

HemoCue® Hb 201 Microcuvettes

The HemoCue Hb 201 Microcuvettes are designed for use with the HemoCue Hb 201+ Analyzer and the HemoCue Hb 201 DM Analyzer (referred to as the HemoCue Hb 201 Analyzer in this document). HemoCue Hb 201 Microcuvettes are available in individual packages or in vials. Please read the relevant Operating Manual for proper use of the system¹.

Intended Purpose/Intended Use

Quantitative determination of hemoglobin in capillary, venous and arterial whole blood, using a specially designed analyzer, the HemoCue Hb 201 Analyzer, and specially designed microcuvettes, the HemoCue Hb 201 Microcuvettes. HemoCue Hb 201 Microcuvettes are for *In Vitro* Diagnostic use only. The HemoCue Hb 201 Analyzer is only to be used with HemoCue Hb 201 Microcuvettes.

IVD Medical Device Directive

The HemoCue Hb 201 Microcuvettes comply with the IVD Medical Device Directive 98/79/EC and carry the CE mark

Principles of the method/procedure

Principle of the method

The reaction in the microcuvette is a modified azidemethemoglobin reaction. The erythrocytes are hemolyzed to release the hemoglobin. The hemoglobin is converted to methemoglobin and then combined with azide to form azidemethemoglobin. The measurement takes place in the analyzer in which the transmittance is measured and the absorbance and hemoglobin level is calculated. The absorbance is directly proportional to the hemoglobin concentration.

Principle of the procedure

The system consists of an analyzer together with microcuvettes. The microcuvette serves both as a pipette and as a measuring cuvette and is for single-use only. A blood sample of approximately 10 µL is drawn into the cavity by capillary action. The analyzer measures at two wavelengths in order to compensate for turbidity, and the hemoglobin level is calculated and presented. The HemoCue Hb 201 system is calibrated against the international reference method for hemoglobin determination, ICSH³ and needs no further calibration.

Composition

The microcuvette is made of polystyrene plastic. Reagents; <600 µg/g microcuvette sodium deoxycholate, <300 µg/g microcuvette sodium azide, <300 µg/g microcuvette sodium nitrite, <350 µg/g microcuvette nonreactive ingredients.

Warning and precautions

The microcuvettes are for *In Vitro* Diagnostic use only. Always handle blood specimens with care as they may be infectious. Consult local environmental authorities for proper disposal.

Storage and handling of the HemoCue Hb 201 Microcuvettes

The microcuvettes are to be stored at a temperature of 15–30 °C (59–86 °F) and in a dry place. Do not refrigerate. Use the microcuvettes prior to the expiration date that is printed on each package. Once the seal of the vial is broken, the microcuvettes are stable for three months. Keep the vial properly closed. All unused microcuvettes should remain in the original package.

Specimen collection and preparation

Capillary, venous or arterial blood may be used. Appropriate anticoagulants (e.g. EDTA or heparin) may be used, preferably in solid form to avoid dilutional effects. Mix all specimen tubes thoroughly on a mechanical mixer for at least 2 minutes or invert the tube 8–10 times by hand. Hemoglobin remains unchanged for days, provided that the blood does not become infected. If the specimen has been stored in a refrigerator, it will be viscous and the blood should be allowed to warm up to room temperature before mixing².

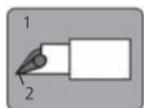
Directions for use

Materials required

- HemoCue Hb 201 Analyzer
- HemoCue Hb 201 Microcuvettes
- Lancet (for capillary samples)
- Pipette or other transfer device (for venous, arterial or control material samples)
- Lint-free wipe (non-fraying)
- Hydrophobic plastic or glass slide (for venous, arterial or control material samples)

Procedure

The operating temperature of the HemoCue Hb 201 system is 15-30 °C (59-86 °F). Please read the Operating Manual for proper use of the system¹. See relevant manual for information on repeat capillary sampling. For further information please contact HemoCue.



1. Optical eye
2. Filling end



Remove the microcuvette from the package. Close the vial. Hold the microcuvette opposite the filling end and bring into contact with the specimen, allowing the cavity to fill completely. Always avoid touching the optical eye. Do not refill the cavity of the microcuvette.



When collection tubes or control material are used, dispense an aliquot of the well-mixed specimen onto a hydrophobic plastic or glass slide.



Wipe off the outside of the microcuvette with a clean lint-free wipe, being careful not to touch the open end. If air bubbles are seen in the optical eye of the microcuvette, discard the microcuvette and take a new sample. Small air bubbles around the edge do not influence the result.



Place the filled microcuvette in the cuvette holder of the analyzer. Close the cuvette holder. After 15-60 seconds the result will appear on the display. Pull the cuvette holder out to its loading position and discard the used microcuvette.

Quality control

The HemoCue Hb 201 Analyzer has an internal electronic selftest. Every time the analyzer is turned on, it will automatically verify the measurement performance. This test is performed at regular intervals if the analyzer remains switched on. If quality control checks are required for regulatory reasons, contact HemoCue for current recommendations regarding controls. Please refer to local guidelines for recommended frequency of use.

Limitations of the method

- a) The measurement should be made as soon as possible after the blood has been drawn into the microcuvette. If readings are made after 10 minutes of filling the microcuvette, false results may be obtained.
- b) Mixing samples for an extended period can produce increased oxygen pressure and viscosity that may give falsely results.
- c) If “HHH” is displayed, the result exceeds the measuring range of the system.
- d) Values above 23.5 g/dL (235 g/L, 14.6 mmol/L) must be confirmed using a suitable laboratory method.
- e) Acetaminophen (20 mg/dL), ascorbic acid (3 mg/dL), conjugated bilirubin (40 mg/dL), unconjugated bilirubin (20 mg/dL), creatinine (30 mg/dL), ibuprofen (40 mg/dL), leukocytes ($600 \times 10^9 / L$), lipemia (intralipid 4000 mg/L, triglycerides approximately 1000 mg/dL), salicylic acid (50 mg/dL), tetracycline (20 mg/dL), trombocytes ($2100 \times 10^9 / L$), urea (500 mg/dL), uric acid (20 mg/dL) have not been found to interfere. The highest concentration or percentages tested is referred to in brackets. Interference studies have been performed according to NCCLS Document EP-7⁴.
- f) pH values between 6.3-9.0 do not interfere with the system.
- g) Sulfhemoglobin is not measured with this method.

Expected values²

Children	11.0-14.0 g/dL (110-140 g/L, 6.8-8.7 mmol/L)
Women	12.0-15.0 g/dL (120-150 g/L, 7.4-9.3 mmol/L)
Men	13.0-17.0 g/dL (130-170 g/L, 8.1-10.5 mmol/L)

Children, 2 years to teenage, gradually increase to adult values.

Due to a wide range of conditions (dietary, geographical, etc) which affect normal values, it is recommended that each laboratory establish its own normal range.

Specific performance characteristics

Within-run and Total precision

Within-run precision was determined according to the NCCLS Document EP5-A⁵. The results given below in "Within-run precision" and "Total precision" come from 1 batch of HemoCue Hb 201 Microcuvettes and 5 HemoCue Hb 201⁺ Analyzers. No recalibration was performed during the analyzing period. Commercially available controls at 2 different levels were used. The hemoglobin concentration was measured in duplicate twice a day, morning and afternoon, during 20 consecutive days.

Control level	N	\bar{x} g/dL	Within-run Precision		Total Precision	
			SD g/dL	CV %	SD g/dL	CV %
1	400	7.70	0.057	0.74	0.100	1.30
2	400	15.36	0.078	0.51	0.109	0.71

Accuracy

The results of the comparison studies between the HemoCue Hb 201 system and the International Council for Standardization in Haematology method (ICSH)³ are summarized in the table below. The study was performed on four HemoCue Hb 201⁺ Analyzer which had not been recalibrated during the study period.

Study	N	Min g/dL	Max g/dL	Regression line	Correlation coefficient (r)
1	498	4.1	20.5	$Y = 1.009X - 0.008$	0.998
2	103	9.0	17.7	$Y = 0.971X + 0.584$	0.934

1 = ICSH (Cyanmethemoglobin method), venous EDTA blood, multicenter study

2 = ICSH (Cyanmethemoglobin method), capillary blood

Bibliography

1. HemoCue Hb 201 Operating Manuals
2. Dacie and Lewis, Practical Haematology, Ninth Edition, 2001.
3. Reference and Selected Procedures for the Quantitative Determination of Hemoglobin in Blood; Approved Standard NCCLS Document H15-A
4. Interference testing in clinical chemistry NCCLS approved guideline; NCCLS Document EP-7
5. Evaluation of precision performance of clinical chemistry devices; approved Guideline NCCLS Document EP5-A

Symbols used



Attention, see instructions for use



Batch code



Use by
(Year Month Day)



In vitro diagnostic medical device



Catalog number



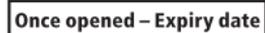
Date of opening



Do not reuse



Temperature limitation



Open vial expiry date. Must not exceed the "Use by" date



CE mark

PATENTED

This product is covered by one or more patents

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