## iCare Advanced ABO & RhD Blood Typing Rapid Test (Lateral Flow Assay)

| REF | GS110801C01 | GS110801C25 |
|---|---|---|

***A rapid test for qualitative detection of ABO and RhD blood typing using fresh whole blood samples. For professional in vitro diagnostic use only.***

### 【INTENDED USE】

The ABO & RhD Blood Typing Rapid Test is a lateral flow immunoassay intended for the qualitative detection of human ABO and RhD blood typing in fresh fingertip blood, venous anticoagulant whole blood or red blood cell suspensions.

### 【TEST PRINCIPLE】

The ABO & RhD Blood Typing Rapid Test applies immune chromatography for testing, the sample will be under the capillary action to move forward along the test card, and the red blood cells will be captured by the monoclonal anti-A, anti-B and anti-D immobilized respectively in nitrocellulose membrane indicating that the test is positive. The test card also contains a quality control line (C), which shall appear in magenta regardless of whether there is a line or not.

### 【MATERIALS PROVIDED】

| Contents | 1 Test /Kit | 25 Tests /Kit |
|---|---|---|
| | GS110801C01 | GS110801C25 |
| Test card individually foil pouched with a desiccant | 1 | 25 |
| Disposable plastic dropper | 1 | 25 |
| Sample diluent | 1 | 2 |
| Package insert | 1 | 1 |

### 【AVAILABLE UPON REQUEST】

1. Alcohol swab;
2. Blood sampling Lancet;
3. Timer

### 【MATERIALS REQUIRED BUT NOT PROVIDED】

Biohazard Container, Timer, Protective Gloves

### 【STORAGE AND STABILITY】

1. The test kit should be stored at a temperature between 2-30 °C. Do not freeze the kit or its components.
2. The shelf life of the kit is as indicated on the outer package (24 months from date of manufacture).
3. This test kit is stable until the expiration date marked on the outer package and foil pouch. Ensure all test components are at room temperature (15-30°C) before use.
4. Perform the test immediately after taking out the test card from the foil pouch.

### 【WARNINGS AND PRECAUTIONS】

1. This test kit is for *in vitro* diagnostic use only.
2. Do not reuse the test card and kit components.
3. These instructions must be carefully read and strictly followed by a trained healthcare professional to achieve accurate results. All users have to read the instructions before performing test.
4. The sample should be fresh whole blood samples. Do no use hemolytic samples which may generate false test result.
5. Do not open foil pouch until the sample is collected and ready for testing.
6. Do not mix or interchange different specimens.
7. Do not mix reagent of different lots or those for other products.
8. Do not store the test kit in direct sunlight.
9. If specimens contain too much cold agglutinin, it will cause false positive. In this case, wash the specimens 2-3 times with 37℃ physiological saline to remove the cold agglutinin, then identify the blood group.
10. 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 could easily cause false negative.
11. Only samples that are clear and with good fluidity, and without particles and floc, can be used in this test, or it may result in RBC staying in the sample region, and misidentified as positive test result.
12. Dispose used test card in suitable biohazards waste container.

### 【SAMPLE COLLECTION】

1. Using standard venous phlebotomy procedure, collect a whole blood sample using a tube containing any of the following anticoagulants: EDTA, heparin, or sodium citrate. Other anticoagulants have not been tested and may give an incorrect result. If the specimens are not tested at the time of collection, the whole blood can be stored at 2°C -8°C for 3 days. Before testing, mix the blood tube gently by inversion several times to ensure a homogeneous sample.
2. Excessive or low concentrations of red blood cells in the sample can lead to abnormal results. A whole blood sample with red blood cell concentration of 20%-60% is recommended.
3. For the following samples, physiological sodium chloride solution is needed to wash the red blood cells of the subjects 2-3 times, and normal AB plasma (supernatant centrifuged at 2000rpm for 3min) is used to prepare 50% red blood cell suspension, and then the blood group is detected:
   (1) Samples containing more cold agglutinins (need to be washed with physiological sodium chloride solution at 37℃);
   (2) Samples containing more fibrin;
   (3) Whole blood samples with cholesterol, triglyceride, hemoglobin or bilirubin concentrations higher than those in the table as below:

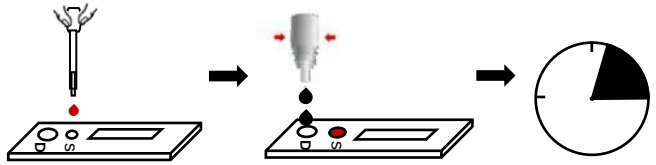
| Cholesterol | Triglyceride | Hemoglobin | Bilirubin |
|---|---|---|---|
| 41.6mmol/L | 57.6mmol/L | 20.0g/L | 0.6mmol/L |

   (4) Whole blood samples with red blood cell concentration lower than 20% or higher than 60%.
4. Red blood cells of patients with positive anti-human globulin test (Coombs Test), neonatal hemolytic disease or acquired hemolytic anemia interfere with the identification of blood type because antibody globulin is adsorbed on the surface of red blood cells. In such a case, absorption-elution test should be carried out.

### 【TEST PROCEDURE】

Do not open the foil pouch until just before use, and the test is recommended to be used under low humidity (RH≤70%) environment.

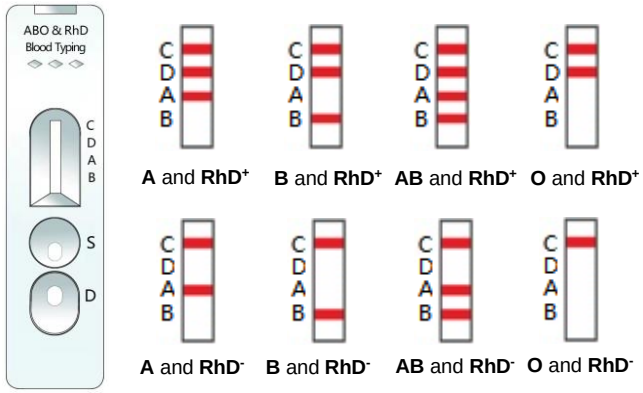
1. Equilibrate all kit components and specimens to room temperature (15-30ºC) prior to testing.
2. Take out the test card from the foil pouch and place on a clean dry surface.
3. Identify the test card for each specimen.
4. Suck the sample with plastic dropper, and add one drop (10μl) of sample in the “S” well of the test card.
5. Add two drops of sample diluents to the “D” well after the specimen is added.
6. Read the results at 2–15 minutes: a strong positive result can be interpreted within 2 minutes, but a negative result must be interpreted after 15 minutes, and the result after 15 minutes is no longer valid.




Add one drop (10μl) of sample in “S" well. Add two drops of sample diluents in “D” well. Interpret the result at 2-15 minutes.

⚠ **Caution**: Use a new clean dropper for every sample to avoid cross-contamination.

### 【INTERPRETATION OF TEST RESULTS】




⚠ **Caution:**

1. The band in the Test Line (D/A/B) can show the color depth. However, within the specified observation time, regardless of the color of the ribbon, even a very weak ribbon should be judged as a positive result;
2. Invalid Result: If the Quality Control Line (C) is not observed, the test result would be invalid regardless of whether the Test Line (D/A/B) is displayed or not.

### 【LIMITATIONS】

1. ABO blood group should be tested both by blood typing reagents and reverse typing reagents. If the testing results are not conforming, further experiment is required.
2. The anti-D used in ABO & RhD Blood Typing Rapid Test is monoclonal antibody and cannot react with DVI variants.
3. Excessive or low concentrations of red blood cells in the sample can lead to abnormal results. A whole blood sample with red blood cell concentration of 20%-60% is recommended.

### 【REFERENCES】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3. Titlestad K, Georgsen J, Andersen H, et al. Detection of irregular red cell antibodies: more than 3 years of experience with a gel technique and pooled screening cells [J]. Vox Sang, 1997, 73(4): 246.
4. Parker PI, Scott Y, McArdle B, et al. Automated blood grouping by gel technology [J]. Br J Biomed Sci ,1995, 52(4): 266.

**【INDEX OF SYMBOLS】**

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|---|---|---|---|
| | Consult instruction for use | IVD | For *in vitro* diagnostic use only |
| | Temperature limit | REF | Catalog number |
| | Do not reuse | LOT | Lot number |
| | Manufacturer | | Use By |
| | Date of manufacture | | Contains sufficient for <X> tests |
| | Do not use if package is damaged | | Keep dry |
| | Caution | | Keep away from sunlight |

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