Lyophilized S.A.R.P. is stable until the expiration date on the label when stored at 2 to 8°C. The reconstituted control plasma is stable for eight hours at 2 to 8°C or 30 days at -20°C.

Components offered individually

<table>
<thead>
<tr>
<th>Cat. No.</th>
<th>Component</th>
</tr>
</thead>
<tbody>
<tr>
<td>5370</td>
<td>Lyophilized Platelets (4.5 x 5 mL)</td>
</tr>
<tr>
<td>5185</td>
<td>Coagulation S.A.R.P. (1.0 x 10 mL)</td>
</tr>
<tr>
<td>5358</td>
<td>Tris-Buffered Saline (1 x 35 mL)</td>
</tr>
<tr>
<td>5365</td>
<td>Helena Ristocetin (10 mg/mL)</td>
</tr>
<tr>
<td>5372</td>
<td>Ristocetin Control Abnormal Control Plasma (5 x 0.5 mL)</td>
</tr>
</tbody>
</table>

Helena Ristocetin Cofactor Assay Kit

<table>
<thead>
<tr>
<th>Cat. No.</th>
<th>Component</th>
</tr>
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<tbody>
<tr>
<td>5370</td>
<td>Helena Ristocetin Cofactor Assay Kit</td>
</tr>
</tbody>
</table>

Other Supplies and Equipment

- The Helena Ristocetin Cofactor Assay Kit must be ordered individually.

For Sales, Technical and Order Information, and Service Assistance, call 1-800-553-6169 toll free.

LIMITATIONS

The ristocetin cofactor activity fails to reflect accurately von Willebrand's disease in several situations such as pregnancy, ingestion of commercial fresh frozen plasma, or in patients with von Willebrand's disease and a von Willebrand factor inhibitor. In these cases, the method may overestimate ristocetin cofactor activity.

For use with the Helena Ristocetin Cofactor Assay Kit, the Helena Ristocetin Response Curve Kit, the Helena Ristocetin Cofactor Assay Report Form, and the Helena Ristocetin Cofactor Abnormal Control Plasma.

For Sales, Technical and Order Information, and Service Assistance, call 1-800-553-6169 toll free.

REFERENCES

A random sample of 22 normal plasma specimens was tested for ristocetin cofactor activity. An established range of 58-166% (0.58-6.16 units/mL) was obtained from 100 normal plasma samples with 95% confidence limits of 54-170% (0.54-1.70 units/mL). It was then calculated that a sample size of 38 would yield a confidence limit of 95% for the true mean with a standard error of less than 5%.

BIBLIOGRAPHY


PERFORMANCE CHARACTERISTICS

| Correlation study were done using the Helena Ristocetin Cofactor Assay Method on the AggRAM and the PACKS-4. Each sample was tested by two methods resulting in a linear regression equation for each assay. The method was in good agreement with the other method, and the assay was specific for von Willebrand factor activity.

PREPARATION

1. Pipette 250 µL of Helena's lyophilized platelet suspension and 250 µL of Tris-Buffered Saline. Swirl gently and allow to stand 10 minutes at room temperature, then mix well.

Stabilizers have been added to assure stability. The reconstituted plasma is stable for eight hours at 2 to 8°C or 30 days at -20°C.

Patient results should be compared to normal ranges run under the same conditions. The following steps are for standard volume; for micro volume use onehalf of the standard volume.

1. 100 µL of deionized water
2. 100 µL of deionized water

Stabilizers have been added to assure stability. The reconstituted plasma is stable for eight hours at 2 to 8°C or 30 days at -20°C.

INSTRUMENTS

A. Recorder Preparation

The plasma has been found negative for Hepatitis B Antigen (HBsAg) and HIV antibody; however, it should be handled with the same precautions as with any human plasma.

Patients with a complete thrombocytopenia or a platelet count of less than 30,000 should be tested within 30 minutes.

Ristocetin is a lipophilic substance. Stabilizers have been added to assure stability. The reconstituted plasma is stable for eight hours at 2 to 8°C or 30 days at -20°C.

WARNING: FOR IN-VITRO DIAGNOSTIC USE. Avoid ingestion.

The Helena Ristocetin Cofactor Assay Kit contains a human thromboplastic agent obtained from normal human plasma. The plasma has been found negative for Hepatitis B Antigen (HBsAg) and HIV antibody; however, it should be handled with the same precautions as with any human plasma.

Patients with a complete thrombocytopenia or a platelet count of less than 30,000 should be tested within 30 minutes.

Stabilizers have been added to assure stability. The reconstituted plasma is stable for eight hours at 2 to 8°C or 30 days at -20°C.

WARNING: FOR IN-VITRO DIAGNOSTIC USE. Avoid ingestion.

The Helena Ristocetin Cofactor Assay Kit contains a human thromboplastic agent obtained from normal human plasma. The plasma has been found negative for Hepatitis B Antigen (HBsAg) and HIV antibody; however, it should be handled with the same precautions as with any human plasma.

Patients with a complete thrombocytopenia or a platelet count of less than 30,000 should be tested within 30 minutes.
A random sampling of 22 normal plasma specimens was tested for ristocetin cofactor activity. The Helena Ristocetin Cofactor Assay Kit is intended for the quantitation of an activity that reflects von Willebrand factor activity.

SUMMARY
The rate of ristocetin-induced agglutination is related to the concentration of von Willebrand factor and an percent normal activity can be obtained from the aggregram tracing.

REAGENTS
1. Lyophilized Platelets

Lyophilized Platelets contain washed formalin-fixed platelets in a tris-buffereed saline.

2. Coagulation S.A.R.P. (Specially Assayed Reference Plasma)

Coagulation S.A.R.P. is prepared from a pool of fresh citrated plasma obtained from healthy individuals. The pool is buffered and lyophilized to insure stability for an extended period of time. The ristocetin cofactor activity of the reconstituted product is stable for eight hours at 2 to 8°C. The rate of ristocetin induced agglutination is related to the concentration of von Willebrand factor and percent normal activity can be obtained from the aggregram tracing.

Components offered individually
Cat. No.
Lyophilized Platelets (5 x 5.0 mL)
3570
Lyophilized S.A.R.P. (10 x 1.0 mL)
5185
Lyophilized S.A.R.P. (25 x 0.2 mL)
5365
Helena Ristocetin (10 mg/mL) 2 x 1.5 mL
5393
Ristocetin Cofactor Abnormal Control Plasma (5 x 0.5 mL)
5373

Other supplies and equipment

1. The Helena Ristocetin Cofactor Assay Kit must be ordered individually.

2. Reconstitute S.A.R.P. with 1.0 mL of deionized water.

3. Storage and Stability: Lophotrophin S.A.R.P. is stable until the expiration date indicated on the vial when stored at 2 to 8°C. The ristocetin cofactor activity is related to the concentration of von Willebrand factor and percent normal activity can be obtained from the aggregram tracing.

WARNING: IN-VITRO DIAGNOSTIC USE. Avoid injection.

Preparation for use: Reconstitute each vial with 5.0 mL of the Helena Tris-Buffereed saline. Allow to stand approximately 20 minutes, then mix well. Vortexing for 1.5 minutes improves uniform suspension of platelets. An alternative method to vortexing is aspiration of the 5 mL of platelet suspension into a 5 mL syringe, with a 21 or 23 needle and forcibly returning the suspension to the vial for 1 to 2 times.

Lyophilized S.A.R.P. can be reconstituted with the recommended standard volumes. Use the report form provided and the slope values obtained from the linear portion of the standard curve. Multiply the test results by the factor of dilution.


