5. When performing factor assays, more than one vial of reagent may be needed. To eliminate vial-to-vial variation, multiple vials should be reconstituted, allowed to dissolve and pooled.

6. Prepare a new standard curve each time assays are performed. Even thought standard curves are often used, vial-to-vial variation, technique differences and instrument variance require the standard curve to be generated. Helena's Coagulation S.A.R.P. (Cat. No. 5185) is recommended for use as the standard.

STEP-BY-STEP METHOD

A. Specimen and Reagent Preparation

1. Recover the appropriate number of vials of Factor XII Deficient Substrate with 1.0 mL deionized water. Swirl gently and allow to stand approximately 15 minutes at room temperature to ensure complete dissolution. A final concentration of approximately 0.8 mL is required for each specimen assayed.

2. Recover the appropriate number of vials of Coagulation S.A.R.P. with 1.0 mL deionized water. Swirl gently and allow to stand for 10 minutes to ensure complete dissolution. This will be used as the standard.

3. Prepare APTT reagent according to the package insert. Prepare the diluted plasma sample and maintain on ice until tested.

4. Start a stopwatch immediately and incubate the mixture at 37°C. If testing is delayed for more than 2 hours, the plasma may be stored at -20°C or colder. If testing is delayed for more than 2 hours, the plasma may be stored at -20°C. If testing is delayed for more than 2 hours, the plasma may be stored at -20°C.

5. Number a set of four 12 x 75 mm test tubes for the standard curve and each specimen.

B. Standard Curve Preparation

1. Prepare the following dilutions of Coagulation S.A.R.P. with Owen's Veronal Buffer:

<table>
<thead>
<tr>
<th>Dilution</th>
<th>mL</th>
<th>Actual Activity</th>
</tr>
</thead>
<tbody>
<tr>
<td>1</td>
<td>0.1</td>
<td>1.0</td>
</tr>
<tr>
<td>2</td>
<td>0.2</td>
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</tr>
<tr>
<td>3</td>
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</tr>
<tr>
<td>4</td>
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<td>4.0</td>
</tr>
<tr>
<td>5</td>
<td>0.5</td>
<td>5.0</td>
</tr>
</tbody>
</table>

2. Cover tubes and invert gently but thoroughly. Avoid shaking since excess bubble formation causes prolonged results.

3. Perform duplicate determinations. The standard curve and standard and unknown dilutions as follows:

   - Pipette into the reaction in the order specified:
     - 0.1 mL Factor XII Deficient Substrate Plasma
     - 0.1 mL 1:10 dilution of Coagulation S.A.R.P. or test plasma

4. Start a stopwatch immediately and incubate the mixture at 37°C for 2 minutes. Use this mixture to perform APTT assays according to the APTT reagent package insert.

Quality Control

Quality Control for factor assays involves multiple components. Each laboratory should determine an expected range for its particular population and instrument-reagent system. Helena's procedure determines Factor XII activity by using a modification of the activated partial thromboplastin time (APTT) test and a Factor XII deficient substrate plasma.

INTERPRETATION OF RESULTS

Individuals with a deficiency in Factor XII do not suffer from hemorrhagic conditions, but they have a profoundly abnormal clotting time. The Factor XII deficient plasma does not produce an activated partial thromboplastin time (APTT) in the presence of silicone or glass. Two methods are available to determine Factor XII activity: one stage clotting and two stage clotting.

1. The one stage clotting method depends upon having a substrate plasma lacking the factor being measured. A severely deficient plasma (less than 1% activity) has a prolonged activated partial thromboplastin time. The APTT procedure determines Factor XII activity by using a modification of the activated partial thromboplastin time (APTT) test and a Factor XII deficient substrate plasma.

2. The two stage clotting method involves using a normal plasma as a substrate for platelet rich plasma (PRP) clotting. The clot accelerating activity generated in plasma by glass contact is referred to as Activation Product. Coagulation S.A.R.P. as follows: Exposure of normal plasma to glass markedly accelerates the clotting mechanism. The clot accelerating activity generated in plasma by glass contact is referred to as Activation Product. Coagulation S.A.R.P. or test plasma.

3. The Factor XII Expected Values: 50-150% of the normal plasma.

4. Number a set of four 12 x 75 mm test tubes for the standard curve and each specimen.

5. Start a stopwatch immediately and incubate the mixture at 37°C for 2 minutes. Use this mixture to perform APTT assays according to the APTT reagent package insert.

EXPECTED VALUES

Factor XII Expected Values:

<table>
<thead>
<tr>
<th>Factor XII Expected Values</th>
<th>Percentage of Normal</th>
</tr>
</thead>
<tbody>
<tr>
<td>50-150%</td>
<td></td>
</tr>
</tbody>
</table>

BIBLIOGRAPHY


INTENDED USE

The Factor XII Deficient Substrate Plasma is intended for the quantitative determination of Factor XII (Hageman Factor) in patients not having a congenital or acquired deficiency of this coagulation protein.

SUMMARY

Numerous coagulation factors have been identified in the blood, and each factor is a protein component of the plasma or platelet. Abnormalities of more of the factors may result in a notable hemorrhagic condition, the severity of which is governed by the degree of the deficiency. Deficiencies of the blood clotting factors may be congenital or acquired. The congenital deficiencies are, in general, single deficiency states while the acquired deficiencies may be multiple in nature, and commonly associated with liver disease, vitamin K deficiency or anticoagulant therapy. Factor XII deficiency is transmitted as an autosomal recessive or dominant trait. Both sexes are affected equally.

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Deficient Substrate Plasma with 1.0 mL deionized water. Swirl gently and allow to stand approximately 15 minutes at room temperature to ensure complete dissolution. Approximately 0.8 mL is required for each specimen assayed.

3. Dilutions of the test specimen exceeding 1:40 are not recommended since the amount of clotting factor measured, investigation is so small. When less than 2% of the factor is added to a standard substrate, the clotting times become less reproducible and the standard curve will begin to plateau.

EXPECTED VALUES

Factor XIII Deficient Plasma is intended for the quantitative determination of Factor XII (Hageman Factor) in patients with a deficiency or a partially acquired deficiency of this clotting protein.

SUMMARY

Numerous coagulation factors have been identified in the blood, and assay procedures for each of these factors have been developed. More of the factors may result in a notable hemorrhagic condition, the congenital or acquired factor deficiencies. The deficiencies of the blood clotting factors may be congenital or acquired. The congenital deficiencies are, in general, single deficiency states while the acquired deficiencies may be multiple and commonly associated with liver disease, viral disease, Vitamin K deficiencies, or the ingestion of anticoagulant drugs, among others.

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