



ABO Blood Grouping RapiCard™ InstaTest (Whole Blood)

REF 201012

PIC BG201012VV86



ABO Blood Grouping RapiCard™ InstaTest

| | |
|-----------|--------------------|
| Principle | Solid Phase Method |
| Detection | Qualitative |

PRODUCT FEATURES

- High Sensitivity and Specificity
- Built in Internal Controls
- Simplified Workflow, Non-invasive, and Safe
- Rapid and Faster Results

INTENDED USE

The ABO Blood Grouping Rapid Test Cassette (Whole Blood) is a solid-phase method test cassette for the regular ABO blood group detection. The test is intended for professional use to help diagnose the blood type.

SIGNIFICANCE AND SUMMARY

Human blood has a variety of blood types, and the most common blood type system is ABO (blood types are divided into A, B, AB and O types according to the presence or absence of A and B antigens in red blood cells). When the corresponding antigens and antibodies of ABO blood group meet, red blood cells will have agglutination reaction, resulting in red blood cell hemolysis, which is life-threatening. Therefore, ABO blood group identification, or ABO blood group antigen test, is an important prerequisite for ensuring safe blood transfusion and avoiding related diseases.

The ABO Blood Grouping Rapid Test Cassette (Whole Blood) is a solid-phase method test cassette for the regular ABO blood group detection.

ASSAY PRINCIPLE

The assay starts with a sample applied to the Specimen well (S) and add provided washing buffer later to the “Buffer” well. The monoclonal anti-A, 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 that the test is positive. A negative sample does not produce an immune response, after adding washing buffer, the RBC can be washed away, and the absence of the RBC indicates that the test is negative.

SPECIMEN COLLECTION AND STORAGE

The ABO Blood Grouping Rapid Test Cassette (Whole Blood) can be performed using whole blood from venipuncture or fingerstick.

To collect Fingerstick Whole Blood Specimens:

- Wash the hand with soap and warm water or clean with an alcohol pad. Allow to dry.
- Massage the hand without touching the puncture site by rubbing down the hand towards the fingertip of the middle or ring finger.
- Puncture the skin with a lancet. Wipe away the first sign of blood.
- Gently rub the hand from wrist to palm to finger to form a rounded drop of blood over the puncture site.
- Add 1 drop of fingerstick Whole Blood specimen to the each “S” well by using dropper provided.

The Venipuncture Whole Blood specimens:

- Whole blood collected by venipuncture should be stored at 2-8°C if the test is to be run within 2 days of collection. Do not freeze whole blood specimens.
- If specimens are to be shipped, they should be packed in compliance with local regulations covering the transportation of etiologic agents.
- EDTA K2, Heparin Sodium, Sodium Citrate and Potassium Oxalate can be used as the coagulant tube for collecting the blood specimen.

REAGENTS

The test contains monoclonal anti-A and monoclonal anti-B coated particles.

Materials provided with the kit

- Test Cassettes
- Droppers



- Washing Buffer
- Package Insert

Materials required but not provided

- Timer
- Lancets
- Pipette
- Alcohol Pads

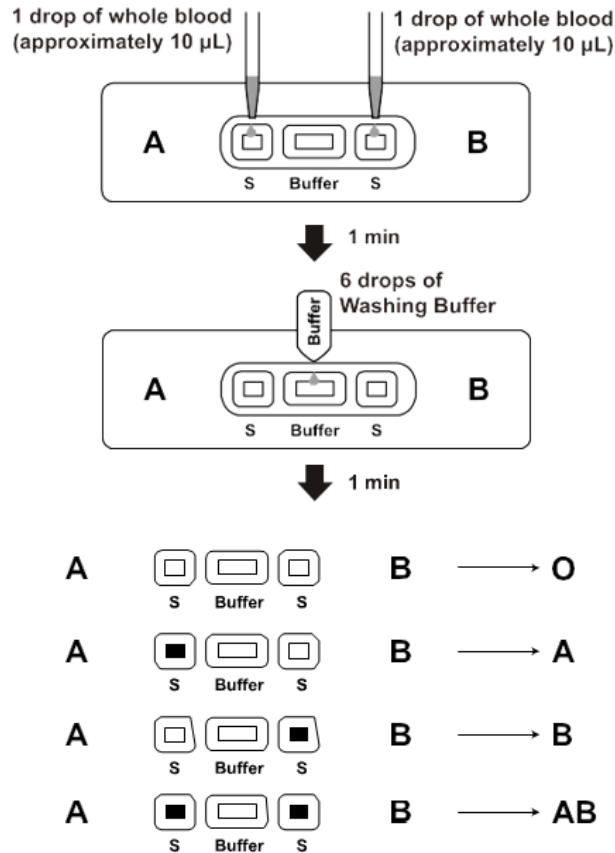
ASSAY PROCEDURE

Allow the test, specimen, buffer and/or controls to reach room temperature (15-30°C) prior to testing.

1. Remove the test cassette from the sealed foil pouch and use it as soon as possible. Best results will be obtained if the assay is performed within one hour.
2. Place the cassette on a clean and level surface.
3. Hold the dropper vertically and transfer **1 drop of whole blood** (approximately 10 µL) to each “S” well of test cassette. See illustration below.
4. Add **6 drops (approximately 420 µL)** of washing buffer to “Buffer” well in **1 minute** after the specimen is added.
5. Interpret test results in **1 minute** on “S” well. Do not interpret the result after 30 minutes.

Note: If a small amount of red blood cells is observed in the “S” well at reading time, please add 2-3 drops of washing buffer to “Buffer” well and read the results immediately.

Note: It is suggested not to use the buffer, beyond 6 months after opening the vial.



RESULTS

| Monoclonal anti-A | Monoclonal anti-B | Results (Blood Phenotype) |
|-------------------|-------------------|---------------------------|
| - (White) | - (White) | O |
| + (Red) | - (White) | A |
| - (White) | + (Red) | B |
| + (Red) | + (Red) | AB |

LIMITATIONS OF THE ASSAY

1. It is possible that technical or procedural errors, as well as other interfering substances in the whole blood specimen may cause erroneous results.
2. The results of this test are not the only basis for the determination of blood type in clinical practice.
3. For the following samples, it is necessary to wash the red blood cells of the subject with 37 °C normal saline for 2-3 times, prepare 20% red blood cell suspension, and then detect the blood type:
 - Specimens containing more cold agglutinins;
 - Chylous whole blood sample;
 - Whole blood samples with erythrocyte content higher than 50%;
 - Whole blood samples with excessive concentrations of bilirubin, lipids and hemoglobin (>800µmol/L of bilirubin; >5g/L of hemoglobin; >50 mmol/L of triglyceride; >100 mmol/L of cholesterol).
4. The reasons of too few antigenic sites (such as subtype), weakened antigenicity (such as leukemia or malignant tumor), inappropriate proportion of antigen and antibody on the red blood cells of the subjects make the reaction not obvious. After adding the samples, the reaction time needs to be prolonged.
5. For people with positive Coombs Test, hemolytic disease of newborn or acquired hemolytic anemia, the identification of blood group is disturbed because of the adsorption of antibody globulin on the surface of red blood cells. In such cases, absorption and diffusion test is needed.

EXPECTED VALUES

The ABO Blood Grouping Rapid Test Cassette (Whole Blood) has been compared with other commercial test, demonstrating an overall accuracy of >99.9%.



PERFORMANCE CHARACTERISTICS

Accuracy

The ABO Blood Grouping Rapid Test Cassette (Whole Blood) has been compared with another commercial test. The following results were tabulated:

For ABO Test:

| Method | Results | Other Commercial Test | | | | Total Results |
|-----------------------------------|---------|-----------------------|--------|---------|--------|---------------|
| | | Type A | Type B | Type AB | Type O | |
| Rapid Test Cassette (Whole Blood) | Type A | 401 | 0 | 0 | 0 | 351 |
| | Type B | 0 | 304 | 0 | 0 | 354 |
| | Type AB | 0 | 0 | 124 | 0 | 124 |
| | Type O | 0 | 0 | 0 | 371 | 371 |
| Total Results | | 401 | 304 | 124 | 371 | 1200 |
| Accuracy | | >99.9% | >99.9% | >99.9% | >99.9% | >99.9% |

Precision

Intra-Assay

Within-run precision has been determined by using 3 replicates of four specimens: Type A, Type B, Type AB and Type O specimens. The specimens were correctly identified >99% of the time.

Inter-Assay

Between-run precision has been determined by 3 independent assays on the same 4 specimens: Type A, Type B, Type AB and Type O specimens. Three different lots of the ABO Blood Grouping Rapid Test Cassette have been tested using these specimens. The specimens were correctly identified >99% of the time.

Interfering Substances

The ABO Blood Grouping Rapid Test Cassette (Whole Blood) has been tested for the following potentially interfering substances, spiked with Type A, Type B, Type AB and Type O negative specimens.

Bilirubin: 800µmol/L
 Hemoglobin: 5g/L
 Cholesterol: 100mmol/L
 Triglyceride: 50mmol/L
 None of the substances at the concentration tested interfered test results of the assay.

PRECAUTIONS

Please read all the information in this package insert before performing the test.

- For professional in vitro diagnostic use only. Do not use after the expiration date.
- The test should remain in the sealed pouch until ready to use.
- All specimens should be considered potentially hazardous and handled in the same manner as an infectious agent.
- The used test should be discarded according to the local regulations.
- Please make sure that an appropriate amount of samples are used for testing. Too much or too little sample size may lead to deviation of results.
- As this product is visual inspection, please do not interpret in dim light to ensure accurate results.

STORAGE AND STABILITY


Store as packaged at room temperature or refrigerated (2-30°C). The test is stable through the expiration date printed on the sealed pouch. The test must remain in the sealed pouch until use. DO NOT FREEZE. Do not use beyond the expiration date.

REFERENCES

- Mitra R, Mishra N, Rath GP. Blood groups systems. Indian J Anaesth. 2014; 58(5): 524-28.
- Sinor LT, Rachel JM, Beck ML, Bayer WL, Coenen WM, Plapp FV. Solid-phase ABO grouping and Rh typing. Transfusion. 1985; 25(1): 21-3.
- Ching E. Solid phase red cell adherence assay: A tubeless method for pretransfusion testing and other applications in transfusion science. Transfus Apher Sci 2012; 46: 287- 91.
- Uthemann, H., Prager, E.M, Sturfels, L., Lenhard, V. A new solid phase method for ABO grouping, Rh phenotyping and Kell determination. Infus Ther Transfus Med. 1999; 26: 244-6.

MANUFACTURER AND BRAND DETAILS

ISO 13485:2016



bsi
ISO 13485
Quality Management for Medical Devices
CERTIFIED

Diagnostic Automation/Cortez Diagnostics, Inc.
 21250 Califa Street, Suite 102 and 116,
 Woodland Hills, California 91367 USA

| | |
|----------------------------------|--|
| Date Adopted | 2024-06 |
| Brand Name | RapiCard™ InstaTest |
| REF 201012 | ABO Blood Grouping RapiCard™ InstaTest (Whole Blood) |
| PIC | BG201012VV86 |
| Revision Date: 02-18-2020 | |