













## WARRANTY

This product is designed to perform as described on the label and package insert. The manufacturer disclaims any implied warranty of use and sale for any other purpose. In the event of performance changes or product malfunction, please contact manufacturer.

## BIBLIOGRAPHY

1. Xu guanghai, Chen lixia. Experimental evaluation of quantitative determination of plasma d-dimer[J]. Chinese Journal of Misdiagnosis. 2010, 10(09):2064-2065.
2. Chen jiuyan. Detection of d-dimer and its application in the diagnosis and treatment of thrombotic diseases. Shanxi Journal of Medicine. 2008, 37(24): 1123-1125.

## SYMBOL KEYS

 Temperature Limitation	 Consult Instructions for use	 Date of Manufacture	 Do not reuse
 Manufacturer	 IVD In vitro Diagnostic Medical Device	 This side up	 Use by
 Contains sufficient for <n> tests	 REF Catalogue Number	 LOT Batch Number / Lot Number	 DEVICE Device



Manufactured by:

**Zephyr Biomedicals**

A Division of Tulip Diagnostics (P) Ltd.

M 46-47, Phase III B, Verna Industrial Estate, Verna, Goa - 403 722, INDIA.

Regd. Office: Gitanjali, Tulip Block, Dr. Antonio Do Rego Bagh, Alto Santacruz, Bambolim Complex P.O., Goa - 403 202, INDIA.

Website: www.tulipgroup.com Email: sales@tulipgroup.com

# **FIAcheck™**

## **D-Dimer**

**Fluorescence Immunoassay for Quantitative determination of D-Dimer in Human Plasma**

**DEVICE**

FOR IN VITRO DIAGNOSTIC USE ONLY

Store at 4°C to 30°C

## INTENDED USE

**FIAcheck™ D-Dimer** Fluorescence Immunoassay is intended for the in-vitro quantitative measurement of D-Dimer in human plasma.

## INTRODUCTION

During coagulation sequence of reactions occurs in the body in response to variety of external and or internal stimuli. The enzymatic cascade reaction terminates in the conversion of Fibrinogen to Fibrin, by the enzyme Thrombin. The fibrin gel is then converted to a stable fibrin clot by thrombin activated Factor XIII.

Finally, the fibrin network is dissolved by the enzyme Plasmin to generate cross-linked fibrin degradation products (XL FDP). D-Dimer comprising of two D fragments cross linked together, is the smallest plasmin resistant molecular unit present within the cross linked fibrin degradation products. Detection of D-Dimer is invaluable as a diagnostic marker for thrombotic conditions such as DIC, DVT and PE. The role of the pretest clinical probability score and/or the D-Dimer concentration in the diagnostic management of deep venous thrombosis has been supported by several different studies. The strategy of combining clinical assessment with D-Dimer testing in the initial evaluation of outpatients with suspected deep venous thrombosis is a potentially powerful means to rule out the DVT rapidly and safely, without the need for ultrasonography.

D-Dimer levels can also be used to monitor thrombolytic therapy with t-PA and with streptokinase, thrombotic complications in pregnancy, acute myocardial infarction, sickle cell crisis, severe septic infections, liver disease, DIC accompanying snake bite and prognosis and response to therapy in cancer. D-Dimer testing has been evaluated as a predictive factor for recurrences of VTE after discontinuation of oral anticoagulant therapy.

## PRINCIPLE OF THE TEST

**FIAcheck™ D-Dimer** is based on principle of agglutination of antibodies/anti-sera with respective antigen in immuno-chromatographic format using fluorophores as signal generators. The **FIAcheck™ D-Dimer** test device is coated with immobilized D-Dimer mouse monoclonal antibody 1 on the test line, goat anti chicken IgY in control line and a mixture of D-Dimer mouse monoclonal antibody 2 and Chicken IgY labeled with fluorescent microspheres on the binding pad.

D-Dimer in sample binds to the D-Dimer mouse monoclonal antibody 2 labeled with fluorescent microspheres in the binding pad.

The fluorescent labeled Ag-Ab complex moves forward due to capillary action and is captured by the immobilized D-Dimer mouse monoclonal antibody 1 forming a double antibody sandwich and produces the test line. Chicken IgY labelled with fluorescent microspheres binds with goat anti chicken IgY to produce the control line. When the **FIAcheck™** test device is inserted in the **FIAcheck™** analyzer, it scans both the test line and control line. The ratio of the two fluorescence values is used to calculate the concentration of the analyte present in the sample.

## MATERIALS AND COMPONENTS

**Materials provided with the test kits:**

- **FIAcheck™ D-Dimer** test device in a sealed pouch with desiccant.
- QR Code card for calibration.
- Sample Diluent. Ready to use.
- Empty vials for sample dilution.

**Materials required but not provided**

- Precision pipettes: 100-1000µl
- Disposable pipette tips
- Disposable Gloves
- **FIAcheck™** Analyzer (Time Resolved Fluorescence Immunoassay Analyzer)
- Digital Thermometer
- Stopwatch

## STORAGE AND STABILITY

1. **FIAcheck™ D-Dimer** kit is stable at 4°C to 30°C upto expiry date printed on the label. DO NOT FREEZE.

2. **FIcheck™** Test device should be used within 30 minutes once the foil pouch is opened.
3. If the colour of the desiccant has changed from blue to pink or colourless at the time of opening the pouch, kindly discard the device and use another device.
4. Once opened, the sample diluent can be stored between 4°C to 30°C for remaining duration of shelf life.

#### SAMPLE COLLECTION

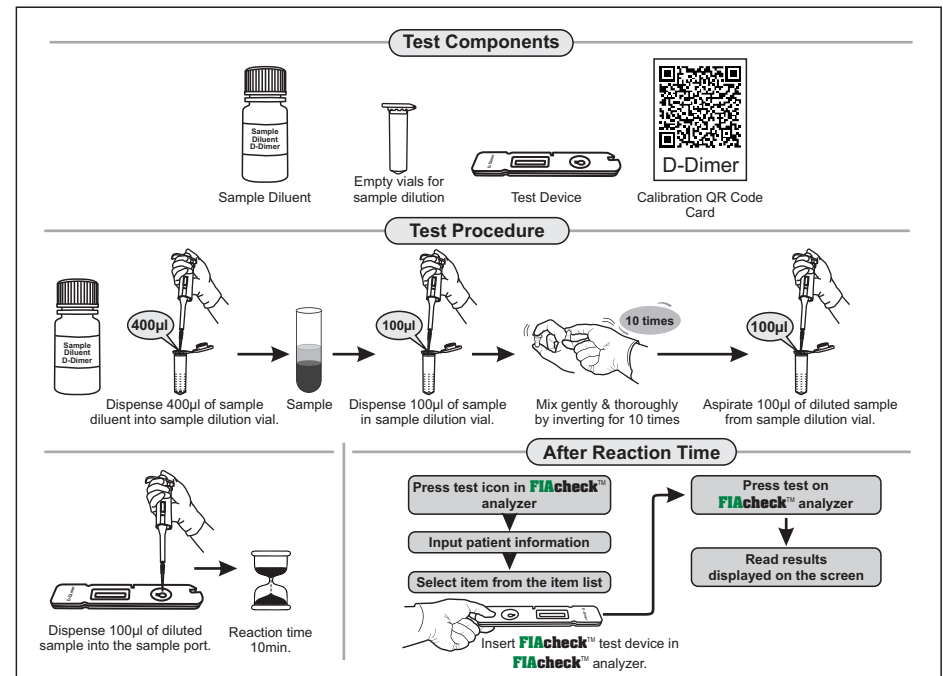
1. Only human Plasma sample should be used. Other bodily fluids and samples may not give accurate result.
2. Plasma can be anti-coagulated with Heparin and Sodium citrate or Tri sodium citrate under aseptic conditions.
3. The test should be performed within 4 hours after the sample collection at room temperature.
4. Avoid grossly hemolytic, lipemic or turbid samples.
5. Preferably use fresh samples. However, samples can be stored for 3 days at 2°C to 8°C, and if more than 3 days, they should be stored at -20°C.
6. The sample should be recovered to room temperature (18°C to 30°C) before testing. Avoid repeated freezing and thawing of samples as it can affect the test values.
7. Samples containing precipitate or particulate matter should be clarified by centrifugation prior to use.
8. Samples should be free from particulate matter and microbial contamination.

#### PRECAUTIONS

1. Only for In vitro diagnostic use.
2. Bring all reagents and samples to room temperature before use.
3. After the test device is removed from the sealed pouch, it should be used immediately or within 30 minutes of opening the pouch.
4. Do not reuse the tested **FIcheck™** device. Do not use sample dilution vial for more than one sample.
5. Do not use damaged **FIcheck™** test device or pouch.
6. All samples should be considered potentially infectious and discarded appropriately as per Standard Bio-Safety guidelines.
7. Do not use kit after the expiry date.
8. Do not mix components of one kit with another.
9. Always use new tip for each sample and reagent.
10. Scan QR code card specific to the lot you are using.
11. Ambient temperature of testing environment directly impacts the accuracy of results. Ideal working temperature is 18°C to 30°C.
12. It is highly recommended to mix the sample diluent and sample mixture thoroughly by gently inverting the vial 10 times. (Refer pictorial presentation.)
13. It is not recommended to use the sample diluent and sample mixture beyond specified time.
14. The **FIcheck™** test device should be read immediately after the specified reaction time. Delay in reading might affect the accuracy of results.
15. The **FIcheck™** test device should be used only in conjunction with **FIcheck™** analyzer for accurate and reliable results.

#### TEST PROCEDURE

1. To calibrate the **FIcheck™ D-Dimer** kit, scan the QR code card provided with the kit.
2. Dispense 400 µl of sample diluent into the empty sample dilution vial.
3. Add 100 µl of the test sample into this sample diluent & mix by rinsing the tip 3 times.
4. Close the lid of the sample dilution vial, label with sample identity and mix the content of the vial by gently inverting it for 10 times. (See pictorial representation).
5. Remove **FIcheck™ D-Dimer** test device from sealed pouch and place it horizontally on a clean table, label the device with sample identity.
6. Dispense 100 µl of the above mixture at the sample port in the **FIcheck™ D-Dimer** test device.
7. Incubate at room temperature (18°C to 30°C) for 10 minutes.
8. After 10 minutes, insert the test device immediately into the **FIcheck™** analyzer and read results.



#### Expected Range

**Cut-Off Value: 0.5 µg/mL**

D-Dimer concentration is determined using samples obtained from 200 apparently healthy individuals. It is recommended that each laboratory establish its own reference range for the population it serves.

#### PERFORMANCE CHARACTERISTICS

1. Measuring Range: 0.1- 10 µg/mL.
2. Lower Detection Limit: ≤0.1 µg/mL.
3. Upper Detection Limit: ≥10 µg/mL.
4. Accuracy: Based on comparison experiments, the relative standard deviation of ≤15%, and the correlation coefficient of  $r \geq 0.990$  was observed.
5. Within-Run Precision: ≤15%.
6. Between-Run Precision: ≤15%.
7. Hook Test: No hook effect with high concentration sample. Hook test was conducted with reference material exceeding the upper limit of measuring range, and the detection result was greater than the upper limit of detection.
8. In an internal Study, **FIcheck™ D-Dimer** was evaluated against commercially available licensed kit with 100 random clinical samples and **FIcheck™ D-Dimer** has demonstrated 100% clinical correlation with the commercially available licensed kit.

D-Dimer Levels	No. of samples	<b>FIcheck™ D-Dimer</b>	Reference method
Normal	80	80	80
Low	8	8	8
High	12	12	12

9. In an external Study, **FIcheck™ D-Dimer** has been evaluated by a NABL accredited lab against their reference method. In this evaluation **FIcheck™ D-Dimer** has demonstrated 100% correlation with the reference method.

\*Data file: Zephyr Biomedicals (A Division of Tulip Diagnostics (P) Ltd).

#### LIMITATIONS OF THE ASSAY

1. As with all diagnostic tests, a definite clinical diagnosis should not be based on the results of a single test but should only be made by the physician after all clinical and laboratory findings have been evaluated.
2. This kit is only for human plasma.