# 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

#### 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 P100R 100 Tests

#### Includes the following:

2°C - 8°C	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

Water, sodium hydroxide and surfactants. Preservative: Reagent 2

sodium azide Tricine buffer with surfactants, anti-coagulants and Reagent 3

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.
- 2. 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

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.

andnational regulations.

P305+P351+ If In EYES: Rinse cautiously with water for several P338

minutes. Remove contact lenses, if present and easy to

do. Continue rinsina.

P337+P313 If eye irritation persists: Get medical attention.

P501 Dispose of contents/container in accordance with local

andnational regulations.

Reagent 3 contains n-Dodecyl-N,N-dimethyl-3-ammonio-1propanesulfonate (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

andnational 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.
- Recap Reagent bottles immediately after use. Do not interchange bottle caps. The cap color must match the label color.
- Do not use test components beyond the expiration dates printed on the labels. Always check expiration dates prior to performing test.
- 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

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

## G. INDICATIONS OF INSTABILITY

- Inspect Reagent vials for precipitate. Do NOT use if precipitate is present.
- 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

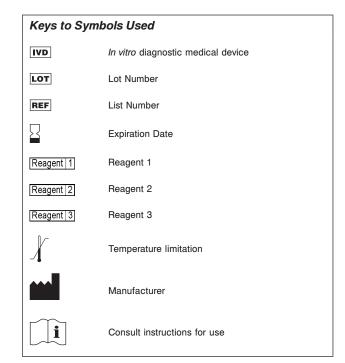
#### K. REFERENCES

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

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