UAB „ProSangvis“

V.Putvinskio g.38-10, LT-44211, Kaunas
Įmonės kodas: 3000 89105, PVM kodas: LT 100001537918
Duomenys kaupiami ir saugomi LR juridinių asmenų registre

1 priedas

VšĮ Nacionalinis kraujo centras
Žolyno g. 34, Vilnius
(Adresatas (perkančioji organizacija))

PASIŪLYMAS
DĖL DIAGNOSTINIŲ REAGENTŲ, SKIRTŲ DONORŲ VENINIO KRAUJO IMUNOHEMATOLOGINIAM IŠTYRIMUI IMUNOHEMATOLOGINIU ANALIZATORIUMI „GALILEO“ PIRKIMO

2015-09-03 Nr.P-075
(Data)

Kaunas
(Sudarymo vieta)

Tiekėjo pavadinimas */Jeigu dalyvauja ūkio subjektų grupė, surašomi visi dalyvių pavadinimai/*	**UAB „ProSangvis“**
Tiekėjo adresas */Jeigu dalyvauja ūkio subjektų grupė, surašomi visi dalyvių adresai/*	V. Putvinskio g. 38-10, LT-44211 Kaunas
Už pasiūlymą atsakingo asmens vardas, pavardė	Rimantas Stakauskas
Telefono numeris	+370655 53397
Fakso numeris	+370 – 37 – 222326
El. pašto adresas	info@prosangvis.lt

Šiuo pasiūlymu pažymime, kad sutinkame su visomis pirkimo sąlygomis, nustatytomis kvietime dalyvauti apklausoje.

UAB „ProSangvis“

V.Putvinskio g.38-10, LT-44211, Kaunas
Įmonės kodas: 3000 89105, PVM kodas: LT 100001537918
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Mes siūlome šias prekes:

Eil. Nr.	Prekių, paslaugų pavadinimas	Mato vnt.	Kiekis	Vieneto kaina Eur be PVM	Suma Eur be PVM
1.	Reagentai, kraujo grupių ABO nustatymui (tiesioginės ir atvirkštinės agliutinacijos būdu), RhD, Kell antigenų nustatymui tiesioginės agliutinacijos būdu: 1. Monokloninis reagentas , turintis IgM antikūnus prieš A antigeną (anti-A); 2. Monokloninis reagentas, turintis IgM antikūnus prieš B antigeną (anti-B); 3. Monokloninis reagentas, turintis IgM antikūnus prieš A ir B antigenus (anti-AB); 4. Monokloninis reagentas, turintis IgM antikūnus prieš D antigeną (anti-D) ir neagliutinuojantis su D antigeno kategorijomis ir D silpnu variantu; 5. Reagentas, turintis dviejų skirtingų D klonų IgM+IgG antikūnus prieš D antigeną (anti-D) ir agliutinuojantis su D antigeno kategorijomis ir D silpnu variantu; 6. Monokloninis reagentas, turintis IgM antikūnus prieš Kell antigeną (anti-K); 7. Reagentas (eritrocitai), turintis A_1 antigeną, natūralių antikūnų plazmoje nustatymui; 8. Reagentas (eritrocitai), turintis B antigeną, natūralių antikūnų plazmoje nustatymui; 9. Kontrolinis reagentas (Neigiama kontrolė).	Tyrimas			
2.	Reagentai, kraujo grupių ABO nustatymui (tiesioginės ir atvirkštinės agliutinacijos būdu), RhD antigeno nustatymui tiesioginės agliutinacijos būdu: 1. Monokloninis reagentas , turintis IgM antikūnus prieš A antigeną (anti-A); 2. Monokloninis reagentas, turintis IgM antikūnus prieš B antigeną (anti-B); 3. Monokloninis reagentas, turintis IgM antikūnus prieš A ir B antigenus (anti-AB); 4. Monokloninis reagentas, turintis IgM antikūnus prieš D antigeną (anti-D) ir neagliutinuojantis su D antigeno kategorijomis				

Kodas 3000 89105
PVM kodas: LT100001537918
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E-mail. info@prosangvis.lt

UAB „ProSangvis“

V.Putvinskio g.38-10, LT-44211, Kaunas
Įmonės kodas: 3000 89105, PVM kodas: LT 100001537918
Duomenys kaupiami ir saugomi LR juridinių asmenų registre

Eil. Nr.	Prekių, paslaugų pavadinimas	Mato vnt.	Kiekis	Vieneto kaina Eur be PVM	Suma Eur be PVM
	ir D silpnu variantu; 5. Reagentas, turintis dviejų skirtingų D klonų IgM+IgG antikūnus prieš D antigeną (anti-D) ir agliutinuojantis su D antigeno kategorijomis ir D silpnu variantu; 6. Reagentas (eritrocitai), turintis A_1 antigeną, natūralių antikūnų plazmoje nustatymui; 7. Reagentas (eritrocitai), turintis B antigeną, natūralių antikūnų plazmoje nustatymui; 8. Kontrolinis reagentas (Neigiama kontrolė).	Tyrimas			
3.	Reagentai, Rh D antigeno variantų bei kategorijų nustatymui netiesioginiu antiglobulininiu testu.	Tyrimas			
4.	Reagentai, Rh fenotipo nustatymui: anti-C IgM antikūnai, anti-c IgM antikūnai, anti-E IgM antikūnai, anti-e IgM antikūnai.	Tyrimas			
5.	Reagentai antieritrocitinių antikūnų nustatymui naudojant polispecifinį antiglobulininį serumą ir ne mažiau kaip dviejų O kraujo grupės donorų tipuotus eritrocitus, kurių fenotipe turi būti šie antigenai:C, c, D, E, e, K, k, Fy^a, Fy^b, Jk^b, S, s, M, N, Le^a, Le^b.	Tyrimas			
				Bendra pasiūlymo kaina su PVM:	**46769,10**

Bendra pasiūlymo kaina įskaitant visas išlaidas ir visus mokesčius, su PVM - **46769,10** Eur (*keturiasdešimt šeši tūkstančiai septyni šimtai šešiasdešimt devyni eurai, dešimt cnt.*),

taikomas PVM dydis - 5 %, sudaro **2227,10** Eur (*du tūkstančiai du šimtai dvidešimt septyni eurai, dešimt cnt.*)

UAB „ProSangvis“

V.Putvinskio g.38-10, LT-44211, Kaunas
Įmonės kodas: 3000 89105, PVM kodas: LT 100001537918
Duomenys kaupiami ir saugomi LR juridinių asmenų registre

Kartu su pasiūlymu pateikiami šie dokumentai:

Eil. Nr.	Pateiktų dokumentų pavadinimas	Dokumento puslapių skaičius
1.	UAB „Prosangvis“ registravimo pažymėjimo kopija	1
2.	Įgaliojimo atstovauti gamintoją kopija ir vertimas	2
3.	Siūlomos prekės atitikties nustatytiems kokybės reikalavimams dokumentai (CE ir ISO sertifikatų kopijos)	15
4.	Pažyma dėl tyrimo metodų validavimo	1
5.	Pažyma dėl prekių galiojimo laiko	1
6.	Pažyma dėl kokybės sertifikatų	1

Direktorius
(Tiekėjo arba jo įgalioto asmens pareigų pavadinimas)

(Parašas)

Rimantas Stakauskas
(Vardas ir pavardė)

Kodas 3000 89105
PVM kodas: LT100001537918
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UAB „ProSangvis“

V.Putvinskio g.38-10, LT-44211, Kaunas
Įmonės kodas: 3000 89105, PVM kodas: LT 100001537918
Duomenys kaupiami ir saugomi LR juridinių asmenų registre

VšĮ Nacionalinis kraujo centras

PAŽYMA

DĖL TYRIMŲ METODŲ VALIDAVIMO

2015-09-03

Kaunas

Šiuo dokumentu patvirtiname, kad UAB „Prosangvis“ siūlomi gamintojo Immucor reagentai, įranga ir metodai yra validuoti tyrimus atlikti donoriniame kraujyje.

Direktorius UAB "ProSangvis" Joint-Stock Company Ltd. LIETUVOS RESPUBLIKA * REPUBLIC OF LITHUANIA * KAUNAS * Rimantas Stakauskas

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UAB „ProSangvis“

V.Putvinskio g.38-10, LT-44211, Kaunas
Įmonės kodas: 3000 89105, PVM kodas: LT 100001537918
Duomenys kaupiami ir saugomi LR juridinių asmenų registre

VšĮ Nacionalinis kraujo centras

PAŽYMA

DĖL PREKIŲ GALIOJIMO LAIKO

2015-09-03

Kaunas

Šiuo dokumentu patvirtiname, kad UAB „Prosangvis“ siūlomų reagentų galiojimo laikas pristatymo dieną ne trumpesnis kaip 2/3 viso galiojimo laiko.

Direktorius LIETUVOS RESPUBLIKA * REPUBLIC OF LITHUANIA * KAUNAS * UAB "ProSangvis" Joint-Stock Company Ltd. Rimantas Stakauskas

Kodas 3000 89105
PVM kodas: LT100001537918
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UAB „ProSangvis“

V.Putvinskio g.38-10, LT-44211, Kaunas
Įmonės kodas: 3000 89105, PVM kodas: LT 100001537918
Duomenys kaupiami ir saugomi LR juridinių asmenų registre

VšĮ Nacionalinis kraujo centras

PAŽYMA

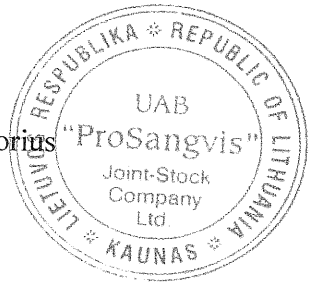
Dėl kokybės sertifikatų

2015-09-03

Kaunas

Šiuo dokumentu patvirtiname, kad UAB „Prosangvis“ siūlomų reagentų kokybės sertifikatai išduodami kiekvienai pateikiamai reagentų serijai.

Direktorius



Rimantas Stakauskas

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LIETUVOS RESPUBLIKA

JURIDINIŲ ASMENŲ REGISTRAS

REGISTRAVIMO PAŽYMĖJIMAS

Pavadinimas:	**UAB "Prosangvis"**
Kodas:	**3000 89105**
Teisinė forma:	**Uždaroji akcinė bendrovė**
Įregistravimo data:	**2005 m. vasario 17 d.**
Registro tvarkytojas:	**Valstybės įmonė Registrų centras**
Pažymėjimą išdavė:	**Valstybės įmonės Registrų centro Kauno filialas**

LIETUVOS RESPUBLIKA Valstybės įmonė Registrų centras 2020/11

Juridinių asmenų registravimo skyriaus grupės vedėja **Vilimantė Aučinikienė**

Pažymėjimas išduotas: **2005 m. vasario 17 d.**

Nr. 059316

2004 UAB „GRAFIJA" 00194

IMMUCOR GAMMA

To whom it may concern

Manufacturer's authorization form

Date of issue:
February 20th 2009

We, IMMUCOR Medizinische Diagnostik GmbH, hereby authorize, Prosangvis Ltd., Putvinskio str. 38-10, LT- 44211, Kaunas , Lithuania, in Lithuania to participate in tenders and offer all of Immucor products manufactured in Norcross/USA, New Scotland / Canada,Rodermark / Germany.

Place and Date: Rodermark, 2009-02-20

Jean-Jacques de Jaegher
Vice President International

For and on behalf of Immucor Inc. and
Immucor Medizinische Diagnostik GmbH

IMMUCOR Medizinische Diagnostik GmbH
www.immucor.com

IMMUCOR GAMMA

Tiems, kuriuos tai liečia

Įgaliojimas

Išdavimo data:
2009 m. vasario 20 d.

Mes, IMMUCOR Medizinische Diagnostik GmbH, įgaliojame UAB Prosangvis, Putvinskio g. 38-10, LT- 44211, Kaunas, Lietuva, Lietuvoje dalyvauti pirkimų konkursuose ir siūlyti visus Immucor produktus, pagamintus Norcross/JAV, Naujojoje Škotijoj/Kanada ir Rodermark/Vokietija.

Vieta ir data:

Jean-Jacques de Jaegher
Tarptautinis vice prezidentas
Immucor Inc. ir Immucor Medizinische
Diagnostik GmbH vardu

Kopija tikra

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

Lloyd's Register
LRQA

CERTIFICATE OF APPROVAL

This is to certify that the Quality Management System of:

ImmucorGamma Europe
Immucor Medizinische Diagnostik GmbH
Adam-Opel Strasse 26A,
D-63322 Rödermark
Germany

has been approved by Lloyd's Register Quality Assurance to the following Quality Management System Standards:

ISO 13485:2003
EN ISO 13485:2012

The Quality Management System is applicable to:

Design and manufacture of in vitro diagnostic reagents for transfusion diagnostics. Sale and distribution of in vitro diagnostic reagents for transfusion and transplant diagnostics. Manufacturing, sale, distribution, installation, servicing and repair of instrumentation for transfusion diagnostics including associated training.

This certificate is valid only in association with the certificate schedule bearing the same number on which the locations applicable to this approval are listed.

This certificate forms part of the approval identified by certificate number LRQ 4000904

Approval
Certificate No: LRQ 4000904/A

Original Approval: 24 July 2003

Current Certificate: 24 July 2015

Certificate Expiry: 23 July 2018

Issued by: Lloyd's Register Quality Assurance Limited

UKAS
MANAGEMENT
SYSTEMS
001

1 Trinity Park, Bickenhill Lane, Birmingham, B37 7ES, United Kingdom

Lloyd's Register
LRQA

CERTIFICATE SCHEDULE

ImmucorGamma Europe
Immucor Medizinische Diagnostik GmbH
Adam-Opel Strasse 26A,
D-63322 Rödermark
Germany

Head Office
Immucor Medizinische Diagnostik GmbH
Adam-Opel Strasse 26A,
D-63322 Rödermark
Germany

Activities
Design and manufacture of in vitro diagnostic reagents for transfusion diagnostics. Sale and distribution of in vitro diagnostic reagents for transfusion and transplant diagnostics. Manufacturing, sale, distribution, installation, servicing and repair of instrumentation for transfusion diagnostics including associated training.

Locations
Immucor Italia S.p.a.
Via Ettore Bugatti, 12,
20142 Milano
Italy

Activities
Sale and distribution of in vitro diagnostic reagents for transfusion and transplant diagnostics. Sale, distribution, installation, servicing and repair of instrumentation for transfusion diagnostics including associated training.

Immucor (Portugal) Diagnósticos Médicos Lda.
Edificio Prime,
Av. da Quinta Grande, No 53,
Piso 7, Fracção A, Alfragide,
2610-156 Amadora (Lisbon)
Portugal

Sale and distribution of in vitro diagnostic reagents for transfusion and transplant diagnostics. Sale, distribution, installation, servicing and repair of instrumentation for transfusion diagnostics including associated training.

Immucor S.L.,
Parc Technologic del Valles,
C/Argenters, 7, Edif. II, Local cB,
08290 Cerdanyola (Barcelona)
Spain

Sale and distribution of in vitro diagnostic reagents for transfusion and transplant diagnostics. Sale, distribution, installation, servicing and repair of instrumentation for transfusion diagnostics including associated training.

UKAS MANAGEMENT SYSTEMS
001

Approval Certificate No: LRQ 4000904/A
1 Trinity Park, Bickenhill Lane, Birmingham, B37 7ES, United Kingdom

Lloyd's Register
LRQA

CERTIFICATE SCHEDULE

ImmucorGamma Europe
Immucor Medizinische Diagnostik GmbH
Adam-Opel Strasse 26A,
D-63322 Rödermark
Germany

Locations	Activities
Immucor France 8, rue de la Croix Jarry, 75013 Paris France	Sale and distribution of in vitro diagnostic reagents for transfusion and transplant diagnostics. Sale, distribution, installation, servicing and repair of instrumentation for transfusion diagnostics including associated training.
Immucor UK (also trading as Quest Biomedical and IBG Immucor) 2 Cranbook Way, Solihull Business Park, Solihull, West Midlands, B90 4GT	Sale and distribution of in vitro diagnostic reagents for transfusion and transplant diagnostics. Sale, distribution, installation, servicing and repair of instrumentation for transfusion diagnostics including associated training.

Approval
Certificate No: LRQ 4000904/A

Original Approval:	24 July 2003
Current Certificate:	24 July 2015
Certificate Expiry:	23 July 2018

UKAS MANAGEMENT SYSTEMS
001

Lloyd's Register
LRQA

CERTIFICATE OF APPROVAL

This is to certify that the Quality Management System of:

ImmucorGamma Europe
Immucor Medizinische Diagnostik GmbH
Adam-Opel Strasse 26A,
D-63322 Rödermark
Germany

has been approved by Lloyd's Register Quality Assurance
to the following Quality Management System Standards:

ISO 9001:2008

The Quality Management System is applicable to:

Design and manufacture of in vitro diagnostic reagents for transfusion diagnostics. Sale and distribution of in vitro diagnostic reagents for transfusion and transplant diagnostics. Manufacturing, sale, distribution, installation, servicing and repair of instrumentation for transfusion diagnostics including associated training.

This certificate is valid only in association with the certificate schedule bearing the same number on which the locations applicable to this approval are listed.

This certificate forms part of the approval identified by certificate number LRQ 4000904

Approval
Certificate No: LRQ 4000904/C

Original Approval: 30 November 2011

Current Certificate: 24 July 2015

Certificate Expiry: 23 July 2018

Issued by: Lloyd's Register Quality Assurance Limited

UKAS
MANAGEMENT
SYSTEMS
001

1 Trinity Park, Bickenhill Lane, Birmingham, B37 7ES, United Kingdom

Lloyd's Register
LRQA

CERTIFICATE SCHEDULE

ImmucorGamma Europe
Immucor Medizinische Diagnostik GmbH
Adam-Opel Strasse 26A,
D-63322 Rödermark
Germany

Head Office
Immucor Medizinische Diagnostik GmbH
Adam-Opel Strasse 26A,
D-63322 Rödermark
Germany

Activities
Design and manufacture of in vitro diagnostic reagents for transfusion diagnostics. Sale and distribution of in vitro diagnostic reagents for transfusion and transplant diagnostics. Manufacturing, sale, distribution, installation, servicing and repair of instrumentation for transfusion diagnostics including associated training.

Locations
Immucor Italia S.p.a.
Via Ettore Bugatti, 12,
20142 Milano
Italy

Activities
Sale and distribution of in vitro diagnostic reagents for transfusion and transplant diagnostics. Sale, distribution, installation, servicing and repair of instrumentation for transfusion diagnostics including associated training.

Immucor (Portugal) Diagnósticos Médicos Lda.
Edifício Prime,
Av. da Quinta Grande, No 53,
Piso 7, Fracção A, Alfragide,
2610-156 Amadora (Lisbon)
Portugal

Sale and distribution of in vitro diagnostic reagents for transfusion and transplant diagnostics. Sale, distribution, installation, servicing and repair of instrumentation for transfusion diagnostics including associated training.

Immucor S.L.,
Parc Technologic del Valles,
C/Argenters, 7, Edif. II, Local cB,
08290 Cerdanyola (Barcelona)
Spain

Sale and distribution of in vitro diagnostic reagents for transfusion and transplant diagnostics. Sale, distribution, installation, servicing and repair of instrumentation for transfusion diagnostics including associated training.

UKAS MANAGEMENT SYSTEMS
001

Approval Certificate No: LRQ 4000904/C
1 Trinity Park, Bickenhill Lane, Birmingham, B37 7ES, United Kingdom

Lloyd's Register
LRQA

CERTIFICATE SCHEDULE

ImmucorGamma Europe
Immucor Medizinische Diagnostik GmbH
Adam-Opel Strasse 26A,
D-63322 Rödermark
Germany

Locations	Activities
Immucor France 8, rue de la Croix Jarry, 75013 Paris France	Sale and distribution of in vitro diagnostic reagents for transfusion and transplant diagnostics. Sale, distribution, installation, servicing and repair of instrumentation for transfusion diagnostics including associated training.
Immucor UK (also trading as Quest Biomedical and IBG Immucor) 2 Cranbook Way, Solihull Business Park, Solihull, West Midlands, B90 4GT	Sale and distribution of in vitro diagnostic reagents for transfusion and transplant diagnostics. Sale, distribution, installation, servicing and repair of instrumentation for transfusion diagnostics including associated training.

Approval
Certificate No: LRQ 4000904/C

Original Approval:	30 November 2011
Current Certificate:	24 July 2015
Certificate Expiry:	23 July 2018

UKAS MANAGEMENT SYSTEMS
001

Lloyd's Register
LRQA

EC CERTIFICATE – FULL QUALITY ASSURANCE SYSTEM

In accordance with the requirements of the In Vitro Diagnostic Medical Devices Directive 98/79/EC and the Medical Devices Regulations 2002, UK Statutory Instrument 2002 No. 618

This is to certify that the Quality Management System of:

Immucor, Inc.
3130 Gateway Drive
Norcross, Georgia 30071, USA

has been assessed against the requirements of Annex IV of the In Vitro Diagnostic Medical Devices Directive 98/79/EC, and the Medical Devices Regulations 2002 and conforms to the requirements for the products shown on the attached certificate schedule.

Approval is subject to the maintenance of the quality system in accordance with the requirements of the above Directive and Regulations. In addition for List A products approval is subject to the continued compliance with the EC Design Examination Certificate(s) as listed on the attached schedule and continued satisfactory compliance with the requirements for verification of manufactured product.

Authorisation is hereby given to use the LRQA Notified Body Registration Number in accordance with the requirements of the specified Directives/Regulations in relation to the products as identified above.

This certificate forms part of the approval identified by certificate number UQA 0113238

Certificate No:	0113238/C
Original Approval:	November 12, 2003
Current Certificate:	March 1, 2015
Certificate Expiry:	February 28, 2018

LRQA Notified Body Number 0088

Martha Winfield

Issued by: Lloyd's Register Quality Assurance Limited

Lloyd's Register
LRQA

EC CERTIFICATE – FULL QUALITY ASSURANCE SYSTEM
CERTIFICATE 0113238/C SCHEDULE

has been assessed against the requirements of Annex IV of the In Vitro Diagnostic Medical Devices Directive 98/79/EC, and the Medical Devices Regulations 2002 and conforms to the requirements for the products shown below:

Immucor, Inc.
3130 Gateway Drive
Norcross, Georgia 30071, USA

Annex II List A Products:

Products	EC Design Examination Certificate
corQC Test System	0088/0113238/00053
corQC EXTEND Standard	0088/0113238/00101
corQC EXTEND 1, 2 and 3	0088/0113238/00101
corQC EXTEND Complete	0088/0113238/00101
Weak D Cells	0088/0113238/00083
Referencells-4 (Group A1, A2, B and O)	0088/0113238/00092
Referencells-2 (Group A1 and B)	0088/0113238/00092
Referencells-1 (Group A2)	0088/0113238/00092
WB corQC	0088/0113238/00104

Annex II List B Products:

Products

Checkcell
Checkcell (Weak)
Panoscreen I and II
Panoscreen I, II and III
Hemantigen
Panocell-10
Capture-CMV (plates)
Capture-CMV Indicator Red Cells
Capture-CMV Positive Control Serum (Strong)
Panocell-16
Panocell-20
Panocell-10, Ficin-Treated
Capture-R Ready-Screen (I and II)
Capture-R Ready-Screen (Pooled Cells)
Capture-R Ready-ID
pHix
Capture-R Ready-ID Extend I
Capture-R Ready-ID Extend II

Hiramford, Middlemarch Office Village, Siskin Drive, Coventry CV3 4FJ, United Kingdom

Lloyd's Register
LRQA

EC CERTIFICATE – FULL QUALITY ASSURANCE SYSTEM
CERTIFICATE 0113238/C SCHEDULE

has been assessed against the requirements of Annex IV of the In Vitro Diagnostic Medical Devices Directive 98/79/EC, and the Medical Devices Regulations 2002 and conforms to the requirements for the products shown below:

Immucor, Inc.
3130 Gateway Drive
Norcross, Georgia 30071, USA

Annex II List B Products Cont.
Products

Capture-CMV Controls (Kit):
- Capture-CMV Positive Control Serum (Weak)
- Capture-CMV Negative Control Serum

Capture-R Ready Indicator Red Cells
Capture LISS

Capture-R Controls (Kit):
- Capture-R Positive Control Serum (Weak)
- Capture-R Negative Control Serum

Bovine Albumin Solution 22%
ImmuAdd
Gamma-clone® Anti-Jk^a (Monoclonal)
Gamma-clone® Anti-Jk^b (Monoclonal)
Gamma-clone® Anti-Fy^a (Monoclonal)

Capture-R Ready Screen (3)
Anti-Jka
Anti-Jkb
Gamma PeG
Capture-R Ready-Screen (4)

Gamma-Clone Anti-Human Globulin, Anti-IgG, -C3d; Polyspecific (Murine Monoclonal)
Gamma-Clone Anti-Human Globulin, Anti-IgG (Murine Monoclonal)

Schedule Issue: 9

Date of Schedule Issue: March 1, 2015

LRQA Notified Body Number 0088

Martha Wingfield
Issued by: Lloyd's Register Quality Assurance Limited

Lloyd's Register
LRQA

APPROVAL OF CONFORMITY CERTIFICATE

In accordance with the requirements of the In Vitro Diagnostic Medical Devices Directive 98/79/EC and the Medical Devices Regulations 2002, UK Statutory Instrument 2002 No. 618

This is to certify that the Quality Management System of:

Dominion Biologicals Limited
5 Isnor Drive
Dartmouth, Nova Scotia B3B 1M1
Canada

has been assessed against the requirements of Annex IV of the In Vitro Diagnostic Medical Devices Directive 98/79/EC, and the Medical Devices Regulations 2002 and conforms to the requirements for the products shown on the attached certificate schedule.

Approval is subject to the maintenance of the quality system in accordance with the requirements of the above Directive and Regulations. In addition for List A products approval is subject to the continued compliance with the EC Design Examination Certificate(s) as listed on the attached schedule and continued satisfactory compliance with the requirements for verification of manufactured product.

Authorisation is hereby given to use the LRQA Notified Body Registration Number in accordance with the requirements of the specified Directives/Regulations in relation to the products as identified above.

This certificate forms part of the approval identified by certificate number UQA 0113245

Certificate No:	0113245/C
Original Approval:	February 4, 2004
Current Certificate:	April 1, 2015
Certificate Expiry:	December 31, 2017

LRQA Notified Body Number 0088

Issued by: Lloyd's Register Quality Assurance Limited

Lloyd's Register
LRQA

APPROVAL OF CONFORMITY CERTIFICATE
CERTIFICATE 0113245/C SCHEDULE

has been assessed against the requirements of Annex IV of the In Vitro Diagnostic Medical Devices Directive 98/79/EC, and the Medical Devices Regulations 2002 and conforms to the requirements for the products shown below:

Dominion Biologicals Limited
5 Isnor Drive
Dartmouth, Nova Scotia
Canada B3B 1M1

Annex II List A Products:

Products
NOVACLONE™ Anti-A Murine Monoclonal and Galileo
NOVACLONE™ Anti-B Murine Monoclonal and Galileo
NOVACLONE™ Anti-A,B Murine Monoclonal and Galileo
NOVACLONE™ Anti-D IgM + IgG Monoclonal Blend and Galileo
NOVACLONE™ Diluent Control and Galileo
NOVACLONE™ Anti-CII (RH2) Human Monoclonal IgM Rh Typing Reagent
NOVACLONE™ Anti-E (RH3) Human Monoclonal IgM Rh Typing Reagent
NOVACLONE™ Anti-e (RH5) Human Monoclonal IgM Rh Typing Reagent
NOVACLONE™ Anti-c (Rh4) Human Monoclonal IgM Rh Typing Reagent

Annex II List B Products:

Products
NOVACLONE™ Anti-IgG Murine Monoclonal Blend
NOVACLONE™ Anti-IgG Murine Monoclonal Blend (Green)
NOVACLONE™ Anti-IgG, -C3d Polyspecific Murine Monoclonal Blend
NOVACLONE™ Anti-IgG, -C3d Polyspecific (Green) Murine Monoclonal Blend
NOVACLONE™ Anti-C3d Murine Monoclonal

Schedule Issue: 7
Date of Schedule Issue: April 1, 2015
LRQA Notified Body Number 0088

Issued by: Lloyd's Register Quality Assurance Limited

Hiramford, Middlemarch Office Village, Siskin Drive, Coventry CV3 4FJ, United Kingdom

Lloyd's Register
LRQA

CERTIFICATE OF APPROVAL

This is to certify that the Quality Management System of:

Immucor, Inc.
3130 Gateway Drive
Norcross, Georgia 30071, USA

has been approved by Lloyd's Register Quality Assurance
to the following Quality Management System Standards:

ISO 13485:2003

The Quality Management System is applicable to:

Design and Manufacture of In Vitro Diagnostic Devices and Biological Products for Blood Bank and Clinical Laboratory Applications. Design, Manufacture, and Servicing of Instrumentation for Blood Bank and Clinical Laboratory Applications.

This certificate forms part of the approval identified by certificate number UQA 0113238

Approval
Certificate No: UQA 0113238/A

Original Approval: February 13, 2003
Current Certificate: March 1, 2015
Certificate Expiry: February 28, 2018

Issued by: Lloyd's Register Quality Assurance, Inc. for and
on behalf of Lloyd's Register Quality Assurance Limited

UKAS
MANAGEMENT
SYSTEMS
001

1330 Enclave Parkway, Suite 200, Houston, Texas 77077, USA
For and on behalf of Hiramford, Middlemarch Office Village, Siskin Drive, Coventry CV3 4FJ, United Kingdom
The use of the UKAS Accreditation Mark indicates Accreditation in respect of those activities covered by the Accreditation Certificate Number 001

Lloyd's Register
LRQA

EC DESIGN EXAMINATION CERTIFICATE

This is to certify that Lloyd's Register Quality Assurance, a Notified Body under the terms of:
the In Vitro Diagnostic Medical Devices Directive 98/79/EC;
the Medical Devices Regulations 2002, UK Statutory Instrument 2002 No. 618;
did (in accordance with Annex IV clause 4 of the Directive) undertake an EC Design Examination on the stated products to ensure their conformity with the requirements of the Directive which apply to them.
The products identified below were shown to comply.

This certificate is issued to:

MANUFACTURER:	**ImmucorGamma Europe** **Immucor Medizinische Diagnostik GmbH** **Adam-Opel-Strasse 26A** **63322 Rödermark** **Germany**
PRODUCT NAME:	**See Schedule**
PRODUCT DESCRIPTION:	**In vitro diagnostic reagents and reagent products, including control materials, for determining blood groups: ABO system, rhesus (C, c, D, E, e) and anti-K**
DESIGN DOSSIER REFERENCE:	**TF-GER-201 (List A) CN-060 2013-09-23**

This Certificate is not valid for products, the design or characteristics of which have been varied from those examined. The manufacturer shall notify LRQA of any modification or changes to the products in order to maintain a valid certificate.

This certificate's validity is subject to continued satisfactory completion of the verification of manufactured product, as required by the Directive.

Certificate No:	0088/4000904/00059
Original Approval:	8 December 2003
Current Certificate:	8 December 2013
Certificate Expiry:	7 December 2018

LRQA Notified Body Number 0088

Issued by: Lloyd's Register Quality Assurance Limited

71 Fenchurch Street, London EC3M 4BS United Kingdom.

Lloyd's Register
LRQA

EC DESIGN EXAMINATION CERTIFICATE
CERTIFICATE 0088/4000904/00059 SCHEDULE

ImmucorGamma Europe
Immucor Medizinische Diagnostik GmbH
Adam-Opel-Strasse 26A
63322 Rödermark
Germany

Product Name

immuClone Anti-A IgM and Galileo
immuClone Anti-B IgM and Galileo
immuClone Anti-A,B IgM and Galileo
immuClone Anti-D rapid IgM and Galileo
immuClone Anti-D fast IgM
immuClone Anti-D duo IgM + IgG and Galileo
immuClone Anti-CDE IgM + IgG and Galileo
immuClone (1) Anti-C IgM and Galileo
immuClone (1) Anti-c IgM and Galileo
immuClone (1) Anti-E IgM and Galileo
immuClone (1) Anti-e IgM and Galileo
immuClone (2) Anti-C IgM and Galileo
immuClone (2) Anti-c IgM and Galileo
immuClone (2) Anti-E IgM and Galileo
immuClone (2) Anti-e IgM and Galileo
immuClone (1) Anti-K (Kell) IgM and Galileo
immuClone (2) Anti-K (Kell) IgM and Galileo
immuClone Rh-Hr Control and Galileo
Automated immuClone Anti-K (Kell) Galileo IgM
Anti-K (Kell) quick

This Schedule is only valid in association with the EC Design Examination certificate bearing the same number

Original Approval:	8 December 2003
Current Certificate:	8 December 2013
Certificate Expiry:	7 December 2018

LRQA Notified Body Number 0088

Issued by: Lloyd's Register Quality Assurance Limited

71 Fenchurch Street, London EC3M 4BS United Kingdom.

Lloyd's Register
LRQA

EC DESIGN EXAMINATION CERTIFICATE

This is to certify that Lloyd's Register Quality Assurance, a Notified Body under the terms of:
the In Vitro Diagnostic Medical Devices Directive 98/79/EC;
the Medical Devices Regulations 2002, UK Statutory Instrument 2002 No. 618;
did (in accordance with Annex IV clause 4 of the Directive) undertake an EC Design Examination on the stated products to ensure their conformity with the requirements of the Directive which apply to them. The products identified below were shown to comply.

This certificate is issued to:

MANUFACTURER:	**Dominion Biologicals Limited** **5 Isnor Drive** **Dartmouth, Nova Scotia** **Canada B3B 1M1**
PRODUCT NAME:	**Novaclone™ Anti-A Murine Monoclonal and Galileo** **Novaclone™ Anti-B Murine Monoclonal and Galileo** **Novaclone™ Anti-A,B Murine Monoclonal and Galileo** **Novaclone™ Anti-D IgM & IgG Monoclonal Blend and Galileo**
PRODUCT DESCRIPTION:	**In vitro diagnostic reagents for determining ABO and RhD blood groups**
DESIGN DOSSIER REFERENCE:	**DEC Renewal Dossier 2014-01-06**

This Certificate is not valid for products, the design or characteristics of which have been varied from those examined. The manufacturer shall notify LRQA of any modification or changes to the products in order to maintain a valid certificate.

This certificate's validity is subject to continued satisfactory completion of the verification of manufactured product, as required by the Directive.

Certificate No:	0088/0113245/00062
Original Approval:	February 4, 2004
Current Certificate:	February 2, 2014
Certificate Expiry:	February 1, 2019

LRQA Notified Body Number 0088

Martha Wingfield
Issued by: Lloyd's Register Quality Assurance Limited