

Affirmagen® Affirmagen® 4

REF

Affirmagen 707930
Affirmagen 4 707910

INTENDED USE

For confirmation of ABO forward (red cell) grouping in the Ortho® BioVue System
FOR IN VITRO DIAGNOSTIC USE

SUMMARY AND EXPLANATION

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

PRINCIPLE OF 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 (1:3,000), neomycin sulfate (1:10,000) and gentamicin (1:20,000) 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 A₁ and B red cells

AFFIRMAGEN 4

A four-vial set consisting of one vial each of A₁, A₂, B and group O red cells

STORAGE REQUIREMENT

Store at 2 to 8°C.

Do not freeze.

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 to provide the required centrifugation parameters for this system. Proper calibration of the centrifuge is essential to achieve accurate test results.

SPECIMEN COLLECTION AND PREPARATION

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 to 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 manual BioVue cassette testing only. When using 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 BioVue System cassettes containing reverse diluent columns such as Reverse Diluent or ABO-Rh/Reverse Grouping cassettes
2. Ortho BioVue System Centrifuge
3. Micropipetter for delivery of 10 μ L and 40 μ L
4. Disposable pipette tips
5. Ortho BioVue System Work Rack (Product Code 707830)

Test Procedure

1. Consult the package insert 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 μ L of the appropriate AFFIRMAGEN reagent to the reaction chamber.
5. Add 40 μ L of test serum or plasma to the appropriate reaction chambers. **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.
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 A₂ 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.

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 A₁, group A₂ and group B cells. All sample reverse grouping results agreed with the historical forward grouping results with two exceptions. The A₂ 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.

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

SUMMARY OF REVISIONS

Updated address.

**BIBLIOGRAPHY / BIBLIOGRAPHIE / LITERATUR / BIBLIOGRAFIA / BIBLIOGRAFI / BIBLIOGRAFIE / LITTERATUR /
Βιβλιογραφία / LITTERATURFÖRTECKNING**

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.

**KEY TO SYMBOLS / LÉGENDE DES SYMBOLES /
SYMBOL-LEGENDE / CLAVE DE LOS SÍMBOLOS /
LEGENDA DEI SIMBOLI / SIMBOLOGIA /
FORKLARING TIL SYMBOLER / ΕΠΕΞΗΓΗΣΗ
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Atenção: Consulte as instruções de utilização /
Obs.: Se brugsanvisning / Προσοχή: Ελέγξτε οδηγίες χρήσης /
Obs! Se bruksanvisningen*



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Número de lote / Lotto numero / Número de lote /
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*Use by/expiration date (CCYY-MM-DD) /
Utiliser avant/date d'expiration (AAAA-MM-JJ) /
Benutzen vor/Verfallsdatum (JJJJ-MM-TT) /
Usese antes de/Fecha de caducidad (SSAA-MM-DD) /
Data di scadenza (AAAA-MM-GG) /
Utilizar até/data de validade (SSAA-MM-DD) /
Anvendes senest/udløbsdato (ÅÅÅÅ-MM-DD) /
/ημερομηνία λήξης (AAEE-MM-HH) /
Används före/Utgångsdatum (ÅÅÅÅ-MM-DD)*



*Store between / Conserver entre / Lagern zwischen /
Almacenar entre / Conservare ad una temperatura tra /
Armazemar entre / Opbevares mellem / Φύλαξη μεταξύ /
Förvaras mellan*



*For In Vitro Diagnostic Use / Pour Diagnostic In Vitro /
In-vitro-Diagnostikum / Para uso diagnóstico in vitro /
Per uso diagnostico in vitro / Para diagnósticos In Vitro /
Til diagnostisk brug in vitro / Για διαγνωστική χρήση
In Vitro / För diagnostisering in vitro*



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*Product Code / Code produit / Artikelnummer / Código del
producto / Codice prodotto / Código do Produto /
Produktkode / Κωδικός Προϊόντος / Produktkod*



*This end up / Haut / Diese Seite nach oben / Este extremo
hacia arriba / Questa estremità in alto / Este Lado Para Cima /
Denne side op / Η Συσκευασία Πρέπει να Είναι Όρθια από
Αυτήν την Πλευρά / Denna sida upp*

EC **REP**

Ortho-Clinical Diagnostics
Johnson & Johnson
50-100 Holmers Farm Way
High Wycombe
Buckinghamshire
HP12 4DP
United Kingdom



Ortho-Clinical Diagnostics, Inc.

a *Johnson & Johnson* company

Raritan, New Jersey 08869

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