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

To learn more about Alere Triage® Solutions, visit alere.com

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. 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 minutes3
- Uses highly sensitive fluorescence immunoassay technology3
- Utilizes the preferred and specific 3B6 D-dimer antibody3

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

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%)

Wells Clinical Prediction Rule for Pulmonary Embolism

Clinical feature

<table>
<thead>
<tr>
<th>Points</th>
</tr>
</thead>
<tbody>
<tr>
<td>D-dimer $&lt;1.5$</td>
</tr>
<tr>
<td>D-dimer $&gt;1.5$</td>
</tr>
<tr>
<td>Heart rate $&gt;100$</td>
</tr>
<tr>
<td>Immobilisation or surgery within past 3 weeks</td>
</tr>
<tr>
<td>Respiratory symptoms</td>
</tr>
<tr>
<td>Hypoxia</td>
</tr>
<tr>
<td>Malignancy</td>
</tr>
</tbody>
</table>

Total Points

PE = pulmonary embolism

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Antibody specificity plays a significant role in distinguishing D-dimer from other fibrin degradation products (FDPs). The Alere Triage D-Dimer Test utilizes the 3B6 monoclonal antibody which is highly specific to cross-linked D-dimer. The 3B6 antibody detects only cross-linked FDPs for accurate measurement of the sample.

D-dimer assays are known to have varying sensitivities.1,2,3 ELISA and FA 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 detect antibodies which yield higher sensitivity.4

Latex agglutination assays can be highly subjective and have been shown to demonstrate nearly 100% sensitivity.5

The Alere Triage D-Dimer Test demonstrates nearly 100% sensitivity.6

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

The 3B6 antibody 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 Meter for the qualitative determination of cross-linked fibrin degradation products containing D-dimer in EDTA whole blood and plasma specimens.

The Alere Triage D-Dimer Test is an aid in the assessment and evaluation of patients suspected of having disseminated intravascular coagulation (DIC). The Alere Triage D-Dimer Test is used as an aide in the assessment and evaluation of thromboembolic events including pulmonary embolism.

**Expected values.**

The expected values were calculated non-parametrically and represent the 90th percentile of the population tested. The expected values from 208 apparently healthy individuals are less than 600 ng/mL. The 90th percentile of measurements of patients suspected of having disseminated intravascular coagulation (DIC) is less than 400 ng/mL. Each laboratory should establish a reference range for their testing population.

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

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

- 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).

- The Alere Triage® D-Dimer Test is used as an aide in the assessment and evaluation of thromboembolic events including pulmonary embolism.

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.
Not all D-dimer tests are created equal.

The right test and the right antibody

Antibody specificity plays a significant role in distinguishing D-dimer from other fibrin degradation products (FDPs). The Alere Triage® D-Dimer Test employs a fluorescence immunoassay technology (FIA) which is highly specific to cross-linked D-dimer. The 3B6 antibody used in the Alere Triage® D-Dimer assay detects only cross-linked D-dimer, which is highly specific to cross-linked FDPs.

Intended Use.

The Alere Triage® D-Dimer Test is a fluorescence immunoassay to be used with the Alere Triage® Meter for the qualitative determination of cross-linked fibrin degradation products containing D-dimer in whole blood samples.

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).

The Alere Triage® D-Dimer Test is used as an aid in the assessment and evaluation of thromboembolic events including pulmonary embolism.

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 independent of race, age, gender, and test methodology.
- The 3B6 antibody used in the Alere Triage® D-Dimer test detects only cross-linked D-dimer, which is highly specific to cross-linked FDPs.

References


Wells Clinical Prediction Rule for Deep Venous Thrombosis

<table>
<thead>
<tr>
<th>Clinical Feature</th>
<th>Points</th>
</tr>
</thead>
<tbody>
<tr>
<td>Age &gt; 60 years</td>
<td>1</td>
</tr>
<tr>
<td>Previous venous thromboembolism</td>
<td>1</td>
</tr>
<tr>
<td>Pregnancy, recent or anticipated in 3 mo</td>
<td>1</td>
</tr>
<tr>
<td>Index leg swelling</td>
<td>1</td>
</tr>
<tr>
<td>Unilateral calf swelling of greater than 3 cm (below tibial tuberosity)</td>
<td>1</td>
</tr>
<tr>
<td>Entire leg swollen</td>
<td>1</td>
</tr>
<tr>
<td>Unilateral pitting edema (below tibial tuberosity)</td>
<td>1</td>
</tr>
<tr>
<td>Thromboembolic symptoms (e.g., localized tenderness along distribution of deep veins)</td>
<td>1</td>
</tr>
<tr>
<td>Paralysis, paresis, or immobilization of lower extremity</td>
<td>1</td>
</tr>
<tr>
<td>Active cancer (treatment within 6 months, or palliation)</td>
<td>1</td>
</tr>
<tr>
<td>Cancer therapy (within 12 weeks)</td>
<td>1</td>
</tr>
<tr>
<td>Bedridden for more than 3 days because of surgery</td>
<td>1</td>
</tr>
<tr>
<td>Current smoking</td>
<td>1</td>
</tr>
<tr>
<td>History of previous DVT</td>
<td>1</td>
</tr>
<tr>
<td>History of stroke, TIA, or myocardial infarction</td>
<td>1</td>
</tr>
<tr>
<td>Previous PE</td>
<td>1</td>
</tr>
<tr>
<td>Chronic obstructive pulmonary disease</td>
<td>1</td>
</tr>
<tr>
<td>History of diabetes</td>
<td>1</td>
</tr>
<tr>
<td>Anti-coagulated on admission</td>
<td>1</td>
</tr>
</tbody>
</table>

Total Points

Risk score interpretation (probability of DVT):< 1 point: low risk (3%)1 to 2 points: moderate risk (17%)3 to 4 points: high risk (75%)
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Risk score interpretation (probability of PE):

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Wells Clinical Prediction Rule for Pulmonary Embolism

<table>
<thead>
<tr>
<th>Clinical feature</th>
<th>Points</th>
</tr>
</thead>
<tbody>
<tr>
<td>Distancing/limping of leg</td>
<td>3</td>
</tr>
<tr>
<td>Clammy skin</td>
<td>2</td>
</tr>
<tr>
<td>Heart rate &gt; 100 beats per minute</td>
<td>1.5</td>
</tr>
<tr>
<td>Immobilization or surgery within past 3 weeks</td>
<td>1.5</td>
</tr>
<tr>
<td>Abnormal LFT tests</td>
<td>1</td>
</tr>
<tr>
<td>Hypertension</td>
<td>1</td>
</tr>
<tr>
<td>Malignancy</td>
<td>1</td>
</tr>
<tr>
<td>Total Points</td>
<td>12</td>
</tr>
</tbody>
</table>

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<tr>
<th>Clinical feature</th>
<th>Points</th>
</tr>
</thead>
<tbody>
<tr>
<td>Clinical symptoms or DVT</td>
<td>3</td>
</tr>
<tr>
<td>DVT diagnosis less than 48 hours</td>
<td>3</td>
</tr>
<tr>
<td>Heart rate greater than 100 beats per minute</td>
<td>1.5</td>
</tr>
<tr>
<td>Infection or surgery within past 4 weeks</td>
<td>1.5</td>
</tr>
<tr>
<td>Recent or ongoing bleeding</td>
<td>1</td>
</tr>
<tr>
<td>Immobilization</td>
<td>1</td>
</tr>
<tr>
<td>Malignancy</td>
<td>1</td>
</tr>
<tr>
<td>Total Points</td>
<td></td>
</tr>
</tbody>
</table>

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