Comparison of the New QuikRead go® wrCRP+Hb Point-of-Care Test to Four Clinical Laboratory Methods

J. Ramberg, S. Heikura, A. Katnikov, T. Kaukanen, H. Paloheimo, J. Raussi

Orion Diagnostica Oy, P.O.Box 83, 02101 Espoo, Finland

AIM OF THE STUDY

The aim of the study was to demonstrate that the new QuikRead go wrCRP+Hb test gives accurate and reliable C-reactive protein (CRP) and haemoglobin (Hb) results. Comparisons of CRP results were made to four clinical laboratory methods and Hb results to the ICSH (International Council for Standardisation in Haematology) standard method 1995.[1]

BACKGROUND

CRP is an acute-phase protein present in low concentration in the blood of healthy individuals.[2] Measurement of CRP aids in the detection and evaluation of infection, tissue injury and inflammatory disorders. It provides information for the diagnosis, therapy and monitoring of inflammatory disorders. Modestly elevated CRP values as well as patient-specific variations within the range of 0.5–5 mg/l have been shown to be clinically relevant e.g. in neonatal sepsis[3], recurrent coronary events[4] and conditions that include systemic inflammatation (such as COPD[5] and Rheumatoid arthritis[6]).

Hb is the iron-containing protein in red blood cells that carries oxygen. Determining its concentration is a common procedure in both primary health care and acute care.

MATERIALS AND METHODS

A new, easy-to-use point-of-care (POC) test, QuikRead go wrCRP+Hb, has been introduced to the QuikRead go platform. The test gives two results, the CRP and the Hb value, from one whole blood sample in a single analysis. CRP can be measured also on serum and plasma samples.

The measurement of CRP using the QuikRead go wrCRP+Hb test is an immunoturbidimetric assay based on agglutination reaction. The Hb assay is based on photometric measurement of oxyhemoglobin.

The sample is added into a cuvette which is closed with a reagent cap. The cuvette is placed into the QuikRead go instrument which automatically measures CRP and in whole blood samples, also Hb, in two minutes. The sample volume is 10 µl. The CRP measurement range is 0.5–300 mg/l in whole blood and 0.5–180 mg/l in serum or plasma. The system automatically detects the sample type (whole blood or serum/plasma) and the CRP value is corrected based on the hematocrit level of the sample. The Hb measurement range is 50–245 g/l.

In this study we evaluated the performance of the QuikRead go wrCRP+Hb test against four different clinical chemistry analysers. CRP method comparison with pooled heparin plasma samples was made against Roche Modular with CRPL3 reagent, Siemens Advia 1800 with Wide range C-Reactive Protein (wrCRP) reagent, Beckman Coulter AU640 with Beckman Coulter CRP Latex reagent and Abbott Architect c 8000 with CRP vario, Architect system reagents. Plasma samples were used, because whole blood samples cannot be measured with clinical chemistry analysers.

The Hb test was evaluated against the ICSH standard 1995 method (cyanomethemoglobin) using whole blood samples.

Hospital and private laboratories performed measurements with clinical chemistry analysers, the QuikRead go wrCRP+Hb tests were performed in Orion Diagnostica.

RESULTS

Linear correlation

Passing-Bablok regression analysis was used in CRP calculations and the results are presented in figures 1–4. The Hb test of the QuikRead go wrCRP+Hb kit (y) test was evaluated against (x) the reference method, ICSH 1995. The results are presented in figure 5.

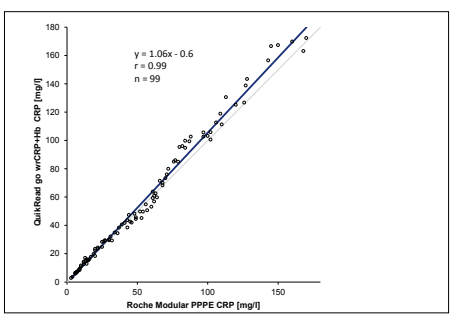


Fig. 1. QuikRead go wrCRP+Hb kit CRP test (y) compared to Roche Modular PPPE CRP test (x)

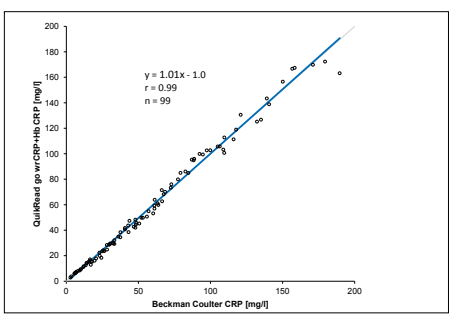


Fig. 2. QuikRead go wrCRP+Hb kit CRP test (y) compared to Beckman Coulter CRP test (x)

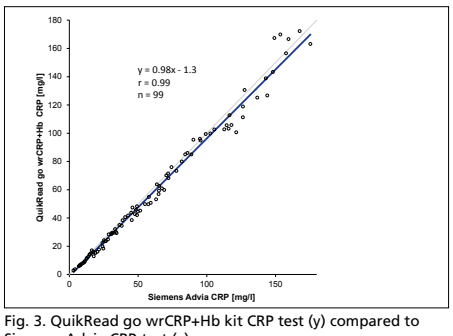


Fig. 3. QuikRead go wrCRP+Hb kit CRP test (y) compared to Siemens Advia CRP-test (x)

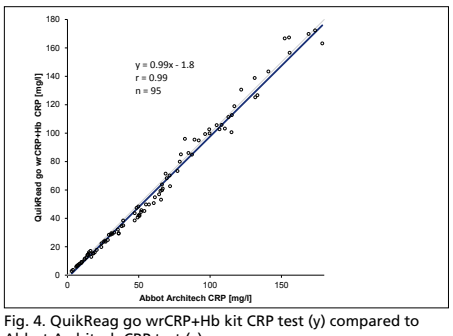


Fig. 4. QuikReag go wrCRP+Hb kit CRP test (y) compared to Abbot Architech CRP test (x)

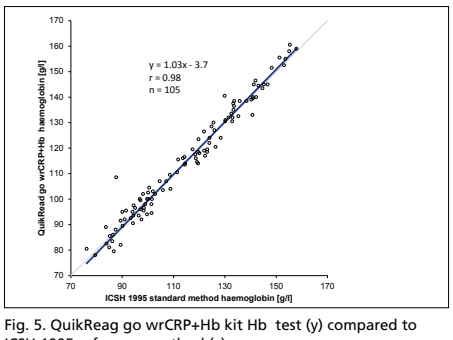


Fig. 5. QuikReag go wrCRP+Hb kit Hb test (y) compared to ICSH 1995 reference method (x)

Precision of the CRP and haemoglobin tests

Within run, between-day and total precision studies were performed according to the CLSI guideline EP5-A2 on 20 consecutive days. Precison of the QuikRead go wrCRP test was evaluated with both whole blood and plasma samples; Hb test with whole blood samples.

Also CRP and Hb controls were tested. Within run, between day and total precisions were calculated with Analyze-it application. The precision results are presented in table 1 (CRP) and table 2 (Hb).

Table 1. Precision of the QuikRead go wrCRP+Hb test; CRP results

Sample material	Sample level	Days of measurements	Mean CRP [mg/l]	Within run CV%	Between-day CV%	Total CV%
Whole blood	Low	20	2.0	4.1	4.0	6.8
	Medium	20	66	4.9	4.8	6.9
	High	20	185	4.2	1.7	4.9
Plasma	Low	20	2.3	4.6	2.2	5.1
	Medium	20	48	2.4	1.4	3.4
	High	20	136	2.7	1.3	4.0
Controls	Low	20	2.3	4.5	3.5	7.0
	Medium	20	22	5.0	3.7	6.6

Table 2. Precision of the QuikRead go wrCRP+Hb test; Hb results

Sample material	Sample level	Days of measurements	Mean Hb [g/l]	Within run CV%	Between-day CV%	Total CV%
Whole blood	Low	20	96	2.5	3.3	4.4
	Medium	20	132	2.2	4.0	4.9
	High	20	164	2.2	3.0	4.0
Control	Medium	20	171	1.5	0.8	1.7

The total precision (CV%) during 20 days was 3.4–7.0% for the CRP test and 1.7–4.9% for the Hb test.

DISCUSSION AND CONCLUSION

In this study, the QuikRead go wrCRP+Hb test was compared to several laboratory methods. The correlation of the QuikRead go wrCRP+Hb test to all the tested laboratory methods was very good, all correlation coefficients being over 0.98.

The Hb results of the QuikRead go CRP+Hb test correlated very well with the ICSH 1995 reference method.

The wide CRP measuring range of the QuikRead go wrCRP test increases the usefulness of this POC test in different clinical applications.

The QuikRead go wrCRP+Hb test is a fast, reliable and precise method for simultaneous testing of CRP and Hb.

REFERENCES

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