

Dia-PTT



ACTIVATED PARTIAL THROMBOPLASTIN TIME REAGENT

Cat. No.: 71048 **12 x 4 ml**
Cat. No.: 71030 **6 x 4 ml**
Cat. No.: 71024 **12 x 2 ml**

PRODUCT NAME

Dia-PTT activated partial thromoplastin time reagent.

INTENDED USE

(For In Vitro Diagnostic Use Only)

Dia-PTT is a rabbit brain phospholipid reagent used for determination of Activated Partial Thromboplastin Time (APTT).

SUMMARY AND EXPLANATIONS

Dia-PTT reagent is a rabbit brain extract phospholipid. The APTT test is a sensitive screening test for the intrinsic coagulation pathway. Dia-PTT 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 reagent is optimally used for presurgical screening and monitoring for heparin therapy, as well. Dia-PTT reagent with the corresponding deficient plasmas is also suitable for determination of activity of intrinsic coagulation pathway.

PRINCIPLE

Dia-PTT reagent initiates the activation the intrinsic coagulation pathways in the presence of standardized amount of phospholipid and contact activator (micronized silica). 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 reagent is a freeze-dried, phospholipid from rabbit brain, which contains micronized silica in buffered medium with preservative.

PRECAUTIONS

- Person installing the Dia-PTT reagent must be a trained laboratory professional!
- By calculating with inappropriate data or using the supplied data improperly, erroneous results may occur!
- Dia-PTT 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 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!

Using of stirring bar is necessary during the measurement!

SPECIMENS

Dia-PTT 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 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-CaCl₂ solution in order to achieve correct result!

STORAGE AND STABILITY

Dia-PTT 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 | 1 | 10 | 14 |

Do not freeze it!

EXPECTED RESULTS

Dia-PTT 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 | 33,9 | 28,4 | 40,2 |

LIMITATIONS

The result of APTT test with Dia-PTT 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 |
|------------|-------------|------------|
| 6,8 g/L | 10 mmol/L | 240 µmol/L |

PERFORMANCE CHARACTERISTICS

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

| Sample | Intra-Assay | | Inter-Assay | |
|------------|-------------|-------|-------------|-------|
| | 1 | 2 | 3 | 4 |
| n | 10 | 10 | 10 | 10 |
| Mean (sec) | 41,3 | 64,3 | 41,4 | 66,0 |
| CV (%) | 0,576 | 0,458 | 1,226 | 2,096 |

MATERIALS REQUIRED BUT NOT PROVIDED

- CaCl₂ for measuring (Dia-CaCl₂; 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.
- Magnetic stirrer for mixing (Magnetic stirrer; Cat. No.: DT-ST).

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.

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 |
|  | 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 |  | In vitro diagnostic medical device |
|  | Contains sufficient for <n> tests |  | This side up |
|  | CE mark | | |