Platelet PGD*prime*® Controls

VERAX BIOMEDICAL

A. INTENDED USE

Platelet PGD*prime* Controls are only for use with the Platelet PGD*prime* Test as assay Quality Control Samples to verify the performance of the Platelet PGD*prime* Test.

B. SUMMARY AND EXPLANATION

The Platelet PGD*prime* Controls are used to verify the user's ability to properly perform the test and interpret test results. Failure of the Platelet PGD*prime* Controls to perform as expected may also indicate deterioration of the Platelet PGD*prime* Reagents or Platelet PGD*prime* Test Device.

C. PRINCIPLE OF THE PROCEDURE

The Positive Control contains bacterial antigens (in a matrix containing a buffered solution of human and bovine protein and preservatives) that react with all six (6) detection lines on the Platelet PGD*prime* Test Device. The Negative Control contains the same matrix without bacterial antigens and therefore will not react with any of the detection lines.

Positive or Negative Control is added to a Sample Processing Tube provided with the Platelet PGD*prime* Test. Reagent 1A is added to the control sample and mixed. Reagent 1B is then added and mixed. A Transfer pipette (provided with the test) is used to add the treated sample to Well 1 of the Platelet PGD*prime* Test Device. Reagent 2 is added when the sample liquid has flowed into the GP/GN Test Result window. After the test has run to completion, the results are analyzed. The Positive Control should result in six visible detection lines, three in the Gram-positive (GP) and three in the Gram-negative (GN) Test Result Window. The Negative Control should result in no visible detection lines.

D. REAGENTS AND MATERIALS

Materials Provided

Platelet PGD*prime* Controls REF PRM30C-CE 30 Tests

18°C / 2°C	30 Tests
CONTROL +	1 x 8 mL
CONTROL –	1 x 8 mL

CONTROL – HEPES and Tricine buffers, human serum proteins and bovine protein stabilizer. Preservatives: ProClin 300® and sodium azide.

CONTROL + HEPES and Tricine buffers, human serum proteins and bovine protein stabilizer, lipoteichoic acid and bacterial antigens. Preservatives: ProClin 300 and sodium azide.

Materials Required

Platelet PGD*prime* Test

REF PRM100-CE 100 Tests

REF PRM20-CE 20 Tests

Materials Required But Not Provided - Refer to the Platelet PGDprime Test package insert.

E. WARNINGS AND PRECAUTIONS

For *In Vitro* Diagnostic Use

Warnings

1. The Platelet PGD*prime* Controls contain human sourced and/ or potentially infectious components. No known test method can offer complete assurance that products derived from human sources or inactivated microorganisms will not transmit infection. Therefore, all human sourced materials should be considered potentially infectious. It is recommended that these reagents be handled in accordance with the OSHA Standard on Bloodborne Pathogens using Universal Precautions.[1] Bio-safety level 2 or other appropriate bio-safety practices should be used for materials that contain or are suspected of containing infectious agents.
2. The human derived components within the Positive and Negative Controls are non-reactive for hepatitis B surface Antigen (HBsAg), human immunodeficiency virus type 1 ribonucleic acid (HIV-1 RNA), antibodies to human immunodeficiency virus types 1 and 2 (anti-HIV-1/HIV-2), antibody to hepatitis C virus (anti-HCV) and HCV RNA, anti-HTLV-I/II and West Nile Virus (WNV) RNA when tested by FDA-licensed assays.
3. Read the package insert completely before using the product. Follow the instructions carefully. Not doing so may result in inaccurate test results.
4. Do not use materials after their stated expiration date.

Reagent Precautions

This product contains sodium azide as a preservative. Contact with acids liberates very toxic gas. This material and its container must be disposed of in bio-hazardous waste according to your laboratory procedure and required regulations.

Handling Precautions

Handle Controls properly:

1. Do not combine partially used bottles of Positive or Negative Control.
2. Do not remove dropper tips from Control bottles.
3. Do not touch exposed dropper tip of the Positive or Negative Control.
4. Recap Control bottles immediately after use. Do not interchange bottle caps. The cap colors must match the label colors.
5. Check expiration dates prior to performing test.
6. Do not use if Controls have not been stored at 2 - 8 °C. It is not necessary to equilibrate Controls to room temperature prior to use.

F. STORAGE INSTRUCTIONS

Store Platelet PGD*prime* Controls at 2 - 8 °C. Once opened, use prior to the expiration date on the vial.

G. INDICATIONS OF INSTABILITY

1. Inspect Control bottles for precipitate. Do NOT use if precipitate is present.
2. Failure of the Platelet PGD*prime* Controls to perform as expected may indicate deterioration of the Platelet PGD*prime* Reagents or the Platelet PGD*prime* Test Device.

H. CONTROL TEST PROCEDURE

Refer to the Platelet PGD*prime* Test package insert for *Control Processing* and *Performing the Test.*

I. INTERPRETATION OF RESULTS

Refer to the Platelet PGD*prime* Test package insert for *Interpretation of Results.*

J. LIMITATIONS

Refer to the Platelet PGD*prime* Test Package Insert.

K. REFERENCES

1. 29CFR 1910.1030; Occupational Safety and Health Standards: Bloodborne Pathogens

Keys to Symbols Used

IVD	*In vitro* diagnostic medical device
LOT	Lot Number
REF	List Number
	Expiration Date
CONTROL −	Negative Control
CONTROL +	Positive Control
	Temperature limitation
	Manufacturer
	Attention, see instructions for use
EC REP	Authorized Representative

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