INTRODUCTION

The DxH 520 is a small hematology analyzer capable of performing CBC and 5-part differential in fresh whole blood samples, both venous and capillary.

Medical care of children and adolescents is significantly dependent on reference intervals to properly interpret laboratory test results.

Multi-center studies were performed to assess comparability to DxH 800 hematology analyzer and to verify or establish reference intervals in pediatric populations.

The following parameters were studied: White Blood Cells (WBC), Red Blood Cells (RBC), Hemoglobin (Hgb), Hematocrit (Hct), Mean Corpuscular Volume (MCV), Mean Corpuscular Hemoglobin (MCH), Mean Corpuscular Hemoglobin Concentration (MCHC), Red Cell Distribution Width (RDW), RDW-SD, Platelets (PLT), Mean Platelet Volume (MPV), Lymphocyte (LY%, LY#), Monocyte (MO%, MO#), Neutrophil (NE%, NE#), Eosinophil (EO%, EO#), and Basophil (BA%, BA#).

METHODS

Whole blood samples were tested within 8 hours of collection on the DxH 520 and DxH 800 analyzers. Samples generating review flags or suspect messages were excluded from the study. All were residual specimens.

Reference Intervals

- 208 specimens from healthy children were enrolled that included 20 neonates (0 to 30 days), 27 infants (31 days to 2 years), 94 children (3 to 12 years) and 67 adolescents (13 to 21 years)

- Even gender distribution within each age group was targeted

Method Comparison

- Ninety-one samples from children (<22 years) with various clinical conditions were enrolled

- Results from DxH 520 were compared to the predicated DxH 800 results

RESULTS

Reference intervals for the neonate age group were verified from existing published ranges using the transferee method. The robust method was used to calculate two sets of reference intervals partitioned by combining data from the infant and children age groups, and from the adolescent age group (Tables 1, 2).

Results were analyzed according to CLSI EP28-A3c guidelines.

Results from clinical samples on DxH 520 were compared to DxH 800 results (Table 3). These results were analyzed according to CLSI EP09-A3c guidelines.

Age and gender demographics are outlined in Tables 4 (Reference Interval) and 5 (Method Comparison).

REFERENCES

Soldin, Steven J., Edward C. Wong, and Brugnara Carlo, eds. Pediatric Reference Intervals. 7th ed. ACCP Press; 2010


CONCLUSION

Reference Intervals for CBC and differential parameters have been established for combined genders of pediatric age groups (0 to 30 days, 31 days to 12 years, 13 to 21 years) on the DxH 520 Hematology analyzer.

Regression statistics were calculated from the pediatric clinical samples. Bias at the 50th percentile meet product specifications for these parameters.