INSTRUCTIONS FOR USE

ReaCell AB0 test cells
5-10 % suspension
for manual technique

REF 42140, 42340

IVD CE 1011

ReaCell AB0 test cells are intended to be used for determination of AB0 blood group antibodies (anti-A, anti-B) in human serum or plasma.

Intended use – Overview:
The test is based on the principle of haemagglutination. (On certain conditions in the presence of red blood cells bearing the correspondent antigens, some serum to be tested may perform haemolysis instead of haemagglutination. Haemolysis could be an acceptable result, however if it makes the evaluation doubtful, the reaction can be modified to agglutination by changing circumstances of the reaction.) Based on the results of the reactions with anti-A / anti-B reagents, 4 blood groups of the AB0 system can be differentiated as follows:

reactions of red blood cells	anti-A	anti-B	anti-A,B	blood groups
	-	-	-	0
	+	-	+	A
	-	+	+	B
	+	+	+	AB

The detection of anti-A and/or anti-B in the serum/plasma is a complementary part of blood grouping; the presence or absence of anti-A and/or anti-B antibodies supports the evaluation of the reactions between the red blood cells and test sera.

Composition:
ReaCell AB0 kit consists of 1-1 vials of A_1, A_2, B and 0 blood group cells. The A_1 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!

Samples:
Blood sample to be tested should be collected from vein, not older than 24 hours, completely coagulated, or collected in anticoagulant (citrate or EDTA). Blood samples collected in heparin are not suitable, since heparin disintegrates in a couple of hours, and the sample could begin to coagulate, leading to doubtful results.

Control:
It is recommended to use **Rea IQC Total Blood Kit** (REF 44130) as internal control.

Required reagents and equipment:
- glass test tubes, 10 or 12 x 75 mm
- tube rack
- stirrer-mixer
- plates or slides
- automatic adjustable pipettes
- laboratory centrifuge

Procedure:
Blood grouping on plate:
1. Gently shake each ReaCell AB0 vial to homogenize the suspension.
2. Register the ID of the sample to be tested on the plate or slide.
3. Apply 4 drops of the serum/plasma of the sample, taking care not to create contact between the drops.
4. Add 1 drop of each ReaCell AB0 (A_1, A_2, 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.

Evaluation of results:
- In case of **0** blood group the reaction is positive (there is agglutination) with cells: A_1, A_2, B, and negative with 0.
- In case of **A** blood group the reaction is positive with cells: B, and negative with A_1, A_2 and 0.
- In case of **B** blood group the reaction is positive with cells: A_1, A_2, and negative with B and 0.
- In case of **AB** blood group there is no positive reaction with the AB0 test cells.

reactions of the serum/plasma of blood samples				blood groups
A_1	A_2	B	0	
+	+	+	-	0
-	-	+	-	A
+	+	-	-	B
-	-	-	-	AB

+ = agglutination
- = no agglutination

If there is agglutination, the result is positive, and the corresponding antibodies are present in the test serum/plasma. If there is no agglutination, the result is negative, and the corresponding antibodies are not in the test serum/plasma.
The AB0 group of a subject can only be unambiguously determined if there is strict concordance between the results of the red blood cell test and the plasma test (Landsteiner rule).
In case of any discordance, forward the sample to the competent blood transfusion center or department.

Limitations of the method:
Weak or even negative reactions inducing discordance between the red blood cell and plasma tests may be observed in neonatal subjects, because of their inactive antibody production. The absence of anti-A/-B can also be experienced in the case of (innate or acquired) immunocompromised patients.
If the serum to be tested does not contain the antibody corresponding the Landsteiner rule, then further examinations need to be done, or the diagnosis should be cleared up with the consultant.
The intensity of the obtained reactions may vary patient by patient, moreover may vary seasonally in case of the same patient as well. If the reactions are in strict accordance with Landsteiner rule, they should be accepted independently from their strength. Unexpected positive reaction may point to the presence of irregular antibodies (anti-A_1, anti-H or other IgM type allo- or autoantibody) in the serum/plasma. Such results should be further examined.
Turbidity, change in color or haemolysis may point to bacterial or other contamination. The reagent with these characteristics cannot be used anymore.

Precautions:
All reagents of human origin and all substrates that have come into contact with the samples must be handled as potentially infectious materials.
Red Blood Cell concentrates, and the plasma used in Rea IQC Total Blood Kit has been tested by the Hungarian Blood Transfusion Service under the operative decree 3/2005. (II. 10.) EüM regarding blood products for transfusion. All human blood products used in production were found non-reactive for Lues, HIV1-2, HbsAg and HCV by procedures recommended by the European Council, however, none of the methods currently known can absolutely guarantee that the products do not contain any transmissible pathogen.
It is recommended to wear gloves and safety goggles.
Special protective measures, conditions for waste disposal and disinfection should be implemented following local regulations.

Packaging:
4x10 ml (REF 42140)
4x10 ml (REF 42340)

Bibliography:
Gál Gy. – Szabó J. (szerk): Transzfúziós alapismeretek és transzfúziológiai szabályzat, SZOTE Vértranszfúziós Intézet, Szeged, 1998.
AABB Technical Manual 18th Edition Bethesda, Maryland USA, 2015
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 as a result of this use, a serious incident occurs, please report it to REAGENS Ltd. to info@reagenskft.hu email address and to your (local) national Competent Authority.

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Version: 12v

INSTRUCTIONS FOR USE

ReaCell AB0 test cells
1,5 ± 0,5 % suspension
for micro technique

REF 42170

IVD CE 1011

ReaCell AB0 test cells are intended to be used for determination of AB0 blood group antibodies (anti-A, anti-B) in human serum or plasma.

Intended use – Overview:
The test is based on the principle of haemagglutination. (On certain conditions in the presence of red blood cells bearing the correspondent antigens, some serum to be tested may perform haemolysis instead of haemagglutination. Haemolysis could be an acceptable result, however if it makes the evaluation doubtful, the reaction can be modified to agglutination by changing circumstances of the reaction.) Based on the results of the reactions with anti-A / anti-B reagents, 4 blood groups of the AB0 system can be differentiated as follows:

reaction of red blood cells	anti-A	anti-B	anti-A,B	Blood group
	-	-	-	0
	+	-	+	A
	-	+	+	B
	+	+	+	AB

The detection of anti-A and/or anti-B in the serum/plasma is a complementary part of blood grouping; the presence or absence of anti-A and/or anti-B antibodies supports the evaluation of the reactions between the red blood cells and test sera.

Composition:
ReaCell AB0 kit consists of 1-1 vials of A_1, A_2, B and 0 blood group cells. The A_1 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 1,5 ± 0,5 % ready-to-use suspension and are packaged in 5 and 10 ml vials fitted with a calibrated dropper. Dropper volume is approx. 50 µl.

Storage 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!

Samples:
The venous blood sample should be tested within 72 hours, collected in anticoagulant (citrate or EDTA).
The samples to be tested must be stored at +4°C (±2°C) till the beginning of the tests. At the time of the test, centrifuge the blood samples at 3000 RPM for 3 minutes.

Control:
It is recommended to use **Rea IQC Total Blood Kit** (REF 44130) as internal control.

Required reagents and equipment:
- automated microplate system
- microplates
- Physiological Buffered Saline Solution (REF 15015)
- laboratory centrifuge

Procedure:
The automated system dilutes the plasma with physiological buffered saline solution in the wanted proportion, and dilutes the test cells with physiological buffered saline solution as well. The diluted plasma and test cells are pipetted to the microplates, which are incubated, and the system starts the reading of results.
Determination of blood groups with ReaCell AB0 test cells should be performed according to the user manual of the automated system.

Evaluation:
The reading and evaluation of the samples is done automatically by the automated microplate system.
If the RBC sedimentation creates uniform coating, which fully covers the microplate well, the agglutination is finished, the reaction is positive. The plasma contains the antibody corresponding to the antigen present on the RBC.
If the RBC sediment forms a dense pellet in the well's bottom the agglutination has not taken place, the result is negative and the antibody can not be revealed with the used method.
Intermediate pictures showing a firm pellet with several diffuse ring around are considered as limit value results.

The AB0 blood group can only be determined clearly for one sample, if the RBC antigens reaction with test sera results justifies plasma antibody test result, according to Landsteiner rule.
In case of any discordance, forward the sample to the competent blood transfusion center or department.

Limitations of the method:
In case of newborns the reaction with AB0 cells may not be present, however the child's antibody evolves only after 3 months age. Weak or even negative reactions inducing discordance between the red blood cell and plasma tests may be observed in neonatal subjects, because of their inactive antibody production. The absence of Anti-A/-B can also be experienced in the case of (congenital or acquired) immunocompromised patients.
If the serum to be tested does not contain the antibody corresponding the Landsteiner rule further examinations are to be made, or the diagnosis should be cleared up with the consultant.
The intensity of the reactions obtained may vary patient by patient, moreover may vary seasonally in case of the same patient as well. If the reactions are in strict accordance with Landsteiner rule they should be accepted independently from their strength. Unexpected positive reaction may point to the presence of irregular antibodies (anti-A_1, anti-H or else IgM type allo- or autoantibody) in the serum/plasma. Such results should be further examined.
Turbidity, change in colour or haemolysis may point to bacterial or other contamination. The reagent with these characteristics cannot be used anymore.

Precautions:
All reagents of human origin and all substrates that have come into contact with the samples must be handled as potentially infectious materials.
Red Blood Cell concentrates, and the plasma used in Rea IQC Total Blood Kit has been tested by the Hungarian Blood Transfusion Service under the operative decree 3/2005. (II. 10.) EüM regarding blood products for transfusion. All human blood products used in production were found non-reactive for Lues, HIV1-2, HbsAg and HCV by procedures recommended by the European Council, however, none of the methods currently known can absolutely guarantee that the products do not contain any transmissible pathogen.
It is recommended to wear gloves and safety goggles.
Special protective measures, conditions for waste disposal and disinfection should be implemented following local regulations.

Packaging:
4 x 10 ml (REF 42170)

Bibliography:
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