INSTRUCTIONS FOR USE

ReaCell AB0 test cells
3 ± 1% suspension
for Manual and Automated Test Tube Technique

IVD CE 1011

REF 42150. 42151. 42152. 42153. 42154. 42180. 42190. 42200. 42210. 42220. 42230. 42240

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 acceptable result as well, however if it makes the evaluation doubtful the reaction can be modified towards agglutination by changing circumstances of the reaction. On the basis of results gained by reactions with anti-A / anti-B reagents 4 blood groups of the AB0 system can be differentiated:

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; by 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 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 3 ± 1 % ready-to-use suspension and are packaged in 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:
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:
Manual test tube technique:
- test tube 12x75 mm
- test tube rack
- pipettes (25 µl, 50 µl)
- laboratory centrifuge

Procedure:
Manual test tube technique:
1. Gently shake the AB0 test cells, to obtain homogeneous suspension.
2. For each sample test mark one or more special test tubes, with the sample number and the test cell name as many the ReaCell AB0 kit contains.
3. Add 100-100 µl (2-2 drops) of sample of centrifuged plasma to each test tubes.
4. Add 50-50 µl (1-1 drop) of appropriate test cells to the right test tube.
5. Shake gently the test tubes to homogenize the suspensions.
6. Incubate the test tubes on room temperature for 10 minutes. Centrifuge the test tubes on 3000 RPM for 20 seconds.
7. Shaking gently the test tube, we can observe the agglutination. If the red blood cells are agglutinated in one or more clots the reaction is resulted positive, if the suspension remains homogenous the reaction result is negative. Please take a note of results.

Evaluation:
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 those of 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:
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 (doctor).
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 other IgM type allo- or autoantibody) in the serum/plasma. Such result 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 in accordance with 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 in accordance with local regulations.

Packaging:

4 x 5 ml (REF 42210) A_1,A_2,B,0	2 x 10 ml (REF 42180) A_1,B
4 x 10 ml (REF 42150) A_1,A_2,B,0	3 x 10 ml (REF 42190) A_1,A_2,B
10 ml (REF 42151) A_1	3 x 10 ml (REF 42200) A_1,B,0
10 ml (REF 42152) A_2	2 x 5 ml (REF 42220) A_1,B
10 ml (REF 42153) B	3 x 5 ml (REF 42230) A_1,A_2,B
10 ml (REF 42154) 0	3 x 5 ml (REF 42240) A_1,B,0

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.

REAGENS Kft.
Wysocki u. 1,
Budapest 1155, Hungary

Date: 2023.08.18.
Version: 17v

INSTRUCTIONS FOR USE

ReaCell AB0 test cells
0,8 ± 0,1% suspension
for Micro Technique

IVD CE 1011

REF 42500. 42520. 42521. 42522. 42523. 42524. 42530. 42540. 42550. 42560. 42570. 42580

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

Intended purpose – 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 acceptable result as well, however if it makes the evaluation doubtful the reaction can be modified towards agglutination by changing circumstances of the reaction. On the basis of results gained by reactions with anti-A / anti-B reagents 4 blood groups of the AB0 system can be differentiated:

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; by 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 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 0,8 ± 0,1 % ready-to-use suspension and are packaged in 5 or 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:
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, making the results doubtful.

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

Required reagents and equipment:
Micro technique:
- U-well microplate
- pipettes (25 µl, 50 µl)
- microplate shaker
- microplate centrifuge
- reader mirror, or automated reader
- 1 % of Na_2EDTA solution

Gel column technique:
- neutral card
- pipettes (25 µl, 50 µl)
- gel card centrifuge

Procedure:
Microplate technique:
Before use, let the microplate and the AB0 test cells reach room temperature.
1. Shake the AB0 test cells gently, to obtain homogeneous suspension.
2. Mark or label the microplate with an identifier.
3. If we are using native blood sample, drop 25-25 µl of 1% Na_2EDTA solution in each well, and add 50-50 µl of sera to the right place. In case of using anticoagulated blood sample sera, EDTA solution is not needed.
4. Add 50-50 µlof A_1, A_2, B, 0 test cells to the right well.
5. Shake the plate on the highest grade for 1-2 minutes, and incubate at room temperature for 10 minutes.
6. Centrifuge the plate on 1000 RPM for 3 minutes.
7. To read the result, shake the plate in steps,
   - for 2 seconds shake the plate on the highest grade,
   - for 1-3 seconds on middle grade,
   - for 1 minute on the lowest grade to gather the agglutinates.
8. The result can be read macroscopically with reader mirror, or with automated reader.

If the red blood cells are agglutinated in one or more clots, the reaction is positive. If the suspension remains homogenous, the reaction is negative.
Note: In case of micro technique, there is no differentiation on testing cells and testing sera, however the Rh(D) determination is done at the same time on the same plate. The actual IFU explains only the AB0 test cells reactions and evaluations.

Gel column technique:
Before use, let the microplate and the AB0 test cells reach room temperature.
1. Shake the AB0 test cells gently, to obtain homogeneous suspension.
2. Mark the card and remove the foil.
3. Drop 50-50 µl of A_1, A_2, B, and 0 test cells into the right gel chamber.
4. Add 25-25 µl sera to each drop.
5. Incubate the gel card at room temperature for 10 minutes.
6. Centrifuge for 10 minutes.
7. Read the result and register.

The reaction is negative, when all the red blood cell are gathered in the bottom of the gel chamber. All reactions, which are on the top of the gel chamber (++++), or are in the middle of the gel chamber are positive.

Evaluation:
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.
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4 x 10 ml (REF 42520) A_1,A_2,B,0	3 x 10 ml (REF 42540) A_1,A_2,B
10 ml (REF 42521) A_1	3 x 10 ml (REF 42550) A_1,B, 0
10 ml (REF 42522) A_2	2 x 5 ml (REF 42560) A_1,B
10 ml (REF 42523) B	3 x 5 ml (REF 42570) A_1,A_2,B
10 ml (REF 42524) 0	3 x 5 ml (REF 42580) A_1,B,0

Bibliography:

Gál Gy. – Szabó J. (szerk): Transzfúziós alapismeretek és transzfúziológiai szabályzat, SZOTE Vértranszfúziós Intézet, Szeged, 1998.
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