

Platelet PGDprime[®] Reagents



A. INTENDED USE

The Platelet PGDprime Reagents are only for use with the Platelet PGDprime Test.

B. SUMMARY AND EXPLANATION OF THE TEST

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

C. PRINCIPLES OF THE PROCEDURE




Refer to the Platelet PGDprime Test Package Insert.

D. REAGENTS AND MATERIALS




Materials Provided

Platelet PGDprime Reagents	REF	PRM100R	100 Tests
Platelet PGDprime Reagents	REF	PRM20R	20 Tests

Includes the following:

	100 Test	20 Test
	2 x 10 mL	1 x 10 mL
	2 x 10 mL	1 x 10 mL
	2 x 10 mL	1 x 10 mL

Reagents

-  Water, sodium hydroxide and surfactants.
-  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.
-  Phosphate buffer with surfactants.
Preservative: Sodium azide.

See Reagent Precautions below.

Materials Required

Platelet PGDprime 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

- Read the Platelet PGDprime Test and Platelet PGDprime Controls package inserts completely before using the product. Follow the instructions carefully. Not doing so may result in inaccurate test results.
- The Platelet PGDprime Reagents have been validated for use with the Platelet PGDprime Test and Platelet PGDprime Controls only.
- Each operator performing the test must be able to distinguish between the following colors: Yellow, Blue and Red.
- 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 thoroughly 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 thoroughly 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 PGD_{prime} Test Package Insert and the Platelet PGD_{prime} 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

	<i>In vitro</i> diagnostic medical device
	Lot Number
	List Number
	Expiration Date
	Reagent 1A
	Reagent 1B
	Reagent 2
	Temperature limitation
	Manufacturer
	Consult instructions for use



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