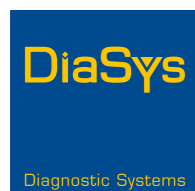


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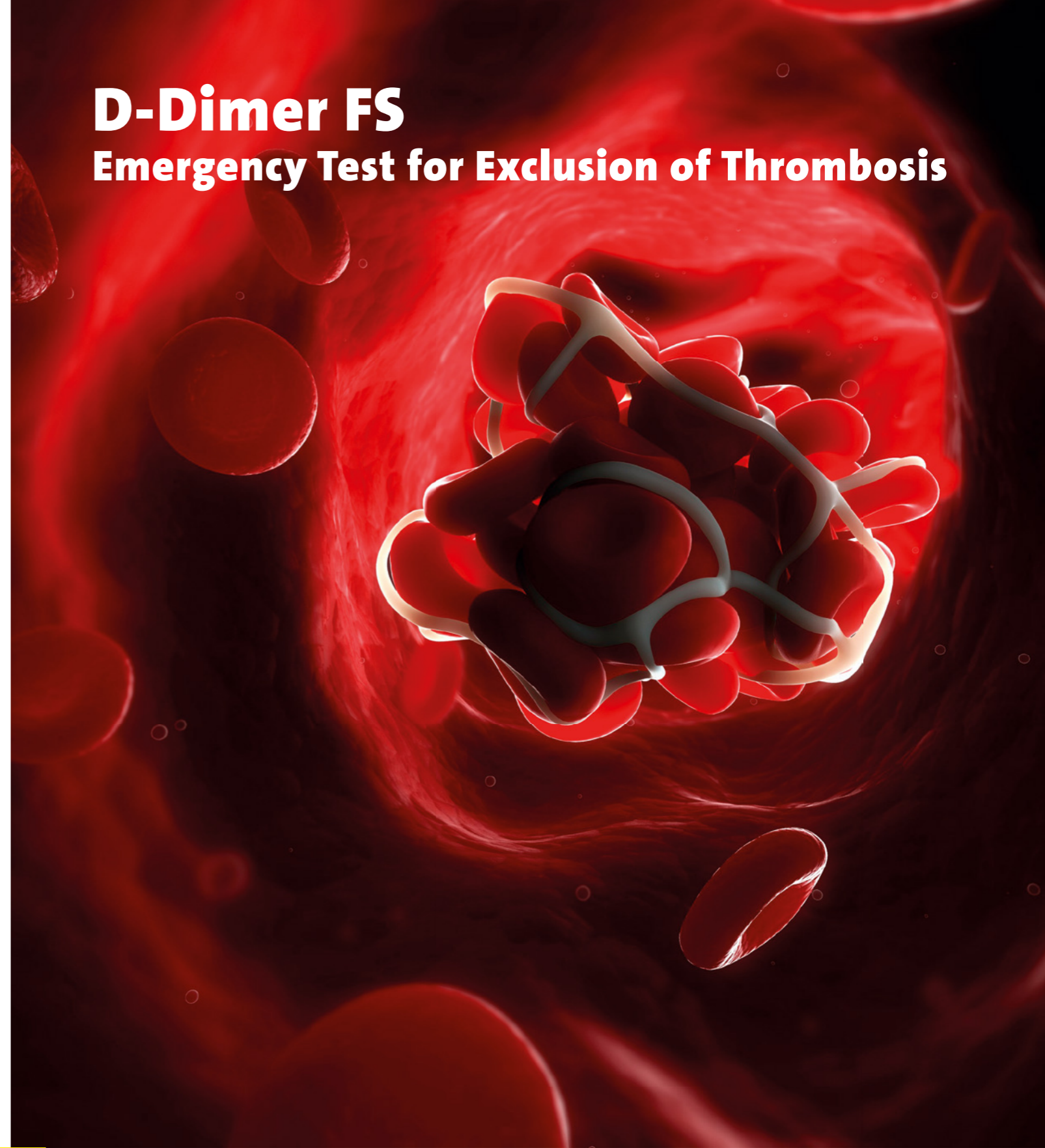


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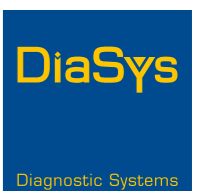
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# D-Dimer FS

## Emergency Test for Exclusion of Thrombosis



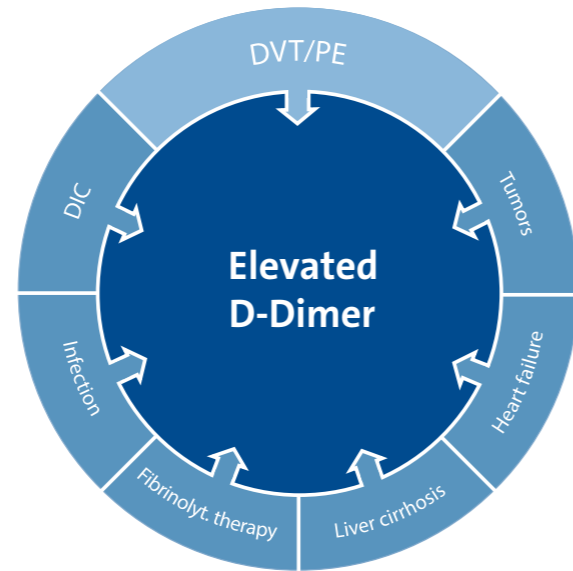
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## Clinical Relevance

The fibrin degradation product, D-dimer is detectable after plasmin degradation of cross-linked fibrin. Elevated D-dimer values indicate increased thrombin activity and fibrin formation and are therefore an indirect marker of venous thrombotic events (VTE). D-dimer values are increased in various conditions, such as cancer, liver cirrhosis or infections, which make a reliable diagnosis of a thrombotic event difficult. However, D-dimer results have a high negative predictive value (NPV) in order to exclude deep vein thrombosis (DVT) and pulmonary embolism (PE).

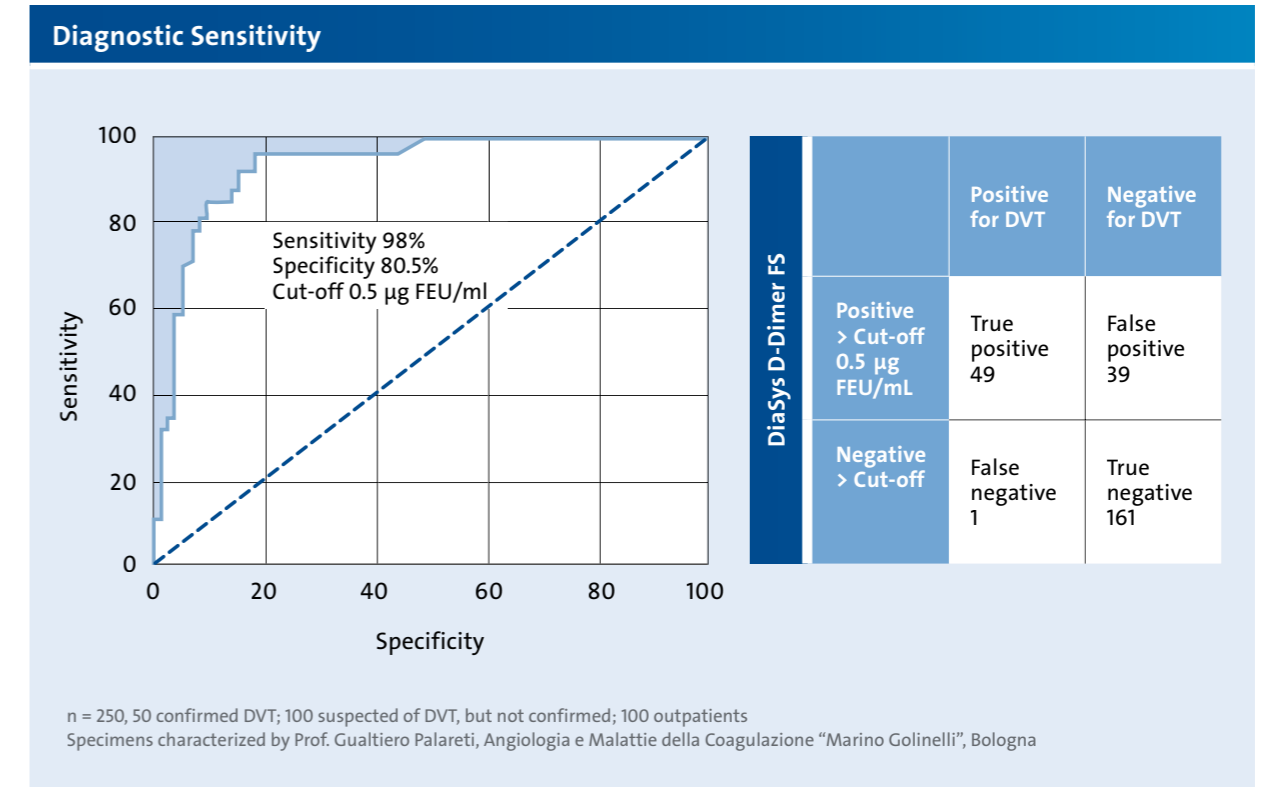


## Diagnostic Value of D-Dimer

Individuals with signs or symptoms suggestive of a thromboembolic phenomenon are initially screened with a D-dimer test to exclude DVT or PE. DVT is ruled out in patients with D-dimer levels below the cut-off value of 0.5 µg FEU/mL, whereby values above this cut-off have to undergo further investigations as sonography or phlebography.

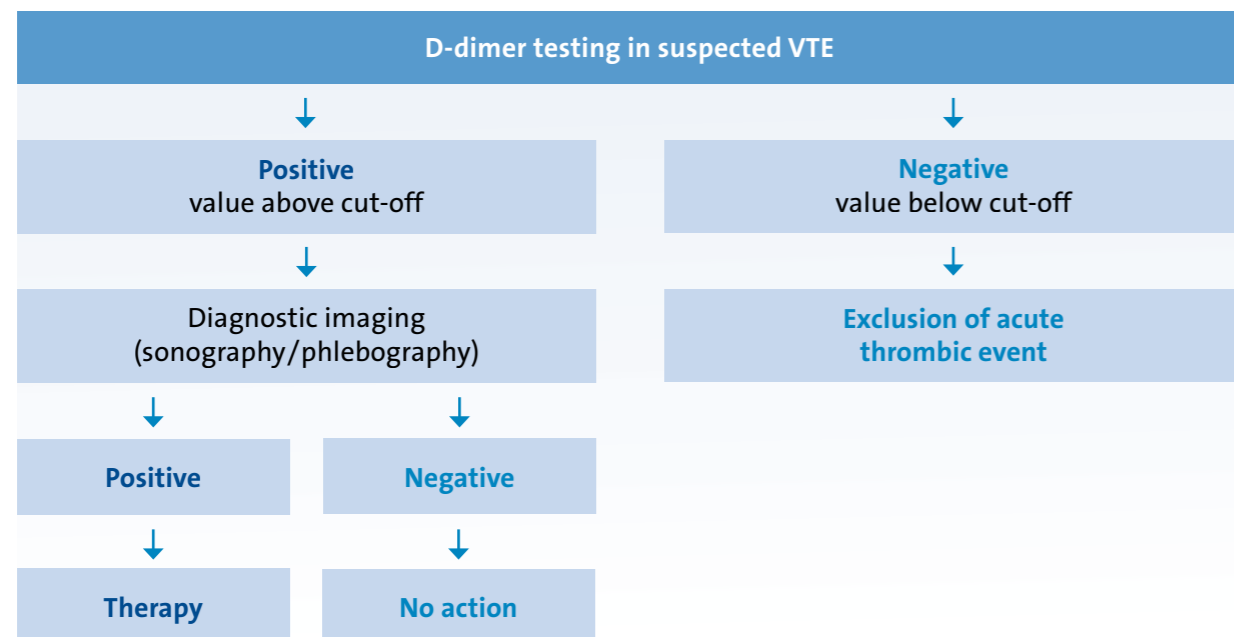
The D-Dimer FS reagent has demonstrated diagnostic sensitivity of 98% and diagnostic specificity of 80.5% for DVT at a cut-off value of 0.5 µg FEU/mL. D-dimer levels below 0.5 µg FEU/mL have a NPV of 99.4% for exclusion of DVT. These results are according to CLSI requirements of a diagnostic sensitivity of ≥ 97% and a NPV of ≥ 98%

## Performance Characteristics



**Precision**

Intra-assay N = 20	Mean (µg FEU/mL)	CV (%)	Inter-assay N = 20	Mean (µg FEU/mL)	CV (%)
Low level sample	37.3	0.58	Low level sample	0.66	4.59
Medium level sample	59.5	0.79	Medium level sample	0.95	2.18
High level sample	113	0.33	High level sample	3.59	1.10



## Test Characteristics

- Ready-to-use 2-component reagent
- Wide measuring range up to 8.7 µg FEU/mL
- High prozone security up to 50 µg FEU/mL
- Excellent precision
- Superior onboard and calibration stability of 6 weeks
- Applicable to various clinical chemistry analyzers

