

AxSYM D-dimer Assay Characteristics*

Method	Microparticle Enzyme Immunoassay (MEIA)
Units	ng FEU**/mL
Time to first result	15 minutes
Throughput	Up to 57 tests/hour
Sample type	Plasma (Citrated, Lithium Heparin or EDTA)
Sample storage	2–8 °C ≤ 8 h; –20 °C for 6 months with 3 freeze-thaw cycles
Sample preparation	Centrifuge for 15 min at 3000 rpm within 2 hours of collection
Sample volume	86 µL (STAT); 150 µl (routine)
Calibrators	0, 450, 1200, 2300, 4500, 9000 ng FEU**/mL
Controls	2 levels
Reagent stability	336 hours cumulative on board
Calibration curve stability	Typically 14 days
Limit of detection	50 ng FEU**/mL
Standardisation	Aligned to Biomerieux VIDAS D-dimer assay

* Preliminary data. Assay is in development.

** FEU: Fibrinogen equivalent units

Ordering Information

Description	List Number
AxSYM D-dimer Reagent Kit (100 tests)	3L85-20
AxSYM D-dimer Calibrator Kit	3L85-01
AxSYM D-dimer Control Kit	3L85-10
AxSYM D-dimer Assay Disk	3L86

Available Cardiac Assays on the AxSYM:

Troponin-I, CK-MB, Myoglobin, BNP, Homocysteine

References

1. Tovey C and Wyatt S, British Medical Journal, 2003, 326, 1180–1184.
2. Gardiner C et al., British J Haematol, 2005, 128, 842–848.
3. Kelly J and Hunt BJ, Chest, 2003, 12, 1116–1119.



AxSYM[®] D-dimer Assay

Rapid: 15 minutes to first result, STAT capability

Expected NPV ≥ 98%

High Precision



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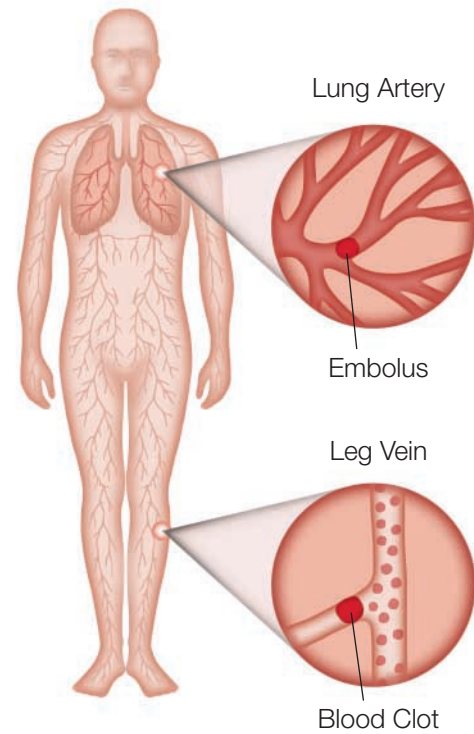
AXIS-SHIELD



D-dimer

Deep vein thrombosis and pulmonary embolism are relatively common medical conditions that contribute to individual patient morbidity and mortality as well as global health care costs. The annual incidence in developed countries is around 1:1000¹.

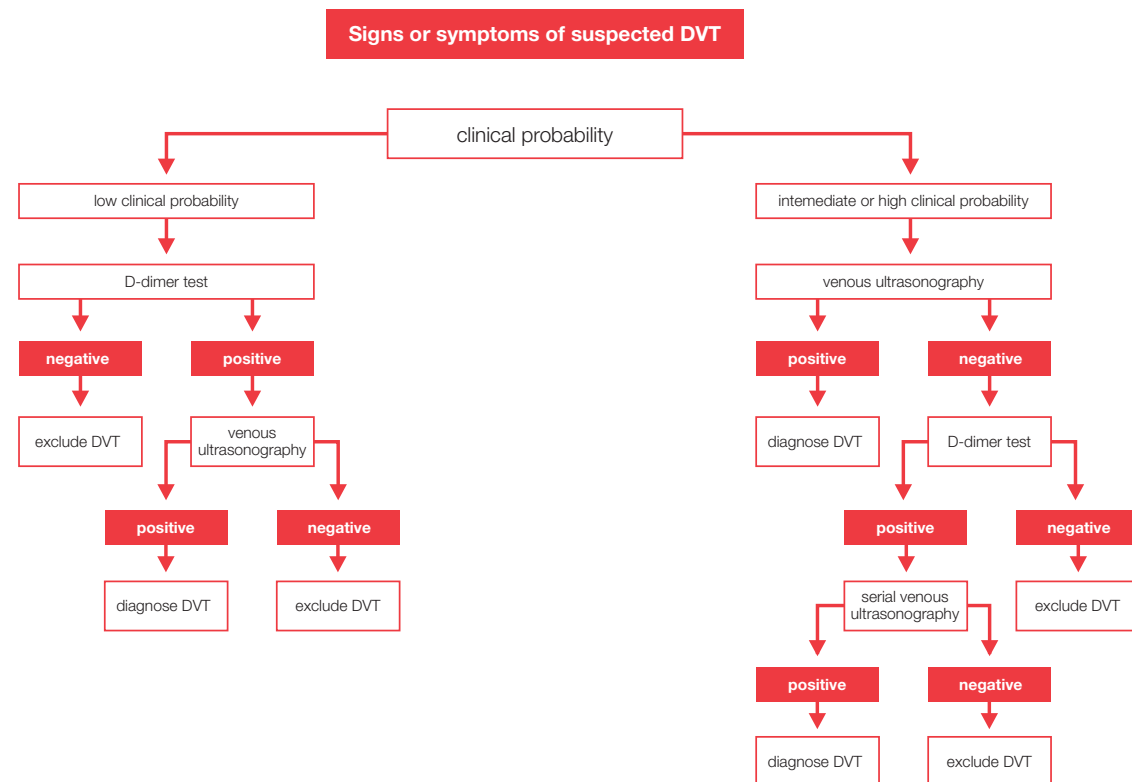
Deep vein thrombosis and pulmonary embolism



Numerous studies have indicated that D-dimer assays can be used as a reliable marker to rule out suspected venous thromboembolism (VTE), both deep vein thrombosis (DVT) and pulmonary embolism (PE).

D-dimer is a soluble fibrin degradation product released when cross-linked fibrin is degraded by plasmin. D-dimer is a coagulation marker that reflects the degree of thrombin turnover. DVT can be ruled-out in approximately one third of suspected patients reducing the requirement for imaging or invasive testing and so reducing total cost of diagnosis^{2,3}.

Typical exclusion protocol for investigation of subjects with suspected DVT



The AxSYM D-dimer Assay

AxSYM D-dimer assay is a microparticle enzyme immunoassay for the quantitative determination of D-dimer in human plasma.

AxSYM D-dimer Key Features

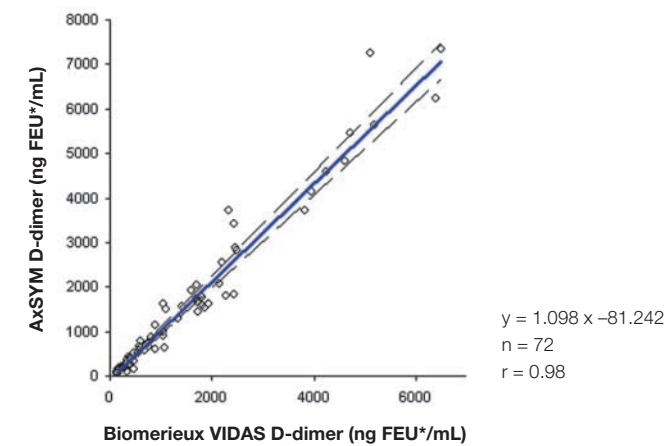
Features	Benefits
15 minutes to first result	Allows STAT testing for urgent samples
4–6% CV around the cut-off	Confidence in accuracy of result at cut-off
Expected NPV \geq 98%	Allows exclusion of DVT
Reportable range up to 9000 ng FEU*/mL	Reduces need for sample dilutions
Citrated, Li-Heparin and EDTA plasma all suitable sample types	No sample splitting in the routine clinical chemistry laboratory

* FEU: Fibrinogen equivalent units

Correlation

The assay has been designed to correlate well to the VIDAS D-dimer assay.

Method comparison (Passing-Bablok) AxSYM D-dimer to Biomerieux VIDAS D-dimer assay



* FEU: Fibrinogen equivalent units

Precision

A precision study was performed over 20 days. During that time the controls were tested twice daily in duplicate ($n = 80$) on each of two instruments.

Instrument	Low Control Mean (ng/mL)	Within Run %CV	Total %CV
1	599.7	3.0	4.6
2	604.5	4.5	5.6

Instrument	High Control Mean (ng/mL)	Within Run %CV	Total %CV
1	4451.6	4.9	6.1
2	4379.9	6.8	7.3