PERFORMANCE OF DxH 520 HEMATOLOGY ANALYZER IN PEDIATRIC POPULATIONS

Astrid C Smit[1], Aprille Seidel[1], Justin Rohrbach[1], Robert Magari[1], Karen Lo[1], Javier Martin[1], Khosrow Adeli [2], Victoria Higgins[2], Meer-Taher Shabani-Rad[3], Maureen Cyfra[3], Mike Keeney [4], Ben Hedley[4], Magdalena Czader[5], Lin Wang[5] and Liliana Tejidor[1]

[1]Beckman Coulter, Inc. Miami, FL, [2]The Hospital for Sick Children, Toronto, ON, [3]Calgary Laboratory Services, Calgary, AB, [4]London Health Sciences Center, London, ON, [5]Indiana University Health, Indianapolis, IN.

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 analyses. 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 predicate DxH 800 results

RESULTS

Reference intervals for the neonate age group were verified from existing published ranges using the transference 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).

Parameter	Unit	Min	Max
WBC	10³ cells/µL	5.86	16.69
RBC	10⁶ cells/µL	3.16	5.74
HGB	g/dL	10.00	20.00
HCT	%	30.5	57.2
MCV	fL	85.0	126.0
MCH	pg	29.9	36.4
MCHC	g/dL	28.0	37.0
RDW	%	14.3	18.2
RDW-SD	fL	46.3	65.7
PLT	10³ cells/µL	95.0	586.0
MPV	fL	7.80	12.20
Ly	%	8.00	82.70
Mo	%	4.00	20.60
Ne	%	10.60	66.10
Eo	%	0.00	7.00
Ba	%	0.00	1.00
Ly#	10³ cells/µL	1.17	8.38
Mo#	10³ cells/µL	0.28	1.70
Ne#	10³ cells/µL	1.18	11.43
Eo#	10³ cells/µL	0.03	0.80
Ba#	10³ cells/µL	0.00	0.11

Table 1 Verified Reference Intervals for Neonates (n = 20)

Parameter	Units	Ages 31 Days to 12 Years (Infant and Child) (n=121)			Ages 13 to 21 Years (Adolescent) (n=67)		
		Mean	95% Confidence Limits Low	High	Mean	95% Confidence Limits Low	High
WBC	10³ cells/µL	7.38	2.88	11.38	6.21	3.21	9.10
RBC	10⁶ cells/µL	4.61	4.01	5.22	4.79	3.95	5.62
HGB	g/dL	12.81	11.06	14.57	13.73	11.16	16.29
HCT	%	38.0	33.1	43.0	41.0	34.4	47.6
MCV	fL	82.5	74.6	90.5	85.6	76.6	95.1
MCH	pg	27.8	24.6	31.2	28.7	25.2	32.3
MCHC	g/dL	33.7	32.0	35.5	33.5	31.9	35.2
RDW	%	15.0	12.8	16.9	14.8	12.5	16.8
RDW-SD	fL	42.3	35.3	49.2	43.7	37.2	50.6
PLT	10³cells/µL	317.3	164.5	454.3	270.5	128.4	393.9
MPV	fL	9.05	7.33	10.74	9.58	7.79	11.35
Ly	%	42.73	15.09	66.93	35.83	16.14	55.86
Mo	%	7.09	2.81	11.07	7.67	1.64	12.94
Ne	%	46.21	21.68	73.50	53.60	32.53	74.10
Eo	%	3.78	0.00	8.88	2.71	0.00	5.85
Ba	%	0.19	0.00	0.37	0.19	0.00	0.44
Ly#	10³ cells/µL	3.16	0.00	5.80	2.16	0.92	3.33
Mo#	10³ cells/µL	0.52	0.11	0.90	0.47	0.08	0.82
Ne#	10³ cells/µL	3.41	0.24	6.20	3.40	0.67	5.81
Eo#	10³ cells/µL	0.28	0.00	0.70	0.16	0.00	0.35
Ba#	10³ cells/µL	0.01	0.00	0.03	0.01	0.00	0.03

Table 2 Pediatric Reference Intervals for DxH520

Analyte	Unit	N	Means DxH800	DxH520	Difference	95% Conf. Lower	95% Conf. Upper	Slope	95% Conf. Lower	95% Conf. Upper	Intercept	95% Conf. Lower	95% Conf. Upper	Correlation	Bias at 50th Percentile Level	Bias	95% Conf. Lower	95% Conf. Upper	Acceptance Limit
WBC	10³ cells/uL	80	8.545	8.509	-0.036	-0.132	0.060	0.982	0.972	0.992	0.040	0.019	0.061	0.999	6.857	-0.085	-0.144	-0.026	0.34
RBC	10⁶ cells/uL	91	3.803	3.827	0.024	0.008	0.039	1.013	0.998	1.028	-0.025	-0.079	0.029	0.997	3.747	0.023	0.008	0.038	0.11
HGB	g/dL	91	11.078	11.182	0.103	0.060	0.147	1.022	1.000	1.043	-0.135	-0.369	0.098	0.997	11.165	0.105	0.061	0.149	0.33
HCT	%	91	33.125	33.104	-0.021	-0.180	0.138	0.994	0.972	1.016	0.178	-0.504	0.861	0.996	33.259	-0.022	-0.183	0.140	1.33
MCV	fL	91	87.770	87.279	-0.491	-0.778	-0.204	1.027	0.989	1.066	-2.903	-6.250	0.443	0.986	88.180	-0.479	-0.772	-0.186	2.65
MCH	pg	91	29.499	29.576	0.077	-0.057	0.211	0.973	0.919	1.027	0.882	-0.648	2.411	0.979	29.576	0.075	-0.060	0.210	1.48
MCHC	g/dL	91	33.575	33.867	0.292	0.112	0.472	0.863	0.701	1.025	4.902	-0.525	10.330	0.788	33.571	0.292	0.125	0.460	1.68
RDW	%	91	16.075	16.259	0.184	-0.017	0.385	0.961	0.859	1.063	0.810	-0.783	2.403	0.953	15.419	0.209	0.020	0.399	2.00
RDWSD	fL	91	48.716	49.786	1.069	0.476	1.663	0.915	0.843	0.987	5.202	1.797	8.607	0.964	46.375	1.268	0.732	1.804	7.50
PLT	10³cells/uL	68	308.183	313.679	5.496	-1.106	12.098	1.018	0.979	1.058	-3.279	-10.007	3.449	0.991	280.456	1.909	-4.066	7.884	28.05
MPV	fL	75	8.823	9.363	0.540	0.358	0.722	0.967	0.795	1.138	0.832	-0.648	2.311	0.777	8.643	0.546	0.370	0.723	1.00
LY	%	55	33.223	33.879	0.656	0.207	1.105	0.992	0.956	1.027	0.938	-0.131	2.006	0.990	32.994	0.658	0.199	1.117	3.30
LY	10³ cells/uL	55	2.585	2.594	0.009	-0.037	0.056	0.986	0.966	1.006	0.042	0.035	0.049	0.997	1.842	0.016	-0.021	0.053	0.20
MO	%	55	11.519	10.942	-0.576	-0.882	-0.271	0.983	0.921	1.045	-0.382	-1.089	0.325	0.990	9.225	-0.537	-0.847	-0.227	2.00
MO	10³ cells/uL	55	0.832	0.787	-0.044	-0.073	-0.015	0.900	0.722	1.078	0.021	-0.080	0.122	0.984	0.629	-0.042	-0.064	-0.020	0.20
NE	%	55	51.881	51.800	-0.081	-0.415	0.253	1.009	0.992	1.026	-0.560	-1.492	0.371	0.998	53.534	-0.066	-0.407	0.276	5.35
NE	10³ cells/uL	55	4.837	4.793	-0.044	-0.118	0.030	0.974	0.940	1.009	0.004	-0.024	0.032	0.998	3.649	-0.089	-0.193	0.015	0.36
EO	%	55	2.711	3.026	0.315	0.137	0.494	0.957	0.831	1.082	0.433	0.132	0.734	0.970	1.672	0.360	0.193	0.527	1.50
EO	10³ cells/uL	55	0.198	0.219	0.021	0.007	0.036	1.039	0.939	1.139	0.013	-0.005	0.032	0.970	0.120	0.018	0.005	0.032	0.15
BA	%	55	0.666	0.352	-0.314	-0.470	-0.159	0.084	-0.067	0.236	0.296	0.197	0.395	0.245	0.557	-0.214	-0.262	-0.165	1.00
BA	10³ cells/uL	55	0.052	0.029	-0.023	-0.034	-0.012	0.615	0.468	0.762	0.001	-0.001	0.002	0.526	0.043	-0.018	-0.023	-0.012	0.10

Table 3 Regression Statistics

Age Group	Female	Male	Total
Neonate (0 to 30 days)	13	7	20
Infant (31 days to 2 years)	14	13	27
Child (3 to 12 years)	48	46	94
Adolescent (13 to 21 years)	33	34	67
TOTAL	108	100	208

Table 4 Gender Distribution by Age of Reference Interval cohort

Age Group	Female	Male	Total
Neonate (0 to 30 days)	1	4	5
Infant (31 days to 2 years)	8	8	16
Child (3 to 12 years)	18	19	37
Adolescent (13 to 21 years)	12	21	33
TOTAL	39	52	91

Table 5 Gender Distribution by Age of Accuracy to Predicate Cohort

REFERENCES

Soldin, Steven J., Edward C. Wong, and Brugnara Carlo, eds. Pediatric Reference Intervals. 7th ed. AACC Press; 2011

https://seattlechildrenslab.testcatalog.org/show/CBC-No-Diff (30 May 2018)

CLSI EP28-A3c Defining, Establishing, and Verifying Reference Intervals in the Clinical Laboratory; Approved Guideline. October 2010

CLSI EP09-A3 Measurement Procedure and Bias Estimation Using Patient samples; Approved Guideline-Third Edition. August 2013

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.