**INTENDED USE**

BIOSCOT Anti-Jk\(^a\) and Jk\(^b\) are monoclonal human IgM blood grouping reagents which will detect the Jk\(^a\) and Jk\(^b\) antigens respectively, when tested according to the tube technique. These reagents are designed for use by operators trained in serological techniques.

**INTRODUCTION**

The Kidd Group System

Allen et al described Anti-Jk\(^a\) in 1951. Plaut et al discovered the allele Jk\(^b\) in 1953. Pinkerton et al reported the first example of a Jk(a-b-) individual in 1959. Antibodies in the Kidd system may cause immediate and delayed haemolytic transfusion reactions. They occasionally cause haemolytic disease of the newborn.

The frequencies of phenotypes in the Kidd system vary in different populations. In the general Caucasian population frequencies are approximately:

<table>
<thead>
<tr>
<th>PHENOTYPE</th>
<th>FREQUENCY</th>
</tr>
</thead>
<tbody>
<tr>
<td>Jk(a+b+)</td>
<td>49%</td>
</tr>
<tr>
<td>Jk(a+b-)</td>
<td>28%</td>
</tr>
<tr>
<td>Jk(a-b+)</td>
<td>23%</td>
</tr>
<tr>
<td>Jk(a-b-)</td>
<td>exceedingly rare</td>
</tr>
</tbody>
</table>

**PRINCIPLE OF THE REAGENT**

When used by the recommended technique these reagents 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).

These reagents have been optimised for use as supplied by the recommended technique without further dilution or additions.

These products are supplied filtered to 0.22 μm.

**MATERIALS**

Product code BI Anti-Jk\(^a\) (cell line MS-15) blood grouping reagent and Product code BE Anti-Jk\(^b\) (cell line MS-8) blood grouping reagent are composed of monoclonal human IgM antibodies in a buffer solution containing macromolecular chemical potentiators. These reagents contain 0.1% (w/v) sodium azide and bovine material. Each vial (2 mL) contains sufficient material for approximately 50 tests.

**PRECAUTIONS**

1. All blood products should be treated as potentially infectious. The human donor or the cell line used to produce these reagents has been tested and found to be negative for Anti-HIV, Anti-HCV, HBsAg, EBV and Mouse Antibody Production (MAP) viruses. No known tests can guarantee that any product derived from human blood is free from infectious agents. Care must be taken in the use and disposal of each container and its contents.

2. These reagents contain 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. These products should be clear. Turbidity may indicate bacterial contamination. These reagents should not be used if a precipitate, fibrin gel or particles are present.

4. These reagents are for professional in vitro diagnostic use only.

5. The bovine material is obtained from USDA approved sources or from sources for which 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. These products 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.

These reagents have been characterised by the procedures recommended in these instructions for use; their suitability for use in other techniques must be determined by the user.

In the event of changes in 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 products at 2-8°C until the expiry date detailed on the product label.

Failure to store the products 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. Blood should be collected by an approved phlebotomy technique. Samples can be collected into EDTA, Citrate or CPDA anticoagulants or as a clotted sample. 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**

- Test tube
- Isotonic saline
- 37°C Incubator
- Timer
- Centrifuge (1000 rcf)

**RECOMMENDED TECHNIQUE**

1. **TUBE TECHNIQUE**

1.1 Prepare a 3-5% suspension of test red cells in isotonic saline.

1.2 Add one drop (40 μl) of Anti-Jk\(^a\) or Anti-Jk\(^b\) reagent to an appropriately labelled test tube.

1.3 Add one drop (40 μl) of the suspension of test red cells.

1.4 Mix well and incubate at 37°C for 5 minutes.

1.5 Centrifuge at 1000 rcf for 20 seconds.

1.6 Gently agitate the tube to dislodge the red cells and examine macroscopically for agglutination.

1.7 Incubate all negative tests at 37°C for a further 10 minutes and repeat steps 1.5 and 1.6. This may enhance the reaction strength in typing cells of rare phenotypes.
LIMITATIONS

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

Enzyme treated red cells may give a falsely positive reaction with BIOSCOT Anti-Jk^a Blood Grouping Reagent.

Weaker reactions may be obtained when testing older blood samples.

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

PERFORMANCE CHARACTERISTICS

Anti-Jk^a (cell line MS-15) monoclonal human IgM blood grouping reagent BI and Anti-Jk^b (cell line MS-8) monoclonal human IgM blood grouping reagent BE have been tested by the recommended technique with donor, clinical and neonatal specimens. The sample population represented all major phenotypes. The total number of tests (n), and the calculated sensitivity and specificity for each technique are displayed below:

<table>
<thead>
<tr>
<th>TECHNIQUE</th>
<th>Anti-Jk^a Product Code BI</th>
<th>Anti-Jk^b Product Code BE</th>
</tr>
</thead>
<tbody>
<tr>
<td></td>
<td>Sensitivity</td>
<td>Specificity</td>
</tr>
<tr>
<td>Tube</td>
<td>n</td>
<td>%</td>
</tr>
<tr>
<td></td>
<td>726</td>
<td>99.6</td>
</tr>
<tr>
<td></td>
<td>666</td>
<td>99.5</td>
</tr>
</tbody>
</table>

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