penetration time of glove material**
The exact break through time has to be found out by the manufacturer of the protective gloves and has to be observed.
· **Eye protection:** Safety glasses
· **Body protection:** Protective work clothing

9 Physical and chemical properties

· **Information on basic physical and chemical properties**	
· **General Information**	
· **Appearance:**	
· **Form:**	Liquid on inert carrier material
· **Colour:**	Different according to colouring
· **Odour:**	Odourless
· **Odour threshold:**	Not determined.
· **pH-value:**	Not determined.
· **Change in condition**	
· **Melting point/Melting range:**	Undetermined.
· **Boiling point/Boiling range:**	Undetermined.
· **Flash point:**	Not applicable.
· **Flammability (solid, gaseous):**	Not applicable.
· **Ignition temperature:**	
· **Decomposition temperature:**	Not determined.
· **Self-igniting:**	Product is not selfigniting.
· **Danger of explosion:**	Product does not present an explosion hazard.
· **Explosion limits:**	
· **Lower:**	Not determined.
· **Upper:**	Not determined.
· **Vapour pressure:**	Not determined.
· **Density:**	Not determined.
· **Relative density**	Not determined.
· **Vapour density**	Not determined.
· **Evaporation rate**	Not determined.
· **Solubility in / Miscibility with**	
· **water:**	Fully miscible.

(Contd. on page 5)

BIO-RAD

Safety data sheet
according to 1907/2006/EC, Article 31

Printing date 03.07.2013 Version number 1 Revision: 28.05.2013

(Contd. of page 4)

· **Partition coefficient (n-octanol/ water):**	Not determined.
· **Viscosity:**	
· **Dynamic:**	Not determined.
· **Kinematic:**	Not determined.
· **Solvent content:**	
· **Organic solvents:**	0,0 %
· **Water:**	8,6 %
· **Other information**	No further relevant information available.

10 Stability and reactivity

· **Reactivity**
· **Chemical stability**
· **Thermal decomposition / conditions to be avoided:**
No decomposition if used according to specifications.
· **Possibility of hazardous reactions** No dangerous reactions known.
· **Conditions to avoid** No further relevant information available.
· **Incompatible materials:** No further relevant information available.
· **Hazardous decomposition products:**
No dangerous decomposition products known.

11 Toxicological information

· **Information on toxicological effects**
· **Acute toxicity:**
· **LD/LC50 values relevant for classification:**
Sodium Azid is used as a preservative. (Concentration < 0.1%)

26628-22-8 Sodium Azide		
Oral	LD50	27 mg/kg (rat)
Dermal	LD50	20 mg/kg (rabbit)

· **Primary irritant effect:**
· **on the skin:** No irritant effect.
· **on the eye:** No irritating effect.
· **Sensitization:** No sensitizing effects known.
· **Additional toxicological information:**
The product is not subject to classification according to the calculation method of the General EU Classification Guidelines for Preparations as issued in the latest version.
When used and handled according to specifications, the product does not have any harmful effects to our experience and the information provided to us.

12 Ecological information

· **Toxicity**
· **Aquatic toxicity:** No further relevant information available.
· **Persistence and degradability** No further relevant information available.

(Contd. on page 6)

BIO-RAD

Safety data sheet
according to 1907/2006/EC, Article 31

Printing date 03.07.2013 Version number 1 Revision: 28.05.2013

(Contd. of page 5)

· **Behaviour in environmental systems:**
· **Bioaccumulative potential** No further relevant information available.
· **Mobility in soil** No further relevant information available.
· **Additional ecological information:**
· **General notes:**
Water hazard class 1 (German Regulation) (Self-assessment): slightly hazardous for water
Do not allow undiluted product or large quantities of it to reach ground water, water course or sewage system.
· **Results of PBT and vPvB assessment**
· **PBT:** Not applicable.
· **vPvB:** Not applicable.
· **Other adverse effects** No further relevant information available.

13 Disposal considerations

· **Waste treatment methods**
· **Recommendation**
Smaller quantities can be disposed of with household waste.
· **Uncleaned packaging:**
· **Recommendation:**
Disposal must be made according to official regulations.
· **Recommended cleansing agents:**
Water, if necessary together with cleansing agents.

14 Transport information

· **UN-Number**	
· **ADR, ADN, IMDG, IATA**	Void
· **UN proper shipping name**	
· **ADR, ADN, IMDG, IATA**	Void
· **Transport hazard class(es)**	
· **ADR, ADN, IMDG, IATA**	
· **Class**	Void
· **Packing group**	
· **ADR, IMDG, IATA**	Void
· **Environmental hazards:**	
· **Marine pollutant:**	No
· **Special precautions for user**	Not applicable.
· **Transport in bulk according to Annex II of MARPOL73/78 and the IBC Code**	Not applicable.
· **Transport/Additional information:**	Not dangerous according to the above specifications.
· **UN "Model Regulation":**	-

(Contd. on page 7)

BIO-RAD

Safety data sheet
according to 1907/2006/EC, Article 31

Printing date 03.07.2013 Version number 1 Revision: 28.05.2013

(Contd. of page 6)

15 Regulatory information

- **Safety, health and environmental regulations/legislation specific for the substance or mixture**
  - **Labelling according to EU guidelines:**
    Observe the general safety regulations when handling chemicals.
    The product is not subject to identification regulations under EU Directives and the Ordinance on Hazardous Materials (German GefStoffV).
- **Chemical safety assessment:**
  A Chemical Safety Assessment has not been carried out.

16 Other information

This information is based on our present knowledge. However, this shall not constitute a guarantee for any specific product features and shall not establish a legally valid contractual relationship.

- **Department issuing MSDS:**
  DiaMed GmbH
  Pra Rond 23
  CH-1785 Cressier FR
  (Switzerland/Schweiz/Suisse/Svizzera)
  - **Abbreviations and acronyms:**
    ADR: Accord européen sur le transport des marchandises dangereuses par Route (European Agreement concerning the International Carriage of Dangerous Goods by Road)
    IMDG: International Maritime Code for Dangerous Goods
    IATA: International Air Transport Association
    GefStoffV: Gefahrstoffverordnung (Ordinance on Hazardous Substances, Germany)
    LC50: Lethal concentration, 50 percent
    LD50: Lethal dose, 50 percent
  - *** Data compared to the previous version altered.**

BIO-RAD

Safety data sheet
according to 1907/2006/EC, Article 31

Printing date 11.09.2014 Version number 1 Revision: 19.03.2014

1 Identification of the substance/mixture and of the company/undertaking

· **Product identifier**

· **Trade name:** Solutions for Red Cells and Reagents

· **Bio-Rad MSDS Number:** 2044M

· **References and packagings (Id-N°):**

05751 ID-Diluent 1
05761 ID-Diluent 2
05740 ID-CellStab
05710 ID-CellWash-P
06311 ID-Papain
12140 DiaBrom
20100 Diluent N.A.
40560 Ec-Stabilizing Solution
40230 DiaMed CellFreeze
40240 DiaMed CellThaw

· **Relevant identified uses of the substance or mixture and uses advised against**
No further relevant information available.

· **Application of the substance / the mixture** In vitro diagnostic medical device or component.

· **Details of the supplier of the safety data sheet**

· **Manufacturer/Supplier:**
DiaMed GmbH
Pra Rond 23
CH-1785 Cressier FR
(Switzerland/Schweiz/Suisse/Swizzera)
Tel: +41 (0)26 674 51 11
Fax: +41 (0)26 674 51 45

· **Further information obtainable from:** fds-msds.ch@bio-rad.com

· **Emergency telephone number:** Tel.: 145 oder/or/ou +41 442 51 51 51

2 Hazards identification

· **Classification of the substance or mixture**
The product is not classified according to the Globally Harmonized System (GHS).

· **Label elements**

· **GHS label elements** Void

· **Hazard pictograms** Void

· **Signal word** Void

· **Hazard statements** Void

· **Other hazards**

· **Results of PBT and vPvB assessment**

· **PBT:** Not applicable.

· **vPvB:** Not applicable.

3 Composition/information on ingredients

· **Chemical characterization: Mixtures**

· **Description:** Mixture of substances listed below with nonhazardous additions.

(Contd. on page 2)

BIO-RAD

Safety data sheet
according to 1907/2006/EC, Article 31

Printing date 11.09.2014 Version number 1 Revision: 19.03.2014

(Contd. of page 1)

· **Dangerous components:** Void

4 First aid measures

· **Description of first aid measures**

· **General information:** No special measures required.

· **After inhalation:** Supply fresh air; consult doctor in case of complaints.

· **After skin contact:** Generally the product does not irritate the skin.

· **After eye contact:** Rinse opened eye for several minutes under running water.

· **After swallowing:** If symptoms persist consult doctor.

· **Most important symptoms and effects, both acute and delayed**
No further relevant information available.

· **Indication of any immediate medical attention and special treatment needed**
No further relevant information available.

5 Firefighting measures

· **Extinguishing media**

· **Suitable extinguishing agents:**
CO2, powder or water spray. Fight larger fires with water spray or alcohol resistant foam.
Use fire extinguishing methods suitable to surrounding conditions.

· **Special hazards arising from the substance or mixture** No further relevant information available.

· **Advice for firefighters**

· **Protective equipment:** No special measures required.

6 Accidental release measures

· **Personal precautions, protective equipment and emergency procedures** Not required.

· **Environmental precautions:** Dilute with plenty of water.

· **Methods and material for containment and cleaning up:**
Absorb with liquid-binding material (sand, diatomite, acid binders, universal binders, sawdust).

· **Reference to other sections**
See Section 7 for information on safe handling.
See Section 8 for information on personal protection equipment.
See Section 13 for disposal information.

7 Handling and storage

· **Precautions for safe handling** No special measures required.

· **Information about fire - and explosion protection:** No special measures required.

· **Conditions for safe storage, including any incompatibilities**

· **Storage:**

· **Requirements to be met by storerooms and receptacles:** No special requirements.

· **Information about storage in one common storage facility:** Not required.

· **Further information about storage conditions:** see related package insert.

· **Specific end use(s)** No further relevant information available.

(Contd. on page 3)

BIO-RAD

Safety data sheet
according to 1907/2006/EC, Article 31

Printing date 11.09.2014 Version number 1 Revision: 19.03.2014

(Contd. of page 2)

8 Exposure controls/personal protection

· **Additional information about design of technical facilities:** No further data; see item 7.

· **Control parameters**
· **Additional information:** The lists valid during the making were used as basis.

· **Exposure controls**
· **Personal protective equipment:**
· **General protective and hygienic measures:**
The usual precautionary measures are to be adhered to when handling chemicals.
· **Respiratory protection:** Not necessary if room is well-ventilated.
· **Protection of hands:**

Protective gloves

The glove material has to be impermeable and resistant to the product/ the substance/ the preparation.
· **Material of gloves**
The selection of the suitable gloves does not only depend on the material, but also on further marks of quality and varies from manufacturer to manufacturer.
The selection of the suitable gloves does not only depend on the material, but also on further marks of quality and varies from manufacturer to manufacturer. As the product is a preparation of several substances, the resistance of the glove material can not be calculated in advance and has therefore to be checked prior to the application.
· **Penetration time of glove material**
The exact break through time has to be found out by the manufacturer of the protective gloves and has to be observed.
· **Eye protection:** Safety glasses
· **Body protection:** Protective work clothing

9 Physical and chemical properties

· **Information on basic physical and chemical properties**	
· **General Information**	
· **Appearance:**	
· **Form:**	Fluid
· **Colour:**	Various colours
· **Odour:**	Odourless
· **Odour threshold:**	Not determined.
· **pH-value:**	Not determined.
· **Change in condition**	
· **Melting point/Melting range:**	Undetermined.
· **Boiling point/Boiling range:**	100 °C
· **Flash point:**	Not applicable.
· **Flammability (solid, gaseous):**	Not applicable.

(Contd. on page 4)

BIO-RAD

Safety data sheet
according to 1907/2006/EC, Article 31

Printing date 11.09.2014 Version number 1 Revision: 19.03.2014

(Contd. of page 3)

· **Ignition temperature:**	
· **Decomposition temperature:**	Not determined.
· **Self-igniting:**	Product is not selfigniting.
· **Danger of explosion:**	Product does not present an explosion hazard.
· **Explosion limits:**	
· **Lower:**	Not determined.
· **Upper:**	Not determined.
· **Vapour pressure:**	Not determined.
· **Density:**	Not determined.
· **Relative density**	Not determined.
· **Vapour density**	Not determined.
· **Evaporation rate**	Not determined.
· **Solubility in / Miscibility with**	
· **water:**	Fully miscible.
· **Partition coefficient (n-octanol/water):**	Not determined.
· **Viscosity:**	
· **Dynamic:**	Not determined.
· **Kinematic:**	Not determined.
· **Solvent content:**	
· **Organic solvents:**	0,0 %
· **Other information**	No further relevant information available.

10 Stability and reactivity

· **Reactivity**
· **Chemical stability**
· **Thermal decomposition / conditions to be avoided:**
No decomposition if used according to specifications..
· **Possibility of hazardous reactions** No dangerous reactions known.
· **Conditions to avoid** No further relevant information available.
· **Incompatible materials:** No further relevant information available.
· **Hazardous decomposition products:** No dangerous decomposition products known.

11 Toxicological information

· **Information on toxicological effects**
· **Acute toxicity:**
· **Primary irritant effect:**
· **on the skin:** No irritant effect.
· **on the eye:** No irritating effect.
· **Sensitization:** No sensitizing effects known.
· **Additional toxicological information:**
The product is not subject to classification according to the calculation method of the General EU Classification Guidelines for Preparations as issued in the latest version.

(Contd. on page 5)

BIO-RAD

Safety data sheet
according to 1907/2006/EC, Article 31

Printing date 11.09.2014 Version number 1 Revision: 19.03.2014

(Contd. of page 4)

When used and handled according to specifications, the product does not have any harmful effects to our experience and the information provided to us.

12 Ecological information

· **Toxicity**
· **Aquatic toxicity:** No further relevant information available.
· **Persistence and degradability** No further relevant information available.
· **Bioaccumulative potential** No further relevant information available.
· **Mobility in soil** No further relevant information available.
· **Additional ecological information:**
· **General notes:** Generally not hazardous for water
· **Results of PBT and vPvB assessment**
· **PBT:** Not applicable.
· **vPvB:** Not applicable.
· **Other adverse effects** No further relevant information available.

13 Disposal considerations

· **Waste treatment methods**
· **Recommendation** Smaller quantities can be disposed of with household waste.
· **Uncleaned packaging:**
· **Recommendation:** Disposal must be made according to official regulations.
· **Recommended cleansing agents:** Water, if necessary together with cleansing agents.

14 Transport information

· **UN-Number** · **ADR, ADN, IMDG, IATA**	Void
· **UN proper shipping name** · **ADR, ADN, IMDG, IATA**	Void
· **Transport hazard class(es)** · **ADR, ADN, IMDG, IATA** · **Class**	Void
· **Packing group** · **ADR, IMDG, IATA**	Void
· **Environmental hazards:** · **Marine pollutant:**	No
· **Special precautions for user**	Not applicable.
· **Transport in bulk according to Annex II of MARPOL73/78 and the IBC Code**	Not applicable.
· **Transport/Additional information:**	Not dangerous according to the above specifications.

(Contd. on page 6)

BIO-RAD

Safety data sheet
according to 1907/2006/EC, Article 31

Printing date 11.09.2014 Version number 1 Revision: 19.03.2014

(Contd. of page 5)

· **UN "Model Regulation":**	-

15 Regulatory information

· **Safety, health and environmental regulations/legislation specific for the substance or mixture**
· **GHS label elements** Void
· **Hazard pictograms** Void
· **Signal word** Void
· **Hazard statements** Void
· **Chemical safety assessment:** A Chemical Safety Assessment has not been carried out.

16 Other information

This information is based on our present knowledge. However, this shall not constitute a guarantee for any specific product features and shall not establish a legally valid contractual relationship.

· **Department issuing MSDS:**
DiaMed GmbH
Pra Rond 23
CH-1785 Cressier FR
(Switzerland/Schweiz/Suisse/Svizzera)
· **Abbreviations and acronyms:**
ADR: Accord européan sur le transport des marchandises dangereuses par Route (European Agreement concerning the International Carriage of Dangerous Goods by Road)
IMDG: International Maritime Code for Dangerous Goods
IATA: International Air Transport Association
EINECS: European inventory of Existing Commercial Chemical Substances
ELINCS: European List of Notified Chemical Substances
CAS: Chemical Abstracts Service (division of the American Chemical Society)
· * **Data compared to the previous version altered.**

BIO-RAD

Safety data sheet
according to 1907/2006/EC, Article 31

Printing date 07.08.2013 Version number 1 Revision: 12.06.2013

*

1 Identification of the substance/mixture and of the company/ undertaking

· **Product identifier**

· **Trade name:** ID Screening, Identification and Quality Control Testcells

· **Bio-Rad MSDS Number:** 2012M

· **References and packagings (Id-N°):**

45022 ID-DiaCell ABO A1, A2, B, O
45082 ID-DiaCell ABO A1, A2, B
45352 ID-DiaCell ABO A1, B, O
45092 ID-DiaCell ABO A1, B
06012 ID-DiaCell A1
06022 ID-DiaCell A2
06032 ID-DiaCell B
06042 ID-DiaCell O
45012 ID-DiaCell ABO/I-II-III
45002 ID-DiaCell ABO/I-II
45070 ID-DiaScreen I-VI
45200 ID-DiaScreen I-II-III-IV
45210 ID-DiaScreen VP-VIP
45660 ID-DiaScreen Prophylax
45184 ID-DiaCell I-II-III
45404 ID-DiaCell I-II-III
45194 ID-DiaCell IP-IIP-IIIP
45414 ID-DiaCell IP-IIP-IIIP
45151 ID-DiaCell I-II
45330 ID-DiaCell I-II-III Asia (Mia+)
05980 ID-Dia (Diego) Positive
06291 ID-I Negative Cell
06060 ID DiaCell SF
06070 ID-DiaCell Pool
45161 ID-DiaPanel
45670 ID-DiaPanel Plus 6
45171 ID-DiaPanel-P
45341 ID-Internal Quality Control
45840 DiaMed Basic Q.C.
45950 DiaMed Q.C. System
45530 DiaMed Quality Control Survey Basic
45650 DiaMed Quality Control Survey Advanced

· **Relevant identified uses of the substance or mixture and uses advised against**
No further relevant information available.
· **Application of the substance / the preparation**
In vitro diagnostic medical device or component.

· **Details of the supplier of the safety data sheet**
· **Manufacturer/Supplier:**
DiaMed GmbH
Pra Rond 23
CH-1785 Cressier FR
(Switzerland/Schweiz/Suisse/Svizzera)
Tel: +41 (0)26 674 51 11
Fax: +41 (0)26 674 51 45

· **Further information obtainable from:** fds-msds.ch@bio-rad.com

(Contd. on page 2)

BIO-RAD

Safety data sheet
according to 1907/2006/EC, Article 31

Printing date 07.08.2013 Version number 1 Revision: 12.06.2013

(Contd. of page 1)

· **Emergency telephone number:** Tel.: 145 oder/or/ou +41 442 51 51 51

2 Hazards identification

· **Classification of the substance or mixture**
The product is not classified according to the Globally Harmonized System (GHS).

· **Classification according to Directive 67/548/EEC or Directive 1999/45/EC**
Not applicable.
· **Information concerning particular hazards for human and environment:**
The product does not have to be labelled due to the calculation procedure of the "General Classification guideline for preparations of the EU" in the latest valid version.
· **Classification system:**
The classification is according to the latest editions of the EU-lists, and extended by company and literature data.

· **Label elements**

· **Labelling according to EU guidelines:**
Observe the general safety regulations when handling chemicals.
The product is not subject to identification regulations under EU Directives and the Ordinance on Hazardous Materials (German GefStoffV).

· **Other hazards**
· **Results of PBT and vPvB assessment**
· **PBT:** Not applicable.
· **vPvB:** Not applicable.

3 Composition/information on ingredients

· **Chemical characterization: Mixtures**
· **Description:**
Mixture of substances listed below with nonhazardous additions.
· **Additional information:**
For the wording of the listed risk phrases refer to section 16.

4 First aid measures

· **Description of first aid measures**
· **General information:** No special measures required.
· **After inhalation:**
Supply fresh air; consult doctor in case of complaints.
· **After skin contact:** Generally the product does not irritate the skin.
· **After eye contact:**
Rinse opened eye for several minutes under running water.
· **After swallowing:** If symptoms persist consult doctor.
· **Information for doctor:**
· **Most important symptoms and effects, both acute and delayed**
No further relevant information available.

(Contd. on page 3)

BIO-RAD

Safety data sheet
according to 1907/2006/EC, Article 31

Printing date 07.08.2013 Version number 1 Revision: 12.06.2013

(Contd. of page 2)

· **Indication of any immediate medical attention and special treatment needed**
No further relevant information available.

5 Firefighting measures

· **Extinguishing media**
· **Suitable extinguishing agents:**
CO2, powder or water spray. Fight larger fires with water spray or alcohol resistant foam.
Use fire extinguishing methods suitable to surrounding conditions.
· **Special hazards arising from the substance or mixture**
No further relevant information available.
· **Advice for firefighters**
· **Protective equipment:** No special measures required.

6 Accidental release measures

· **Personal precautions, protective equipment and emergency procedures**
Not required.
· **Environmental precautions:**
Dilute with plenty of water.
Do not allow to enter sewers/ surface or ground water.
· **Methods and material for containment and cleaning up:**
Absorb with liquid-binding material (sand, diatomite, acid binders, universal binders, sawdust).
· **Reference to other sections**
No dangerous substances are released.
See Section 7 for information on safe handling.
See Section 8 for information on personal protection equipment.
See Section 13 for disposal information.

7 Handling and storage

· **Handling:**
· **Precautions for safe handling** No special measures required.
· **Information about fire - and explosion protection:**
No special measures required.
· **Conditions for safe storage, including any incompatibilities**
· **Storage:**
· **Requirements to be met by storerooms and receptacles:**
No special requirements.
· **Information about storage in one common storage facility:**
Not required.
· **Further information about storage conditions:**
see related package insert
· **Specific end use(s)** No further relevant information available.

8 Exposure controls/personal protection

· **Additional information about design of technical facilities:**
No further data; see item 7.

(Contd. on page 4)

BIO-RAD

Safety data sheet
according to 1907/2006/EC, Article 31

Printing date 07.08.2013 Version number 1 Revision: 12.06.2013

(Contd. of page 3)

· **Control parameters**
· **Additional information:**
The lists valid during the making were used as basis.
· **Exposure controls**
· **Personal protective equipment:**
· **General protective and hygienic measures:**
The usual precautionary measures are to be adhered to when handling chemicals.
· **Respiratory protection:**
Not necessary if room is well-ventilated.
· **Protection of hands:**

Protective gloves

The glove material has to be impermeable and resistant to the product/ the substance/ the preparation.
· **Material of gloves**
The selection of the suitable gloves does not only depend on the material, but also on further marks of quality and varies from manufacturer to manufacturer. As the product is a preparation of several substances, the resistance of the glove material can not be calculated in advance and has therefore to be checked prior to the application.
· **Penetration time of glove material**
The exact break through time has to be found out by the manufacturer of the protective gloves and has to be observed.
· **Eye protection:** Safety glasses
· **Body protection:** Protective work clothing

9 Physical and chemical properties

· **Information on basic physical and chemical properties**	
· **General Information**	
· **Appearance:**	
· **Form:**	Fluid
· **Colour:**	Red
· **Odour:**	Characteristic
· **Odour threshold:**	Not determined.
· **pH-value at 20 °C:**	7,4
· **Change in condition**	
· **Melting point/Melting range:**	Undetermined.
· **Boiling point/Boiling range:**	Undetermined.
· **Flash point:**	Not applicable.
· **Flammability (solid, gaseous):**	Not applicable.
· **Ignition temperature:**	
· **Decomposition temperature:**	Not determined.

(Contd. on page 5)

SECTION 1: Identification of the substance/mixture and of the company/undertaking

1.1 Product identifier

Trade name: Seraclone™

This safety data sheet pertains to the following products:
801320 Seraclone™ Anti-A (ABO1) 10 ml
801325 Seraclone™ Anti-A (ABO1) 10x10 ml

1.2 Relevant identified uses of the substance or mixture and uses advised against

General use: Use as laboratory reagent.
Only for industrial users.

1.3 Details of the supplier of the safety data sheet

Company name: Bio-Rad Medical Diagnostics GmbH
Street/POB-No.: Industriestr. 1
Postal Code, city: 63303 Dreieich
Germany
WWW: www.medizinische-diagnostik-dreieich.de
E-mail: contact.bmd@bio-rad.com
Telephone: +49 (0)6103-3130-0
Telefax: +49 (0)6103-3130-646

Dept. responsible for information:
Produktmanagement Transfusion
Telephone: 06103 3130-611
Telefax: 06103 3130-724

1.4 Emergency telephone number

GIZ-Nord, Germany, Telephone: +49 (0)551-19240

SECTION 2: Hazards identification

2.1 Classification of the substance or mixture

Classification according to EC regulation 1272/2008 (CLP)

This mixture is classified as not hazardous.

2.2 Label elements

Labelling (CLP)

Hazard statements: not applicable

Precautionary statements:

2.3 Other hazards

May be harmful if swallowed.

BIO-RAD

SAFETY DATA SHEET
according to Regulation (EC) No. 1907/2006 (REACH) and Regulation (EU) No 453/2010

Revision date: 9/10/2014
Version: 1
Language: en-GB,IE
Date of print: 3/6/2015

Seraclone™
Material number 186038

SECTION 3: Composition / information on ingredients

3.1 Substances: not applicable

3.2 Mixtures

Chemical characterisation: Aqueous solution of anorganic salts and organic compounds.
Contains proteine of different origins (human, bovine, murine) and dyestuffs.

Additional information: Contains sodium azide < 0.1% as preservative.

SECTION 4: First aid measures

4.1 Description of first aid measures

In case of inhalation: Provide fresh air. Seek medical treatment in case of troubles.

Following skin contact: Remove residues with water. Change contaminated clothing. In case of skin reactions, consult a physician.

After eye contact: Immediately flush eyes with plenty of flowing water for 10 to 15 minutes holding eyelids apart. In case of eye irritation consult an ophthalmologist.

After swallowing: Rinse mouth and drink large quantities of water.
Induce vomiting when the affected person is not unconscious. Observe risk of aspiration if vomiting occurs.
Seek medical attention. Never give anything by mouth to an unconscious person.

4.2 Most important symptoms and effects, both acute and delayed

May be harmful if swallowed.

4.3 Indication of any immediate medical attention and special treatment needed

Treat symptomatically.

SECTION 5: Firefighting measures

5.1 Extinguishing media

Suitable extinguishing media:
Product is non-combustible. Extinguishing materials should therefore be selected according to surroundings.

5.2 Special hazards arising from the substance or mixture

Fires in the immediate vicinity may cause the development of dangerous vapours. In the event of a fire, the following may be produced when the water evaporates: Carbon monoxide and carbon dioxide.

5.3 Advice for firefighters

Special protective equipment for firefighters:
Wear self-contained breathing apparatus. Wear protective equipment.

Additional information: Hazchem-Code: -
Do not allow fire water to penetrate into surface or ground water.

SECTION 6: Accidental release measures

6.1 Personal precautions, protective equipment and emergency procedures

Avoid contact with the substance. Provide adequate ventilation. Wear personal protection equipment. Do not breathe vapour/aerosol.

6.2 Environmental precautions

Do not allow to penetrate into soil, waterbodies or drains.

6.3 Methods and material for containment and cleaning up

Soak up with absorbent materials such as sand, siliceus earth, acid- or universal binder. Store in special closed containers and dispose of according to ordinance. Final cleaning.

6.4 Reference to other sections

Refer additionally to section 8 and 13.

SECTION 7: Handling and storage

7.1 Precautions for safe handling

Advices on safe handling: Avoid contact with skin and eyes. Do not breathe vapours. Wear protective equipment. Keep all containers, equipment and working place clean.

7.2 Conditions for safe storage, including any incompatibilities

Requirements for storerooms and containers: Keep containers tightly closed and at a temperature between 2 °C and 8 °C.

Hints on joint storage: Do not store together with acids/alkalies and oxidation agents.

Storage class: 12 = Non-combustible liquids

7.3 Specific end use(s)

No information available.

SECTION 8: Exposure controls/personal protection

8.1 Control parameters

Additional information: Contains no substances with occupational exposure limit values.

8.2 Exposure controls

Provide good ventilation and/or an exhaust system in the work area.

Personal protection equipment

Occupational exposure controls

Respiratory protection: Provide fresh air. If vapours form, use respiratory protection. The filter class must be suitable for the maximum contaminant concentration (gas/vapour/aerosol/particulates) that may arise when handling the product.

Hand protection: Protective gloves according to EN 374.
Glove material: Nitrile rubber - Breakthrough time: >480 min.
Observe glove manufacturer's instructions concerning penetrability and breakthrough time.

Eye protection: Tightly sealed goggles according to EN 166.

Body protection: Wear suitable protective clothing.

General protection and hygiene measures:
Avoid contact with skin and eyes. Change contaminated clothing. After work, wash hands and face.

SECTION 9: Physical and chemical properties

9.1 Information on basic physical and chemical properties

Appearance:	Form: liquid Colour: blue
Odour:	odourless
Odour threshold:	no data available
pH value:	no data available
Melting point/freezing point:	no data available
Initial boiling point and boiling range:	approx. 100 °C
Flash point/flash point range:	no data available
Evaporation rate:	no data available
Flammability:	non-flammable
Explosion limits:	LEL (Lower Explosion Limit): not applicable UEL (Upper Explosive Limit): not applicable
Vapour pressure:	no data available
Vapour density:	no data available
Density:	no data available
Solubility:	no data available
Partition coefficient: n-octanol/water:	no data available
Auto-ignition temperature:	not applicable
Thermal decomposition:	no data available
Viscosity, dynamic:	no data available
Explosive properties:	not applicable
Oxidizing characteristics:	no data available

9.2 Other information

Additional information: no data available

SECTION 10: Stability and reactivity

10.1 Reactivity

refer to 10.3

10.2 Chemical stability

Stable under recommended storage conditions.

10.3 Possibility of hazardous reactions

No hazardous reactions known.

10.4 Conditions to avoid

Protect against heat /sun rays.

10.5 Incompatible materials

Strong oxidizing agents, strong acids and alkalis.

10.6 Hazardous decomposition products

In the event of a fire, the following may be produced when the water evaporates: Carbon monoxide and carbon dioxide.

Thermal decomposition: no data available

SECTION 11: Toxicological information

11.1 Information on toxicological effects

Toxicological effects: Acute toxicity (oral): Based on available data, the classification criteria are not met. May be harmful if swallowed.

Acute toxicity (dermal): Lack of data.

Acute toxicity (inhalative): Lack of data.

Skin corrosion/irritation: Lack of data.

Eye damage/irritation: Lack of data.

Sensitisation to the respiratory tract: Lack of data.

Skin sensitisation: Lack of data.

Germ cell mutagenicity/Genotoxicity: Lack of data.

Carcinogenicity: Lack of data.

Reproductive toxicity: Lack of data.

Effects on or via lactation: Lack of data.

Specific target organ toxicity (single exposure): Lack of data.

Specific target organ toxicity (repeated exposure): Lack of data.

Aspiration hazard: Lack of data.

SECTION 12: Ecological information

12.1 Toxicity

Aquatic toxicity: sodium azide: Very toxic to aquatic organisms, may cause long-term adverse effects in the aquatic environment.

12.2. Persistence and degradability

Further details: no data available

12.3 Bioaccumulative potential

Partition coefficient: n-octanol/water:
no data available

12.4 Mobility in soil

no data available

12.5 Results of PBT and vPvB assessment

no data available

BIO-RAD

SAFETY DATA SHEET
according to Regulation (EC) No. 1907/2006 (REACH) and Regulation (EU) No 453/2010

Seraclone™
Material number 186038

12.6 Other adverse effects

General information: Do not allow to penetrate into soil, waterbodies or drains.

SECTION 13: Disposal considerations

13.1 Waste treatment methods

Product

Waste key number: 16 10 02 = aqueous liquid wastes other than those mentioned in 16 10 01

Recommendation: Small quantities can be disposed of with the domestic waste or burnt, with due observance of regulations of local authorities. Large quantities are hazardous waste and must be disposed of accordingly.

Contaminated packaging

Recommendation: Dispose of waste according to applicable legislation.
Handle contaminated packages in the same way as the substance itself.
Non-contaminated packages may be recycled.

SECTION 14: Transport information

14.1 UN number

ADR/RID, IMDG, IATA-DGR:
not applicable

14.2 UN proper shipping name

ADR/RID, IMDG, IATA-DGR:
Not restricted

14.3 Transport hazard class(es)

ADR/RID, IMDG, IATA-DGR:
not applicable

14.4 Packing group

ADR/RID, IMDG, IATA-DGR:
not applicable

14.5 Environmental hazards

Marine pollutant: No

14.6 Special precautions for user

No dangerous good in sense of these transport regulations.

14.7 Transport in bulk according to Annex II of MARPOL 73/78 and the IBC Code

no data available

SECTION 15: Regulatory information

15.1 Safety, health and environmental regulations/legislation specific for the substance or mixture

National regulations - Great Britain

Hazchem-Code: -

15.2 Chemical Safety Assessment

For this mixture a chemical safety assessment is not required.

SECTION 16: Other information

Further information

Date of first version: 5/8/2014

Department issuing data sheet

Contact person: see section 1: Dept. responsible for information

For abbreviations and acronyms, see: ECHA Guidance on information requirements and chemical safety assessment, chapter R.20 (Table of terms and abbreviations).

The information in this data sheet has been established to our best knowledge and was up-to-date at time of revision. It does not represent a guarantee for the properties of the product described in terms of the legal warranty regulations.

SECTION 1: Identification of the substance/mixture and of the company/undertaking

1.1 Product identifier

Trade name: Seraclone™

This safety data sheet pertains to the following products:
801345 Seraclone™ Anti-B (ABO2) 10 ml
801350 Seraclone™ Anti-B (ABO2) 10x10 ml

1.2 Relevant identified uses of the substance or mixture and uses advised against

General use: Use as laboratory reagent.
Only for industrial users.

1.3 Details of the supplier of the safety data sheet

Company name: Bio-Rad Medical Diagnostics GmbH
Street/POB-No.: Industriestr. 1
Postal Code, city: 63303 Dreieich
Germany
WWW: www.medizinische-diagnostik-dreieich.de
E-mail: contact.bmd@bio-rad.com
Telephone: +49 (0)6103-3130-0
Telefax: +49 (0)6103-3130-646
Dept. responsible for information:
Produktmanagement Transfusion
Telephone: 06103 3130-611
Telefax: 06103 3130-724

1.4 Emergency telephone number

GIZ-Nord, Germany, Telephone: +49 (0)551-19240

SECTION 2: Hazards identification

2.1 Classification of the substance or mixture

Classification according to EC regulation 1272/2008 (CLP)

This mixture is classified as not hazardous.

2.2 Label elements

Labelling (CLP)

Hazard statements: not applicable

Precautionary statements: not applicable

Special labelling

EUH208 Contains Trisodium 5-hydroxy-1-(4-sulphophenyl)-4-(4-sulphophenylazo)pyrazole-3-carboxylate = tartrazine. May produce an allergic reaction.

EUH210 Safety data sheet available on request.

2.3 Other hazards

May be harmful if swallowed.

SECTION 3: Composition / information on ingredients

3.1 Substances: not applicable

3.2 Mixtures

Chemical characterisation: Aqueous solution of anorganic salts and organic compounds.
Contains proteine of different origins (human, bovine, murine).

Hazardous ingredients:

Ingredient	Designation	Content	Classification
EC No. 217-699-5 CAS 1934-21-0	Trisodium 5-hydroxy-1-(4-sulphophenyl)-4-(4-sulphophenylazo)pyrazole-3-carboxylate	< 1 %	Resp. Sens. 1; H334. Skin Sens. 1; H317.

Full text of H- and EUH-statements: see section 16.

Additional information: Contains sodium azide < 0.1% as preservative.

SECTION 4: First aid measures

4.1 Description of first aid measures

In case of inhalation: Provide fresh air. Seek medical treatment in case of troubles.

Following skin contact: Remove residues with water. Change contaminated clothing. In case of skin reactions, consult a physician.

After eye contact: Immediately flush eyes with plenty of flowing water for 10 to 15 minutes holding eyelids apart. In case of eye irritation consult an ophthalmologist.

After swallowing: Rinse mouth and drink large quantities of water.
Induce vomiting when the affected person is not unconscious. Observe risk of aspiration if vomiting occurs.
Seek medical attention. Never give anything by mouth to an unconscious person.

4.2 Most important symptoms and effects, both acute and delayed

May be harmful if swallowed.

4.3 Indication of any immediate medical attention and special treatment needed

Treat symptomatically.

SECTION 5: Firefighting measures

5.1 Extinguishing media

Suitable extinguishing media:
Product is non-combustible. Extinguishing materials should therefore be selected according to surroundings.

#148.8

5.2 Special hazards arising from the substance or mixture

Fires in the immediate vicinity may cause the development of dangerous vapours. In the event of a fire, the following may be produced when the water evaporates: Carbon monoxide and carbon dioxide.

5.3 Advice for firefighters

Special protective equipment for firefighters:
Wear self-contained breathing apparatus. Wear protective equipment.

Additional information: Hazchem-Code: -

Do not allow fire water to penetrate into surface or ground water.

SECTION 6: Accidental release measures

6.1 Personal precautions, protective equipment and emergency procedures

Avoid contact with the substance. Provide adequate ventilation. Wear personal protection equipment. Do not breathe vapour/aerosol.

6.2 Environmental precautions

Do not allow to penetrate into soil, waterbodies or drains.

6.3 Methods and material for containment and cleaning up

Soak up with absorbent materials such as sand, siliceus earth, acid- or universal binder. Store in special closed containers and dispose of according to ordinance. Final cleaning.

6.4 Reference to other sections

Refer additionally to section 8 and 13.

SECTION 7: Handling and storage

7.1 Precautions for safe handling

Advices on safe handling: Avoid contact with skin and eyes. Do not breathe vapours. Wear protective equipment. Keep all containers, equipment and working place clean.

7.2 Conditions for safe storage, including any incompatibilities

Requirements for storerooms and containers:
Keep containers tightly closed and at a temperature between 2 °C and 8 °C.

Hints on joint storage: Do not store together with acids/alkalies and oxidation agents.

Storage class: 12 = Non-combustible liquids

7.3 Specific end use(s)

No information available.

SECTION 8: Exposure controls/personal protection

8.1 Control parameters

Additional information: Contains no substances with occupational exposure limit values.

8.2 Exposure controls

Provide good ventilation and/or an exhaust system in the work area.

Personal protection equipment

Occupational exposure controls

Respiratory protection: Provide fresh air. If vapours form, use respiratory protection. The filter class must be suitable for the maximum contaminant concentration (gas/vapour/aerosol/particulates) that may arise when handling the product.

Hand protection: Protective gloves according to EN 374.
Glove material: Nitrile rubber - Breakthrough time: >480 min.
Observe glove manufacturer's instructions concerning penetrability and breakthrough time.

Eye protection: Tightly sealed goggles according to EN 166.

Body protection: Wear suitable protective clothing.

General protection and hygiene measures:
Avoid contact with skin and eyes. Change contaminated clothing. After work, wash hands and face.

SECTION 9: Physical and chemical properties

9.1 Information on basic physical and chemical properties

Appearance:	Form: liquid Colour: colourless
Odour:	odourless
Odour threshold:	no data available
pH value:	no data available
Melting point/freezing point:	no data available
Initial boiling point and boiling range:	approx. 100 °C
Flash point/flash point range:	no data available
Evaporation rate:	no data available
Flammability:	non-flammable
Explosion limits:	LEL (Lower Explosion Limit): not applicable UEL (Upper Explosive Limit): not applicable
Vapour pressure:	no data available
Vapour density:	no data available
Density:	no data available
Solubility:	soluble in Ethanol
Water solubility:	soluble
Partition coefficient: n-octanol/water:	no data available
Auto-ignition temperature:	not applicable
Thermal decomposition:	no data available
Viscosity, dynamic:	no data available
Explosive properties:	not applicable
Oxidizing characteristics:	no data available

9.2 Other information

Additional information: no data available

SECTION 10: Stability and reactivity

10.1 Reactivity

refer to 10.3

10.2 Chemical stability

Stable under recommended storage conditions.

10.3 Possibility of hazardous reactions

No hazardous reactions known.

10.4 Conditions to avoid

Protect against heat /sun rays.

10.5 Incompatible materials

Strong oxidizing agents, strong acids and alkalis.

10.6 Hazardous decomposition products

In the event of a fire, the following may be produced when the water evaporates: Carbon monoxide and carbon dioxide.

Thermal decomposition: no data available

SECTION 11: Toxicological information

11.1 Information on toxicological effects

Toxicological effects: Acute toxicity (oral): Based on available data, the classification criteria are not met. May be harmful if swallowed.

Acute toxicity (dermal): Lack of data.

Acute toxicity (inhalative): Lack of data.

Skin corrosion/irritation: Lack of data.

Eye damage/irritation: Lack of data.

Sensitisation to the respiratory tract: Lack of data.

Skin sensitisation: Lack of data.

Germ cell mutagenicity/Genotoxicity: Lack of data.

Carcinogenicity: Lack of data.

Reproductive toxicity: Lack of data.

Effects on or via lactation: Lack of data.

Specific target organ toxicity (single exposure): Lack of data.

Specific target organ toxicity (repeated exposure): Lack of data.

Aspiration hazard: Lack of data.

SECTION 12: Ecological information

12.1 Toxicity

Aquatic toxicity: sodium azide: Very toxic to aquatic organisms, may cause long-term adverse effects in the aquatic environment.

12.2. Persistence and degradability

Further details: no data available

12.3 Bioaccumulative potential

Partition coefficient: n-octanol/water:
no data available

12.4 Mobility in soil

no data available

12.5 Results of PBT and vPvB assessment

no data available

12.6 Other adverse effects

General information: Do not allow to penetrate into soil, waterbodies or drains.

SECTION 13: Disposal considerations

13.1 Waste treatment methods

Product

Waste key number: 16 10 02 = aqueous liquid wastes other than those mentioned in 16 10 01

Recommendation: Small quantities can be disposed of with the domestic waste or burnt, with due observance of regulations of local authorities. Large quantities are hazardous waste and must be disposed of accordingly.

Contaminated packaging

Recommendation: Dispose of waste according to applicable legislation.
Handle contaminated packages in the same way as the substance itself.
Non-contaminated packages may be recycled.

SECTION 14: Transport information

14.1 UN number

ADR/RID, IMDG, IATA-DGR:
not applicable

14.2 UN proper shipping name

ADR/RID, IMDG, IATA-DGR:
Not restricted

14.3 Transport hazard class(es)

ADR/RID, IMDG, IATA-DGR:
not applicable

14.4 Packing group

ADR/RID, IMDG, IATA-DGR:
not applicable

14.5 Environmental hazards

Marine pollutant: No

14.6 Special precautions for user

No dangerous good in sense of these transport regulations.

14.7 Transport in bulk according to Annex II of MARPOL 73/78 and the IBC Code

no data available

SECTION 15: Regulatory information

15.1 Safety, health and environmental regulations/legislation specific for the substance or mixture

National regulations - Great Britain

Hazchem-Code: -

15.2 Chemical Safety Assessment

For this mixture a chemical safety assessment is not required.

SECTION 16: Other information

Further information

Wording of the H-phrases under paragraph 2 and 3:
H317 = May cause an allergic skin reaction.
H334 = May cause allergy or asthma symptoms or breathing difficulties if inhaled.
EUH208 = Contains Trisodium
5-hydroxy-1-(4-sulphophenyl)-4-(4-sulphophenylazo)pyrazole-3-carboxylate = tartrazine.
May produce an allergic reaction.
EUH210 = Safety data sheet available on request.

Date of first version: 15/7/2014

Department issuing data sheet

Contact person: see section 1: Dept. responsible for information

For abbreviations and acronyms, see: ECHA Guidance on information requirements and chemical safety assessment, chapter R.20 (Table of terms and abbreviations).

The information in this data sheet has been established to our best knowledge and was up-to-date at time of revision. It does not represent a guarantee for the properties of the product described in terms of the legal warranty regulations.

#255

TO WHOM IT MAY CONCERN :

DECLARATION OF DEALERSHIP

Rome, 30th November 2015

We, Interlab srl, located in Via Rina Monti 26 – 00155 Roma, as producers of electrophoresis instruments and reagents, hereby declares that the following company

Interlux Co. Ltd.

Avieciu str. 16,

LT-08418 Vilnius

Lithuania

is authorized for promotions, sales and after sales service of Interlab products in Lithuania.

Interlab Srl

Roberto Maggi

President

INTERLAB

Tiems, kam tai aktualu

ATSTOVAVIMO PATVIRTINIMAS

Roma, 2015 m. lapkričio mėn. 30 d.

Mes, Interlab srl, įsikūrę Via Rina Monti 26-00155 Romoje, kaip elektroforezės įrenginių ir reagentų gamintojas, deklaruojame, kad toliau paminėta kompanija

UAB „Interlux"
Aviečių g. 16
LT-08418 Vilnius
Lietuva

Yra vienintelė autorizuota įmonė Lietuvoje, turinti teisę atstovauti INTERLAB produktus juos reklamuojant, parduodant ir atliekant popardaviminį servisą.

Interlab Srl
Roberto Maggi
Prezidentas

Vertimo patvirtinimas

Aš, VAIDAS VILMANTAS

vertimų verslo liudijimo nr. MK 478428-1 savininkas patvirtinu, kad patikrinau Lietuvių kalbos vertimą

Interlab srl atstovavimo patvirtinimas
(vertimo pavadinimas)

iš Anglų kalbos dokumento

Interlab srl Declaration of Dealership
(originalaus dokumento pavadinimas)

pagal savo žinias ir įsitikinimus.

Tekstas yra išverstas teisingai ir tiksliai bei be pakeitimų prasmėje.

Aš esu užtikrintas, kad Lietuvių kalbos vertimas atitinka originalų dokumentą.

VILNIUS, LIETUVA 2015-12-01
(Vieta/data) (parašas)

#255

Ministero della Salute
DGFDM
0003710-P-01/02/2011
I.5.l.e.2/2011/15

83778833

MARCA DA BOLLO
Ministero dell'Economia e delle Finanze
€14,62
QUATTORDICI/62

Ministero della Salute

DIPARTIMENTO DELL'INNOVAZIONE
DIREZIONE GENERALE DEI FARMACI E DISPOSITIVI MEDICI
UFFICIO IV

DGFDM/IV/I.5.l.e.2/2011/15/P

VISTA la direttiva 98/79/CE relativa ai dispositivi medico-diagnostici in vitro;
VISTO il D.lgs. n .332/2000 recante attuazione della direttiva 98/79/CE;
VISTA l'istanza del 11/01/2011 presentata dalla ditta Interlab Srl con sede in Via Rina Monti,26 – 00155 Roma (RM), C.F. 02613580584 e P.Iva 01087511000;
CONSIDERATO che la ditta istante ha effettuato i versamenti richiesti dal D.M. 24 Maggio 2004;
VISTI gli atti d'ufficio;

HAVING REGARD *to 98/79/EC directive concerning the in vitro diagnostic medical devices;*
HAVING REGARD *to legislative Decree (D.lgs.) n. 332/2000 reporting the accomplishment of 98/79/EC Directive;*
HAVING REGARD *to the request dated 11/01/2011 submitted by the company Interlab Srl located in Via Rina Monti, 26 – 00155 Roma (RM) – Italy, C.F. 02613580584 - P.Iva 01087511000;*
WHEREAS *this company paid the fees required by Ministerial Decree (D.M.) May 24, 2004;*
HAVING REGARD to *the official deeds;*

SI ATTESTA
IT IS ATTESTED

the la ditta Interlab Srl con sede in Via Rina Monti, 26 – 00155 Roma (RM), C.F. 02613580584 - P.Iva 01087511000; ha marcato CE, come dispositivi medico- diagnostici in vitro, secondo le procedure previste dalla direttiva 98/79/CE, i prodotti:

that the Company Interlab Srl located in Via Rina Monti, 26 – 00155 Roma (RM) – Italy, C.F.02613580584 and P.Iva 01087511000, affixed CE marking as in vitro diagnostics medical devices, according to the Directive 98/79/EC, the following products:

INSTRUMENTS

Code	Description
SSE129M	**GENIO S**: Fully Automated Electrophoresis System for: Serum Proteins, Lipoproteins, Hemoglobins, Urine Proteins, Unconcentrated Urine Proteins and CSF
SSE124M	**MICROTECH 648 ISO:** Fully Automated Electrophoresis System for: Serum Proteins, Lipoproteins, Hemoglobins, Urine Proteins, Unconcentrated Urine Proteins and CSF
SSE126M	**MICROTECH 648 ISO with incubator:** Fully Automated Electrophoresis System for: Serum Proteins, Lipoproteins, Hemoglobins, LDH, CPK, ALP, Urine Proteins, Unconcentrated Urine Proteins and CSF
SSE117M	**MICROTECH 648PC: :** Fully Automated Electrophoresis System for: Serum Proteins, Lipoproteins, Hemoglobins, Urine Proteins, Unconcentrated Urine Proteins and CSF
SSE119M	**MICROTECH 672PC:** Fully Automated Electrophoresis System for: Serum Proteins, Lipoproteins, Hemoglobins, Urine Proteins, Immunofixation, Unconcentrated Urine Proteins and CSF
SSE200M	**Microgel:** Fully Automated Agarose Gel Electrophoresis System for: Serum Proteins, Lipoproteins, Hemoglobins, Unconcentrated Urine Proteins, CSF, LDH, CPK, ALP and Immunofixation
SAE814M	**Easy Mask for Microgel:** tool needed to perform immunofixation and isoenzymes test
SSE203M	**Interlab G26:** Fully Automated Agarose Gel Electrophoresis System for: Serum Proteins, Lipoproteins, Hemoglobins, Unconcentrated Urine Proteins, CSF, LDH, CPK, ALP and Immunofixation
SSE204M	**Interlab G26:** Fully Automated Agarose Gel Electrophoresis System for: Serum Proteins, Lipoproteins, Hemoglobins, Unconcentrated Urine Proteins, CSF, LDH, CPK, ALP and Immunofixation
SAE910M	**Easy Mask for Interlab G26:** tool needed to perform immunofixation and isoenzymes test
SSE202M	**AUTOMATED SAMPLER / DILUTOR ASD 52**

KITS

Code	Description	Package
SRE174K	Serumproteins Kit: Red Ponceau S staining Solution	384 test
SRE186K	Serumproteins Kit: Red Ponceau S staining Solution	192 test
SRE175K	Lipoproteins kit: Sudan Black staining solution	192 test
SRE187K	Lipoproteins kit: Sudan Black staining solution	96 test
SRE176K	Alkaline Hemoglobins kit: Red Ponceau S staining solution	384 test
SRE188K	Alkaline Hemoglobins kit: Red Ponceau S staining solution	192 test
SRE166K	Acid Hemoglobins kit: Red Ponceau S staining solution	96 test
SRE204K	Serumproteins/Conc. Urine Proteins/Conc. CSF Kit: Red Ponceau S staining Solution	384 test
SRE205K	Alkaline Hemoglobins kit: Red Ponceau S staining Solution	192 test