







50 Raffles Place Level 30 Singapore Land Tower Singapore 048623 +65 6632 3781 +65 8368 0800 +65 6637 8880



Purpose

The Blood Grouping Kit (Solid-phase method) can be used for the regular RhD blood group detection.

Test Principle

The assay starts with a sample applied to the sample well and add sample diluents provided. The monoclonal anti-A, anti-A and anti-B immobilized respectively on the pad in sample region can react with the corresponding antigen on the surface of the red blood cells (RBC). A positive sample produces an immune response and the RBC can be captured on the sample region as a red signal, indicating the test is positive. A negative sample does not produce an immune response, after adding sample diluents, the RBC can be washed away and the absence of the RBC indicates that the test is negative.

Reagents and Materials Provided

- 1. Test cards individually foil pouched with a descicant.
- 2. Disposable plastic dropper
- 3. Sample diluents
- 4. Package insert

Storage and Stability

The kit must be stored at $2\sim 30^{\circ}$ C in the sealed pouch under dry conditions

Validity: 24 months

Sample Collection

1. The kit is applicable to fresh whole blood samples.

2. The collection of whole blood samples should be carried out under sterile conditions and the samples must be avoided with hemolytic.

3. Add sample request: whole blood samples 5µl/well.

Before Testing

1. Read carefully and following all instructions strictly in the package insert when testing.

2. Bring the device, sample diluents and specimens to room temperature.

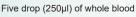
3. Remove test card from the sealed pouch.

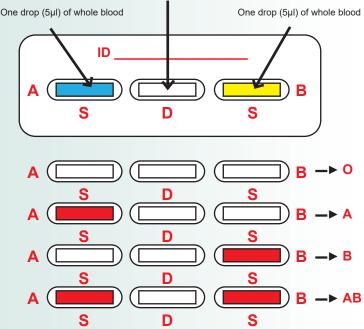
Assay Procedures

1. Suck the whole blood with plastic dropper and add one drop (5μ) of whole blood in easch "S" well of the test card 2. Add five drop (250μ) of sample diluents to each "D" well in one minute after the specimen is added.

3. Interpret test results in one minute on "S" well

Reading the Result





Limitations

ABO blood group should be tested both by blood grouping reagents and reverse grouping reagents. If the testing results are not conforming, further experiment is requested.

This anti-D used in ABO & RhD Blood Grouping kit is monoclonal antibody and cannot react with D^{VI} variants.

Warning and Precautions

- 1. This test kit is for In-Vitro Diagnostic only.
- 2. The sample should be fresh whole blood samples.
- 3. The plastic dropper provided is for one-time use.
- 4. Do not open the foil pouch until the sample is collected and ready for testing.

5. If specimens contain too much cold agglutinin, this will cause false positive. In this case, please wash the specimens 2-3 time with 37°C physiological saline to remove the cold agglutinin, then identify the blood group.

6. If antigenic sites on red blood cells are too less (for example, subtype) or antigenicity weakened (such as leukemia or malignant); or undue proportion of antigen-antibody and so on, these situations can easily cause false negative.

7. Only samples that are clear and with good fluidity and without particles and floc can be used in this test because such things will lead to RBC stay in the sample region and misidentified as positive.



50 Raffles Place Level 30 Singapore Land Tower Singapore 048623 ISO 13485 Certified

> +65 6632 3781 +65 8368 0800

> > +65 6637 8880

