



IVD CAPSULE D-DIMER ON THE ABIOSCOPE®
THE FASTEST POINT-OF-CARE QUANTITATIVE D-DIMER TEST

IDENTIFY THROMBOEMBOLISM IN ONLY 5 MIN FROM ONE DROP OF BLOOD

D-DIMER - A FUNDAMENTAL ELEMENT TO DETECT VENOUS THROMBOEMBOLISM (VTE)



D-Dimer is an early sensitive marker for rapid and early assessment of patients with suspected venous thromboembolism (VTE) such as deep vein thrombosis (DVT) and pulmonary embolism (PE).

Abionic's **IVD CAPSULE D-Dimer**:

- ✓ Is an easy-to-use *in vitro* diagnostic test for the rapid quantification of D-Dimer in human whole blood right at the point-of-care, in only 5 minutes.
- ✓ Enables healthcare professionals to make a first rapid and accurate triage of patients by a non-invasive test.
- ✓ Helps to reduce healthcare costs by preventing unnecessary imaging in healthy patients.

KEY FEATURES - FAST. EASY. RELIABLE

Abionic's **IVD CAPSULE D-Dimer** is the first quantitative immunoassay based on nanofluidic technology, providing precise and accurate result from a single drop of blood, in only 5 minutes.



1 DROP OF BLOOD.

4 simple steps from 50 µl of trisodium citrated venous blood or capillary samples



5 MINUTES.

Only 5-minute measuring time to get accurate actionable results



WIDE MEASURING RANGE.

212 - 1000 ng/ml FEU



LAB QUALITY RESULTS.

Performances equivalent to a laboratory



TEST PROCEDURE - GET RESULTS IN JUST 5 MINUTES WHEN & WHERE TIME MATTERS

1. Collect blood sample & mix it with the provided reagent
2. Fill the capsule with the mixed sample
3. Load the capsule in the abioSCOPE® & start the test
4. Get results in 5 min displayed on the screen

**A TRUE GAME CHANGER IN
VENOUS THROMBOEMBOLISM MANAGEMENT**



CLINICAL EVIDENCE

Strong performances of the IVD CAPSULE D-Dimer on the abioSCOPE®

Precision

The **IVD CAPSULE D-Dimer** on the **abioSCOPE®** has a measuring range from **212 to 1000 ng/ml FEU** of D-Dimer.

The linear range of the **IVD CAPSULE D-Dimer** on the **abioSCOPE®** was determined by diluting a pool of samples with clinically elevated D-Dimer levels in a pool of samples with low D-Dimer levels to obtain concentrations spanning the entire assay range. Regression analysis demonstrated that the assay response was linear with a slope of 0.97 and an intercept of 15.93 in this range. No high-dose hook effect is observed at concentrations below 43500 ng/ml FEU.

The sensitivity study demonstrated a limit of detection (LoD) of **109 ng/ml FEU** and a limit of quantification (LoQ) of **212 ng/ml FEU**.

D-Dimer Level	Mean Value [ng/ml FEU]	Between Day CV%
Level 1	319	6%
Level 2	603	0%
Level 3	1051	0%

Table 1. Summary of the 20 days precision study. The between-day precision was measured with 1 run of 4 replicates per day, for 20 days, on 3 samples covering the assay reportable range.

D-Dimer Level	Mean Value [ng/ml FEU]	Between Lot CV%
Level 1	220	5%
Level 2	382	1%
Level 3	671	2%

Table 2. Summary of the between-lot precision study. The between-lot precision was measured with 3 lots, 5 replicates per day, for 5 days, on 3 samples covering the assay reportable range.

D-Dimer Level	Mean Value [ng/ml FEU]	Between Device CV%
Level 1	261	7%
Level 2	426	4%
Level 3	671	5%

Table 3. Summary of the between-device precision study. The between-device precision was measured on 3 different abioSCOPE with 1 lot, 5 replicates, on 3 samples covering the assay reportable range.

Method Comparison

The **IVD CAPSULE D-Dimer** on the **abioSCOPE®** demonstrated a good comparability with the reference laboratory method VIDAS® D-Dimer Exclusion™ II, bioMérieux.

105 paired samples (sodium citrate venous whole blood on **abioSCOPE®** and corresponding venous plasma on reference method) were assessed on both methods in single replicate according to recommendation of CLSI document EP09-C, 3rd edition¹.

abioSCOPE® vs VIDAS®	
Non-Weighted Deming linear regression	
Slope (95% CI)	1.19 (0.99 to 1.39)
Intercept (95% CI)	-14 (-89 to 60)

Table 4. Comparison of methods. Linear regression statistics were applied to the entire data set covering a range of value of 222 to 930 ng/ml FEU (n = 105).

UNIQUE NANOTECHNOLOGY-BASED PLATFORM

Abionic's Patented Nanofluidic Immunoassay Revolutionizes Point-of-Care Diagnostics

Abionic's technology enables quantitative results for up to 14 specific parameters in a single capsule.

Molecules are forced into a nanochannel, limiting their travel distance to a few hundred nanometers and reducing incubation time to few minutes².

A washing step is not needed as the surface-to-volume ratio is extremely high, and non-specific background is negligible².

D-Dimer level can thus be efficiently quantified within an ultra short assay time, with high precision and accuracy on a closed, small, easy-to-operate platform, providing lab quality results at the point-of-care.

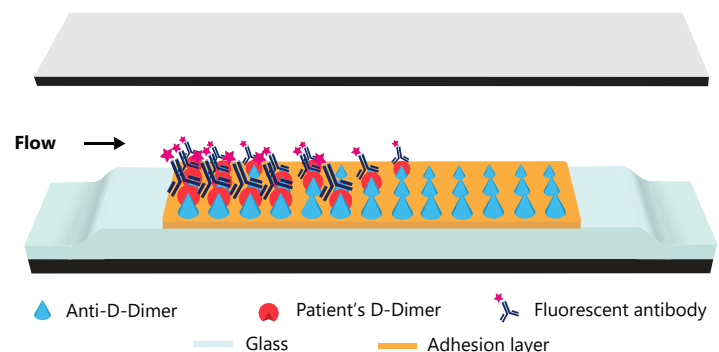


Figure 1. Cross-section through a nanofluidic biosensor

References:

1. Clinical and Laboratory Standards Institute (CLSI), EP09-C, 1st ed. 2018.
2. Nanofluidics Drives Point-of-care Technology for on the Spot Protein Marker Analysis with Rapid Actionable Results. Putallaz, L., Bogaard, P. V. D., Laub, P. & Rebeaud, F. Journal of Nanomedicine & Nanotechnology 2019.

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The abioSCOPE® and the IVD CAPSULE are CE marked.



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