BIOSCOT®

Anti-Le\(^a\) Cell Line: GA2
Product Code: NB

Monoclonal Murine IgA Blood Grouping Reagent

For Tube Technique

**INTENDED USE**

BIOSCOT Anti-Le\(^a\) is a monoclonal murine IgA blood grouping reagent (cell line GA2) which will detect the Le\(^a\) antigen when tested according to the tube technique. This reagent is designed for use by operators trained in serological techniques.

**INTRODUCTION**

The Lewis Blood Group System

As with conventional Lewis antisera, the use of this monoclonal Anti-Le\(^a\) blood grouping reagent enables red blood cells to be classified as one of three phenotypes, Le\(^a+b\)+, Le\(^a-b\)+ and Le\(^a-b\)-. The phenotype Le\(^a+b\)+ is extremely rare, but does exist within the general population.

Agglutination of red blood cells with this reagent indicates the presence of the appropriate antigen on the red cell surface. Lewis antigens are also present in serum and other body fluids. Neonatal cells do not express Lewis antigens in sufficient quantity to be agglutinated by this reagent and will therefore type as Le\(^a-b\)-.

**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).

This reagent has been optimised for use as supplied by the recommended technique without further dilution or additions.

This product is supplied filtered to 0.22 µm.

**MATERIALS**

Product code NB Anti-Le\(^a\) is composed of monoclonal murine IgA antibodies from cell line GA2 in a buffer solution containing macromolecular chemical potentiators. This reagent contains 0.1% (w/v) sodium azide and bovine material. Each vial (2 mL) contains sufficient material for approximately 40 tests.

**PRECAUTIONS**

1. All blood products should be treated as potentially infectious. 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. This reagent is for professional in vitro diagnostic use only.
5. 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.
6. This product should be disposed of either by overnight immersion in disinfectants at appropriate concentrations or by autoclaving.

**ADVICE TO USERS**

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.

This 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.

In the event of changes in the analytical performance of the device or damage to the packaging please contact the Quality Assurance department at Millipore (UK) Ltd.

**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 is required prior to specimen collection. Sample should be collected into EDTA anticoagulant. The specimen should be tested as soon as possible following collection. If a delay in testing should occur, store the specimen at 2-8°C. Specimens displaying gross haemolysis or microbial contamination should not be tested with this reagent. Failure to store the specimens at the correct temperature may result in false positive or false negative results.

**MATERIALS REQUIRED BUT NOT PROVIDED**

Tube Technique:
- Test tube
- Normal/Isotonic saline
- Timer
- Centrifuge (1500 g)

**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 (50 µl) of the suspension of test red cells to an appropriately labelled test tube.
   1.3 Add 1 drop (50 µl) of Anti-Le\(^a\) reagent.
   1.4 Centrifuge for 20 seconds at 1500 g.
   1.5 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.

Red cells that have a positive direct antiglobulin test (DAT) may produce false positive results. The use of BIOSCOT monoclonal control (Product Code: TT) is recommended for detection of such potentially false 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\(^a\) (cell line GA2) monoclonal murine IgA blood grouping reagent NB has been tested by the recommended technique with donor, clinical and neonatal 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:

<table>
<thead>
<tr>
<th>TECHNIQUE</th>
<th>Anti-Le(^a) Product Code NB</th>
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</thead>
<tbody>
<tr>
<td></td>
<td>Sensitivity</td>
</tr>
<tr>
<td>n %</td>
<td>n %</td>
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<tr>
<td>Tube</td>
<td>299 100</td>
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Definitions from the Common Technical Specifications (CTS):
 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.

REFERENCES