IVD

US

HemoCue® Hb 801 Microcuvettes, 4x50 Microcuvettes
HemoCue Hb 801 System consists of HemoCue Hb 801 Analyzer and HemoCue Hb 801 Microcuvettes. Read and follow this package insert together with the operating manual (provided with the analyzer), for optimum performance and safety. For more information, contact the local distributor or HemoCue America.
Only use HemoCue Hb 801 Analyzer together with HemoCue Hb 801 Microcuvettes.

Intended Use
The HemoCue Hb 801 System is intended for the quantitative determination of hemoglobin in capillary or venous whole blood (K_2EDTA and Li-Heparin) in point-of-care settings. The HemoCue Hb 801 System is intended to be used to determine the hemoglobin concentration for adults, adolescents, children, and infants above 1 month old. The HemoCue Hb 801 System is for professional *in vitro* diagnostic use only.

Composition
The microcuvettes are made of polystyrene plastic, and contain no active ingredients.

Precautions
Always wear protective gloves. Handle blood with care, as it may be infectious. Follow local safety procedures for disposal of used microcuvettes.
HemoCue Hb 801 Microcuvettes are for single use only.
For system information regarding precautions, read the operating manual.

Storage and Handling
Store the microcuvettes in 10–40 °C (50–104 °F). Microcuvettes in the vial (opened or unopened) are stable until expiration date, printed on the package. Use the microcuvettes prior to expiration date.
Microcuvettes in the vial (opened or unopened) can be stored for a shorter period of time (6 weeks) between -18–50 °C (0–122 °F). Keep all unused microcuvettes in the original package.

Measuring
Operating temperature for HemoCue Hb 801 System is 10–40 °C (50–104 °F).
For proper use of the system, read the operating manual regarding measuring capillary and venous samples, measuring control material, cleaning and disinfection, principle of method, and technical specifications.
Make sure the microcuvette is completely filled before measuring. Immediately after filling, insert the microcuvette into the analyzer to perform a measurement. Do not let more than 40 seconds pass.

Quality Control
The HemoCue Hb 801 Analyzer has an internal quality control, a self-test. For more information, read the operating manual. If an external quality control is required by local or other regulations, use quality control material: Eurotrol HemoTrol® Duo or Eurotrol HemoTrol® WB. Only use controls recommended by HemoCue.

Expected Values
Due to a wide range of conditions (dietary, geographical, etc.), which affect normal values, it is recommended that each laboratory establishes its own normal range. For general guidance to normal reference values applicable to most healthy adults and children, see reference ranges below.

Subject Group	Age	Hb, g/dL
Infant*	>1 month–2 years	9.4–14.1
Child*	>2–12 years	11.0–15.5
Adolescent**	>12–21 years	10.9–15.1
Adult male*	>21 years	13.0–17.0
Adult female*	>21 years	12.0–15.0

* According to Dacie and Lewis, Practical Haematology
** According to Soldin, Pediatric Reference Intervals

Specific Performance Characteristics

Precision

Results summarized below were determined according to CLSI EP05-A3.

			Repeatability		Within-laboratory Precision		Reproducibility	
Control Level	N	$\bar{x}$ g/dL	SD g/dL	CV %	SD g/dL	CV %	SD g/dL	CV %
1	240	6.34	0.05	0.7	0.04	0.7	0.06	0.9
2	240	11.50	0.05	0.4	0.05	0.5	0.06	0.5
3	240	15.36	0.15	1.0	0.16	1.0	0.17	1.1

Results summarized from capillary precision study (repeatability):

Hb Level g/dL	N	Min g/dL	Max g/dL	SD g/dL	CV %
≤7.0	2	1.4	5.0	0.11	--
>7.0	40	7.1	23.3	--	2.3

Accuracy

Results summarized below were determined according to CLSI EP09-A3.

Study	N	Min g/dL	Max g/dL	Regression Line	Correlation Coefficient (r)
1	102	1.3	23.6	Y = 0.99X + 0.09	1.00
2	100	11.8	18.4	Y = 0.96X + 0.92	0.92

1 = venous blood, compared to the HiCN reference method according to the International Council for Standardization in Haematology (ICSH)
2 = capillary blood, compared to the HiCN reference method according to the International Council for Standardization in Haematology (ICSH)

Method Comparison

Results summarized below were determined according to CLSI EP09-A3.

Study	N	Min g/dL	Max g/dL	Regression Line	Correlation Coefficient (r)
1	264	1.5	25.4	Y = 1.00X - 0.14	1.00
2	233	4.7	23.2	Y = 1.07X - 0.91	0.96

1 = multicenter study, venous blood, compared to HemoCue Hb 301
2 = multicenter study, capillary blood, compared to HemoCue Hb 301

Non-interfering Substances

The following substances have been tested according to CLSI EP07 at hemoglobin concentrations 10±0.5 and 20±1.0 g/dL. No interference was found at following concentrations of the substances tested.

Substance	Test Concentration	Unit
Acetaminophen	1324	µmol/L
Ascorbic acid	342	µmol/L
Creatinine	442	µmol/L
HbCO	10	%
HbO_2	≤ 50	%
Hemolysis	10	g/L
Ibuprofen	2425	µmol/L
MetHb*	25	%
Platelets	2000	x 10^9/L

Substance	Test Concentration	Unit
Total protein	15	g/dL
Salicylic acid	4.34	mmol/L
Simvastatin	49	µmol/L
Tetracycline	34	µmol/L
Triglyceride	1500	mg/dL
Urea	42.9	mmol/L
Uric acid	1.4	mmol/L
Warfarin	32.5	µmol/L

* Multiple concentrations of MetHb up to 25% were tested and do not interfere with hemoglobin measurement at Hb-level 10±0.5 or 20±1.0 g/dL.

Normal blood pH and above, up to 8, at Hb level 10±0.5 or 20±1.0 g/dL do not interfere with the system. The test has been performed according to CLSI EP07.

Limitations

a) Start the measurement immediately after filling the microcuvette. Do not let more than 40 seconds pass.
b) Venous samples (K_2EDTA or Li-Heparin) can be stored and transported for up to 24 hours in room temperature or refrigerator, before measuring.
c) The following substances have been tested according to CLSI EP07 to determine the interfering concentration.

Substance	Concentration (unit)	Hb Concentration (g/dL)	Result
Conjugated bilirubin	>23 (mg/dL)	10	Interfering*
	Up to 40 (mg/dL)	20	Non-interfering
Unconjugated bilirubin	>12 (mg/dL)	10	Interfering*
	>23 (mg/dL)	20	Interfering*
Intralipid®	>214 (mg/dL)	10	Interfering*
	>483 (mg/dL)	20	Interfering*
Leucocytes	>260 x 10^9/L	6.8–14.7	Interfering*

* May give elevated results in higher substance concentrations.

References

1. CLSI EP05-A3; Evaluation of Precision of Quantitative Measurement Procedures; Approved Guideline—Third Edition
2. CLSI EP07-A2; Interference Testing in Clinical Chemistry; Approved Guideline—Second Edition
3. CLSI EP07; Interference Testing in Clinical Chemistry; Approved Guideline—Third Edition
4. CLSI EP09-A3; Measurement Procedure Comparison and Bias Estimation Using Patient Samples; Approved Guideline—Third Edition
5. CLSI EP37; Supplemental Tables for Interference Testing in Clinical Chemistry, First Edition
6. CLSI H15-A3 Reference and Selected Procedures for the Quantitative Determination of Hemoglobin in Blood; Approved Standard—Third Edition
7. Dacie and Lewis, Practical Haematology, Elsevier Limited, 12th Edition, 2016 and references herein
8. HemoCue Hb 801 Operating Manual
9. Soldin, S. J., Pediatric Reference Intervals, AACC Press; 7th edition, 2011

Symbols Used

	Caution	LOT	Batch code
IVD	*In Vitro* Diagnostic medical device	REF	Catalog number
	Do not reuse		Temperature limitation
	Manufacturer		Consult instructions for use
	Use by (year month day)	PATENTED	This product is covered by one or more patents
			Date of manufacture

Manufacturer

HemoCue AB
Kuvettgatan 1
SE-262 71 Ängelholm
Sweden

Phone +46 77 570 02 10
Fax +46 77 570 02 12

info@hemocue.se
hemocue.com

HemoCue Distributor USA

HemoCue America
250 South Kraemer Boulevard
Brea, CA, 92821
USA

Phone (general) 800.881.1611
Phone (customer service) 800.323.1674
Phone (technical support) 800.426.7256
Fax (customer service) 800.333.7043

web@hemocue.com
hemocue.com

151904 220204 US