STANDARD OPERATING PROCEDURE SOP/POCT/72/1

Title: HEMOCUE Hb 201 DM Effective date: 26/05/2021

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Summary of Significant Changes at this Revision

Purpose and Scope	**Items Required**
The HemoCue Hb201 DM used in a POCT setting is to give an instant measurement of the Haemoglobin level of the patient. The Hemocue must only be used by appropriately trained staff.	HemoCue Hb201 DM Mains adapter Docking station Gloves Apron Eye protection Sharps bin Waste bin Lancets Gauze Alcohol swabs HemoCue 201 microcuvettes
Definitions and Abbreviations Hb= Haemoglobin g/L EQA = External quality assurance iQC = Internal quality control	**Grade / Qualifications** **Only to be used by appropriately trained staff.** **Competencies Required** **Current Version of:**

Risk Assessment:
Current Version of: RA/POCT/18

Contents

1. Associated Documentation (available on the POCT intranet page)

- HemoCue DM competency sheet (ref: FM/POCT/COMP/12)
- HemoCue DM operator manual (ref: EXT/POCT/26)
- HemoCue result labels (ref: FM/POCT/15)
- HemoCue DM risk assessment (ref: RA/POCT/18)
- Telephone Policy (ref POL/COMM/6)
- POCT iQC and maintenance log (ref FM/POCT/16)

2. Principle of test

The HemoCue 201DM meter is used for the determination of the total amount of Haemoglobin in whole blood finger prick sample. The system consists of the analyser and specially designed cuvettes containing dried reagents. The cuvette serves as a pipette, reaction vessel and a measuring cuvette. No dilution is required. The haemoglobin measurement takes place in the analyser and is factory calibrated against the haemiglobincyanide (HiCN) method, the international reference method.

Sodium deoxycholate haemolyses the erythrocytes and haemoglobin is released. Sodium nitrite converts haemoglobin to methaemoglobin which, together with sodium azide gives azidemethaemoglobin. The absorbance is measured at two wavelengths (570 and 880 nm) in order to compensate for turbidity in the sample.

3. Purpose of the test

The HemoCue Hb 201 DM system is used for the quantitative determination of haemoglobin in capillary, venous or arterial blood.

4. Sample Type & Additives

Whole blood from:

- Capillary
- Venous
- Arterial

Appropriate anticoagulants EDTA or Heparin maybe used in their solid form to avoid dilutional effects.

5. Patient Preparation

The patients hand must be warm and relaxed and the middle or ring finger should be used only (avoiding fingers with rings on).

The finger must be cleaned with alcohol or suitable disinfectant and allowed to dry.

Wipe away the first 2 or 3 drops of blood after lancing and before collection into the cuvette.

6. Equipment and Storage Conditions

6.1. Radiometer HemoCue Hb 201 DM hand held meter

The meter can be stored at 0 – 50 ‘C, used at 15 - 30 ‘C and should be allowed to reach ambient temperature before use.

The meter should **not** be used at high humidity (>90% non-condensing).

The meter runs off a battery pack but can also be powered from the mains. Device can also be charged on docking station.

6.2. Radiometer HemoCue Hb 201 Microcuvettes

- HemoCue Hb 201 microcuvettes can be stored at room temperature (15-30 degrees centigrade) they must **not** be stored in a refrigerator.
- An unopened vial of microcuvettes are stable until the date printed on the outside of the vial.
- Once opened the microcuvettes are only stable for 3 months. Always keep the vial lid properly closed, available in vials of 50.
- Individually wrapped cuvettes are stable for 15 months from the date of manufacturing, available in boxes of 25.

6.3. Microcuvette Reagents

The HemoCue HB 201+ Microcuvettes contain:

- 40% w/w Sodium Desoxycholate
- 18% w/w Sodium Azide
- 20% w/w Sodium Nitrate
- 22% w/w Nonreactive Ingredients
- Individually wrapped Microcuvettes are available in boxes of 25 or in vials of 50.

6.4. Internal Quality Control solutions

- Hemo Trol should be stored at 2 -8 ‘C.
- Unopened vials are stable until the expiry date on the box
- Once opened vials are stable for 30 days in the fridge (2 – 8 ‘C) or at room temperature (<30’C).
- Once opened, record the new expiry date on the bottles.

7. Internal Quality Control (iQC)

7.1. Selftest

The HemoCue Hb 201DM analyzer has an internal electronic “SELFTEST”. Every time the analyzer is turned on, it will automatically verify the performance of the optronic unit of the analyzer. Upon passing the selftest, the display will show the HemoCue symbol and three flashing dashes indicating the analyzer is ready to perform testing

7.2. HemoCue Hemo Trol Control Solutions

Hemo Trol is an assayed haemoglobin control intended for use in the verification of the precision and accuracy of the HemoCue Hb 201^{+} meter. Each vial consists of 1.0 ml of purified bovine haemolysate.

8. Environmental and Safety Controls

8.1. Health and Safety

In addition to the local Health and Safety policy, the following measures must be taken.

- Full PPE must be worn by all staff performing the finger prick technique.
- Dispose of PPE in an appropriate clinical waste bin.
- All sharps must be disposed of in a sharps bin.
- If the machine is contaminated with blood, wipe with Clinell detergent wipes.
- After use, wipe machine down with Clinell detergent wipes before storing away.

9. Calibration

The system is factory calibrated against the haemiglobincyanide (HiCN) method, the international reference method for the determination of the haemoglobin concentration in blood.

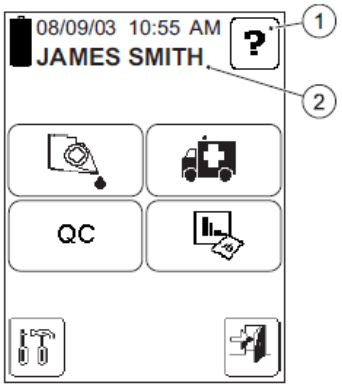
The Hemocue must only be used by competently trained staff, who have successfully completed competence sheet

Competency must be re-assessed every two years.

10. Procedural Steps

10.1. Start-up procedure

1) If mains power is available, connect the adapter to the socket in back of analyser.
2) Pull cuvette holder out to its loading position.
3) Press and hold the black button until the display is activated (all symbols appear on the display)
4) User will be prompted to open cuvette holder unless already open.
5)
6) "Enter Operator ID" screen displays
7) Hold the scan button and scan your barcode or manually type your ID in
8) Once self-test is complete the display contains 4 main icons



2.3.3 Main Menu and Help

FIGURE 2-18

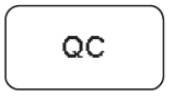
FIGURE 2-18 is referred to as the Main Menu. It is displayed as the Startup Image for all Tests, Setting procedures, etc.

The Help button (1) may be used to display information about other buttons, procedures, etc.

1 Help button

2 Operator name, Operator ID or blank, depending on the settings*

** It is recommended to use the Approved Only setting for operators to ensure optimal operator traceablity.*

Button	Designation	Function
	Patient test button	Activates the Patient Test procedure.
	STAT test button	Activates the STAT (Short Turn Around Time) Test procedure.
	QC test button	Activates the QC (Quality Control) Test procedure.
	Stored data button	Activates the Stored Data function.
	Settings button	Activates the Settings menu.

10.2. Quality Control

The HemoCue Hb 201 DM analyser has an internal quality control, the self-test. Every time the analyser is turned on, it will automatically verify the performance of the analyser. This test is performed every eighth hour if the Analyser is left turned on. The result of the self-test is stored as an EQC (Electronic Quality Control).

1) The HemoTrol control solutions (QC) must be performed on each day of use.
2) Check the QC solutions are in date and bring to room temperature (15 - 25 °C) for 15 minutes if removed from the fridge. The QC is only stable for 30 days once opened.
3) Check the expiry date of the cuvettes (only stable for 90 days once opened).
4) Follow the start-up procedure 10.1
5) Press the “QC” button on the screen
6) Select the level of QC you are about to run
7) “Please Fill and Insert a Cuvette” screen appears
8) Take the cuvette out of the container and reseal immediately.
9) Hold the cuvette by the straight end
10) Gently mix the QC vial 8-10 times then dispense 1 drop of control material onto a hydrophobic surface such a plastic film or a surgical glove. Do not fill the cuvette from the vial
11) Introduce the tip of the cuvette into the QC solution and allow it to fill by capillary action in one continuous process avoiding any air bubbles.

    Do not attempt to refill a partially filled cuvette.
12) Wipe three sides of the cuvette before placing in the cuvette holder
13) Gently push into the measuring position. During the measurement an hour-glass symbol will appear on the display
14) A prompt “Enter Cuvette batch” displays - scan the Cuvette box barcode
15) Next manually enter the QC lot number – Press ”OK”
16) After 15-60 seconds the haemoglobin value of the QC sample is displayed until the cuvette port is opened.
17) The device will display QC result with 3 buttons at the bottom on the screen, a notepad to add a comment, a double cuvette to verify the result and an OK button.
18) Press the “OK” button to accept the result.
19) Open the cuvette holder and dispose of the cuvette according to health and safety procedures.
20) 820all s
21) QC results are stored electronically in the analyser and on POCcelerator middleware.
22) After all QC samples have passed the meter is ready for use for a patient sample.

The HemoCue Hb201DM is working correctly if the control results are within range. If the control is out of range check all consumables are within date and have been stored correctly. If satisfactory then repeat the failed control.

If the quality control results are still out of range then do not use the HemoCue Hb201 DM. Send a venous sample to the laboratory to measure the haemoglobin and contact POCT for further technical support

10.3. Measuring Capillary Blood

1) Follow the start-up procedure 10.1
2) Choose cuvette button on the main display screen.
3) A prompt “Enter Cuvette batch” displays - scan the Cuvette box barcode
4) A prompt “Enter Patient ID (PID)” displays – scan or manually enter the MRN
5) “Verify” is displayed – check the details are correct
6) Press “OK”
7) A prompt “Please Fill and Insert a Cuvette” displays.
8) Take the cuvette out of the container and reseal immediately.
9) Hold the cuvette by the straight end.
10) Make sure the patients hand is warm and relaxed.
11) Use middle or ring fingers for sampling avoiding fingers with rings.
12) Clean the finger with an appropriate alcohol swab .
13) Using your thumb, lightly press the finger from the top of the knuckle towards the tip. This stimulates blood flow towards the sampling point.
14) For best blood flow and least pain, sample at the side of the fingertip, not the centre.
15) While applying light pressure toward the fingertip, puncture the finger using the lancet.
16) Wipe away the first 2 drops of blood with a lint free tissue.
17) Re-apply light pressure towards the fingertip until another drop of blood appears.
18) When the blood drop is large enough, fill the cuvette with blood in one continuous process ensuring that there are no air bubbles present.

DO NOT attempt to refill.

19) Wipe three sides of the cuvette before placing in the cuvette holder.
20) Gently push into the measuring position.
21) During the measurement an hour-glass will be shown on the display.
22) After 15-60 seconds the haemoglobin value of the sample is displayed until the cuvette port is opened
23) The device will display result with 3 buttons at the bottom on the screen, a notepad to add a comment, a double cuvette to verify the result and an OK button.
24) Press the “OK” button to accept the result.
25) All results must be documented in the patients’ notes, signed and dated by the operator using a HemoCue record label (FM/POCT/15 on intranet page). Results will also be electronically recorded in POCcelerator and will transmit into millennium via Ultra once the analyser is placed back into the docking station.
26) Open the cuvette holder and dispose of the cuvette in a clinical waste bin.
27) Turn off the meter by pressing black button until display becomes blank.
28) Push the cuvette holder back into the device.
29) Ensure the meter is cleaned with Clinell detergent wipes and put away or docked.

If sample obtained is insufficient or clotted, record this on the label (FM/POCT/15)

External Quality Assurance (EQA)

In summary:

- External quality assurance samples are to be run every month in line with NEQAS.
- Run EQA as a patient sample, filling cuvette with a syringe, pipette or via a drop onto a glove.
- Record results on return sheet provided.
- EQA reports are returned monthly and reviewed at the POCT meeting and Haematology QC meeting held quarterly.
- EQA results need to be retained for the life time of the analyser.

11. Maintenance

If analyser has been contaminated with blood, or after each day of use maintenance must be performed.

- Turn analyser off.
- Pull cuvette holder out of the loading position – Use a pointed object to depress the catch in the upper right corner of cuvette holder.
- Pull out cuvette holder, keeping catch depressed.
- Clean cuvette holder with alcohol or detergent wipe.
- Push HemoCue Cleaner swab in to the opening of the cuvette holder. Insert 5 – 10 times. If swab is still stained, repeat with a new swab.
- Wait 15 minutes before re-using the machine.
- Replace the cuvette holder.
- Wipe external surfaces with alcohol or detergent wipe.
- Record maintenance performed on iQC / maintenance log (FM/POCT/16)

12. Interferences

1. Sulfhemoglobin is not measured with this method. Carboyhemoglobin levels up to 10% do not interfere with the system.
2. pH values between 6.3 – 9.0 do not interfere with the system.
3. The following compounds tested to the levels indicated have not been found to interfere with this analysis:
    - Acetaminophen (400 mg/L)
    - Ascorbic Acid (3 g/L)
    - Conjugated Bilirubin (40 g/L)
    - Leukocytes (600 x 109/L)
    - Lipemia (Intralipid 4000 mg/L)
    - Triglycerides (55.5 mmol/L)
    - Salicylic Acid (500 mg/L)
    - Tetracycline (20 g/L)
    - platelets (2100 x 109)
    - urea (27.75 mmol/L)
    - Uric Acid (1.11 mmol/L)

13. Reference Ranges and Interpretation

13.10. Analytical Range

0 - 256 g/L

Results above 256 g/L will be displayed as HHH.

13.11. Critical Reference Range

<70 g/L

13.12. Biological Reference Range

Expected values:

Children (after neonatal period)	110 - 140 g/L	11.0 - 14.0 g/dL
Adult Female	120 - 150 g/L	12.0 - 15.0 g/dL
Adult Male	130 - 170 g/L	13.0 - 17.0 g/dL

14. Variation and Limitations

- The HemoCue Hb 201 DM meter is only to be used together with HemoCue Hb 201 Cuvette.
- Using expired or inappropriately stored cuvettes/control solution may cause false QC/patient results.
- Precaution should be taken not to hold the cuvette by the filling end. Fingerprints on the measurement circle of the cuvette will interfere with the measurement of the sample.
- Air bubbles in the optical eye, caused by inadequate filling of the cuvette may result in false results.
- Measurement of haemoglobin should be made as soon as possible after the blood has been drawn into the cuvette. If the readings in the photometer are made later than 10 minutes after the blood has entered the cuvette, false results may be obtained.

15. Trouble Shooting

- If battery symbol appears in display, the batteries are running low, replace as soon as possible, the analyser will still give accurate results.
- Report any problems to the senior nurse on duty, discontinue using until a Sister is available.
- If for any reason the result obtained is unexpected, (either too high or too low), always send a venous EDTA sample to the laboratory for a Full blood count.
- Please refer to the operator manual for full list of errors, explanations and actions required. Operator manual available on QPulse

Copy number	Location held
1	Transfusion Team Office