

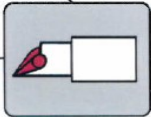


HemoCue Hb 201+: Appendix C – Microcuvettes

Microcuvettes Hemocue Hb 201+			
<p>Microcuvettes Hb 201+:</p> <ul style="list-style-type: none"> Sealed Vial -50 each Box of individually packaged – 50 each Package insert. <p><i>Note: Microcuvettes are designed to be used with the Hemocue Hb 201+ or Hemocue Hb 201 DM Analyzer exclusively.</i></p>	 <p>Sealed Vial – 50 ea</p>	 <p>Box of individually packaged – 50 ea</p>	 <p>View of open microcuvette</p>
<p>Note: Preferred packaging is the Box of individually wrapped microcuvettes.</p>			
Stock Storage			
<ul style="list-style-type: none"> Stock supply is at room temperature (15-30°C) Laboratory – POCT Room 2J8. Document Microcuvette Utilization on Form – located with the stock supply. 			
Ward Storage:			
<ul style="list-style-type: none"> Microcuvettes stored at room temperature with the Hemocue Hb 201+ analyzer. <p><i>Note: Sealed Vial – 50 each – Replace cap immediately. Open container stability is 3 months. Individually packaged – use within 5 minutes of opening package seal.</i></p>			
Sample			
<ul style="list-style-type: none"> 10 uL whole blood. Use fresh capillary blood. (venous or arterial may be used) 			
Principle of the Test			
<ul style="list-style-type: none"> Microcuvette is made of plastic and comprises a body having a cavity with a volume of about 10 uL The Microcuvette contains dry reagents deposited uniformly within the cavity. Whole blood sample is drawn into the cavity by capillary action and is mixed spontaneously with the reagents. No manual mixing is required. Microcuvette is placed into the HemoCue Hb 201+ analyzer and the chemical reaction (Modified azidemethemoglobin reaction), is measured photometrically at endpoint – two wavelengths 570 and 880 nm for turbidity compensation. 			
Microcuvette Reagent Composition			
<ul style="list-style-type: none"> 40 % w/w Sodium Deoxycholate; 18 % w/w Sodium Azide; 20 % w/w Sodium Nitrite; 22 % w/w Nonreactive Ingredients. 			
Measuring Range, reproducibility and accuracy.			
<ul style="list-style-type: none"> Linear to 235 g/L. Confirm results > 235 g/L with laboratory method. Results > 256 g/L are reported as “HHH” on the meter display. Reproducibility: Level 1 (77 g/L) CV = 0.74 %; Level 2 (154 g/L) CV=0.51% Precision: 7 sets data; Range 41 – 210 g/L; Regression Y= 0.981X-1.045; Correlation Coefficient r=0.994-0.999. 			

Test Limitations:

- Measurement is immediately after the blood is drawn into the microcuvette.
- Measurement after 10 minutes of filling the microcuvette will lead to false results.
- Air bubbles present in the center of the microcuvette cavity should be discarded. Air bubbles around the edge do not affect the result.
- Do not hold the microcuvette by the filling end. Wipe excess specimen from the outer surface of the optical eye.

Interfering Substances

Highest concentration tested is referred to in brackets. Following has not been found to interfere:

- Acetaminophen (1324 umol/L); ascorbic acid (170 umol/L); conjugated bilirubin (1365 umol/L); unconjugated bilirubin (324 umol/L); ibuprofen (1939 umol/L); creatinine (2652 umol/L); salicylic acid (3620 umol/L); tetracycline (20 mg/dl); urea (179 mmil/L); uric acid (1190 umol/L); lipaemia (Intralipid 4.6 mmol/L, approx. Triglycerides 13.7 mmol/L).

REFERENCES

HemoCue Hb 201+ Operating Manual. HemoCue AB, Box 1204 SE-262 23 Angelholm, Sweden.
info@hemocue.se www.hemocue.com

HemoCue Hb 201 Microcuvettes, Package Insert. HemoCue AB, Box 1204 SE-262 23 Angelholm, Sweden.
info@hemocue.se www.hemocue.com

Eurotrol HemoTrol, Assayed Controls for In Vitro Diagnostic Use, Package Insert. Eurotrol B.V. Postbus 722 6710 BS Ede, The Netherlands office@eurotrol.com www.eurotrol.com

REVISION & APPROVAL LOG

Version	Revision Type	Description of Change	Revision Date	Technical Approval	Medical Approval
1.0		New document	Jun 2012	Elvira Kozak	Dr. Cathy Halstead
1.1	Minor	Document title and number change. Upload to QMS document control	28 Dec 2016		Dr. Benjamin Jung

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