QUOTIENT

BLOOD GROUPING REAGENT

Anti-Fy^b

ALBAclone®
(Human/Murine Monoclonal)
For Tube Technique

REF **Z154** CE **0843**

INTERPRETATION OF LABELLING SYMBOLS

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

INTENDED USE

This Anti-Fy^b reagent is for the *in vitro* detection and identification of the human Fy^b blood group antigen by direct agglutination.

SUMMARY AND EXPLANATION

Anti-Fy^a and anti-Fy^b were described in 1950 and 1951 respectively. FY*A and FY*B are a pair of alleles on the long arm of chromosome 1, giving rise to three commonly encountered phenotypes: Fy(a+b-), Fy(a+b+) and Fy(a-b+). Fy^a and Fy^b antigens are destroyed when the red blood cells are treated with appropriate concentrations of the proteolytic enzymes ficin, papain, and α-chymotrypsin.

PRINCIPLE OF THE TEST

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

REAGENT DESCRIPTION

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

Product Name	Product Code	Cell Line
Anti-Fy^b	Z154	SpA264LBg1

The formulation also contains bovine material potentiators, 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 to cell ratios are maintained in all test systems.
This reagent complies with the Common Technical Specifications for products defined in Annex II, List B of Directive 98/79/EC on *in vitro* Diagnostic Medical Devices and the recommendations contained in the Guidelines for Blood Transfusion Services in the United Kingdom.

STORAGE CONDITIONS

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

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 use if turbid
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 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.

Harmful to aquatic life with long lasting effects. Avoid release to the environment. Dispose of contents/container in accordance with local/regional/national/international regulations.

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

CAUTION: SOURCE MATERIAL FROM WHICH THIS PRODUCT IS DERIVED WAS FOUND NON-REACTIVE FOR HBsAg, Anti-HIV 1/2 and Anti-HCV. NO KNOWN TEST METHODS CAN OFFER COMPLETE ASSURANCE THAT PRODUCTS DERIVED FROM HUMAN BLOOD WILL NOT TRANSMIT INFECTIOUS DISEASE. APPROPRIATE CARE SHOULD BE TAKEN IN THE USE AND DISPOSAL OF THIS PRODUCT. SOURCE MATERIALS MAY INCLUDE HUMAN COMPONENTS AND ANTIBODY PRODUCING CELLS THAT ARE USED IN THE MANUFACTURE OF POLYCLONAL AND MONOCLONAL PRODUCTS.

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.

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 collected in ACD, CPD, CPDA -1, CP2D, CP2D with AS-3, CPD with AS-1, and CPD with AS-5 may be tested until the expiration date of the donation.

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

MATERIALS

Material provided
- ALBAclone® Anti-Fy^b

Materials required but not provided
- PBS pH 7.0 ± 0.2
- LISS
- Reagent red blood cells suitable for the control of Anti-Fy^b
- 10 x 75 mm or 12 x 75 mm glass test tubes
- Pipettes
- Centrifuge

PROCEDURE

NOTE: This reagent has been standardised for use by the techniques described below and therefore its suitability for use by 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.

Tube Technique - Immediate Spin

1. Prepare a 2-3% suspension of red blood cells in PBS pH 7.0 ± 0.2 (Reagent Red Blood Cells may be used directly from the vial or according to the manufacturer's instructions.) or 1.5-2% in LISS.
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.
6. Record results.

STABILITY OF REACTION

Test results should be read, interpreted and recorded 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 the day of use.

Fy(a+b+) red blood cells should be used as a positive control
Fy(a+b-) red blood cells should be used as a negative control

LIMITATIONS

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.

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.

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.

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

SPECIFIC PERFORMANCE CHARACTERISTICS

Prior to release, each lot of ALBAclone® Anti-Fy^b is tested using recommended methods against a panel of antigen-positive and antigen-negative red blood cells to ensure suitable reactivity.

The ALBAclone® Anti-Fy^b reagent reacts with cells expressing the Fy^x antigen.

Comparator Study Results

During comparator studies (data on file at Alba Bioscience Limited), blood samples were tested with ALBAclone® Anti-Fy^b as follows:

Anti-Fy^b	Trial/Reference Reagent	Comparator Reagent				Total
		Positive		Negative		
		LIS	NIS	LIS	NIS	
Trial Reagent	Positive	79	730	0	3	812
	Negative	0	1	21	526	548
	Total	79	731	21	529	1360
Positive Percentage Agreement						99.6
Negative Percentage Agreement						99.8
Overall Percentage Agreement						99.7

Precision Study Results

Precision studies were performed using multiple operators, days and runs to confirm repeatability and reproducibility of test results in the same run, day and with the same operator and between runs, days and operators. The study took account of variables such as days of the week, times of day and supplementary reagents used in testing. There were no discordant results over 720 data points; all expected positive test outcomes generated unequivocal positive reactions and all expected negative test outcomes generated unequivocal negative reactions.

BIBLIOGRAPHY

1. British Committee for Standards in Haematology: Guidelines for pre-transfusion compatibility procedures in blood transfusion laboratories, *Trans Med* 2013; 23: 3-35
2. National Blood Service: Guidelines for the Blood Transfusion Services in the United Kingdom, ed 8. TSO, 2013
3. Reid ME, Lomas-Francis C, Olsson ML: The Blood Group Antigen FactsBook, ed 3. Academic Press, 2012

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