**QUANTITATIVE DETERMINATION OF ACTIVATED PARTIAL THROMBOPHILIN TEST (APTT) IVD**

Store at 2-8°C

**PRINCIPLE OF THE METHOD**

When phospholipids complex and calcium chloride (CaCl₂) are added to citrated plasma, the factors of intrinsic coagulation system are activated; the time to formation of a fibrin clot is then measured²,³.

**CLINICAL SIGNIFICANCE**

The time measurement of APTT is the most common coagulation procedure performed in routine laboratories, apart from the PT. The APTT is particularly sensitive to defects of the intrinsic coagulation pathway (Factors VIII, IX, XI, XII).

It is commonly used for monitoring heparin anticoagulant therapy¹,².

Clinical diagnosis should not be made on a single test result; it should integrate clinical and other laboratory data.

**REAGENTS**

<table>
<thead>
<tr>
<th>R 1</th>
<th>Ellagic acid 2% solution</th>
<th>Buffers and preservatives</th>
</tr>
</thead>
<tbody>
<tr>
<td>R 2</td>
<td>Calcium chloride (CaCl₂) 0.02M</td>
<td></td>
</tr>
<tr>
<td>Optional</td>
<td>CONTROL NORMAL REF: 1709104</td>
<td>CONTROL PATHOLOGIC REF: 1709106</td>
</tr>
</tbody>
</table>

**PREPARATION**

All the reagents are ready to use.

R1: Stable for 1 month at 2-8°C after opening.

**STORAGE AND STABILITY**

All the components of the kit are stable until the expiration date on the label when stored tightly closed at 2-8°C, protected from light and contamination prevented during their use.

A yellow sediment may form after prolonged storage.

Do not use reagents over the expiration date. Do not freeze.

**SAMPLES**

Plasma from venous puncture diluted 1/10 in trisodium citrate solution 3.8%.

Mixing immediately the blood with anticoagulant. Avoid foaming the specimen.

Centrifuge the sample at 2500 x g for 15 min and transfer the plasma into a siliconized glass or plastic containers.

Turbid, icteric, lipemic or hemolyzed samples may generate erroneous results.

The sample is stable for 2 hours at room temperature (15-25°C) or 28 days if immediately frozen at below -20°C.

**PROCEDURE**

The reagent can be used by manual method, mechanical, photointegrated or other means of clot detection. In case to be used in BIOBASE® analyzer, follow the analyzer’s instructions.

**MANUAL METHOD**

1. Incubate at 37°C the reagents and the sample:
2. Mix thoroughly the reagents.
3. Pipette into a clean and dry tube:

<table>
<thead>
<tr>
<th>Citrated plasma (µL)</th>
<th>100</th>
</tr>
</thead>
<tbody>
<tr>
<td>R 1 (µL)</td>
<td>100</td>
</tr>
</tbody>
</table>

4. Mix and incubate exactly for 5 min. at 37°C (activation time).

5. Pipette:

| R 2 (µL) | 100 |

6. Mix thoroughly.
7. On addition of R2 start stopwatch or timer on the coagulation analyzer and determine the coagulation time.

**CALCULATIONS**

It is possible to report the results as seconds or as APTT ratio, dividing the results of the sample (sec) by the results of plasma Control (sec).

\[
\text{APTT ratio} = \frac{\text{APTT of the patient in seconds}}{\text{APTT of normal plasma (pool %) in seconds}}
\]

**QUALITY CONTROL**

Control sera are recommended to monitor the performance of assay procedures:

CONTROL NORMAL: REF: 1709104

CONTROL PATHOLOGIC: REF: 1709106

If control values are found outside the defined range, check the instrument, reagents and technique for possible errors. Each laboratory should establish its own Quality Control scheme and corrective actions if controls do not meet the acceptable tolerances.

**REFERENCE VALUES**

An exhaustive study has been run with 250 samples of healthy people, and as a result it has been established the following reference values:

**APTT (in seconds)**

24 - 36 sec.

These values are for orientation purpose; each laboratory should establish its own reference range.

**PERFORMANCE CHARACTERISTICS**

**Heparin Sensitivity**

Adequate sensitivity should demonstrate < 30-40% factor activity.

**INTERFERENCES**

Do not use sodium oxalate, EDTA or heparin as anticoagulant.

Oral contraceptives, estrogens or pregnancy interfere in the assay.

A list of drugs and other interfering substances with the determination has been reported.

**NOTES**

1. All laboratory must be clean and free of trace amounts of detergents.
2. Always follow instrument manufacturer’s instructions; the results must be validated by the test laboratory.

**BIBLIOGRAPHY**

2. Arkin C et al. One stage PT and APTT; Approved Guideline vol 16 n° 3 NCCLS 96.

**PACKAGING**

Ref: 1709201

| Cont. | R1: 5 x 4 mL | R2: 5 x 4 mL |

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