



Clearview Simplify D-dimer

How does it work?

D-dimer detection made simple

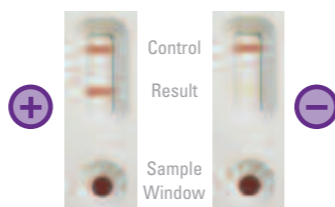
(See pack insert for full instructions)



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 (2-25°C)
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 (2-8°C)

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CSD-SB-VER2-MAR07



Clearview Simplify D-dimer

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



Clearly different. **Clearly better.**

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*Clearview Simplify D-dimer, combined with a validated pre-test probability score, helps to risk-stratify patients suspected of VTE.^{1,2,3}



Clearview Simplify D-dimer

For rapid assessment at the point of care.



Clearview Simplify D-dimer

Clinically proven, highly sensitive, and uses the 3B6 antibody specific for D-dimer.

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

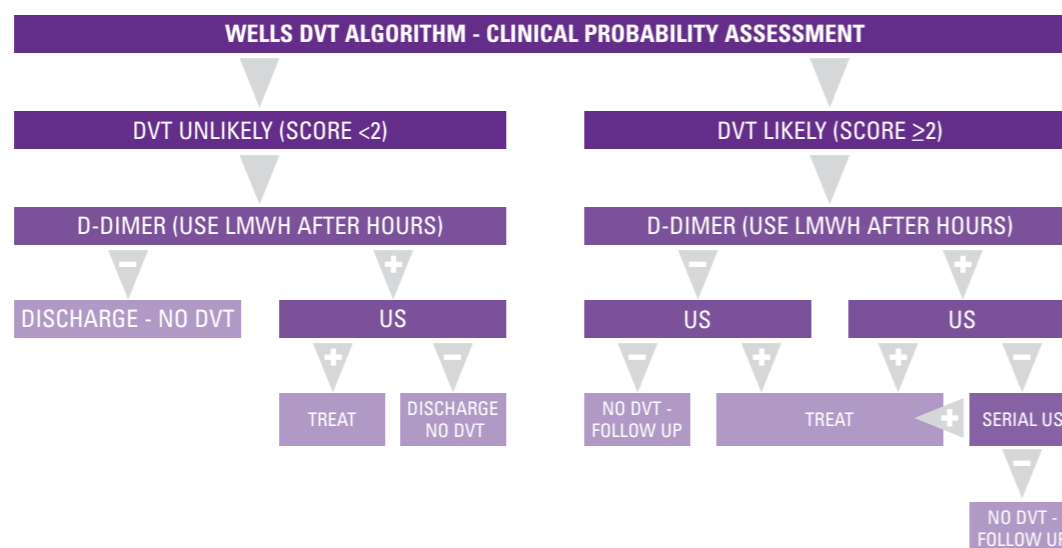
- In combination with a pre-test probability (PTP) score, Clearview Simplify D-dimer can safely rule-out VTE in low or moderate risk patients.^{1,2,3}
- Reduces the number of unnecessary diagnostic imaging procedures.

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.

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

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.



Clearview Simplify D-dimer 100% sensitive in a 527 Outpatient Study with Symptomatic PE⁴

Assay	Sensitivity	Specificity	NPV
Clearview Simplify D-dimer	100% (92.5%-100%)*	47.9% (43.3%-52.6%)*	100% (98.4%-100%)*
bioMerieux Vidas D-dimer new	100% (92.5%-100%)*	48.8% (44.1%-53.4%)*	100% (98.4%-100%)*
Diagnostica Stago STA Liatest D-DI	100% (92.5%-100%)*	47.5% (42.7%-52.3%)*	100% (98.2%-100%)*

* = 95% Confidence Interval

Clearview Simplify D-dimer 100% sensitive in a 120 Outpatient Study with Suspected DVT⁵

Assay	Sensitivity	Specificity	NPV
Clearview Simplify D-dimer	100% (90.0%-100%)*	52.9% (41.8-63.8%)*	100% (92.1-100%)*
bioMerieux Vidas D-dimer new	100% (90.7%-100%)*	48.8% (37.6-60.1%)*	100% (91.2-100%)

* = 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:

1. Kline JA, Wells PS. Methodology for a rapid protocol to rule out pulmonary embolism in the emergency department. *Ann Emerg Med* 2003 Aug;42(2):266-75.
2. Wells PS, Anderson DR et al. Evaluation of D-dimer in the diagnosis of suspected deep-vein thrombosis. *N Engl J Med* 2003;349:1227-35.
3. Wells PS, Anderson DR et al. Derivation of a simple clinical model to categorize patients probability of pulmonary embolism: increasing the models utility with the SimpliRED D-dimer. *J Thromb Haemost* 2000;83:416-20.
4. Toulon P and Meynlad O. D-dimer testing in patients with suspected pulmonary embolism. Performance of a new rapid semi-quantitative solid-phase immunochromatography assay (Simplify D-dimer) and comparison with two automated quantitative assays. *Blood* 2003;102(11):1b-514b: Abstract no. 4149.
5. Cini M, Legnani C et al. A new rapid bedside assay for D-dimer measurement (Simplify D-dimer) in the diagnostic work-up for deep vein thrombosis. *J Thromb Haemost* 2003;1:2681-3