ORTHO

AFFIRMAGEN®
AFFIRMAGEN® 4

INSTRUCTIONS FOR USE

REF

AFFIRMAGEN 707930
AFFIRMAGEN 4 707910

Intended Use

For *in vitro* diagnostic use

For confirmation of ABO forward (red cell) grouping in the Ortho® BioVue System.

Summary and Explanation of the Test

AFFIRMAGEN and AFFIRMAGEN 4 are used to detect expected ABO blood group antibodies in patient and donor samples.

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 or plasma is combined with individual AFFIRMAGEN or AFFIRMAGEN 4 red cells. After centrifugation, the presence or absence of agglutination confirms or invalidates ABO red cell grouping results.

Reagents

Each vial contains a 3% suspension of pooled Rh negative (D-, C-, E-) human red cells in a phosphate-citrate buffered diluent to which a purine, a steroid and nucleosides have been added to maintain reactivity and/or retard hemolysis during the dating period. Chloramphenicol (330 µg/mL), neomycin (70 µg/mL) and gentamicin sulfate (50 µg/mL) have been added to retard bacterial contamination. EDTA disodium salt has been added to prevent complement-mediated hemolysis.

Reagent	Component Description
AFFIRMAGEN	A two-vial set consisting of one vial each of A_1 and B red cells
AFFIRMAGEN 4	A four-vial set consisting of one each of group A_1, A_2, B and O red cells

Storage Requirement

3% AFFIRMAGEN, 3% AFFIRMAGEN 4 (Product Codes 707930, 707910)

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.	≤3 Days (72 Hours) Performance after three 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.

- 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. [1] Dispose of all materials according to applicable guidelines and regulations. [2]

2. Source material from which these products were 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.
3. Do not use beyond labeled expiration date.
4. Erroneous results may be obtained due to improper technique and may invalidate the results obtained with AFFIRMAGEN and AFFIRMAGEN 4.
5. Do not use if marked hemolysis or evidence of contamination is observed.
6. Use the Ortho BioVue System Centrifuge or ORTHO™ Workstation to provide the required centrifugation parameters for this 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.

Reagent Preparation

Use AFFIRMAGEN and AFFIRMAGEN 4 directly from the vials without further modification. The contents of each vial should be resuspended by gentle mixing.

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

AFFIRMAGEN and AFFIRMAGEN 4

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 cassettes containing reverse diluent columns such as Reverse Diluent or ABO-Rh/Reverse cassettes
7. Micropipetter for delivery of 10 µL and 40 µL
8. Disposable pipette tips
9. Ortho BioVue System Work Rack

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 or insert the liner as directed by specific cassette instructions for use.

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 10 µL of the appropriate AFFIRMAGEN reagent to the 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. 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. Room temperature incubation for 5 to 30 minutes prior to centrifugation may enhance the reaction of weak antibodies.

7. Read the front and back of the individual columns for agglutination and/or hemolysis upon test completion.

Quality Control Procedures

AFFIRMAGEN and AFFIRMAGEN 4 should be tested on each day of use with positive and negative controls according to the method described in the Procedure section.

Interpretation of Results

Agglutination and/or hemolysis indicates the presence of an antibody corresponding to an antigen present on the red cells being tested.

Note:	The concentration of EDTA may not prevent hemolysis with all samples.

Agglutination of the group O control cells of AFFIRMAGEN 4 indicates the presence of an antibody other than anti-A and/or anti-B. The antibody should be identified through the use of an antibody identification panel such as RESOLVE® Panel A.

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. In some patients (e.g., newborns, elderly, agammaglobulinemia or other immunocompromised patients), the expected ABO antibodies may be weak or missing. For any recipient whose ABO group cannot be accurately determined, group O red blood cells should be considered as a transfusion alternative.
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. The group O cells provided with AFFIRMAGEN 4 are for use only as a control and should not be used exclusively for the detection of unexpected antibodies.
5. False-positive results may occur if antibodies to components of the preservative solution are present in the serum tested.
6. The presence of EDTA may prevent complement-mediated hemolysis that might be interpreted falsely as a negative reaction in the hemolysin test.
7. When using automated instruments, refer to the limitations contained in the operator's manual provided by the device manufacturer.

Expected Results*

In a clinical study, the reverse grouping results of 544 donor and patient samples tested were 100% concordant when comparing 0.8% AFFIRMAGEN and 3.0% AFFIRMAGEN group A_1, group A_2 and group B cells. All sample reverse grouping results agreed with the historical forward grouping results with two exceptions. The A_2 reagent cells did not detect the anti-A present in two group B samples (one patient and one donor). One additional type O sample known to have warm autoantibodies gave positive results with group O reagent cells.

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

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 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.

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

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

References

1. Laboratory biosafety manual. 2nd ed. World Health Organization, Avenue Appia 20, 1211 Geneva 27 Switzerland, 1993.
2. 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.

Glossary of Symbols

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


Use by or Expiration Date (Year-Month-Day)

LOT Batch Code or Lot Number

REF Catalog Number or Product Code


Manufacturer

EC REP Authorized Representative in the European Community

IVD *In vitro* Diagnostic Medical Device


Temperature Limitation


Consult instructions for use


Serious Health Hazards


This end up

Revision History

Date of Revision	Version	Description of Technical Changes*
2020-07-02	e631300161	• 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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