BIO/DATA CORPORATION

von Willebrand Factor
Normal Control Plasma

PRODUCT DESCRIPTION
von Willebrand Factor Normal Control Plasma is lyophilized citrated human plasma which has been verified for a von Willebrand Factor activity level of 80 to 120 percent.

INTENDED USE
von Willebrand Factor Normal Control Plasma is prepared from a pool of infectious disease negative normal human plasma to be used in the same manner as a patient Platelet Poor Sample to verify the performance and sensitivity of the Ristocetin Cofactor Activity Assay.

PRINCIPLE
The von Willebrand Factor (ristocetin cofactor) is a property of the protein which is quantitated in plasma for the diagnosis and evaluation of von Willebrand syndrome.[4,5] When assayed as a patient specimen, vW Normal Control Plasma ensures the sensitivity of the test system to deficiencies in the von Willebrand factor.

PRECAUTIONS
von Willebrand Factor Normal Control Plasma is for *PROFESSIONAL LABORATORY USE ONLY AND IN-VITRO DIAGNOSTIC USE ONLY AND NOT FOR INJECTION OR INGESTION.* The plasma has been tested at the source and found to be negative for HIV-1Ag, anti-HIV-1/2, Hepatitis B surface antigen, Hepatitis C antibody, and negative by a serological test for syphilis. However, all plasma of human origin should be handled as being potentially hazardous.

Note to user: any serious incident that occurs in relation to this product shall be reported to the manufacturer and the competent authority of the Member State in which the user/and or patient are established.

MATERIALS PROVIDED
Normal Control 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 Control 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 Control Plasma with 0.5mL purified water.

REAGENT STORAGE
The reconstituted Normal Control Plasma is stable for 8 hours when stored at 2° - 8°C in its original tightly sealed container. Dilutions are considerably less stable and should be used within 40 minutes of preparation.

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

To assure proper instrument operation and reagent performance, the use of vW Normal Control Plasma and a von Willebrand Factor Deficient (Abnormal Control) is recommended for each day tests are performed.

EXPECTED VALUES
Normal Control Plasma will yield von Willebrand factor assay results within the normal reference range, typically 80 to 120% activity (0.8 - 1.2 IU).[6] The ability to generate a quantitative value in this range is dependent upon the sensitivity of the assay system in use.[5] Since normal 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.[7] Additionally each laboratory should establish its "expected" ranges for all control material used.

Unexpected assay values should be evaluated to determine the source of deviation. The following may contribute to erroneous results:
1. Non specific agglutination of reagent platelets
2. Incorrect ristocetin concentration
3. Improper reconstitution of normal control plasma
4. Instrument malfunction
5. Procedural error(s)

LIMITATIONS
The von Willebrand Factor Normal Control Plasma is provided to check and verify the performance of the Ristocetin Cofactor assay system including reagents and instrumentation. The use of this material is dependent upon the establishment of expected ranges for the total assay system and not specifically a recovery of a defined assay value. The user must establish the suitability of this material for their specific application and instrumentation.

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
The ristocetin cofactor assay is a non-linear test system. The non-linearity is caused by many factors such as the reaction chemistry and instrumentation. The ristocetin cofactor assay measures a response rate or activity that is not a quantitative measure of the reactants or their concentration.

ACCURACY, PRECISION AND REPRODUCIBILITY
Accuracy
In the ristocetin cofactor assay, accuracy is a relative parameter and is dependent on the test system.

Precision and Reproducibility
The limitations of the ristocetin cofactor assay 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 ± 10%
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%

REFERENCES

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