Performance evaluation of the quantitative point-of-care LumiraDx D-Dimer Test

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Fibrin degradation product D-dimer can be a valuable indicator for venous thromboembolism (VTE). Use of D-dimer testing in primary care settings can be limited by restricted access to laboratory services. This performance evaluation compares a quantitative, point-of-care D-dimer assay (LumiraDx D-Dimer Test) with a reference laboratory-based D-dimer assay.

Methods

Plasma samples from patients presenting to secondary care in the UK, USA and Germany were analysed centrally using the LumiraDx D-Dimer Test and the bioMérieux VIDAS D-Dimer Exclusion II immunoassay™. Method comparison used Passing-Bablok regression analysis with pre-specified equivalence criteria of r≥0.9 and slope of 0.9–1.1. An equivalency study compared fingerstick, venous blood (VB) and plasma samples from the same subject, on the LumiraDx D-Dimer Test from patients presenting to healthcare providers, conducted under the NOVEL-3 study (NCT04375982). Measurements obtained from fingerstick and VB samples were compared with results from plasma samples, using Deming regression. The healthy reference range was determined using plasma samples of healthy volunteers, collected by commercial suppliers in Germany and the USA, which were analysed centrally using the LumiraDx D-Dimer Test and the reference test.

Results

The LumiraDx D-Dimer Test demonstrated equivalence to the bioMérieux VIDAS D-Dimer Exclusion II immunoassay™ for plasma samples (r=0.923, slope of 1.016, n=1767). There was good agreement between fingerstick/VB samples and plasma samples (r=0.980–0.986, n=93) measured using the LumiraDx D-Dimer Test. The healthy reference range 90% percentile for D-dimer was calculated as 533 µg/L fibrinogen equivalent units (FEU). Overall error rates were 1.8% and the test was reported as easy to use by the operators.

Conclusion

The quantitative LumiraDx D-Dimer Test can accurately measure D-dimer levels in a range of blood sample types, including fingerstick samples, which could improve assessment of VTE cases in community and hospital near-patient settings.

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