Clearview Simplify D-dimer

A rapid test to aid the safe rule-out of venous thromboembolism.*

Clearview

Clearly different. Clearly better.

www.clearview.com

*Clearview Simplify D-dimer, combined with a validated pre-test probability score, helps to risk-stratify patients suspected of VTE.1,2,3
Flexible, Fast and Easy to Use

- Uses whole blood (venous or finger-prick) or plasma.
- Two easy steps, built-in procedural control and results within 10 minutes.
- Room temperature storage.
- Suitable for use in the Emergency Department, Doctors Office or Laboratory.

Cost Effective

- In combination with a pre-test probability (PTP) score, Clearview Simplify D-dimer can safely rule-out VTE in low risk patients.\(^1,2,3\)
- Reduces the number of unnecessary diagnostic imaging procedures.

The Wells pre-test probability (PTP) scoring system for DVT (2).
A score of < 2 categorises the patient as unlikely to have DVT, and ≥ 2 as likely to have DVT.

<table>
<thead>
<tr>
<th>CLINICAL CHARACTERISTIC</th>
<th>SCORE</th>
</tr>
</thead>
<tbody>
<tr>
<td>Active cancer (treatment ongoing or within previous 6 months or palliative)</td>
<td>1</td>
</tr>
<tr>
<td>Paralysis, paresis, or recent plaster immobilisation of the lower extremes</td>
<td>1</td>
</tr>
<tr>
<td>Recently bedridden 3 days or more, or major surgery within the previous 12 weeks</td>
<td>1</td>
</tr>
<tr>
<td>requiring general or regional anaesthesia</td>
<td></td>
</tr>
<tr>
<td>Localised tenderness along the distribution of the deep venous system</td>
<td>1</td>
</tr>
<tr>
<td>Entire leg swollen</td>
<td>1</td>
</tr>
<tr>
<td>Calf swelling at least 3cm greater than asymptomatic side (measured 10cm below tibial tuberosity)</td>
<td>1</td>
</tr>
<tr>
<td>Pitting edema confined to the symptomatic leg</td>
<td>1</td>
</tr>
<tr>
<td>Collateral superficial veins (non-varicose)</td>
<td>1</td>
</tr>
<tr>
<td>Previously documented deep-vein thrombosis</td>
<td>1</td>
</tr>
<tr>
<td>Alternative diagnosis as likely or greater than that of DVT</td>
<td>-2</td>
</tr>
</tbody>
</table>

An example of use of PTP scoring and D-dimer testing in the diagnosis of DVT. Similar protocols exist for PE.\(^1,2,3\)
US = Bi-lateral leg vein ultrasonography. LMWH = Low molecular weight heparin.

WELLS DVT ALGORITHM - CLINICAL PROBABILITY ASSESSMENT

**DVT UNLIKELY (SCORE <2)**

- **D-DIMER (USE LMWH AFTER HOURS)**
  - **US**
    - **DISCHARGE - NO DVT**
      - **TREAT**

**DVT LIKELY (SCORE ≥2)**

- **D-DIMER (USE LMWH AFTER HOURS)**
  - **US**
    - **TREAT**
      - **SERIAL US**
        - **NO DVT - FOLLOW UP**
Clearview Simplify D-dimer is highly specific for D-dimer and does not cross-react with other fibrin degradation molecules. The high specificity for D-dimer aids the safe exclusion of patients with suspected VTE.

### Clearview Simplify D-dimer 100% sensitive in a 527 Outpatient Study with Symptomatic PE

<table>
<thead>
<tr>
<th>Assay</th>
<th>Sensitivity</th>
<th>Specificity</th>
<th>NPV</th>
</tr>
</thead>
<tbody>
<tr>
<td>Clearview Simplify D-dimer</td>
<td>100% (92.5%-100%)</td>
<td>47.9% (43.3%-52.6%)</td>
<td>100% (98.4%-100%)</td>
</tr>
<tr>
<td>bioMerieux Vidas D-dimer new</td>
<td>100% (92.5%-100%)</td>
<td>48.8% (44.1%-53.4%)</td>
<td>100% (98.4%-100%)</td>
</tr>
<tr>
<td>Diagnostica Stago STA Liatest D-DI</td>
<td>100% (92.5%-100%)</td>
<td>47.5% (42.7%-52.3%)</td>
<td>100% (98.2%-100%)</td>
</tr>
</tbody>
</table>

* = 95% Confidence Interval

### Clearview Simplify D-dimer 100% sensitive in a 120 Outpatient Study with Suspected DVT

<table>
<thead>
<tr>
<th>Assay</th>
<th>Sensitivity</th>
<th>Specificity</th>
<th>NPV</th>
</tr>
</thead>
<tbody>
<tr>
<td>Clearview Simplify D-dimer</td>
<td>100% (90.0%-100%)</td>
<td>52.9% (41.8-63.8%)</td>
<td>100% (92.1-100%)</td>
</tr>
<tr>
<td>bioMerieux Vidas D-dimer new</td>
<td>100% (90.7%-100%)</td>
<td>48.8% (37.6-60.1%)</td>
<td>100% (91.2-100%)</td>
</tr>
</tbody>
</table>

* = 95% Confidence Interval

### Highly Specific
- The monoclonal antibody 3B6 is highly specific for D-dimer and does not cross-react with other fibrin degradation molecules.
- The high specificity for D-dimer aids the safe exclusion of patients with suspected VTE.

### References:
Clearview Simplify D-dimer

How does it work?

D-dimer detection made simple
(See pack insert for full instructions)

1 1 drop of whole blood (35µl, venous or finger-prick sample) or 20µl plasma.

2 2 drops of buffer.

3 Read results at 10 minutes.

Quality Control

- Built-in procedural control to ensure test accuracy.
- External positive and negative controls are available.

Product Information

**Clearview Simplify D-dimer Test Kit**

- **Catalogue No**: 505285
- **Kit Contents**: 10 Tests, disposable pipettes, buffer, pack insert.
- **Shelf Life**: 21 Months
- **Storage**: Room temperature (2-25ºC)
- **Sample Type**: Whole blood (venous or finger-prick), or plasma
- **Time to Result**: 10 minutes

**Clearview Simplify D-dimer Controls Set**

- **Catalogue No**: 6101KCV
- **Kit Contents**: Positive and negative controls, pack insert
- **Shelf Life**: 18 Months
- **Storage**: Refrigerated (2-8ºC)

Inverness Medical UK has changed its name to Alere

www.alere.co.uk