Biomaghreb

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ANTI-D (IgM + IgG) MONOCLONAL ANTIBODY

IN VITRO DIAGNOSTIC USE

IVD

REF	**40015**	1 x 10 ml
REF	**40022**	10 x 10 ml

CLINICAL SIGNIFICANCE

First described in 1939, the RhD antigen is surpassed in importance only by the antigens of the ABO blood group system. Transfusion of RhD positive blood to a RhD negative recipient or failure to administer prophylactic anti-D to a RhD negative woman can result in the production of anti-D. Consequently, establishing the correct RhD group is fundamental to safe transfusion practice. Certain individuals exhibit a quantitative reduction in the expression of their RhD antigen and are categorised as weak D (Du). Others display a qualitative variation in RhD antigen expression and are referred to as partial RhD. Weak D individuals may also be partial RhD.

REAGENT COMPOSITION

The main component of this reagent is derived from the in vitro culture of the human/mouse heterohybridomas which secretes IgM anti-D and another which secretes IgG anti-D. This is an anti -D blend
The clones used for the production of this reagent are mentioned on the bottle.

SAFETY CAUTIONS

Biomaghreb reagents are intended for use by qualified personnel for in vitro use.

- Refer to the current SDS available on request or at www.biomaghreb.com;
- Verify the integrity of the reagents before use; and
- Disposal of waste: comply with the legislation in force.

For safety reasons, treat any specimen or reagent of biological origin as potentially infectious.
Respect the legislation in force.

SAMPLE PREPARATION

Draw blood on anticoagulant.
Store blood that cannot be examined quickly (no hemolysis should be observed) at +4°C.

PRESERVATION AND STABILITY

At + 4°C until the expiry date indicated on the label.
Preservative: Sodium Azide 1‰.
Strictly reserved for in vitro use.

PROCEDURE

1) On opaline plate

- Place 1 drop of reagent beside 1 drop of total blood (not washed).
- With adapted agitator mix on centrifuge spiral movement to form a circular reaction with 2 cm in diameter.
- Rock several times the plate to homogenize the mixture.
- Read visually for 3 times.

2) In tube : Indirect coombs or LISS Coombs test:

- Wash 3 times the red cells in isotonic saline solution.
- Make a 3 - 5% cell suspension in isotonic saline solution or in low isotonic strength solution(LISS).
- Into test tube mix 2 drops of reagent and 2 drops of cell suspension.
- Incubate at 37°C for 45 minutes (if isotonic saline solution is used) or 15 minutes (LISS).
- Wash 3 times in isotonic saline solution and dry the pellet of last washing -
- Add 1 drop of polyvalent antiglobulin. (follow th antiglobulin procedure).
- Centrifuge at 500 g for 1 minute.
- Resuspend the cells gently.
- Read visually.

PARTICULAR ATTENTION

In indirect coombs (standard or LISS) the albuminal monoclonal anti-D reagent reacts with low D-samples).
For anti-Rhesus monoclonal albumin reagents, a negative albumin control should be used in parallel. The absence of agglutination with the control allows the specificity of a positive reaction with anti-D to be confirmed.

SPECIAL PRECAUTION FOR USE

Humain origin product were found negative for HBs Ag and for antibodies against HCV, HIV-1 and HIV-2 by approved test methods. However,- since no test method can offer complete assurance that infectious agent are absent, this product should be handled observing the same safety precautions employed when handling any potentilly infectious material.

PERFORMANCE LIMITATIONS

The expression of some red cell antigens may decrease in strength during storage, particularly in EDTA and coagulated samples. Better results will be obtained with fresh samples.
Gently resuspend tube tests before reading. Excessive agitation may disrupt the weak agglutination and produce false negative results.
Excessive centrifugation may result in difficulty resuspending the cell button, while inadequate centrifugation may result in agglutinants that disperse easily.
False positive or false negative results may occur due to contamination of test materials, inadequate reaction temperature, improper storage of materials, omission of test reagents, and certain disease states.

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SPECIFIC PERFORMANCE CHARACTERISTICS

Prior to release, each batch of Anti-D is tested by the NBTC(National Blood Transfusion Centre) .


Manufacturer


Use by

In Vitro Diagnostic


Temperature Limitation

Catalogue number


See insert


Harmful


Sufficient for < n > essais

Batch number