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Evaluation of the HemoCue WBC DIFF system for point-of-care counting of total and differential white cells in pediatric samples

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Point of Care Testing (POCT) accelerates the availability of critical labtest information that clinicians require to make rapid treatment decisions and monitor a patient's response. Especially, in pediatric environments, the ability to perform multiple tests with just a few drops of blood is precious.

Total white blood cell (WBC) count and differentiation is an important tool in diagnosing infections. In an emergency care setting, both lymphocytopenia and the neutrophil to lymphocyte count ratio (NLCR) may serve as simple markers for discrimination between severe bacterial and viral infections and are better predictors of bacteremia than routine parameters like CRP level, total WBC and neutrophil count (1, 2).

Recently, HemoCue launched a POCT analyser (HemoCue WBC DIFF system), able to count and differentiate white blood cells, including differentiation (DIFF, absolute and percentage) in neutrophil, lymphocyte, monocyte, eosinophil and basophil counts in capillary or venous whole blood (3). The Hemocue WBC DIFF technique is based on cell counting using a microcuvette with a small volume of only 10 µl of blood. The blood sample is drawn into the cavity of the microcuvette by capillary force. A cell-lysing agent will hemolyse the red blood cells and a staining agent will stain the white blood cells. The microcuvette is placed in the analyser and the numbers of white blood cells are counted by image analysis (4).

This study was undertaken to assess the reliability of the HemoCue WBC DIFF system fulfilling the medical and clinical requirements regarding to accuracy and precision according to CLSI EP9-A2 (5) of measurement for total white blood cell and 5-parts differential count in capillary pediatric samples.

Methods

Samples were obtained from 199 capillary EDTA blood samples from children up to 12 years of age that had been sent to the laboratory for routine blood counts. Samples regarding ages were equally distributed. Reference counts were obtained by a standardized Sysmex XE-5000 automated cell counter (Sysmex Corporation, Kobe, Japan). All samples were analyzed in duplicates on the HemoCue WBC DIFF system and in single replicate on the Sysmex XE-5000 within 8 hours after collection. Time span between analyses on both systems was less than 2 hours for each sample. Two blood smears for manual differential count were made for investigation if any discrepancy occurred. As acceptance criteria for accuracy requirements, the slope for linear regression between both methods should not exceed ± 5% (r≥0.95) for total WBC count and for precision requirements as indicated in table 1. All the data were analyzed using orthogonal regression analysis (Deming regression) and Pearson's correlation coefficient (r). For the calculation of the precision, pooled standard deviations (SD) and coefficient variations (CV) were calculated.

Results

The accuracy of the total WBC count on the HemoCue WBC DIFF analyzer was assessed by 199 samples with a range of 2.6 - 26.9 x 10^9 cells/L in comparison to the reference analyzer. The correlation coefficient was 0.98 and intercept and slope from orthogonal regression analysis were 1.02 and -0,20 (y=-0.2 + 1.02x (x = Sysmex XE-5000 and y = HemoCue WBC DIFF), figure 1A). These findings indicate good comparability within manufacturer's suggested analytic range with no detectable bias. For calculation of the precision 179 samples were included. 20 samples were excluded due to one of the replicates of each sample obtained an error code. Error codes were generated by pre-analytical errors or violation of predefined software limits. The latter were significantly downscaled by newer software versions. The HemoCue DIFF system showed for the total WBC count a maximum CV of 3.6% (table 1). The group WBC 20.1-26.9x10^9 cells/L could not be calculated due to the low number of samples in this group.

133 samples were included in the calculations of correlation coefficients and orthogonal regression analysis for the differential WBC count. 66 samples were excluded due to flagging from the Sysmex XE-5000 and/or HemoCue WBC DIFF system. Scatter plots for the regression analyses are presented in Figure 1B showing good comparability with no detectable bias (neutrophils (0.2 + 0.95x, r=0.98), lymphocytes (0.02 + 1.10x, r=0.94) and eosinophils (0.002 + 1.01x, r=0.93)). The result for monocytes was 0.06 + 0.52x, r=0.61, while calculations for basophils were not performed due to a low count. The flagging frequency was 15%, of which 50% was also flagged by the XE-5000 system. This flagging frequency is acceptable compared with standardized automated cell counters.

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Table 1. Precision of total and differential WBC on the HemoCue WBC DIFF system

Cell type	Number of samples	Range (10^9/L)	SD/%CV	Limits of acceptance
Total WBC	7	2.5 - 3.5	CV 3.3%	CV ≤10%
	169	3.6 - 20.0	CV 3.6%	CV ≤ 5%
Neutrophils	66	1.5 - 3.5	CV 7.2%	CV ≤15%
	80	3.6 - 19.3	CV 4.3%	CV ≤ 8%
Lymphocytes	95	1.1 - 3.5	CV 7.6%	CV ≤15%
	48	3.6 - 8.2	CV 6.1%	CV ≤ 8%
Monocytes	142	0.1 - 1.0	SD 0.07x10^9/L	SD ≤0.3x10^9/L
Eosinophils	145	0.0 - 1.0	SD 0.06x10^9/L	SD ≤0.3x10^9/L
Basophils	146	0.0 - 0.1	SD 0.01x10^9/L	SD ≤0.3x10^9/L

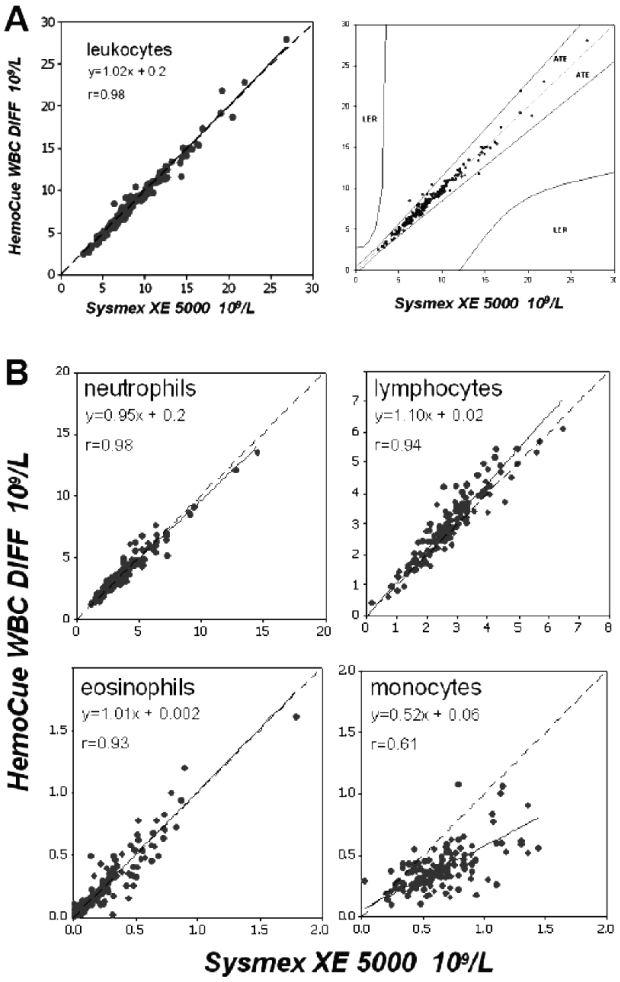

Figure 1. Precision of total and differential WBC on the HemoCue WBC DIFF system. Scatterplots for the HemoCue WBC DIFF system versus Sysmex XE-5000 for (A) total WBC, (B) neutrophils, lymphocytes, eosinophils and monocytes in pediatric samples.

146 samples were included in the calculation of precision. 52 samples were excluded due to one of the replicates of each sample obtained error code or flagging from the HemoCue WBC DIFF system. Precision of the different WBCs in the defined measuring range are indicated in table 1 and were all within the acceptance criteria for pediatric samples.

Conclusion

The total white cell count and differentiation is recognized as an important test for health screening and for diagnosis and clinical management of patients. This study demonstrated that the HemoCue WBC DIFF system is a reliable method for counting and differentiating WBCs in pediatric samples. It correlates well with the Sysmex-XE5000 automated cell counter with acceptable flagging frequency. It is simple to use and provides a rapid provision of results and, thus, eminently suitable for use in a point-of-care setting, facilitating adequate decision making, which could lead to improved clinical outcomes.

References

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