**APTT ELLAGIC ACID**

### Intended Use

APTT is intended for use in performing the activated partial thromboplastin time (APTT) test, and for APTT-based factor assays using ellagic acid activator.

### Summary and Principles

The contact system is activated by the ellagic acid. The cephalic extracted from bovine brain take effect as substitute for PF3. The clot formation begins with the addition of calcium chloride. APTT determination is sensitive to deficiencies in activities of II, V, VIII, IX, X, XI and XII factors due to hereditary disorders, liver disease, and deficiencies of K vitamin and may drug. Activated Partial Thromboplastin Time is also sensitive to the presence of heparin.

### Reagent

Contact Activator: Ellagic Acid, bovine brain phospholipides, preservative.

For *in vitro* diagnostic use.

Reagents are ready to use. Unopened reagent and control are stable until the expiration date shown on the label when stored at 2-8°C. Shake Activator vigorously before use. Opened reagents are stable 5 days at 2-8°C. Do not freeze.

A yellow sediment may form after prolonged storage. Mix gently before use. Erratic values, quality control values outside established ranges, or product color variations could indicate deterioration. However, poor performance could also be due to other factors within the test system.

### Specimen Collection

3.2% (0.105M) trisodium citrate anticoagulant is recommended for coagulation assays. Avoid hemolysis and contamination by tissue fluids. Samples that have less than 90% of the expected fill volume should be rejected. Centrifuge blood for 15 minutes at 1500 x g. Test within 2 hours if samples are held at 22–24°C. For more details on specimen collection and storage, see NCCLS Document H21-A3.

Do not delay mixing the blood with anticoagulant. Avoid foaming the specimen. Use only plastic or siliconized borosilicate glass containers. Turbid, icteric, lipemic, or hemolyzed specimens may generate erroneous results.

Freezing and thawing plasma that contains residual cells will generate damaged cell membranes that can affect results. Acute inflammatory reactions can shorten APTT results because of elevated fibrinogen.

Plasma samples with hematocrits outside the range of 20–55% may be improperly anticoagulated and should be adjusted appropriately.

### Materials Required, But Not Provided

- M LAB Calcium Chloride solution (0.02M)
- Stopwatch or timer
- Precision pipetter: 0.1 ml.

Normal and abnormal controls such as M LAB Coagulation Control Plasmas, Level 1, 2, and 3 APTT is suitable for use with manual, mechanical, photo-optical, or other means of clot detection. Follow manufacturers recommendations for proper use of instrumentation.

### Test Procedure

For manual assays:

1. Prewarm Calcium Chloride (0.02M) 37°C.
2. Add 0.1 ml test plasma to cuvette and prewarm to 37°C.
3. Add 0.1 mL APTT to the test plasma.
4. Mix. Incubate the plasma-reagent mixture at 37°C for 3-5 minutes (activation time).

For consistent results, test all plasmas with the same activation time. Forcibly add 0.1 ml pre-warmed Calcium chloride and time clot formation.

### Quality Control

Normal and abnormal plasmas such as M LAB Coagulation Control Level 1, 2, and 3 should be tested in conjunction with patient plasmas. Level 1 is normal plasma, and Levels 2 and 3 are adjusted to mimic moderately and severely deficient plasmas, respectively. A normal control and at least one abnormal control should be run at the initiation of testing each day and at least once each shift, or with each group of assays. Controls should also be tested with each reagent change or major instrument adjustment. In laboratories where there is a heavy workload of PTs and/or APTTs, test a normal and an abnormal control at a minimum of every 40 samples. Each laboratory should establish a control range to represent the allowable variation in day to day performance for each control.

### Results

Report clotting times for each plasma to the nearest 0.1 second. A Normal Reference Range can also be reported for comparison. Do not report patient values relative to commercial control plasma clotting times. Controls are intended only for quality assurance of the test system.

### Limitations

The biochemistry of coagulation involves a series of reactions that are influenced by many pre-test conditions. These variables must be controlled to obtain reproducible results.

### Technique

Plasma pH will increase if exposed to air. Store samples stoppered. APTT was designed to work at 37°C ± 0.5°C. Frequently check the temperature of all heating elements. All lab ware must be clean and free of trace amounts of detergents.

Always follow instrument manufacturer’s instructions for proper maintenance.

### Interfering Substances

Icteric and turbid plasmas can influence the APTT. Was detected interference from drugs. Further tests will be needed to determine the cause of unexpected abnormal results.
Expected Values

Every laboratory should be established own reference intervals in relation to own population.

APPT 22 - 30 sec.
APPT (ratio) 0.85 - 1.15

Performance Characteristics

Precision

<table>
<thead>
<tr>
<th></th>
<th>INTRA - ASSAY (sec.)</th>
<th>INTER - ASSAY (sec.)</th>
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</thead>
<tbody>
<tr>
<td>n = 8</td>
<td>Mean</td>
<td>SD</td>
</tr>
<tr>
<td>PTT Low</td>
<td>29.50</td>
<td>0.2204</td>
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<tr>
<td>PTT High</td>
<td>45.62</td>
<td>0.3105</td>
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Each laboratory should establish its own heparin sensitivity curve using the same heparin source used for therapy in that institution. Variations can result from different brands of heparin, tissue origin, and salt forms.

References