

Reagent Red Blood Cells

Biotestcell[®] A₁ & B

Biotestcell[®] A₂

3.0 to 3.4%

Pooled cells for Reverse Grouping by tube test

FOR IN-VITRO DIAGNOSTIC USE
NO U.S. STANDARD OF POTENCY
U.S. License Number: 1798

Package size

REF	816057100	VOL	2 x 10 mL	Biotestcell [®] A ₁ & B
REF	816047100	VOL	1 x 10 mL	Biotestcell [®] A ₂

Intended Use

Biotestcell[®] A₁ & B and Biotestcell[®] A₂ are used for the detection of antibodies to A and B antigens in test serum or plasma.

Summary

Between 1900 and 1902, Landsteiner and associates discovered the ABO system of red blood cell antigens. The importance of this discovery is the recognition that antibodies are present when the corresponding antigens are lacking. The ABO system is the only blood group system in which the reciprocal antibodies are consistently and predictably present in most people. Due to this reciprocity, a blood type determination is considered valid if serum isoagglutinins correspond with red blood cell antigens¹.

Biotest Reagent Red Blood Cells A₁ & B and A₂ are used to test for the presence or absence of the corresponding antibodies in reverse grouping for the ABO system. Routine pretransfusion studies always include tests for the ABO antigens and reverse grouping.

Phenotype Frequency (%)²

	Caucasians	Blacks	Asians	Mexican
A ₁	33	19	27	22
A ₂	10	8	Rare	6
B	9	20	25	13
O	44	49	43	55
A ₁ B	3	3	5	4
A ₂ B	1	1	Rare	Rare

Principle of the Test

The test principle is a hemagglutination test. The antigens of the Reagent Red Blood Cells react with the respective antibodies in the serum or plasma to be tested.

The existence or lack of Anti-A and/or Anti-B antibodies must correspond with the existence or lack of A and/or B antigens on the Reagent Red Blood Cells.

Reagent

Human Reagent Red Blood Cells, ready-to-use, for plasma or serum grouping. Biotestcell[®] A₁ & B and Biotestcell[®] A₂ are available suspended 3.0 to 3.4% in modified Alsevers solution and can be used immediately following careful resuspension. Biotestcell[®] A₁ & B and Biotestcell[®] A₂ are produced every 4 weeks.

Biotestcell[®] A₁ & B and Biotestcell[®] A₂ have the following antigen combinations:

Biotestcell [®] A ₁	A ₁ Rh negative (D negative) (cc̄ddee)
Biotestcell [®] B	B Rh negative (D negative) (cc̄ddee)
Biotestcell [®] A ₂	A ₂ Rh negative (D negative) (cc̄ddee)

Preservative:

0.01% Neomycin, 0.033% Chloramphenicol, 5 ppm Amphotericin B

Precautions

- For In-vitro diagnostic use.
- Store at 2 to 8°C.
- Do not use beyond the expiration date.
- Do not use damaged vials.
- Do not use if markedly hemolyzed or discolored
- Handle and dispose of reagents as potentially infectious

- Caution: Do not pipette by mouth. The absence of all viruses has not been determined.
- Caution: ALL BLOOD PRODUCTS SHOULD BE TREATED AS POTENTIALLY INFECTIOUS. SOURCE MATERIAL FROM WHICH THIS PRODUCT WAS DEFIVED WAS FOUND NEGATIVE WHEN TESTED WITH FDA LICENSED EIA/ELISA TESTS. NAT TESTING WAS NOT PERFORMED. NO KNOWN TEST METHOD CAN OFFER ASSURANCE THAT PRODUCTS DERIVED FROM HUMAN BLOOD WILL NOT TRANSMIT INFECTIOUS AGENTS.
- Caution: This product contains Natural Rubber Latex Which May Cause Allergic Reactions.

Specimen Collection

Fresh samples of clotted or EDTA anticoagulated whole blood collected following general blood sampling guidelines are acceptable. The specimen should be tested as soon as possible after collection. If testing is delayed, EDTA and clotted specimens should be stored at 2 to 8°C.

Blood specimens exhibiting gross hemolysis or contamination should not be used.

Clotted samples or those collected in EDTA older than ten days can be tested, however antibody reactivity has been shown to decrease in older samples. Stored samples should be allowed to reach room temperature (18 to 26°C) prior to testing.

Materials

Material provided

- Biotestcell[®] A₁ & B and Biotestcell[®] A₂

Material required but not provided

- Pipettes (drop volume 40 to 50µl)
- Glass tubes 10 x 75mm or 12 x 75mm
- Serological centrifuge
- Interval Timer
- Markers
- Optical aid (optional). The use of an optical aid for agglutination reading must be validated by the user.

Test procedure

Tube Test

Resuspend Reagent Red Blood Cells prior to use and allow to reach room temperature.

1. Place two drops of sample serum/plasma to be tested into each properly labelled tube (A₁, B and/or A₂).
2. Add one drop of Biotestcell[®] A₁ & B and/or Biotestcell[®] A₂ to the tube labelled for it and mix.
3. Centrifuge for 20 seconds at 800 -1000 x g.
4. Gently dislodge the red blood cell button and observe for agglutination.
5. Record results

Stability of the Reaction

Following centrifugation, all tube tests should be read immediately and results interpreted without delay. Time delays may cause a dissociation of the antigen-antibody complexes resulting to false negative or more often weak positive reactions.

Quality Control

To confirm the reactivity or specificity of Biotest Reagent Red Blood Cells A₁ & B and A₂, each should be tested with Anti-A and Anti-B, preferably from normal blood donors, of known ABO blood group. Each Reagent Red Blood Cells is satisfactory for use if it reacts only with the corresponding antibody.

Interpretation of results

Agglutination of the red blood cells is a positive result and indicates the presence of the corresponding antibody. No agglutination is a negative result and indicates the absence of the corresponding antibody.

An agglutination viewer may facilitate the reading of tube tests (as recommended by the AABB Technical Manual, 15th edition).

FOR REFERENCE USE ONLY: DO NOT USE in place of package inserts provided with each product.

Reaction patterns, red blood cell antigens and isoagglutinins

Reagent sera with Patient red blood cells			Reagent Red Blood Cells with Patient serum/plasma			Blood Group
Anti-A	Anti-B	Anti-AB	A ₁	A ₂ *	B	
+	0	+	0**	0***	+	A
0	+	+	+	+	0	B
0	0	0	+	+	+	O
+	+	+	0	0	0	AB

+ = agglutination

0 = no agglutination

*Testing with A₂ Reagent Red Blood Cells is not required, but most commonly used to identify anti-A₁ in the sera of group A people.

**A positive reaction may indicate an unexpected anti-A₁ in a person with A₂ blood group.

***A positive reaction may indicate an unexpected anti-H in a person with A₁ blood group.

Limitations

- In very rare cases weak reactions (reaction strength under 3+) or hemolysis may occur.
- Since serum characteristics may react at different strengths, incubation for 15 to 30 minutes at room temperature may be performed.
- Generally, newborns and young babies do not show test reaction due to missing isoagglutinins. Isoagglutinins may also be absent in elderly patients.
- The reactivity of the product may decrease during the dating period and therefore should not be used after the expiration date.
- Not for use in detection or identification of unexpected antibodies.
- Not recommended to be used instead of major crossmatch for the detection of unexpected antibodies.

Specific Performance Characteristics

Testing is performed in accordance with FDA recommended methods. The final release testing is performed according to the product specific SOPs. Each lot of Biotest Reagent Red Blood Cells is tested in the Quality control by package insert method against a panel of blood grouping reagents to insure suitable reactivity. The result must react appropriately positive or negative.

No FDA Standard of potency. For the product performance it is necessary to adhere to the recommended method in the instructions for use.











For Technical Support or further product information, contact Biotest Diagnostics Corporation at 800-522-0090.

Note

Each facility should verify the optimum spin time for the specific centrifuge in use.

Manual techniques are to be performed according to the manufacturer's instructions. Each deviation from these instructions is the sole responsibility of the user. Used test material must be discarded as hazardous material. Manage waste according to local, state and national regulations.

Glossary of Symbols

Symbol	Definition	Symbol	Definition
	Batch Code		<i>In vitro</i> diagnostic medical device
	Caution, consult accompanying documents		Consult instructions for use.
	Manufacturer		Use by YYYY-MM-DD
	Contains sufficient quantity for <n> tests.		Catalog number
	Temperature limitation		Volume

Bibliography

1. Mark E. Brecher, MD et al. Technical Manual 15th Edition, Bethesda, MA: AABB, 2005.
2. Marion E. Reid, Christine Lomas-Francis, The Blood Group Antigen FactsBook, New York, NY: Academic Press, 2004.