



# ADVANCED PARTIAL RhD TYPING KIT ALBAclone® (Human/Murine Monoclonal IgG) For Tube Techniques

IN THE USA: FOR RESEARCH USE ONLY  
NOT FOR DIAGNOSTIC PROCEDURES

REF Z293



- 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.

CAUTION: THIS PRODUCT OR ANY OF ITS COMPONENTS ARE NOT SUITABLE FOR ROUTINE RhD TYPING OF DONOR/PATIENT SAMPLES.

## 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



Manufacturer

## INTENDED USE

This ALBAclone® Advanced Partial RhD Typing Kit is for the *in vitro* classification of human partial RhD and weak D types 1 and 2 by indirect agglutination. The product is not suitable for routine RhD typing.

## SUMMARY AND EXPLANATION

The use of a kit for determination of partial RhD types is recommended in the current version of the Guidelines for the Blood Transfusion Services in the United Kingdom. See the reaction profile for details on the differentiation offered by this kit.

## PRINCIPLE OF THE TEST

When used by the recommended techniques, each anti-D sera in the kit will cause agglutination (clumping) of red blood cells expressing the antigen (D epitope(s)) to which each anti-D is directed. Lack of agglutination means that the antigen (epitope) to which each antibody is directed is not present. Partial or weak D type is determined on review of the pattern of reactivity obtained when testing red blood cell sample with all 12 antibodies.

## REAGENT DESCRIPTION

The main components of this reagent are derived from the *in vitro* culture of the IgG secreting human/mouse heterohybridomas: LHM76/58, LHM76/59, LHM174/102, LHM50/2B, LHM169/81, ESD1, LHM76/55, LHM77/64, LHM70/45, LHM59/19, LHM169/80 and LHM57/17.

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. The reagent is stable until the expiration date stated on the product label.

## 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 a sink, flush with a large volume of water to prevent azide build-up. Handle and dispose of reagents as potentially infectious, in accordance with local, state, and national laws.

CAUTION: SOURCE MATERIAL FROM WHICH THIS PRODUCT WAS DERIVED, WAS FOUND NEGATIVE WHEN TESTED IN ACCORDANCE WITH CURRENT FDA REQUIRED TESTS (INCLUDING HBsAg, ANTI-HIV 1/2 AND ANTI-HCV). NO KNOWN TEST METHODS CAN OFFER

ASSURANCE THAT PRODUCTS DERIVED FROM HUMAN BLOOD WILL NOT TRANSMIT INFECTIOUS AGENTS. APPROPRIATE CARE SHOULD BE TAKEN IN THE USE AND DISPOSAL OF THIS PRODUCT.

Contains material of murine origin; therefore, handle appropriately as the absence of murine viruses has not been determined.

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

This reagent is for *in vitro* professional 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.

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.

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® Advanced Partial RhD Typing Kit

### Materials required but not provided

- Isotonic Saline/blood bank saline/PBS
- LISS (optional)
- Reagent red cells suitable for the control of Anti-D
- Polyspecific Anti-Human Globulin/Anti-Human IgG
- IgG sensitized red blood cells
- 10 x 75 mm or 12 x 75mm glass test tubes
- Pipettes
- Optical aid
- Centrifuge
- Timer
- Heating block/waterbath

## TEST PROCEDURES

### General Information

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. When using supplemental testing equipment (i.e. centrifuge),

follow the procedures that are contained in the operator's manual provided by the device manufacturer.

## RECOMMENDED TECHNIQUES

### LISS, Indirect Antihuman Globulin Test

- Add 2 drops of reagent to a glass test tube.
- Add 2 drops of 1.5-2% LISS suspended cells.
- Mix the contents of the test tube and incubate at 37 °C ± 1 °C for 15 minutes
- Wash the test 3-4 times with a large excess of isotonic saline/blood bank saline/PBS (e.g. 4 mL of saline per 10 (or 12) × 75 mm glass tube).

NOTE: (i) allow adequate spin time to sediment the red cells.

(ii) make sure that most of the residual saline is removed at the end of each wash.

- Add 2 drops of anti-human globulin reagent to each test tube.
- Mix the contents of the test tube and centrifuge.
- 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.
- 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.
- To all negative tests add IgG sensitized reagent red cells, such as Quotient ALBAcyte® IgG Sensitized Red Blood Cells.

### Saline, Indirect Antihuman Globulin Test.

- Add 2 drops of reagent to a glass test tube.
- Add 1 drop of 2-3% saline suspended red cells.
- Mix the contents of the test tube and incubate at 37 °C ± 1 °C for 15 minutes.
- Wash the test 3-4 times with a large excess of isotonic saline/blood bank saline/PBS (e.g. 4 mL of saline per 10 (or 12) × 75 mm glass tube).

NOTE: (i) allow adequate spin time to sediment the red cells.

(ii) make sure that most of the residual saline is removed at the end of each wash.

- Add 2 drops of the anti-human globulin reagent to each tube.
- Mix the contents of the test tube and centrifuge.
- 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.
- 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.
- To all negative tests add IgG sensitized reagent red cells, such as Quotient ALBAcyte® IgG Sensitized Red Blood Cells.

## QUALITY CONTROL

Quality control of reagents is essential and should be performed on the day of use and in accordance with local, state and federal regulations. It is recommended that as a minimum at least one example of red cells of the phenotype R<sub>1r</sub> be used as a positive control and rr red cells be used as a negative control for each anti-D reagent.

## PERFORMANCE LIMITATIONS

- Weak D samples may react with all kit components to varying degrees due to variation in antigen site density.
- Driblocks and water baths promote better heat transfer and are recommended for 37 °C tests, particularly where the incubation period is 30 minutes or less.
- The expression of certain red cell antigens may diminish in strength during storage, particularly in EDTA and clotted samples. Better results will be obtained with fresh samples.
- Tube tests should be read by a 'tip and roll' procedure. Excessive agitation may disrupt weak agglutination and produce false negative results.
- It is important to use the recommended g force during centrifugation as excessive centrifugation can lead to difficulty in re-suspending the cell button, while inadequate centrifugation may result in agglutinates that are easily dispersed.
- 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.
- Direct antiglobulin test positive samples will react by the indirect antiglobulin test irrespective of their RhD status.
- Refer to reaction profile sheet for additional limitations.
- New variant RhD types may be encountered which have not yet been added to the reaction profile of the kit. If you have tested a sample which gives a clear reaction pattern, and your sample is not identified by the kit, please contact Quotient to discuss your results.

## SPECIFIC PERFORMANCE CHARACTERISTICS

The reaction profile overleaf applies to all current and previous batches of the ALBAclone<sup>®</sup> Advanced Partial RhD Typing Kit. We may update the reaction profile between lots – check our website for the most up-to-date version of the reaction profile, supplementary information and recent findings. [www.quotientbd.com](http://www.quotientbd.com)

## BIBLIOGRAPHY

1. Wagner *et al.* (2000). Weak D alleles express distinct phenotypes. *Blood*. 95, 2699-2708.
2. Reid, M.E., Lomas-Francis, C. and Olsson, M.L. (1997). *The Blood Group Antigen Facts Book*. 3<sup>rd</sup> Edition. Academic Press.
3. Guidelines for the Blood Transfusion Services in the United Kingdom (2013). UK Blood Transfusion Services. 8<sup>th</sup> Edition. The Stationary Office.

## DATE OF ISSUE

2016-03-04

Quotient  
Alba Bioscience Limited  
Ellen's Glen Road  
Edinburgh  
Scotland, UK  
EH17 7QT

Customer Service Tel: +44 (0) 131 445 6159  
Customer Service Fax: +44 (0) 131 445 6184  
E-Mail: [customer.serviceEU@quotientbd.com](mailto:customer.serviceEU@quotientbd.com)  
Web: [www.quotientbd.com](http://www.quotientbd.com)

## US Distributor

Quotient  
301 South State Street  
S-204  
Newtown  
PA 18940  
USA

Customer Service Tel: 1-888-284-1901  
Product Technical Support Tel: 1-888-228-1990  
Customer Service Fax: 1-888-694-5208  
E-Mail: [customer.serviceUS@quotientbd.com](mailto:customer.serviceUS@quotientbd.com)  
Web: [www.quotientbd.com](http://www.quotientbd.com)



Alba Bioscience Limited  
Ellen's Glen Road  
Edinburgh  
Scotland, UK  
EH17 7QT