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
Normal Control Plasma is used to control against erroneous results in von Willebrand factor (Ristocetin Cofactor) assays. It is also used to verify Ristocetin Cofactor Assay performance and sensitivity.

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 *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.

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:	better than ± 10%
Instrument to Instrument Reproducibility:	better than ± 15%
Reagent Lot to Lot Variation:	better than ± 10.5%
Laboratory to Laboratory (same test system):	better than ± 12.5%

REFERENCES

1. Born, GVR and Cross, MJ. The Aggregation of Blood Platelets. J. Physiol [London] 168:178, 1963.
2. Weiss HJ: Aspirin and platelets in drugs and hematologic reactions. Dimittov and Nodine (eds.). Grune and Stratton, New York, 1974.
3. Triplett DA, Harms CS, Newhouse P, Clark C: Platelet Function. Laboratory Evaluation and Clinical Application. ASCP, 1978.
4. Gralnick HR, Sultan Y, Coller BS: von Willebrand's disease: Combined qualitative and quantitative abnormalities. N Eng J Med 296(18):1024, 1977.
5. Bowie EJW,Owen CA: Abnormalities of factor VIII. In Triplett DA: Laboratory evaluation of coagulation. pg 116, American Society of Clinical Pathologists Press, Chicago, 1982.
6. Zuzel M, Nilsson IM, Aberg M: A method for measuring plasma ristocetin cofactor activity. Thromb Res 12(5): 745, 1978.
7. National Committee for Clinical Laboratory Standards, NCCLS. Assays of von Willebrand Factor Antigen and Ristocetin Cofactor Activity: Approved Guideline. HS1-A Vol 22 No 20. Sep'02.

PRODUCT AVAILABILITY

PRODUCT	NET CONTENTS	CATALOG NUMBER
vW Normal Control Plasma	3 x 0.5mL	106426
vW Abnormal Control Plasma	3 x 0.5mL	101270
ADP	3 x 0.5mL	101312
Arachidonic Acid	3 x 0.5mL	101297
BETA/Pak®		
(ADP, Collagen, Ristocetin)	1 x 0.5mL each	101580
Collagen	3 x 0.5mL	101562
Epinephrine	3 x 0.5mL	101311
Lyophilized Platelets	3 x 4 mL	101595
Lyophilized Platelets	1 x 10 mL	101258
PAR/Pak® II		
(ADP, Collagen, Epinephrine)	2 x 0.5mL each	101310
Ristocetin		
AggRecetin® 1.5mg/mL	15mg	100968
AggRecetin 1.0-1.5mg/mL	15mg	100970
AggRecetin Bulk	100mg	101241
vW Factor Assay®	10 Determinations	101246
vW Factor Assay	20 Determinations	103025
vW Normal Reference Plasma	3 x 0.5mL	101269

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