

**1/ INTENDED USE**

The STA® - C.K. Prest® (®) kit provides reagents for the determination of the kaolin-activated partial thromboplastin time (APTT), according to Langrell R.D. et al. (1) and Larrieu M.J., Weilland C. (3) by analysing of the STA® reagents (in brackets). The STA® reagents have been assigned to the moderate complexity category per CLIA 1988 - CDC Analyte Code 0498 - CDC Test System Codes 4677 and 4875.

**2/ SUMMARY AND EXPLANATION**

The APTT test is a general coagulation screening test of the coagulation factors XII, XI, IX, VII, V, II and fibrinogen.

A prolongation of the APTT is encountered in the following situations (3):

- Congenital Deficiencies
  - if the prothrombin time (PT) is normal, the following factors may be deficient:
    - factor VIII (STA® - Deficient VIII, REF 00725)
    - factor IX (STA® - Deficient IX, REF 00724)
    - factor XII (STA® - Deficient XII, REF 00723)
  - if all these factors are normal, a deficiency in HMWK is suggested.
- Acquired Deficiencies and Abnormal Conditions
  - Liver diseases
  - Consumption coagulopathy (DIC)
  - Circulating anticoagulants (LA type or circulating anticoagulant factor against factor II and X)
- During heparin or vitamin K antagonist therapy
- Treatments with thrombin inhibitors (e.g., hirudin, argatroban...)

**3/ TEST PRINCIPLE**

The APTT test is a recalcification of plasma in the presence of a standardized amount of cephalin (platelet substitute) and a factor XII activator (kaolin). The APTT reagent is the mixture of coagulation factors XII, XI, IX, V, II, and fibrinogen.

The APTT test is performed by the patient's plasma being tested in the instrument (see the Reference Manual of the analyzer model). Then select the test(s) to be performed.

**4/ REAGENT PRINCIPLES**

- The stirring-bar that is to be added to the reagent vial should never be the source of contamination. To ensure that stirring-bars are contamination-free, rinse them with distilled water and dry them carefully to remove all traces of moisture before adding them to reagent vials. In addition, decontaminate stirring-bars once a week according to the following procedure:
  - immerse the bars in a vial of STA® - Desorb U (REF 00705) and let them soak for 30 minutes with constant magnetic stirring;
  - use tweezers to transfer the bars from the Desorb solution vial to a vial of distilled water and let them soak for another 30 minutes with constant magnetic stirring;
  - finally, remove the stirring-bars from the distilled water vial and dry them carefully to remove all traces of moisture.

**6/ SPECIMENT COLLECTION AND TREATMENT**

Sample collections must be in conformity with the recommendations for haemostasis tests.

- Collect blood (9 vol.) in 0.109 M (i.e., 3.2 %) trisodium citrate anticoagulant (1 vol.) Use sample collection tubes made of plastic or siliconized glass. (In the USA the following CLIS guidelines H211-AS (12) and H261-AS (13) may be followed). When monitoring heparin therapy, use preferentially CTAD tubes available from Becton Dickinson, specially designed sample collection tube to prevent heparin inactivation (8).

- Centrifuge blood samples for 15 minutes at 2000-2500 x g. Collect the plasma in plastic vials.

- Plasmas remain stable for 4 hours at 20 ± 5 °C (10).
- If on heparin therapy, plasmas remain stable for 2 hours at 20 ± 5 °C when collected with citrate anticoagulant and for 4 hours at 20 ± 5 °C when collected with CTAD tubes.

**7/ REAGENT PREPARATION AND STORAGE**

**Preparation**

- Shake a vial of Reagent 2 (R2) well and transfer its entire contents into a vial of Reagent 1 of the same kit. Allow the reconstituted Reagent 1 to stand at room temperature (23 ± 5 °C) for 30 minutes. Then transfer the Reagent 1 vial gently to obtain a homogenous suspension. Add a stirring-bar (REAG 00972) to the vial and install the perfluorinated cap on it. Then, place the reagent in the instrument and after 20 minutes additional time for stabilization/mixing, the reagent is ready for use.

**Storage**

- The reagents in intact vials are stable until the expiration date indicated on the APTT reagent kit. After reconstitution:
  - With the stirring-bar (rifmite) and refrigerate at 5 °C ± 2 °C. The reconstituted reagent is stable for 48 hours on STA Compact®.
  - In its original capped vial for 7 days at 5 °C.

- Do not freeze.

**9/ LIMITATIONS**

- Normal values may vary depending on local conditions. Therefore, it is necessary to determine each laboratory's own normal range and acceptable control values for their particular local patient population. In general, values are considered normal if they fall within the range of ± 2 standard deviations (X ± 2 SD) (5).
- The APTT value of the plasmas being tested for their particular local patient population. In general, values are considered normal if they fall within the range of ± 2 standard deviations (X ± 2 SD) (5).
- For example, 327 normal human plasmas were tested with the STA® - C.K. Prest® on the STA® analyzer. The observed mean time was 29.6 seconds with a standard deviation of 2.4 seconds.
- If the prothrombin time (PT) is normal, the following factors may be deficient:
  - factor II (STA®- Deficient II, REF 00721)
  - factor V (STA®- Deficient V, REF 00720)
  - factor VIII (STA® - Deficient VIII, REF 00725)
  - factor IX (STA® - Deficient IX, REF 00724)
  - factor XII (STA® - Deficient XII, REF 00723)
- Plasma controls (viscosity, clotting time, trace metals) should be checked at least daily.

**12/ EXPECTED VALUES**

Normal values may vary depending on local conditions. Therefore, it is necessary to determine each laboratory's own normal range and acceptable control values for their particular local patient population. In general, values are considered normal if they fall within the range of ± 2 standard deviations (X ± 2 SD) (5).

For example, 327 normal human plasmas were tested with the STA® - C.K. Prest® on the STA® analyzer. The observed mean time was 29.6 seconds with a standard deviation of 2.4 seconds.

The APTT is statistically lengthened in newborn babies (7). By contrast, shortened times are found in older populations (4).

**13/ PERFORMANCE CHARACTERISTICS**

Different samples were used for the intra-assay and inter-assay reproducibility studies on the STA® Results obtained with STA® - C.K. Prest® are shown below:

<table>
<thead>
<tr>
<th>Sample</th>
<th>Intra-Assay Reproducibility</th>
<th>Inter-Assay Reproducibility</th>
</tr>
</thead>
<tbody>
<tr>
<td>Sample 1</td>
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<td>21</td>
</tr>
<tr>
<td>Sample 2</td>
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<tr>
<td>Sample 3</td>
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<td>10</td>
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<tr>
<td>Sample 4</td>
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<td>32</td>
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</table>

**REFERENCES**


