

CLIAwaived.com

HemoPoint® H2

Accurate hemoglobin and hematocrit results with one simple test.

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CLIAwaived.com - 4332 Corte de la Fonda - San Diego, CA 92130
Toll Free : (888) 882-7739 - Phone (858) 481-5031
FAX: (801) 720-7568 - www.cliawaived.com

The World's Source For Clinical Diagnostics



Get precise hemoglobin and hematocrit results —both in the same test!

One test. Two results.

Fast.

Using a single drop of blood, Stanbio's **Hemo**Point® **H2** offers accurate results for both hemoglobin and hematocrit tests—in less than a minute! The easy-to-read touch screen displays the current time, battery status and allows for easy operation.

Advanced.

Utilizing proven microcuvette technology, the **Hemo**Point® **H2** features a proprietary "soft load" cuvette holder to minimize blood contamination of the meter. The hemoglobin result is flagged if it is outside the user-defined limits.

Easy to Use.

The **Hemo**Point® **H2**'s user-friendly sampling technique minimizes training time and its rechargeable battery makes it completely mobile. Recall the last 100 test results with the touch of a button and attach an optional printer to record patient's test results—immediately, or from stored memory!



HemoPoint® **H2** Products

Catalog No. G3000-001

Photometer

Includes **Hemo**Point® **H2** Photometer, user guide, quick reference guide, optics cleaner, control cuvette, power adaptor, training CD and wall chart



Catalog No. 3010-100

100 Microcuvettes

Includes two containers of 50 cuvettes each

Catalog No. 3010-200

200 Microcuvettes

Includes four containers of 50 cuvettes each



Catalog No. 3060-601

Hgb Controls

Includes set of six dropper bottles:
2 x 1.5 mL-low, 2 x 1.5 mL-normal, 2 x 1.5 mL-high

Catalog No. 3050-001

Optics Cleaner

Catalog No. G3100-001

Printer, DPU-414

Thermal printer with power adaptor and cable

HemoPoint® **H2** Specs

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%

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ISO13485:2003 KEMA CERTIFIED

CPT CODE: 85018QW

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HemoPoint® H2 PRECISION EVALUATION

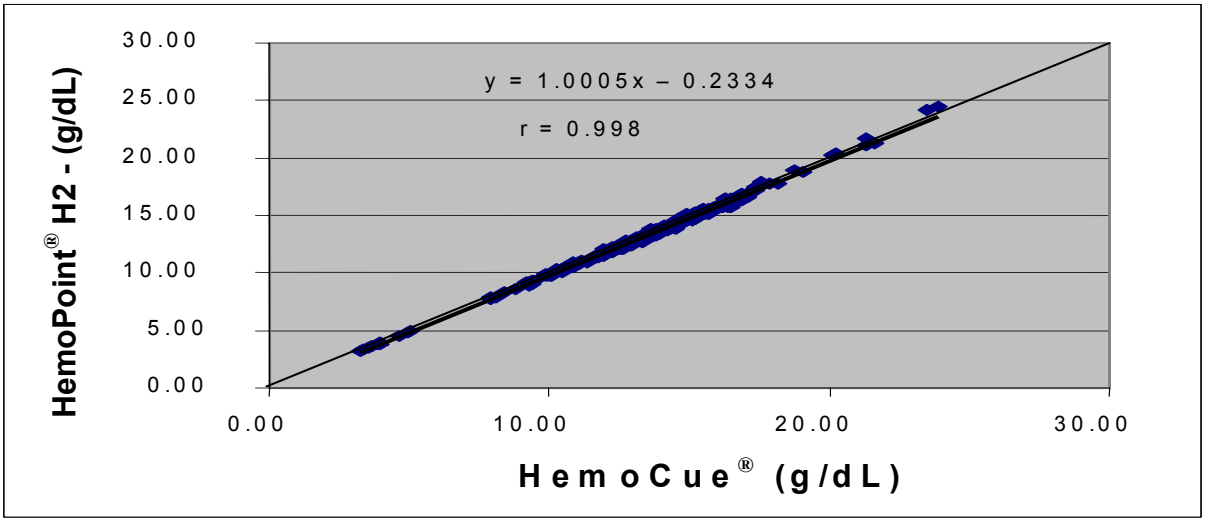
Precision Evaluation with Control Material

	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.

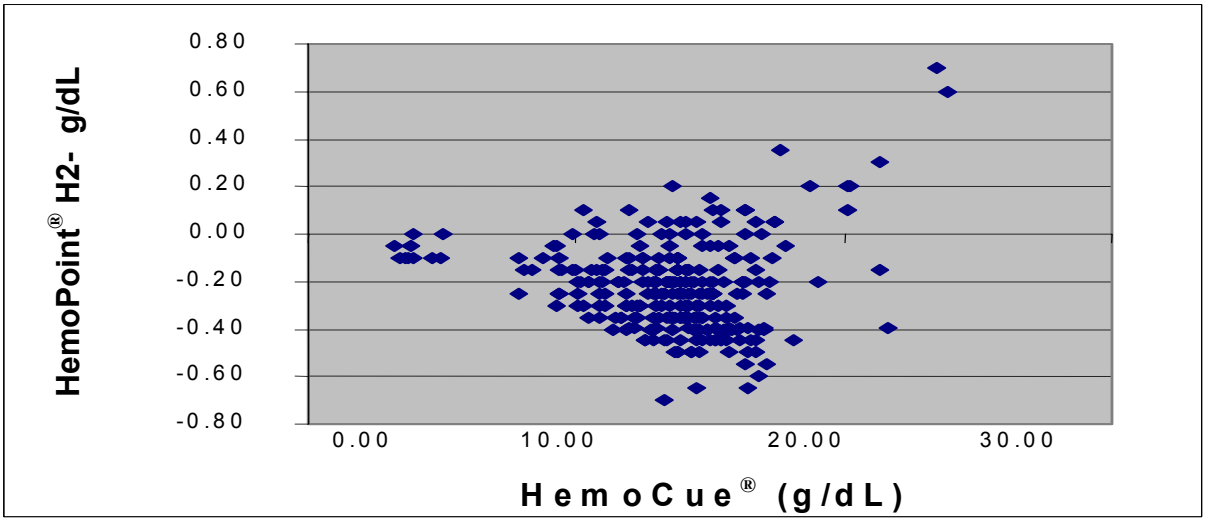
WHOLE BLOOD SITE STUDY SUMMARY

HemoPoint® H2 vs. HemoCue® Site Study



Scatter Plot for **HemoPoint® H2** system (Mean of Replicates) vs. HemoCue® system (Mean of Replicates), venous samples summary of all study sites (including children as well as diluted and concentrated samples).

HemoPoint® H2 vs. HemoCue® Site Study



Bias Plot **HemoPoint® H2** system (Mean of Replicates) vs. HemoCue® system (Mean of Replicates), venous samples summary of all study sites (including children and diluted/concentrated samples).

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

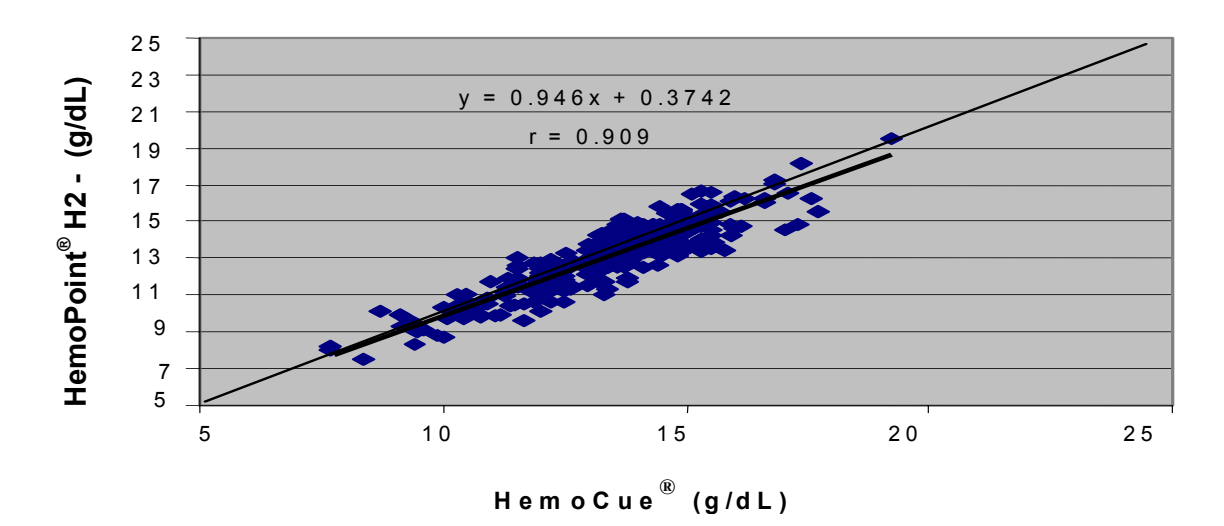
Parameter		95% Confidence interval upper limit	95% Confidence interval lower limit
Intercept (g/dL)	-0.233	-0.334	-0.133
Slope of the regression line	1.00	0.993	1.008
Correlation coefficient (r)	0.998		
Standard error, SE for residuals (g/dL)	0.189		
n (number of samples)	286		
Bias (mean difference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

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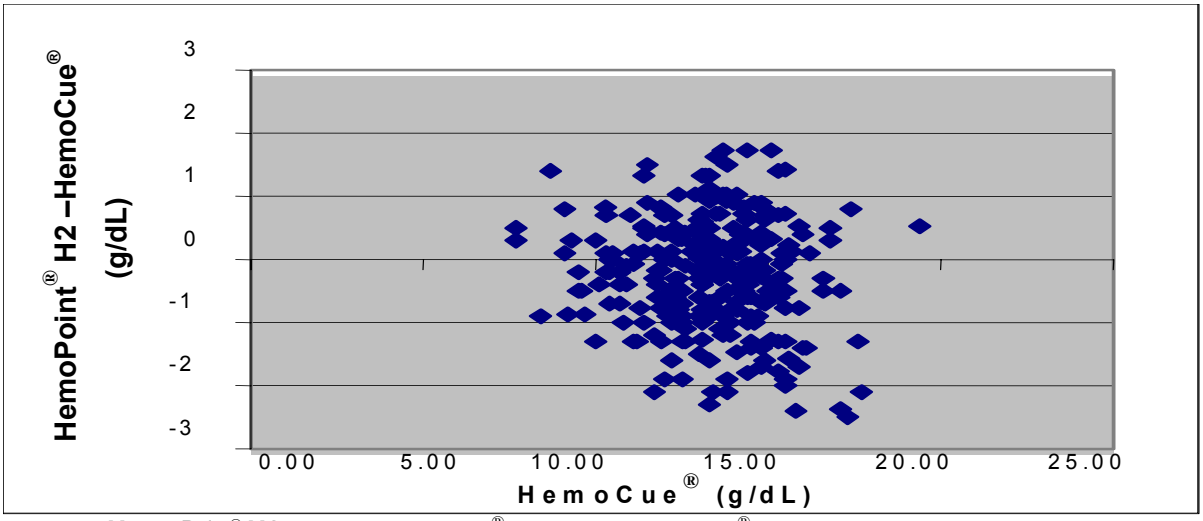
CAPILLARY BLOOD SITE STUDY SUMMARY

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®)

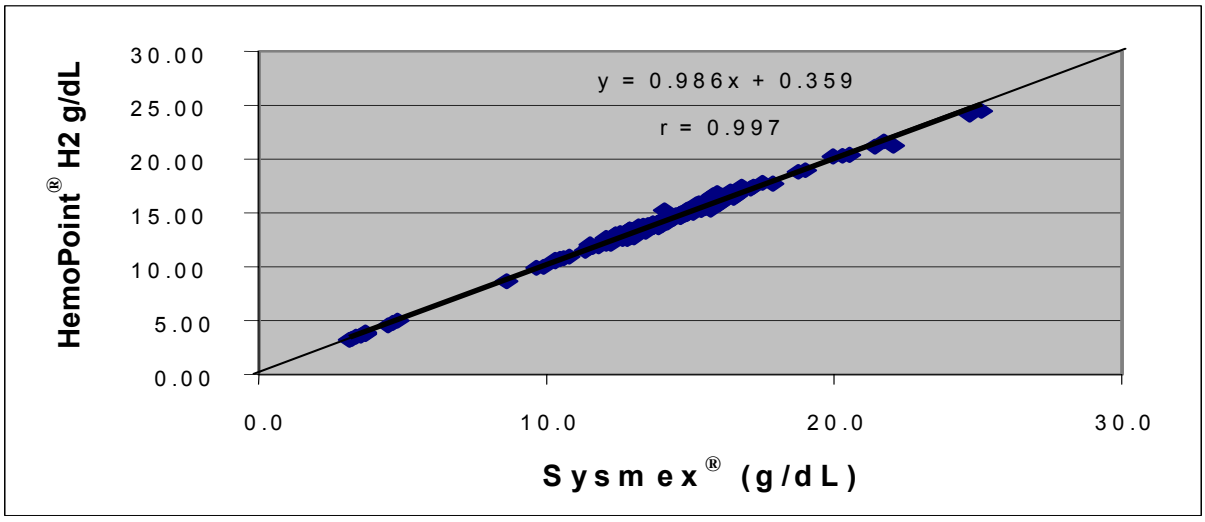
Parameter		95% Confidence interval upper limit	95% Confidence interval lower limit
Intercept (g/dL)	0.374	-0.326	1.074
Slope of the regression line	0.946	0.894	0.998
Correlation coefficient R	0.909		
Standard error, SE for residuals (g/dL)	0.819		
n (number of samples)	275		
Bias (mean difference in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

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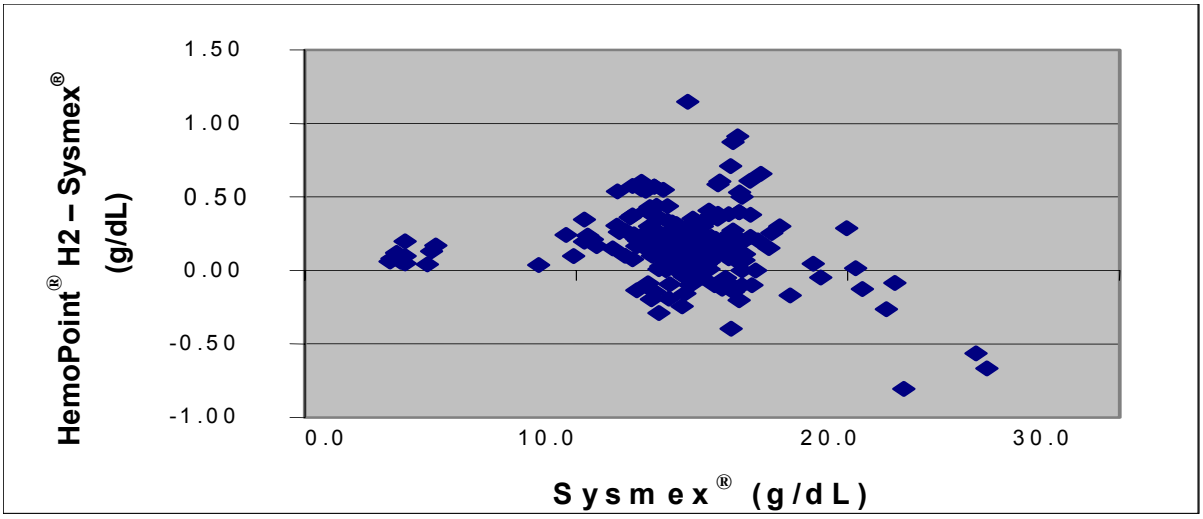
SYSMEX® HEMATOLOGY ANALYZER SITE STUDY SUMMARY

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.

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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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