ORTHO

Reagent Red Blood Cells
0.8% SELECTOGEN®

INSTRUCTIONS FOR USE

REF 6902315

Rx ONLY

Intended Use

For *in vitro* diagnostic use

For the detection of unexpected blood group antibodies using the ID-Micro Typing System™ gel Test methods.

Summary and Explanation of the Test

0.8% SELECTOGEN is a set of two group O human red blood cells which have been typed for common clinically significant antigens, as well as some rare antigens. 0.8% SELECTOGEN is used to detect unexpected antibodies in patient or donor serum. The detection of unexpected blood group antibodies depends on the method and/or medium and the temperature of reactivity of the antibody involved.

Principles of the Procedure

Hemolysis or agglutination of 0.8% SELECTOGEN in the presence of serum may indicate the presence of an antibody directed against a corresponding antigen which is present on 0.8% SELECTOGEN. The specificity of the antibody can be determined through the use of 0.8% RESOLVE® Panel A Reagent Red Blood Cells.

Reagents

0.8% SELECTOGEN is composed of two vials of human red blood cells which are labeled 0.8% SELECTOGEN I and 0.8% SELECTOGEN II. 0.8% SELECTOGEN I is a 0.8% suspension of group O red blood cells derived from the blood of an individual donor having the Rh haplotype R_1 (DCe). 0.8% SELECTOGEN II is a 0.8% suspension of group O red blood cells derived from an individual donor with Rh haplotype R_2 (DčE).

The accompanying ANTIGRAM® Antigen Profile lists the antigens present on (+) and absent from (0) each cell of 0.8% SELECTOGEN. One or both of the red blood cell donors used in 0.8% SELECTOGEN may have been held in frozen storage.

The cells are suspended in a low ionic strength diluent, to which a purine and nucleoside have been added to maintain reactivity and/or retard hemolysis during the dating period. Trimethoprim (32 µg/mL) and sulfamethoxazole (160 µg/mL) have been added to retard bacterial contamination.

Use 0.8% SELECTOGEN directly from the vials. As with all reagent red blood cells, the reactivity of the cells may decrease during the dating period. The rate at which antigen reactivity (e.g., agglutinability) is lost is partially dependent upon individual donor characteristics that are neither controlled nor predicted by the manufacturer.

Do not use if marked hemolysis or evidence of contamination is observed.

No U.S. Standard of Potency.

- **Do not freeze.**
- Do not use beyond expiration date.
- The expiration date of each lot is no longer than 63 days, excluding the days in frozen storage, from the date of collection of red blood cells from any donor in the lot.
- Studies demonstrate consistent performance of this product from the time the vial is opened until the specified expiration date.
- Store at 2–8 °C.

Caution:	**All blood products should be treated as potentially infectious. Source material from which this product was derived was found negative 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.**

Specimen Collection, Preparation and Storage

- Either serum or plasma may be used.
- Specimen collection should be accomplished by accepted medical procedures.

- No special preparation of the patient is required prior to specimen collection.
- Bacterial contamination may interfere with the results and interpretation of the test.
- Specimen storage should be within applicable regulating agencies' requirements.
- If specimens are stored before testing, they should be stored at 2–8 °C.

Procedure

This product is to be used directly from the vial without further modification. Follow the Procedure section in the respective gel test Instructions for Use requiring a 0.8% red cell suspension in a low ionic strength diluent. Supplemental reagent red cells or autologous red cells may require modification to a 0.8% concentration according to the instructions in the relevant ID-Micro Typing System Instructions for Use.

Materials Provided

Reagent Red Blood Cells 0.8% SELECTOGEN I and 0.8% SELECTOGEN II

Materials Required but Not Provided

Please refer to the ID-Micro Typing System Instructions for Use for additional materials required for use.

- ORTHO® Workstation
- ORTHO Optix™ Reader
- ORTHO VISION® Analyzer
- ORTHO VISION® Max Analyzer

Results

Interpretation

1. Hemolysis or agglutination is a positive test result and reflects the presence of an antibody-antigen reaction.
2. No hemolysis or agglutination is a negative test result and indicates the absence of an antibody-antigen reaction.
3. Due to the complexities associated with the Duffy blood group system in the black population, it cannot be assumed that cells which are labeled Fy(a+b-) or Fy(a-b+) are homozygous for the Fy^a or Fy^b antigen.

Stability of Final Reaction Mixture

All results should be read and recorded upon test completion.

Control of Error

1. 0.8% SELECTOGEN should be tested on day of use with weak antibodies following the procedure for the respective test method.
2. A control consisting of the serum and autologous red blood cells prepared according to the ID-Micro Typing System Instructions for Use may be tested in parallel with 0.8% SELECTOGEN. A positive reaction indicates patient abnormality which should be resolved before the test results can be interpreted.

Limitations of the Procedure

1. For optimal reactivity, the sample under study should be tested against 0.8% SELECTOGEN I and 0.8% SELECTOGEN II individually.
2. Antibodies specific for low-incidence antigens not present on the test cells will not be detected.
3. Contaminated blood specimens may interfere with the test results.
4. Improper technique may invalidate the results obtained with this reagent.
5. False-positive results may occur if antibodies to components of the preservative solution are present in the sample tested.
6. These cells are contained in a low ionic strength diluent. The addition of other potentiators to the gel test card is not recommended and may affect the test results.
7. Complement-dependent antibodies may not be detected if a plasma specimen is used.
8. For antibody detection and identification, different serological methods are optimal for different antibodies. No single antibody screening or identification method optimally detects all antibodies. In some low ionic strength test systems, certain Anti-E and Anti-K antibodies have been reported to be nonreactive.

Specific Performance Characteristics

When properly stored and used for the detection of unexpected blood group antibodies, these reagent red blood cells will detect antibodies directed against the antigens present on them within the limitations of the respective test system used. The complete antigen profile will vary with each individual lot. Both 0.8% SELECTOGEN I and 0.8% SELECTOGEN II are positive for the following high-incidence blood antigens: Lu^b, Js^b, Kp^b and Yt^a unless otherwise noted on the accompanying ANTIGRAM Antigen Profile. Additionally, they have been tested and found negative for Js^a, Kp^a, Wr^a, Di^a, Vw, V, Lu^a and C^w unless otherwise noted on the accompanying ANTIGRAM Antigen Profile. 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. Each lot of product is checked for compatibility with the ID-Micro Typing System gel test cards.

Meets requirements of the FDA.

Technical questions concerning this reagent should be directed in the U.S. to Ortho Care™ Technical Solutions Center at 1-800-421-3311. Outside of the U.S., the company distributing this product should be contacted.

Note: For further information about the performance data using ORTHO VISION® Analyzer, ORTHO VISION® Max Analyzer, and ORTHO Optix™ Reader, please refer to the Instruction for Use of the related ID-Micro Typing System (ID-MTS™ Gel Card IFU).

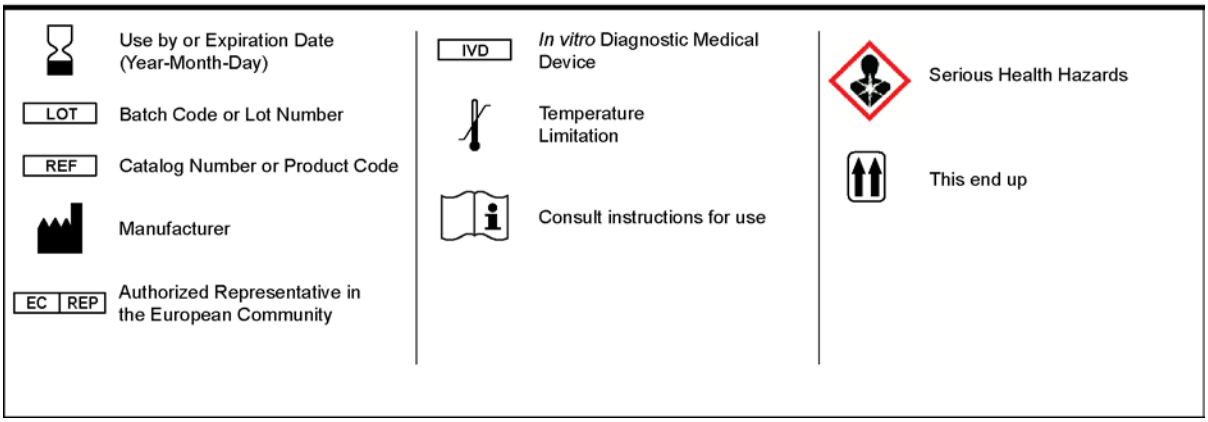
*ID-Micro Typing System is a trademark of Micro Typing Systems, Inc.

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. Beattie KM. Control of the antigen-antibody ratio in antibody detection/compatibility tests. *Transfusion* 1980;20:277-284.
3. Allen JC, Bruce M, Mitchell R. The preservation of red cell antigens at low ionic strength. Transfusion 1990;30:423.
4. Lapierre Y, Rigal D, Adam J, Josef D, Meyer F, Greber S, Drot C. The gel test: a new way to detect red cell antigen-antibody reactions. *Transfusion* 1990;30:109.
5. Malyska H, Weiland D. The gel test. *Laboratory Medicine* 1994;25:81.
6. Technical manual. 14th ed. Bethesda, MD: American Association of Blood Banks, 2002.
7. Yaskanin DD, Jakway JL, Ciavarella DJ. Red blood cell diluent composition is important for detection of some anti-E. Immunohematology 2000;16:142.
8. Merry AH, Thomson EE, et al. Quantitation of antibody binding to erythrocytes in LISS. Vox Sang 1984;47:125.
9. Issitt PD. From kill to overkill: 100 years of (perhaps too much) progress. *Immunohematology* 2000;16:18-25.

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*
2021-02-23	e631202995	• Materials Required but Not Provided: – Added ORTHO® Workstation – Added ORTHO Optix™ Reader – Added ORTHO VISION® Analyzer – Added ORTHO VISION® Max Analyzer • Specific Performance Characteristics: – Added note for ORTHO VISION® Analyzer, ORTHO VISION® Max Analyzer, and ORTHO Optix™ Reader performance characteristics. • New format; technically equivalent to e631202994

* 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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