



CLIAwaived.com



## HemoPoint<sup>®</sup> H2

Accurate hemoglobin  
and hematocrit results  
with one simple test.

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**CLIAwaived<sup>™</sup>.com**

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

# One test. Two results.

## Fast.

Using a single drop of blood, Stanbio's **HemoPoint® 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 **HemoPoint® 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 **HemoPoint® 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 **HemoPoint® 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%                               |



ST BIO  
LABORATORY

## HemoPoint® H2 SPECIFICATIONS

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|                               |                                      |
|-------------------------------|--------------------------------------|
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| Total Precision CV .....      | < 1.2%                               |

## HemoPoint® H2 PRECISION EVALUATION

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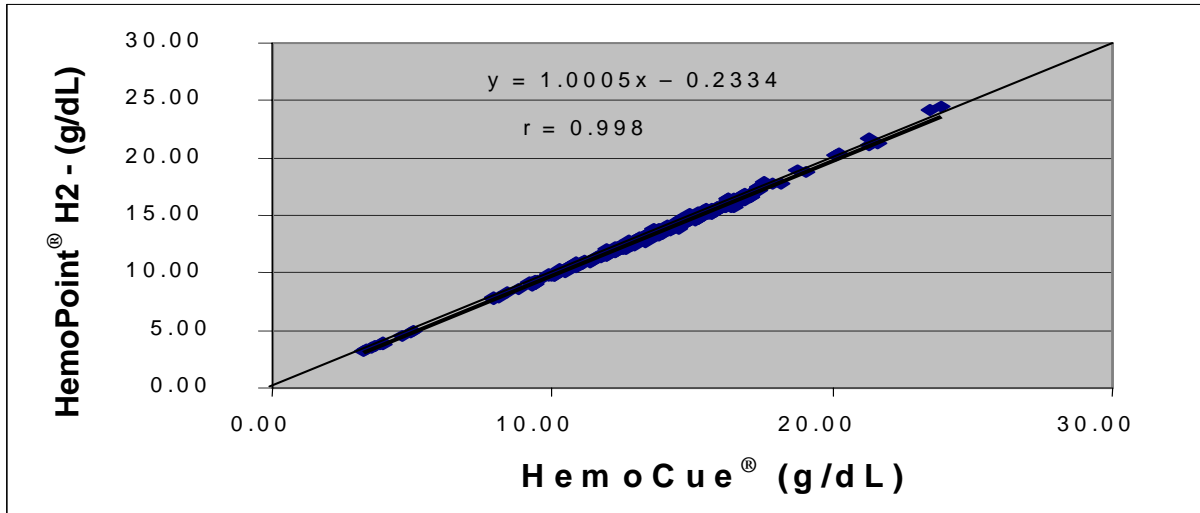
### Precision Evaluation with Control Material

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

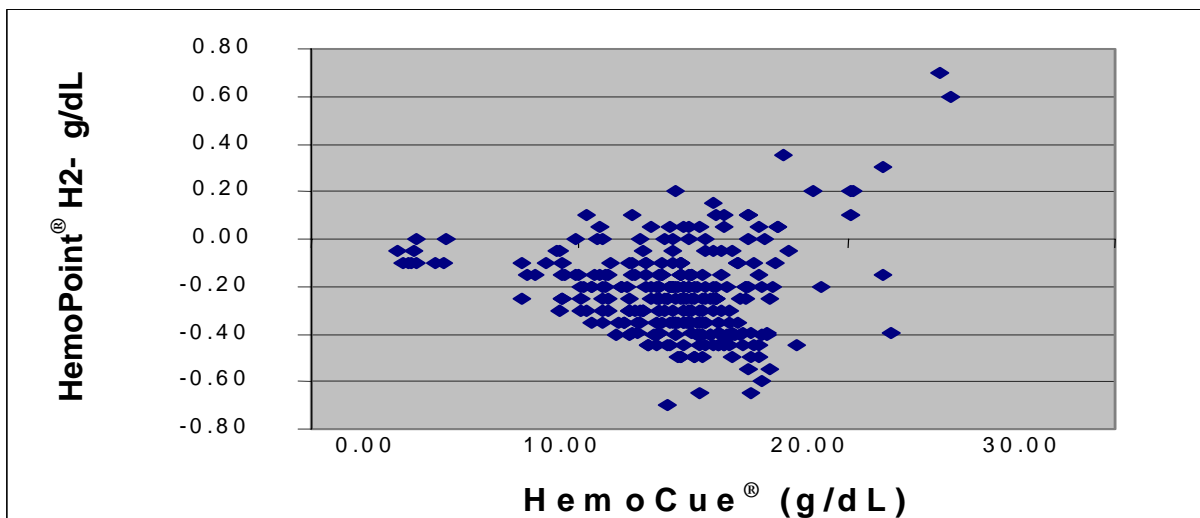
# WHOLE BLOOD SITE STUDY SUMMARY

## 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).

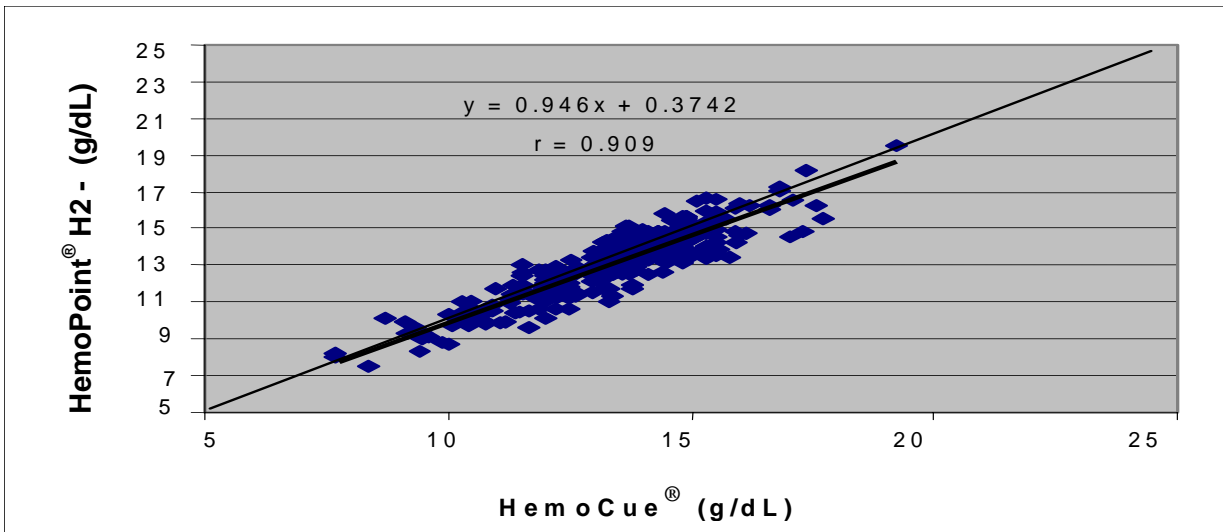
## Linear Agreement/Bias (HemoPoint® H2 vs. HemoCue®)

| Parameter                               |        | 95% Confidence interval<br>upper limit | 95% Confidence interval<br>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).

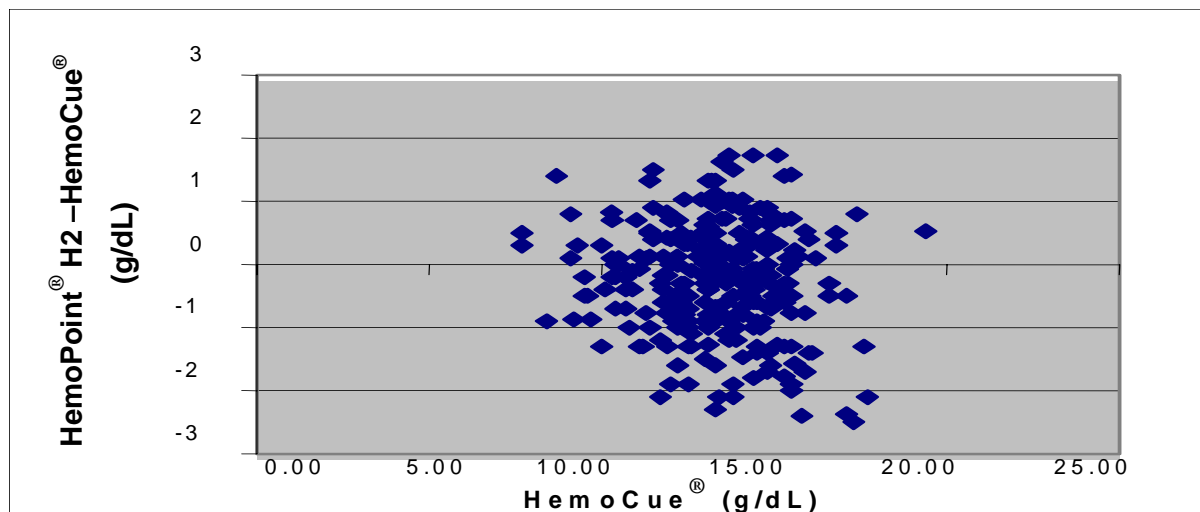
## CAPILLARY BLOOD SITE STUDY SUMMARY

### 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.

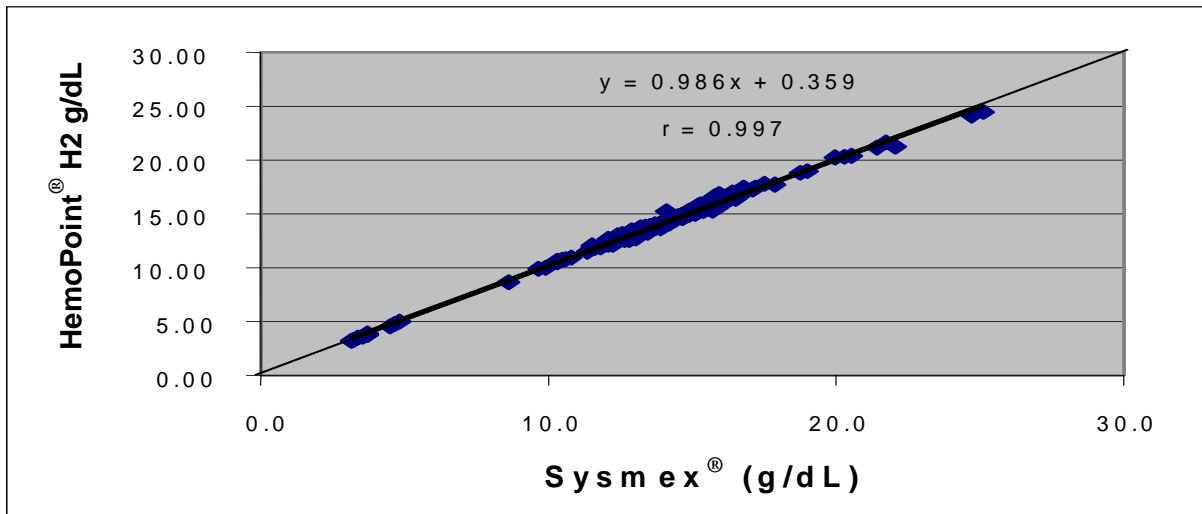
### Linear Agreement/Bias (HemoPoint® H2 vs. HemoCue®)

| Parameter                               |        | 95% Confidence interval<br>upper limit | 95% Confidence interval<br>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.

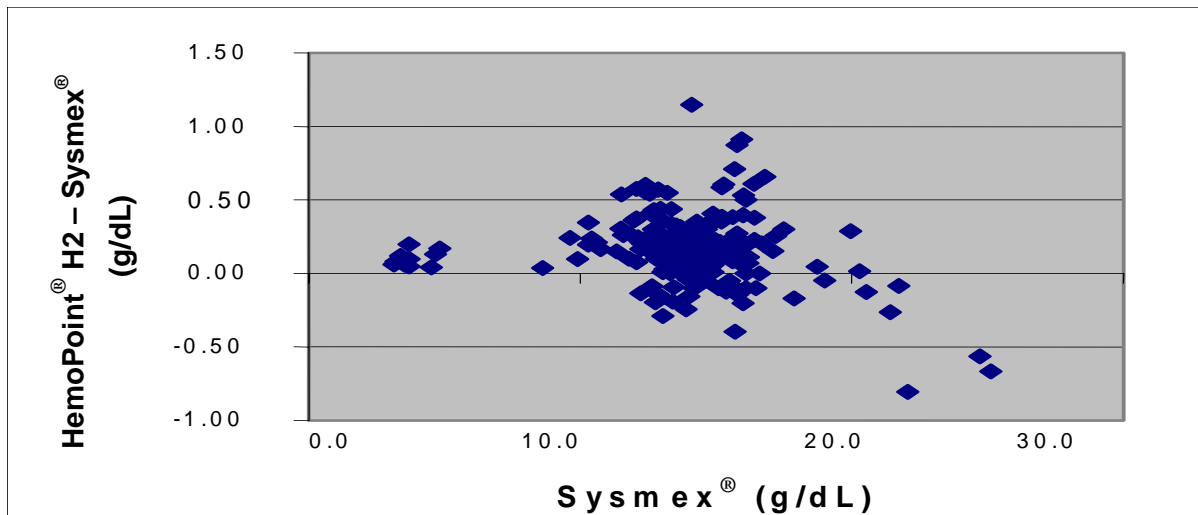
# SYSMEX<sup>®</sup> HEMATOLOGY ANALYZER SITE STUDY SUMMARY

## HemoPoint<sup>®</sup> H2 vs. Sysmex<sup>®</sup> Site Study



Scatter Plot for HemoPoint<sup>®</sup> H2 system (Mean of Replicates) vs. Sysmex<sup>®</sup> venous samples, summary of all study sites.

## HemoPoint<sup>®</sup> H2 vs. Sysmex<sup>®</sup> Site Study



Bias Plot HemoPoint<sup>®</sup> H2 system (Mean of Replicates) vs. Sysmex<sup>®</sup>, venous samples, summary of all study sites.

## Linear Agreement/Bias (HemoPoint<sup>®</sup> H2 vs. Sysmex<sup>®</sup> SE 9500)

| Parameter                               |       | 95% Confidence interval<br>upper limit | 95% Confidence interval<br>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<sup>®</sup> H2 system (Mean of Replicates) compared with Sysmex<sup>®</sup> SE 9500, venous samples summary of all study sites.

## REFERENCES

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- 1 HemoCue<sup>®</sup> 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