

BLOOD GROUPING REAGENT

Anti-Fy^b

ALBAclone®

(Human / Murine Monoclonal)
For Tube Techniques

REF Z154U

- 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



Manufacturer



Rx only

INTENDED USE

The Anti-Fy^b reagent is for the *in vitro* detection and identification of human Fy^b positive red blood cells by direct agglutination.

SUMMARY AND EXPLANATION

Anti-Fy^a and anti-Fy^b (Anti-FY1 and Anti-FY2) were described in 1950 and 1951 respectively. Genes encoding the Fy^a and Fy^b

antigens are 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 techniques, 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 IgM antibody derived from the *in vitro* culture of the IgM secreting human/murine heterohybridoma of cell line SpA264LBg1

Product Name	Product Code	Cell Line
Anti-Fy ^b	Z154U	SpA264LBg1

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

The volume delivered by the reagent bottle dropper 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.

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 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.

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 which was used has been 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 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 hemolyzed 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

- Isotonic saline
- 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
- Optical aid (optional)
- Centrifuge
- Timer

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 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

Tube Technique – Immediate Spin/5 Minute incubation and Spin

- 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.)
- Add 1 drop of blood grouping reagent to a glass test tube.
- Add 1 drop of red blood cells suspension. Steps 2 and 3 may be performed in either order.
- Mix the contents of the test tube and centrifuge.
Note: Test may be incubated up to 5 minutes at 18-24 °C prior to centrifugation.
- 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.

7. Record results.

Refer to Performance Limitations section for additional guidance on the use of this product

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 the day of use and in accordance with local, state and federal regulations.

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.

False positive test results are rarely seen with low-protein reagents. False positive agglutination may be due to a positive direct antiglobulin test (DAT), cold agglutinins, or abnormal serum proteins. If false positive results are suspected, or local regulations require, and a control test for spontaneous agglutination is desired, ALBAcheck® - BGS Monoclonal Control (Z271U) or 6-10% albumin in saline may be substituted for the blood grouping reagent in the testing procedure. A negative result would serve as an appropriate control. If the monoclonal control test gives a positive reaction, a valid interpretation of the results obtained in red blood cell testing cannot be made without further investigation.

PERFORMANCE 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 inadequately 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.

Cells modified by proteolytic enzymes must not be used, as Fy^b antigens may be destroyed.

SPECIFIC PERFORMANCE CHARACTERISTICS

Prior to release, each lot of ALBAclone® Anti-Fy^b is tested by FDA recommended methods against a panel of antigen-positive

and antigen-negative red blood cells to ensure suitable reactivity.

This reagent has been shown to react with red blood cells of Fy^a phenotype.

Comparator Study Results

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

Anti-Fy ^b		Comparator Reagent			One-sided 95% Exact lower confidence limit
		Positive	Negative	Total	
Trial Reagent	Positive	730	3	733	
	Negative	1	526	527	
	Total	731	529	1260	
Positive Percent Agreement*				99.9	0.99
Negative Percent Agreement*				99.4	0.99

* Indicates agreement between the ALBAclone® Anti-Fy^b and comparator reagents only and does not indicate which reagent gave the correct result(s).

Classification	Number of Discrepancies	Comment
DAT Positive	1	Reagents which use an IAT method are not recommended for testing of samples with a positive DAT.
Weak antigen expression	1	ALBAclone® Anti-Fy ^b reagent showed reactivity against a known example of Fy ^a antigen.
Unresolved	2	ALBAclone® Anti-Fy ^b reagent and comparator reagent continued to show a different result following repeat testing. No molecular results were available.

In performance evaluation studies, 1260 samples were tested with ALBAclone® Anti-Fy^b (Monoclonal) (IgM). The following factors may have had an impact on the outcome of the testing: Indirect Antiglobulin Test method applied to samples with a positive DAT, testing of Fy^a cells or previously transfused clinical patients.

The positive percent agreement at the one-sided 95% exact lower confidence limit was 0.99 for agglutination tests based on a comparison of interpreted results. The negative agreement at the one-sided 95% exact lower confidence limit was 0.99 for agglutination tests based on a comparison of interpreted results.

Results were evaluated against comparable FDA approved products using the appropriate methods for the comparators.

Precision Study Results

As part of the performance evaluation, precision and lot to lot 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 the testing.

There were no discordant results; all antigen positive test outcomes generated unequivocal positive reactions and antigen negative test outcomes generated unequivocal negative reactions.

BIBLIOGRAPHY

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