LYOPHILIZED PLATELETS

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 a standardized and fixed suspension of human platelets routinely used as a component of a Ristocetin Cofactor Assay Activity Test.

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.[1-3] 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.[2-4] Levels of Ristocetin cofactor activity are determined by the ability of a test plasma and Ristocetin to induce agglutination of a standardized platelet suspension. [5-6]

PRECAUTIONS
Lyophilized Platelets are for PROFESSIONAL LABORATORY USE ONLY AND *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 I/II) 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

MATERIALS REQUIRED BUT NOT PROVIDED
1. Platelet Aggregometer
2. Aggregometer cuvettes
3. Disposable Stir Bars
4. Ristocetin A Sulfate
5. Normal Reference Plasma
6. Abnormal Control Plasma

INSTRUMENTATION
Lyophilized Platelets will perform as described when used on most optical platelet aggregometers.[1] 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 reproductively. 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 refrigeration 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.[1, 5, 6, 8] 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. [7] However, values over 40% do not rule out the possibility of a variant of von Willebrand Syndrome. (See LIMITATIONS.) 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. [3,4]

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

1. Brinkhous KM, Graham JE, Cooper HA, Allain JP, Wagner RH: Assay of von Willebrand Factor in von Willebrand Disease and Hemophilia. Use of a Macroscopic Platelet Aggrecation Test. Thromb Res 6:267, 1975.
2. Olsen JD, Brockway WJ, Fass DN, Magnuson MA, Bowie EJW: Evaluation of Ristocetin-von Willebrand Factor Assay and Ristocetin-Induced Platelet Aggregation. AM J Clin Path 63:210, 1975.
3. Miller CH, Graham JB, Goldin LR, Elston RC: Genetics of Classic von Willebrand's Disease, I. Phenotypic Variation within Families. Blood 54:117, 1979.
4. Nelson IM, Holmberg L: von Willebrand's Disease Today. Clinics in Hematology Vol.8 No.1, 1979.
5. Brinkhous KM, Read MS: Preservation of Platelet Receptors for Platelet Aggregating Factor by Air Drying, Freezing, or Lyophilization: New Stable Platelet Preparations for von Willebrand Factor Assays. Thomb Res 13:591, 1978.
6. Ramsey R, Evatt BK: Rapid Assay for von Willebrand Factor Activity Using Formalin-fixed Platelets and Microtitration Technic. AM J Clin Path 72:996, 1979.
7. Zimmerman TS, Abildgaard CR, Meyer D: The Factor VIII Abnormality in Severe von Willebrand's Disease. N Eng J Med 301:1307, 1979.
8. Allain JP, Cooper HA, Wagner RH, et al: Platelets Fixed with Paraforaldehyde: A New Reagent for Assay of von Willebrand Factor and Platelet Aggregating Factor. J Lab Clin Med 85:318. 1975.

For a complete list of available products please go to our web site www.biodatacorp.com or contact customer service below.

155 Gibraltar Road, Horsham, PA 19044 U.S.A.
(800) 257-3282 U.S.A. (215) 441-4000 Worldwide
(215) 443-8820 Fax Worldwide
E-mail: customer.service@biodatacorp.com
Internet: www.biodatacorp.com
An ISO 13485 Registered Company

EC REP EMERGO EUROPE, Prinsessegracht 20, 2514 AP The Hague, The Netherlands

Printed in U.S.A.

Instructions for Use No. 101277 Rev. T