Seraclone® Control ABO+Rh
Reagent for the negative control in ABO and Rh-typing with Seraclone® ABO- and Rh reagents

FOR IN-VITRO DIAGNOSTIC USE
For Tube test
Rx only

Package size
REF 805171100 VOL 10 mL Seraclone® Control ABO+Rh

Intended Use
Seraclone® Control ABO+Rh is used for tube test as negative control in ABO and Rh blood grouping with Seraclone® ABO+Rh Blood Grouping Reagents.

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 reciprocal antibodies are consistently and predictably present in most people. Due to this reciprocity, an ABO blood type determination is considered valid if serum typing corresponds with the red blood cell antigen grouping. Bio-Rad Anti-A, Anti-B and Anti-A,B blood group reagents are used to test for the presence or absence of the corresponding antigens. Routine pretransfusion studies always include tests for the ABO antigens. The D (RH1) antigen is the most important red blood cell antigen after A and B. Cells that have the D (RH1) antigen are “Rh positive”. Cells that do not have the D (RH1) antigen are “Rh negative”. Soon after the discovery of the Rhesus factor, it became obvious that some red blood cells were weaker reacting with anti-D than other “normal” D-positive red blood cells (Stratton, 1946). These Rhesus antigens were grouped under the heading of Du. It was also apparent that some Du red blood cells reacted more strongly with anti-D reagents than others. Routine pretransfusion studies always include tests for the D antigen.

Test principle
The test principle is a hemagglutination test. The antigens (characteristics) of the ABO as well as the Rh system react with the corresponding antibodies in the Seraclone® ABO- and Rh reagents. Samples with autoimmune antibodies, cold antibodies or rouleaux formation may show false positive reactions in testing with monoclonal antibodies. Thus a positive and a negative control should be performed with each test. A negative reaction is visible as a homogenous red cell suspension with no agglutinates. Seraclone® Control ABO+Rh can be used in tube testing.

Reagent
RVU
OBSERVABLE INDICATIONS
Do not use if markedly turbid
Do not use damaged vials
Seraclone® Control ABO+Rh is not of human origin. It contains all components of Seraclone® ABO- and Rh-reagents but not the antibodies. Thus it is suited as negative control in ABO typing and Rh-D-typing with Rh reagents.

Seraclone® Control ABO+Rh
Preservative: 0.1% Sodium azide

• No U.S. Standard of Potency
• For In-vitro Diagnostics use
• Use as furnished, do not dilute

Precaution
• 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: This product contains Natural Rubber Latex Which May Cause Allergic Reactions.
• Warning: Contains Sodium azide (Na3H5), 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 samples 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® Control ABO+Rh

Materials required but not provided
• Seraclone® Anti-A (ABO1) REF 801325100
• Seraclone® Anti-B (ABO2) REF 801350100
• Seraclone® Anti-A,B (ABO3) REF 801375100
• Seraclone® Anti-D (RH1) Blend REF 802042100
• Seraclone® Anti-D (RH1) Blend REF 802022100
• Seraclone® Anti-C (RH2) REF 802250100
• Seraclone® Anti-C (RH4) REF 802341600
• Seraclone® Anti-E (RH3) REF 802336100
• Seraclone® Anti-e (RH5) REF 8023670100
• Pipettes sterile saline
• Glass tubes 10 x 75mm or 12 x 75mm
• Serological centrifuge
• Interval timer
• Markers
• Agglutination viewer (optional).

Test procedure
Tube test
For each blood sample test for ABO- and Rh-determination, a parallel negative control can be performed with Seraclone® Control ABO+Rh. The test has to be performed according to the method chosen for ABO and Rh testing, e.g.:
1. Prepare a 3 to 5% suspension of red blood cells to be tested in isotonic saline.
2. Place one drop control reagent into an appropriately labeled tube.
3. Add one drop (approx. 40 to 50 µL) of red blood cell suspension into appropriate tube and mix.
4. Incubate according to the method chosen for ABO and Rh testing.
5. Centrifuge:
   a. 20 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 reading is not recommended.
7. Record results.

Stability of 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 complex(es) resulting to false negative or more often weak positive reactions.

Quality Control
To confirm the reactivity or specificity of Bio-Rad Seraclone® ABO Blood Grouping Reagents (Anti-A, Anti-B, Anti-A,B) and Rh Blood Grouping Reagents (Anti-D, Anti-D Blend, Anti-C, Anti-E, Anti-e, 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, Anti-A,B and Anti-D. Seraclone® Control ABO+Rh may be used.

Interpretation of Results
No agglutination of the red cells to be tested with Seraclone® Control ABO+Rh: the result of the blood typing and Rh-factor determination is valid.
Agglutination of the red cells to be tested with Seraclone® Control ABO+Rh: the result of the blood typing and Rh-factor determination is not valid.
An agglutination viewer may facilitate the reading of tube tests (as recommended by the AABB Technical Manual)³.
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 cryptoantigens (T-, Tn-, Tk activated cells). Anti-B reacts correctly negative with acquired B characteristics.

<table>
<thead>
<tr>
<th>Reagent with Patient red Blood cells</th>
<th>Reagent red blood cells with Patient serum/plasma</th>
<th>Blood Group</th>
</tr>
</thead>
<tbody>
<tr>
<td>Anti-A Anti-B Anti-AB Phenotype</td>
<td>Anti-A Anti-B Anti-AB Blood Group</td>
<td></td>
</tr>
<tr>
<td>+ 0 +</td>
<td>00 +</td>
<td>A</td>
</tr>
<tr>
<td>0 + +</td>
<td>00 +</td>
<td>B</td>
</tr>
<tr>
<td>0 0 0</td>
<td>+ + +</td>
<td>O</td>
</tr>
<tr>
<td>- + +</td>
<td>0 0 0</td>
<td>AB</td>
</tr>
</tbody>
</table>

*Testing with A2 cells is not required
Reagent sera with
patient red blood cells

<table>
<thead>
<tr>
<th>Anti-D Control Weak D Test</th>
<th>Interpretation</th>
</tr>
</thead>
<tbody>
<tr>
<td>+ 0 0 0 0</td>
<td>Rh positive</td>
</tr>
<tr>
<td>0 + + + 0</td>
<td>* Rh positive</td>
</tr>
<tr>
<td>+ + + + 0</td>
<td>Invalid Test</td>
</tr>
</tbody>
</table>

+ = agglutination
0 = no agglutination

* A test for weak D may be performed on samples that test negative with Anti-D to determine the Rh status. Certain groups of patients may require testing for weak D. Follow facility specific policies for determining which samples require weak D testing.

**Testing is not valid unless the sample can be shown to react negatively with an appropriate Rh control (e.g. Bio-Rad Seraclone® ABO+Rh Control [REF 805171100]) or exhibits a negative direct antiglobulin test.

Limitations

- Turbidity or other visible changes of the reagent may indicate a bacterial contamination. In this case the reagent must be discarded. The cause for the change must be examined by the manufacturer.
- 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.
- 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 reactions to be 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
  - Cold Antibodies
  - Incorrect incubation
  - Incorrect calibration/centrifugation
  - Incorrect reading technique
  - Antibodies to antibiotics or other reagents

Specific Performance Characteristics

Testing is performed in accordance with FDA approved methods. The final release testing is performed according to the product specific SOPs. As part of the release process, each lot of Bio-Rad Reagent is tested according to the package insert method to insure suitable reactivity. For the product performance it is necessary to adhere to the recommended method in the instructions for use.

For Technical Support or further product information, contact Bio-Rad Laboratories Inc., at 800-224-8723.

Note

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>LOT</td>
<td>Batch Code</td>
<td>[V]</td>
<td>In vitro diagnostic medical device</td>
</tr>
<tr>
<td>❞</td>
<td>Caution, consult accompanying documents</td>
<td>[I]</td>
<td>Consult instructions for use.</td>
</tr>
<tr>
<td>☑</td>
<td>Manufacturer</td>
<td>☑</td>
<td>Use by YYYY-MM-DD</td>
</tr>
<tr>
<td>☐</td>
<td>Contains sufficient quantity for &lt;n&gt; tests</td>
<td>[REF]</td>
<td>Catalog number</td>
</tr>
<tr>
<td>☑</td>
<td>Temperature limitation</td>
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Bibliography


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