

HemoCue Hb 201+: Quality Control or Proficiency Test Procedure

PURPOSE:



This procedure provides instructions for Quality Control and Quality Assurance testing for hemoglobin determination using Quality solutions of known and unknown concentration of Hemoglobin to the operator using the Hemocue Hb 201+ analyzer

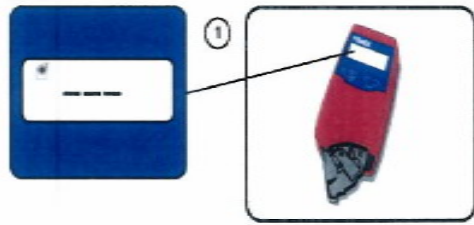
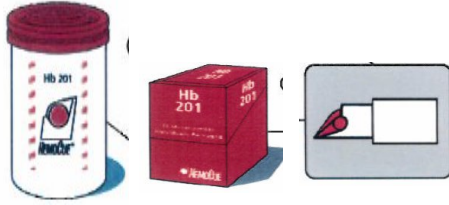
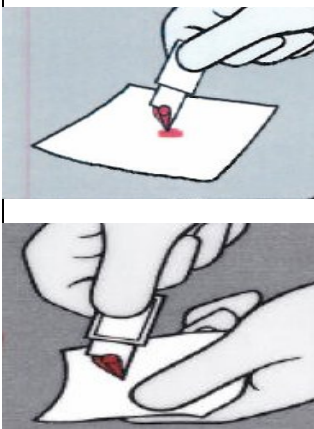
REQUIRED MATERIALS:



- 1) Hemocue Hb 201+ Analyzer, AC adapter, 4 type AA batteries
- 2) Hemocue Hb 201 Microcuvettes (Vial or Individually packaged)
- 3) Lint free tissue
- 4) Parafilm – 2 X 2 square is adequate for each level of Quality Solution.
- 5) Daily: Quality Control (QC) – Eurotrol HemoTrol 3 Levels – Low, Normal, and High
- 6) Proficiency – Levels 1 and 2; QC Levels 1,2, and 3. (unknown whole blood from Hematology Lab).
- 7) Gloves



PROCEDURE:

	<ul style="list-style-type: none"> Quality Control is performed daily with patient use Minimum QC requirement: Weekly – Hematology Lab; Monthly – Clinics/Medical Mobile Unit 	Related Documents
1.	Assemble Materials on workspace	
2.	Obtain HemoCue Hb 201+: Form A - Result Record Form. Confirm: <ul style="list-style-type: none"> Hemocue Hb 201 Microcuvettes Lot # and expiry is current. Quality Control Levels Low, Normal, and High Lot # and expiry is current. <i>Note: Enter Current Lot # of microcuvettes and Eurotrol solution onto HemoCue Hb 201+: Form A - Result Record Form</i>	HemoCue Hb 201+: Form A - Result Record Form HemoCue Hb 201+: Appendix A - Quality Control Solution
3.	Ready HemoCue 201+ If AC power available <ul style="list-style-type: none"> Plug the power adaptor into the power inlet at the back of the instrument. If AC power not available <ul style="list-style-type: none"> Insert 4 type AA batteries, 1.5 V, into the battery compartment. <i>Note: If a battery symbol appears on the display the Hemocue will continue to give accurate results. Replace batteries as soon as possible.</i>	
4.	Turn HemoCue HB 201+ ON <ul style="list-style-type: none"> Press and hold the left button to activate the display (ON/OFF) Display shows the version number of the program All symbols appear on the display. The analyzer verifies the optic and electronic performance. Hemocue displays the most recent result. 	ON/OFF BUTTON  PREVIOUS RESULT 

5.	Prepare Hemocue for loading a microcuvette	
	<ul style="list-style-type: none"> Pull the microcuvette holder out After 10 seconds the display will show three flashing dashes and the Hemoglobin symbol Indicates that self test is passed. If the Self Test fails an error code will appear. (refer to appendix X) 	
6.	Prepare HemoCue Microcuvette for use.	
	<ul style="list-style-type: none"> Obtain microcuvette. Room Temperature Storage (15-30°C) Confirm Lot # and Expiry date with Record Form. Open package just before use. Handle microcuvette opposite to fill end. Place on clean working surface. 	
7.	Place Gloves on.	
8.	Prepare Quality Control (QC) or Proficiency test sample for testing.	
	<ul style="list-style-type: none"> Vial is at room temperature before use. Mix QC or Proficiency sample 8 – 10 times before sampling. Dispense first drop onto a tissue. Dispense second drop onto parafilm square. 	
	<i>If Quality Solution is</i>	<i>Then</i>
	Daily QC	<i>Eurotrol - Levels Low, Normal and High.</i>
	Monthly Proficiency Test	<i>Unknown whole blood– Levels 1 and</i>
9.	Aspirating the sample into the microcuvette	
	<ul style="list-style-type: none"> Touch open end of microcuvette to drop of quality control or proficiency solution. Fill in one continuous process. DO NOT REFILL microcuvette. Wipe off excess blood from outside of the microcuvette. Use lint free tissue. Be careful not to touch the open end of the microcuvette which will result in blood being drawn out of the microcuvette. Look for air bubbles in the filled microcuvette, if present, discard. Small bubbles around the edge can be ignored. 	

10. Hemoglobin measurement.	<ul style="list-style-type: none"> Place the filled microcuvette in the cuvette holder. Within 10 minutes of filling the microcuvette if there is a delay. Push the cuvette holder to the measuring position. During the measurement the hourglass symbol will display. 												
11. Hemoglobin Result	<ul style="list-style-type: none"> Hemoglobin value is displayed after 15-60 seconds. The result will remain on the display as long as the cuvette holder is in the measuring position. Do Not open the cuvette holder until the result is documented If using batteries, the analyzer will automatically turn off after 5 minutes 												
<p><i>Note: If the analyzer turns off automatically – turn the analyzer ON – the result displayed is the previous result.</i></p>													
12. Quality Control Result Review.	<p>If Quality Solution is</p> <table border="1" style="width: 100%;"> <tr> <td style="width: 30%;"><i>Daily QC</i></td> <td> <ul style="list-style-type: none"> Record QC result for Low, Normal or High Level Record date </td> </tr> <tr> <td>If Daily QC solution is</td> <td>Then</td> </tr> <tr> <td>Within QC range</td> <td>Proceed to next level of QC</td> </tr> <tr> <td>Not within QC range</td> <td>Refer to troubleshooting guide.</td> </tr> <tr> <td>Monthly Proficiency Test</td> <td> <ul style="list-style-type: none"> Record as per a patient result. Include date and time performed. </td> </tr> </table>		<i>Daily QC</i>	<ul style="list-style-type: none"> Record QC result for Low, Normal or High Level Record date 	If Daily QC solution is	Then	Within QC range	Proceed to next level of QC	Not within QC range	Refer to troubleshooting guide.	Monthly Proficiency Test	<ul style="list-style-type: none"> Record as per a patient result. Include date and time performed. 	<p>HemoCue Hb 201+: Form A - Result Record Form</p> <p>HemoCue Hb 201+: Appendix E - Troubleshooting Guide</p>
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13. HemoCue Maintenance	<table border="1" style="width: 100%;"> <tr> <td style="width: 30%;">Discard microcuvette</td> <td> <ul style="list-style-type: none"> Biohazard waste container for infection control. </td> </tr> <tr> <td>Clean cuvette holder</td> <td> <ul style="list-style-type: none"> Cuvette holder is cleaned after each day of use After a test if contamination of the cuvette holder is visible. </td> </tr> </table>		Discard microcuvette	<ul style="list-style-type: none"> Biohazard waste container for infection control. 	Clean cuvette holder	<ul style="list-style-type: none"> Cuvette holder is cleaned after each day of use After a test if contamination of the cuvette holder is visible. 							
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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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