ORTHO

Reagent Red Blood Cells
(Pooled Cells)
0.8% AFFIRMAGEN®
0.8% AFFIRMAGEN® 3

INSTRUCTIONS FOR USE

REF

719201
719211

Rx ONLY

Intended Use

For *in vitro* diagnostic use

For ABO serum grouping using the ID-Micro Typing System™ gel Test methods.

Summary and Explanation of the Test

A and B antigens on red blood cells have a chemical structure closely resembling antigens of bacteria and plants to which everyone is constantly exposed. As a result of this exposure, almost everyone over the age of six months who lacks the A or B antigen produces the corresponding antibody. Reverse (serum) grouping tests are used to detect these expected blood group antibodies and confirm the red cell typing (forward grouping). Serum grouping tests should employ at least A_1 and B cells. A_2 cells may be included to resolve ABO blood grouping discrepancies. A_2 cells assist in the recognition of anti-A_1 that may be present in the serum of individuals belonging to A subgroups. Discrepancies between the red cell and serum grouping tests must be resolved before an ABO blood group can be assigned.

0.8% AFFIRMAGEN and 0.8% AFFIRMAGEN 3 are used to detect expected ABO blood group antibodies in patient and donor samples using the ID-Micro Typing System.

Principles of the Procedure

The reverse (serum) grouping procedure relies upon the expected presence or absence of the alloagglutinins anti-A and/or anti-B to confirm ABO blood grouping.

In this procedure, the patient or donor serum is combined with individual 0.8% AFFIRMAGEN red cells. After centrifugation, the presence or absence of agglutination confirms or invalidates ABO red cell grouping results (see INTERPRETATION).

Reagents

0.8% AFFIRMAGEN: a two-vial set consisting of one vial each of A_1 and B red cells or

0.8% AFFIRMAGEN 3: a three-vial set consisting of one vial each of A_1, A_2 and B red cells.

Each vial contains a 0.8% suspension of pooled Rh negative (D- C- E-) donor red cells 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 (160 µg/mL) and sulfamethoxazole (800 µg/mL) have been added to retard bacterial contamination. In addition, EDTA disodium salt has been added to prevent complement mediated hemolysis. Such hemolysis might be falsely interpreted as a negative reaction.

Use 0.8% AFFIRMAGEN 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 (i.e., 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 77 days from the date of collection of red blood cells from any donor in the lot.
- 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

- No special preparation of the patient or donor is required prior to specimen collection.
- Specimen collection should be accomplished by accepted medical procedures.
- Either serum or plasma is acceptable.
- Bacterial contamination may interfere with the results and interpretations of the test.
- Specimen storage should be within applicable regulatory 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 gentle mixing. Follow the Procedure section contained in the respective gel test Instructions for Use requiring a 0.8% red cell suspension in a low ionic strength diluent.

Materials Provided

0.8% AFFIRMAGEN or 0.8% AFFIRMAGEN 3

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

Interpretation

Agglutination indicates the presence of an antibody corresponding to an antigen present on the red cells being tested. Based on the presence or absence of agglutination, the blood group of the individual may be determined by using the following table.

EXPECTED REVERSE (SERUM) GROUPING RESULTS

REAGENT RED CELLS			BLOOD GROUP
A_1	A_2	B	
+	+	+	O
0	0	+	A
+	0	+	A (subgroup of A) with anti-A_1
+	+	0	B
0	0	0	AB
+	0	0	AB (subgroup of A) with anti-A_1

Stability of Final Reaction Mixture

All results should be read and recorded upon test completion.

Control of Error

1. Since A_1, A_2 and B cells have many other blood group antigens, a discrepancy between cell and serum grouping tests may occur because the serum contains unexpected antibodies other than anti-A and/or anti-B. To exclude this possibility, evaluation of antibody screening results using group O cells with known antigenic composition may be helpful.
2. 0.8% AFFIRMAGEN and 0.8% AFFIRMAGEN 3 should be tested on each day of use with positive and negative controls according to the method described in the respective gel test Instructions for Use requiring a 0.8% red cell suspension in low ionic strength diluent.

Limitations of the Procedure

1. Reverse (serum) grouping performed on the serum of an infant may give misleading results until the infant is approximately six months of age. Antibodies found in the infant's circulation prior to this time are usually of maternal origin.

2. Sera from patients with agammaglobulinemia will not have normal levels of anti-A and/or anti-B and may not react correctly in this procedure.
3. The A_2 cells may not be agglutinated by low-titered anti-A found in the sera of infants and elderly individuals who are group O and group B.
4. Improper technique may invalidate the results obtained with 0.8% AFFIRMAGEN and 0.8% AFFIRMAGEN 3.

Specific Performance Characteristics

The ABO group and Rh type of the cells are demonstrated by testing in at least two independent laboratories. These cells are shown to react with normal physiological concentrations of anti-A and/or anti-B in samples. 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.

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.

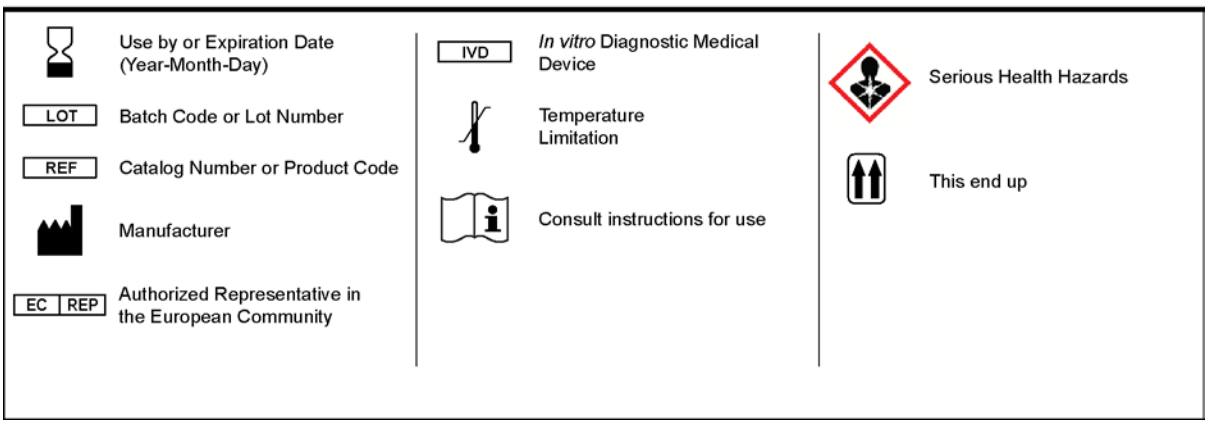
Note: For further information about the performance data using ORTHO VISION® Analyzer, ORTHO VISION® Max Analyzer, and ORTHO Optix™ Reader, please refer to the Instruction for Use of the related ID-Micro Typing System (ID-MTS™ Gel Card IFU).

References

1. Allan JC, Bruce M, Mitchell R. The preservation of red cell antigens at low ionic strength. *Transfusion* 1990;30:423-426.
2. Issitt PD, Anstee DJ. Applied blood group serology. 4th ed. Durham, NC: Montgomery Scientific, 1998.
3. 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;30:109-113.
4. Malyska H, Weiland D. The gel test. Laboratory Medicine 1994;25:81.
5. Race RR, Sanger R. Blood groups in man. 6th ed. Oxford: Blackwell Scientific, 1975.
6. Technical manual. 12th ed. Bethesda, MD: American Association of Blood Banks, 1996.
7. ID-Micro Typing System is a trademark of Micro Typing Systems, Inc.

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	e631203816	• 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 e631203815

* 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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