AMERICAN BIOCHEMICAL & PHARMACEUTICALS LTD.

REF ABP-LYO-PLT
3 X 4.0mL
Lyophilized Platelets

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PRODUCT DESCRIPTION

Lyophilized Platelets are prepared from fresh human blood. The platelets are fixed and standardized to provide a consistent test mixture, then lyophilized to ensure long term stability and an extended shelf life. The GP 1b receptor for vWF remains active. A buffered saline solution is provided with the lyophilized platelets. Once reconstituted, the platelet suspension will have an approximate platelet count of 200,000/cumm.

Note: platelet counts must be performed using a manual method (hemocytometer) only.

INTENDED USE

Lyophilized Platelets are for use in the determination of von Willebrand Factor functional activity using the Ristocetin Cofactor Activity Assay.

TEST PRINCIPAL

The Ristocetin Cofactor Activity assay measures the proportional relationship between vWF activity and the agglutination response of the standardized, fixed platelets expressing the GP 1b receptor in the presence of Ristocetin and the test plasma. [5] Comparison of the agglutination results of a patient's PPP with standard curve yields a quantitative vWF activity level. [2,4,7,8]

The formalin-fixed platelet is the basis for the multiple variations of the Ristocetin Cofactor Activity Assay Used to determine the von Willebrand Factor concentration.

PRECAUTIONS

Lyophilized Platelets are for IN-VITRO DIAGNOSTIC USE ONLY. They are NOT intended for injection.

All platelets and plasmas of human origin must be handled as being potentially biohazardous.

The platelets have been tested at the source and found to be negative for HIV-1A, anti HIV 1/2, Hepatitis B surface antigen, Hepatitis C antibody, Human T Lymphotropic types I and II, Anti-HTLV I/II and by serological test for Syphilis.

Use personal protective equipment. Do not get in eyes, on skin or on clothing.

MATERIALS PROVIDED

Lyophilized Platelets. Store at 2° - 8°C prior to reconstitution.

TRIS Buffered Saline, pH 7.5. Store at 2° - 8°C

MATERIALS REQUIRED BUT NOT PROVIDED

1. Platelet Aggregometer
2. Aggregometer Test Cuvettes
3. Disposable Stir Bars
4. Ristocetin A Sulfate
5. Normal Reference Plasma
6. Abnormal Control Plasma

RESUSPENSION OF LYOPHILIZED PLATELETS

1. Add 4.0mL of the TRIS Buffered Saline from the kit to one 4.0mL vial of lyophilized platelets.
2. Allow to rock gently at room temperature 20°-25°C for at least 30 minutes.

NOTE: Studies have demonstrated that degassing of reagents prior to use will minimize the variables and improve reproducibility. This is best achieved by rocking the platelet suspension for 30 minutes after reconstitution.

REAGENT STORAGE

The reconstituted lyophilized platelets are stable for 30 days when stored in their original, tightly closed container at 2° - 8°C

REAGENT DISPOSAL

Unused or expired Lyophilized Platelets are formalin-fixed and must be disposed of as a biohazardous waste in accordance with local regulations and laboratory policy. Exposure to the environment is prohibited in certain jurisdictions.

PROFESSIONAL LABORATORY USE ONLY

TEST PROCEDURE

Several variations of the Ristocetin Cofactor Activity Assay based on the use of formalin-fixed platelets have been described in the literature and are in routine use.[1,5,6,8] Follow your laboratory's Instructions for Use procedure.

PERFORMANCE CHARACTERISTICS

The Lyophilized Platelets were tested with normal, abnormal and reference von Willebrand plasmas as well as plasma from known normal donors. Results show that the lyophilized platelets can detect normal and abnormal vWD plasmas with adequate accuracy and sensitivity over the clinically significant range.

EXPECTED VALUES

A Ristocetin Cofactor activity of 40% or less is considered abnormal and an indication of von Willebrand Disease. Values between 40 and 50 are considered non-diagnostic and the sample/patient should be retested.[10] Values greater than 45% activity do not rule out the possibility of a von Willebrand variant and should be followed up. Laboratories should establish a reference range for the population each serves.

QUALITY CONTROL

The use of normal and abnormal von Willebrand plasmas on test days assures that the lyophilized platelets are functioning properly for use in the test system.

LIMITATIONS

The use of fixed and lyophilized platelets in the Ristocetin Cofactor Activity Assay is well established. This assay is, however, only a portion of the workup required to detect, diagnose and confirm the presence and type of von Willebrand Disease affecting a particular patient.[9]

A significant limitation of the Ristocetin Cofactor Assay is its inaccuracy and variability at activity levels below 10u/L, regardless of the assay mechanics.[10]

WARRANTY

This product is warranted to perform to these specifications when used in accordance with labeling. American Biochemical and Pharmaceuticals Ltd. disclaims any implied warranty of merchantability and fitness for any other purpose and in no event shall American Biochemical and Pharmaceuticals Ltd. be liable for any consequential damages arising out of the aforesaid warranty.

SELECTED REFERENCES

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