Revised February 2007
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0.8% Selectogen®
0.8% Surgiscreen®
0.8% Resolve® Panel A
0.8% Resolve® Panel B

REF

0.8% Selectogen	**719602**
0.8% Surgiscreen	**719102**
0.8% Resolve Panel A	**719502**
0.8% Resolve Panel B	**719522**

INTENDED USE

For use with the Ortho BioVue® System to detect or identify unexpected blood group antibodies

FOR IN VITRO DIAGNOSTIC USE

SUMMARY AND EXPLANATION

Detection and identification of unexpected blood group antibodies are important to assure optimal outcomes for transfusion, pregnancy and disease state management. Red cells at a concentration of 0.8% in a low ionic strength diluent are designed to enhance serological detection of clinically significant antibodies in the BioVue System.[1] When compared to the published ANTIGRAM® Antigen Profile, the pattern of reactivity of the individual cells aids in the identification of the antibody.

PRINCIPLE OF PROCEDURE

Hemolysis or agglutination in the presence of a test serum or plasma indicates the presence of antibody(ies) directed against corresponding antigen(s) present on the reagent red blood cells.

REAGENTS

Each vial contains a 0.8% suspension of group O individual donor cells in a low ionic strength diluent to which a purine and a nucleoside have been added to maintain reactivity and/or retard hemolysis during the dating period. Trimethoprim (160 µg/mL) and sulfamethoxazole (800 µg/mL) have been added to retard bacterial contamination. The accompanying ANTIGRAM Antigen Profile lists the antigens present on each reagent red cell.

Reagent	Component Description
0.8% SELECTOGEN	A two-cell set for detection of unexpected antibodies
0.8% SURGISCREEN	A three-cell set for detection of unexpected antibodies
0.8% RESOLVE Panel A	An 11-cell set for identification of unexpected antibodies
0.8% RESOLVE Panel B	An 11-cell set to supplement primary panels for identification of unexpected antibodies

STORAGE REQUIREMENT

Store at 2 to 8°C.

Do not freeze.

PRECAUTIONS

1. Handle all blood and materials in contact with blood as if capable of transmitting infectious agents. It is recommended that blood and materials in contact with blood be handled using established good laboratory practices.[2] Dispose of all materials according to applicable guidelines and regulations.[3]
2. Source material from which these products were derived was found negative for hepatitis B surface antigen (HBsAg) and antibodies to hepatitis C virus (HCV) and human immunodeficiency virus type 1 (HIV-1) and type 2 (HIV-2) when tested in accordance with current FDA required tests. No known test methods can offer assurance that products derived from human blood will not transmit infectious agents.
3. Do not use beyond labeled expiration date.
4. Erroneous results may be obtained due to improper technique.
5. Do not mix red cells from individual vials.
6. Do not use if marked hemolysis or evidence of contamination is observed.
7. Do not add potentiators when using 0.8% red blood cells.
8. Use the Ortho BioVue System Centrifuge to provide the required centrifugation parameters for the Ortho BioVue System. Proper calibration of the centrifuge is essential to achieve accurate test results.

SPECIMEN COLLECTION AND PREPARATION

No special preparation of the patient/donor is required prior to specimen collection. Blood should be collected by approved medical techniques. Either serum or plasma may be used. Samples should be tested as soon as possible following collection. If a delay in testing occurs, the sample should be stored at 2 to 8°C. Red blood cell suspensions for autocontrol or supplemental antigen testing should be prepared using ORTHO® 0.8% Red Cell Diluent according to instructions for use.

REAGENT PREPARATION

Use 0.8% reagent red blood cells directly from the vials as provided. The contents of each vial should be resuspended by gentle mixing. Assure that reagents and samples are at room temperature before use.

PROCEDURE

The procedure identified below is for manual BioVue cassette testing only. When using automated instruments, follow the procedures that are contained in the operator's manual provided by the device manufacturer. Laboratories must follow their approved validation procedures to demonstrate compatibility of this product on automated systems.

Materials Provided

0.8% SELECTOGEN, 0.8% SURGISCREEN, 0.8% RESOLVE Panel A or 0.8% RESOLVE Panel B

Materials Required But Not Provided

1. Ortho BioVue System cassettes
2. Ortho BioVue System Centrifuge
3. Ortho BioVue System Heat Block, 37°C (Product Code 707820)
4. Ortho BioVue System Work Rack (Product Code 707830)
5. Micropipetter for delivery of 40 µL and 50 µL
6. Disposable pipette tips
7. ORTHO 0.8% Red Cell Diluent

Test Procedure

1. Consult the package insert for specific instructions regarding the Ortho BioVue System cassette in use.
2. Allow the reagents to come to room temperature before use. Orient the cassette with the back label (bar code side) facing you. Label the cassette appropriately for the tests required.
3. Peel off the foil strip on the top of the cassette only exposing the reaction chambers needed for the test(s) being performed.

   NOTE: The cassette should be used within one hour after removal of the foil. Cassettes with covered reaction chambers can be saved and these columns used for additional tests. Do not use the cassette if the liquid level is at or below the top of the glass beads.
4. Add 50 µL of the appropriate 0.8% red blood cells to the appropriate reaction chamber.
5. Add 40 µL of test serum or plasma to the appropriate reaction chamber(s). **Do not touch the pipette tip to the side of the reaction chamber. If this occurs, change pipette tips before proceeding to the next chamber.**
6. Incubate at 37°C for a minimum of 10 minutes to a maximum of 30 minutes.
7. Centrifuge the cassette using the Ortho BioVue System Centrifuge.

   NOTE: Centrifugation should occur within 30 minutes of addition of the samples to the reaction chamber.
8. Read the front and back of the individual columns for agglutination and/or hemolysis upon test completion.
9. Record the reaction strength from the side with the stronger positive result.

Quality Control Procedures

0.8% reagent red blood cells should be evaluated as a component of a test method within an established quality control program.

INTERPRETATION OF RESULTS

Positive Result (+): Agglutination of the red blood cells is a positive test result and indicates the presence of the corresponding antigen. The presence of hemolysis with or without agglutination is considered a positive test result.

Negative Result (-): No agglutination or no hemolysis of the red blood cells is a negative test result and indicates the corresponding antigen is not demonstrable.

Antibody Detection Using 0.8% SELECTOGEN or 0.8% SURGISCREEN

A positive result indicates the presence of an unexpected antibody(ies).

Antibody Identification Using 0.8% RESOLVE Panel A or 0.8% RESOLVE Panel B

Identification of the antibody present in samples may be made by matching the reactions observed in the test with the ANTIGRAM Antigen Profile furnished with the reagent. If the antibody specificity is not evident, additional cells may be required. A positive autocontrol indicates the presence of an antibody directed against red cells from the patient sample.

LIMITATIONS OF THE PROCEDURE

1. The Test Procedure and Interpretation of Results must be followed closely to assure the accuracy of the test results. A laboratory that institutes the Ortho BioVue System should have a program that will train personnel on the proper use and handling of the product.
2. Antibodies specific for low-incidence antigens not present on the test cells will not be detected.
3. Positive results may occur if antibodies to components of the preservative solution are present in the sample tested.
4. Complement-dependent antibodies may not be detected if a plasma specimen is used.
5. Optimal reaction conditions vary across antibody specificities. No single test method will detect all antibodies.[5]

EXPECTED RESULTS[4]*

Three hundred sixty-three random and 80 nonrandom patient samples were evaluated using the Ortho BioVue System Poly Cassette (Anti-Human Globulin; polyspecific) and 0.8% SURGISCREEN. Antibody-positive samples were tested using 0.8% RESOLVE Panel A.

Samples	Random	Nonrandom	Total
Number Tested	363	80	443
Number Negative	331	38	369
Number Positive	32	42	74

The nonrandom population included 30 antibody-negative and 50 antibody-positive samples previously tested by an independent test method. Eight samples previously identified as containing antibodies were negative in BioVue and confirmed as negative using an independent test method. The remaining 42 samples were confirmed as antibody positive.

ANTIBODY DISTRIBUTION

Antibody Detected	Random Samples	Nonrandom Samples	Total Samples
D, C, E, c, e, C^w	8	19	27
K	7	5	12
Jk^a, Jk^b	4	2	6
Fy^a	2	1	3
M, S, Le^a, Le^b	2	5	7
Mixed**	2	10	12
Auto antibody	1	0	1
Nonspecific	6	0	6
TOTAL	**32**	**42**	**74**

* Data on file at Ortho-Clinical Diagnostics, Inc.
** Samples contained both Rh-hr and non-Rh-hr antibodies

SPECIFIC PERFORMANCE CHARACTERISTICS*

The complete antigen profile will vary with each individual lot. The presence or absence of each antigen listed on the accompanying ANTIGRAM Antigen Profile is demonstrated by testing in at least two independent laboratories. At least two sources of antiserum are used to test each antigen unless rarity of the antiserum precludes it. Each cell sample is shown to have a negative direct antiglobulin test indicating that no human IgG or human complement components are detectable on the cell surface. Cells used in 0.8% SELECTOGEN and 0.8% SURGISCREEN are tested by hemagglutination assay and found negative for HLA Class I (Bg).

* Data on file at Ortho-Clinical Diagnostics, Inc.

SUMMARY OF REVISIONS

Section	Revision
LIMITATIONS OF THE PROCEDURE	Added limitations 4 and 5.
BIBLIOGRAPHY	Updated bibliography.
Updated EC REP address.	

BIBLIOGRAPHY / BIBLIOGRAPHIE / LITERATUR / BIBLIOGRAFIA / BIBLIOGRAFI / BIBLIOGRAFIE / LITTERATUR / Βιβλιογραφία / LITTERATURFÖRTECKNING

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3. Biotechnology – Laboratories for Research, Development & Analysis – Guidelines for Handling, Inactivating and Testing of Waste. BS EN12740, BSI, 389 Cheswick High Road, London, W4 4AL, 1999.
4. Reis K, Jakway J, Glasner U. Automated column agglutination technology (CAT) sensitivity using ready-to-use 0.8% reagent red blood cells (RRBC). Transfusion 2001;41:Suppl 110S.
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KEY TO SYMBOLS / LÉGENDE DES SYMBOLES / SYMBOL-LEGENDE / CLAVE DE LOS SÍMBOLOS / LEGENDA DEI SIMBOLI / SIMBOLOGIA / FORKLARING TIL SYMBOLER / ΕΠΕΞΗΓΗΣΗ ΣΥΜΒΟΛΩΝ / FÖRKLARING TILL SYMBOLERNA

The following symbols may have been used in the labeling of this product. / Les symboles suivants ont pu être utilisés pour étiqueter ce produit. / Es ist möglich, dass die folgenden Symbole bei der Etikettierung dieses Produktes verwendet wurden. / Los siguientes símbolos pueden haber sido empleados en el etiquetado de este producto. / Nelle etichette di questo prodotto possono essere stati utilizzati i simboli seguenti. / Os seguintes símbolos podem ter sido utilizados no rótulo deste produto. / Følgende symboler kan være anvendt ved mærkningen af dette produkt. / Τα ακόλουθα σύμβολα ενδέχεται να έχουν χρησιμοποιηθεί στη σήμανση αυτού του. / Följande symboler kanha använts vid märkningen av denna produkt.

Attention: See instructions for use /
Attention : Se référer aux instructions d'utilisation/
Wichtig: Siehe Gebrauchsanweisung /
Atención: Ver las instrucciones de uso /
Attenzione: Vedi le istruzioni per l'uso /
Atenção: Consulte as instruções de utilização /
Obs.: Se brugsanvisning / Προσοχή: Βλέπετε οδηγίες χρήσης /
Obs! Se bruksanvisningen

Lot Number / Numéro de lot / Los-Nummer /
Número de lote / Lotto numero / Número de lote /
Lot-nummer / Αριθμός παρτίδας / Lot-nummer

Use by/expiration date (CCYY-MM-DD) /
Utiliser avant/date d'expiration (AAAA-MM-JJ) /
Benutzen vor/Verfallsdatum (JJJJ-MM-TT) /
Úsese antes de/Fecha de caducidad (SSAA-MM-DD) /
Data di scadenza (AAAA-MM-GG) /
Utilizar até/data de validade (SSAA-MM-DD) /
Anvendes senest/udløbsdato (ÅÅÅÅ-MM-DD) /
/ημερομηνία λήξης (AAEE-MM-HH) /
Används före/Utgångsdatum (ÅÅÅÅ-MM-DD)

Store between / Conserver entre / Lagern zwischen /
Almacenar entre / Conservare ad una temperatura tra /
Armazenar entre / Opbevares mellem / Φύλαξη μεταξύ /
Förvaras mellan

For In Vitro Diagnostic Use / Pour Diagnostic In Vitro /
In-vitro-Diagnostikum / Para uso diagnóstico in vitro /
Per uso diagnostico in vitro / Para diagnósticos In Vitro /
Til diagnostisk brug in vitro / Για διαγνωστική χρήση
In Vitro / För diagnostisering in vitro

Authorized Representative / Mandataire /
Bevollmächtigter / Representante autorizado /
Rappresentante autorizzato / Representante Autorizado /
Autoriseret repræsentant / Εξουσιοδοτημένος Αντιπρόσωπος */ Auktoriserad representant*

Product Code / Code produit / Artikelnummer / Código del producto / Codice prodotto / Código do Produto /
Produktkode / Κωδικός Προϊόντος / Produktkod

This end up / Haut / Diese Seite nach oben / Este extremo hacia arriba / Questa estremità in alto / Este Lado Para Cima /
Denne side op / Η Συσκευασία Πρέπει να Είναι Όρθια από Αυτήν την Πλευρά / Denna sida upp

EC REP

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