BIOSCOT®

Anti-Le^b

Monoclonal Human IgA
Blood Grouping Reagent

CE 0123 IVD

REF NY-2ML-B
NY-10X2ML-B

Cell Line: P3F234MD4

Tube Technique

INTENDED USE

BIOSCOT® Anti-Le^b (cell line P3F234MD4) monoclonal human IgA blood grouping reagent is used to ensure the immunological compatibility of blood and blood components intended for transfusion. This qualitative reagent will detect the presence or absence of the Le^b (LE2) antigen on the surface of human red blood cells when tested according to the tube technique. The reagent is designed for in vitro diagnostic, professional use by operators trained in serological techniques.

PRINCIPLE OF THE REAGENT

When used by the recommended technique this reagent will cause agglutination (clumping) of red cells carrying the specific antigen (positive test). Lack of agglutination of the red cells demonstrates the absence of the specific antigen (negative test).

The reagent has been characterised by the procedures recommended in these instructions for use, its suitability for use in other techniques must be determined by the user.

PRECAUTIONS

1. All blood products should be treated as potentially infectious. The human donor or the cell line used to produce the Anti-Le^b reagent has been tested and found to be negative for HIV1 + 2, HBV and HCV. Care must be taken in the use and disposal of each container and its contents.
2. This reagent contains 0.1% (w/v) sodium azide. Sodium azide may be toxic if ingested and may react with lead or copper plumbing to form highly explosive salts. On disposal, flush with large quantities of water.
3. This product should be clear. Turbidity may indicate bacterial contamination. This reagent should not be used if a precipitate, fibrin gel or particles are present.
4. The source of bovine material is either USDA approved or from sources where origin information is available. The donor animals have been inspected and certified disease free and are deemed to have low TSE (Transmissible Spongiform Encephalopathy) risk.
5. This product should be disposed of either by overnight immersion in disinfectants at appropriate concentrations or by autoclaving.

CONTROLS

It is recommended that a positive control and a negative control should be tested in parallel with each batch of tests. Tests must be considered invalid if controls do not show the expected reactions.

It is not required to use a reagent control in parallel with all tests using this reagent. Only in typing the red cells of patients known to have auto-antibodies or protein abnormalities is the use of a reagent control such as BIOSCOT® Monoclonal Control (Product code: TT) recommended. This should be tested in parallel with the reagent.

STORAGE

Store the opened / unopened product at 2-8°C until the expiry date detailed on the product label.

Failure to store the product at the correct temperature, for example, storage at higher temperature or repeated freezing and thawing, may result in accelerated loss of reagent activity.

SPECIMEN COLLECTION

No special preparation of the patient/donor is required prior to specimen collection. Blood should be collected by an approved phlebotomy technique into tubes containing EDTA or CPD. The specimen should be tested as soon as possible following collection. Samples that cannot be tested within 24 hours of collection should be stored at 2-8°C. Testing should be carried out within 14 days of collection. Specimens displaying gross haemolysis or microbial contamination should not be tested with this reagent. Failure to store the specimens in the correct conditions may result in false positive or false negative results.

MATERIALS PROVIDED

Product code NY Anti-Le^b blood grouping reagent is composed of monoclonal human IgA antibodies from cell line P3F234MD4 in a buffer solution containing macromolecular chemical potentiators. This reagent contains 0.1% (w/v) sodium azide and bovine material.The product is supplied filtered to 0.22 µm. The reagent has been optimised for use by the recommended techniques without further dilution or additions.
Contents:

1 x reagent vial for REF NY-2ML-B
10 x reagent vials for REF NY-10X2ML-B
1 x information sheet

MATERIALS REQUIRED BUT NOT PROVIDED

Tube Technique:
- Test tube
- Normal saline/isotonic saline
- Timer
- Centrifuge (1000 rcf)

RECOMMENDED TECHNIQUE

1. TUBE TECHNIQUE

1.1. Prepare a 3-5% suspension of test red cells in normal saline / isotonic saline.
1.2. Add 1 drop (40-50 µl) of the suspension of test red cells to an appropriately labelled test tube.
1.3. Add 1 drop (40-50 µl) of Anti-Le^b reagent.
1.4. Mix well and incubate at room temperature for 5 minutes.
1.5. Centrifuge for 1 minute at 1000 rcf.
1.6. Gently agitate the tube to dislodge the red cells and examine macroscopically for agglutination.

LIMITATIONS

Cells modified by proteolytic enzymes must not be used as non-specific aggregation will occur.

Weaker reactions may be obtained when testing older blood samples.

Antigen variant cells may produce unexpected positive or negative reactions with samples previously typed with blood grouping reagents of polyclonal or other cell line-derived monoclonal sources.

Red cells that have a positive antiglobulin test (DAT) may produce false positive results. The use of BIOSCOT® Monoclonal Control reagent (Product code: TT) is recommended for detection of such positive results.

False positive or false negative results may occur through contamination of test materials or any deviation from the recommended technique

PERFORMANCE CHARACTERISTICS

Anti-Le^b (cell line P3F234MD4) monoclonal human IgA blood grouping reagent NY has been tested by the recommended technique with donor and clinical specimens collected in EDTA. The sample population represented all major phenotypes. The total number of tests (n), and the calculated sensitivity and specificity for this technique is displayed below:

TECHNIQUE	Anti-Le^b Product Code NY			
	Sensitivity		Specificity	
	n	%	n	%
Tube	328	100	124	100

Diagnostic Sensitivity: The probability that the device gives a positive result in the presence of the target marker.

Diagnostic Specificity: The probability that the device gives a negative result in the absence of the target marker**.**

ANALYTICAL PERFORMANCE

This blood grouping reagent(s) exhibited unequivocal positive or negative results by all recommended techniques. Performance was found to be acceptable in terms of repeatability, reproducibility and robustness.

FURTHER INFORMATION

For technical assistance contact: SigmaAldrich.com/techservice

Any serious incident that has occurred in relation to this reagent must be reported to Millipore (UK) Ltd and the competent authority of the Member State in which the user and/or the patient is established.

The summary of safety and performance (SSP) for this device is available in the European database on medical devices (Eudamed) at https://ec.europa.eu/tools/eudamed, where it is linked to the Basic UDI-DI (405325NYBTR72).

BIBLIOGRAPHY

1. Guidelines for the Blood Transfusion Services in the United Kingdom. 8th Edition 2013. The Stationary Office.
2. Issitt, P.D. and Anstee, D.J. Applied Blood Group Serology 4th Edition, Montgomery Scientific Publications, 1998.
3. AABB Technical Manual 20th Edition,2020.

SUMMARY OF CHANGES

1. Rebranding & reorganisation of layout.
2. Identification of contents of packaging.
3. Update Intended Use section
4. Update specimen collection section
5. Clarification of drop volume within recommended techniques
6. Change centrifugation parameters from g to rcf.
7. Update performance characteristics data.
8. Removal of CTS definition
9. Addition of analytical performance
10. Addition of Further Information section.
11. Addition of technical service contact information.
12. Addition of requirement to contact Millipore (UK) Ltd and competent authority in the case of a serious incident involving this reagent.
13. Addition of information related to summary of safety and performance (SSP).
14. Removal of Introduction and References sections.
15. Addition of Bibliography section
16. Addition of Summary of Changes section.
17. Remove fax number.

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