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Biotestcell-I8 / Biotestcell-I11

Reagent red blood cells for antibody identification

REF	816 020	8 x 4 ml	Biotestcell-I8
REF	816 021	11 x 4 ml	Biotestcell-I11
PRES	Preservative:	0.01 % Neomycin sulfate, 0,033 % Chloramphenicol, 5 ppm Amphotericin B	

IVD Diagnostic reagent for in vitro use only
To be used by trained laboratory personnel only.

Test purpose
Antibody identification is used to determine antibodies against red cell antigens. If an antibody detection test shows irregular antibodies, antibody identification is used to determine specificity and clinical relevance.
Biotestcell-I8 / Biotestcell-I11 is used for the exact identification of irregular antibodies which were found in an antibody detection test with Biotestcell-P, Biotestcell-P1, P2 or Biotestcell-P3. Biotestcell-I8 / Biotestcell-I11 is used in tube test or solid phase test Solidscreen II and is suited for all routine testing. Use of these Reagent Red Blood Cells with Solidscreen II on the TANGO optimo and TANGO infinity is not approved by Health Canada.

Test principle
The test principle is a hemagglutination test or solid phase test. Antigens bound to reagent red blood cells react with the corresponding antibodies in the serum or plasma directly or after addition of Anti-Human Globulin. In a tube test agglutination will occur, in a solid phase test (Solidscreen II) a layer of red blood cells across the bottom of the wells will be observed.

Reagent
Biotestcell-I8 / Biotestcell-I11 are reagent red blood cells with polyvalent antigens.
Biotestcell-I8 / Biotestcell-I11 contain the following antigens: D, C, C^w, E, c, e, K, k, Fy^a, Fy^b, Lu^a, Lu^b, Jk^a, Jk^b, Js^b, M, N, S, s, Le^a, Le^b, P_1, Xg^a, Co^a.
Biotestcell-I11 can also identify antibodies against Di^a, Kp^a and Js^a.
For the exact antigen content of each production lot, please refer to the enclosed table. Biotestcell-I8 / Biotestcell-I11 is also suited for use with enzymes (papain, ficin, bromelin, trypsin) or supplements (albumin, LISS). The shelf life of enzyme treated reagent red blood cells is listed in the instructions for use of the respective enzymes.
Biotestcell-I8 / Biotestcell-I11 is suspended approximately 3 % in a modified Alsevers solution and can be used immediately after cautious resuspension.

Reagents and material needed but not supplied
3-phase-tube test
- Pipettes (drop volume 40-50 µl)
- Isotonic saline solution
- Anti-Human Globulin (e. g. Anti-Human-Globulin Color REF 804 120, 804 115, 804 130 or Anti-Human-Globulin Solidscreen II REF 806 515)
- IgG-coated red cells (e.g. Coombscell-E REF 816 030)
- Glass tubes
- Laboratory centrifuge

Solidscreen II
Please refer to the instructions for use of Solidscreen II Strip (REF 806 521).

Sample material
Fresh serum or plasma collected following general blood sample guidelines are acceptable. The samples should be tested as quickly as possible after sampling. If this is not possible, storage of the plasma or serum at 2 - 8° C for up to 7 days is recommended. Only serum or EDTA plasma are suitable for testing on TANGO optimo and TANGO infinity. For the detection of complement-dependent antibodies plasma must not be used because the anticoagulants inhibit complement.
Note: Blood specimens exhibiting gross hemolysis or contamination should not be used.

Test procedure
Resuspend reagent red blood cells prior to use and bring up to room temperature.

3-phase-test
If enzymes or supplement (albumin, LISS) is used, please refer to the respective instructions for use.

1. phase: immediate centrifugation test
a) In properly marked tubes place 2 drops of serum to be tested. An autocontrol should be performed parallel. For autocontrol wash red blood cells twice with isotonic saline solution.
b) Add 1 drop of corresponding red cell suspension to tube and mix. (If desired, a second set of tubes with enzyme treated or albumin treated Biotestcell-I8 or Biotestcell-I11 can be tested).
c) Centrifuge for 2 minutes at 150-200 x g or 20 seconds at 800-1000 x g.
d) Gently dislodge the cell button and observe for agglutination.
Often the immediate centrifugation test shows expression of anti-M, -N, -P and cold reactive antibodies.

2. phase: centrifugation test after incubation
a) Incubate 30-60 minutes at 37°C.
b) Centrifuge for 2 minutes at 150-200 x g or 20 seconds at 800-1000 x g.
c) Gently dislodge the cell button and observe for agglutination.
With the centrifugation test after incubation mainly Rh-antibodies as well as incomplete antibodies are detected.

3. phase: indirect antiglobulin-test
a) Wash the cells 3 times with isotonic saline. Decant supernatant saline completely.
b) Add 2 drops of anti-human-globulin to the packed red blood cells and mix.
c) Centrifuge for 2 minutes at 150-200 x g or 20 seconds at 800-1000 x g.
d) Gently dislodge the cell button and observe for agglutination.
This test shows incomplete antibodies such as anti-Duffy, anti-Kidd, all Rh-antibodies.

Solid phase test Solidscreen II
For the exact test procedure as well as a table of expected reactions please refer to the detailed instructions for use of Solidscreen II Strip (REF 806 521).

Interpretation of results
3-phase tube test: Biotestcell-I8 / Biotestcell-I11 are compared to antigen pattern and are read accordingly. Negative reactions indicate the absence of the tested antibody. Positive reactions indicate antibody presence. They can easily be identified by reading the antigen pattern. For verification an additional antigen test of the red blood cells should be performed. Detected antigens prove the absence of the corresponding antibodies, unless there are autoantibodies. Negative results in an antiglobulin-test should be verified with IgG coated red blood cells in a tube test: Add 1 drop of IgG coated red cells, mix and centrifuge for 2 minutes at 150-200 x g or 20 seconds at 800-1000 x g.

Reaction positive: The negative reaction in the indirect antiglobulin-test is valid, reactive anti-human-globulin is present.
Reaction negative: A technical error was made and the test must be repeated.

Negative reactions in the 3-phase-test and subsequent positive reactions with IgG coated cells indicate that the serum contains no detectable antibodies against one of the listed antigens (enclosed antigen pattern).
For quantitative antibody detection the serum should be diluted and mixed with the corresponding red blood cells of Biotestcell-I8 / Biotestcell-I11. The test method depends on the detected antibody (saline medium, albumin testing, indirect antiglobulin- or enzyme test).

Evaluation of the reaction strength is carried out according to the Technical Manual[1]:

Reaction strength	Agglutination
4+	One single agglutinate
3+	Several large agglutinates.
2+	Medium-size agglutinates, clear background
1+	Small agglutinates, turbid background
+/-	Barely visible agglutination, turbid background
-	No agglutination

Shelf life
Tube Test
After opening the vial the product can be stored under proper storage conditions (2 - 8°C) until the expiry date. The expiry date is printed on the label. Since antigenicity may decrease, the reagent red blood cells should not be used after the expiry date. ◄

Automated Testing
Unopened Reagent Red Blood Cells (RRBC) must be stored at 2 - 8°C until the expiry date. After placing on the TANGO inifinity or TANGO optimo the RRBCs can be used within 7 days.

Performance characteristics and limitations of the method
- Low frequency antigens may not always be present on the Reagent Red Blood cells. Therefore, negative reactions with the identification Reagent Red Blood Cells do not always indicate the absence of unexpected antibodies.
- Because some antibodies show a doses effect, the antigen density on the test cells needs to be considered when evaluating the test results (homozygous or heterozygous hereditary disposition). A heterozygous expression of the antigen may result in non-detection of weak antibodies depending on the used test method.
- In very rare cases HLA Class I Antigens or low frequent antigens within the product may lead to wrong positive reactions.
- The reactivity of the product may decrease during the dating period. The rate of decrease in reactivity is partially dependent on individual donor characteristics that are neither controlled nor predicted by the manufacturer.
- Do not use if markedly hemolyzed, slight hemolysis before the expiry date does not affect the reactivity.
- Grossly icteric blood samples, blood samples with abnormally high concentrations of protein or blood samples from patients who have received plasma expanders of high molecular weight may give false positive results.
- Fibrin, clots, particulates or other artifacts may cause an anomalous result.
- False positive result may cause by cross reactions with patient medication (e.g. antibiotics, plasma expanders of high molecular weight, monoclonal antibodies).
- False positive results may occur due to HTLA antibodies.
- Negative reactions will be obtained if the sample contains antibodies present in concentrations too low to be detected by the test method employed. No test method is capable of detecting all red cell antibodies.

In case of unclear results with unknown causes, our Bio-Rad Service (Tel. +49-6103-3130-611) will assist you.

Warning and precautions
- Do not use damaged vials.
- Turbidity, hemolysis or other visible changes may indicate a bacterial contamination. In this case, the product must not be used.
- Do not mix vials of different lots of Biotestcell-I8 / Biotestcell-I11 as reactions patterns for result interpretation vary.
- Manual techniques are to be performed according to the manufacturer's instructions. Each deviation from these instructions is the sole responsibility of the user.
- Biotestcell-I8 / Biotestcell-I11 is suited for use in Solidscreen II-test and our fully automated blood typing system TANGO optimo and TANGO infinity. ◄
- Used test material must be discarded as hazardous material. Waste management information can be found in the safety data sheet.
- Source material from which this product was derived was found negative for anti-HIV-1/-2, anti-HCV, HBsAg and anti-Lues. Nevertheless, all blood products must be regarded as potentially infectious and appropriate safety precautions are recommended.
- This product contains natural rubber latex which may cause allergic reactions.
- Internal quality controls according to national guidelines are recommended at regular intervals.
- Consult **downloads.bio-rad.com** to download the valid version of the instructions for use.

Biotestcell-I8 / Biotestcell-I11 are produced every 4 weeks.

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Glossary of Symbols

⚠	Consult the warnings and precautions

References

(1) Technical Manual, 19th edition, Section 1, American Association of Blood Banks

Key: Underline = Addition or significant change ◄= Deletion of text

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