

**Quantitative determination of D-Dimer in Citrate Plasma**  
Only for *In Vitro* Diagnostic use

**ORDER INFORMATION**

REF	CONT
TDR 20	1x20 ML
TDR 40	1x40 ML

**CLINICAL SIGNIFICANCE**

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

**PRINCIPLE**

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.

**REAGENT COMPOSITION**

Reagent I : Tris buffer, Sodium Azide 0.95 g/L  
 Reagent II : Latex particles coated with anti-human D-Dimer monoclonal antibody.  
 D-Dimer- CAL : Lyophilized vial, Conc., is stated on the vial label.

**SAFETY PRECAUTIONS AND WARNINGS**

- For in vitro diagnostic use only.
- DO NOT pipette by mouth. Avoid contact with skin and eyes. If spilt, thoroughly, wash affected areas with water. For further information, consult the D-Dimer Reagent Material Safety Data Sheet.
- Reagent contains Sodium Azide as a preservative. This may react with copper or lead plumbing to form explosive metal azides. Upon disposal, flush with large amounts of water to prevent azide build up.
- Do not use the reagent after the expiration date printed on the kit.
- Components from human origin have been tested and found to be negative for the presence of HBsAg, HCV and antibody to HIV(1/2). However handle the calibrator cautiously as potentially infectious material.

**SAMPLE COLLECTION AND PRESERVATION**

Only the specimens listed below were tested and found acceptable. For specimen collection and preparation, only use suitable tubes or collection containers.

**Specimen:** Citrate Plasma samples on an empty stomach are the recommended specimens.

**Citrate Plasma:** Collect fresh Citrated Plasma using standard sampling tubes. When processing samples in primary tubes, follow the instructions of the tube manufacturer.

For samples with Absorbance interference, including samples of hemolysis and turbidity, may affect the test results. Sample recollection is recommended.

**Stability :** Store Citrate Plasma less than 7 days at 2 ~ 8°C, 1 month at -20°C ~ -15°C. Protected from light and avoid repeated freeze thaw cycles. Centrifuge samples containing precipitate before performing the assay.

**REAGENT PREPARATION**

**R1: Ready for use; R2: Ready for use.**  
Swirl the latex vial (R2) gently before use.

**D-Dimer calibrator:** Lyophilized calibrators

**REAGENT STABILITY**

All the component of the kit are stable until the expiry date on the label when stored tightly closed at 2-8°C and contaminants prevented during there use, Do not use expired reagents.

**D-Dimer Calibrator:** stable till expiry at 2-8°C. Do not freeze.

**Calibration**

It is recommended to use the D-Dimer Calibrator for calibration. Dissolve the lyophilized D-Dimer calibrator with 1ml distilled water/Diluent, and dilute to 6 calibrators as follows, Multiply the concentration of the D-Dimer calibrator by the corresponding factor stated in the table below to obtain the D-Dimer concentration of each dilution

Calibrator Dilution	1	2	3	4	5	6
Calibrator D-Dimer (µl)	-	10	25	50	75	100
NaCl 9 g/dL (µl)	100	90	75	50	25	-
Factor	0	0.1	0.25	0.50	0.75	1.0

**Calibration frequency**

Recalibration is recommended:

- as a blank calibration after 24 hours
- as a blank calibration after reagent bottle change
- as a two point calibration every 30 days if the reagent always on-board
- as a two point calibration after reagent lot change
- as a two point calibration if required following quality control procedures

Calibration verification: Not necessary

AUTOMATED PARAMETERS	
<b>Wavelength</b>	630 nm
<b>Cuvette</b>	1 cm light path
<b>Reaction Temperature</b>	37 °c
<b>Measurement</b>	Against Reagent blank
<b>Reaction</b>	Fix-time Kinetic
<b>Curve</b>	Non-Linear (Spline, Logic Log 4 Para)
<b>Reaction Direction</b>	Increasing
<b>Buffer Reagent R -1</b>	300 µl
<b>Sample/calibrator Volume</b>	20 µl
<b>Incubation (R1 + Sample)</b>	3 minutes
<b>Latex Reagent R2</b>	100 µl
<b>Delay Time</b>	20 Seconds
<b>Read Time</b>	3 minutes
<b>Linearity</b>	10000 ng/ml

**ASSAY PROCEDURE**

**PIPETTE INTO TEST TUBES**

	Reagent Blank	CAL	SAMPLE
Buffer Reagent – R1	300 µl	300 µl	300 µl
Saline	20 µl	-	-
Standard	-	20 µl	-
Sample	-	-	20 µl
Mix well and incubate for 3 minutes at 37°C			
Latex Reagent – R2	100 µl	100 µl	100 µl
Mix well, and read the absorbance after 20 sec A1 and after 3 minutes A2 of the sample addition.			

## CALCULATION

**Calibration Curve:** Multipoint Non-linear curve (Spline, Logic log - 4Para)

**Result calculation :** The corresponding  $\Delta A$  is calibrated by the calibrator concentration. The D-Dimer concentration in the sample is read out from the calibration curve through the  $\Delta A$  of the sample.

## LINEARITY

The method is linear to a concentration of 200 -10,000 ng/ml. If the concentration exceeds this value, the sample should be diluted 1:5 with 0.9% saline solution and reassayed.

## REFERENCE INTERVAL

< 500 ng/ml

The reference range should be determined by each hospital to confirm with the characteristics of the region being tested.

**Detection Limit: Values  $\leq 200$  ng /ml may give Non- reproducible results.**

## QUALITY CONTROL

To ensure adequate quality control ,Normal and abnormal control with assayed values should be run as unknown samples.

## Limitations and Interference











- 1.Lipemia (Intralipid): no interference up to 250mg/dl of intralipid.
- 2.hemoglobin: no interference up to 500mg/ dl.
- 3.Bilirubin: no interference up to 40mg/ dl.

The result may vary with different analyzers or calibrations. For diagnostic purposes, the results should always be assessed in conjunction with the patient's medical history, clinical examination and other findings.

## BIBLIOGRAPHY

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3. Shisou, K, Fujimaki, M: Assay of Stabilized FDP, Japan Society on Thrombosis and Homeostasis, 2(1): 82, 1991
4. Himizu M, evaluation of D-dimer assay on LPIA-100, JJCLA, 16(1): 59, 1991
5. Matsuda M, New detection method of DD/E complex, KENSA, 18(2): 15, 1988

## GLOSSARY OF SYMBOL

	Consult Instruction for Use	<b>LOT</b>	Lot Number
<b>REF</b>	Catalog Number		Date of Manufacturing
	Store between		Use By or Expiration Date
	Manufacturer	<b>IVD</b>	For <i>in vitro</i> Diagnostic use only
	Keep away from sunlight	<b>CONT</b>	Content of the kit
	Tests per Kit		Do Not Use if Damaged
	Do not reuse		Keep Dry



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