

PRODUCT DESCRIPTION

von Willebrand Factor Abnormal Control Plasma is lyophilized citrated human plasma which has been selectively depleted of von Willebrand Factor.

INTENDED USE

Abnormal Control Plasma is prepared from a pool of normal infection negative human plasma which has been partially depleted of vW Factor and then lyophilized. It is used to verify the performance and sensitivity of the Ristocetin CoFactor Activity test.

PRINCIPLE

The Ristocetin Cofactor Assay 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, Abnormal Control Plasma ensures the sensitivity of the test system to deficiencies in the von Willebrand factor.

PRECAUTIONS

von Willebrand Factor Abnormal 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 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

Abnormal 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

Abnormal Control Plasma will perform as described when used on most optical platelet aggregometers¹. 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 Abnormal Control Plasma with 0.5mL purified water.

REAGENT STORAGE

The reconstituted Abnormal 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

Abnormal Control Plasma will yield von Willebrand factor assay results below the Normal Reference range, typically less than 45% activity.⁶ The ability to generate a quantitative value in this range is dependent upon the sensitivity of the assay system in use.⁸ 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 materials 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 abnormal control plasma
4. Instrument malfunction
5. Procedural error(s)

LIMITATIONS

The von Willebrand Factor Abnormal 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.

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| 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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