

Laboratory Evaluation of a New Lateral-Flow-Based Point-of-Care Rapid Test for Assessment of Chronic Systemic Inflammation

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Abstract

The determination of C-reactive protein (CRP) by means of a highly sensitive laboratory method as an independent biomarker for assessment of chronic systemic vascular inflammation and cardiovascular risk is recommended by therapeutic guidelines for diabetes and cardiovascular disease in the United States and in Europe. The purpose of this investigation was to investigate the specificity and sensitivity of a newly developed lateral-flow-based point-of-care (POC) rapid test with semi-quantitative visual reading in comparison with a laboratory reference standard method.

The high-sensitivity CRP concentrations of 66 samples were determined by means of turbidimetry and the POC test (5 µl serum/10 µl capillary whole blood, 10 minutes) was independently performed by three investigators blinded to each other's results. The visual readings were classified, as recommended by the American Heart Association, to represent a low risk (0–1 mg/liter), moderate risk (>1–3 mg/liter), or high risk (>3–10 mg/liter) or to indicate an unspecific inflammation (>10 mg/liter).

According to the reference method, there were 17 samples in the low-risk group, 19 samples in the moderate-risk group, and 26 samples in the high-risk group, and 4 samples showed an unspecific inflammation. All three investigators reached very conclusive results. The range of agreement between the visual readings of the investigators and the laboratory method ranged between 94% and 97%. The sensitivity for assessment of moderate-to-high cardiovascular risk was 100% (45/45 were detected), and the specificity ranged between 90% and 95%.

The newly developed lateral-flow-based POC rapid test showed an excellent agreement between individual visual reading and the laboratory reference method. It may therefore be suitable for a fast and convenient screening, which, after laboratory test confirmation, may help to identify patients with elevated risk of macrovascular disease.

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Abbreviations: (CRP) C-reactive protein, (CVD) cardiovascular disease, (hs) high sensitivity, (POC) point of care

Keywords: cardiovascular disease, chronic systemic inflammation, high-sensitivity C-reactive protein, point-of-care rapid test

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