1. Scope and application

This document provides instructions to ensure safe and accurate bedside hemoglobin measurement using the HemoCue 301 system. This procedure describes the different steps to obtain the result. The device can be used in primary health care, in clinical trials, as a point-of-care testing device, etc.

2. Responsibilities

<table>
<thead>
<tr>
<th>Function</th>
<th>Activities</th>
</tr>
</thead>
<tbody>
<tr>
<td>Lab Technician</td>
<td>• complies with this procedure&lt;br&gt;• keeps a record of all the data (direct print-out, transfer to pc, in lab note book)&lt;br&gt;• follows the Quality Assurance regulations and keeps a record of all the quality controls&lt;br&gt;• applies the maintenance procedures&lt;br&gt;• informs the lab manager when there is a problem with the device</td>
</tr>
<tr>
<td>Lab Quality Manager</td>
<td>• checks that the internal quality procedures are followed correctly&lt;br&gt;• ensures that the quality control data is properly recorded&lt;br&gt;• subscribes the laboratory in an external quality program in order to evaluate the quality of the lab data</td>
</tr>
<tr>
<td>Lab Manager</td>
<td>• checks that the lab technicians follow the procedure&lt;br&gt;• checks that maintenance is done at the right time&lt;br&gt;• takes action when reparation is needed&lt;br&gt;• formulates a maintenance contract with the supplier&lt;br&gt;• checks that data is properly recorded&lt;br&gt;• supervises the lab quality manager</td>
</tr>
</tbody>
</table>

3. References

- HemoCue 301 User Manual
- www.hemocue.com

4. Procedures

4.1 Principle of the test

The absorbance of whole blood is measured at Hb/HbO₂ isobestic point. It is read by spectrophotometry at 506 and 880 nm to compensate for turbidity.

4.2 Safety

All blood samples are potentially infectious. Follow standard safety precautions.
4.3 Specimen

- **Special conditions for patient preparation**: none
- **Type of sample**: capillary (finger stick) or anticoagulated venous or arterial blood (EDTA or heparin in solid form, no fluoride)
- **Volume of sample**: 10 µl of whole blood
- **Sterility**: not needed
- **Time between collection and measurement**:
  - capillary: immediately
  - venous/arterial: Hemoglobin is stable for days if the specimen does not get infected. If the blood is kept in the fridge, allow it to warm up to room temperature before testing.
- **Rejection criteria**:
  - hemolyzed or clotted samples
  - blood collected in sodium citrate or in tubes containing a gel separator
  - samples with bacterial or fungal infection
  - blood samples not or incorrectly labeled

4.4 Equipment and reagents

- HemoCue Hb 301 analyzer
- HemoCue Hb 301 microcuvettes
- 4 type AA batteries (1.5 V) and/or mains adapter
- Non sterile, single use gloves
- Tissue or gauze
- Alcohol swabs, sterile lancets
- Venous blood collection set (needles, syringe, sample tubes)
- Control solutions (Eurotrol Hb 301 control Low/Normal/High)
- HemoCue Cleaner swabs
- Pipette
- Parafilm or glass slide

4.5 Procedure

- Check the expiry date of the microcuvettes and the date of opening of the vial. If expired, do NOT use the cuvettes. Take a new batch of cuvettes that are not expired.
- Switch on the machine: Press and hold left button. The display is activated.
- Optronic unit is automatically checked.
- The display shows 3 flashing dashes: the analyzer is ready to use.
- Pull out the cuvette holder
- The most recent result is displayed
- **For fingerstick blood**:
  - Clean the fingertip with 70% alcohol and allow to dry
  - Puncture the fingertip (middle or ring finger) with a sterile lancet
  - Wipe away first 2 - 3 drops of blood
  - Fill the microcuvette in one continuous process. The correct amount of blood (10 µl) is drawn into the microcuvette. The microcuvette should be completely filled. Do NOT refill!!
• For venous/arterial blood:
  o Mix the sample well (invert 8 -10 times by hand)
  o Place a drop of blood onto a hydrophobic surface (e.g. parafilm) or glass slide, using a pipette.
  o Fill the microcuvette in one continuous process. The correct amount of blood (10 µl) is drawn into the microcuvette. The microcuvette should be completely filled. Do NOT refill!!

• Wipe away any excess of blood on the outside of the microcuvette tip
• Check for air bubbles in the filled microcuvette. If present, use a new microcuvette
• Place the filled microcuvette in the cuvette holder (within 40 seconds after filling the cuvette!)
• Push the cuvette holder to its measuring position
• After 10 seconds the haemoglobin measurement is displayed
• Read and record the result. Remove and discard the microcuvette in the appropriate bio-hazard container. Push the cuvette holder back into the instrument.

• There is no memory to store the results.
• You can view the results on the display, print them out (immediately after each measurement) or transfer them to a computer (special software required). (check the operating manual)

4.6 Quality control
• The analyzer has an internal electronic self-test, to check the optronic unit. This test is performed every time the analyzer is switched on and at regular intervals when the analyzer remains switched on.
• A daily quality control has to be done with the recommended controls:
  ➔ Eurotrol Hb 301 control Low/Normal/High

4.7 Reporting results
• In g/dl or g/l
• Measuring range: 0 - 25.6 g/dl
• Conversion to SI units: g/dl x 0.6206 = mmol/l
• The normal ranges are: (depending on altitude/region, check local data)
  o Male adult: 14 - 18 g/dl
  o Female adult: 12 - 16 g/dl
  o Newborn: 17 - 23 g/dl
  o Infants: 11 - 14 g/dl

Note: Hb measurements in capillary blood give higher results than in venous blood (~ 0.5 g/dl)
4.8 Storage and stability

- Use the microcuvettes prior to expiry date
- Store the microcuvettes at 15 - 40 °C. Do NOT refrigerate.
- Keep the vial closed. When opened, the microcuvettes are stable for 3 months. Write down the date of opening on the vial.
  An unopened vial can be stored for a shorter period (6 weeks) between -18°C - 50°C.
- Store the analyzer at 0-50°C. Operate the analyzer at 10 - 40°C, 5 - 90% non-condensing relative humidity.

4.9 Maintenance

- Check that the analyzer is turned off
- Clean the cuvette holder every day with alcohol or mild detergent (check operating manual)
- Clean the optical unit once a month with a HemoCue cleaner (cleaning swab). Clean also after 50 measurements or when an error message is shown. (check operating manual)
  Wait for 15 minutes before replacing the cuvette holder.
- Clean the cover with alcohol or mild detergent

4.10 Causes of error

- Insufficient or non-uniform filling of the microcuvette (Rouleaux, agglutination): repeat the test
- Air bubbles in the microcuvette
- Incorrect mixing of the venous/arterial blood
- Excessive squeezing of the finger when collecting capillary blood
- High humidity (use individually wrapped microcuvettes)
- Troubleshooting: (see operating manual for more troubleshooting)

**Troubleshooting Guide**

If you are unable to resolve the problem by following this Troubleshooting Guide, please contact your local HemoCue distributor or HemoCue AB. The analyzer should be cleaned as recommended under “Maintenance” prior to service or disposal. Consult local environmental authorities for proper disposal. The analyzer has no serviceable parts.

<table>
<thead>
<tr>
<th>Symptom</th>
<th>Explanation</th>
<th>Action</th>
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<tbody>
<tr>
<td>The analyzer shows an</td>
<td>May be a temporary fault.</td>
<td>Turn off the analyzer and turn it on again after 30 seconds. Take a</td>
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<tr>
<td>error code</td>
<td></td>
<td>new microcuvette and repeat the measurement. If the problem continues,</td>
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<tr>
<td></td>
<td></td>
<td>see specific error code below.</td>
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<tr>
<td>E00</td>
<td>Nostable endpoint of the measurement is found</td>
<td>1a. Check the expiration date for the microcuvettes.</td>
</tr>
<tr>
<td></td>
<td>within the time range.</td>
<td>1b. Take a new microcuvette and repeat the measurement.</td>
</tr>
<tr>
<td></td>
<td>1. The cuvette is faulty.</td>
<td>2. The analyzer needs service. Contact your distributor.</td>
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<tr>
<td></td>
<td>2. The circuit board is out of order.</td>
<td></td>
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<tr>
<td>E01–E05</td>
<td>Dirty optronic unit or faulty electronics or</td>
<td>1a. Turn off the analyzer and clean the optronic unit as described in</td>
</tr>
<tr>
<td></td>
<td>optronic unit.</td>
<td>the maintenance section.</td>
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<td></td>
<td></td>
<td>1b. The analyzer needs service. Contact your distributor.</td>
</tr>
<tr>
<td>E05</td>
<td>Unstable blank value. The analyzer might be</td>
<td>1. Turn off the analyzer and allow it to reach room temperature. If the</td>
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<td></td>
<td>cold.</td>
<td>problem continues, the analyzer needs service. Contact your distributor.</td>
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<tr>
<td>E07</td>
<td>The battery power is too low.</td>
<td>1a. The batteries need to be replaced. Turn off the analyzer and</td>
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<td>replace the batteries, 4 type AA.</td>
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<td></td>
<td>1b. Use the power adapter.</td>
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<tr>
<td>E08</td>
<td>The absorbance is too high.</td>
<td>1a. Check that the analyzer and microcuvettes are used according to</td>
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<tr>
<td></td>
<td>1. Light blocking item in the cuvette holder</td>
<td>the HemoCue hb 301 operating manual and instructions for use.</td>
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<tr>
<td></td>
<td></td>
<td>1b. The analyzer needs service. Contact your distributor.</td>
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5. Records and archives

<table>
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<th>Appendices &amp; Forms for completion</th>
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<td>Barbara Barbé</td>
<td>02/11/2011</td>
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<tr>
<td>Reviewed by</td>
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<td>An Vermaelen</td>
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<td>Jan Jacobs</td>
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