# D - Dimer Kit
# CliniQuant
## Latex Turbidimetry

Meril Diagnostics

*In Vitro* diagnostics medical device
Read this pack insert thoroughly before use

| REF DDMFSR-01 | R1 D-Dimer Reagent | R2 D-Dimer Reagent | R3 D-Dimer Calibrator |
|---|---|---|---|
| Pack size | 1 x 30 ml | 1 x 10 ml | 1 x 1 ml |

### INTENDED USE
This reagent is intended for quantitative determination of D-Dimer concentration in citrate plasma by latex turbidimetry.

### CLINICAL SIGNIFICANCE
Increase of D-Dimer in blood testifies the blood clot is formed and fiberinolytic activity has functioned. It is known that high value of D-Dimer is indicated in diseases such as malignant tumor, vascular disease.

### PRINCIPLE OF THE METHOD
The D-Dimer contained in the sample reacts with the latex sensitized with anti-human D-Dimer monoclonal antibody (mouse) and forms aggregates, which are determined optically for calculation of D-Dimer concentration.

### KIT COMPONENTS
R1-D-Dimer Reagent
R2-D-Dimer Reagent
R3-D-Dimer Calibrator – Concentration is lot specific, see vial label.

### MATERIALS REQUIRED BUT NOT PROVIDED
Laboratory instrumentation, Spectrophotometer UV/VIS with thermostatic cuvette holder or clinical chemistry analyzer: semi automated, calibrated micropipettes, glass or high quality polystyrene cuvettes, test tube/rack, heating bath, controls, saline, Deionised water

### REAGENT PREPARATION , STORAGE & STABILITY
Reagent 1, Reagent 2 is ready to use. Reagent 3 is lot specific either lyophilized or liquid.
If Reagent 3 is in lyophilized form then reconstitute it with 1 ml Deionised water mentioned on the vial label. Close the vial and let stand for 10 minutes. Dissolve the contents of the vial by swirling gently avoiding formation of foam. Do not shake and if Reagent 3 is in liquid form then it is ready to use.
Keep away from direct light sources.
Stability: unopened reagents and calibrator are stable up to expiration date on labels at 2-8 °C. Do not freeze the reagents.
Stability since first opening of bottle: Preferable within 30 days at 2-8°C.
Mix reagent R2 well before placing on the analyzer & before processing.

### WARNINGS AND PRECAUTIONS
1. For *in vitro* use only.
2. This pack insert must be completely understood prior to operation. Do not modify the test procedure or substitute reagents from other manufacturers or other lots unless the reagent is stipulated as interchangeable. It is recommended to handle carefully by entitled and professionally educated person.
3. Do not pipette by mouth. Use disposable gloves while performing the assay. Wash hands thoroughly when finished.
4. Perform the test according to the general "Good Laboratory Practice" (GLP) guidelines.
5. Do not use reagents beyond the expiry date.
6. In case of skin contact with any of the reagents, wash thoroughly with running water.

### SPECIMEN
**Citrate Plasma** : Stability : -20°C for 30 days and Room temperature for 8 hours. Do not use hemolysed or lipemic sample.

**Programme Parameter for MERILYZER CliniQuant**

| | |
|---|---|
| Reading Mode | Fixed Time |
| Standard Conc. | lot specific |
| Filter - 1 (nm) | 620 nm |
| Temperature | 37° C |
| Volume (µl) | 400 |
| Delay Time (Sec) | 60 |
| Read Time (Sec) | 120 |
| Reaction Direction | Increase |
| Reference Low | 0 |
| Reference High | 0.5 |
| Linearity Limit | 10 |

**TEST PROCEDURE**

| Dispense | Standard | Sample |
|---|---|---|
| Reagent 1 | 360 µl | 360 µl |
| Reagent 2 | 120 µl | 120 µl |
| Standard | 20 µl | - |
| Sample | - | 20 µl |
| Mix, incubate for 60 seconds at 37°C, then record absorbance as A1. After exactly 120 seconds, record again absorbance as A2. | | |

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## RESULT CALCULATION

Serum:

D-Dimer mg/L = A2-A1(sample)/A2-A1(Calibrator) x concentration of Calibrator

## REFERENCE VALUES

<0.5 mg/L.

It is recommended that each laboratory verifies this range or derives reference interval for the population it serves.

## QUALITY CONTROL AND CALIBRATION

It is recommended to perform internal quality control with assayed normal and assayed abnormal to confirm the validity of the test and assure the accuracy of patient result.

Using the recommended Calibrator or the Standard included, calibrate the assay:

a. When using a new reagent or lot

b. When QC values are out of range.

## PERFORMANCE CHARACTERISTICS

### 1.Linearity

The linearity up to 10 mg/L.

### 2. Sensitivity/ Limit of detection (LOD)

The limit of detection is 0.017 mg/L.

The limit of quantification is 0.05 mg/L.

### 3. Interferences

No interference has been observed for the following

Bilirubin up to 40 mg/dl.

Hemoglobin up to 500 mg/dl.

Triglycerides up to 250 mg/dl.

### 4. Precision

Intra-assay precision

| | Mean | SD | CV |
|---|---|---|---|
| n = 20 | mg/L | mg/L | % |
| Control L1 | 0.37 | 0.01 | 3.21 |
| Control L2 | 1.74 | 0.04 | 2.41 |

Inter-assay precision

| | Mean | SD | CV |
|---|---|---|---|
| n = 20 | mg/L | mg/L | % |
| Control L1 | 0.36 | 0.01 | 3.55 |
| Control L2 | 1.76 | 0.02 | 1.26 |

### 5. Methods Comparison

Comparison was done between D-Dimer Reagent (y) & reference D-Dimer Kit (x) using 20 samples gave following results:

$y = 0.9900x + 0.0113$

$r^2 = 0.995$

## LIMITATIONS

Samples with values above 10 mg/L should be diluted with 0.9% saline, re-run and multiply results by dilution factor.

## WASTE DISPOSAL

This product is made to be used in professional laboratories. Please consult local regulations for correct waste disposal.

## REFERENCES


1. Sandkamp, M. et al. Clin. Chem. 36:20-23 (1990).
2. Wo, J.H. et al. Clin. Chem. 39:209-212 (1993).
3. Grinstead, G.F. The Fats of Life. 4:1-9 (1990).
4. Utermann G. et al. Science 246:904-910 (1989).
5. Marcovina, S.M. et al. J. Lipid Res. 37:2569-2585 (1996).
6. Data on file: Meril Diagnostics.



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Symbols used on Meril Diagnostics labels:

| | | | |
|---|---|---|---|
| REF | Catalogue number | | Temperature limit |
| LOT | Batch code | | Caution |
| | Use by date | | Keep away from sunlight |
| | Keep dry | | Consult Instruction for use |
| | Manufacturer | IVD | *In Vitro* diagnostics medical device |
| | Date of manufacture | | Do not use if package is damaged |