Blood Grouping Reagents

**Anti-A (ABO1)**
Seraclone® Murine Monoclonal (A003)

**Anti-B (ABO2)**
Seraclone® Murine Monoclonal (B005)

**Anti-A,B (ABO3)**
Seraclone® Murine Monoclonal Blend (BS63/BS85)

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

**Package size**

<table>
<thead>
<tr>
<th>REF</th>
<th>VOL</th>
<th>10 x 10 mL</th>
<th>Seraclone® Anti-A (ABO1)</th>
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</table>

**Intended Use**
For the determination of the A (ABO1), B (ABO2), A,B (ABO3) antigens of red blood cells using the tube test.

**Summary**
Between 1900 and 1902, Landsteiner and associates discovered the ABO system of red blood cell antigens. The importance of this discovery is the recognition that antibodies are present when the corresponding antigens are lacking. The ABO system is the only blood group system in which the recognition that antibodies are present when the corresponding antigens are lacking. The absence of both A and B antigens defines blood type O.

**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. 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 when tested with Seraclone Anti-A or Seraclone Anti-B and up to 14 days when tested with Seraclone Anti-A,B. Donor blood stored in citrate anticoagulant may be tested until the expiration date of the donor unit.

**Materials provided**
- Seraclone® Anti-A (ABO1), Seraclone® Anti-B (ABO2) and/or Seraclone® Anti-A,B (ABO3)

**Materials required but not provided**
- Pipettes
- Isotonic saline or Phosphate Buffered Solution (PBS). (PBS only when tested with Seraclone® Anti-A,B)
- Negative control (e.g. Bio-Rad Seraclone® Control ABO+Rh [REF 805171100])
- Glass tubes 10 x 75mm or 12 x 75mm
- Serological centrifuge
- Interval timer
- Markers
- Agglutination viewer (optional)

**Test Procedure**
1. Prepare a 3 to 5% suspension of red blood cells to be tested in saline or PBS*.
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 labelled tube and mix.
4. Centrifuge for:
   a. 20 seconds at 800 to 1000 g, or
   b. at a time and speed appropriate for the centrifuge calibration
5. 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.
6. Record results.

*PBS is only approved for Seraclone® Anti-A,B

They are derived from hybridoma cell lines which are produced by fusing mouse antibody producing B lymphocytes with mouse myeloma cells and demonstrate consistent specificity and reproducibility characteristic for monoclonal antibodies. Both antibodies derived from a single clone (sister cells of one hybridoma cell) and a mixture of different antibodies derived from several clones are called monoclonal.

Antibodies are diluted in a buffered protein solution containing bovine albumin, ethylenediamine tetraacetate (EDTA), and as colorant Patent Blue (Anti-A) or Tartrazine (Anti-B).

Seraclone® Anti-A (ABO1) clone A003 (IgM)
Seraclone® Anti-B (ABO2) clone B005 (IgM)
Seraclone® Anti-A,B (ABO3) clones BS63/BS85 (IgM/IgG)

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 murine viruses has not been determined.
- Caution: This Product Contains Natural Rubber Latex Which May Cause Allergic Reactions.
- Warning: Contains sodium azide (Na₃N₄), 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.

**Phenotype Frequency (%)**

<table>
<thead>
<tr>
<th>Phenootype Frequency (%)</th>
<th>Caucasians</th>
<th>Blacks</th>
<th>Asians</th>
<th>Mexican</th>
</tr>
</thead>
<tbody>
<tr>
<td>A1</td>
<td>33</td>
<td>19</td>
<td>27</td>
<td>22</td>
</tr>
<tr>
<td>A2</td>
<td>10</td>
<td>8</td>
<td>Rare</td>
<td>6</td>
</tr>
<tr>
<td>B</td>
<td>9</td>
<td>20</td>
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<td>AB</td>
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<tr>
<td>A:B</td>
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<td>4</td>
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<tr>
<td>A:B</td>
<td>1,1</td>
<td>1</td>
<td>Rare</td>
<td>Rare</td>
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</table>

**Principle of the test**
The test principle is hemagglutination. The antibodies in Seraclone® Anti-A (ABO1), Seraclone® Anti-B (ABO2), and Seraclone® Anti-A,B (ABO3) bind to the corresponding antigen on red blood cells being tested and cause an antigen-antibody reaction visible as red blood cell agglutination. The four ABO blood groups A, B, AB and O are defined by the presence or absence of A and B antigens on red blood cells.

The absence of both A and B antigens defines blood type O.
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 in false negative or more often weak positive reactions.

Quality Control
The reactivity of all blood grouping 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 ABO Blood Grouping Reagents (Anti-A, Anti-B, Anti-A,B), each should be tested with antigen-positive (preferably from heterozygous or weak antigen expression) and antigen-negative red blood cells, respectively. Each reagent is satisfactory for use if it reacts only with antigen-positive red blood cells. Confirmation of results in forward grouping must be obtained by performing the reverse grouping test. A negative control should be performed on samples testing positive with Anti-A, Anti-B and Anti-D. Seraclone® Control ABO+Rh may be used.

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.

Reaction patterns, red blood cell antigens and isoagglutinins
The interpretation of results in testing infant blood samples may be difficult due to the fact that infant serum does not necessarily contain the natural occurring ABO antibodies for antigens absent from the red blood cells.

In all other cases, any discrepancy between forward and reverse grouping has to be resolved before the ABO blood group is recorded. The reagents do not react with crypt cell antigens (T-, Tn-, Tk activated cells). Anti-B must be carried out using different monoclonal and/or human polyclonal Anti-A Blood Grouping Reagents.

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 part of the release process each lot of Bio-Rad Blood Grouping 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. Seraclone® Anti-A has the ability to detect minute quantities of A-antigens on red cells (e.g. Ax). However, this capability allows clinical insignificant numbers of A antigens to be detected as in rare cases of B individuals with elevated A antigen level (e.g. B(A) phenomena).

The product meets FDA potency requirements.

The performance of the Bio-Rad Anti-A and Anti-B was confirmed against FDA approved reference reagents in a Multi Center Field Trial.

The performance of the reformulated Seraclone® Anti-A,B was confirmed in-house performance evaluations in 2016.

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>
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<tbody>
<tr>
<td>LOT</td>
<td>Batch Code</td>
<td>IVD</td>
<td>In vitro diagnostic medical device</td>
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<tr>
<td>☐</td>
<td>Consult accompanying documents</td>
<td>☐</td>
<td>Consult instructions for use.</td>
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<tr>
<td>☑</td>
<td>Manufacturer</td>
<td>☑</td>
<td>Use by YYYY-MM-DD</td>
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<td>Contains sufficient quantity for &lt;n&gt; tests.</td>
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<td>☑ Catalog number</td>
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<tr>
<td>☑</td>
<td>Temperature limitation</td>
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<td>☑ Volume</td>
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Bibliography

Key: Underline = Addition of changes  ◄ = Deletion of text