

Platelet PGD[®] Microfuge Tubes and Disposable Pipettes



A. INTENDED USE

The Platelet PGD Microfuge Tubes and Disposable Pipettes are only for use with the Platelet PGD Test.

B. SUMMARY AND EXPLANATION OF THE TEST

Platelet PGD Microfuge Tubes and Disposable Pipettes are single use, disposable accessories for use with the Platelet PGD Test. They are used in the processing of samples prior to addition to the Platelet PGD Test Device for detection of aerobic and anaerobic Gram-positive and Gram-negative bacteria in leukocyte-reduced apheresis platelets (LRAP) at the time of adjunct quality control testing and in the processing of Platelet PGD Controls.

C. PRINCIPLES OF THE PROCEDURE

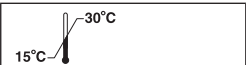
Platelet PGD Microfuge Tubes and Disposable Pipettes are specifically for use with the Platelet PGD Test. Similar laboratory disposables should not be substituted.

D. REAGENTS AND MATERIALS

Materials Provided

Microfuge Tubes and Disposable Pipettes for the Platelet PGD Test **REF** P100D

Includes the following:

	100 Tests
Disposable Pipettes	100 each
Microfuge Tubes	100 each

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

1. 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 Microfuge Tubes and Disposable Pipettes have been validated for use with the Platelet PGD Test only. Do not substitute similar laboratory supplies.

Handling Precautions

Handle and perform test properly: Do not re-use Microfuge Tubes or Disposable Pipettes.

F. STORAGE INSTRUCTIONS

Store Platelet PGD Microfuge Tubes and Disposable Pipettes at 15 - 30 °C.

For the following categories - Refer to the Platelet PGD Test Package Insert and the Platelet PGD Controls Package Insert.

G. SPECIMEN COLLECTION AND PREPARATION FOR ANALYSIS

H. TEST PROCEDURE




I. LIMITATIONS

J. REFERENCES

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Keys to Symbols Used

IVD	<i>In vitro</i> diagnostic medical device
LOT	Lot Number
REF	List Number
Disposable Pipettes	Disposable Pipettes
Microfuge Tubes	Microfuge Tubes
	Temperature limitation
	Manufacturer
	Consult instructions for use



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