Clinical Performance of the INNOVANCE® D-Dimer assay to exclude DVT:

The INNOVANCE® D-Dimer assay was evaluated in a multi-center study to validate the exclusion of DVT using fresh specimens collected from 455 consecutive patients presenting to the emergency department with suspected DVT. Of these 455 patients, 29 were excluded for a total of 426 patients available for final analysis.

All patients were evaluated using the Wells' rules to estimate a likely or unlikely pre-test probability (PTP) of DVT18. Patient specimens were tested with the INNOVANCE® D-Dimer assay and results were compared to a cutoff value of 0.50 mg/L (FEU). A D-dimer result < 0.50 mg/L (FEU) was considered negative and a D-dimer result ≥ 0.50 mg/L (FEU) was considered positive.

Patients with a positive D-dimer result were evaluated by imaging methods, e.g. compression ultrasound and/or venography. Patients with a negative D-dimer, as well as those with negative imaging results, were followed for three months to evaluate potential development of DVT. All patients were subject to imaging at the physicians' discretion.

The overall prevalence of DVT in those patients available for final analysis was 21.8 % (93/426). The following instrument-specific sensitivity, specificity and negative predictive value (NPV) with upper and lower 95 % confidence limits (CL) were obtained with the INNOVANCE® D-Dimer clinical cutoff of 0.50 mg/L (FEU).

	DVT Patients (n)	Cutoff mg/L FEU	Sensitivity (CL*) %	Specificity (CL) %	NPV (CL) %
All Patients:	426	0.50	100.0 (96.1 – 100.0)	34.5 (29.4 – 39.9)	100.0 (96.8 – 100.0)
Patients with unlikely pre-test probability:	267	0.50	100.0 (83.9 – 100.0)	37.0 (31.0 – 43.4)	100.0 (96.0 – 100.0)

Clinical Performance of the INNOVANCE D-Dimer assay to exclude PE

The INNOVANCE D-Dimer assay was evaluated in a multi-center study to validate the exclusion of PE using fresh specimens collected from 701 consecutive patients presenting to the emergency department with suspected PE. Of these 701 patients, 54 were excluded for a total of 647 patients available for final analysis.

All patients were evaluated using the Wells' rules to estimate a high, moderate or low pre-test probability (PTP) of PE[11]. Patient specimens were tested with the INNOVANCE D-Dimer assay and results were compared to a cutoff value of 0.50 mg/L (FEU). A D-dimer result <0.50 mg/L (FEU) was considered negative and a D-dimer result ≥0.50 mg/L (FEU) was considered positive.

Patients with a positive D-dimer result and/or a high PTP were evaluated by imaging methods, e.g. spiral CT and/or VQ scan. Patients with a negative D-dimer result and a low or moderate PTP (these patients underwent imaging at the physician's discretion), and patients with negative imaging results, were followed for three months to evaluate potential development of PE.

The overall prevalence of PE in those patients available for final analysis was 13.8% (89/647). The following instrument-specific sensitivity, specificity and negative predictive value (NPV) with upper and lower 95% confidence limits (CL) were obtained with the INNOVANCE D-Dimer clinical cutoff of 0.5 mg/L (FEU).

All Patients:

	PE Patients (n)	Cutoff mg/L FEU	Sensitivity (CL) %	Specificity (CL) %	NPV (CL) %
All Patients:	647	0.50	98.9 (93.9 – 100.0)	39.6 (35.5 – 43.8)	99.6 (97.5 – 100.0)
Patients with unlikely pre-test probablilty:	616	0.50	98.6 (92.5 – 100.0)	40.4 (36.3 – 44.7)	99.6 (97.5 – 100.0)

*CL = lower and upper 95 % confidence limits