



GB/US

HemoCue® Hb 301 Microcuvettes

The HemoCue Hb 301 Microcuvettes are designed for use with the HemoCue Hb 301 Analyzer. Please read the Operating Manual for proper use of the system¹.

Intended Purpose/Intended Use

The HemoCue Hb 301 System is designed for quantitative point-of-care whole blood hemoglobin determination in primary care or blood donation settings using a specially designed analyzer, the HemoCue Hb 301 Analyzer, and specially designed microcuvettes, the HemoCue Hb 301 Microcuvettes. The HemoCue Hb 301 System is for *In Vitro* Diagnostic use only. The HemoCue Hb 301 Analyzer is only to be used with HemoCue Hb 301 Microcuvettes.

IVD Medical Device Directive

The HemoCue Hb 301 Microcuvettes comply with the IVD Medical Device Directive 98/79/EC and carry the CE mark.

Principles of the method/procedure

The system consists of an analyzer together with microcuvettes. The microcuvette serves both as a pipette and as a measuring cuvette. A blood sample of approximately 10 µL is drawn into the cavity by capillary action. The measurement takes place in the analyzer, which measures the absorbance of whole blood at a Hb/HbO₂ isobestic point. The analyzer measures at two wavelengths (506 and 880 nm) in order to compensate for turbidity. The HemoCue Hb 301 System is calibrated against the hemiglobincyanide (HiCN) method, the international reference method for the determination of the hemoglobin concentration in blood³. The system is factory calibrated and needs no further calibration.

Composition

The microcuvette is made of polystyrene plastic and contains no active 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. The microcuvette is for single-use only.

Storage and handling of the HemoCue Hb 301 Microcuvettes

Microcuvettes are to be stored at 10–40 °C (50–104 °F). Microcuvettes in an opened or unopened vial are stable until expiration date printed on package. Use microcuvettes prior to expiration date. An unopened vial of microcuvettes can be stored for a shorter period of time (6 weeks) between -18–50 °C (0–122 °F). Keep vial properly closed. All unused microcuvettes should remain in original package.

Specimen collection and preparation

Capillary, venous or arterial blood may be used. EDTA or heparin should be used as anticoagulant, preferably in solid form to avoid dilutional effects. Tubes containing fluoride should not be used. 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.

Procedure

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.

Quality Control

The HemoCue Hb 301 Analyzer has an internal quality control, the "self test". 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. Upon passing the self test, the display will show the HemoCue symbol and three flashing dashes, indicating that the analyzer is ready to perform a measurement. An error code will be displayed if the self test fails. Follow local guidelines regarding quality control procedures. If a quality control test is to be performed, Hb 301 Control (available at different levels) from Eurotrol B.V. is recommended by HemoCue AB. For further information regarding quality controls contact HemoCue AB.

Limitations of the method









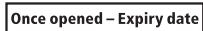


- a) The measurement needs to be started no later than 40 seconds after filling the microcuvette. If a second sample is to be taken, it is important that this is done after the measurement of the first sample is complete.
- b) Do not remeasure the microcuvette.
- c) Mixing samples for an extended period can produce increased oxygen pressure and viscosity that may give falsely results.
- d) If "HHH" is displayed, the result exceeds the measuring range of the system.
- e) Values above 23.0 g/dL (230 g/L, 14.3 mmol/L) must be confirmed using a suitable laboratory method.
- f) Following substances have not been found to interfere: Acetaminophen (20 mg/dL), ascorbic acid (4 mg/dL), conjugated bilirubin (8.4 mg/dL for Hb <10 g/dL, 20.3 mg/dL for Hb >10 g/dL), unconjugated bilirubin (5.2 mg/dL for Hb <10 g/dL, 13.5 mg/dL for Hb >10 g/dL), cholesterol (340 mg/dL), creatinine (30 mg/dL), HbCO (25%), hemolysis (25%), ibuprofen (40 mg/dL), leukocytes ($400 \times 10^9/L$), lipemia (intralipid 2400 mg/L, triglycerides approximately 770 mg/dL), methemoglobin (14%), salicylic acid (50 mg/dL), tetracycline (20 mg/dL), thrombocytes (2250×10^9), urea (500 mg/dL), uric acid (20 mg/dL). The highest concentration or percentages tested is referred to in brackets. Interference studies have been performed according to NCCLS Document EP7⁴.
- g) pH values between 6.3–9.0 do not interfere with the system.
- h) A limited number of samples from individuals with thalassemia have been tested. The results were slightly elevated.
- i) A limited number of samples from individuals with sickle cell anemia have been tested. The results were found to be accurate.
- j) Tubes containing flouride should not be used.


Bibliography

1. HemoCue Hb 301 Operating Manual.
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 EP7.

For additional study information, please refer to the Operating Manual¹.

Symbols used

| | | | | | |
|--|---------------------------------------|---|---------------------------------|---|---|
|  | Caution |  | Batch code |  | Use by (Year Month Day) |
|  | In vitro diagnostic medical device |  | Catalogue number |  | Date of opening |
|  | Do not reuse |  | Temperature limitation |  | Open vial expiry date. Must not exceed the "Use by" date |
|  | CE mark |  | Consult instructions for use | | |

 This product is covered by one or more patents

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