**PRODUCT DESCRIPTION**

Lyophilized Platelets are a standardized and fixed platelet suspension derived from human blood. The platelets are lyophilized to ensure stability during long term storage. Premeasured Tris Buffered Saline Diluent is supplied with the platelets. Upon reconstitution, the platelet suspension will have a count of approximately 200,000/ul (using hemacytometer methodology).

**INTENDED USE**

Lyophilized Platelets are for use in the quantitation of von Willebrand factor in plasma.

**PRINCIPLE**

Ristocetin cofactor is the in vitro activity of the von Willebrand factor (VIII:vWF) which is responsible for the agglutination of platelets in the presence of Ristocetin. Decreased von Willebrand factor is associated with von Willebrand syndrome, thus making quantitation of Ristocetin cofactor activity most valuable in the diagnosis and evaluation of this coagulopathy. Levels of Ristocetin cofactor activity are determined by the ability of a test plasma and Ristocetin to induce agglutination of a standardized platelet suspension.

**PRECAUTIONS**

Lyophilized Platelets are for IN-VITRO DIAGNOSTIC USE ONLY AND NOT FOR INJECTION OR INGESTION. The platelets have been tested at the source and found to be negative for HIV-1Ag, anti-HIV-1/2, Hepatitis B surface antigen, Hepatitis C antibody, Human T-Lymph tropic type I and II (anti-HTLV III) and negative by a serological test for Syphilis. However, all plasma and platelets of human origin should be handled as being potentially hazardous.

**MATERIALS PROVIDED**

Lyophilized Platelets. Store at 2° to 8° C prior to reconstitution. Tris Buffered Saline, pH 7.5. Store at 2° to 8° prior to reconstitution.

**INSTRUMENTATION**

Lyophilized Platelets will perform as described when used on most optical platelet aggregometers. Follow the manufacturer’s instructions for operating the Aggregometer in use.

**RESUSPENSION OF LYOPHILIZED PLATELETS**

NOTE: Studies at Bio/Data Corporation have demonstrated that degassing of the reagents prior to use will minimize the variables and improve reproducibly. This can be achieved by mechanically rocking the platelet suspension for 30 minutes while reconstituting or warming.

To a vial of 10mL Lyophilized Platelets, add 10mL of the Tris Buffered Saline or to a vial of 4mL Lyophilized Platelets, add 4mL of the Tris Buffered Saline that is provided and allow to rock at room temperature for at least 30 minutes. Reconstituted platelets are stable for 30 days when stored at 2° to 8° C in the original closed container. After reconstitution and prior to use, it is also necessary to mechanically mix the platelets for at least 30 minutes at room temperature to allow the suspension to equilibrate and degas.

NOTE: Reagents must be at room temperature (15° to 28° C) prior to reconstitution. Stored reagent must be brought to room temperature prior to use.

**REAGENT STORAGE**

The reconstituted Lyophilized Platelets are stable for 30 days when stored at 2° to 8° C in its original tightly sealed container.

**TEST PROCEDURE**

Several modifications of the von Willebrand factor assay employing fixed platelets have been described in the literature. The platelet suspension should be used as indicated by the assay method currently in use in the laboratory. FOR A DETAILED PROCEDURE, REQUEST THE VW FACTOR ASSAY® TECHNICAL BULLETIN (NO. 103023).

**QUALITY CONTROL**

The use of normal control plasma (containing von Willebrand factor) and an abnormal control plasma (deficient in von Willebrand factor) will assure daily quality control of the platelet suspension (see PRODUCT AVAILABILITY).

**EXPECTED VALUES**

A result of less than 40% von Willebrand factor is considered abnormal and suggestive of von Willebrand Syndrome. However, values over 40% do not rule out the possibility of a variant of von Willebrand Syndrome. Since reference ranges for von Willebrand factor reported in the literature and varied, a reference range should be established by each laboratory.

**LIMITATIONS**

The quantitation of von Willebrand factor is considered by some to be the single most important assay for the diagnosis of von Willebrand Syndrome. However, diagnosis of the variant forms of this coagulopathy necessitates a series of clinical and laboratory evaluations including patient and family history, bleeding time, factor VIII related antigen, and factor VIII coagulant activity.

**PERFORMANCE CHARACTERISTICS**

The Lyophilized Platelets were tested with the plasmas of known von Willebrand Syndrome patients, as well as normal plasmas in the presence of Ristocetin. Studies have shown that the accuracy and sensitivity of the platelets are such that varying levels of von Willebrand factor can be detected.

**REFERENCES**


**PRODUCT AVAILABILITY**

**PRODUCT**

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<thead>
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<th>Product</th>
<th>Net Contents</th>
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</table>

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