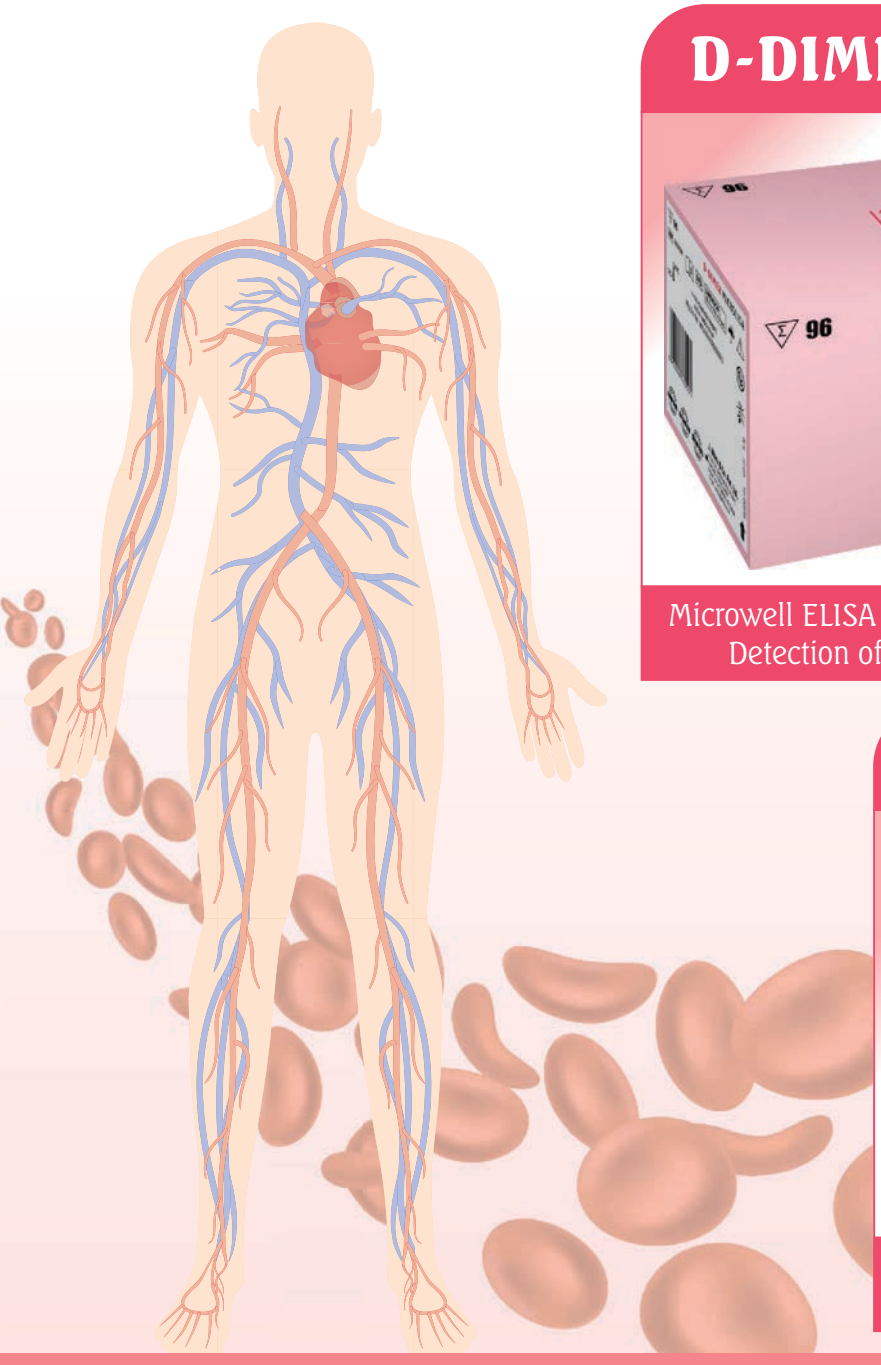
J. Mitra & Co. Pvt. Ltd.

.....a vision to serve mankind™

EARLY D-DIMER DIAGNOSIS

aids in management of COVID-19 patients



D-DIMER MICROLISA

Microwell ELISA Immunoassay for the Quantitive Detection of D-Dimer in Human Plasma

D-DIMER QUANTI CARD

Fluorescence based Immunoassay for quantitative measurement of D-Dimer in human plasma

D- Dimer overview:

D-Dimer is a fibrin degradation product, 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.

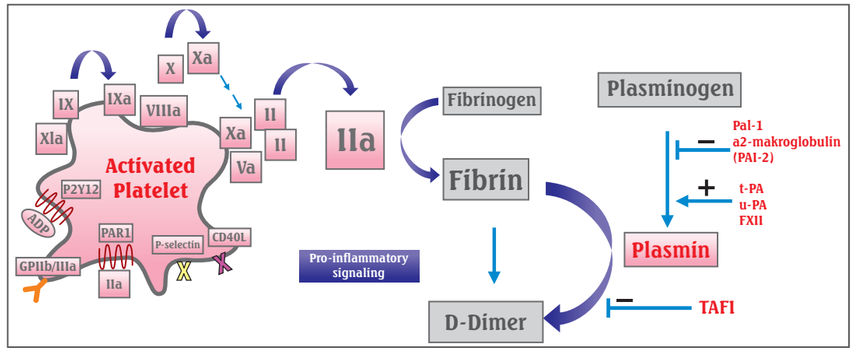
D-dimer concentration may be determined by a blood test to help diagnose thrombosis. Elevated D-Dimer levels are found in cases of:

- Disseminated intravascular coagulation(DIC)
- Venous thromboembolism (VTE)
- Deep vein thrombosis (DVT)
- Infections
- Cancer
- Liver Disease
- Pulmonary embolism (PE)

In clinical diagnostics, D Dimer testing is used as a sensitive method for ruling out Pulmonary Embolism (PE) as well as Deep Vein Thrombosis (DVT).

Pathophysiology of D-dimer formation:

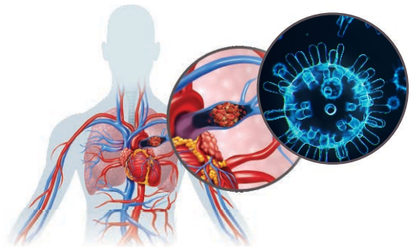
D-dimer formation involves the thrombin-catalyzed conversion of fibrinogen into fibrin monomers. Thrombin enzymatically cleaves two cryptic polymerization sites, which leading to the generation of both highly self-adhesive fibrin monomers and fibrino peptides.



Fibrin monomers then bind to one another to form a soluble network Simultaneously, the complex between soluble fibrin polymers, thrombin, and plasma factor VIII promotes the formation of VIIIa factor, which catalyzes covalent crosslinking of fibrin polymer via intermolecular bonds formed between lysine and glutamine residues, thus enabling the generation of stable and insoluble clots.

Plasmin is activated from plasminogen by tissue plasminogen activator (t-PA) at the fibrin surface and cleaves fibrin at specific sites . The products of this reaction are the conventionally-defined fibrin degradation products (FDP). Continual breakdown generates the fragment D-dimer.

D-Dimer Signficance in Covid-19 Infection:



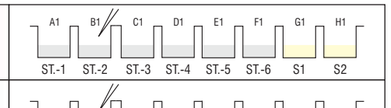
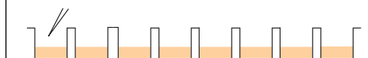
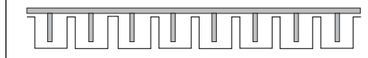
In COVID 19 Pandemic, Elevated D-dimer levels have prognostic importance as they are associated with disease severity and mortality. Mortality rate is high in patients having COVID-19 infection with high D-Dimer& Pulmonary embolism. Therefore Early “D-Dimer” diagnosis aids in management of COVID-19 patients.

D-DIMER MICROLISA

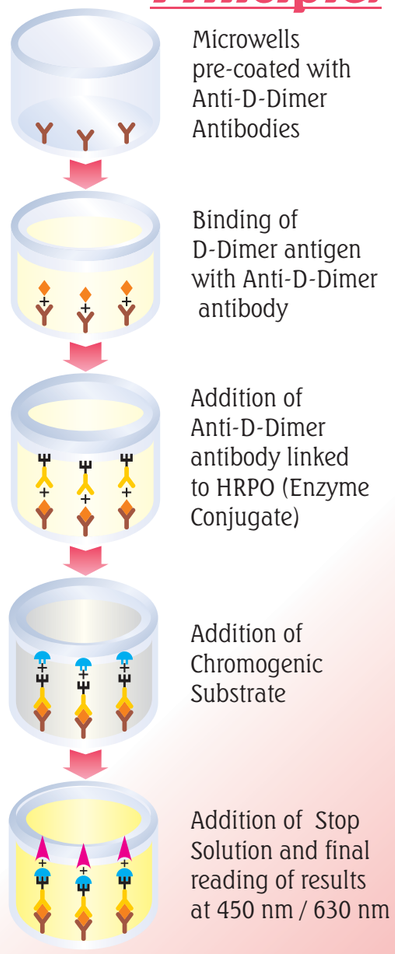
Microwell ELISA Immunoassay for the Quantitive Detection of D-Dimer in Human Plasma

- Based on Sandwich ELISA principle
- Ready to use Enzyme conjugate
- Measuring Range: 25 ng/ml to 10000 ng/ml.
- Analytical Sensitivity: 25 ng/ml
- Total Test Time: 55 minutes.
- Shelf life: 15 month at 2-8°C
- Breakaway Microwells provided in 24 test pack.
- Accuracy Coefficient (R^2) : 0.995
- Highly specific
- Convenient pack size: 96 Test

Test Procedure:

Add 25 µl each of 6 standars & sample in respective well	
Add 100 µl Assay Diluent in each well	
Cover the plate and incubate for 20 minutes at 37°C	
Wash (3 cycles)	
Add 100 µl Enzyme Conjugate (Ready to use) in each well	
Cover the plate and incubate for 20 minutes at 37°C	
Wash (3 cycles)	
Add 100 µl working substrate in each well	
Incubate in dark for 15 min at room temperature.	
Add 100 µl Stop Solution and read result at 450 nm/630 nm.	

Principle:



Microwells pre-coated with Anti-D-Dimer Antibodies

Binding of D-Dimer antigen with Anti-D-Dimer antibody

Addition of Anti-D-Dimer antibody linked to HRPO (Enzyme Conjugate)

Addition of Chromogenic Substrate

Addition of Stop Solution and final reading of results at 450 nm / 630 nm

anti-D-Dimer antibody

D-Dimer in the sample

HRPO labelled anti-D-Dimer antibody

Chromogenic Substrate TMB

Stop Solution

D-DIMER QUANTI CARD

Fluorescence based Immunoassay for quantitative measurement of D-Dimer in human plasma

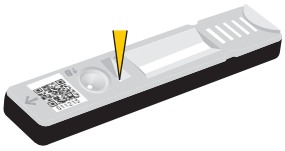
- Principle: Based on most advanced fluorescence competitive immunoassay
- QR Code on each cartridge includes lot specific data, no chip required
- Individual pouched test cartridge
- Analytical Sensitivity: 50 ng/ml
- Measuring Range: 50 - 10,000 ng/ml.
- Results within 30 Minutes
- Long Shelf Life: 15 Months At 2-8°C
- Convenient pack size: 25 tests

Test Procedure

Step-1

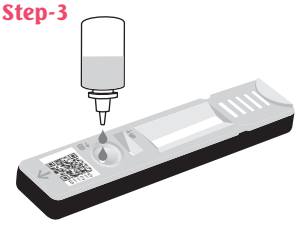
Unscrew the D-DIMER Conjugate vial (Dried) & add 100 µl of Plasma sample

Step-2



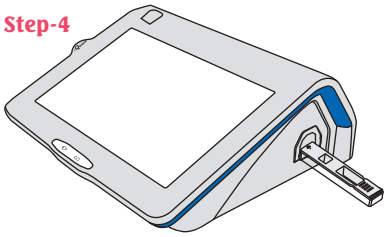
Load 50µl of the mixture using micropipette to the sample well of the Cartridge & incubate for 20 minutes at RT (20-30°C)

Step-3



Add 2 drops of assay buffer in the buffer well of the test cartridge and leave the cartridge for another 10 minutes at RT (20-30°C)

Step-4



Place test cartridge in the Analyzer and Read Result.*

Precision

Within-run (Reproducibility) and between-run precision (Repeatability) have been determined by testing 3 samples with D-Dimer concentration: 238.4ng/ml, 3224.5ng/ml and 7512.6ng/ml in 10 replicates and C.V (%) for all 3 samples is ≤ 10%.

Accuracy

The accuracy of D-Dimer Quanti Card with 75 clinical specimens in comparison with CLIA has been checked .The following results were obtained:

Slope : 0.9842 Y-Intercept : 80.076 R^2 : 0.996

Specificity

No significant interference with the D-Dimer measurement was observed on spiking the test specimen with other Biomolecules at higher concentration ; Bilirubin (20mg/dL), Triglyceride (1000mg/dL), Glucose (500mg/dL), Haemoglobin (500mg/dL) and Albumin (10g/dL) .

Also Connect with us on:

ISO 9001:2015

ISO 13485:2016
ICMED 13485

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