

Platelet PGD[®] Reagents



A. INTENDED USE

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

B. SUMMARY AND EXPLANATION OF THE TEST

Platelet PGD Reagents are for use with the Platelet PGD Test. They are used in the processing of platelet samples prior to addition to the Platelet PGD Test Device and in the processing of Platelet PGD Controls.

C. PRINCIPLES OF THE PROCEDURE


Refer to the Platelet PGD Test Package Insert.

D. REAGENTS AND MATERIALS

Materials Provided

Platelet PGD Reagents	REF P20R	20 Tests
	REF P100R	100 Tests

Includes the following:

	20 Test	100 Test
Reagent 1	1 x 6 mL	2 x 12 mL
Reagent 2	1 x 6 mL	2 x 12 mL
Reagent 3	1 x 3 mL	2 x 6 mL

Reagents

- Reagent 1** Water, methanol and surfactants. Preservative: ProClin[®] 300
- Reagent 2** Water, sodium hydroxide and surfactants. Preservative: sodium azide
- Reagent 3** Tricine buffer with surfactants, anti-coagulants and protein (bovine, mouse, rabbit) stabilizers. Preservatives: ProClin 300 and sodium azide

See Reagent Precautions below.

Materials Required

Platelet PGD Test

REF P20	20 Tests
REF P100	100 Tests
REF P20C	20 Tests with Platelet PGD Controls
REF P100C	100 Tests with Platelet PGD Controls

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

E. WARNINGS AND PRECAUTIONS

For *In Vitro* Diagnostic Use

Warnings

- Read the Platelet PGD Test and Platelet PGD Controls package inserts completely before using the product. Follow the instructions carefully. Not doing so may result in inaccurate test results.
- The Platelet PGD Reagents have been validated for use with the Platelet PGD Test and Platelet PGD Controls only.
- Each operator performing the test must be able to distinguish between the following colors: Green, 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 1 contains methanol and the signal word is Danger.



- H 226 Flammable liquid and vapor
- H302 Harmful if swallowed
- H312 Harmful in contact with skin
- H319 Causes serious eye irritation
- H370 Causes damage to organs
- P210 Keep away from heat/sparks/open flames/hot surfaces
No smoking.
- P280 Wear protective gloves/protective clothing/eye protection/face protection.
- P312 Call a Poison Center or doctor if you feel unwell.
- P501 Dispose of contents/container in accordance with local and national regulations.

Reagent 2 contains sodium hydroxide and the signal word is Warning.



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

Reagent 3 contains n-Dodecyl-N,N-dimethyl-3-ammonio-1-propanesulfonate (DDAPS) and the signal word is Warning.



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

Reagents 2 and 3 contain sodium azide. Contact with acids liberates very toxic gas.

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 1, 2 or 3.
2. Do not remove dropper tips from Reagent bottles.
3. Do not touch exposed dropper tip of Reagent 1, 2 or 3.
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 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 Controls to perform as expected may indicate deterioration of the Platelet PGD Reagents or the Platelet PGD Test Device.

For the following categories refer to the Platelet PGD Test Package Insert and the Platelet PGD 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 1
	Reagent 2
	Reagent 3
	Temperature limitation
	Manufacturer
	Consult instructions for use



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