

Biotest Hemoglobin Measuring System

Summary of a premarketing evaluation organised by SKUP Report SKUP/2001/17



The Biotest Hemoglobin Measuring System (Biotest) is used for determination of the haemoglobin concentration in human blood. Biotest consists of an absorption photometer called Biotest Hemoglobin Tester and of Biotest Hemoglobin disposable microcuvettes which contain dried reagents. In the cuvettes, haemoglobin is converted to azide methaemoglobin. The system measures the endpoint of the reaction bichromatically.

It is possible to draw the sample, 10 μ L blood, directly into the Biotest cuvette from a capillary puncture. The cuvette can be read almost immediately in the Biotest Hemoglobin Tester. The measuring range is 0 – 256 g/L.

The first part of this premarketing evaluation has been performed by experts under "standardised conditions", i.e. by experienced laboratory technologists in a department of clinical chemistry. The second part was performed under "real life conditions" by ordinary users of this kind of tests, i. e. by staff in two primary care centres.

The routine method for B-Haemoglobin in the Department of Clinical Chemistry, Malmö University Hospital, is based on photometric measurement of cyanmethaemoglobin in the cellcounter Coulter GenS. This method is accredited and was used as the designated comparison method in this evaluation.

Preliminary analytical quality goals for this evaluation were derived from biological variation and set to allow a total error of less than ± 5 %.

Results

Testing with venous samples in the Department of Clinical Chemistry.

The within-series imprecision for Biotest with venous EDTA samples was good with CV around 0,7 %. The between-day imprecision was good. This CV was 1,2 %.

The linear correlation between Biotest and the comparison method was good with $r^2 = 1,00$.

The slope of the regression line was 0,989 and the intercept was -1,1 g/L.

Together, our findings indicate that the values from Biotest, with venous samples, are slightly lower, on average -1,9 % (or -2,6 g/L), than the values from the comparison method. However, this small deviation is of no clinical importance.

These individual results fulfil our analytical quality goals with a total error of less than ± 5 %.

Testing with venous samples in Primary Care Centres.

These results are similar to those obtained in the Department of Clinical Chemistry.

The within-series imprecision in the Primary Care Centres was as good as in the Department of Clinical Chemistry. The CVs were 0,7 % and 0,4 % respectively.

The linear correlation between Biotest and the comparison method was good with $r^2 = 0,98$ and 0,99. The slopes of the regression lines were 1,057 and 0,984 respectively.

The intercepts were -10,7 and -1,2 g/L. The regression line obtained for one of the two Primary Care Centres combines a comparatively bigger negative intercept with a steeper slope.

These Biotest values were lower, on the average -2,2 % (or -3,0 g/L), than the values obtained with the comparison method.

These individual results fulfil our analytical quality goals with a total error of less than ± 5 %.

Testing with capillary samples in the Primary Care Centres.

The within-series imprecision calculated from duplicate values from the same capillary puncture was acceptable in both centres. However, the CV-values varied from 0,9 % in one centre to 3,0 % in the other. The difference illustrates that imprecision can vary depending on the type of lancet used, sampling technique and the skill of the sample collector.

The linear correlation between Biotest and the comparison method was less good with $r^2 = 0,93$ and $0,95$. The slopes of the regression lines were 1,056 and 1,037 respectively. The intercepts were -5,0 and -3,2 g/L.

Biotest results obtained with capillary samples were lower, on average -1,9 % (or -3,0 g/L), than those of the comparison method with venous samples.

These individual results do not fulfil our analytical quality goals, which is a total error of less than ± 5 %.

Some general experiences from measuring B-Haemoglobin in capillary samples

During this evaluation some general problems with capillary samples became obvious.

The main part of the inaccuracy in a capillary result does not arise when the sample is sucked up into the cuvette. It is a preanalytical error occurring already in the capillary puncture.

The haemoglobin concentration in capillary puncture blood is for some individuals higher and for others lower than the corresponding venous blood concentration. For this reason, B-Haemoglobin results from capillary samples are less reliable. This preanalytical error is valid not only for Biotest, but for all instruments using capillary samples for measuring B-Haemoglobin. This observation does not disqualify capillary samples for B-Haemoglobin, but the requester of the analysis has to consider whether the capillary analytical quality is good enough in the existing clinical situation.

Despite that there were many individuals with big differences between the concentrations in the capillary and the venous sample, we could find no difference between the mean concentrations of haemoglobin in capillary and venous samples when results from many individuals were compared.

Practical points of view

All personnel involved in the evaluation summarised their opinion about the Biotest system as being quick and easy to use.

Conclusion

Biotest showed good precision when using venous samples. The within-series imprecision was around CV 0,7 %. The Biotest results had a good linear correlation with, and showed only small deviations from, the comparison method results, both in the Department of Clinical Chemistry and in the two Primary Care Centres. The bias was on average -2 % or -3 g/L.

Good duplicate precision can also be obtained with Biotest with capillary samples, but this requires proper sample collection. The within-series imprecision, calculated from duplicates collected from the same capillary puncture, was CV 0,9 % and 3,0 % respectively.

The bias was about the same as with venous samples. However, the haemoglobin concentrations in capillary puncture blood often deviate from that in the corresponding venous blood. For this reason, B-Haemoglobin results from capillary samples are less reliable. This preanalytical source of error is valid not only for Biotest, but for all instruments using capillary samples for measuring B-Haemoglobin.

Biotest is quick and easy to use.

The complete report is found at www.skup.nu