Reagent Red Blood Cells
0.8% RESOLVE® Panel C System
0.8% RESOLVE® Panel C Untreated
0.8% RESOLVE® Panel C Ficin Treated

INSTRUCTIONS FOR USE

REF 6902319

Rx ONLY

Intended Use

For *in vitro* diagnostic use

For the identification of unexpected blood group antibodies in the ID-Micro Typing System™ Gel Test methods.

Summary and Explanation of the Test

Unexpected antibodies detected in serum or plasma must be identified to determine clinical significance. Antibody identification is accomplished by testing the serum or plasma against a panel of reagent red cells bearing different antigens. The presence or absence of red cell agglutination or hemolysis is determined and compared with the antigen profile of the reagent cells. With samples that contain multiple antibody specificities or exhibit weak reactivity, it may be necessary to use additional test methods to identify the antibody specificity(ies). The use of enzyme-treated reagent red cells is one of the primary means by which antibody differentiation and recognition can be accomplished.

Proteolytic enzymes modify red cell antigens in ways that enhance the reactivity of some antigen/antibody reactions and destroy or alter others. The reactions of Rh, Lewis, Kidd and P system blood group antibodies are usually enhanced along with most cold agglutinins. Enzyme treatment destroys or alters antigens in the MNS and Duffy systems as well as Xg^a, Pr, Ch^a, Rg^a and JMH, thus reducing or eliminating the reactivity of the corresponding antibody. Some antibodies may become hemolytic in the presence of enzyme-treated reagent cells and fresh serum.

0.8% RESOLVE Panel C System consists of untreated and ficin-treated panels of reagent red cells from 11 group O individual donors and an ANTIGRAM® Antigen Profile for use in antibody identification studies. Testing with ORTHO 0.8% RESOLVE Panel C Ficin Treated may be performed concurrently or subsequent to testing with 0.8% RESOLVE Panel C Untreated. Serologic studies with ficin-treated reagent red cells should be considered adjunct tests and not be used as the sole means of antibody identification.

Principles of the Procedure

Using the conditions under which the antibody was originally detected, the serum/plasma is combined with a sample of each panel member. Agglutination and/or hemolysis indicates the presence of an antibody or antibodies directed against an antigen present on the corresponding reagent red cell. Antibody identification is facilitated by recording the results of testing and grading the strength of reactivity.

Reagents

0.8% RESOLVE Panel C Untreated is a series of human red blood cells in 0.8% suspensions from 11 group O individuals. 0.8% RESOLVE Panel C Ficin Treated consists of the same corresponding red blood cells that have been treated with the proteolytic enzyme ficin prior to suspension. The accompanying ANTIGRAM Antigen Profile lists the blood group factors determined to be present on (+) and absent from (0) each red blood cell.

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% RESOLVE Panel C Untreated and 0.8% RESOLVE Panel C Ficin Treated 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, discoloration or evidence of contamination is observed.

No U.S. Standard of Potency.

Storage Requirement

Reagent	Storage Condition	Stability
Unopened	Refrigerated 2–8 °C (36–46 °F)	Expiration Date
Opened for manual use or non-continuous use on ORTHO VISION / ORTHO VISION Max Analyzer	Refrigerated 2–8 °C (36–46 °F) Use at room temperature 18-25 °C (64–77 °F)	Use until expiration date if tightly capped and stored at 2–8 °C (36–46 °F) when not in use.*
Freshly opened for continuous use on ORTHO VISION / ORTHO VISION Max Analyzer	Use at room temperature 18-25 °C (64–77 °F) on analyzer when using the ORTHO VISION Evaporation Cap.	≤3 Days (72 Hours) Panel cells are not intended for further use after spending 72 hours on-board the analyzer, even if returned to refrigerated temperatures.**

* Studies demonstrate consistent performance of this product from the time the vial is opened until the specified expiration date. Replace cap and store at 2–8 °C (36–46 °F) when not in use.

** Discard any remaining reagent after three days of continuous on-board storage. Performance after continuous on-board storage has not been validated.

- **Do not freeze.**
- Do not use beyond expiration date.
- The expiration date of each lot is no longer than 77 days from the date of collection of red blood cells from any donor in the lot.

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. The contents of each vial should be resuspended by gently mixing.

ID-Micro Typing System

The use of ID-Micro Typing System Anti-IgG Gel Card is recommended for use with Untreated RESOLVE Panel C cells. The use of ID-Micro Typing System Buffered Gel Card is recommended for use with Ficin Treated RESOLVE Panel C cells. Refer to the appropriate ID-Micro Typing System Instructions for Use for test method instructions. For supplemental reagent red cells or autologous red cells that require modification to a 0.8% concentration prior to testing, refer to the appropriate ID-Micro Typing System Instructions for Use for test method instructions.

Materials Provided

0.8% RESOLVE® Panel C Untreated

0.8% RESOLVE® Panel C Ficin Treated

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. Identification of the antibody present in the serum/plasma may be made by matching the reactions obtained with the ANTIGRAM Antigen Profile furnished with the reagent. If the antibody specificity is not evident, testing with additional cells may be required.
4. Reactions obtained with 0.8% Resolve Panel C Ficin Treated are likely to be different than the reactivity obtained with the untreated panel as reactivity with certain antibodies will be enhanced while others are diminished or eliminated. Interpretation must be made considering the various effects of enzymes in antigen/antibody reaction.
   The following specificities are examples of antibodies whose reactivity may be enhanced when testing is performed with ficin-treated red cells: Anti-D, -C, -E, -c̄, -e, -f, -Jk^a, -Jk^b, -Le^a, -Le^b, -P_1, -I, -IH, -Vel, -PP_1P^k and -P.
   The following specificities are examples of antibodies whose reactivity may be eliminated or reduced when testing is performed with ficin-treated red cells: Anti-Fy^a, -Fy^b, -M, -N, -S, -s̄, -Xg^a, -Pr, -Ch^a, -Rg^a and JMH.

Stability of Final Reaction Mixture

All results should be read and recorded upon test completion.

Control of Error

Quality Control requirements will vary based on regional and national guidance, standards, regulations, and professional preferences. Each laboratory must develop specific quality control procedures accordingly.

Limitations of the Procedure

1. Antibodies specific for low-incidence antigens not present on the test cells will not be detected.
2. Contaminated blood specimens or test materials may interfere with the test results. Do not use if discoloration of test column is observed.
3. Improper technique may invalidate the results obtained with these reagents.
4. False-positive test results may occur if antibodies to components of the 0.8% Red Cell Diluent are present in the sample tested.
5. If multiple antibodies are present in the sample, testing with additional cells may be required for identification.
6. These cells are contained in a low ionic strength diluent. The addition of other potentiators to the cards is not recommended and may affect the test results.
7. Warm or cold autoagglutinins may be enhanced in tests performed with ficin-treated red cells.
8. Excess ficin or overtreatment of cells may cause nonspecific agglutination.
9. Ficin-treated cells are more prone to lysis than untreated cells when tested against hemolytic antibodies such as anti-Le^a, anti-Le^b, anti-Jk^a, anti-Vel and anti-PP_1P^k.
10. Complement-dependent antibodies may not be detected if a plasma specimen is used.
11. A positive reactive autocontrol, using either ficin-treated or untreated cells, indicates a serological abnormality that must be resolved before test results can be interpreted.
12. 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.
13. Exposure to light (specifically Ultraviolet and Fluorescent light) or extended room temperature may induce non-specificity or false positive results. Exposure to light sources should be minimized during use. Store reagents at 2–8 °C when not in use.
14. As the red cells age, the red cell membrane can become rigid due to biochemical and biomechanical changes during in vitro storage and therefore prevent the red cells from traveling completely through the column. False positive reactions may occur from cells of certain donor subpopulations.
15. Reagent Red Blood Cells stored on automated analyzer systems can be affected by evaporation, particularly in extreme laboratory conditions of low humidity and high temperature, even with the use of ORTHO VISION Evaporation Cap. Evaporation may lead to a “Too Many Cells (TMC)” error.

Specific Performance Characteristics

When properly stored and used for the identification of unexpected blood group antibodies, these reagent red blood cells will aid in the identification of 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 of reagent red cells. 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 reagent cell surface.

Technical questions concerning the reagent should be directed to Ortho Care™ Technical Solutions Center at 1-800-421-3311.

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

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5. Ellisor SS. Action and application of enzymes in immunohematology. In: Seminar on antigen-antibody reactions revisited. Washington, DC: American Association of Blood Banks, 1982:133-174.
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9. Merry AH, Thomson EE, Lagar J, et al. Quantitation of antibody binding to erythrocytes in LISS. *Vox Sang* 1984;47:125-132.
10. 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.

Use by or Expiration Date (Year-Month-Day)	*In vitro* Diagnostic Medical Device	Serious Health Hazards
Batch Code or Lot Number	Temperature Limitation	This end up
Catalog Number or Product Code	Consult instructions for use	
Manufacturer	Lift Here	
Authorized Representative in the European Community		

Revision History

Date of Revision	Version	Description of Technical Changes*
2025-12-03	e631202538	• Storage Requirement: Section expanded to include table for manual, on-board and open vial stability • Limitations of the Procedure: New limitation added regarding evaporation

* 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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