Reagent Red Blood Cells

Biotestcell® A_1 & B

Biotestcell® A_2

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: 1845
Rx only

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® A_1 & B and Biotestcell® A_2 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 antigens[1].

Bio-Rad Reagent Red Blood Cells A_1 & B and A_2 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
0	44	49	43	55
A_1B	3	3	5	4
A_2B	1	1	Rare	Rare

PRINCIPLES 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

[IVD]
OBSERVABLE INDICATIONS.
Do not use if markedly hemolyzed or discolored.
Do not use damaged vials.

Human Reagent Red Blood Cells, ready-to-use, for plasma or serum grouping. Biotestcell® A_1 & B and Biotestcell® A_2 are available suspended 3.0 to 3.4% in modified Alsevers solution and can be used immediately following careful resuspension. Biotestcell® A_1 & B and Biotestcell® A_2 are produced every 4 weeks.

Biotestcell® A_1 & B and Biotestcell® A_2 have the following antigen combinations:

Biotestcell® A_1	A_1 Rh negative (D negative)	(¢¢ddee)
Biotestcell® B	B Rh negative (D negative)	(¢¢ddee)
Biotestcell® A_2	A_2 Rh negative (D negative)	(¢¢ddee)

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.
- 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 DERIVED 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 DERIED FROM HUMAN BLOOD WILL NOT TRANSMIT INFECTIOUS AGENTS.
- Caution: This Product Contains Natural Rubber Latex Which May Cause Allergic Reactions.
- Consult **downloads.bio-rad.com** to download the valid version of this instruction for use.

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, specimens should be stored at 2 to 8°C or the plasma or serum can be separated from red blood cells and frozen. Stored samples should be allowed to reach room temperature prior to testing.
Note: Blood specimens exhibiting gross hemolysis or contamination should not be used.
Clotted or EDTA samples older than ten days can be tested, however antibody reactivity has been shown to decrease in older samples.

MATERIALS

Material provided

- Biotestcell® A_1 & B and Biotestcell® A_2

Material required but not provided

- Pipettes
- Glass tubes 10 x 75mm or 12 x 75mm
- Serological centrifuge
- Interval timer
- Markers
- Agglutination viewer (optional)

TEST PROCEDURE

Tube Test

Resuspend Reagent Red Blood Cells prior to use and allow to reach room temperature. The procedures below intended as guidelines. It may be desirable to modify these procedures based on in-house requirements or standard operating procedures.

1. Place two drop**s** (approx. 40 to 50 µL each) of sample serum/plasma to be tested into each properly labelled tube (A_1, B and/or A_2).
2. Add one drop of corresponding Reagent Red Blood Cells to the appropriate tube and mix.
3. Centrifuge for:
   a. 20 seconds at 800 to 1000 x g or
   b. at a time and speed appropriate for the centrifuge calibration.
4. Gently dislodge the red blood cell button and observe for macroscopic agglutination. Negative reactions may be examined with an agglutination viewer, however, microscopic examination is not recommended.
5. Record results

Note: Since serum characteristics may react at difference strengths, incubation for 15 to 30 minutes at room temperature may be performed additionally.

STABILITY OF 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 Bio-Rad Reagent Red Blood Cells A_1 & B and A_2, each should be tested with Anti-A and Anti-B, preferably from normal blood donors, of known ABO blood group or with a quality control product specifically designed for the quality evaluation of A_1 & B and/or A_2 Reagent Red Blood Cells. 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)[1].

Reaction pattern for ABO-Reagent with red blood cells

Anti-A	Anti-B	Anti-A,B	Blood Group
positive	negative	positive	A
negative	positive	positive	B
negative	negative	negative	O
positive	positive	positive	AB

Reaction pattern for ABO Reagent Red Blood Cells with serum/plasma

A_1	A_2*	B	Blood Group
negative**	negative***	positive	A
positive	positive	negative	B
positive	positive	positive	O
negative	negative	negative	AB

*Testing with A_2 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-A_1 in a person with A_2 blood group.
***A positive reaction may indicate an unexpected anti-H in a person with A_1 blood group.

M Bio-Rad Medical Diagnostics GmbH
Industriestr. 1, D-63303 Dreieich, Germany

LIMITATIONS

- In very rare cases weak reactions (reaction strength under 3+) or hemolysis may occur.
- ◄
- Generally, newborns and young babies do not show test reaction due to missing isoagglutinins. Isoagglutinins may also be absent in elderly patients or disease states.
- False positive reactions might occur due to:
  - Cold antibodies
  - Auto antibodies
  - Panagglutinins
  - patient's medication (e.g. antibiotics, plasma expanders of high molecular weight)
- Do not use if markedly hemolyzed, slight hemolysis before the expiry date does not affect the reactivity.
- Fibrin, clots, particulates or other artifacts may cause anomalous results.
- 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 antiglobulin crossmatch for the detection of unexpected antibodies.
- If testing is only performed with Biotestcell A1&B and/or Biotestcell A2, blood group Bombay will not be detected. To detect blood group Bombay, additional testing with red blood cells of blood group O is recommended.

SPECIFIC PERFORMANCE CHARACTERISTICS

Testing is performed in accordance with FDA recommended methods.
The final release testing is performed according to the product specific SOPs. As part of the release process, each lot of Bio-Rad Reagent Red Blood Cells is tested according to the 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 Bio-Rad Laboratories, Inc., at 800-224-6723.

NOTE

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
[LOT]	Batch Code	[IVD]	*In vitro* diagnostic medical device
!	Consult the instructions for use for important cautionary information such as warnings and precautions	I	Consult instructions for use
M	Manufacturer	e	Use by YYYY-MM-DD
s	Contains sufficient quantity for <n> tests	[REF]	Catalog number
t	Temperature limitation	[VOL]	Volume

BIBLIOGRAPHY

1. John D. Roback, MD et al. Technical Manual 17th Edition, Bethesda, MA: AABB, 2011.
2. Marion E. Reid, Christine Lomas-Francis, The Blood Group Antigen FactsBook, New York, NY: Academic Press, 2004.

Key: Underline = Addition of changes ◄ = Deletion of text