ORTHO

0.8% SELECTOGEN®
0.8% SURGISCREEN®
0.8% RESOLVE® Panel A
0.8% RESOLVE® Panel B

INSTRUCTIONS FOR USE

REF

0.8% SELECTOGEN 719602
0.8% SURGISCREEN 719102
0.8% RESOLVE Panel A 719502
0.8% RESOLVE Panel B 719522

Intended Use

FOR *IN VITRO* DIAGNOSTIC USE

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

Summary and Explanation of the Test

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.

Principles of the 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

0.8% SELECTOGEN or SURGISCREEN (Product Codes: 719602, 719102)

Reagent	Storage Condition	Stability
Unopened	Refrigerated 2–8 °C (36–46 °F)	Expiration Date
Freshly Opened for use on ORTHO VISION® / ORTHO VISION® Max Analyzer	Use at Room Temperature on Analyzer when using the ORTHO VISION Evaporation Cap.	≤5 Days (120 Hours) Performance after five days of continuous use on-board the system has not been validated.
Freshly Opened for use on ORTHO AutoVue® Innova / Ultra	Use at Room Temperature. If the instrument is not continually in use, Ortho recommends the reagents be removed from the system and refrigerated. Reagent red cells should be inspected for settling and resuspended if analyzer has been idle for more than 2 hours.	Maximum of 24 hours, in three eight-hour shifts with refrigeration overnight in between shifts.

0.8% RESOLVE Panel A and 0.8% RESOLVE Panel B (Product Codes: 719502, 719522)

Reagent	Storage Condition	Stability
Unopened	Refrigerated 2–8 °C (36–46 °F)	Expiration Date
Freshly Opened for use on ORTHO VISION® / ORTHO VISION® Max Analyzer	Use at Room Temperature	Use until expiration date if capped and stored at 2–8 °C (36–46 °F) when not in use.
Freshly Opened for use on ORTHO AutoVue® Innova / Ultra	Use at Room Temperature. If the instrument is not continually in use, Ortho recommends the reagents be removed from the system and refrigerated. Reagent red cells should be inspected for settling and resuspended if analyzer has been idle for more than 2 hours.	Maximum of 24 hours, in three eight-hour shifts with refrigeration overnight in between shifts.

- Replace cap when not in use.
- **Do not freeze.**
- These products have been studied under simulated use conditions when used with semi-automated platforms that demonstrate that each product is suitable for its intended use through the expiration date.

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 or ORTHO™ Workstation 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, Preparation and Storage

- 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, samples should be stored at 2–8 °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 BioVue cassette testing only. When using semi-automated or 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 VISION® Analyzer
2. ORTHO VISION® Max Analyzer
3. ORTHO AutoVue® Innova / ORTHO AutoVue® Ultra Analyzer
4. Ortho BioVue System Centrifuge or ORTHO™ Workstation
5. ORTHO Optix™ Reader
6. Ortho BioVue System Heat Block, 37 °C
7. Ortho BioVue System cassettes
8. Micropipetter for delivery of 40 µL and 50 µL
9. Disposable pipette tips
10. Ortho BioVue System Work Rack
11. ORTHO 0.8% Red Cell Diluent

Test Procedure

1. Consult the Instructions for Use 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 chambers.

Caution:	**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 or ORTHO™ Workstation.

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]
6. When using automated instruments, refer to the limitations contained in the operator's manual provided by the device manufacturer.

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

† Samples contained both Rh-hr and non-Rh-hr antibodies

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

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 has been demonstrated by testing with at least two sources of antiserum unless rarity of the antiserum precludes it. Each of these tests have been conducted and interpreted independently. 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).

Technical questions concerning these reagents should be directed to Ortho Care™ Technical Solutions Center.

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

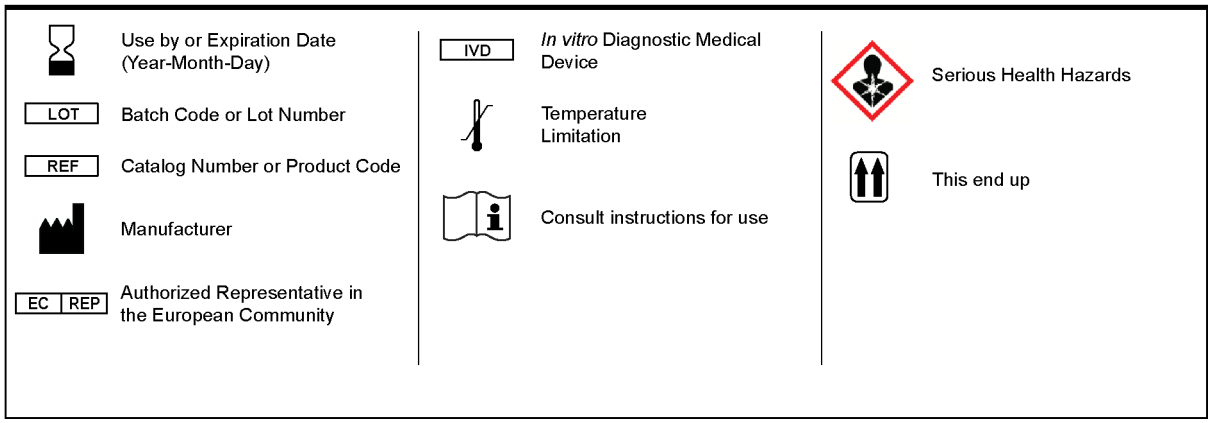
References

1. Löw B, Messeter L. Antiglobulin test in low ionic strength salt solution for rapid antibody screening and crossmatching. Vox Sang 1974;26:53.
2. Laboratory biosafety manual. 2nd ed. World Health Organization, Avenue Appia 20, 1211 Geneva 27 Switzerland, 1993.

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.
5. Issit PD. From kill to overkill: 100 years of (perhaps too much) progress. *Immunohematology* 2000;16:18.

Glossary of Symbols

The following symbols may have been used in the labeling of this product.



Revision History

Date of Revision	Version	Description of Technical Changes*
2020-07-02	e631300209	• Storage Requirement: Section expanded to include table for on-board and open vial stability • Procedure: Amended first paragraph to remove reference to manual testing and added semi-automated instruments • Materials Required but Not Provided: Added Ortho Optix™ Reader

* The change bars indicate the position of a technical amendment to the text with respect to the previous version of the document.

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