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.

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.

Reagent
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

Precaution
• For In-vitro diagnostic use
• Use as furnished, do not dilute

Materials required but not provided
• Seraclone® Anti-A (AB01)
• Seraclone® Anti-B (AB02)
• Seraclone® Anti-A-B (AB01,2)
• Seraclone® Anti-D (RH1) Blend
• Seraclone® Anti-C (RH2)
• Seraclone® Anti-E (RH3)
• Seraclone® Anti-D (RH1) Blend

Test procedure
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 of red blood cell suspension into the tube labeled for it and incubate.
4. Incubate or centrifuge for 20 seconds at 800-1000 x g (according to the method chosen for ABO and Rh testing).
5. Gently dispose red blood cell button and observe for agglutination.

Materials provided
Seraclone® Control ABO+Rh

FOR IN-VITRO DIAGNOSTIC USE

Materials provided
Seraclone® Control ABO+Rh

Intended Use
Seraclone® Control ABO+Rh is used for tube test as negative control in ABO and Rh typing with Seraclone® ABO- and Rh 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.

Biotest 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 D antigen. 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 Rh 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 D red blood cells reacted more strongly with anti-D reagents than others.

Routine pretransfusion studies always include tests for the D antigen.

Caution: This product contains Natural Rubber Latex Which May Cause Allergic Reactions.

WARNING: Contains sodium azide (NaN₃), 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 purchased from BSE-free US sources, Boval Company L.P. in Cleburne, Tx, USA and Millipore in Kankakee, IL, USA.

Specimen Collection
Fresh samples of clotted, EDTA or citrate anticoagulated whole blood collected following general blood sample 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® Control ABO+Rh

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

**Limitations**
Turbidly 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. It is recommended that an appropriate control be tested in parallel.
- 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

**Specific Performance Characteristics**
Testing is performed in accordance with FDA approved methods. The final release testing is performed according to the product specific SOPs. Each lot of Biotest Reagent is tested in the Quality control by 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 Biotest Diagnostics Corporation at 800-522-0090.

**Note**
Each facility should verify the optimum spin time for the specific centrifuge in use. 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>
</tr>
<tr>
<td>△</td>
<td>Caution, consult accompanying documents</td>
</tr>
<tr>
<td>⚠</td>
<td>Manufacturer</td>
</tr>
<tr>
<td>◐</td>
<td>Contains sufficient quantity for &lt;n&gt; tests.</td>
</tr>
<tr>
<td>⋙</td>
<td>Temperature limitation</td>
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<tr>
<td>I</td>
<td>Use by YYYY-MM-DD</td>
</tr>
<tr>
<td>[LOT]</td>
<td>In vitro diagnostic medical device</td>
</tr>
<tr>
<td>[IVD]</td>
<td>Consult instructions for use.</td>
</tr>
<tr>
<td>[REF]</td>
<td>Catalog number</td>
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**Bibliography**