Blood Grouping Reagent

Anti-C (RH2)
Seraclone Human Monoclonal (MS24)

Anti-č (RH4)
Seraclone Human Monoclonal (MS33)

Anti-E (RH3)
Seraclone Human Monoclonal (MS260/MS12)

Anti-e (RH5)
Seraclone Human Monoclonal (MS16/MS21/MS63)

FOR IN-VITRO DIAGNOSTIC USE
For Tube Testing
MEETS FDA POTENCY REQUIREMENTS
U.S. License Number: 1798

Package size
REF 802280100 VOL 5 mL Seraclone Anti-C (RH2)
REF 802346100 VOL 5 mL Seraclone Anti-č (RH4)
REF 802336100 VOL 5 mL Seraclone Anti-E (RH3)
REF 802370100 VOL 5 mL Seraclone Anti-e (RH5)

Intended Use
For the determination of the Rhesus antigens C (RH2), E (RH3), č (RH4), e (RH5) of red blood cells using the tube test.

Summary
More than 50 antigens belong to the Rhesus blood group system. The antigens C, č, E and e, along with D, are the principle antigens of the Rh system. Although many other antigens have been identified, the antibodies associated with these 5 antigens are responsible for the majority of hemolytic transfusion reactions and cases of hemolytic disease of the fetus and newborn associated with the Rh system. For the determination of Rh phenotypes the C, č, E and e antigens on the red blood cells are tested with Anti-C (RH2), Anti-č (RH4), Anti-E (RH3) and Anti-e (RH5). If the red blood cells carry only big C or little c (or E or e) the individual is treated as being homozygous for that particular antigen (allele). The most probable genotype can be presumed by determining the phenotype. The ethnic origin influences the genotype, which can be seen in the table.

Incidence of the More Common Genotypes in D+ Persons

<table>
<thead>
<tr>
<th>Antigens Present</th>
<th>Genotype</th>
<th>Incidence (%)</th>
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<tbody>
<tr>
<td></td>
<td>DCE</td>
<td>Mod. Rh-hr</td>
</tr>
<tr>
<td>D,č,e</td>
<td>DCe/ce</td>
<td>Rwr</td>
</tr>
<tr>
<td></td>
<td>DCe/Dce</td>
<td>Rwr,Rwr</td>
</tr>
<tr>
<td></td>
<td>Dce/ce</td>
<td>Rwr,Rwr</td>
</tr>
<tr>
<td></td>
<td>D,C,e</td>
<td>DCE/ce</td>
</tr>
<tr>
<td></td>
<td>D,c,E,e</td>
<td>DcE/ce</td>
</tr>
<tr>
<td></td>
<td>D,c,E</td>
<td>DcE/DcE</td>
</tr>
<tr>
<td></td>
<td>D,c,E,e</td>
<td>DcE/ce</td>
</tr>
<tr>
<td></td>
<td>D,c,e</td>
<td>Dce/ce</td>
</tr>
<tr>
<td></td>
<td>D,c,e</td>
<td>Dce/ce</td>
</tr>
</tbody>
</table>

Biotest Seraclone® Rhesus Blood Group Reagents are used to test for the presence or absence of the Rhesus antigens C, č, E, e, D. Routine pretransfusion studies always include tests for the D antigen. Other Rhesus reagents like Biotest Seraclone® Anti-C (RH2), Seraclone® Anti-č (RH4), Seraclone® Anti-E (RH3) and Seraclone® Anti-e (RH5) 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-C (RH2), Seraclone® Anti-č (RH4), Seraclone® Anti-E (RH3) and Seraclone® Anti-e (RH5) 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-C (RH2), Seraclone® Anti-č (RH4), Seraclone® Anti-E (RH3) and Seraclone® Anti-e (RH5) 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. Seraclone® Anti-E (RH3) does react with E⁺, Anti-C.

The antibodies are diluted in an isotonic saline solution containing bovine albumine.

Anti-č

The antibodies are diluted in a buffered saline solution containing macromolecular potentiator.

Anti-E and Anti-e

Antibodies are diluted in a buffered protein solution containing macromolecular potentiators.

The following antibodies are produced using intermediate products produced for Biotest 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-C (RH2) clone MS24 (IgM)
Seraclone® Anti-č (RH4) clone MS33 (IgM)
Seraclone® Anti-E (RH3) clone MS260/MS12 (IgM/IgG)
Seraclone® Anti-e (RH5) clone MS16/MS21/MS63 (IgM/IgG/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 (Na₃N), 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 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-C (RH2), Seraclone® Anti-č (RH4), Seraclone® Anti-E (RH3) and/or Seraclone® Anti-e (RH5)
Materials required but not provided

- Pipettes (drop volume 40 to 50 μl)
- Isotonic saline solution
- Negative Control (e.g. Biotest Seraclone® Control ABO+Rh

Specific Performance Characteristics
Testing is performed in accordance with FDA recommended methods. The final release testing is performed according to the product specific SOPs. Each lot of Biotest blood group reagent is tested in the Quality control by 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 Biotest Anti-C, Anti-c and Anti-E, Anti-e was confirmed against a FDA approved reference reagent in a Multi Center Field Trial.

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.

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>[LOT]</td>
<td>Batch Code</td>
<td>[IVD]</td>
<td>In vitro diagnostic medical device</td>
</tr>
<tr>
<td>△</td>
<td>Caution, consult accompanying documents</td>
<td>☐</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>
<td>[VOL]</td>
<td>Volume</td>
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### Bibliography