Alere™

Pulmonary embolism?

A rapid disposition can be a matter of life or death.

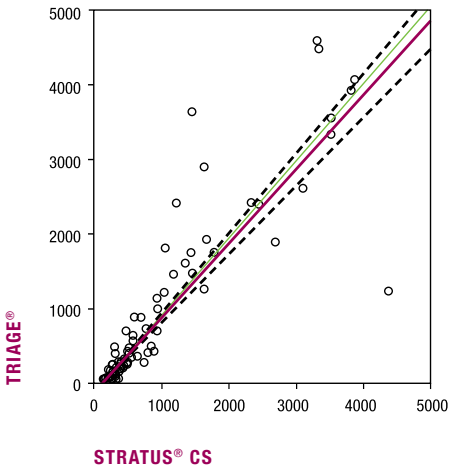
Not all D-dimer tests are created equal.

Learn more

- D-dimer assays are known to have varying sensitivities.[8,9,10]
- ELISA and FIA assays have high sensitivity in patients with suspected PE (pulmonary embolism) and DVT (deep vein thrombosis) and are distinguishable from latex agglutination assays due to the presence of capture and detection antibodies which yield higher sensitivity.[9]
- Latex agglutination assays can be highly subjective and have been shown to have 80% sensitivity versus sandwich immunoassays (ELISA and FIA) which demonstrate nearly 100% sensitivity.[10]

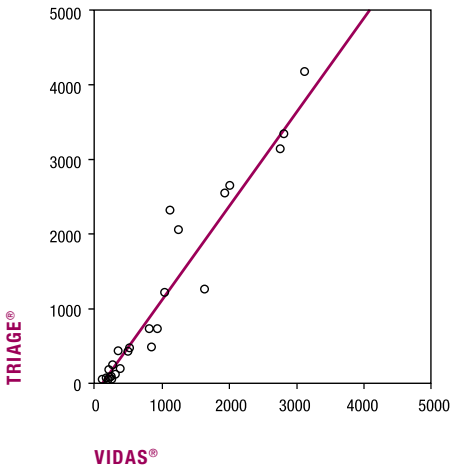
The Alere Triage® D-Dimer Test employs a fluorescence immunoassay technology (FIA).[3]

Alere Triage® D-Dimer Test vs. Stratus CS[3]



Slope	Intercept ng/mL	Correlation Coefficient
0.999	-85.89	r = 0.92

Alere Triage® D-Dimer Test vs. VIDAS[11]



Slope	Intercept ng/mL	Correlation Coefficient
1.330	-204.36	r = 0.962

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Speed and sensitivity can mean life or death.

You need to know quickly whether you are dealing with a **PE** or a **DVT**. **Over 10% of patients who develop a pulmonary embolism die within the first hour.**[1] Often these symptoms are nonspecific and similar to other diagnoses.

> *"Knowledge of the D-dimer test influences the physician in how the clinical probability for PE is scored. This will have direct clinical consequences, such as unnecessary imaging testing or inappropriate exclusion of the diagnosis. Physicians should therefore make sure that they examine the patient before they take notice of the D-dimer test result."*[2]

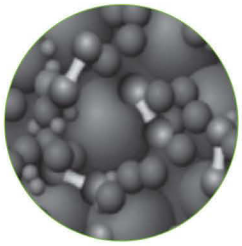
Alere Triage® D-Dimer Test. A rapid, quantitative immunoassay.

- Performed on the Alere Triage® MeterPro
- Results in approximately 20 minutes[3]
- Uses highly sensitive fluorescence immunoassay technology[3]
- Utilizes the preferred and specific 3B6 D-dimer antibody[3]

A whole blood rapid D-dimer test has been shown to be associated with a shorter emergency department (ED) length of stay (LOS) and fewer hospital admissions.[4] Another recent study demonstrated that the most cost-effective diagnostic strategy in the ED for a suspected thromboembolic event is a D-dimer test.[5]

Over 60% of U.S. hospitals use an Alere Triage® product.[6,7]

The right test and the right antibody.



- Antibody specificity plays a significant role in distinguishing D-dimer from other fibrin degradation products (FDPs).[5]
- The Alere Triage® D-Dimer Test utilizes the 3B6 monoclonal antibody which is highly specific to cross-linked D-dimer.[6]

The 3B6 antibody used in the Alere Triage® D-Dimer assay detects only cross-linked FDPs for accurate measurement of the sample.

Intended Use.

- The Alere Triage® D-Dimer Test is a fluorescence immunoassay to be used with the Alere Triage® Meters for the quantitative determination of cross-linked fibrin degradation products containing D-dimer in EDTA whole blood and plasma specimens.[3]
- The Alere Triage® D-Dimer Test is used as an aid in the assessment and evaluation of patients suspected of having disseminated intravascular coagulation (DIC).[3]
- The Alere Triage® D-Dimer Test is used as an aide in the assessment and evaluation of thromboembolic events including pulmonary embolism.[3]

Expected values.

- The expected values were calculated non-parametrically and represent the 95th percentile of the population tested. The expected values from 208 apparently healthy individuals are less than 600 ng/mL. The 90th percentile of measurements is less than 400 ng/mL. Each laboratory should establish a reference range which is representative of the patient population to be evaluated.[3]

Wells Clinical Prediction Rule for Deep Vein Thrombosis

Clinical feature	Points
Active cancer (treatment within 6 months, or palliation)	1
Paralysis, paresis, or immobilization of lower extremity	1
Bedridden for more than 3 days because of surgery (within 12 weeks)	1
Localized tenderness along distribution of deep veins	1
Entire leg swollen	1
Unilateral calf swelling of greater than 3 cm (below tibial tuberosity)	1
Unilateral pitting edema	1
Collateral superficial veins	1
Previously documented DVT	1
Alternative diagnosis as likely as or more likely than DVT	-2
Total Points	

DVT = deep vein thrombosis

Risk score interpretation (probability of DVT):

- >/= 3 points: high risk (75%)
- 1 to 2 points: moderate risk (17%)
- < 1 point: low risk (3%)

Wells PS, Anderson DR, Rodger M, et al. Derivation of a simple clinical model to categorize patients probability of pulmonary embolism: increasing the models utility with the SimpliRED D-dimer. *Thromb Haemost.* 2000;83(3):416-420.

Wells Clinical Prediction Rule for Pulmonary Embolism

Clinical feature	Points
Clinical symptoms of DVT	3
Other diagnosis less likely than PE	3
Heart rate greater than 100 beats per minute	1.5
Immobilization or surgery within past 4 weeks	1.5
Previous DVT or PE	1.5
Hemoptysis	1
Malignancy	1
Total Points	

PE = pulmonary embolism

DVT = deep vein thrombosis

Risk score interpretation (probability of PE):

- > 6 points: high risk (78.4%)
- 2 to 6 points: moderate risk (27.8%)
- < 2 points: low risk (3.4%)

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References

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4. Lee-Lewandrowski E, Nichols J, Van Cott E, et al. Implementation of a rapid whole blood D-dimer test in the emergency department of an urban academic medical center: impact on ED length of stay and ancillary test utilization. *Am J Clin Pathol.* 2009;132(3):326-331.

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10. Michiels JJ, Gadisseur A, van der Planken M, et al. Different accuracies of rapid enzyme-linked immunosorbent, turbidimetric, and agglutination D-dimer assays for thrombosis exclusion: impact on diagnostic work-ups of outpatients with suspected deep vein thrombosis and pulmonary embolism. *Semin Thromb Hemost.* 2006;32(7):678-693.

11. Lee-Lewandrowski E, Van Cott EM. Evaluation of the Biosite Triage® quantitative whole blood D-dimer assay and comparison with the bioMerieux VIDAS® D-dimer exclusion test: validation and utility for use in the central laboratory and at the point of care. *Point of Care.* 2005;4(3):133-137.

To learn more about Alere Triage® Solutions,
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