

D-Dimer

D-Dimer (FIA)

REF: IN047706



Intended use

The infinosiTM D-Dimer is a fluorescence immunoassay (FIA) for the in vitro quantitative determination of D-Dimer in Human plasma. For professional use only.

Summary

References¹⁻⁵

D-dimer (or D dimer) is a fibrin degradation product (or FDP), a small protein fragment present in the blood after a blood clot is degraded by fibrinolysis. It is so named because it contains two D fragments of the fibrin protein joined by a cross-link.

D-dimer concentration may be determined by a blood test to help diagnose thrombosis. Since its introduction in the 1990s, it has become an important test performed in patients with suspected thrombotic disorders. While a negative result practically rules out thrombosis, a positive result can indicate thrombosis but does not rule out other potential causes. Its main use, therefore, is to exclude thromboembolic disease where the probability is low. In addition, it is used in the diagnosis of the blood disorder disseminated intravascular coagulation. A four-fold increase in the protein is a strong predictor of mortality in those suffering from COVID-19.

D-dimer testing is of clinical use when there is a suspicion of deep venous thrombosis (DVT), pulmonary embolism (PE) or disseminated intravascular coagulation (DIC). It is under investigation in the diagnosis of aortic dissection.

Test principle

Sandwich principle. Total duration of assay: **15 minutes**

Sample is added to the sample well of the test, then the fluorescence-labeled detector anti-D-Dimer antibody binds to D-Dimer antigen in blood specimen. As the sample mixture migrates on the nitrocellulose matrix of test strip by capillary action, the complexes of detector antibody and D-Dimer are captured to anti-D-Dimer antibody that has been immobilized on test strip.

The more D-Dimer antigen is in blood specimen, the more complexes are accumulated on test strip. Signal intensity of fluorescence of detector antibody reflects amount of D-Dimer captured and instrument for infinosiTM tests shows D-Dimer concentrations in blood specimen.

Reagents

Materials provided

- **Test Cartridge**, 25 pcs, individually packaged
- **ID Chip**, 1 pcs
- **Sample Buffer**, 25 tubes
- **IFU**, 1 copy

Materials required (but not provided)

- infinosiTM 2020 FIA analyzer
- D-Dimer control (DiaSino control is recommended)
- Transfer pipette set (100 µL size)
- Centrifuge (for plasma and serum only)
- Timer

Precautions and warnings

- For in vitro diagnostic use only.
- Carefully follow the instructions and procedures described in this instructions before testing.
- The test cartridge should remain in its original sealed pouch until ready to use. Do not use it if the pouch is damaged or the seal is broken.
- Do not use reagents beyond the labeled expiry date.
- Do not mix or use components from kits with different Lots.
- Don't use Test Cartridge if its Lot does not match with ID Chip that is inserted onto the instrument.
- The infinosiTM D-Dimer should be used only in conjunction with the instrument for infinosiTM tests.
- The tests should be applied by professionally trained staff working in certified laboratories at some remove from the patient and clinic at which the sample is taken by qualified medical personnel.
- infinosiTM D-Dimer assay is single use only. Do not reuse it.
- The Test Cartridge and instrument for infinosiTM tests should be used away from vibration and magnetic field. During normal usage, the Test Cartridge may generate slight vibration, which should be regarded as normal.
- Use separate clean pipette tips and buffer tubes for different specimens. The pipette tips and detector buffer tubes should be used for one specimen only.

infinosiTM

- Do not smoke, eat, or drink in areas in which specimens or kit reagents are handled.
- Blood specimens, used test cartridges, pipette tips and sample buffer tubes are potentially infectious. Proper laboratory safety techniques, handling and disposal methods should be followed in accordance with standard procedures and relevant regulations observed by microbiological hazard materials.
- The results should be interpreted by the physician along with clinical findings and other laboratory test results.

Incident report

Any suspected serious incidents related to this assay shall be immediately reported to DiaSino, DiaSino's Authorized Representative in the EU, and the national competent authorities of the Member States where the users and/or patients are located.

Storage and stability

- Store the test kit at 2-30°C, the stability is up to the expiration date printed on package.
- Test cartridge and sample buffer should be used within 1 hour after opening the pack.

Specimen collection and preparation

- The test can be performed with Human plasma.
- Collect serum samples in accordance with correct medical practices.
- Separate the plasma from blood as soon as possible to avoid hemolysis.
- Test should be performed immediately after the specimens have been collected.
- Do not leave the specimens at room temperature for prolonged periods. Specimens may be stored at 2-8 °C for up to 3 days. For long-term storage, specimens should be kept below -20°C.

Quality control

- Quality control tests are a part of the good testing practice to confirm the expected results and validity of the assay and should be performed at regular intervals.
- The control tests should be performed immediately after opening a new test lot to ensure the test performance is not altered.
- Quality control tests should also be performed whenever there is any question concerning the validity of the test results.
- Control materials are provided on demand with infinosiTM tests. For more information regarding obtaining the control materials, contact [DiaSino Laboratories Co., Ltd](#) for assistance.

Test setup

- Ensure that the lot number of the cartridge matches that of the sample buffer, and the ID Chip.
- If the sealed cartridge and sample buffer have been stored in refrigerator, place them at room temperature (18-25 °C) at least 30 minutes before measurement.
- Turn on the instrument for infinosiTM tests. Refer to the *'instrument for infinosiTM tests Operation Manual'* for the complete information and operating instructions.

Test procedure

1. Insert ID Chip into the instrument for infinosiTM tests and read ID chip information.
2. Using a pipette to transfer **50 µL** of sample (Human plasma) to the **sample buffer tube** provided in the kit.
3. Close the lid of the sample mixing tube and mix the sample thoroughly for **5-10 seconds** by tapping or inverting the tube.
4. Pipette out **100 µL of sample mixture** and load it onto the sample well on the cartridge.
5. Leave the sample-loaded cartridge at room temperature for **15 minutes**.
6. Insert the sample-loaded cartridge into the cartridge holder of instrument for infinosiTM tests. Ensure proper orientation of the cartridge before pushing it all the way inside the cartridge holder.
7. Press **"Test"** button on the instrument for infinosiTM tests.
8. Instrument for infinosiTM tests will start scanning the sample-loaded cartridge immediately.
9. Read the test result on the display screen of the instrument for infinosiTM tests.
10. Print out the testing results when press **"Print"** button on the instrument for infinosiTM tests.

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Limitations - interference

- This test has been developed for testing human plasma only.
- The results of infinosis™ D-Dimer should be evaluated with all clinical and laboratory data available. If D-Dimer test results do not agree with the clinical evaluation, additional tests should be performed.
- The false positive results may come from cross-reactions with some similar antibodies in blood, and similar epitopes from non-specific components in blood capturing fluorescent labeled antibodies.
- The false negative results may from some unknown substance blocking epitope adhering antibodies, unstable or degenerated D-Dimer that cannot be identified due to prolonged time and temperature and storage condition of sample and reagent.
- Other factors may interfere with infinosis™ D-Dimer and may cause erroneous results. These include technical or procedural errors, as well as additional substances in blood specimens.
- For diagnostic purposes, the results should always be assessed in conjunction with the patient's medical history, clinical examination and other findings.

Measuring range

0.1-10 mg/L (defined by the lower detection limit and the maximum of the master curve). Values below the lower detection limit are reported as < 0.1 mg/L. Values above the measuring range are reported as > 10 mg/L.

Lower detection limit

0.1 mg/L

The detection limit represents the lowest analyte level that can be distinguished from zero. It is calculated as the value lying two standard deviations above that of the lowest standard (master calibrator, standard 1+2 SD, repeatability study, n = 21).

Expected values

0-0.5 mg/L

Expected values may vary with age, sex, diet and geographical location. Each laboratory should determine its own expected values as dictated by good laboratory practice.

Specific performance data

Representative performance data are given below. Results obtained in individual laboratories may differ.

Precision

Intra-assay

Determined by using 10 replicates of specimen of 5.0 mg/L D-Dimer

CV ≤ 15%

Inter-assay

Determined by using 3 replicates for each of three lots using D-Dimer specimen levels at 5.0 mg/L, CV ≤ 15%.

Linearity

A serial concentration of D-Dimer controls at 0.8 mg/L, 1.0 mg/L, 2.0 mg/L, 5.0 mg/L, 6.0 mg/L, 8.0 mg/L were each tested for three times, the Correlation Coefficient is: $r \geq 0.9960$.

Method comparison

A comparison of the Infinosis™ D-Dimer assay (y) with the Roche D-Dimer STAT assay (x) using 187 clinical samples gave the correlation: $r=0.9556$

References

1. Adam SS, Key NS, Greenberg CS (March 2009). "D-dimer antigen: current concepts and future prospects". *Blood*. 113 (13): 2878–87. doi:10.1182/blood-2008-06-165845. PMID 31594601.
2. Tasic N, Paixao T, Goncalves L (January 2020). "Biosensing of D-dimer, making the transition from the central hospital laboratory to bedside determination". *Talanta*. 207 (2): 2878–2887. doi:10.1016/j.talanta.2019.120270. PMID 19008457.
3. <https://www.theatlantic.com/health/archive/2020/04/coronavirus-immune-response/610228/>
4. Velavan, Thirumalaisamy P.; Meyer, Christian G. (25 April 2020). "Mild versus severe COVID-19: laboratory markers". *International Journal of Infectious Diseases*. 95: 304–307. doi:10.1016/j.ijid.2020.04.061. PMID 32344011.
5. General Practice Notebook > D-dimer

infinosis™

Symbols



In vitro diagnostic
medical device



Temperature
limit



Consult
instructions for use



Catalog number



Batch code



Date of
manufacture



Use-by date



Contains sufficient
for <n> tests



Manufacturer



Do not re-use



Do not use if package is damaged
and consult instructions for use



European
Conformity



Authorized representative in
the European Community



diasino

DiaSino Laboratories Co., Ltd
No.68 Jingnansi Road National Eco & Tech Development Area
Zhengzhou 450000, P.R. China. info@diasino.com



CMC Medical Devices & Drugs S.L.
C/Horacio Lengo N° 18, CP 29006 Málaga, Spain. Tel: +34 9512 14054