DIAGON
Solutions beyond imagination

INSTRUCTION FOR USE

Dia-PT LIQUID

PROTHROMBIN TIME REAGENT

Cat. No.: 82096	**12 x 8 ml**
Cat. No.: 82048	**12 x 4 ml**
Cat. No.: 82024	**12 x 2 ml**
Cat. No.: 82012	**6 x 2 ml**

PRODUCT NAME

Dia-PT LIQUID prothrombin time reagent.

INTENDED USE

(For In Vitro Diagnostic Use Only)

Dia-PT LIQUID is a liquid, ready to use, rabbit brain thromboplastin reagent used for determination of Prothrombin Time (PT).

SUMMARY AND EXPLANATIONS

Dia-PT LIQUID reagent is a rabbit brain extract thromboplastin, which contains tissue factor, lipids and calcium ions. The PT test according to Quick is a sensitive screening test for the extrinsic coagulation pathway. Dia-PT LIQUID as a reagent for PT is highly sensitive to vitamin K antagonists, decreased level of factors in extrinsic pathway (factor II, V, VII, and X), hereditary or acquired coagulation disorders and liver failure. Therefore, the PT by Dia-PT LIQUID reagent is optimally used for presurgical screening and monitoring for oral anticoagulant therapy (OAT), as well. Dia-PT LIQUID reagent with the corresponding deficient plasmas is also suitable for determination of activity of extrinsic coagulation pathway.

PRINCIPLE

Dia-PT LIQUID reagent as a calcium thromboplastin, induces the formation of fibrin clot when added to patient's plasma. The time of this clotting process is measurable manually or with optical and mechanical coagulation analysers.

ACTIVE INGREDIENTS

Dia-PT LIQUID reagent is a tissue thromboplastin from rabbit brain, which contains calcium ions and preservative.

PRECAUTIONS

- Person installing the Dia-PT LIQUID reagent must be a trained laboratory professional!
- By calculating with inappropriate data or using the supplied data improperly, erroneous results may occur!
- Dia-PT 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-PT 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-PT 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 24 hours. Do not store the sample at 2-8°C. Refer to Clinical and Laboratory Standards Institute (CLSI) guidelines H21-A5.

TEST PROCEDURE

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

1.	**Reagent warming up to 37°C**	**~15min**
2.	**Adding sample into cuvette**	**50µl**
3.	**Sample incubation**	**2min**
4.	**Adding PT reagent into cuvette**	**100µl**
5.	**Simultaneously start the timer**	**~1min**

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.

STORAGE AND STABILITY

Dia-PT 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)	37	20-25	15-19	2-8
Day	2	4	5	12

Do not freeze it!

EXPECTED RESULTS

Dia-PT 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=PT/MNPT), which means the clotting time of the sample divided by the mean normal prothrombin time (MNPT). Method dependent MNPT value in the value sheet is only for information, because it depends on the measuring circumstances and population.
3. Percentage, which means the proportional part of the normal PT activity, which is calculable from the calibration curve. Method dependent master curve in the value sheet can be used for the calculation.
4. International Normalized Ratio (INR), which means the ratio raised to the power of International Sensitivity Index (ISI) [INR=$(PT/MNPT)^{ISI}$]. Method dependent ISI value in the value sheet can be used for the calculation. The INR is the only officially recognized dimension of the result at vitamin K antagonists treated patients.

The normal range expressed in INR is 0,8-1,2. Every laboratory should determine its own MNPT value and reference range. Accurate and general conversion of percentage into INR (or back) is not possible! The conversion table on the Diagon website helps the usage of reagent with manual method (www.diagon.com/ /Customer support).

LIMITATIONS

The result of PT test with Dia-PT 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:

Heparin	Hemoglobin	Triglicerid	Bilirubin
0,75 IU/mL	6,8 g/L	8 mmol/L	270 µmol/L

PERFORMANCE CHARACTERISTICS

The reproducibility test of Dia-PT 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)	11,3	18,3	11,3	19,0
CV (%)	0,590	0,387	1,521	1,094

MATERIALS REQUIRED BUT NOT PROVIDED

- 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. De Caterina R et al: Vitamin K antagonists in heart disease: Current status and perspectives (Section III). Thromb Haemost; 110: 1087-1107; 2013.

DIAGON LTD.
Baross u. 48-52. 1047 Budapest, Hungary
Tel.: +36 1 3696500
Fax.: +36 1 3696301
Web: www.diagon.com
E-mail: diagon@diagon.com

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		