Blood Grouping Reagent

Anti-Jk\(^a\) (JK1)
Seraclone® Human Monoclonal (MS15)

Anti-Jk\(^b\) (JK2)
Seraclone® Human Monoclonal (MS8)

FOR IN-VITRO DIAGNOSTIC USE
For Tube Testing
MEETS FDA POTENCY REQUIREMENTS
U.S. License Number: 1845

Package size REF 808179100 VOL 2 mL Seraclone® Anti-Jk\(^a\) (JK1)
REF 808184100 VOL 2 mL Seraclone® Anti-Jk\(^b\) (JK2)

Intended Use
For the determination of the Kidd antigens Jk\(^a\) (JK1) and Jk\(^b\) (JK2) of red blood cells using the tube test.

Summary
The Kidd antigen was first identified in 1951 when the corresponding antibody was found to cause hemolytic disease of the fetus and newborn (HDFN). Although Kidd antibodies have been shown to cause generally mild HDFN, they have been implicated in severe hemolytic transfusion reactions (HTR). The HTR are often delayed due to an anamnestic response to the Kidd antigen.

The frequencies of the common phenotypes are shown in the table.

<table>
<thead>
<tr>
<th>Phenotype</th>
<th>Whites</th>
<th>Blacks</th>
<th>Asians</th>
</tr>
</thead>
<tbody>
<tr>
<td>Jk((a+b−))</td>
<td>28</td>
<td>57</td>
<td>23</td>
</tr>
<tr>
<td>Jk((a+b+))</td>
<td>49</td>
<td>34</td>
<td>50</td>
</tr>
<tr>
<td>Jk((a−b+))</td>
<td>23</td>
<td>9</td>
<td>27</td>
</tr>
</tbody>
</table>

Bio-Rad Seraclone® Anti-Jk\(^a\) and Seraclone® Anti-Jk\(^b\) Blood Group Reagents are used to test for the presence or absence of the Jk\(^a\) and Jk\(^b\) antigens. Bio-Rad Seraclone® Anti-Jk\(^a\) and Seraclone® Anti-Jk\(^b\) are used principally in the resolution of antibody problems or in family studies.

Principle of the Test
The test principle is hemagglutination. The antibodies in Seraclone® Anti-Jk\(^a\) (JK1) and Seraclone® Anti-Jk\(^b\) (JK2) bind to the corresponding antigen on red blood cells and cause an antigen-antibody reaction visible as red blood cell agglutination.

Reagent
As the reactive components Seraclone® Anti-Jk\(^a\) (JK1) and Seraclone® Anti-Jk\(^b\) (JK2) contain human monoclonal antibodies of the immunoglobulin class IgM. They are derived from cell culture supernatant and demonstrate the consistent specificity and reproducibility characteristic for monoclonal antibodies.

Antibodies are diluted in a isotonic saline solution containing bovine albumin.

The following antibodies are produced using intermediate products produced for Bio-Rad Medical Diagnostics GmbH in a shared manufacturing agreement with Millipore (UK) Ltd., 9 Fleming Road, Kirkton Campus, EH547BN, Livingston, UK; License Number 1721.

Seraclone® Anti-Jk\(^a\) (JK1)  clone MS15 (IgM)
Seraclone® Anti-Jk\(^b\) (JK2)  clone MS8 (IgM)

Preservative: 0.1% Sodium azide.

Precautions
- For In-vitro diagnostic use.
- Store at 2 to 8°C.
- Do not use beyond the expiration date.
- Do not use if turbid.
- Handle and dispose of reagents as potentially infectious.
- Caution: Do not pipette by mouth. The absence of all viruses has not been determined.
- Caution: This Product Contains Natural Rubber Latex Which May Cause Allergic Reactions.
- Warning: Contains sodium azide (Na\(_3\)N\(_2\)), which may react with lead or copper plumbing to form explosive azides. If discarded in the sink, flush with large amounts of water to prevent the build-up of explosive metal azides.
- The bovine albumin used for the production of this reagent is sourced from donor animals of U.S. origin that have been inspected and certified by U.S. Veterinary Service inspectors to be disease free.

Specimen Collection
Fresh samples of clotted, EDTA or citrate anticoagulated whole blood collected following general blood sampling guidelines are acceptable. The specimen should be tested as soon as possible after collection. If testing is delayed, EDTA and clotted specimens should be stored at 2 to 8°C, citrated specimens (donor segments) at 1 to 6°C. Blood specimens exhibiting gross hemolysis or contamination should not be used.

Clotted samples or those collected in EDTA may be tested within ten days from collection. Donor blood stored in citrate anticoagulant may be tested until the expiration date of the donor unit.

Materials
Materials provided
- Seraclone® Anti-Jk\(^a\) (JK1) and/or Seraclone® Anti-Jk\(^b\) (JK2)

Materials required but not provided
- Pipettes
- Isotonic saline or Phosphate Buffered Saline (PBS ;pH 7.2 +/-0.1)
- Glass tubes 10 x 75mm or 12 x 75 mm
- Serological centrifuge
- Interval timer
- Markers
- Agglutination viewer (optional).

Test Procedure
Tube test
1. Prepare a 3 to 5% suspension of red blood cells to be tested in saline.
2. Place one drop reagent into an appropriately labelled tube.
3. Add one drop (approx. 40 to 50 µL) of red blood cell suspension into the tube and mix.
4. Incubate at room temperature (15 to 30°C) for 15 to 30 minutes.
5. Centrifuge for:
   a. 60 seconds at 800 to 1000 x g, or
   b. at a time and speed appropriate for the centrifuge calibration.
6. Gently dislodge red blood cell button and observe for macroscopic agglutination. Negative reactions may be examined with an agglutination viewer however microscopic examination is not recommended
7. Record results

Stability of the Reaction
Following centrifugation, all tube tests should be read immediately and results interpreted without delay. Time delays may cause a dissociation of the antigen-antibody complexes resulting to false negative or more often weak positive reactions.

Quality Control
The reactivity of all blood typing reagents should be confirmed by testing with known positive and negative red blood cells on each day of use.
To confirm the reactivity or specificity of Bio-Rad Monoclonal Anti-Jk<sup>a</sup>, Anti-Jk<sup>b</sup> Blood Grouping Reagents, each should be tested with antigen-positive (preferably from heterozygous individuals) and antigen-negative red blood cells, respectively. Each reagent is satisfactory for use if it reacts only with antigen-positive red blood cells.

**Interpretation of Results**

Agglutination of the red blood cells is a positive result and indicates the presence of the corresponding antigen. No agglutination is a negative result and indicates the absence of the corresponding antigen. An agglutination viewer may facilitate the reading of tube tests (as recommended by the AABB Technical Manual). Frequencies in the population are listed in the “Summary” section.

**Limitations**

- Samples with a positive direct antiglobulin test, cold agglutinins, or rouleaux formation may show false positive results in testing with monoclonal antibodies. Results on these samples must be interpreted with caution. False positive results or reaction suspected to be due to cold agglutinins should be resolved according to in-house procedures.
- Some conditions that may cause false positive results are:
  - Contamination of sample or reagents
  - Autoantibodies
  - Improper storage or preparation of red blood cells
  - Antibodies to antibiotics or other reagents
  - Cold antibodies

**Specific Performance Characteristics**

Testing is performed in accordance with FDA recommended methods. The final release testing is performed according to the product specific SOPs. As a part of the release process, each lot of Bio-Rad Blood Group Reagent is tested according to the package insert method against a panel of antigen positive red blood cells (heterozygous antigen expression and if possible weakened antigen expression) to insure suitable reactivity. The products meet FDA potency requirements. The specificity testing for the presence of contaminating antibodies is performed according to the product specific SOPs. For the product performance it is necessary to adhere to the recommended method in the instructions for use.

The performance of the Bio-Rad Anti-Jk<sup>a</sup> and Anti-Jk<sup>b</sup> was confirmed against FDA approved reference reagents in a Multi Center Field Trial.

For Technical Support or further product information, contact Bio-Rad Laboratories, Inc. at 800-224-6723.

**Note**

- Manual techniques are to be performed according to the manufacturer’s instructions. Each deviation from these instructions is the sole responsibility of the user.
- Used tests must be discarded as hazardous material. Manage waste according to local, state and national regulations.

---

**Glossary of Symbols**

<table>
<thead>
<tr>
<th>Symbol</th>
<th>Definition</th>
<th>Symbol</th>
<th>Definition</th>
</tr>
</thead>
<tbody>
<tr>
<td><code>[LOT]</code></td>
<td>Batch Code</td>
<td><code>[IVD]</code></td>
<td><em>In vitro diagnostic medical device</em></td>
</tr>
<tr>
<td><code>[⚠]</code></td>
<td>Caution, consult accompanying documents</td>
<td><code>[I]</code></td>
<td>Consult instructions for use.</td>
</tr>
<tr>
<td><code>[△]</code></td>
<td>Manufacturer</td>
<td><code>[×]</code></td>
<td>Use by YYYY-MM-DD</td>
</tr>
<tr>
<td><code>[▼]</code></td>
<td>Contains sufficient quantity for &lt;n&gt; tests.</td>
<td><code>[REF]</code></td>
<td>Catalog number</td>
</tr>
<tr>
<td><code>[📅]</code></td>
<td>Temperature limitation</td>
<td><code>[VOL]</code></td>
<td>Volume</td>
</tr>
</tbody>
</table>

**Bibliography**