

APTT



(Activated Partial Thromboplastin Time Reagent)

8 x 3 ml

88 05 12

INTENDED USE

APTT is intended for use as a partial thromboplastin reagent for the activated partial thromboplastin time test (APTT); coagulation factor assays based on the APTT; the method is suitable for manual automated and semiautomated methods.

CLINICAL SIGNIFICANCE

Prolongation of the APTT with Coagulen-APTT and correctly prepared plasma under controlled conditions, is due to disruption of the intrinsic coagulation mechanism (Factors XII, XI, IX, VIII, X, V, and II). Such disruption of intrinsic coagulation may be due to congenital or acquired factor deficiencies, or the presence of inhibitors or interfering substances.

Coagulen-APTT is extremely sensitive to heparin. In practice a heparin level in normal plasma of 0.2 - 0.3 IU/ml corresponds to an APTT of approximately 1.5 - 2.0 times that of Coagulen-Norm. Heparin concentrations of 0.3 - 0.5 IU/ml will correspond to an APTT of 2 - 3 times that of Coagulen-Norm.

TEST PRINCIPLE

If plasma is recalcified in the presence of a chemical activator and partial thromboplastin, a solid fibrin clot forms within a specific period of time. Should any defect of Intrinsic coagulation be presented, it takes longer than normal for a clot to form.

PREPARATION OF REAGENTS

To reconstitute Coagulen-APTT mix carefully with 3 ml distilled water. It is useable immediately.

REAGENT STABILITY

The stability periods quoted below, are based on the results of a rigorous and independent Quality Control Program performed under optimum storage conditions.

In practice, the reagents may however be subjected to extreme climatic conditions and factors such as contamination with pipettes. Therefore, the use of the Coagulen-Control Plasma range of internal quality control plasmas is recommended to monitor the stability of reconstituted reagents stored for prolonged periods.

Once reconstituted and stored under optimal conditions.

Coagulen-APTT is stable for:

30 days if refrigerated (4° - 8° C)

7 days at room temperature (20° - 25° C)

Unopened vials of Coagulen-APTT, stored between 4° - 8° C, are stable until the expiry date printed on the vial label and packaging material.

COLLECTION AND HANDLING OF SPECIMENS

Blood should be collected from the patient by clean venepuncture directly into a one tenth volume of 0.109 m (3.2%) trisodium citrate using a double syringe technique. The specimen should be centrifuged (2.700 rpm / 10 min.) as soon as possible after venesection. The platelet poor plasma should be separated into a polystyrene test tube. The separated plasma should be stored at room temperature and tested within 3 hours after blood collection.

PROCEDURE (MANUAL METHOD);EQUIPMENT

1. 13 x 100 mm glass tubes.
2. Constant temperature device (waterbath or heating block)
3. 2 Stopwatches.
4. 0,1 ml precision pipettes
5. 0,025 m Calcium chloride

TEST PROCEDURE

1. Preheat calcium chloride to 37° C
2. Pipette 0.1 ml of reconstituted Coagulen-APTT into the bottom of a 13 x 100 mm glass tube.
3. Add 0.1 ml of test or control plasma to the reagent in the tube and simultaneously start a stopwatch. Mix the contents of the tube gently and incubate at 37° C for exactly 3 minutes.
4. After exactly 3 minutes incubation, add 0.1 ml pre-warmed calcium chloride and at the same time start the second stop watch.
5. Gently tilt the tube back and forth until a gel clot forms. Stop the watch at this time and record the time taken for clot formation in seconds. All determinations should be done in duplicate and results expressed as mean times.

A normal control Coagulen-Norm and an abnormal control Coagulen-Abnorm should be run with each batch of determinations.

Although only the manual method is described, Coagulen-APTT may also be used with automated or semi-automated coagulation instruments utilizing optico-mechanical or optical clot sensing methods. Refer to the directions of the manufacturer of the instrument for exact procedures.

RESULTS

Results of APTT determinations with Coagulen-APTT may be reported in seconds when testing the efficiency of the intrinsic coagulation mechanism or monitoring heparin therapy. The result is evaluated by comparing it to a normal range established for that particular laboratory.

LIMITATIONS OF THE PROCEDURE

Reliable APTT results can be obtained and interpreted correctly only if the test is performed under optimal and constant conditions. External factors that may influence the test, such as the patient's diagnosis and therapy should also be known.

To obtain accurate results

1. Use clean, undamaged glassware.
2. Reconstitute and store reagents according to the manufacturer's directions.
3. Ensure that the test is carried out at 37° C
4. Ensure that the test plasma sample is correctly obtained and stored.
5. Perform the test within the time constraints set by the reagent manufacturer.
6. Perform all tests in duplicate and report mean clotting times.
7. The ability of individuals to detect the formation of a clot varies. It is therefore important that every technologist who performs the test by manual methods establishes his own control times.
8. The use of the Coagulen-Control Plasma range of quality control plasmas in a well designed internal quality assurance program is essential for consistent and reliable results.
9. Haemolyzed, icteric or lipaemic plasmas will usually not interfere with manual procedures, but results should be carefully evaluated when optical density methods are used.

EXPECTED VALUES

Normal Patient APTT 23-40 seconds.

The methods, instrumentation and environment under which this test may be performed vary greatly from laboratory to laboratory. Every laboratory should therefore establish a normal range for its population with fresh citrated plasma samples, and in-house values with normal and abnormal Coagulen-Control Plasma.

REFERENCES

1. Proctor R.R., Rapport SI, Amer. J. Clin. Pathol.; 36: 212-21 (1961).
2. Bell W.N., Alton H.G., Nature, 174: 880 (1954).