

Platelet PGDprime® Processing Tubes, Sample and Transfer Pipettes



A. INTENDED USE

The Platelet PGDprime Processing Tubes, Sample and Transfer Pipettes are only for use with the Platelet PGDprime Test.

B. SUMMARY AND EXPLANATION OF THE TEST

Platelet PGDprime Processing Tubes, Sample and Transfer Pipettes are single use, disposable accessories for use with the Platelet PGDprime Test. They are used in the processing of platelet samples prior to addition to the Platelet PGDprime Test Device and in the processing of Platelet PGDprime Controls.

C. PRINCIPLES OF THE PROCEDURE

Platelet PGDprime Processing Tubes, Sample and Transfer Pipettes are specifically for use with the Platelet PGDprime Test. Similar laboratory disposables should not be substituted.

D. REAGENTS AND MATERIALS

Materials Provided

Processing Tubes, Sample and Transfer Pipettes for the Platelet PGDprime Test **REF** PRM100D

Includes the following:

| | |
|--------------------------|-----------|
| | 100 Tests |
| Processing Tubes | 100 each |
| Sample Pipettes | 100 each |
| Transfer Pipettes | 100 each |

Materials Required

Platelet PGDprime Test

REF PRM100 100 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 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.
2. The Platelet PGDprime Processing Tubes, Sample and Transfer Pipettes have been validated for use with the Platelet PGDprime Test only. Do not substitute similar laboratory supplies.

Handling Precautions

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

F. STORAGE INSTRUCTIONS

Store Platelet PGDprime Processing Tubes, Sample and Transfer Pipettes at 15 - 30 °C.

For the following categories - Refer to the Platelet PGDprime Test Package Insert and the Platelet PGDprime 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 |
| Sample Pipettes | Sample Pipettes |
| Transfer Pipettes | Transfer Pipettes |
| Processing Tubes | Processing Tubes |
| | Temperature limitation |
| | Manufacturer |
| | Consult instructions for use |



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