EN

Biotestcell-P3

Reagent red blood cells for antibody detection

REF 816017

VOL 3 x 10 ml

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

The detection of antibodies against reagent red blood cells antigen (antibody detection test) is part of blood typing and compatibility tests. Biotestcell-P3 is used for the detection of irregular antibodies in a tube test or solid phase test Solidscreen II and is suited for 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 cells across the bottom of the wells will be observed.

Reagent

Biotestcell-P3 are reagent red blood cells with polyvalent antigens of three single blood donors in separate vials for the detection of red blood cell antibodies. Biotestcell-P3 contains the following antigens: D, C, C^w, E, c, e, K, k, Kp^b, 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. For the exact antigen content of each production lot, please refer to the enclosed table. Biotestcell-P3 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-P3 is suspended approximately 3 % in a modified Alsevers solution and can be used immediately after careful resuspension.

Material required 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 and 804 130 or Anti-Human-Globulin Solidscreen II REF 806 515)
- IgG-coated red blood 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. Only serum or EDTA plasma are suitable for testing on TANGO optimo and TANGO infinity. 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. 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 blood cell suspension to tube 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.

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.

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.

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

A positive reaction with Biotestcell-P1 and/or Biotestcell-P2 and/or Biotestcell-P3 indicates the presence of antibodies against the respective antigen. Antibody identification can be performed with Biotestcell-I8/Biotestcell-I11.

Negative results in an antiglobulin-test should be verified with IgG coated red cells: 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: the test was not properly performed and 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 list).

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 RRBC 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 screening 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 reagent red blood 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 questionable results of unknown origin 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 bacterial contamination. In this case, the product must not be used
- Do not mix vials of different lots of Biotestcell-P3 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-P3 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.

Bio-Rad Medical Diagnostics GmbH
Industriestr. 1, D-63303 Dreieich, Germany
Tel.: +49-6103-3130-0, Fax: +49-6103-3130-724
www.bio-rad.com, techsupport.bmd@bio-rad.com

CE 0197

186247/33 – 2022-02-07

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-P3 is produced every 4 weeks.

Glossary of Symbols

⚠	Consult the warnings and precautions

References

(1) Technical Manual, 17th edition, Section 1, American Association of Blood Banks

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

Bio-Rad Medical Diagnostics GmbH
Industriestr. 1, D-63303 Dreieich, Germany
Tel.: +49-6103-3130-0, Fax: +49-6103-3130-724
www.bio-rad.com, techsupport.bmd@bio-rad.com

CE 0197