ACTIVATED PARTIAL THROMBOPLASTIN TIME (PTT)
(LIQUID REAGENT)

For In-Vitro diagnostic and professional use only

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(LIQUID REAGENT)

Store at: 2-8°C

APPLICATION
Activated Partial Thromboplastin Time (PTT) is commonly used for pre-surgical screening for intrinsic factor deficiency, monitoring heparin therapy, in the detection of Lupus Anticoagulants, and quantitative determination of the Factor VIII, IX, XI, and XII relevant with the intrinsic coagulation system.

PRINCIPLE
In the test, citrated test plasma is mixed with PTT reagent for a specified period of time. The time required for clotting formation is the activated partial thromboplastin time (PTT). The degree of prolongation is proportional to the severity of single factor deficiency, or in a cumulative deficiency of all the factors involved.

MATERIALS
MATERIALS PROVIDED:
• PTT Liquid Reagent.
• Plasma Normal Control.

MATERIALS REQUIRED BUT NOT PROVIDED:
• CaCl₂ (25mmol)

Specimen collection
1. Plasma obtained from whole blood samples that had been collected in a tube with 0.109M sodium citrate as an anticoagulant, nine parts of freshly collected whole blood should be immediately added to one part of anticoagulant. Centrifuge the whole blood specimen at 2500xg for 15 minutes. Separate the plasma using a plastic pipette and place it in a plastic test tube. Perform the activated partial thromboplastin time assay within 4 hours.
2. Add 1ml distilled water to vial mix well and allow it to stand for 15 minutes at ambient temperature to ensure it dissolved completely.
3. Allow the PTT reagent to reach room temperature before use.
4. Add 25µl of CaCl₂ solution to each tube.
5. Add 25µl of sample, controls to the tubes prepared in step 2.
4. Incubate for 3 minutes at 37°C.
5. Add 25µl of CaCl₂ solution to each tube, start the stop watch, mix in a water bath (37°C) for 20 seconds, then record the time required for clot formation.

REFERENCE VALUES:
Normal control sample(s): 26-36 seconds;
For best results, each laboratory should determine a reference range for its particular population and instrument reagent system.

STORAGE AND STABILITY

PTT Reagent can be stored at 2-8°C for 30 days after opening.
PTT Reagent should not be frozen and thawed.
Do not mix or use the components of this kit with the components of any other kit with different lot numbers.
Throughout testing all test tubes, syringes and pipettes should be plastic.
Throughout testing all test tubes, incubation time should keep in constant and incubation temperature should keep at 36.5-37.5°C.
Each laboratory should establish a Quality Control program that includes both normal and abnormal control plasmas to evaluate instrument, reagent tested daily prior to performing tests on patient plasmas. Monthly quality control charts are recommended to determine the mean and standard deviation of each of the daily control plasma. All assays should include controls, and if any of the controls are outside the established reference ranges, then the assay should be considered invalid and no patient results should be reported.
Turbid solution of CaCl₂ may be indicative of product deterioration.

NORMAL REFERENCE/CONTROL HUMAN PLASMA

The PT, PTT, TT, and FIB assay procedure are routinely used to identify and quantitate deficiencies in clotting mechanism as well as to monitor anticoagulant therapy. All human blood donations used in the preparation of our products have been tested individually and found to be negative for HbsAg, HCV and HIV antibody. However, we recommend that all material of human origin should be considered as potentially hazardous and be handled with...
appropriate care.

**INTENDED USE**

NCP use in factor II, V, VII, VIII, IX, and it is used as a control of precision and accuracy for PT, PTT, TT, FIB.

**REAGENTS**

NCP (Lyophilized product)

**PREPARATION AND TEST PROCEDURE**

1. Gently add 1ml distilled water to each vial of thrombin, mix well and allow it to stand for 15 minutes at ambient temperature to ensure it influence completeness.
2. According to the different examination experiment, other steps same with the samples which to testing.

**ATTENTION**

1. For in vitro diagnostic use only, avoid taking in. when operation should defer to the patient plasma treatment, keep one's eyes peeled.
2. Each experiment best determines two NCP every day, and establishment anticipated QC range for own instrument-reagent system.
3. The plasma root in Human's matter, crossed the HTLV-III/HIV, HBsAg and the HCV testing, only donations with negative findings are used for manufacture. Nevertheless, since absence of infections agents cannot be proven, all materials obtained from human blood should always be handled with due care, observing the precautions recommended for biohazardous material.

**STORAGE AND STABILITY**

Storage at 2°C-8°C, NCP can be used labeled expiry date.

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**Stability after reconstitution:**

At 2°C-8°C4 hours

**REFERENCE RANGE**

<table>
<thead>
<tr>
<th>Product</th>
<th>Reference Value</th>
</tr>
</thead>
<tbody>
<tr>
<td>PT liquid</td>
<td>11-14 sec</td>
</tr>
<tr>
<td>PTT liquid</td>
<td>20-40 sec</td>
</tr>
<tr>
<td>Fib liquid</td>
<td>3.03 g/L</td>
</tr>
<tr>
<td>TT liquid</td>
<td>10-14 sec</td>
</tr>
<tr>
<td>PT lyophilized</td>
<td>11-14 sec</td>
</tr>
<tr>
<td>Fib lyophilized</td>
<td>3.03g/L</td>
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<td>10-14 sec</td>
</tr>
</tbody>
</table>

**NOTE**

Each laboratory should determine a reference range for its particular population and instrument reagent system.

**REFERENCES:**


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**ATLAS MEDICAL**

William James House, Cowley Road, Cambridge, CB4 0WX

Tel: ++44 (0) 1223 858 910
Fax: ++44 (0) 1223 858 524

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