Multisite precision study with QuikRead go® wrCRP+Hb test in Mehiläinen

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Aim of the study

The aim of the study was to evaluate the precision of new QuikRead go wrCRP and QuikRead go wrCRP+Hb tests (Orion Diagnostica, Espoo, Finland) at three point of care (POC) sites.

Background

CRP is an acute phase plasma protein, which is used as a marker for infection, inflammation, and tissue injury.[1] Measurement of CRP can be used as an aid for diagnosis, monitoring and treatment decisions of bacterial infections and inflammatory diseases. The use of CRP POC tests for acute respiratory infections in general practice reduces the antibiotic prescription rate, which can reduce antibiotic consumptions and antibiotic resistance.[2] The elevated low CRP values are clinically relevant e.g. in neonatal infections,[3,4] in risk assessment of cardiovascular events,[5] and conditions that include systemic inflammation, such as exacerbation of COPD.[6]
Hb is the iron-containing protein in red blood cells that carries oxygen. Hb concentration determination is a common procedure in both primary health care and acute care that may provide information about the overall health of the patient.

Materials and methods

The precision of the CRP and Hb assays on the QuikRead go wrCRP+Hb were evaluated in the multisite precision study performed at three different POC sites (private practices, Mehiläinen). CRP test is based on the immunoturbidimetric assay and agglutination reaction, whereas the Hb assay is a photometric measurement of oxyhaemoglobin. The measuring range for CRP is 0.5–200 mg/l and for Hb 50–220 g/l.
Multisite precision study was performed according to 3*5*5 test protocol (3 sites – 5 days – 5 replicates per run) in CLSI EP5-A3 guideline[7] using three (3) CRP and three (3) Hb controls at low, medium and high levels. In addition, repeatability was evaluated with a panel of ten left-over whole blood samples that were shared into aliquots and distributed to three study sites. Each operator measured ten replicates in one run in one day (3 sites – 1 day – 10 replicates per run). Results were analysed with Two Factor Nested ANOVA and One Factor ANOVA by Analyse-it® (Analyse-it, Ltd, Leeds, UK).
By the end of the study, the operators filled in a questionnaire about the usability of the QuikRead go wrCRP+Hb test system.

Results / Multisite precision

Results from multisite precision study according to 3*5*5 test protocol are presented as coefficient of variation (CV%) in Figure 1. The repeatability CV of CRP assay was ≤ 5.3%, and within site precision ≤ 5.6 %, and reproducibility CV ≤ 6.6 % (Figure 1A). The repeatability CV of Hb assay was ≤ 3.1 %, within site precision CV ≤ 3.6 %, and reproducibility CV ≤ 5.3 % (Figure 1b).

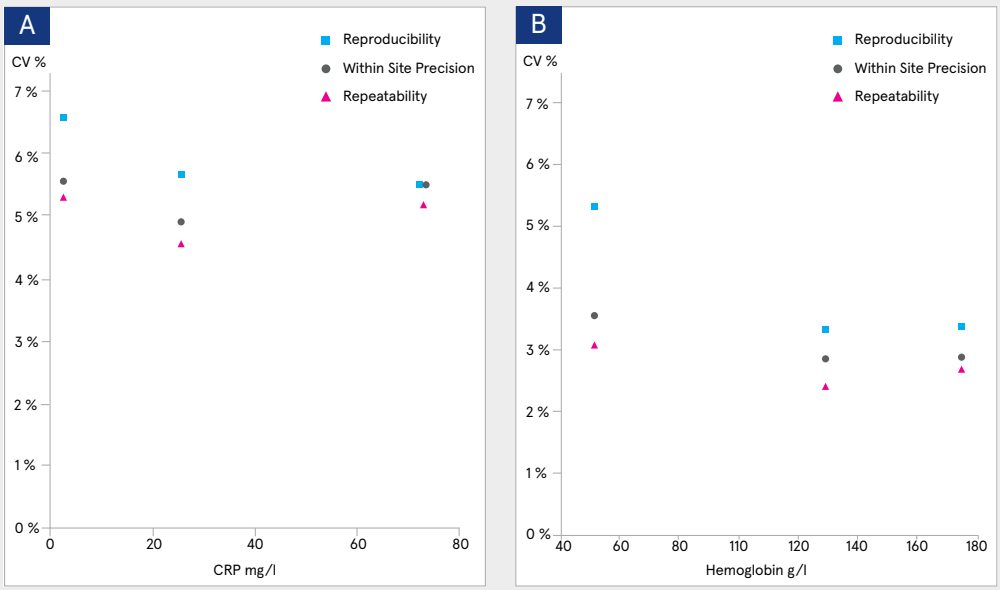

Figure 1.
The statistical analysis of A) CRP and B) Hb from the multisite precision study according the 3*5*5 test protocol.

9038-03EN, 10/2021. Not intended for the US market.

Results / Multisite repeatability

CRP concentrations of the whole blood panel ranged from 0.6 to 219 mg/l. With the lowest sample level (CRP 0.6 mg/l) both repeatability and reproducibility standard deviations (SD) were 0.13 mg/l. Precision at higher sample levels is presented as CV % in Figure 2A. Repeatability CV of CRP was ≤ 8.7 %. Reproducibility in one out of ten samples was increased (CV 13.1%) due to a minor difference in average concentration between the sites (2.7 mg/l, 3.2 mg/l, and 3.3 mg/l). A similar difference was not seen in the multisite precision study performed with control material having the same CRP concentration level. Reproducibility of other samples was ≤ 8.7 %. Hemoglobin concentrations ranged from 100 to 181 g/l. Reproducibility and repeatability CV % are presented in Figure 2B. Repeatability CV of Hb was ≤ 3.3 % and reproducibility CV ≤ 5.0%.

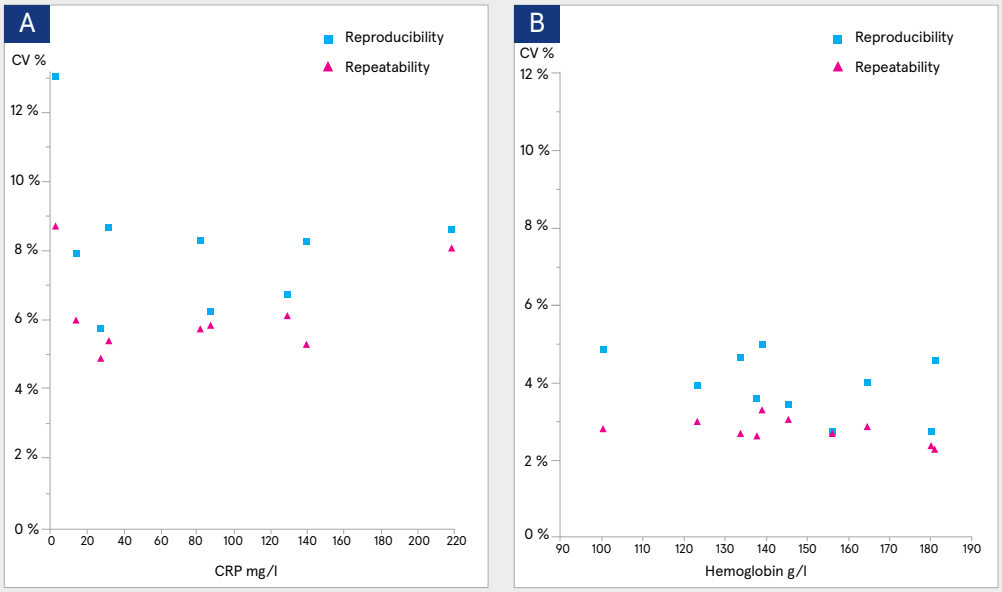

Figure 2.
The statistical analysis of A) CRP and B) Hb results from the multisite repeatability study with whole blood samples.

Usability of QuikRead go wrCRP+Hb

All four operators who performed the CRP and Hb assays evaluated the usability of QuikRead go wrCRP+Hb test and the instructions for use by filling out a questionnaire. Operators agreed that the test is easy to perform and instructions were clear.

Conclusions

Multisite precision study at three point-of-care sites showed good repeatability and within site precision for the CRP assays. Reproducibility of the CRP assays, containing all sources of variation (site, operator, instrument, day), was excellent. Repeatability, within site precision, and reproducibility of the Hb assay were good.
Repeatability testing with native samples showed excellent repeatability and reproducibility for the CRP assay at the low concentration level. Also at higher CRP concentrations repeatability was excellent and overall reproducibility good. Both repeatability and reproducibility of the Hb assay were good. The operators at all three point-of-care sites evaluated that the test was easy to perform.
In conclusion, QuikRead go wrCRP and QuikRead go wrCRP+Hb are easy and reliable for CRP and/or Hb determination in POC test environment.

References

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