## Performance Characteristics

### Correlation Studies

Correlation studies were done using the Helena Ristocetin Cofactor Assay Method on the AggRAM and the PACKS-4 assay. Forty samples were tested by both methods in a linear regression equation of $y = 0.97x + 1.3$ (where $y$ is the AggRAM method and $x$ is the PACKS-4 method) and a correlation coefficient of 0.97.

### Linear Regression Equation

$$y = 0.97x + 1.3$$

### Limitations

The ristocetin cofactor activity fails to reflect accurately von Willebrand's disease in several situations such as pregnancy, infusion of commercial Factor VIII concentrates\(^a\), or administration of 1-deamino(8-arginine) vasopressin (DOCA)\(^b\). In such situations ristocetin induced aggregation may be correct, yet the bleeding time remains prolonged. In addition, VIIRF-RCU values may be normal in Type II B von Willebrand's disease even though the bleeding time is prolonged\(^c\).

## References


### Components Offered Individually

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### Other Supplies and Equipment

- Sodium citrate solution
- Deionized water
- Aggregometer cuvettes
- Stir bars
- Ristocetin
- Deionized water
- Glass syringes

### Storage and Stability

- Lysophosphatidyl Plasma: Stable until the expiration date indicated on the label when stored at 2 to 8°C.
- S.A.C.-1: Stable for 30 days at -20°C.
- S.A.C.-2: Stable for 30 days at -20°C.
- Helena Ristocetin: Stable for 30 days at -20°C.
- Ristocetin Control Plasma: Stable for 30 days at -20°C.

### Signs of Deterioration

- Cloudiness, turbidity, foreign particulate matter.
- Change in color.

### Signs of Deterioration

- Change in color.
- Change in consistency.
- Change in smell.

### Materials Provided

- Patient kit - Cat. No. 5356

### Materials Required but not provided in the kit:

- Glass syringes
- Deionized water
- Aggregometer cuvettes
- Stir bars
- Helena Ristocetin
- Deionized water
- Glass syringes
- Platelets
- Sodium citrate solution

### STEP-BY-STEP METHOD

1. **Prepare aggregometer for use as recommended in the Operator's Manual.**

   - Reconstitute one vial of Ristocetin with 1.0 mL of deionized water. Swirl gently and allow to stand at room temperature for complete dissolution.

2. **Prepare aggregometer for use as recommended in the Operator's Manual.**

   - Reconstitute one vial of Ristocetin with 1.0 mL of deionized water. Swirl gently and allow to stand at room temperature for complete dissolution.

3. **Prepare aggregometer for use as recommended in the Operator's Manual.**

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4. **Prepare aggregometer for use as recommended in the Operator's Manual.**

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5. **Prepare aggregometer for use as recommended in the Operator's Manual.**

   - Reconstitute one vial of Ristocetin with 1.0 mL of deionized water. Swirl gently and allow to stand at room temperature for complete dissolution.

6. **Prepare aggregometer for use as recommended in the Operator's Manual.**

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7. **Prepare aggregometer for use as recommended in the Operator's Manual.**

   - Reconstitute one vial of Ristocetin with 1.0 mL of deionized water. Swirl gently and allow to stand at room temperature for complete dissolution.

8. **Prepare aggregometer for use as recommended in the Operator's Manual.**

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10. **Prepare aggregometer for use as recommended in the Operator's Manual.**

    - Reconstitute one vial of Ristocetin with 1.0 mL of deionized water. Swirl gently and allow to stand at room temperature for complete dissolution.
The Helena Ristocetin Cofactor Assay Kit is intended for the quantitation of ristocetin cofactor activity which reflects von Willebrand factor activity.

**SUMMARY**

The von Willebrand factor protein is the protein which controls the bleeding time and it also acts as a coagulant in von Willebrand's disease. Several variant forms of ristocetin cofactor have been identified in von Willebrand’s disease that have been identified. They are usually differentiated into normal and variant forms of von Willebrand Factor VIII and Factor VIII von Willebrand factor. The ristocetin cofactor is a protein which acts as an agonist in von Willebrand’s disease. The assay is an indirect method to determine the presence of the antigen in the absence of the antigen in the presence of the antibiotic. The estimation of the ristocetin cofactor activity may reflect the quantitation of an activity thought to reflect von Willebrand factor activity.

**PRINCIPLE**

The Helena Ristocetin Cofactor Assay Kit measures the ability of a patient’s plasma to aggregate formalin-fixed platelets in a tri-tube saline. WARNING: FOR IN-VITRO DIAGNOSTIC USE. Avoid ingestion.

**Preparation for Use:** Reconstitute each vial with 10 mL of the Tria-Buffered saline. Allow to stand approximately 20 minutes, then mix well. Vortexing for 1-5 minutes improves uniform suspension of platelets. Storage and Stability: Helena Lyophilized platelets are stable until the expiration date printed on the vial label when stored at 2 to 8°C. The reconstituted product is stable for 30 days when stored at 2 to 8°C. Before use, the reconstituted platelets to come to room temperature and resuspend platelets by mixing thoroughly.

**Signs of Deterioration:** The lyophilized product is a light suspension of platelets. Large fakery particles may be indicative of product deterioration.

**CAUTION:** All reagents and returnable reference plasma are offered individually.

**Instruments:**

- AggRAM Stir Bars 1489
- PACKS-4 Platelet Aggregation System 1471
- AggRAM/PACKS-4 Cuvettes (200) 1473

**BIBLIOGRAPHY**

1. Zimmern, T.S., Ruzza, Z.M., Pareti, F.I., Mannucci, P.M., et al., Heightened Interaction between ristocetin and von Willebrand factor and the percent normal activity can be obtained from the aggregometer tracing.

**REAGENTS**

- Lymphoplated Platelets
- RISTOCETIN COFACTOR ASSAY

**LIMITATIONS**

The ristocetin cofactor activity fails to reflect normally von Willebrand’s disease in several situations such as pregnancy, infusion of commercial Factor VIII concentrates\(^1\), or administration of 1-deamino (8-d-arginine)-Pro. 167®. In such instances, one may be misled, yet the bleeding time remains prolonged. In addition, VWF:RCo levels may be normal in Type IIb von Willebrand’s disease even though the bleeding time is prolonged.\(^2\)

**PERFORMANCE CHARACTERISTICS**

**Correlation Studies:** Correlation studies were done using the Helena Ristocetin Cofactor Assay Method on the AggRAM and the PACKS-4 aggregation analyzers. Four samples were tested by both methods in a linear regression equation of Y = 0.99T + 1.5 (where Y is the AggRAM method and X is the PACKS-4 method) and a correlation coefficient of 0.974.

**REFERENCES**


5. HELA Lyophilized Aggregometer System, 1471

6. HELA Lyophilized Platelets

7. HELA Lyophilized Plasma

8. HELA Ristocetin

**SUMMARY**

The von Willebrand factor protein is the protein which controls the bleeding time and it also acts as a coagulant in von Willebrand’s disease. Several variant forms of ristocetin cofactor have been identified in von Willebrand’s disease that have been identified. They are usually differentiated into normal and variant forms of von Willebrand Factor VIII and Factor VIII von Willebrand factor. The ristocetin cofactor is a protein which acts as an agonist in von Willebrand’s disease. The assay is an indirect method to determine the presence of the antigen in the absence of the antigen in the presence of the antibiotic. The estimation of the ristocetin cofactor activity may reflect the quantitation of an activity thought to reflect von Willebrand factor activity.

**PRINCIPLE**

The Helena Ristocetin Cofactor Assay Kit measures the ability of a patient’s plasma to aggregate formalin-fixed platelets in the presence of ristocetin. The Helena ristocetin cofactor is a protein which acts as an agonist in von Willebrand’s disease. The patient results should reflect the quantitation of an activity thought to reflect von Willebrand factor activity.

**INSTRUMENTS**

Helena Ristocetin Cofactor Assay Reagents are suitable for use with any turbidimetric aggregation monitoring device. Recommended is the AggRAM Analyst or the PACKS-4 Platelet Aggregation System (Cat. No. 1486).

**SPECIMEN COLLECTION AND HANDLING**

Specimen: Plasma obtained from whole blood collected with 3.2% sodium citrate or an anticoagulant is the specimen of choice.

**STORAGE AND STABILITY:** This plasma contains a human citrated plasma from an individual. The plasma contains a human citrated plasma from an individual. The plasma should be handled with the same precautions as whole blood and stored in the refrigerator at 2 to 8°C.

**REFERENCE RANGE**

A random sample of 22 normal plasma specimens was tested for ristocetin cofactor activity. An established range of 58-166% (0.58-1.66 units/mL) was obtained. It is recommended that each laboratory determine an expected range for its particular instrument and specimen/anticoagulant system. Low values are an indication of von Willebrand’s disease.

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