

HemoPoint[®] H2

Specifications and Technical Data



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HemoPoint® H2 SPECIFICATIONS

Methodology	Optical absorption photometry
Principle.....	Azidemethemoglobin
Calibration.....	Factory calibrated
Sample Type.....	Capillary, venous, or arterial blood
Sample Size	10 µL
Hematocrit Range.....	36 – 54% (calculated)
Linearity	0 – 23.5 g/dL
Within Run Precision CV.....	< 1%
Total Precision CV	< 1.2%



HemoPoint® H2 PRECISION EVALUATION

Precision Evaluation with Control Material

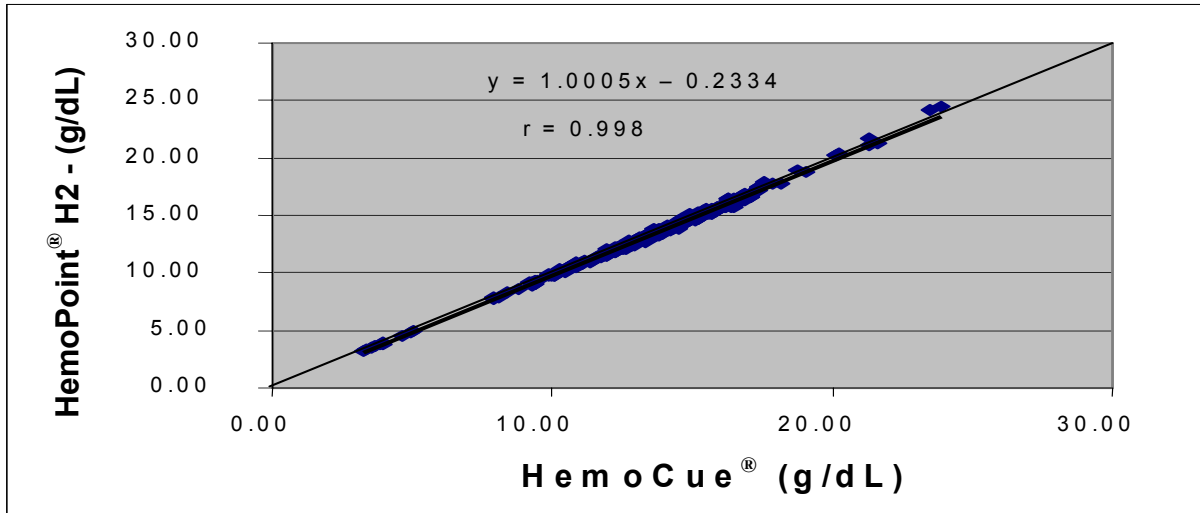
	HemoPoint® H2 Microcuvette (measured in HemoPoint® H2 Photometer)
Hemoglobin/low (8.2 g/dL) Within-Run precision (NCCLS EP5-A): Total precision (NCCLS EP5-A):	SD _{wr} 0.081 g/dL, CV 1.0% SD _T 0.092 g/dL, CV 1.2%
Hemoglobin/normal (12.0 g/dL) Within-Run precision (NCCLS EP5-A): Total precision (NCCLS EP5-A):	SD _{wr} 0.067 g/dL, CV 0.6% SD _T 0.111 g/dL, CV 0.9%
Hemoglobin/high (16.0 g/dL) Within-Run precision (NCCLS EP5-A): Total precision (NCCLS EP5-A):	SD _{wr} 0.039 g/dL, CV 0.2% SD _T 0.062 g/dL, CV 0.4%
Between-Day Imprecision Single observation, 20 days	8.0 g/dL: SD 0.080 g/dL, CV 1.0% 11.8 g/dL: SD 0.094 g/dL, CV 0.8% 15.7 g/dL: SD 0.091 g/dL, CV 0.6%

Results of precision evaluation experiment measuring a HemoPoint® H2 microcuvette in a HemoPoint® H2 photometer.

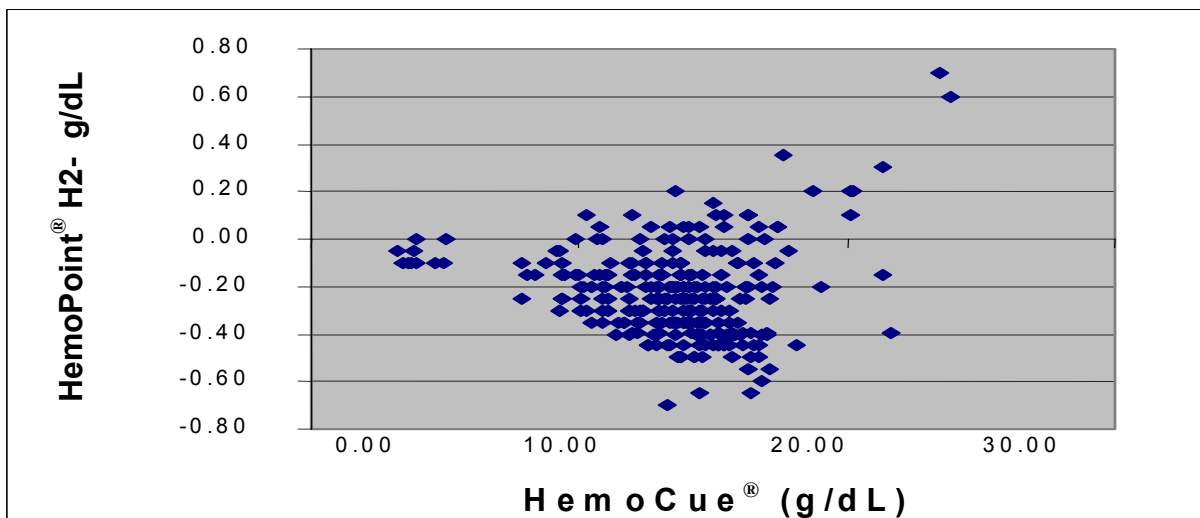


WHOLE BLOOD SITE STUDY SUMMARY

HemoPoint® H2 vs. HemoCue® Site Study



HemoPoint® H2 vs. HemoCue® Site Study



Linear Agreement/Bias (HemoPoint® H2 vs. HemoCue®)

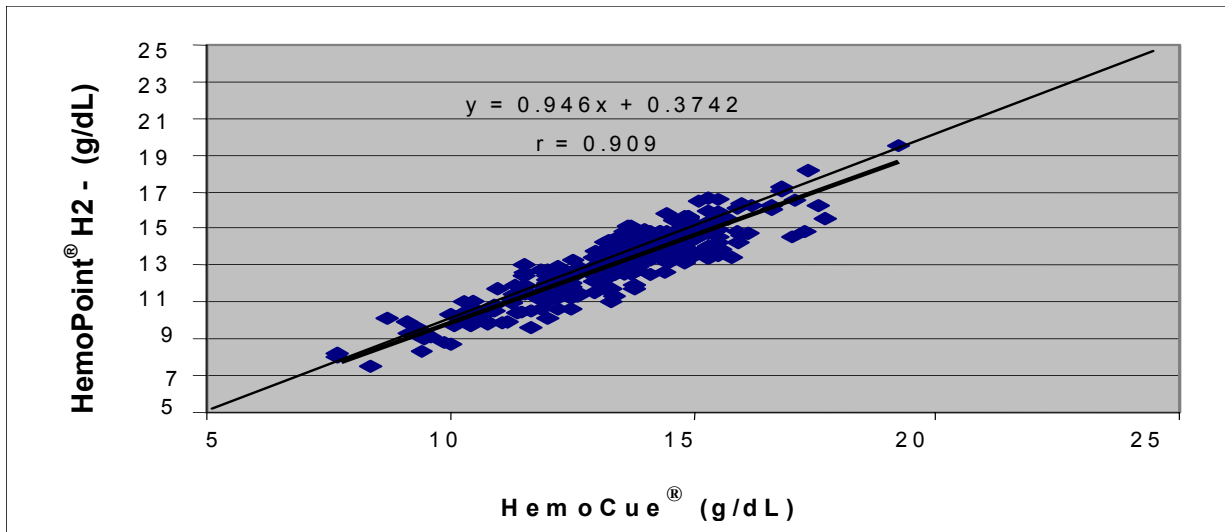
Parameter		95% Confidence interval upper limit	95% Confidence interval lower limit
Intercept (g/dL)	-0.233	-0.334	-0.133
Slope of the regression line	1.00	0.993	1.008
Correlation coefficient (r)	0.998		
Standard error, SE for residuals (g/dL)	0.189		
n (number of samples)	286		
Bias (mean difference in g/dL)	-0.226	-0.248	-0.204

Calculation of linear agreement and bias. HemoPoint® H2 system (Mean of Replicates) compared with HemoCue® system (Mean of Replicates), venous samples summary of all study sites (including children and diluted/concentrated samples).



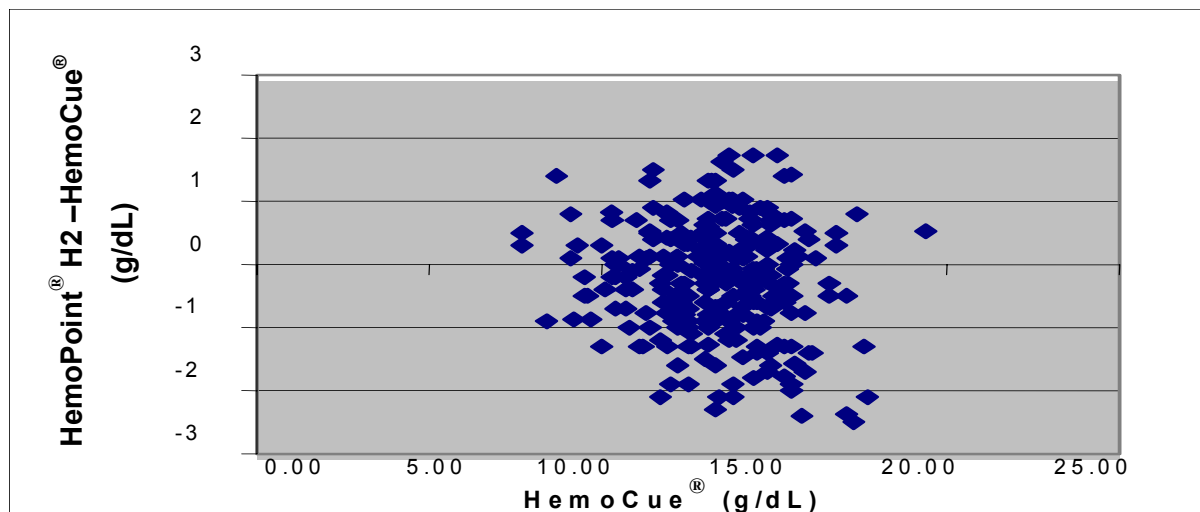
CAPILLARY BLOOD SITE STUDY SUMMARY

HemoPoint® H2 vs. HemoCue® Site Study



Scatter Plot for HemoPoint® H2 system vs. HemoCue® system, capillary samples summary of all study sites.

HemoPoint® H2 vs. HemoCue® Site Study



Bias Plot **HemoPoint® H2** system– HemoCue® system vs. HemoCue® system, capillary samples summary of all study sites.

Linear Agreement/Bias (HemoPoint® H2 vs. HemoCue®)

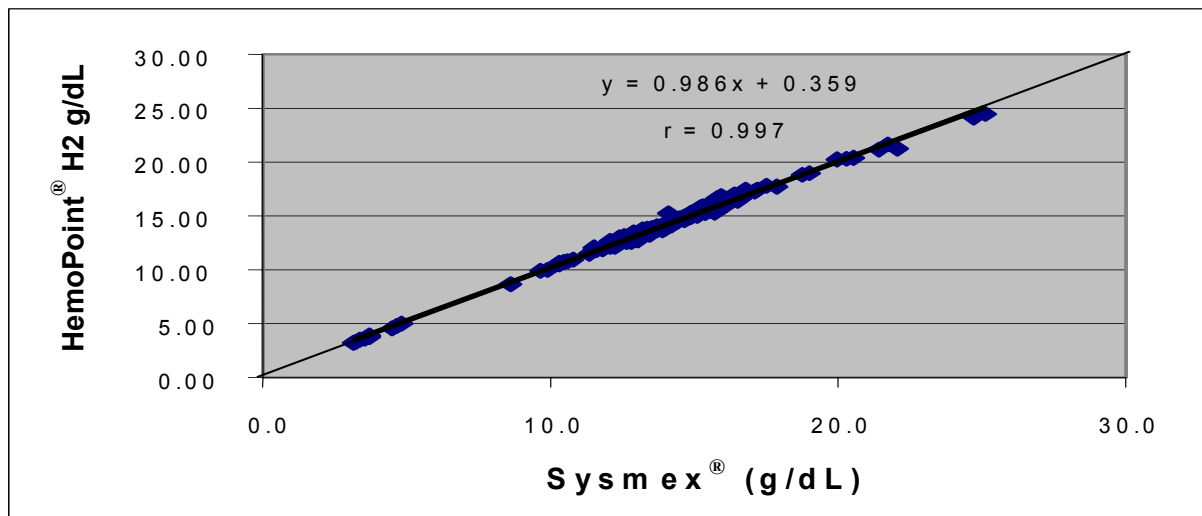
Parameter		95% Confidence interval upper limit	95% Confidence interval lower limit
Intercept (g/dL)	0.374	-0.326	1.074
Slope of the regression line	0.946	0.894	0.998
Correlation coefficient R	0.909		
Standard error, SE for residuals (g/dL)	0.819		
n (number of samples)	275		
Bias (mean difference in g/dL)	-0.347	-0.445	-0.250

Calculation of linear agreement and bias. **HemoPoint® H2** system compared with HemoCue® system, capillary samples summary of all study sites.



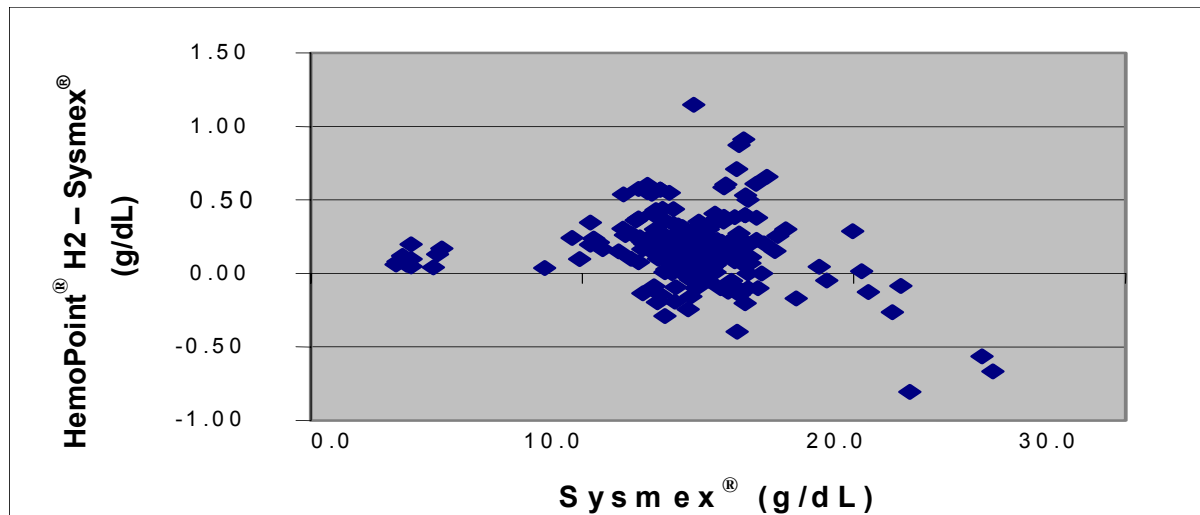
SYSMEX[®] HEMATOLOGY ANALYZER SITE STUDY SUMMARY

HemoPoint[®] H2 vs. Sysmex[®] Site Study



Scatter Plot for HemoPoint[®] H2 system (Mean of Replicates) vs. Sysmex[®] venous samples, summary of all study sites.

HemoPoint[®] H2 vs. Sysmex[®] Site Study



Bias Plot HemoPoint[®] H2 system (Mean of Replicates) vs. Sysmex[®], venous samples, summary of all study sites.

Linear Agreement/Bias (HemoPoint[®] H2 vs. Sysmex[®] SE 9500)

Parameter		95% Confidence interval upper limit	95% Confidence interval lower limit
Intercept (g/dL)	0.359	0.210	0.508
Slope of the regression line	0.986	0.976	0.996
Correlation coefficient (r)	0.997		
Standard error, SE for residuals (g/dL)	0.240		
n (number of samples)	195		
Bias (mean difference in g/dL)	0.165	0.244	0.017

Calculation of linear agreement and bias. HemoPoint[®] H2 system (Mean of Replicates) compared with Sysmex[®] SE 9500, venous samples summary of all study sites.



REFERENCES

- 1 HemoCue[®] Blood Hemoglobin Photometer, Operating Manual, HemoCue AB, Ängelholm, Sweden
- 2 Reference and Selected Procedures for the Quantitative Determination of Hemoglobin in Blood; Approved Standard-Third Edition, NCCLS
- 3 Insert, B-Hemoglobin Microcuvettes, HemoCue AB, Ängelholm, Sweden

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