

# BLOOD GROUPING REAGENT

## Anti-D alpha

### ALBAclone®

## (Human/Murine Monoclonal IgM) For Slide and Tube Techniques

**REF Z031U**

- **FOR IN VITRO DIAGNOSTIC USE**
- **Meets FDA potency requirements**
- **Discard if turbid**
- **Preservative: 0.1% (w/v) sodium azide**

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

### INTERPRETATION OF LABELING SYMBOLS



Batch code



Use by (YYYY-MM-DD)



Product code



Storage temperature limitation (2-8 °C)



In vitro diagnostic medical device



Consult instructions for use

www.quantenbio.com



Manufacturer

### INTENDED USE

This Anti-D reagent is for the *in vitro* detection and identification of human RhD blood group status by direct agglutination.

### SUMMARY AND EXPLANATION

First described in 1939, the RhD antigen is surpassed in importance only by the antigens of the ABO blood group system. Transfusion of RhD positive blood to an RhD negative recipient or failure to administer prophylactic Anti-D to an RhD negative woman can result in the production of Anti-D. Consequently, establishing the correct RhD group is fundamental to safe transfusion practice. Certain individuals exhibit a quantitative reduction in the expression of their

RhD antigen and are categorized as weak D. Others display a qualitative variation in RhD antigen expression and are referred to as partial RhD. Weak D individuals may also be partial RhD.

This monoclonal Anti-D reagent will directly agglutinate red blood cells from most weak D and partial RhD except DVI.

### PRINCIPLE OF THE TEST

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

### REAGENT DESCRIPTION

The main component of this reagent is derived from the *in vitro* culture of the IgM secreting human/mouse heterohybridoma:

|              |              |           |
|--------------|--------------|-----------|
| Product Name | Product Code | Call Line |
| Anti-D alpha | Z031U        | LDM1      |

The formulation also contains bovine material, potentiators, EDTA and 0.1% (w/v) sodium azide.

NOTE: The volume delivered by the reagent dropper bottle is approximately 40 µL. Care should be taken to ensure that appropriate serum: cell ratios are maintained in all test systems.

### WARNINGS AND PRECAUTIONS

For *in vitro* diagnostic use only

Products should be used by qualified personnel

Do not use beyond the expiration date

Do not dilute

The format of the expiration date is expressed as YYYY-MM-DD (Year-Month-Day)

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 build-up.

This reagent is of animal origin (murine and bovine), therefore care must be taken during use and disposal as there is a potential infection risk.

**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.**

The bovine material used in the manufacture of this reagent was collected in a USDA approved facility.

Monoclonal antibodies exhibit a high degree of potency, avidity and specificity. When using such antibodies, great care should be taken to avoid cross contamination.

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

### STORAGE

The reagent should be stored at 2-8 °C.

### 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.

Clotted samples or those collected in EDTA should be tested within fourteen days from collection. Donor blood may be tested until the expiration date of the donation.

Special care should be taken if hemolyzed samples must be tested. Grossly icteric or contaminated blood specimens should not be used.

### MATERIALS

#### Material provided

- ALBAclone® Anti-D alpha

#### Materials required but not provided

- Isotonic saline
- Reagent red blood cells suitable for the control of Anti-D
- Pipets
- 10 x 75 mm or 12 x 75 mm glass test tubes
- Optical aid (optional)
- Centrifuge
- Glass slides (optional)
- Timer
- Heating block/waterbath

### PROCEDURES

#### General Information

NOTE: This reagent has been standardized for use by the techniques 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 time period, a timer should be used.

It is recommended to allow reagents to reach 20-24 °C prior to use.

When using supplemental testing equipment (i.e. centrifuge), follow the procedures that are contained in the operator's manual provided by the device manufacturer.

Two tube techniques offering different incubation times are described below. Both are equal and will give comparable results. The user can choose the incubation time within the range that is most compatible with their current laboratory procedures.

#### Tube Technique - Immediate Spin

1. Prepare a 2-4% suspension of red blood cells in isotonic saline solution (Reagent Red Blood Cells may be used directly from the vial or according to the manufacturer's instructions).
2. Add 1 drop of blood grouping reagent to a glass test tube.
3. Add 1 drop of red blood cell suspension. Steps 2 and 3 may be performed in either order.
4. Mix the contents of the test tube and centrifuge.

NOTE: Suggested centrifugation: 900-1000 g (approx. 3400 rpm) for 10 seconds or a time and speed appropriate for the centrifuge used that produces the strongest reaction of antibody with antigen-positive red blood cells, yet allows easy re-suspension of antigen-negative red blood cells.

5. After centrifugation, gently shake the tube to dislodge the cell button from the bottom and immediately observe macroscopically for agglutination. Negative reactions may be examined with an optical aid.

6. Record results.

#### Tube Technique – 15 Minute Incubation/Spin

1. Prepare a 2-4% suspension of red blood cells in isotonic saline solution (Reagent Red Blood Cells may be used directly from the vial or according to the manufacturer's instructions).
2. Add 1 drop of blood grouping reagent to a glass test tube.
3. Add 1 drop of red blood cell suspension. Steps 2 and 3 may be performed in either order.
4. Mix the contents of the test tube and incubate at 37 ± 1 °C for 15 minutes.

