Overview

Useful For
Measuring apixaban concentration in selected clinical situations (eg, renal insufficiency, assessment of compliance, periprocedural measurement of drug concentration, suspected overdose, advanced age and extremes of body weight)

Special Instructions
- Coagulation Guidelines for Specimen Handling and Processing

Method Name
Chromogenic Assay

NY State Available
Yes

Specimen

Specimen Type
Plasma Na Cit

Advisory Information
This assay is not indicated for monitoring low-molecular-weight heparin (LMWH) or unfractionated heparin (UFH) concentrations. The presence of UFH and LMWH will cause the apixaban anti-Xa level to be falsely elevated.

Necessary Information
If priority specimen, mark request form, give reason, and request a call-back.

Specimen Required

Specimen Type: Platelet-poor plasma

Collection Container/Tube: Light-blue top (3.2% sodium citrate)

Submission Container/Tube: Plastic vial

Specimen Volume: 1 mL

Collection Instructions:

1. Specimen should be drawn 2 to 4 hours (peak) after a dose or just prior (trough) to the next dose for apixaban concentrations.

2. For complete instructions, see Coagulation Guidelines for Specimen Handling and Processing in Special Instructions.

3. Centrifuge, transfer all plasma into a plastic vial, and centrifuge plasma again.

4. Aliquot plasma into a plastic vial leaving 0.25 mL in the bottom of centrifuged vial.
5. Freeze plasma immediately (no longer than 4 hours after collection) at -20 degrees C or, ideally, < or =-40 degrees C.

Additional Information:

1. A double-centrifuged specimen is critical for accurate results as platelet contamination may cause spurious results.

2. Each coagulation assay requested should have its own vial.

Forms

If not ordering electronically, complete, print, and send a Coagulation Test Request (T753) with the specimen.

Specimen Minimum Volume

0.5 mL

Reject Due To

All specimens will be evaluated at Mayo Clinic Laboratories for test suitability.

Specimen Stability Information

<table>
<thead>
<tr>
<th>Specimen Type</th>
<th>Temperature</th>
<th>Time</th>
<th>Special Container</th>
</tr>
</thead>
<tbody>
<tr>
<td>Plasma Na Cit</td>
<td>Frozen</td>
<td>42 days</td>
<td></td>
</tr>
</tbody>
</table>

Clinical and Interpretive

Clinical Information

Apixaban, an oral anticoagulant that directly inhibits factor Xa, has been approved by the FDA for prophylaxis of thrombosis in atrial fibrillation and surgical patients and treatment of venous thromboembolism (VTE). Unlike warfarin, it does not require routine therapeutic monitoring. However, in selected clinical situations, measurement of drug level would be useful (eg, renal insufficiency, assessment of compliance, periprocedural measurement of drug concentration, suspected overdose, advanced age, and extremes of body weight).

Predicted Apixaban Steady-state Exposure Concentrations(1)

<table>
<thead>
<tr>
<th>Prevention of VTE: elective hip or knee replacement surgery</th>
<th>Apixaban C-min (ng/mL)</th>
<th>Apixaban C-max (ng/mL)</th>
</tr>
</thead>
<tbody>
<tr>
<td>2.5 mg twice daily</td>
<td>51 (23-109)</td>
<td>77 (41-146)</td>
</tr>
</tbody>
</table>
## Test Definition: APIXA
Apixaban, Anti-Xa, P

<table>
<thead>
<tr>
<th>Prevention of stroke and systemic embolism: NVAF</th>
<th></th>
</tr>
</thead>
<tbody>
<tr>
<td>2.5 mg twice daily</td>
<td>79 (34-162)</td>
</tr>
<tr>
<td>5 mg twice daily</td>
<td>103 (41-230)</td>
</tr>
</tbody>
</table>

<table>
<thead>
<tr>
<th>Treatment of DVT, treatment of PE and prevention of recurrent DVT and PE (VTEt)</th>
<th></th>
</tr>
</thead>
<tbody>
<tr>
<td>2.5 mg twice daily</td>
<td>32 (11-90)</td>
</tr>
<tr>
<td>5 mg twice daily</td>
<td>63 (22-77)</td>
</tr>
<tr>
<td>10 mg twice daily</td>
<td>120 (41-335)</td>
</tr>
</tbody>
</table>

Median (5th-95th percentile)

VTE-venous thromboembolism, NVAF- nonvalvular atrial fibrillation, DVT-deep vein thrombosis, PE-pulmonary embolism

### Reference Values

<10 ng/mL

### Interpretation

The lower limit of detection of this assay is 10 ng/mL.

Therapeutic reference ranges have not been established. See Clinical Information section for peak and trough drug concentrations observed from clinical trials.

### Cautions

Routine monitoring of apixaban is not indicated. Therapeutic reference ranges have not been established, however, peak and trough levels observed in clinical trials at different dosing are available. Apixaban concentration may be affected by drug interactions and liver or renal disease.

Apixaban levels measured within 2 to 4 hours after administration of andexanet may by falsely elevated with this assay.

### Clinical Reference


**Performance**

**Method Description**

The apixaban, anti-Xa assay is performed on the Instrumentation Laboratory ACL TOP 700 using the HemosIL Liquid Anti-Xa kit. The liquid Anti-Xa kit is a 1-stage chromogenic assay based on a synthetic chromogenic substrate and on factor Xa inactivation. Factor Xa is neutralized directly by apixaban. Residual factor Xa is quantified with a synthetic chromogenic substrate. The paranitroaniline released is monitored kinetically at 405 nm and is inversely proportional to the apixaban in the sample.(Package insert: HemosIL Liquid Anti-Xa kit. Instrumentation Laboratory Company, rev. 11/2011)

**PDF Report**

No

**Day(s) and Time(s) Test Performed**

Monday through Friday

**Analytic Time**

1 day

**Maximum Laboratory Time**

3 days

**Specimen Retention Time**

7 days

**Performing Laboratory Location**

Rochester

**Fees and Codes**

**Fees**

- Authorized users can sign in to **Test Prices** for detailed fee information.
- Clients without access to Test Prices can contact **Customer Service** 24 hours a day, seven days a week.
- Prospective clients should contact their Regional Manager. For assistance, contact **Customer Service**.

**Test Classification**

This test has been modified from the manufacturer’s instructions. Its performance characteristics were determined by Mayo Clinic in a manner consistent with CLIA requirements. This test has not been cleared or approved by the U.S. Food and Drug Administration.

**CPT Code Information**
## LOINC® Information

<table>
<thead>
<tr>
<th>Test ID</th>
<th>Test Order Name</th>
<th>Order LOINC Value</th>
</tr>
</thead>
<tbody>
<tr>
<td>APIXA</td>
<td>Apixaban, Anti-Xa, P</td>
<td>74214-8</td>
</tr>
</tbody>
</table>

<table>
<thead>
<tr>
<th>Result ID</th>
<th>Test Result Name</th>
<th>Result LOINC Value</th>
</tr>
</thead>
<tbody>
<tr>
<td>APIX1</td>
<td>Apixaban, Anti-Xa, P</td>
<td>74214-8</td>
</tr>
<tr>
<td>APIX2</td>
<td>Interpretation</td>
<td>69049-5</td>
</tr>
<tr>
<td>APIX3</td>
<td>Cautions</td>
<td>62364-5</td>
</tr>
</tbody>
</table>