ABO & RhD Blood Grouping Kit
(Dot-filtration method)

Instructions for use | IVD | For in vitro diagnostic use only.

REF | A11001001 | Σ | 25 Tests

【Product Name】

ABO & RhD Blood Grouping Kit (Dot-filtration method)

【Intended Use】

This kit is used for qualitative detection of the antigens of the ABO and D antigen of Rh blood group systems on human red blood cell in whole blood or 10% red cell suspensions in physiological saline, the test is applicable to everybody (including infants and pregnant women etc.).

⚠ ***For professional use only.***

【Summary】

The ABO Blood Group System

In 1900, Karl Landsteiner discovered that the serum of some individuals would agglutinate the red cells of others and that this phenomenon could be used to classify individuals into different blood group phenotypes. Four common phenotypes are recognized – O, A, B and AB. Subgroups of the A and B antigens have since been identified. The ABO phenotype of an individual is usually determined by the agglutination reactions of the individual's red cells with Anti-A, Anti-B and Anti-A, B antisera (forward grouping). In testing blood samples from adults, confirmation of the ABO blood group can be provided by the reactions of the individual's plasma with standard A and B red cells suspensions (reverse grouping).

The Rh Blood Group System

The observations of Levine and Stetson in 1939 and Landsteiner and Weiner in 1940 provided the basis for current understanding of the clinical significance and laboratory detection of Anti-D. Approximately 15% of Caucasians and 0.3% of Asian Han ethnic group lack the RhD antigen and are easily stimulated by an RhD positive pregnancy or blood transfusion to produce anti-D. This may cause haemolytic disease of the newborn or severe haemolytic transfusion reactions.

Weak and Partial D

The term weak D, denotes individuals with a reduced number of entire D antigen sites per red cell. The term partial D, signifies individuals with missing D epitopes. D category VI (DVI) lacks the most D epitopes with extremely weak D antigenicity. D^{VI} receptors are normally treated as D negative receptors for safety when receiving blood transfusion.

【Test Principle】

The test is based on the principle of antigen-antibody immunoabsorption. The monoclonal anti-A、anti-B and anti-D are immobilized respectively on the porous solid carrier. When the red blood cells (RBC) in sample react with the solid carrier, the RBC can be captured on solid carrier as a red signal, indicating that the test is positive. if there is no immune response, the RBC will not be captured, and the absence of the red signal indicates that the test is negative.

【Main Components】

The following components are included in the ABO & RhD Blood Grouping Kit Rapid Test Kit:

Supplied materials:

Component	Main Ingredients	Quantity
Test Cartridge	1) Blue fiberglass coated with anti-A monoclonal antibodies (murine IgM antibody,cell line BIRMA-1); 2) Yellow fiberglass coated with anti-B monoclonal antibodies (murine IgM antibody, cell line LB-2); 3) Red fiberglass coated with anti-D monoclonal antibodies (human IgM antibody, cell line RUM-1)	25 PCS
Sample diluent	Na2HPO4·12H2O: 3.152mg/mL NaH2PO4·2 H2O: 0.187mg/mL NaCl：8.5mg/mL Proclin 300: 0.1%	7ml/ vial *2
Disposable Pipettes	10μL	25 PCS
IFU	/	1 PCS

Optional Materials:

1. Sterile lancets (for Fingerstick Whole Blood only)
2. Alcohol pads (for Fingerstick Whole Blood only)

Materials Required but not Provided:

1. Clock or timer
2. Blood collection devices
3. Disposable gloves

【Storage Conditions and Shelf Life】

Component	Storage- Temperature limitation	Stability
Test Cartridge		1) This kit shall be stable for 24 months stored in sealed and dry environment at 2~30℃。 2) After being taken out from aluminum foil bag, the test card shall be used within 1 hour at 2~30℃ and less than 80% humidity.
Sample diluent		The buffer is stable up to 24 months. Please refer to use-by date on the label.

⚠【Warnings and Precautions】

1. All blood products should be treated as potentially infectious. The murine sources, human donors or the cell lines used to produce these reagents have been tested and certified disease free. No known tests can guarantee that any product derived from human blood is free from infectious agents. All reagents and samples shall be handled as pollution source.
2. For fingertip blood without anticoagulant, the sample diluents must be added at 1 minute after the loading of specimen. Since the specimen does easily clot, delay of adding sample diluents will impact the test result.
3. Do not use expired kits.
4. Do not reuse the card and other disposable components in this kit..

【Specimen Collection and Preparation】

1. Applicable sample types: human venous whole blood (with anticoagulant)/fresh fingertip blood/10% red cell suspensions in physiological saline.

Some instructions for the specimens:

1) Whole blood sample with anticoagulant, including venous blood and fingertip peripheral blood, shall be stored at 2-8℃ when not tested and shall be tested within 72 hours. EDTA and sodium citrate are recommended as anticoagulant, other anticoagulants may impact test results.

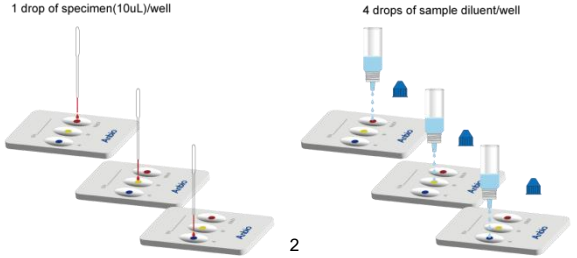
2) Fingertip peripheral blood without anticoagulant: must be tested within 1 minute after being sampled.

3) 10% red blood cell suspension in physiological saline is valid within 24 hours. Preparation: Centrifuge the whole blood containing anticoagulant after being washed 3 times, then add 9 volumes of normal saline to 1 volume of packed red blood cell.

2. The venous whole blood and fingertip blood should be collected in aseptic condition, avoid the specimen with hymolysis, hyperlipidemia and hyperbilirubinemia.

【Test Procedure】

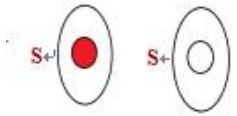
1. Prepare specimens, balance refrigerated specimens to room temperature and mark all the specimens.
2. Remove the test card from the foil pouch, refrigerated kit must be balanced to room temperature; open the aluminum foil pouch and take out the card to the test table.
3. Add 1 drop of specimen into each well in S well with the disposable dropper (if a pipettor is used, add 10μl to each well); 1 minute later, immediately add 4 consecutive drops of sample diluent to each well in S well;If fingertip peripheral blood without anticoagulant is used,after adding sample,immediately add sample diluent.
4. 1 minute later, observe result in S well. Do not observe test result after 30 minutes.



【Limitations of Procedure】

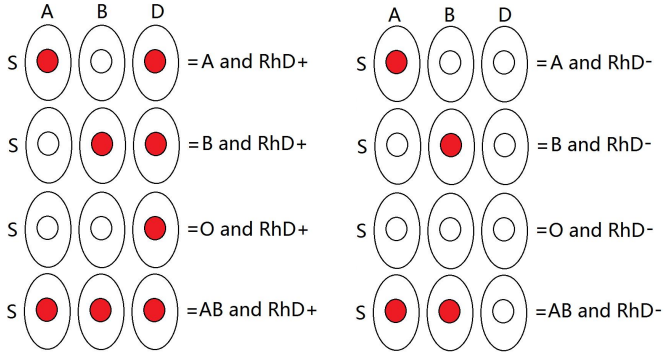
1. Too few antigen sites on red blood cells of the subject (e.g. subgroups), weakened antigenicity (e.g. in leukemia or malignant tumor), or improper antigen-antibody proportion causes inconspicuous reaction. Reaction time shall be extended to 2 minutes after sample loading is finished.
2. For any patient with positive anti-human globulin test (Coombs test), hemolytic disease of the newborn or acquired hemolytic anemia, their red blood cells surfaces absorb antibody globulins, which interfere with the identification of blood group. So absorption-elution tests shall be performed in these cases.
3. The following specimens should be wash 2-3 times with 37 ℃ physiological saline, then prepared to be 10% red cell suspension.
1) Containing too much cryoagglutinin;
2) Whole blood sample with Bilirubin, Cholesterol, Hemoglobin and Triglyceride beyond concentration limit (refer to Table 2)
3) Chylus whole blood sample
4) Containing more than 50% red blood cell
5) Containing less than 10% red blood cell
4. ABO blood grouping needs a reverse grouping at the same time (to test the antibodies in plasma with A1 and B red blood cells); the final blood group will be confirmed when the forward grouping and reverse grouping results are consistent. If not, other reagents and methods shall be used to confirm the blood group.
5. This kit can detect most Ax samples and Weak D and partial D samples. This kit cannot detect D^{VI}. If all the weak D and partial D samples need to be detected, the negative results shall be examined by other methods.

【Interpretation of Results】



Positive Negative

The results interpretation diagram of ABO & RhD Blood Grouping Test



【Performance Characteristics】

1. Antibody titer before lyophilization (Table 1):

Antibody	Red blood cell	Titer
Anti-A monoclonal antibody	A_1	≥1：128
	A_2	≥1：32
	A_2B	≥1：16
Anti-B monoclonal antibody	B	≥1：128
Anti-D monoclonal antibody	RhD positive	≥1：64

2. If following substances are within the concentration limit, hemolysis, jaundice and hyperlipidemia will not interfere with test results (Table 2)

Name	Bilirubin	Cholesterol	Hemoglobin	Triglyceride
Concentration limit	600.0μmol/L	41.6mmol/L	5.0g/L	28.8mmol/L

3. A performance assessment of the reagents was conducted on 3251 blood samples from blood donors drawn using the recommended EDTA anticoagulant. The study showed 100 % specificity and accuracy in common ABO-D phenotypes.

【Index of Symbols】

IVD	In vitro diagnostic medical device		Do not re-use
	Do not use if package is damaged and consult instructions for use		Consult instructions for use or consult electronic instructions for use
	Caution		Manufacturer
30℃ 2℃	Temperature limit	LOT	Batch code
	Use-by date		Keep dry
	Keep away from sunlight	REF	Catalog number
	Date of manufacture	Σ	Contains sufficient for <n> tests

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