INSTRUCTIONS FOR USE

ReaCell AB0 test cells 5-10 % suspension for manual technique
REF: 42340
ReaCell AB0 test cells can be used to detect human sera or plasma AB0 blood group system antibodies (anti-A, anti-B).
The ReaCell AB0 reverse blood grouping reagent can only be used by a qualified professional user with knowledge and experience in immunohematology.

Principle – Overview:

The technique used is based on the principle of hemagglutination. (Some samples to be tested may haemolyse red blood cells carrying the corresponding antigen instead of agglutination. Haemolysis can also be an acceptable result.)

The detection of anti-A and/or anti-B in the serum/plasma of a blood sample is an additional part of AB0 blood-grouping; the presence or absence of anti-A/anti-B supports the evaluation of red blood cell reactions to test sera (Landsteiner rule).

Composition:

ReaCell AB0 kit consists of 1-1 vials of A1, A2, B and 0 blood group cells. The A1 group test cells are RhD negative.
Preservative solution: 1 mmol/l chloramphenicol; 0,4 mmol/l neomycin-sulphate.
The red blood cells are prepared in 5-10 % ready-to-use suspension and are packaged in 10 ml vials fitted with a calibrated dropper. Dropper volume is approx. 50 µl.

Storage and transporting conditions:

The reagents must be stored and transported between +2 and +8°C. Using according to the recommended methods, their performance is guaranteed by the manufacturer from first opening until the expiry date on the label. Do not use beyond expiry date. It is advised to minimize the time outside the refrigerator. Avoid leaving the reagents at room temperature between uses. DO NOT FREEZE!

Specimen:

Blood samples that are less than 72 hours old, completely coagulated or inhibited (citrated, EDTA) are required. Blood samples inhibited from clotting by heparin are not suitable because the rapid degradation of heparin and the onset of clotting may render the results of the tests uncertain. Samples in gel tubes are not suitable for testing because they may give false positive reactions.

Control: The Rea IQC Total Blood Kit (REF 44130) is recommended for internal quality control.

Required materials:

- test tubes, 10 or 12 x 75 mm
- test tube rack
- stirrer-mixer
- plates or slides
- pipettes
- laboratory centrifuge

Procedure:

Blood grouping on plate:

1. Shake the ReaCell AB0 test cells gently to homogenise the suspension.
2. Write the ID of the sample to be tested on the plate or slide.
3. Measure 4 drops 50-50 µl of the serum/plasma of the sample, taking care not to create contact between the drops.
4. Add 1 drop 50 µl of each ReaCell AB0 (A1, A2, B, 0) to the drops of serum/plasma. Mix the drops of serum/plasma with ReaCell AB0 well, taking care not to cause contamination.
5. Incubate the plate/slide at room temperature for 10 minutes.
6. Hold the plate and give it a rolling movement for 3 minutes.
7. Macroscopically observe and record the result.

Note: Normally the two parts of blood grouping (red blood cell test and plasma test) are performed at the same time, on the same plate or slide; however, these instructions for use details only the results and interpretation of serum/plasma test.

Interpretation of results:

If agglutination is detected, the result is positive, the corresponding antibody is present in the tested serum/plasma. In the absence of agglutination, the result is negative, the corresponding antibody is missing from the serum/plasma. The blood group property AB0 can only be unambiguously determined in a test sample if the result of erythrocyte antigens determined by antibody reagents is confirmed by the result of the serous/plasma antibody test result (Landsteiner rule).

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

The reaction of the sera / plasma of the blood to be tested with the test red blood				Blood group
A1	**A2**	**B**	**0**	
+	+	+	o	**0**
o	o	+	o	**A**
+	+	o	o	**B**
o	o	o	o	**AB**

For agglutination, "+", if there is no agglutination, "o" is used

In case of discrepancies, the sample must be sent to the competent blood supply or transfusiology department.

Limitations of the method:

Reactions with AB0 test cells may be absent in newborns, as children do not produce anti-A and/or anti-B appropriate to their blood type until about 3-6 months of age. In immune-compromised state (inherited or acquired immunodeficiency, immunosuppressive therapy; old age), anti-A/-B antibodies may also be missing.
If the plasma/sera to be tested does not contain antibodies according to Landsteiner's rule, tests should be continued, except in the case of newborns, and the diagnosis clarified with the attending physician.
In the same person, the amount of anti-A or anti-B, the strength of the reaction may vary.
If the reaction occurs where and only where required by the Landsteiner rule, the test result can be evaluated.
Unexpected positive agglutination may indicate the presence of an irregular antibody (anti-A1, anti-H, or other IgM class allo- or autoantibody) in the sera/plasma. This phenomenon needs to be investigated.
Turbidity, discoloration, haemolysis may indicate bacterial or other contamination. Such a reagent is unsuitable for use.

Performance characteristics:

The human sourced leukodepleted erythrocytes for ReaCell test cells are collected from donors with known A1, A2, B and 0 antigen property, registered by the HNBTS (OVSz). The raw material collected is serologically tested according to professional standards and applicable legislation. During production, serological testing of blood groups is performed routinely. The strength of the reaction observed during testing depends on the quantity of antibodies (anti-A, anti-B) in the sample or test reagent.

Precautions:

All blood reagents and material coming into direct contact with samples shall be considered potentially infectious. The use of any device derived from substances of human origin carries a potential biohazard. Red cell concentrates used in the manufacture of this product are regulated in accordance with the current regulations on blood products for transfusion (3/2005 (II.10.) EüM Regulation) and has not been shown to be reactive in the prescribed infectious agent tests, but this does not exclude the possibility of transmission of any infection.
It is recommended to wear protective gloves and glasses. Disposal of residues must be carried out in accordance with the relevant hygiene and contaminant waste disposal regulations.

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

Literature:

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.

Incident reporting:

For end-user/third party in the European Union and in countries with identical regulatory regime (Regulation 2017/746/EU on In vitro Diagnostic Medical Devices); if during the use of this device or because of this use, a serious incident occurs, please report it to REAGENS Kft. to info@reagenskft.hu email address and to your (local) National Competent Authority.

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SRN: HU-MF-000019161

Symbols used:

REF	Catalogue reference
LOT	Batch Number
IVD	In vitro diagnostic
	Consult instruction for use
	Expiry date (YYYY.MM.DD)
	Storage temperature
	Legal manufacturer

The Summary of Safety and Performance (SSP) will be available on https://ec.europa.eu/tools/eudamed once EUDAMED is operational. This document is available in several languages. In the event of doubts or discrepancies, the wording in the master document in Hungarian shall take precedence.

Changes to the instruction for use compared from the previous version, are marked with gray.

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