von Willebrand Factor
Normal Reference Plasma

PRODUCT DESCRIPTION
von Willebrand Factor Normal Reference Plasma is lyophilized human plasma standardized using World Health Organization reference material to give consistent 90 - 110% of von Willebrand factor activity. It is traceable to a WHO prepared standard.

INTENDED USE
Normal Reference Plasma is prepared from a pool of citrated normal infection-negative human plasma which has been lyophilized. It is used to construct a standard curve for the vW Ristocetin Cofactor Activity Test.

PRINCIPLE
Von Willebrand factor (vW factor, VIIIR, WF, Ristocetin Cofactor) is the property of the factor VIII protein which is responsible for the agglutination of platelets in the presence of Ristocetin.[2-4] Decreased quantities or abnormalities of the von Willebrand factor are associated with the von Willebrand Syndrome, thus making quantitation of the factor most valuable in the diagnosis and evaluation of this coagulopathy.[3-5] Levels of von Willebrand factor are determined by the ability of a test plasma and Ristocetin to induce agglutination of a standardized platelet suspension.[6,7]

PRECAUTIONS
Normal Reference Plasma is for PROFESSIONAL LABORATORY USE ONLY AND *IN-VITRO* DIAGNOSTIC USE ONLY AND NOT FOR INJECTION OR INGESTION. The plasma and 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.

NOTE TO USER: Any serious incident that occurs in relation to this device shall be reported to the manufacturer and the competent authority of the Member State in which the user and/or the patient is established.

MATERIALS PROVIDED
Normal Reference Plasma, 3 x 0.5mL. Store at 2° to 8° C prior to reconstitution.

MATERIALS REQUIRED BUT NOT PROVIDED
1. Platelet Aggregometer
2. Purified water (distilled, deionized or reagent grade), pH 5.3 - 7.2
3. Pipettors (0.5mL volumes)
4. Disposable Stir bars
5. Aggregometer cuvettes

INSTRUMENTATION
Normal Reference Plasma will perform as described when used on most optical platelet aggregometers[1]. Follow the manufacturer's instructions for operating the aggregometer in use.

RECONSTITUTION
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.

Reconstitute a vial of Normal Reference Plasma with 0.5mL purified water.

REAGENT STORAGE
The reconstituted Normal Reference Plasma is stable for 8 hours when stored at 2° - 8°C in its original tightly sealed container.

QUALITY CONTROL
Laboratories should follow generally accepted quality control practices when proficiency testing is not available.

To assure proper instrument operation and reagent performance, a control specimen should be evaluated each day that tests are performed. The control specimen should be prepared in the same manner as the test specimen. For von Willebrand factor assays, the use of a vW Normal Control Plasma and a von Willebrand factor deficient (Abnormal Control) is recommended for each day tests are performed.

EXPECTED VALUES
A result of less than 40% von Willebrand factor is considered abnormal and suggestive of von Willebrand Syndrome.[8] 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 are dependent on blood type, each laboratory should establish blood type specific reference ranges for its patient population.[9]

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.[8] However, diagnosis of the various forms of the 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.[4,5]

PERFORMANCE CHARACTERISTICS
Studies have shown that this product will perform as described prior to its expiration date when procedural and storage directions are followed.

Linearity:
Platelet aggregation induced by common agonists (ADP, Arachidonic Acid, Collagen, Epinephrine and Ristocetin) is a nonlinear test system for the following parameters: Lag Phase, Primary Slope, Secondary Slope, biphasic response and disaggregation. The non-linearity is caused by many factors such as the reaction chemistry and instrumentation. Platelet aggregation measures a response rate or activity that is not a quantitative measure of the reactants or their concentration.

ACCURACY, PRECISION AND REPRODUCIBILITY
Accuracy
In platelet aggregation, accuracy is a relative parameter and is dependent on the test system.

Precision and Reproducibility
The limitations of platelet aggregation make it difficult to provide typical precision or reproducibility ranges. However, there is an experienced based consensus for these parameters (see below). Each laboratory must establish its own limits for test acceptability.

Test to Test Reproducibility:	less than ± 7.5%
Instrument to Instrument Reproducibility:	less than ± 15%
Reagent Lot to Lot Variation:	less than ± 10.5%
Laboratory to Laboratory (same test system):	less than ± 12.5%

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