coagulation defects is possible. For example, a normal PT and abnormal APTT means that the defect lies in the first stage of the clotting mechanism.

Causes of prolonged APTT

- Hemophilia
- Vitamin K deficiency
- Liver disease
- Presence of circulating anticoagulants
- DIC disease (chronic or acute).

Shortened APTT occurs in:

- Extensive cancer, except when liver is involved
- Immediately after acute hemorrhage
- Very early stages of DIC.

Circulating Anticoagulants

Usually occurs as an inhibitor of a specific factor (e.g. factor VIII). Most commonly seen in the development of anti-factor VIII or anti-factor IX in 5 to 10% of hemophiliacs. Anticoagulants that develop in the treated hemophiliac are detected by prolonged APTT. Circulating anticoagulants also can be detected in some cases:

- Following repeated plasma transfusions
- Drug reactions
- Tuberculosis
- Chronic glomerulonephritis
- Systemic lupus erythematosus
- Rheumatoid arthritis.

NORMAL AND ABNORMAL CONTROL PLASMAS FOR COAGULATION ASSAYS PLASMATROL H-I/II®

(*Courtesy:* Tulip Group of Companies)

Summary

Tulip Plasmatrol H-l and Plasmatrol H-ll are two level human plasma controls that are suitable for use as normal and abnormal control plasma for PT, APTT, TT and fibrinogen testing using clot based methods. Coagulation controls provide a means of day-to-day quality control in the hemostasis laboratory for control of accuracy and precision.

Reagent

Plasmatrol is a stabilized and freeze dried preparation of selected human plasma with values determined and assigned for specific clot based tests, which are lot specific. The plasma controls are assayed using Tulip coagulation reagents.

Reagent Storage and Stability

Unopened vials should be stored at 2–8°C and are stable up to the expiry date mentioned on the vial labels. After reconstitution the shelf life of the control plasma is 3 hours at 25–30°C and 8 hours when stored at 2–8°C.

Principle

The properties of the control plasma are similar to those of pooled fresh plasmas. Since, the plasma controls have assigned values, when substituted in place of a sample, in clot based coagulation assays, they can be used for laboratory quality assurance.

Note

1. In vitro diagnostic reagent for laboratory and professional use only. Not for medicinal use.
2. The source material used for preparation of the reagent is screened by third generation assays for HBsAg, HCV and HIV antibodies and are found to be non-reactive. However, handle the material as if it is infectious, as no known test method can assure that infectious agents are absent.

Preparation of the Reagent

1. Reconstitute the control plasma with exactly 1 mL of bi-distilled water. Avoid using water-containing preservatives.
2. Re-stopper the vial and allow to stand until, the hydration is complete (usually 5–7 minutes).
3. Mix by gently swirling and inversion, avoiding froth formation. Do not shake.
4. Allow to stand and equilibrate for a further 15 minutes before use.
5. Use the reconstituted plasma within 3 hours of reconstitution.

Test Procedure

1. Use the reconstituted Plasmatrol controls in the same manner as freshly prepared titrated platelet poor plasma from a patient.
2. Use the procedure as laid out in the Uniplastin, Liquiplastin®, Liquicelin-E®, Fibroscreen, Fibroquant pack inserts.

Expected Values

1. The expected value of specific assays are provided on the assay value sheet accompanying each kit, and are lot specific.

2. The expected values are obtained using replicate assay of each manufactured lot of Plasmatrol, manually and using mechanical coagulometers such as Hemostar, Hemostar XF.
3. The individual laboratory values should fall within the expected values.
4. It must however be noted that each laboratory should establish its own normal values and reference range according to GLP.

Remarks

1. When used appropriately, Plasmatrol controls are subjected to the limitations of the assay system deployed.
2. If proper values are not obtained it may indicate problems with one or more variables of the assay system.
3. Stability of the reagent is dependent on storage and handling conditions. Since these can vary between laboratories, each laboratory should determine the stability of the reagent under usual operating conditions.
4. Incorrect mixing of control plasma and reagent, insufficient preparation of plasma/reagent, contaminated reagents and glassware, etc. are a potential source of error.
5. Due to interlaboratory variations in techniques, standardization of test procedures and calibration of equipments, some variation from assigned mean values may be expected.

FIBROSCREEN THROMBIN TIME TEST FOR QUALITATIVE ESTIMATION OF FIBRINOGEN FIBROSCREEN®

(*Courtesy:* Tulip Group of Companies)

Summary

At present there are known to be at least eleven factors in circulating blood, which are required for normal hemostasis. Deficiency in any of these factors viz. Factors I, II, V, VII, VIII, IX, X, XI and XIII results in a notable hemorrhagic condition, and the severity of the bleeding is proportional to the degree of deficiency. In order to treat the hemorrhagic condition, it is important to identify and quantify the deficient factor.

Fibroscreen reagent is one such test reagent, which can identify the deficiency of factor I (fibrinogen). The reagent is used as a source of thrombin to determine the qualitative reactivity of fibrinogen.

Reagent

Fibroscreen reagent is a lyophilized preparation of bovine thrombin of 50 NIH/mL. Reconstitute with 1 mL of distilled water; wait for 5 minutes, do not shake and mix gently by swirling till the solution attains homogeneity. Further keep aside for 10 minutes to attain equilibrium. Gently swirl the vial while drawing the reagent for use. Once reconstituted it is ready to use reagent for the thrombin time test.

Storage and Stability

1. Store the unopened reagent vials at 2–8°C. Do not freeze.
2. The shelf-life of the reagent is as per the expiry date mentioned on the reagent vial label and carton label.
3. Once reconstituted the Fibroscreen reagent is stable for 6 days when stored at 2–8°C and for 4 hours at room temperature (20–25°C), provided it is not contaminated. Extreme care has to be taken to maintain aseptic precautions while reconstituting, retrieving and handling reagents to prevent contamination. The Fibroscreen reagent vial must be replaced at 2–8°C immediately upon retrieving the reagent for the day's work.

Principle

When a known quality and concentration of Fibroscreen reagent is added to citrated plasma, by observing the time required for clot formation and the quality of clot formed, a qualitative estimation of fibrinogen in the sample can be obtained.

Note

1. In vitro diagnostic reagent for laboratory and professional use. Not for medicinal use.
2. The reagent contains 0.1% sodium azide as preservative.
3. Fibroscreen thrombin reagent is not from a human source, hence contamination due to HBsAg, HIV and HCV is practically excluded.
4. It is very important that absolutely clean and dry micropipettes be used to aspirate and dispense the reagent.
5. Avoid exposure of the reagent to elevated temperatures, direct light and contamination. Immediately replace cap after use and store at recommended temperature.

Quality Control

A known normal control should be run in parallel with each batch of tests. This control may be Tulip plasma coagulation control Plasmatrol-I or freshly drawn normal plasma.