血型二代说明书(条型)
210x297mm、70g双胶纸、双面彩色印刷、对折
01.05.03.1511-221204

CMYK:10/100/80/25

CMYK:0/0/0/100

InTec PRODUCTS, INC.

01.05.03.1511-221204
REF ITP51003-DS100
ITP51003-DS40

ABO&RhD Blood Grouping Kit (Solid-phase method)

For in vitro diagnostic use only. IVD
Please read the instructions for use carefully prior to use and strictly follow the instructions.

REAGENTS AND MATERIALS PROVIDED

Test strip

Plastic Dropper

Sample Diluent

Instructions for use

COMPONENTS OF THE KIT

REF	Device Type	Sample Diluent		Plastic Dropper
		Main Ingredients	Volume	
ITP51003-DS40	Test Strip Device (individually sealed), 40 tests/kit	10mM phosphate buffer	⩾6ml	⩾40
ITP51003-DS100	Test Strip Device (canister packed), 100 tests/kit		⩾14ml	⩾100

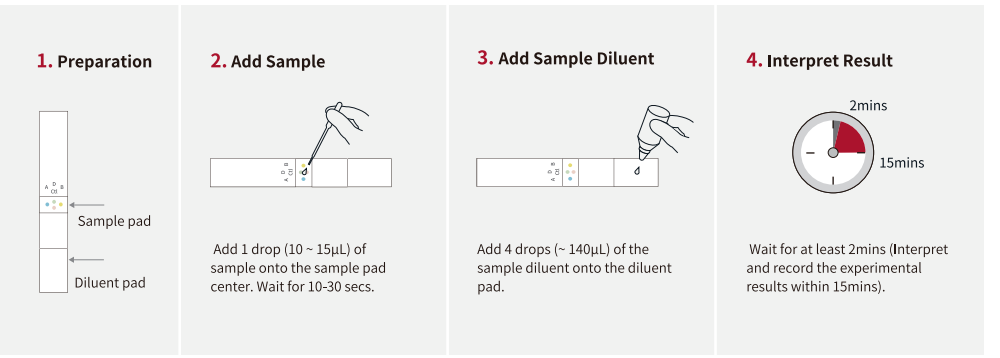
SPECIMEN REQUIREMENTS

1. This product is applicable for fresh finger prick blood / anticoagulated venous whole blood.
2. Fresh fingertip peripheral blood should be used immediately after collection.
3. Human intravenous anticoagulated whole blood samples are recommended to be tested within 72 hours, stored at 2-8°C and not be frozen. Clinically used anticoagulants (EDTA, heparin, citrate) do not affect the test results.

TEST PROCEDURE

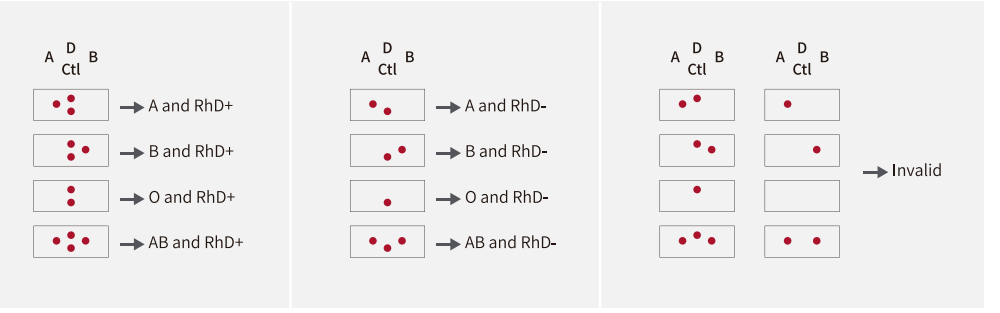
Please read the instructions for use thoroughly before performing any tests. Prior to use, the product should be taken out from the storage condition, equilibrated to room temperature (10~30°C) , placed on a flat surface. Refer to the attached drawings for operation steps.

1. **Preparation:** Refrigerated samples shall be removed from the storage condition and equilibrated to room temperature (10~30°C); Stratified samples should be turned upside down 3 times prior to use, and fully mixed.
2. **Add Sample:** The tested sample should be drawn with a plastic dropper (or pipette) included in the kit. When detecting fresh finger prick blood / anticoagulated venous whole blood, add 1 drop (10~15uL) to the sample pad center, and make sure that the four dots are completely covered.
3. **Add Sample Diluent:** Wait for 10-30 secs after adding sample， then successively add 4 drops (~ 140μL) of the sample diluent (no bubbles) to the diluent pad.
4. **Interpret Result:** After adding the sample diluent for at least 2mins, then observe the results in the sample pad. It is recommended to interpret and record the experimental results within 15mins.



RESULT INTERPRETATION

1. **Positive (+) :** Immune binding reaction occurs between RBC antigen to be detected and corresponding solid blood group antibody, and red dots are shown at the corresponding detection points and Ctl point, indicating a positive reaction. Red dots appear at both detection and Ctl region (even very weak) indicates a positive result.
2. **Negative (-):** No immune binding reaction occurs between the RBC antigen to be detected and the solid blood group antibody, no RBC is captured, red blood cells are completely rinsed out, and a red dot is shown at Ctl point, indicating a negative reaction.
3. **Positive control:** After detection, the red Ctl point in the sample pad were positive control.
4. **Invalid:** Regardless of whether red dots are displayed at points A, B and D, if the red dot is not displayed at Ctl point, the test result is invalid.



LIMITATIONS

1. This product is intended to detect the ABO&RhD blood group antigen, and the detection result alone is not the only basis for clinical determination of blood group.
2. Weak expressions of the D antigen may not be detected, the D^{VI} epitope expression of the D antigen is not detected with this reagent, and further detection is needed when weak reaction and negative reaction occur at D detection point.
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 30%-60% is recommended.
4. Samples with severe hemolysis, hyperlipemia and hyperbilirubinemia should be avoided.

INTENDED USE

The kit is intended to qualitatively detect ABO blood group system A/B antigen and Rh blood group system D antigen in fresh finger prick blood / anticoagulated venous whole blood.
Human blood contains a wide variety of blood groups, of which ABO and RhD are the most common[1,2]. Blood group identification is a crucial test item prior to clinical blood transfusion, and has important clinical significance. When the blood group antigen on the surface of red blood cells comes in contact with the corresponding antibody, red blood cells will undergo agglutination reaction, which will eventually lead to hemolysis of red blood cells and endanger life. As a result, correct identification of ABO and RhD blood group antigens is an essential prerequisite to ensure safe blood transfusion and avoid related diseases.

TEST PRINCIPLE

This product adopts immunochromatography technology to qualitatively detect human blood group antigen by using known blood group antibodies. Firstly, anti-A monoclonal antibody, anti-B monoclonal antibody, anti-D monoclonal antibody and anti-RBC monoclonal antibody are pre-coated on the reaction membrane. When detecting samples, the samples are dripped into the sample pad of the reaction membrane, and then the sample washing solution is dripped into the diluent pad. When different red blood cell antigens in the sample to be detected react with the solid-phase antibody at the pre-coated position, red blood cells are trapped at the fixed detection points on the reaction membrane (i.e., antibody pre-coating points), showing red dots, which are positive reactions, indicating that the surface of red blood cells has corresponding blood group antigens. If no antigen-antibody immune reaction occurs, red blood cells can not be intercepted, but move forward into the absorption pad by chromatography, and the detection point on the reaction membrane does not develop color, which is a negative reaction. Red blood cells should display red at each control point, whether positive or negative, otherwise the experiment is invalid.

STORAGE AND SHELF LIFE

1. Storage conditions: store at 2-30°C, avoiding direct sunlight and high humidity.
2. Shelf life: 24 months after manufacturing date.
3. Canister Packed Test Strip Device: the 25 test strips should be used within 2 months after opening the canister, or discarded after 2 months. Please close the canister cap immediately after taking out the test strip.
4. After the test strip is taken out of the sealed pouch, the test device must be performed within 30mins . Please use immediately in high humidity environment (≥80%RH).

PRODUCT PERFORMANCE

1. The following substances have no influence on the test results at the given concentrations (Table 1).

Substance name	Concentration	Substance name	Concentration
Cholesterol	≤41.6mmol/L	Hemoglobin	≤20.0g/L
Triglyceride	≤57.6mmol/L	Bilirubin	≤0.6mmol/L

2. Clinical Performance

ABO & RhD blood grouping based on different methods (Table 2).

ABO & RhD blood grouping	Method, n (%)		
	Tube	Gel	Solid-phase
O	1026 (37.3)	1026 (37.3)	1026 (37.3)
A	622 (22.6)	622 (22.6)	622 (22.6)
B	748 (27.2)	748 (27.2)	748 (27.2)
AB	354 (12.9)	354 (12.9)	354 (12.9)
RhD Positive	2728 (99.5)	2728 (99.5)	2728 (99.5)
RhD Negative	22 (0.5)	22 (0.5)	22 (0.5)
Total (number of cases)	2750	2750	2750

Among them, special clinical samples are as follows (Table 3).

Disease	Total (number of cases)	100% agreement results with the gold standard tube method
Tumor	9	100%
Leukemia	8	
Anemia	8	
Old man	12	
Infant	12	
Autoimmune disease	11	
Total (number of cases)	60	

Head-To-Head Comparison of blood grouping results between solid-phase method, tube method and gel method, all the methods have 100% agreement results for ABO & RhD blood grouping.

Coincidence rate of positive and negative specimens of solid phase method towards tube method (Table 4).

ABO & RhD blood grouping	Coincidence Rate of Positive Specimens(%)	Coincidence Rate of Negative Specimens (%)	Total Coincidence Rate(%)
O	100 (95%CI*: 99.63%~100.00%)	100 (95%CI*: 99.78%~100.00%)	100 (95%CI*: 99.86%~100.00%)
A	100 (95%CI*: 99.39%~100.00%)	100 (95%CI*: 99.82%~100.00%)	100 (95%CI*: 99.86%~100.00%)
B	100 (95%CI*: 99.49%~100.00%)	100 (95%CI*: 99.81%~100.00%)	100 (95%CI*: 99.86%~100.00%)
AB	100 (95%CI*: 98.93%~100.00%)	100 (95%CI*: 99.84%~100.00%)	100 (95%CI*: 99.86%~100.00%)
RhD	100 (95%CI*: 99.86%~100.00%)	100 (95%CI*: 85.14%~100.00%)	100 (95%CI*: 99.86%~100.00%)

*CI: Confidence Interval

PRECAUTIONS

1. Oxalic acid anticoagulant, coagulant or partially coagulant specimens should not be used for testing.
2. Do not perform the test under environment which leads to rapid evaporation (e.g.＞40°C and ＜40% RH, close to a running fan or air conditioner).
3. This product is disposable, and cannot be reused after dropping samples or sample diluent.
4. The test strip is sensitive to damp environment, so the cover of the bottle should be tightly closed immediately after the test strip is taken out of the bottle, and the taken-out test strip should be used as soon as possible.
5. The four dots are displayed in the sample pad of the test strip, and the color will be washed away after sample loading or rinsing.
6. Make sure that the four dots are completely covered when adding the sample. Otherwise, the test result is invalid.
7. Dots often show a torch-like shape, which is a normal phenomenon of strong positive reaction.
8. When the sample stays in the strip, it may be that the absorbent paper is lifted up. Please press the overlap between absorbent paper and reaction membrane.
9. For the following samples, 0.85% sodium chloride solution is needed to wash the red blood cells of the subjects 2-3 times, and 0.85% sodium chloride solution is used to prepare 40% 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°C);
   (2) Samples containing more fibrin;
   (3) Whole blood samples with cholesterol, triglyceride, hemoglobin and bilirubin concentrations higher than those in Table 1;
   (4) Whole blood samples with red blood cell concentration lower than 30% or higher than 60%.
10. 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.
11. Clinical samples, experimental wastes, disposable articles and other materials exposed to the test should be treated as potential infectious substances, and corresponding preventive measures should be adopted.

GLOSSARY OF SYMBOLS

	CAUTION		KEEP DRY		DO NOT REUSE		DATE OF MANUFACTURE
	KEEP AWAY FROM SUNLIGHT	30°C 2°C	TEMPERATURE LIMITATION (2-30°C)		CONSULT INSTRUCTIONS FOR USE		
	MANUFACTURER	IVD	IN VITRO DIAGNOSTIC MEDICAL DEVICE	Σ N	CONTAINS SUFFICIENT FOR 〈N〉 TESTS		DO NOT USE IF PACKAGE IS DAMAGED
LOT	BATCH CODE	REF	CATALOGUE NUMBER		USE-BY DATE		

BIBLIOGRARHY

1. Dhruva G, Agravat A, Bhankhodia V. Comparison of conventional TUBE agglutination method versus ERYCARD™2.0 for the ABO blood grouping system-A Pilot Study. Int J Res Med. 2015; 4(1): 59-61.
2. Mitra R, Mishra N, Rath GP. Blood groups systems. Indian J Anaesth. 2014; 58(5): 524-28.

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