



For veterinary use of the HemoCue Hb 201 system.

### 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). Please read the relevant Operating Manual for proper use of the system<sup>1</sup>.

### Intended Purpose/Intended Use

Quantitative determination of hemoglobin in capillary and venous 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.

### 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, ICSH<sup>3</sup> 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 or venous 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 mixing<sup>2</sup>.

### *Procedure*

The operating temperature of the HemoCue Hb 201 system is 15-30 °C (59-86 °F). Collect the blood sample according to normal procedures. Venous or capillary samples can be used. When collecting blood in tubes with anticoagulantia, make sure to fill the tubes with the correct amount of blood and mix the sample thoroughly.

Follow the procedure for filling the cuvette and measuring the sample as described in the Operating Manual<sup>1</sup>. For further information please contact HemoCue.

### 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-7<sup>4</sup>.
- f) pH values between 6.3-9.0 do not interfere with the system.
- g) Sulfhemoglobin is not measured with this method.


### 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

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### Symbols used

- |  |                                 |   |                            |   |   |
|--|---------------------------------|---|----------------------------|---|---|
|   | Caution                         |  | Use by<br>(Year Month Day) |  | Catalog number  |
|  | Consult<br>instructions for use |  | Temperature limitation     |  | Date of opening   |
|   | Do not reuse                    |  | Batch code                 |  |   |
|  | CE mark                         |   |                            |   | Open vial expiry date. Must not<br>exceed the "Use by" date |

 This product is covered by one or more patents

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