Platelet PGD*prime*® Reagents

VERAX BIOMEDICAL

A. INTENDED USE

The Platelet PGD*prime* Reagents are only for use with the Platelet PGD*prime* Test.

B. SUMMARY AND EXPLANATION OF THE TEST

Platelet PGD*prime* Reagents are for use with the Platelet PGD*prime* Test on platelet samples and Platelet PGD*prime* Controls. Reagents 1A and 1B are used in the processing of platelet samples or Platelet PGD*prime* Controls prior to addition to the Platelet PGD*prime* Test Device. Reagent 2 reconstitutes the gold conjugate dried in the PGD*prime*Test Device.

C. PRINCIPLES OF THE PROCEDURE

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

D. REAGENTS AND MATERIALS

Materials Provided

Platelet PGD*prime* Reagents	REF	PRM100R	100 Tests
Platelet PGD*prime* Reagents	REF	PRM20R	20 Tests

Includes the following:

2°C–8°C	100 Test	20 Test
Reagent 1A	2 x 10 mL	1 x 10 mL
Reagent 1B	2 x 10 mL	1 x 10 mL
Reagent 2	2 x 10 mL	1 x 10 mL

Reagents

Reagent 1A — Water, sodium hydroxide and surfactants.

Reagent 1B — Water, HEPES and Tricine buffers, surfactants, and protein stabilizers (bovine, mouse and rabbit), biotinylated rabbit polyclonal and mouse monoclonal antibodies. Preservatives: ProClin 300® and sodium azide.

Reagent 2 — Phosphate buffer with surfactants. Preservative: Sodium azide.

See Reagent Precautions below.

Materials Required

Platelet PGD*prime* Test

REF	PRM100	100 Tests
REF	PRM20	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. Read the Platelet PGD*prime* Test and Platelet PGD*prime* Controls package inserts completely before using the product. Follow the instructions carefully. Not doing so may result in inaccurate test results.
2. The Platelet PGD*prime* Reagents have been validated for use with the Platelet PGD*prime* Test and Platelet PGD*prime* Controls only.
3. Each operator performing the test must be able to distinguish between the following colors: Yellow, Blue and Red.
4. Do not use materials after their stated expiration dates.

Reagent Precautions

Reagents were classified according to OSHA 29 CFR 1910.1200 and 1910.1030, Globally Harmonized System of Classification and Labelling of Chemicals (GHS) and applicable European Community (EC) Directives. Applicable Classification, Hazard(H) and Precautionary (P) statements are listed below. Safety Data Sheets are available upon request. Refer to SDS for complete Precautionary Statements.

Reagent 1A — The signal word is Warning.



H315	Causes skin irritation.
H319	Causes serious eye irritation.
P264	Wash hands, forearms and exposed areas thouroughly after handling.
P280	Wear protective gloves/protective clothing/eye protection/face protection.
P302+P352	If on SKIN: Wash with plenty of soap and water.
P305+P351+P338	If In EYES: Rinse cautiously with water for several minutes. Remove contact lenses, if present and easy to do. Continue rinsing.
P332+P313	If skin irritation persists: Get medical advice/attention.
P337+P313	If eye irritation persists: Get medical advice/attention.
P501	Dispose of contents/container in accordance with local regional, national, territorial and international regulations.

Reagent 1B — The signal word is Warning.



H315	Causes skin irritation.
H319	Causes serious eye irritation.
P264	Wash hands, forearms and exposed areas thouroughly after handling.
P280	Wear protective gloves/protective clothing/eye protection/face protection.
P302+P352	If on SKIN: Wash with plenty of soap and water.
P305+P351+P338	If In EYES: Rinse cautiously with water for several minutes. Remove contact lenses, if present and easy to do. Continue rinsing.
P332+P313	If skin irritation persists: Get medical advice/attention.
P337+P313	If eye irritation persists: Get medical attention.
P501	Dispose of contents/container in accordance with local regional, national, territorial and international regulations.

Reagent 2 — The signal word is Warning.



H315	Causes skin irritation.
H319	Causes serious eye irritation.
P280	Wear protective gloves/protective clothing/eye protection/face protection.
P302+P352	If on SKIN: Wash with plenty of soap and water.
P305+P351+P338	If In EYES: Rinse cautiously with water for several minutes. Remove contact lenses, if present and easy to do. Continue rinsing.
P332+P313	If skin irritation persists: Get medical advice/attention.
P337+P313	If eye irritation persists: Get medical attention.
P501	Dispose of contents/container in accordance with local regional, national, territorial and international regulations.

General Safety Precautions

Follow good laboratory practices and use Universal Precautions when handling all samples and materials.[1] Dispose of all test materials including reagents and controls in bio-hazardous waste according to your laboratory procedure and required regulations.

Handling Precautions

Handle and perform test properly:

1. Do not combine leftover volumes of Reagents 1A, 1B or 2.
2. Do not remove dropper tips from Reagent bottles.
3. Do not touch exposed dropper tip of Reagent 1A, 1B or 2.
4. Recap Reagent bottles immediately after use. Do not interchange bottle caps. The cap color must match the label color.
5. Do not use test components beyond the expiration dates printed on the labels. Always check expiration dates prior to performing test.
6. Do not use Reagents if they have not been properly stored at 2 - 8 °C. It is not necessary to equilibrate Reagents to room temperature prior to use.

F. STORAGE INSTRUCTIONS

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

G. INDICATIONS OF INSTABILITY

1. Inspect Reagent vials 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.

For the following categories refer to the Platelet PGDprime Test Package Insert and the Platelet PGDprime Controls Package Insert.

H. SPECIMEN COLLECTION AND PREPARATION FOR ANALYSIS

I. TEST PROCEDURE

J. LIMITATIONS

K. REFERENCES

1. 29CFR 1910.1030; Occupational Safety and Health Standards: Bloodborne Pathogens
2. ST/SG/AC.10/30/Rev.4 Globally Harmonized System of Classification and Labelling of Chemicals (GHS)

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Keys to Symbols Used

IVD	*In vitro* diagnostic medical device
LOT	Lot Number
REF	List Number
	Expiration Date
Reagent 1A	Reagent 1A
Reagent 1B	Reagent 1B
Reagent 2	Reagent 2
	Temperature limitation
	Manufacturer
	Consult instructions for use

VERAX BIOMEDICAL

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