Test Definition: DDITT

D-Dimer, Plasma

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

Turbidimetric Immunoassay

NY State Available

Yes

Specimen

Specimen Type

Plasma Na Cit

Specimen Required

Specimen Type: Platelet-poor plasma
Supplies: Sarstedt Aliquot Tube, 5 mL (T914)
Collection Container/Tube: Light-blue top (3.2% sodium citrate)
Submission Container/Tube: Plastic vial
Specimen Volume: 1 mL plasma
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

Plasma: 0.5 mL

Reject Due To

Gross hemolysis	Reject

Gross lipemia	OK
Gross icterus	OK

Specimen Stability Information

Specimen Type	Temperature	Time	Special Container
Plasma Na Cit	Frozen (preferred)	90 days	
	Ambient	4 hours	

Clinical & Interpretive

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, pulmonary embolism, deep vein thrombosis, 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 US Food and Drug Administration 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, therefore, 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.

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. 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:
-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

1. Brill-Edward P, Lee A. D-dimer testing in the diagnosis of acute venous thromboembolism. Thromb Haemost. 1999;82(2):688-694
2. Heit JA, Minor TA, Andrews JC, Larson DR, Li H, Nichols WL. Determinants of plasma fibrin D-dimer sensitivity for acute pulmonary embolism as defined by pulmonary angiography. Arch Pathol Lab Med. 1999;123(3):235-240. doi:10.1043/0003-9985(1999)123
3. Heit JA, Meyers BJ, Plumhoff EA, Larson DR, Nichols WL. Operating characteristics of automated latex immunoassay tests in the diagnosis of angiographically-defined acute pulmonary embolism. Thromb Haemost. 2000;83(6):970
4. Bates SM, Grand'Maison A, Johnston M, Naguit I, Kovacs MJ, Ginsberg JS. A latex D-dimer reliably excludes venous thromboembolism. Arch Intern Med. 2001;161(3):447-453. doi:10.1001/archinte.161.3.447
5. Levi M, Ten Cate H. Disseminated intravascular coagulation. N Engl J Med. 1999;341(8):586-592. doi:10.1056/NEJM199908193410807
6. Righini M, Van Es J, Den Exter PL, et al. Age-adjusted D-dimer cutoff levels to rule out pulmonary embolism: the ADJUST-PE study. JAMA. 2014;311(11):1117-1124. doi:10.1001/jama.2014.2135
7. Schouten HJ, Geersing GJ, Koek HL, et al. Diagnostic accuracy of conventional or age adjusted D-dimer cut-off values in older patients with suspected venous thromboembolism: systematic review and meta-analysis. BMJ. 2013;346:f2492. doi:10.1136/bmj.f2492
8. Feinstein DI, Marder VJ, Colman RW. Consumptive thrombohemorrhagic disorders. In: Colman RW, Hirsh J, Marder VJ, et al. eds. Hemostasis and Thrombosis: Basic Principles and Clinical Practice. 3rd ed. JB Lippincott Co.; 2001;1197-1234

Performance

Method Description

The principle of immunological measurement is used on the ACL TOP to directly measure and record the amount of an analyte. This technique assesses the physical concentration of the analyte (and not its activity) by measuring change in optical density. Although similar to the turbidimetric method, the immunological method relies on the formation of antigen-antibody complexes to affect light transmission.

Immunological testing of the D-dimer on ACL TOP is at 671-nm wavelength and uses the principle of measuring absorbance in the cuvette. An optical sensor reads the light that passes through the cuvette. The light is absorbed by the fluid in the cuvette in direct proportion to the concentration of antigen-antibody complexes. The amount of light reaching the photodetector is converted into an electrical signal that is proportional or inversely proportional to the analyte concentration.

When a plasma containing D-dimer is mixed with the latex reagent and the reaction buffer included in the HemosIL D-Dimer HS 500 kit, the coated latex particles agglutinate. The degree of agglutination is directly proportional to the concentration of D-dimer in the sample and is determined by measuring the decrease of transmitted light caused by the aggregates (turbidimetric immunoassay). (Package insert: HemosIL D-Dimer HS 500. Instrumentation Laboratory Company; 04/2018)

PDF Report

No

Day(s) Performed

Monday through Sunday

Report Available

Same day/1 day

Specimen Retention Time

1 day

Performing Laboratory Location

Mayo Clinic Laboratories - Rochester Main Campus

Fees & 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 account representative. For assistance, contact Customer Service.

Test Classification

Test Definition: DDITT

D-Dimer, Plasma

This test has been cleared, approved, or is exempt by the US 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

Test ID	Test Order Name	Order LOINC® Value
DDITT	D-Dimer, P	48067-3

Result ID	Test Result Name	Result LOINC® Value
DDITT	D-Dimer, P	48067-3