Blood Grouping Reagent

Anti-Fy(a)
Anti-Fy(b)

For Indirect Antiglobulin Tests

- IVD In Vitro Diagnostic Medical Device
- Consult Instructions for Use
- 2 C 8 C Temperature limitation
- Discard if markedly turbid

CAUTIONS: DO NOT PIPETTE BY MOUTH. ALL BLOOD PRODUCTS SHOULD BE TREATED AS POTENTIALLY INFECTIOUS. THIS PRODUCT HAS COMPONENTS (DROPPER BULBS) THAT CONTAIN DRY NATURAL RUBBER.

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518-4

Intended Use:

Blood Grouping Reagent	Blood Grouping Reagent
For Indirect Antiglobulin Tests	For Indirect Antiglobulin Tests
(Duffy a) Human Polyclonal	(Duffy a) Human Polyclonal
(Duffy b) Human Polyclonal	(Duffy b) Human Polyclonal
Coombs reactive	Coombs reactive

Anti-Fy(a) and Anti-Fy(b) blood grouping reagents detect the corresponding antigens on human erythrocytes in indirect antiglobulin tests (IAT) performed in tubes.

Summary:

In 1950, Cutbush et. al. found an agglutinin in the serum of a haemophiliac who had been transfused several times, that defined a hitherto unrecognized blood group antigen. The antigen was named after the patient –Duffy and designated.

In the following year, Ikin et al described the antibody which defines the antithetical partner of the original Duffy antigen. The two antigens are designated Fy(a) and Fy(b) The genes which code for the antigens of the Duffy system are located on chromosome 1 and are co-dominant. The frequencies of these antigens in the central European population are:-

Fy(a+b+)	47%
Fy(a-b+)	33%
Fy(a+b-)	18%
Fy(a-b-)	0.06%

The phenotypes can be determined by serological tests using Anti-Fy(a) and Anti-Fy(b).

Principle:

When used by the recommended technique, the agglutination of red cells in the indirect antiglobulin test indicates the presence of the antigen the reagent is directed against.

No agglutination generally indicates absence of the antigen (see LIMITATIONS).

Anti Fy(a) is used in parallel with Anti-Fy(b) to determine the complete Fy(a and b) phenotype of the red cells under test.

Reagents:

Anti-Fy(a) and Anti-Fy(b) are manufactured from selected raw material, according to processes defined by a quality management system which ensures a specific product with high avidity.

These reagents are to be used as supplied without further dilution or additions.

The Bovine Albumin Solution used in manufactory of these reagents is sourced from donor animals of United States origin that have been inspected and certified by US Veterinary Service inspectors to be disease free. This ruminant-based product is deemed to have low-TSE (Transmissible Spongiform Encephalopathy) risk.

Sodium azide (< 0.1% final concentration) has been added to each reagent as a preservative.

Precautions:

For professional in vitro diagnostic use only.

▲ Sodium azide (< 0.1%) has been added as a preservative to these reagents. ▲

Sodium azide may react with lead and copper plumbing to form explosive compounds. If discarded into the sink, flush with a large volume of water to prevent azide build-up.

Store at 2-8°C when not in use. Do not freeze or expose to elevated temperatures.

Key: Underline = Addition or significant change; ▲ = Deletion of text

BLOOD GROUPING REAGENT

Anti-Fy(a)
Anti-Fy(b)

For Indirect Antiglobulin Tests

IMMUCOR

Discard if markedly turbid Discard if markedly turbid

Avoid contaminating this product during use. Contamination will adversely affect a product's performance during its shelf life. Marked turbidity may indicate reagent deterioration or contamination. Do not use if a precipitate, fibrin gel or particles are present. Do not use contaminated reagents. Do not use leaking vials. Do not use unlabeled vials.

Do not use beyond the expiry date. The format for the expiry date is CCYY-MM-DD, i.e. the date 28th May, 2005 would be expressed as 2005-05-28.

Handle and dispose of reagent as if potentially infectious. The source material used to produce these reagents has been tested and found to be negative for Anti-HIV, Anti-HCV and HBsAg viruses, but no known tests can guarantee that any product derived from human blood is free from infectious agents.

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Specimen Collection:

Draw a blood specimen using an acceptable phlebotomy technique.

In manual tests, sample drawn into tubes containing EDTA, ACD, CPD, CPDA-1, CP2D or tubes without anticoagulant may be used.

Testing should be performed as soon as possible following collection to minimize the chance that falsely positive or falsely negative reactions will occur due to improper storage or contamination of the specimen. Failure to store the specimens at the correct temperature, for example, storage at higher temperature or repeated freezing and thawing may result in false positive or false negative results.

Samples displaying gross haemolysis or microbial contamination should not be tested with these reagents.

Samples that cannot be tested within 24 hours should be stored at 2-8° C. Do not use samples drawn into tubes with neutral gel separators. False positive results may occur with such samples. EDTA samples can be tested up to 10 days, clotted samples up to 21 days. Cells drawn into heparin, ACD, CPD, CPDA-1 or CP2D may be tested up to the expiration of the anticoagulant.

Procedure:

Materials Provided:

Anti-Fy(a), or Anti-Fy(b) antisera in dropper vials ready for use.

Additional Materials Required:

1. Donor or patient red cells
2. Marking pens
3. Isotonic saline or phosphate-buffered (approximately 15mM) isotonic saline, pH 6.5-7.5
4. Transfer pipettes
5. 10x75mm or 12x75 mm test tubes and a test tube rack
6. Anti-Human Globulin reagent*
7. Serological centrifuge*
8. Interval timer

*It is the user's responsibility to validate an accessory device for its intended use.

Tube Test Method:

1. Label 1 test tube for each blood grouping reagent to be tested.
2. Prepare a 2% suspension of washed red cells in saline solution.
3. Add 2 drops of each blood grouping reagent to the appropriately labeled tube.
4. Add 2 drops of the suspension of red cells.
5. Mix the contents of each tube thoroughly and incubate for 30 minutes at 37°C.
6. Wash 3 times with cold isotonic saline solution.
7. Add 2 drops of Anti-Human Globulin reagent.
8. Mix and centrifuge.*
9. Gently agitate each tube to resuspend the red cells buttons. Examine for agglutination.
10. Record results.
11. All negative reactions should be confirmed using IgG sensitized red cells (e.g. immucor Checkcell) to verify that the anti-human globulin reagent was active.

*Suggested centrifugation time: 1 minute at 900-1000 x g or a time, appropriate for the centrifuge used, that produced the strongest reaction of antibody with antigen-positive cells, yet allows easy resuspension of antigen-negative red cells. The centrifugal force applied should be the minimum required to produce a clear supernatant and a clearly delineated red cell button that can be easily resuspended. No single speed or time can be recommended for all types of available centrifuges or test applications. Centrifuges should be calibrated individually to determine the optimal time and speed required to achieve the desired results.

Stability of the Reaction:

Following centrifugation, all tube tests should be read immediately and results interpreted without delay.

Quality Control:

To confirm the correct reactivity of Anti-Fy(a) and Anti-Fy(b), it is recommended that these reagents be tested each day of use with antigen positive and antigen negative cells. For QC frequency minimum requirements refer to national guidelines. These reagents can be considered to be satisfactory if the antigen-positive cells are agglutinated and antigen negative cells are not agglutinated.

Results:

Positive Test (antigen detected): agglutination of red cells.

Negative Test (antigen not detected): no agglutination of red cells.

Expected red cell typing results:

	Reagent		Frequency Central
Phenotype	Anti-Fy(a)	Anti-Fy(b)	Europeans[2]
Fy(a+ b-)	+	0	18%
Fy(a+ b+)	+	+	47%
Fy(a- b+)	0	+	33%

Limitations:

Falsely positive or falsely negative test results can occur from bacterial or chemical contamination of test materials, inadequate incubation time or temperature, improper centrifugation, improper storage of materials, or omission of test reagents. Incorrect (falsely positive or falsely negative reactions may be obtained if red cell suspensions that are too light or too heavy are used.

Red cells demonstrating a positive direct antiglobulin test cannot be accurately tested for the Fy(a) or Fy(b) antigens with these reagents.

These reagents should produce reactions of 2+ to 4+ in properly calibrated test systems. Reactions of 1+ or weaker (test or control red cells) should be investigated before a phenotype is assigned, as they may be an indication that environmental temperature, centrifugation speed or time or the volume of the reagent or cell suspension used are not optimium or that the reagent is deteriorating.

Antibodies directed at low frequency antigens may occur as unsuspected contaminants in blood grouping reagents of human polyclonal origin. These phenomena may be a source of rare false-positive reactions and may occur with more than one lot of a given specificity. Since manufacturers commonly obtain raw material from the same sources, the same contaminating antibodies may be present in products acquired from different manufacturers. It is not possible for any manufacturer to claim the absence of all contaminating antibodies because red blood cells carrying such antigens are not always available for testing. Suppressed or diminished expression of certain blood group antigens may conversely give rise to false negative reactions. For these reasons, caution should always be exercised when assigning genotypes on the basis of serological test results.

Specific Performance Characteristics:

Prior to release, each lot of Anti Fy(a) and Anti Fy(b) is tested by insert methods against a panel of antigen-positive and antigen-negative red cells to ensure appropriate reactivity and specificity. The performance of this product is dependent on adhering to the recommended methods found in this insert. Additional information regarding specificity testing performed at the time of the manufacture or as performed subsequent to product release may be furnished upon request by consulting Immucor's Technical Services

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1. Cutbush M., Mollison PL, Parkin DM. A new human blood group. Nature 1950;165:188
2. Eckstein R. Immunhämatologie und Transfusionsmedizin. 4th Ed. München, Jena: Urban & Fischer; 2001:42-43
3. Ikin EW, Mourant AE, Pettenkofer HJ et. al. Discovery of the expected haemagglutinin, anti Fy[b]. Nature 1951;168 :1077

REF	Description
0008205	Anti-Fy(a) 5 ml
0008210	Anti-Fy(b) 5 ml

CE 0088

Insert code 518-4
Rev 12/16

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