HemoCue Hb 201^{+} Meter

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1.0 PURPOSE AND SCOPE

To outline the procedures for the use of HemoCue Hb 201$^+$ meters used for Point of Care Testing (PoCT) of blood haemoglobin levels.

2.0 RESPONSIBILITY

The PoCT team is responsible for the maintenance of the HemoCue Hb 201$^+$ meters in use in the Northern Devon Healthcare Trust.

Ward/Location managers
Are responsible for ensuring meters are used in accordance with Trust Policies and are consequently fit for purpose.

Where meters are found to be or suspected of being faulty they are responsible for removing them from service and ensuring that the PoCT team are informed so the appropriate remedial action can be taken.

Meter Users
Complying with Board ratified policies and procedures.

Participation in medical device education and training, and ensuring individual training matrix and Personal Development Portfolios are updated.

Acceptance of individual or team responsibility and accountability for maintaining a safe environment and only operate devices for which the user is competent and this competence can be demonstrated.

Adhering to incident reporting procedures.

3.0 REFERENCES

MDA DB2002(03) Management and Use of IVD Point of Care Test Devices.
BS EN ISO 22870:2006 Point of care testing- Requirements for quality and competence.

4.0 DOCUMENTATION

Manual Standard Operating Procedure: Number POC-SOP-16
HemoCue Hb 201$^+$ Operating Manual POC-EXT-21
HemoCue pack insert POC-EXT-19
HemoCue cuvette pack insert POC-EXT-20

5.0 ACTIONS AND METHODS

5.1 Principle of test

Quantitative determination of haemoglobin in capillary, venous or arterial blood. Sodium deoxycholate haemolyses red cells and haemoglobin is consequently released. Sodium nitrite converts the haemoglobin to methaemoglobin which, together with sodium azide, gives azidemethaemoglobin. The absorbance of azidemethaemoglobin is measured at two wavelengths (570nm and 880nm) the second wave compensates for turbidity in the sample.

5.2 Sample Requirements

A drop of fresh whole venous, capillary or arterial blood. Blood collected into appropriate tubes containing anticoagulant can also be used but it is recommended that the anticoagulant is in solid form, in order to avoid a dilution effect, e.g. EDTA or Heparin/Fluoride

5.3 Personnel applicable.

All members of staff with appropriate training i.e. having completed the relevant competency or manufacturer/PoCT team training.

5.4 External Quality Control

Two fixed whole blood samples are sent from NEQAS (the UK National External Quality Assessment Scheme) monthly.

The samples are sent to Theatre Recovery along with an instruction slip and results record sheet. Results should be returned to the Haematology laboratory on the same day the samples are received.

The results are returned to the Haematology laboratory but the samples are transferred to Theatre 7 with their own record sheet (address label supplied) where both samples are analysed.

Theatre 7 then returns the samples and sheet with the Hb results back to the Haematology laboratory.

The laboratory then enters the results into the computer and they are returned electronically to NEQAS.

The NEQAS results are then returned to the Haematology laboratory, who will inform the user of any unsatisfactory performance.

The user is responsible for dealing with unsatisfactory performance, but the Haematology laboratory/PoCT team are available for advice.

Persistent unsatisfactory performance may result in NEQAS contacting the user in an advisory capacity.

5.5 Internal Quality Control

See QPulse POC-EXT-19.

The manufacturer supplies QC for use with the meter which should be analysed at least weekly. Once opened it is stable for 30 days when properly recapped and stored at 2-8°C or at room temperature 15-30°C.

5.6 Running a Quality Control

1. Check the HemoCue Control Solution is in date.
2. Check that the meter serial number matches the one in the QC log book.
3. Check the expiry date of the microcuvettes. They are stable for 90 days once opened.
4. If mains power is available, connect the adapter (supplied with the meter) to the socket on the back. If no mains power is available, insert the 4 type AA into the battery compartment. If the battery symbol appears on the display the batteries are running low. The analyser will continue to give accurate results but the batteries should be replaced as soon as possible.
5. Press both display buttons on the front of the meter at the same time.
6. Select QC-test by pressing the left button.
7. The Analyser automatically returns to the measuring position and the QC-symbol appears in the display.
8. Take the microcuvette out of the container and reseal the container immediately. Hold the microcuvette by the straight end.
9. The microcuvettes must be stored at room temperature (15 – 30°C) and in the closed container as the reagent is moisture sensitive.
10. Fill the microcuvette with the control solution recommended by HemoCue in one continuous process. It must never be topped up after the first filling.
11. The filled cuvette must be checked visually and inspected for air bubbles which if present can produce erroneously low readings. Small air bubbles around the edge do not influence results.
12. Place the filled microcuvette in the cuvette holder immediately and push into the measuring position. This should be performed within ten minutes after filling the microcuvette.
13. During the measurement and hour glass will appear on the display.
14. After 15-60 seconds the haemoglobin value of the sample is displayed. The result will remain on the display as long as the cuvette holder is in the measuring position. When operating on

battery power the analyser will automatically turn off after approximately 5 minutes.

15. Record the measurement in the logbook immediately and discard the filled microcuvette in the clinical waste.
16. Up to 600 tests are stored on the analyser and can be viewed by using the scroll function.
17. Once the measurement has been made the analyser automatically returns to the measuring position and the QC-symbol disappears from the display. Patient sampling can begin.
18. To deactivate the QC test press both buttons at the same time and then scroll using the right button until another set up activity appears. Hold the right button down for approximately 5 seconds. The analyser automatically returns to the measuring position and the QC symbol is no longer visible.

5.7 Running a Patient Sample

N.B. The following only covers the use of the meter and not the sample collection or clinical aspects, please refer to the relevant policies and procedures prior to undertaking the testing procedure.

1. If mains power is available, connect the adapter (supplied with the meter) to the socket on the back. If no mains power is available, insert the 4 type AA into the battery compartment. If the battery symbol appears on the display the batteries are running low. The analyser will continue to give accurate results but the batteries should be replaced as soon as possible.
2. Check the expiry date of the microcuvettes. They are stable for 90 days once opened.
3. Pull the cuvette holder out to its loading position.
4. Press and hold the left button until the display is activated (all symbols appear on the display).
5. The display shows the version number of the programme, after which it will show an hour glass and "Hb". During this time the analyser will automatically verify the performance of the optronic unit.
6. After 10 seconds the display will show three flashing dashes and the HemoCue symbol. This indicates that the HemoCue Hb 201^{+} is ready for use.
7. Take the microcuvette out of the container and reseal the container immediately. Hold the microcuvette by the straight end.
8. The microcuvettes must be stored at room temperature ($15 - 30^{\circ}C$) and in the closed container as the reagent is moisture sensitive.
9. When the blood drop is large enough, fill the microcuvette in one continuous process. Do not refill.
10. Wipe off excess blood on the outside of the microcuvette tip.
11. **NB**. Make sure that no blood is drawn out of the microcuvette during this procedure.

12. Look for air bubbles in the filled microcuvette. If present, take a new sample however small bubbles around the edge can be ignored.
13. Place the filled microcuvette in the cuvette holder. This should be performed within ten minutes after filling the microcuvette.
14. Push the cuvette holder into its measuring position.
15. During the measurement and hour glass will be shown on the display.
16. After 15-60 seconds the haemoglobin value of the sample is displayed. The result will remain on the display as long as the cuvette holder is in the measuring position. When operating on battery power the analyser will automatically turn off after approximately 5 minutes.
17. Record the result and dispose of the microcuvette according to Trust policy.
18. Ensure the meter is clean when put away.

6. Interpretation

HemoCue Hb 201^+ measuring range is quoted as 0 – 256 g/L.
Values below 80 g/L or above 200 g/L must be confirmed by the haematology laboratory.
Values which trigger a request for blood for transfusion must be confirmed by the haematology laboratory.
Values above 256 g/L will display an error code "HHH".

7. Limitations

It should be noted that oxygenated blood which has been agitated over a long period produces oxygen pressure and viscosity at higher than normal levels. The achievement of accurate results for blood in this condition requires analysis to be undertaken immediately after the cuvette has been filled.
HemoCue supply liquid controls for use on their systems. Other controls available commercially may contain additives that cause turbidity. As the system compensates for turbidity it can give a lower than expected value for control material obtained from other suppliers.
Capillary, venous or arterial blood may be used. Appropriate anticoagulant in solid form (e.g. EDTA or Heparin/Fluoride) must be used for non-capillary samples in order to avoid dilution effect. Whole blood must be at room temperature and thoroughly mixed on a blood sample mixer for at least two minutes or by manual inversion at least 8-10 times.

HemoCue Hb 201 Microcuvettes are for In Vitro Diagnostic use only. The HemoCue Hb 201^+ analyser is only to be used together with HemoCue 201 Microcuvettes.

8. Health and Safety/COSHH

Follow Universal Precautions when handling patient specimens as detailed by the Infection Control Manual. Handle all components and all patient samples as recommended for any potentially infectious human serum or blood specimen in the HHS Publication No. (CDC) 93-8395, Biosafety in Microbiological and Biomedical Laboratories, U.S. Government Printing Office; Washington, DC. Use supplied personal protective equipment. Wipe up spills promptly and decontaminate affected surfaces. Avoid generation of aerosols. Follow appropriate waste handling regulations applicable to your area.

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