



Clearview® Simplify™ D-dimer Comparison Grid

Product Name	Clearview Simplify D-dimer	bioMerieux Vidas® D-dimer New
Format	10 Cassettes	60 strip test kit on Vidas instrument
CLIA Status	Moderate: performed at bedside or laboratory	Moderate: specialized training required
Monoclonal Antibody	D-dimer-specific DD3B6/22 (3B6)	Anti-FbDP P10B5E12C9 and P2C5A10
Instrumentation	None	Required
Training	Minimal	Specialized
Sample	Whole Blood (venous or capillary) or Plasma (Sodium Citrate, EDTA, or Heparin)	Plasma (Sodium Citrate only)
Procedural Steps	2	Multiple
Calibration	None	Required
Time to Result	10 minutes	35 minutes
Shelf Life	12 months	As labeled on kit
Storage	2° to 25°C (refrigerated or room temp)	2° to 8°C

Clearview Simplify D-dimer
10 Test Kit
Order No. 6100KCV
CLIA Non-waived

D-dimer Control Kit
1 Positive, 1 Negative
Order No. 6101KCV

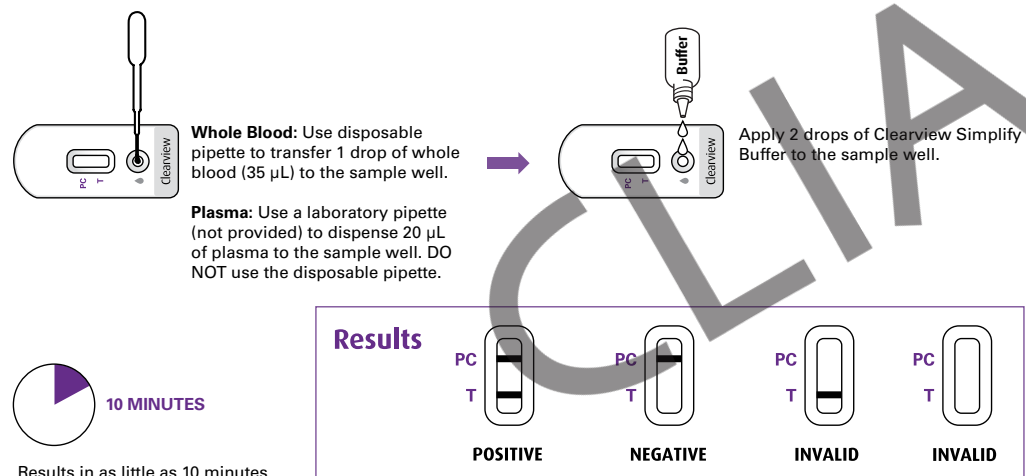


Clearly different.
Clearly better.

LEADING THE WAY IN RAPID TESTING



Clearview Simplify D-dimer Procedure



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When minutes matter most – you can rely on Clearview.

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Clearview® Simplify D-dimer

Clearly different

Clearview's patented innovative technology provides a highly sensitive and specific test for D-dimer.

- **Rapid Response:** Two easy steps, results in 10 minutes.
- **Simplicity:** Easy to use test requires no expensive instrumentation and specialized training.
- **Reliability:** Built-in control ensures accuracy.
- **Flexibility:** Faster results while the patient waits.

Clearly better

Clearview Simplify D-dimer offers important benefits for you and your patients.

- Aid in the diagnosis of deep vein thrombosis (DVT), pulmonary embolism (PE), and disseminated intra-vascular coagulation (DIC).
- Utilizes the patented 3B6/22 Monoclonal Antibody, specific only for D-dimer, which minimizes the false positives that can be seen with competitive tests.
- Reduces the wait for test results.
- Any staff member can perform, eliminating the need for instrumentation and specialized training.



Clearview Simplify D-dimer

Rapid two-step diagnostic test for the detection of D-dimer.



Clearview Simplify D-dimer Technical Comparison — 100% Sensitive in 120 Outpatient Studies with Suspected DVT¹

Assay	Sensitivity	Specificity	Negative PV	Positive PV
Clearview Simplify D-dimer	100% (90.0% – 100%)*	52.9% (41.8% – 63.8%)*	100% (92.1% – 100%)*	46.7% (35.1% – 58.5%)*
bioMerieux Vidas® D-dimer New	100% (90.7% – 100%)*	48.8% (37.6% – 60.1%)*	100% (91.2% – 100%)*	47.5% (36.2% – 59.0%)*

* 95% Confidence Interval

Clearview Simplify D-dimer Technical Comparison — 100% Sensitive in 527 Outpatient Studies with Symptomatic PE²

Assay	Sensitivity	Specificity	Negative PV	Positive PV
Clearview Simplify D-dimer	100% (90.6% – 100%)*	47.9% (43.4% – 52.5%)*	100% (98.0% – 100%)*	15.8% (12.0% – 21.0%)*
bioMerieux Vidas® D-dimer New	100% (90.6% – 100%)*	48.8% (44.2% – 53.3%)*	100% (98.0% – 100%)*	16.0% (12.1% – 20.9%)*
Diagnostica Stago STA® Liatest D-DI	100% (90.6% – 100%)*	47.5% (42.8% – 52.3%)*	100% (97.7% – 100%)*	17.2% (13.0% – 22.3%)*

* 95% Confidence Interval

¹ A new rapid bedside assay for D-dimer measurement (Simplify D-dimer) in the diagnostic workup for deep vein thrombosis. Cini, M, Legnani C, et al. J Thromb Haemost. doi:10.1046/j.1538-7836.2003.00470.x.

² 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; Vol 102, No 11(1b-514b):Abstract #4149.