Hipro Biotechnology Co.,Ltd

EN
ENGLISH

D-Dimer

D-Dimer Test Kit
(Fluorescence Immunoassay Method)
Instructions for Use

Version:A/2

REF HP-Palm-D-Dimer-25

Manufacturer

Shijiazhuang Hipro Biotechnology Co.,Ltd.
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Product Name

General Name: D-Dimer Test Kit
(Fluorescence Immunoassay Method)

Package Specification

25 Tests/Kit
Note: other specifications are available, 10Tests/Kit, 50 Tests/Kit, 100 Tests/Kit.

Intended Use

The Hipro D-Dimer assay is an in vitro diagnostic test for the quantitative measurement of D-Dimer in human plasma or whole blood. It is intended for use in conjunction with a clinical pretest probability (PTP) assessment model to exclude pulmonary embolism (PE) and deep venous thrombosis (DVT) in outpatients suspected of PE or DVT.

For in vitro diagnostic use only .

For prescription use only.

Test Principle

The D-Dimer test kit is a rapid quantitative assay based on the principle of double antibodies sandwich fluorescence immunoassay method.

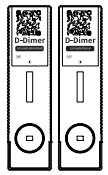
D-Dimer antigen in the sample reacts with mouse anti-human D-Dimer antibody, to form antigen-antibody complexes.

The complexes migrate upward, firstly captured by mouse monoclonal anti-D-Dimer antibody on the T line and then by polyclonal goat anti-mouse IgG antibody on the C line coated in the membrane. After the reaction, the fluorescence immunoassay analyzer calculates the D-Dimer concentration according to the fluorescence intensity of T and C line.

Material Provided

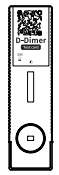
Component	25Kits
Sample diluent	25
Calibration Cassette	2
Test Cassette	25
Instructions for Use	1
Disposable tube with 60μL	50

Calibration Cassette

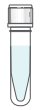


QR code is with built-in parameter for each assay.

Test Cassette



Sample Diluent



Instructions for Use

Disposable tube with 60μL

Volume
60μL

Material Required But Not Provided

Timing device

Storage &Validity

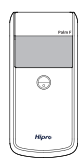
Store test kit at: 2°C-30°C until the expiration date indicated on the label.

Avoid exposure to direct sunlight. The test kit is stable for 18months when unopened.

Perform the test within 1 hour when opened.

Applicable Instrument

Palm F Fluorescence Immunoassay Analyzer



Palm F Fluorescence Immunoassay Analyzer

Specimen type

The specimen type of Hipro D-Dimer test kit is human plasma or whole blood.

-Take blood samples in observance of the standard precautions for the withdrawal of biological fluids.

-Do not use samples that have remained at room temperature for more than 8 hours.

-Due to possible evaporation effects, samples on the analyzer should be measured within 2 hours.

Storage

Fresh collected specimens are stable if stored at 2°C-8°C for up to 24 hours. For longer storage, aliquot, cap tightly, and freeze at -20°C for up to 3months

Avoid repeated freezing and thawing.

Avoid hemolysate.

Required volume

60μL is required for plasma or whole blood, used for dilution. 60μL is required of diluted sample for each determination.

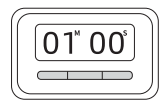
This volume does not include the dead volume(unusable volume in the sample container) or the additional volume required to make replicate test or other tests to be performed on the same sample.

D-Dimer Test Kit Instructions Guide

Before You Begin

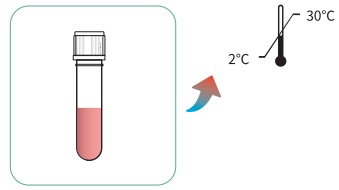
1a Please read the D-Dimer IFU and applicable instrument User Manual carefully before operation. Please follow the instructions strictly.

1b A timing device (phone, clock or timer) is required but not provided.



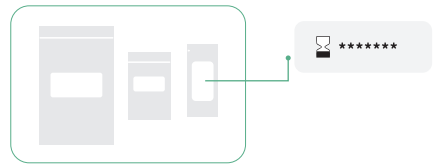
Before You Begin

1c Allow the sample back to room temperature



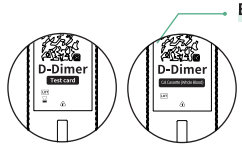
1d Ensure the test kit is at room temperature for at least 30 minutes prior to use.

1e Check on the expiration date on labels of different component.



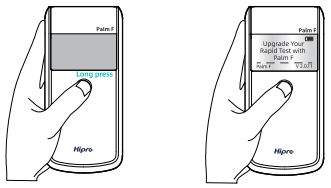
1f Make sure the lot number on calibration cassette and test cassette are same.

Do not misuse the cassettes with different lot.

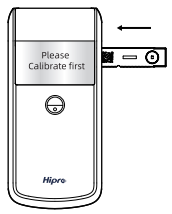


Test Procedures

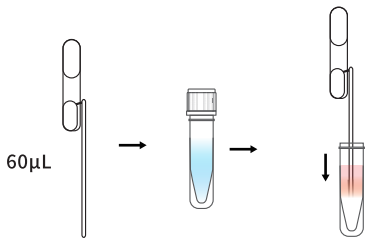
2a Turn on the applicable instrument according to the User Manual.



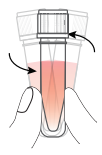
2b Insert the calibration cassette into the analyzer as the direction shows, to let the built-in parameter be read.



3a Use a disposable tube to collect and add 60μL specimen (plasma/whole blood) into sample diluent.



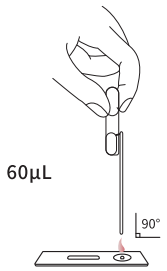
3b Mix the sample with diluent for 30 seconds



Mix for 30 s

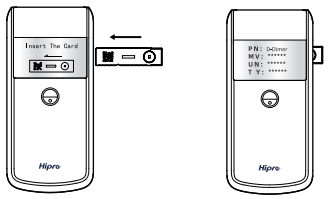
Test Procedures

3c Use a new disposable tube to add 60μLmixed liquid onto the sample well of test cassette.



3d Wait for 15 minutes.

3e Insert the test cassette into the analyzer and the analyzer will display the results automatically.



! Avoid bubbles when collecting samples.

Reference Value

The normal reference range is ⩽0.5mg/L.

189healthy patients were measured and the results (95%) meet the linearity range ⩽0.5mg/L.

The value is indicative only and may differ from other published values as a result of differences in methods and in the population being studied. It is recommended that each laboratory establish its own reference range.

Performance Characteristics

1. **Strip width**

   The width of strip should be ⩾2.5mm.
2. **Liquid flow speed**

   The speed should be ⩾10mm/min.
3. **Linearity**

   Within range 0.2~10 mg/L, the correlation coefficient (r) should be ⩾0.990.
4. **Within-lot precision**

   The coefficient of variation (CV) should be ⩽15%.
5. **Between-lot precision**

   The coefficient of variation (CV) should be ⩽20%
6. **Accuracy**

   The relative deviation should be ⩽15%.
7. **Limit of blank(LoB)**

   The LoB should be ⩽0.1mg/L.

Precautions and limitations

For in vitro diagnostic use

Only experienced laboratory personnel should use this test and handling all laboratory reagents should be based on normal precautions required.

Safety precautions

1. Do not smoke, eat or apply cosmetics in areas in which patients' samples or kit reagents are handled.
2. Laboratory gloves should be worn while handling patients' samples or disposing of solid or liquid wastes.
3. Disposal of all waste material should be in accordance with local guidelines.
4. Avoid electromagnetic or vibration environment for analyzer.
5. Do not insert the polluted cassette into analyzer.

Potential biohazard warning

Some reagents of Hipro test kits contain material of animal origin, even if they are certified as deriving from healthy animals, it is recommended to handle them with the same precaution used for potentially infectious samples.

Limitations-interference

As with all immunoassays, the results of this test can be influenced by factors present in some patients' specimens. The factors include hemoglobin>5mg/mL, triglyceride>15mg/mL, bilirubin>0.2mg/mL, For diagnostic purposes, the results obtained from this assay should always be used in combination with the clinical examination, patient medical history, and other findings.

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Safety Phases

S 37 Wear suitable gloves

S 60 This material and /or its container must be disposed of as hazardous waste.

Symbols used on labels

Symbol	Usage
	Use-By date
LOT	Batch code
	Manufacturer
	Keep Away from Sunlight
	Temperature Limit
IVD	In Vitro Diagnostic Medical device
EC REP	Authorized Representative in the European Community
CE	CE Mark
	Consult Instructions for use
	Keep dry
	Contains sufficient for <n> tests
	Biological risks
	Do not use if package is damaged
	Date of manufacture
	Do Not Reuse

References

1. Department of Medical Administration, Ministry of Health of the People's Republic of China. National Clinical Laboratory Operating Procedures (3rd Edition) [M]. Nanjing: Southeast University Press, 2006.

2. YY/T 1240-2014 D-dimer quantitative detection reagent (box), State Food and Drug Administration, 2014.

3. De Moerioose P, Palareti G, Aguilar C, et al.A multicenter evaluation of a new quantitative highly sensitive D-dimer assay for exclusion of venous thromboembolism [J].Thromb Heamost, 2008,100(3):505-512.

4. Jennings I, Woods TA, Kitchen DP, et al. Laboratory D-dimer measurement; improved agreement between methods through calibration[J].Thromb Haemost,2007,98(5):1127-1135.

Approval Date&Revision Date

Approval Date: Dec 19, 2022

Revision Date: Dec 22, 2023

Revision Date: Sep 18，2024

CE IVD

工艺：70g双胶纸，双面印刷，横向4折页，竖向对折　展开尺寸：32*25cm，公差范围（±2mm）第一页的左上角项目名称为封面