BLOOD GROUPING REAGENT

Anti-Wr^a

ALBAsera®

REF Z231U

For Indirect Antiglobulin Test by Tube Technique

- **Meets FDA potency requirements**
- **Discard if turbid**
- **Preservative: 0.1% sodium azide**

CAUTION: THE ABSENCE OF ALL VIRUSES HAS NOT BEEN DETERMINED. THIS PRODUCT HAS COMPONENTS (DROPPER BULBS) CONTAINING DRY NATURAL RUBBER

INTERPRETATION OF LABEL SYMBOLS

LOT	Batch code
	Use by (YYYY-MM-DD)
2°C 8°C	Storage temperature limitation (2°C– 8°C)
IVD	*In vitro* diagnostic medical device
www.alivedx.com	Consult instructions for use
	Manufacturer
REF	Product Code
Rx only	Rx only

INTENDED USE

The Anti-Wr^a reagent is for the *in vitro* detection and identification of human Wr^a positive red blood cells by the indirect antiglobulin test.

SUMMARY AND EXPLANATION

Anti-Wr^a was first described in 1953 and detects a low incidence blood group antigen which has subsequently been shown to be part of the Diego blood group system. Anti-Wr^a is a frequent component of normal human serum, even in the absence of immunizing episodes, and is commonly found in the serum of individuals with warm auto-immune hemolytic anemia.

Anti-Wr^a has been associated with HDFN and hemolytic transfusion reactions.

PRINCIPLE OF THE TEST

When used by the recommended technique, this reagent will cause agglutination (clumping) of red blood cells carrying the Wr^a antigen. Lack of agglutination of the red blood cells demonstrates the absence of the Wr^a antigen.

REAGENT DESCRIPTION

This reagent has been prepared from plasma collected from blood donors. ABO hemagglutinins were removed by adsorption. Conversion to serum was achieved by the addition of calcium chloride and where necessary, thrombin. Excess calcium was removed by the addition of sodium oxalate. The formulation also contains 0.1% (w/v) sodium azide.

The volume delivered by the reagent dropper bottle is approximately 40 µL; bearing this in mind, care should be taken to ensure that appropriate serum: cell ratios are maintained in all test systems.

STORAGE CONDITIONS

The reagent should be stored at 2-8 °C. Do not use if turbid. Do not dilute. Do not use beyond the notified expiry date.

PRECAUTIONS FOR USE AND DISPOSAL

This reagent contains 0.1% (w/v) sodium azide. Sodium azide may be toxic if ingested and may react with lead and copper plumbing to form explosive compounds. If discarded into sink, flush with a large volume of water to prevent azide buildup.

Handle and dispose of reagents as potentially infectious.

CAUTION: ALL BLOOD PRODUCTS SHOULD BE TREATED AS POTENTIALLY INFECTIOUS. SOURCE MATERIAL FROM WHICH THIS PRODUCT WAS DERIVED WAS FOUND NEGATIVE WHEN TESTED IN ACCORDANCE WITH CURRENT FDA REQUIRED TESTS. NO KNOWN TEST METHODS CAN OFFER ASSURANCE THAT PRODUCTS DERIVED FROM HUMAN BLOOD WILL NOT TRANSMIT INFECTIOUS AGENTS.

This product has components (dropper bulbs) containing dry natural rubber.

This reagent is for *in vitro* diagnostic use only.

SPECIMEN COLLECTION AND PREPARATION

Specimens should be collected by a standard collection technique. The specimen should be tested as soon as possible after collection. If testing is delayed, the specimen should be stored at refrigerated temperatures. Blood specimens exhibiting contamination should not be used. Extreme care should be taken if hemolyzed samples must be tested. Clotted samples or those collected in EDTA should be tested within fourteen days from collection. Donor blood may be tested until the expiry date of the donation.

MATERIALS

Materials provided

- ALBAsera® Anti-Wr^a

Materials required but not provided

- Isotonic saline
- Reagent red blood cells suitable for the control of Anti-Wr^a
- Polyspecific Anti-Human Globulin / Monospecific Anti-Human IgG
- IgG sensitized red blood cells
- 10 x 75 mm or 12 x 75 mm glass test tubes
- Pipettes
- Centrifuge
- Heating block / waterbath
- Optical aid

TEST PROCEDURE

General Information

This reagent has been standardized for use by the technique described below and therefore its suitability for use in other techniques cannot be guaranteed. When a test is required to be incubated for a specific period of time, a timer should be used.

RECOMMENDED TECHNIQUES

37 °C Indirect Antiglobulin

- Add 2 drops of blood grouping reagent to a test tube.
- Add 1 drop of red blood cells suspended to 2-4% in isotonic saline. Reagent red blood cells may be used as provided (preservative suspended).
- Mix the test well and incubate for 15-45 minutes at 37±1 °C.
- Wash the test at least 3 times with a large excess isotonic saline e.g. 4 mL of saline per 12 (or 10) x 75 mm glass tube)

NOTE: (i) allow adequate spin time to sediment the red blood cells.
(ii) make sure that most of the residual saline is removed at the end of each wash.

- Add Anti-Human Globulin to each test tube in the amount specified in the manufacturer's product insert.
- Mix the contents of the test tube well and centrifuge. Suggested centrifugation: 900-1000g (~3400 rpm) for 10-20 seconds or a time and speed appropriate for the centrifuge used that produces the strongest reaction of antibody with antigen-positive cells, yet allows easy re-suspension of antigen-negative cells.
- Gently shake the test tube to dislodge the cell button from the bottom and observe macroscopically for agglutination. Negative reactions may be examined with an optical aid.
- Record results.
- Add IgG sensitized antiglobulin control cells to confirm the validity of negative test results.

STABILITY OF REACTION
Test results should be read and interpreted immediately after centrifugation. Delays may cause dissociation of antigen-antibody complexes resulting in weak positive or false negative reactions.

INTERPRETATION OF RESULTS
Agglutination = positive test result
No agglutination = negative test result

QUALITY CONTROL
Quality control of reagents is essential and should be performed on each day of use and in accordance with local, state and federal regulations. We suggest that the following red blood cell samples are used to control the reactions of this reagent.

Wr(a+) red blood cells should be used as a positive control.
Wr(a-) red blood cells should be used as a negative control.

PERFORMANCE LIMITATIONS
Since the antibodies from which this product has been prepared were stimulated by red blood cells, extensive tests have been undertaken to exclude the presence of additional contaminating blood group antibodies. However, it is impossible to state categorically that reagents of this nature will only contain antibodies of the required specificity.

Direct antiglobulin test positive samples will react by the indirect antiglobulin test irrespective of their Wr^a status.

Driblocks and waterbaths promote better heat transfer and are recommended for 37 °C tests, particularly where the incubation period is 30 minutes or less.

Gently re-suspend tube tests before reading. Excessive agitation may disrupt weak agglutination and produce false negative results.
Excessive centrifugation can lead to difficulty in re-suspending the cell button, while inadequate centrifugation may result in agglutinates that are easily dispersed.

The expression of certain red blood cell antigens may diminish in strength during storage, particularly in EDTA and clotted samples. Better results will be obtained with fresh samples.

Suppressed or weak expression of blood group antigens may give rise to false-negative reactions.

False positive or false negative results can occur due to contamination of test materials, improper reaction temperature, improper storage of materials, omission of test reagents and certain disease states.

SPECIFIC PERFORMANCE CHARACTERISTICS
Prior to release, each lot of ALBAsera® Anti-Wr^a is tested by FDA recommended methods against a panel of antigen-positive and antigen-negative red blood cells to ensure suitable reactivity.

For additional information or technical support, contact Product Technical Support at 1-888-228-1990.

BIBLIOGRAPHY

1. Technical Manual. 17th ed. Bethesda, MD: American Association of Blood Banks, 2011.

2. Standards for Blood Banks and Transfusion Services, 28th Edition. Bethesda, MD. AABB, 2012.

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