DIAGON
Solutions beyond imagination

INSTRUCTION FOR USE

Dia-PTT LIQUID

ACTIVATED PARTIAL THROMBOPLASTIN TIME REAGENT

CE

Cat. No.: 72096	**12 x 8 ml**
Cat. No.: 72048	**12 x 4 ml**
Cat. No.: 72024	**12 x 2 ml**
Cat. No.: 72012	**6 x 2 ml**

PRODUCT NAME

Dia-PTT LIQUID activated partial thromoplastin time reagent.

INTENDED USE

(For In Vitro Diagnostic Use Only)

Dia-PTT LIQUID is a liquid, ready to use, rabbit brain phospholipid reagent used for determination of Activated Partial Thromboplastin Time (APTT).

SUMMARY AND EXPLANATIONS

Dia-PTT LIQUID reagent is a rabbit brain extract phospholipid. The APTT test is a sensitive screening test for the intrinsic coagulation pathway. Dia-PTT LIQUID as a reagent for APTT is highly sensitive to decreased level of factors in intrinsic pathway (factor I, II, V, VIII, IX, X, XI and XII), hereditary or acquired coagulation disorders and liver failure. Therefore, the APTT by Dia-PTT LIQUID reagent is optimally used for presurgical screening and monitoring for heparin therapy, as well. Dia-PTT LIQUID reagent with the corresponding deficient plasmas is also suitable for determination of activity of intrinsic coagulation pathway.

PRINCIPLE

Dia-PTT LIQUID reagent initiates the activation the intrinsic coagulation pathways in the presence of standardized amount of phospholipid and contact activator (ellagic acid). After incubation, the addition of calcium induces the formation of fibrin clot. The time of this clotting process is measurable manually or with optical and mechanical coagulation analysers.

ACTIVE INGREDIENTS

Dia-PTT LIQUID reagent is a phospholipid from rabbit brain, which contains ellagic acid in buffered medium with preservative.

PRECAUTIONS

- Person installing the Dia-PTT LIQUID reagent must be a trained laboratory professional!
- By calculating with inappropriate data or using the supplied data improperly, erroneous results may occur!
- Dia-PTT LIQUID 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!
- According to the present knowledge the reagent does not contain any particles which can spread from animal to human!
- 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-PTT LIQUID reagent is ready to use. 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-PTT LIQUID 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-PTT LIQUID test is an APTT test, which can be used with semi-automated coagulation analysers (Coag 4D) according to the protocol detailed below. The duplicated measurement is recommended.

1.	**$CaCl_2$ reagent warming up to 37°C**	**~15min**
2.	**Adding sample into cuvette**	**50µl**
3.	**Adding APTT reagent into cuvette**	**50µl**
4.	**Sample and reagent incubation**	**3min**
5.	**Adding $CaCl_2$ reagent into cuvette**	**50µl**
6.	**Simultaneously start the timer**	**~2min**

Normal and pathological controls are 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. Use only Dia-$CaCl_2$ solution in order to achieve correct result!

STORAGE AND STABILITY

Dia-PTT LIQUID 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	7	10	14

Do not freeze it!

EXPECTED RESULTS

Dia-PTT LIQUID 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=APTT/MNPTT), which means the clotting time of the sample divided by the mean normal APTT (MNPTT). Method dependent MNPTT value in the value sheet is only for information, because it depends on the measuring circumstances and population.

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

Reference	Mean	Range from	Range to
Second	28,2	23,2	35,2

LIMITATIONS

The result of APTT test with Dia-PTT LIQUID 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	Triglicerid	Bilirubin
3,4 g/L	10 mmol/L	240 µmol/L

PERFORMANCE CHARACTERISTICS

The reproducibility test of Dia-PTT LIQUID reagent on Diagon analysers (Coag Line) gives the following results:

	Intra-Assay		Inter-Assay	
Sample	1	2	3	4
n	10	10	10	10
Mean (sec)	35,8	68,2	34,6	64,1
CV (%)	0,405	0,317	1,085	1,340

MATERIALS REQUIRED BUT NOT PROVIDED

- $CaCl_2$ for measuring (Dia-$CaCl_2$; Cat. No.: 41192; 41048).
- Different levels 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. CLSI: One-Stage Prothrombin Time (PT) Test and Activated Partial Thromboplastin Time (APTT) Test; Approved Guideline-Second Edition. CLSI document: H47-A2; 28:20; 2008.
3. CLSI: How to Define and Determine Reference Intervals in the Clinical Laboratory; Approved Guideline-Second Edition. CLSI document: C28-A2; 20:13; 2000.

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