



GENESIS

Instructions For Use

Anti-Human Globulin Polyspecific IgG/ C3d (Coomb's test)

Product	Cat no.	size
Anti Human Globulin	4106 101	1 X 10 ml

INTENDED USE

Anti-human globulin used in determination of human anti-Ig G and anti-C3d on red blood cells.

BACKGROUND

the use of anti-human globulin serum for detecting red cell-bound non-agglutinating antibodies. In 1957, Dacie et al showed that the antibodies present in antiglobulin sera were directed against certain components of complement. Anti-human globulin reagents detect non-agglutinating antibody molecules as well as molecules of complement attached to red cells following in vivo or in vitro antigen-antibody reactions.

APPLICATIONS

Indirect Anti-globulin Test

- Screening for unexpected antibodies
- Compatibility Testing
- Red cell phenotype
- Identification and titration of antibodies

Direct Anti-globulin Test

- Diagnosis of haemolytic disease of the newborn
- Diagnosis of haemolytic anemia
- Investigation of suspected transfusion reactions

PRINCIPLE OF THE METHOD

When used by the recommended techniques, the reagents will react with immunoglobulin and/or complement attached to the red cell surface, resulting in agglutination (clumping) of adjacent sensitized cells. Cells not sensitized will not be agglutinated

COMPOSITION

Anti-human Globulin Reagent	Rabbit anti-human IgG. Murine Monoclonal anti-human C3d. Patent Blue and Tartrazine dyes. Sodium azide <0.1%
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STORAGE.

1. Store the reagent at 2-8°C. DO NOT FREEZE.
2. The shelf life of the reagent is as per the expiry date mentioned on the reagent vial labels.

ADDITIONAL EQUIPMENT

- Glass test tubes (10 x 75 mm or 12 x 75 mm).
- Pasteur pipettes.
- Water bath at 37°C.
- Centrifuge Sero-fuge or similar.
- Phosphate Buffered Saline (PBS): 8.5 to 9.0 g/L NaCl (0.145 - 0.154 mol/L) pH 7.0 ± 0.2 at 22 ± 1°C.
- Test red cells. Negative Control (Red cells phenotype Rh negative coated with anti-D) y Positive Control (Red cells phenotype Rh positive coated with weak anti-D).

SPECIMEN

Samples should be collected with or without an anticoagulant. The specimen should be tested as soon as possible after collection. Store at 2-8°C. Serums less than 24 hours old kept at 2-8°C since separation from the clot. Blood specimens exhibiting gross hemolysis or contamination should not be used

Symbols in Product Labeling			
EC	REP	Authorized Representative	Expiry date
IVD		For in-vitro diagnostic use	CAUTION, consult instructions for use
REF		Catalogue number	Manufactured by
LOT		Lot number	Temperature Limit
		Consult instructions for use	

PROCEDURE

1). Direct Anti-globulin Technique :

1. Wash test red cells 4 times with PBS, taking care to decant saline between washes and resuspend each cell button after each wash. Completely decant saline after last wash.

2. Add 2 volumes of Anti-Human Globulin to each dry cell button.

3. Mix thoroughly and centrifuge all tubes for 20 seconds at 1000 rcf or for a suitable alternative time and force.

4. Gently resuspend red cell button and read macroscopically for agglutination

2). Indirect Anti-globulin Technique :

1. Prepare a 2-4% suspension of washed test red cells in PBS.

2. Place in a labeled test tube: 2 volumes of test serum + 1 volume of test 3% red cell suspension + 1 volume of test 22% of genesis Bovine albumin.

3. Mix thoroughly and incubate at 37°C for 15 minutes.

4. Wash test cells 4 times with PBS, taking care to decant saline between washes and resuspend each red cell button after each wash. Completely decant saline after last wash.

5. Add 2 volumes of Anti-Human Globulin to each dry cell button.

6. Mix thoroughly and centrifuge all tubes for 20 seconds at 1000 rcf or for a suitable alternative time and force.

7. Gently resuspend red cell button and read macroscopically for agglutination

3). LISS Indirect Anti-globulin Technique :

1. Prepare a 1.5-2% suspension of washed test red cells in LISS.

2. Place in a labeled test tube: 2 volumes of test serum and 2 volumes of test red cell suspension.

3. Mix thoroughly and incubate at 37°C for 15 minutes.

4. Follow steps 4 to 7 of **indirect** above.

Reading

Dislodge the cell pack in the bottom of the tubes by gently tilting or shaking the tube and examine macroscopically for agglutination.

- Negative reaction: A smooth homogeneous resuspension of cells indicates a negative reaction.

- Positive reaction: Agglutination of the red cells indicates they are coated with an antibody.

Interpretation

- Positive reaction: Agglutination of the test red cells constitutes a positive test result, within accepted limitations of test procedure.

- Negative reaction: No agglutination of the test red cells constitutes a negative result, within the accepted limitations of the test procedure.



PRECAUTIONS AND WARNINGS

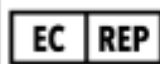
- 1-Wearing personnel protective equipment (overall, gloves, glasses,).
- 2-Do not pipette by mouth.
- 3- In case of contact with eyes or skin; rinse immediately with plenty of soap and water. In case of severe injuries; seek medical advice immediately.

reagent contains sodium azide which is classified as dangerous substance for environment.

BIBLIOGRAPHY

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