Overview

Useful For
Excluding the diagnosis of acute pulmonary embolism or deep vein thrombosis, particularly when results of a sensitive D-dimer assay are combined with clinical information, including pretest disease probability(1-4)

Diagnosis of intravascular coagulation and fibrinolysis, also known as disseminated intravascular coagulation, especially when combined with clinical information and other laboratory test data (eg, platelet count, assays of clottable fibrinogen and soluble fibrin monomer complex, and clotting time assays-prothrombin time and activated partial thromboplastin time)(5)

Method Name
Immunoassay Turbidimetric

NY State Available
Yes

Specimen

Specimen Type
Plasma Na Cit

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. Centrifuge, remove plasma, and centrifuge plasma again.
2. Aliquot plasma into plastic vial leaving 0.25 mL in the bottom of centrifuged vial.

Additional Information: Double-centrifuged specimen is critical for accurate results as platelet contamination may cause spurious results.

Specimen Minimum Volume
0.5 mL

Reject Due To

<p>| | |</p>
<table>
<thead>
<tr>
<th></th>
<th></th>
</tr>
</thead>
<tbody>
<tr>
<td>Gross hemolysis</td>
<td>Reject</td>
</tr>
<tr>
<td>Gross lipemia</td>
<td>OK</td>
</tr>
<tr>
<td>Gross icterus</td>
<td>OK</td>
</tr>
</tbody>
</table>
**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 (preferred)</td>
<td>90 days</td>
<td></td>
</tr>
<tr>
<td></td>
<td>Ambient</td>
<td>4 hours</td>
<td></td>
</tr>
</tbody>
</table>

**Clinical Information**

The specific degradation of fibrin (ie, fibrinolysis) is the reactive mechanism responding to the formation of fibrin. Plasmin is the fibrinolytic enzyme derived from inactive plasminogen. Plasminogen is converted into plasmin by plasminogen activators. The main plasminogen activators are tissue plasminogen activator (tPA) and pro-urokinase, which is activated into urokinase (UK) by, among others, the contact system of coagulation.

In the bloodstream, plasmin is rapidly and specifically neutralized by alpha-2-antiplasmin, thereby restricting its fibrinogenolytic activity and localizes the fibrinolysis on the fibrin clot. On the fibrin clot, plasmin degrades fibrin into various products (ie, D-dimers). Antibodies specific for these products, which do not recognize fibrinogen, have been developed. The presence of these various fibrin degradation products, among which D-dimer is the terminal product, is the proof that the fibrinolytic system is in action in response to coagulation activation.

Elevated D-dimer levels are found in association with disseminated intravascular coagulation (DIC), pulmonary embolism (PE), deep vein thrombosis (DVT), trauma, and bleeding. D-dimer may also be increased in association with pregnancy, liver disease, malignancy, inflammation, or a chronic hypercoagulable state.

**Reference Values**

< or = 500 ng/mL Fibrinogen Equivalent Units (FEU)

D-dimer values < or = 500 ng/mL FEU may be used in conjunction with clinical pretest probability to exclude deep vein thrombosis (DVT) and pulmonary embolism (PE).

**Interpretation**

A normal D-dimer result of 500 ng/mL or less fibrinogen equivalent units (FEU) on the IL D-Dimer HS500 kit has a negative predictive value of approximately 100% (range 97%-100%) and is FDA approved for the exclusion of acute pulmonary embolism (PE) and deep vein thrombosis (DVT) when there is low or moderate pretest probability for PE or DVT.

D-dimer concentrations increase with age and, thus, the specificity for DVT and PE exclusion decreases with age. For DVT or PE exclusion, in addition to clinical pretest probability, age-adjusted D-dimer cutoffs are suggested for patients older than 50 years of age.

Recent evidence suggests using clinical pretest probability and age-adjusted cutoffs to improve the performance of D-dimer testing in patients older than 50 years of age. In recent studies, when compared to a fixed D-dimer cutoff, age-adjusted D-dimer cutoff values (calculated as follows: age [years] x 10 ng/mL) resulted in equivalent outcomes and no additional false negative findings.(6-7)

Increased D-dimer values are abnormal but do not indicate a specific disease state. D-dimer values may be increased as a result of:
Test Definition: DDITT

D-Dimer, P

- Clinical or subclinical disseminated intravascular coagulation/intravascular coagulation and fibrinolysis
- Other conditions associated with increased activation of the procoagulant and fibrinolytic mechanisms such as recent surgery, active or recent bleeding, hematomas, trauma, or thromboembolism
- Association with pregnancy, liver disease, inflammation, malignancy, or hypercoagulable (procoagulant) states

The degree of D-dimer increase does not definitely correlate with the clinical severity of associated disease states.

Cautions

D-dimer results on the ACL TOP coagulation analyzer are not affected by rheumatoid factor up to 1400 IU/mL.

The monoclonal antibody (MA-8D3) used in the latex reagent has major specificity for the D-dimer domain of cross-linked fibrin degradation products (FDP). A low cross-reactivity to FDP was seen with plasma samples spiked with purified fragments D and E above 10 mcg/mL.

Specimens from patients who have received preparation of mouse monoclonal antibody for diagnosis or therapy may contain human antimouse antibody (HAMA). The presence of HAMA may cause an overestimation of results in immunoassays that utilize mouse monoclonal antibodies. The reaction buffer contains a blocking agent against HAMA to minimize this interference on the assay results.

Clinical Reference


Performance

Method Description

HemosIL D-Dimer HS 500 kit on the ACL TOP is a latex enhanced turbidimetric immunoassay.
Test Definition: DDITT
D-Dimer, P

HemosIL D-Dimer HS 500. Instrumentation Laboratory Company, Bedford, MA, 04/2018)

PDF Report
No

Day(s) and Time(s) Test Performed
Monday through Sunday; Continuously

Analytic Time
Same day/1 day

Maximum Laboratory Time
1 day

Specimen Retention Time
1 day

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 cleared or approved by the U.S. Food and Drug Administration and is used per manufacturer's instructions. Performance characteristics were verified by Mayo Clinic in a manner consistent with CLIA requirements.

CPT Code Information
85379

LOINC® Information

<table>
<thead>
<tr>
<th>Test ID</th>
<th>Test Order Name</th>
<th>Order LOINC Value</th>
</tr>
</thead>
<tbody>
<tr>
<td>DDITT</td>
<td>D-Dimer, P</td>
<td>48067-3</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>DDITT</td>
<td>D-Dimer, P</td>
<td>48067-3</td>
</tr>
</tbody>
</table>