# INSTRUCTIONS FOR USE

**ReaCell AB0 test cells 5-10 % red blood cell suspensions**
REF: 42340

## Intended Purpose

ReaCell AB0 test cells can be used to detect human serum and plasma AB0 blood group antibodies (anti-A, anti-B) in human serum and plasma.
They should only be used by trained professionals with knowledge and experience in immunohematology.

## Principle of the test – Overview:

The technique used is based on the principle of haemagglutination. (Some samples to be tested may haemolyse red blood cells carrying the corresponding antigen instead of agglutinating, usually in the case of fresh serum/plasma containing complement.)
The detection of anti-A and/or anti-B in the serum/plasma of a blood sample is a complementary part of AB0 blood group determination; the presence or absence of anti-A/anti-B supports the evaluation of the reactions of red blood cells to antibody reagents (Landsteiner rule).

## Composition:

The ReaCell AB0 product lines were compiled from members with blood types A1, A2, B, and 0 (according to the ReaCell AB0 packaging table).
The A1 test cell is RhD negative.
Preservative: 1 mmol/l chloramphenicol, 0.4 mmol/l neomycin sulphate
The red blood cells are supplied in the form of a 5-10% ready-to-use suspension in 10 ml vials with droppers. The dropper has a volume of approximately 50 µl.

## Storage, transport:

Reagents should be stored between +2 and +8 °C.
The manufacturer guarantees the performance of the reagents when used according to the recommended methods, from the date of manufacture to the expiry date stated on the label. Do not use after the expiry date! Only store the reagents outside the refrigerator for as long as necessary! Avoid leaving them at room temperature between uses! DO NOT FREEZE THE PRODUCT!

## Test material:

The test requires a blood sample that is no more than 72 hours old, completely clotted or anticoagulated (citrate, EDTA). Blood samples anticoagulated with heparin are not suitable because the rapid breakdown of heparin and the onset of clotting can make the test results unreliable. Samples collected in gel tubes are not suitable for blood group serological testing.
Control: The Rea IQC Total Blood Kit (REF 44130) is recommended for internal quality control.

## Required equipment and reagents:

- test tubes
- test tube rack
- stirring rod or other mixing device
- wipe
- plates
- laboratory centrifuge

## Method:

Blood group determination using discs:

1. Gently shake the AB0 test cells to ensure that the suspensions are homogeneous.
2. Write the sample number to be tested on the blood group determination plate.
3. Place 4x1 drops (50-50 µl) of blood sample serum/plasma at appropriate distances from each other.
4. Add 1 drop (50-50 µl) of the appropriate test cell to the serum/plasma drops, then mix thoroughly.
5. Incubate at room temperature (20-28 °C) for 10 minutes.
6. Slowly tilt the plate at an angle of approximately 30°.
7. Read and record the results.

## Interpretation of results:

If agglutination occurs, the result is positive, meaning that the corresponding antibody is present in the serum/plasma tested. If no agglutination occurs, the result is negative, meaning that the corresponding antibody is absent from the serum/plasma.

The AB0 blood group can only be clearly determined in a test sample if the result of the red blood cell antigens determined with antibody reagents is confirmed by the serum/plasma antibody test result (Landsteiner rule).

- In the case of blood group 0, the reaction is positive with A1, A2 and B test cells and negative with 0 cells.
- For blood group A, the reaction is positive with B test cells and negative with A1, A2 and 0 cells.
- For blood group B, the reaction is positive with A1 and A2 test cells and negative with B and 0 cells.
- For blood group AB, the reaction is negative with all AB0 test cells (A1, A2, B, 0).

| The serum/plasma of the blood to be tested with the test red blood cells | | | | Blood group |
|---|---|---|---|---|
| **A1** | **A2** | **B** | **0** | |
| + | + | + | o | **0** |
| o | o | + | o | **A** |
| + | + | o | o | **B** |
| o | o | o | o | **AB** |

+: agglutination, o: no agglutination

If the reaction occurs where specified by Landsteiner's rule, the test result can be evaluated.
In case of deviation, further tests are required.

## Limitations of the method:

Reactions with AB0 test cells may be absent in newborns, as children generally begin to produce anti-A and/or anti-B antibodies corresponding to their blood group after 3 months of age. In cases of immunodeficiency (hereditary or acquired immunodeficiency, immunosuppressive treatment), anti-A/-B antibodies may also be absent.

In the absence of antibodies, except in newborns, testing should be continued, along with clarification of the immunisation history and diagnosis.

The amount of anti-A and anti-B and the strength of the reaction may vary in the same person.

Unexpected positive agglutination may indicate the presence of irregular antibodies in serum/plasma (anti-A1, anti-H, other IgM class allo- or autoantibodies). This phenomenon must be clarified.

Cloudiness, discolouration, haemolysis may indicate bacterial or other contamination. Such reagents are unsuitable for use.

## Performance characteristics:

The raw materials for ReaCell test cells are red blood cell concentrates with a low boundary layer, which have been collected and tested in accordance with professional rules and applicable legislation, verified by blood group serology, and are known to have A1, A2, B and 0 antigen properties, from blood products collected for this purpose.

During the manufacture of the diagnostic product, blood group serological testing is performed.

The AB0 blood group characteristics of the test cell reagents are indicated based on the consistent results of two independent laboratories.

## Safety precautions:

The use of any device derived from human sources carries a potential biological risk. The red blood cell concentrates used in the manufacture of the product have been tested in accordance with the applicable regulations on blood products for transfusion (Decree 3/2005 (II. 10.) EüM) and have not been found to be reactive in the required infectious agent tests, but this does not exclude the possibility of transmission of any infection.

The use of protective gloves and goggles is recommended. When disposing of reagent residues, the applicable regulations on hygiene and infectious waste disposal must be followed.

Packaging: REF 42340 ReaCell AB0 5-10% 4x10 ml

## References:


1. AABB Technical Manual 18th Edition Bethesda, Maryland USA, 2015
2. Guide to the preparation, use and quality assurance of blood components, 11th edition, Council of Europe Publishing, Strasbourg, 2005.


## Reporting unexpected events:

Any serious unexpected events related to the product must be reported to the manufacturer: REAGENS Kft., 1155 Budapest Wysocki utca 1 tel: 06-1-349 8775 fax: 06-1-350 8354, email info@reagenskft.hu, and to the NNGYK-EITI Medical Technology Department at the following link https://ogyei.gov.hu/varatlan_esemeny_jelentes or by email atamd.vig@ogyei.gov.hu .

## Manufacturer:


REAGENS Kft. 1155 Budapest, Wysocki u. 1. Hungary; www.reagenskft.hu, info@reagenskft.hu
SRN: HU-MF-000019161


## Symbols:

| | | | |
|---|---|---|---|
| REF | Reference number | | Expiry date (YYYY.MM.DD) |
| LOT | Manufacturing batch number | | Storage temperature |
| IVD | In vitro diagnostic | | Manufacturer |
| | Read the instructions for use | | |

The Summary of Safety and Performance (SSP) will be available at https://ec.europa.eu/tools/eudamed once EUDAMED is operational.
This document is available in several languages. In case of doubt or discrepancy, the Hungarian version of the basic document shall prevail.

Changes to the user manual compared to the previous version are highlighted in grey.

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