

HemoCue WBC



Summary of an evaluation under the direction of SKUP Report SKUP/2010/73

The HemoCue[®] WBC system (HemoCue WBC) measures the “number concentration” of leukocytes in blood (B—Leukocytes) and is intended for use in primary health care. HemoCue WBC is manufactured by HemoCue AB, Sweden. The HemoCue subsidiary companies are the agents for the system in the Scandinavian countries. HemoCue AB in Sweden ordered this evaluation.

The HemoCue WBC system consists of the HemoCue WBC Analyzer and the HemoCue WBC Microcuvettes. The measurements can be done on whole blood from a capillary finger prick or a venous sample. The sample volume, about 10 µL, is achieved by filling the microcuvette. After the placement of the filled microcuvette in the instrument, the procedure is automatic. HemoCue WBC counts the number of stained leukocytes in the microcuvette by image analysis. The result is displayed on the screen at the end of the test. The measuring range is 0,3 to 30,0 × 10⁹/L. Measurement duration is 3 minutes.

This evaluation is a complete SKUP evaluation. In a hospital laboratory, experienced biomedical scientists carried out HemoCue WBC measurements on venous samples. At two primary care centres, the measurements were carried out on venous and capillary samples from the same patients. These measurements were in one centre performed by nurse assistants and in the other centre by a biomedical scientist.

The comparison method was performed with an Advia 2120 cell counter supplied by Siemens Diagnostics at the Department of Clinical Chemistry, Södra Älvsborgs Sjukhus (SÄS) hospital, Borås, Sweden. The method is accredited by Swedac.

The quality goal for total error set by SKUP was that 95% of the HemoCue WBC results should not deviate more than ±18% from the comparison method results. The theoretical limits of ±15% had then been widened with ±3% considering the analytical quality of the comparison method.

Results

Venous samples in the hospital laboratory

According to quality goals set up by SKUP, the imprecision of HemoCue WBC should not exceed 5,5% in CV. The estimated CV obtained with all venous samples was 3,1%. The between-days imprecision for patient sample results was 4,4% and the same imprecision was found for control blood results. This precision of HemoCue WBC with venous blood in the hospital laboratory fulfilled the quality goal.

According to the quality goals set up by SKUP, the bias of HemoCue WBC should not exceed ±6,0%. HemoCue WBC showed different bias depending on the level of B—Leukocytes. The results were sorted according to the concentration and divided into three level groups. The results in the low and high level groups showed almost no bias. The results in the medium level group (3,8 to 7,7 × 10⁹/L) showed a negative bias of -6,6%. The HemoCue WBC results with venous samples in the hospital almost fulfilled the SKUP quality goal for bias.

Twenty samples containing atypical leukocytes according the Advia cell counter was selected to check the ability of HemoCue WBC to measure such samples correctly. Almost all venous samples showed good agreement between the HemoCue WBC and the Advia results. One sample containing erythroblasts gave, as expected, false high WBC results.

According to the quality goal for total error, 95% of the HemoCue WBC results should not deviate more than $\pm 18\%$ from the comparison method results. In the hospital 95% were inside the limits. With venous samples the HemoCue WBC results fulfilled the SKUP quality goal for total error.

Venous samples at the primary care centres

The imprecision was similar to the imprecision in the hospital laboratory. This precision was good and fulfilled the quality goal.

The bias of HemoCue WBC was estimated for the results divided into two concentration level groups. The bias for the low level group at the two primary care centres was $-16,0\%$ and $-12,1\%$ respectively, and for the high level group $-6,1\%$ and $-5,4\%$ respectively. The quality goal for bias was not fulfilled for the low level group but for the high level group. In contrast to the hospital laboratory evaluation the samples in the primary care evaluation were measured directly after sampling with HemoCue WBC and stored different time before measured with the comparison method. In the first primary care centre the mean storing time was 11,5 hours and in the second 4 hours. This may have influenced the bias.

Capillary samples at the primary care centres

The analytical quality of capillary HemoCue WBC results was evaluated by comparing them with results from the venous comparison method. There was no good agreement between capillary and venous results. The imprecision was $13,4\%$ and $14,1\%$ respectively at the two primary care centres. The quality goal for bias was fulfilled although the uncertainties in the estimates are large. The storing time before the measurements with the comparison method may have influenced the bias as described for venous samples.

Seventy-seven percent (77%) of the capillary results were inside the limits for total error. With capillary samples, the HemoCue WBC results did not fulfil the SKUP quality goal for total error.

User-friendliness

The evaluators' general opinion was that HemoCue WBC was user-friendly and easy to handle. The short shelf life for internal quality control materials already when unopened is a drawback. The mean error code frequency for all measurements in the evaluation was $1,6\%$. Thus the quality goal of less than 2% error codes was fulfilled, although the frequency was significantly higher than 2% on one of the used instruments.

Conclusion

For venous samples the analytical quality of HemoCue WBC was good and fulfilled the quality goals. However, for capillary samples the quality goals were not fulfilled. HemoCue WBC was easy to handle.

Comments from the manufacturer

Comments to report from HemoCue AB are attached to the complete report.

This is a summary of the complete report published on www.skup.nu