

# Performance Evaluation of a new, microfluidic Point of Care Test for C-Reactive Protein

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## Background

C-Reactive Protein (CRP) is one of the most prominent acute phase proteins (APP) that has become a universal biomarker of infection, inflammation and commonly used in clinics to aid assessment of lower respiratory tract infection and the need for antibiotic treatment. LumiraDx CRP Test is a quantitative, rapid point of care (POC) test for use with capillary/venous whole blood/plasma by healthcare professionals. The test provides a determination of C-Reactive Protein in 4 minutes. A performance evaluation was designed to assess precision and accuracy compared to Dimension® Xpand® Plus CRP Test (Siemens, Germany) as reference method, in patients with symptoms of infection, tissue injury or inflammatory disorders.

## Materials

Plasma samples (Lithium Heparin) from 320 patients presenting with symptoms of infection, tissue injury or inflammatory disorders at hospital Emergency Departments (ED), acute medical units or outpatient clinics. Frozen samples were thawed and run simultaneously on the LumiraDx CRP Test and reference method. Matrix equivalency and paired replicate precision was conducted by POC operators on 44 subjects where direct fingerstick blood, venous blood and plasma results were compared in duplicate. The data was analysed by Passing-Bablok regression.

## Results

A method comparison study was conducted with samples across the CRP measuring range of 5.1–245.5 mg/L in subjects 18–88 years of age. Data analysis demonstrated close agreement - reference method r-value 0.99, slope 1.05, Intercept -0.66. Assessment of assay precision (%CV) showed a CRP range of 19.9–185.4 mg/L for the different sample types and mean %CV ranged from 6.41 (plasma) - 8.07 (venous blood).

Matrix comparison showed good agreement between capillary blood direct application vs plasma (r-value 0.974) and venous blood and plasma (r-value 0.981). The overall error rate was 2.9%.

## Conclusion

The LumiraDx CRP test showed excellent agreement to the reference method and very good agreement between samples matrices. Precision was very good for direct fingerstick and venous blood. Fingerstick capillary samples offers doctor's offices the chance to test patients during clinic visits or directly in patient/care homes, without the need for venepuncture or waiting for lab results. The LumiraDx CRP test is a new, useful, portable tool that is easy-to-use to optimise patient treatment and diagnosis.



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