

Dia-TT

THROMBIN TIME REAGENT



Cat. No.: 51036 12 x 3 ml

PRODUCT NAME

Dia-TT thrombin time reagent.

INTENDED USE

(For In Vitro Diagnostic Use Only)

Dia-TT is a freeze-dried reagent used for determination of Thrombin Time (TT).

SUMMARY AND PRINCIPLE

The TT test is designed for the assessment of fibrin formation. The TT is only affected by factors that interfere with thrombin or fibrinogen. The TT is elevated in DIC (FDPs interfere with polymerisation), low fibrinogen levels, dysfibrinogenemia and heparin (very sensitive) only.

PRINCIPLE

The Dia-TT test is performed by adding thrombin to plasma. The added thrombin directly clots fibrinogen of tested plasma.

ACTIVE INGREDIENTS

Dia-TT is a freeze-dried, human thrombin in buffered medium with calcium and preservative.

PRECAUTIONS

- Person installing the Dia-TT reagent must be a trained laboratory professional!
- By calculating with inappropriate data or using the supplied data improperly, erroneous results may occur!
- Dia-TT reagent, due to its ingredients should be handled with care by observing the precautions recommended for biohazards material!
- Reagent coming into contact with specimens and other materials should be handled as if capable of transmitting infection and should be disposed of with proper precautions!
- Avoid microbial contamination of the reagent otherwise erroneous results may occur!
- Each donor unit used in the preparation of this reagent tested with HBsAg, anti-HIV 1-2, anti-HCV, anti-TP screening tests and found to be non-reactive.
- All reagents, waste and utilized disposable laboratory equipment should be considered as hazardous waste! Their handling and disposal should be done according to the valid hazardous material processing regulation.
- Do not use the reagent beyond the expiration date printed on the label!

PREPARATION

Dia-TT reagent is dissolved with the required amount of distilled water, which is indicated on the label. Keep the reagent at room temperature (20-25°C) for at least 30 minutes for proper reconstitution. Swirl the vial gently, horizontally more times (5-10) before using it, but do not shake. Wait until the reagent reaches the working temperature!

SPECIMENS

Dia-TT test requires freshly decalcified plasma. To obtain it, mix nine parts of freshly drawn venous blood with one part trisodium citrate (3,2%; 109mmol/L). The use of higher concentration of trisodium citrate (3,8%; 129mmol/L) is not recommended. Mix the blood carefully and centrifuge plasma before testing. The measurement must be performed within 4 hours. Do not store the sample at 2-8°C. Refer to Clinical and Laboratory Standards Institute (CLSI) guidelines H21-A5.

TEST PROCEDURE

Dia-TT test is a one-stage TT test, which can be used with semi-automated coagulation analysers (Coag 4D) according to the protocol detailed below. The duplicated measurement is recommended.

1.	Adding sample into cuvette	100µl
2.	Sample incubation	2min
3.	Adding TT reagent into cuvette	100µl
4.	Simultaneously start the timer	~1min

Normal control is recommended for verified measuring. Each laboratory should establish its own quality control program. In case of determination by any other coagulometer, please follow the instructions of the manual.

STORAGE AND STABILITY

Dia-TT reagent in intact vial is stable until the expiration date given on the vial, when stored at 2-8°C. Stability after opening in the original vial is shown in below table:

T (°C)	20-25	15-19	2-8
Day	3	7	15

INSTRUCTION FOR USE

EXPECTED RESULTS

Dia-TT test results can be reported in the following units, lot specific sheet in the box will help in the calculation:

1. Seconds, which means the observed clotting time.

2. Ratio (Ratio=TT/MNTT), which means the clotting time of the sample divided by the mean normal TT (MNTT). Method dependent MNTT value in the value sheet is only for information, because it depends on the measuring circumstances and population.

Every laboratory should determine its own MNTT value and reference range. Our reference range is the following on Diagon analysers (Coag Line):

Reference	Mean	Range from	Range to
Second	18,5	15,6	22,2

LIMITATIONS

The result of TT test with Dia-TT reagent may be influenced by drugs and other pre-analytical interfering agents. The potential limits of these parameters were tested on Diagon analysers (Coag Line) with the following result:

Hemoglobin	Triglycerid	Bilirubin
3,4 g/L	4 mmol/L	240 µmol/L

PERFORMANCE CHARACTERISTICS

The reproducibility test of Dia-TT reagent on automated coagulometer gives the following results:

	Intra-Assay	Inter-Assay
Sample	1	1
n	10	10
Mean (sec)	26,8	26,0
CV (%)	2,006	2,882

MATERIALS REQUIRED BUT NOT PROVIDED

- One level of control for quality control (Dia-CONT I-II; Cat. No.: 91020, 91010).
- Optical or mechanical coagulation analyser for measuring, Diagon analysers (Coag Line) are recommended.
















BIBLIOGRAPHY

1. CLSI: Collection, Transport, and Processing of Blood Specimens for Testing Plasma-Based Coagulation Assays and Molecular Hemostasis Assays; Approved Guideline- Fifth Edition. CLSI document: H21-A5; 28:5; 2008.
2. Latallo ZS: Thrombin clotting assays. (Nils U. Bang NU, Beller FK, Deutsch E, Mammen EF: Thrombosis and Bleeding Disorders: Theory and Methods.) Academic Press, New York; 183; 1971.



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SYMBOLS			
	Manufacturer		Use-by date
	Batch code		Catalogue number
	Do not use if package is damaged		Fragile, handle with care
	Keep dry		Temperature limit
	Biological risks		Consult instruction for use
	Caution		<i>In vitro</i> diagnostic medical device
	Contains sufficient for <n> tests		This side up
	CE mark		