Title: Hemoglobin Measurement by HemoCue 201 Plus
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Hemoglobin Measurement by HemoCue 201+

A. PURPOSE:
To provide an accurate and timely method of monitoring hemoglobin (HemoCue whole blood capillary method). Results obtained are considered definitive for purposes of patient care and diagnosis of anemia.

B. PRINCIPLE:
The HemoCue 201+ blood Hemoglobin system consists of disposable microcuvettes with reagent in dry form adhered to walls and a single purpose designed photometer. The microcuvette is used for sampling the blood, as reaction vessel and as measuring cuvette. No dilution is required. Reading of hemoglobin takes place in the photometer, which follows the reaction and reports the result only when the reaction has stopped. Refer to page 36 of the operator’s manual for more information.

C. SPECIMEN REQUIREMENTS:
Capillary direct fingerstick or venous or arterial blood collected in a dry anticoagulant; e.g., K2 EDTA, heparin, or heparin/fluoride is recommended in order to avoid dilutional affect. Sample size – 10 ul.

D. REAGENTS, MATERIALS, EQUIPMENT:
Controls and microcuvettes are ordered from the POC office (X6728)
1. Microcuvette
   a) Used for sampling the blood, as reaction vessel, and as measuring cuvette.
   b) Store at room temperature (15°-30° C). Do not refrigerate.
   c) Vials are stable three months once opened. Date vial with opened expiration date.
      Individually-wrapped cuvettes are stable until the manufacturer’s expiration date.
2. Controls (whole blood hemoglobin control)
   a) Hema-Trol® Low, Normal
   b) Store in refrigerator at 2°-8° C
   c) Stable unopened until the expiration date, 60 days once opened stored at 2-8° C and
      30 days at room temperature. Date vial with opened expiration date.
3. Roche single use disposable lancet.
4. Alcohol wipes.
5. Cotton ball, tissue or gauze.
7. KimWipe® or lintless tissue.
8. Biohazard sharps container.
9. Approved cleaning agents – Clorox Germicidal Wipes; rubbing alcohol.
10. Parafilm or nonporous disposable surface.
E. QC REQUIREMENTS:
1. The HemoCue Hgb 201+ analyzer has an internal electronic “SELF TEST” every time the analyzer is on. The “SELF TEST” will automatically verify the performance of the optronic unit of the analyzer. The “SELF TEST” is performed automatically every second hour if the analyzer remains on.
2. Two levels of external control material, low and normal, are run weekly when patient testing is done and with each new lot of microcuvettes. Record the results on the Quality Control Log. Refer to Hema-Trol Hemocue Hgb 201+ assay sheet for acceptable ranges.

F. PROCEDURE – QC:
1. Allow the QC to warm 15 minutes to room temperature if stored 2-8°C.
2. Mix well, dispense a small drop in a nonporous surface (parafilm). Immediately sample the drop into the microcuvette with one continuous filling motion. Introduce the microcuvette tip into the middle of the drop.
3. Using a lint free tissue, carefully wipe the outside of the microcuvette taking care not to draw any sample onto the tissue.
4. Inspect the microcuvette for proper filling and the absence of bubbles.
5. Place microcuvette into the holder.
6. Push the microcuvette holder into the measuring position.
7. Record QC results on the Quality Control Log. Results that are not within range require corrective action; i.e., repeat, new QC, new microcuvette.

G. PROCEDURE – PATIENT TEST
1. Capillary Sample:
   a) Seat the patient comfortably. If the patient's fingers are cold, it is a good idea to warm the hand from which the sample is to be taken in warm water. It is important that the blood can circulate freely in the sampling finger, so fingers with rings on should not be used. The patient's fingers should be straight but not tense, to avoid the stasis affect which occurs when the fingers are bent.
   b) Using your thumb in a gentle rocking movement, lightly press the finger from the top knuckle to the tip. This stimulates the flow of blood to the sampling point.
   c) Use only the middle finger for sampling. Clean the puncture site with an alcohol pad and wipe dry.
   d) With the thumbs gentle pressure at the tip of the finger, prick at the side of the fingertip. Not only is the blood flow best there, it also causes the least pain.
   e) Using a dry absorbent pad, wipe away the first two or three drops of blood. This stimulates spontaneous blood flow. If necessary, apply light pressure again, until another drop of blood appears.
   f) Make sure that the drop of blood is big enough to fill the microcuvette completely. Introduce the microcuvette tip into the middle of the drop of blood.
   g) Fill the microcuvette in a continuous process. It should never be topped off after the first filling. Wipe off any excess blood from the outside of the microcuvette top with a clean lint free wipe being careful not to touch the tip. Be sure that no blood is drawn out of the microcuvette. If this happens, discard the cuvette and fill a new cuvette.
h) The filled microcuvette should be analyzed immediately. Filled microcuvettes should be inspected for air bubbles, which if present, can produce erroneously low readings. Small air bubbles around the edge do not influence the result.

i) Put the filled microcuvette in the holder. This must be performed within ten minutes after filling the microcuvette.

j) Push the microcuvette holder to the measuring position. During measurement, an hourglass will be shown on the display.

k) After approximately 15 – 60 seconds, the hemoglobin value is displayed in the window.

l) The result will remain on the display as long as the microcuvette holder is in the measuring position. When operating on battery power, the analyzer will automatically turn off after approximately 5 minutes. When energized through an electrical outlet, the meter needs to be turned off. DO NOT leave batteries in the meter when it is energized in an electrical outlet.

m) Discard microcuvette, lancet into sharps container.

n) When testing is complete, turn off and clean the exterior of the instrument after each use. Refer to POC Instrument Cleaning Guide.

2. Venous blood or arterial blood: Sample from a well mixed tube
   Refer to pages 16 and 17 of the Operator Manual.

H. REFERENCE RANGE:
   Reference values:
   
   <1 month = 13.0 - 19.0 g/dL
   1-5 months = 11.0 - 17.0 g/dL
   5 mo up to 2 years = 11.0 - 14.0 g/dL
   2-5 years = 11.0 - 13.0 g/dL
   6-12 years = 11.0 - 15.0 g/dL
   >12 years male = 11.5 - 18.0 g/dL
   >12 years female = 11.5 - 15.5 g/dL

I. MEASURING RANGE:
The HemoCue Hgb 201+ measures accurately between 6.0 – 20.5 g/dL.

J. CRITICAL VALUES:
   1. Hemoglobin results <7.0 g/dl are considered critical values.
   2. All results <7.0 must be repeated in the Hemocue with a new finger puncture.
   3. Hemoglobin results <6.0 require a confirmatory blood sample to be drawn.
   4. Critical values are reported to the provider within 30 minutes and documented in Unity.

K. RESULT DOCUMENTATION: Test order code POC3
   1. Hemoglobin results are documented in the enter/edit function of Unity (Epic).
1.

2. **Critical Values**
   
a) For results less than 6.0, enter results into the comment section as <6.0.

b) Append the “critical value called” documentation under the narrative tab. Search for canned comment by typing POC in the smart test field. Select POC critical value. The following statement will appears (Provider *** notified of critical value and red back on *** at *** by ***). F2 to advance to each of the *** spaces and enter the appropriate information.
3. **Downtime**

In the event of Unity or a network downtime, testing is ordered and results are documented on the hemoglobin record (H8503). This record is scanned into Unity for a permanent report.
L. **LIMITATIONS:**
1. HemoCue Hgb 201+ microcuvettes are for in vitro diagnostic use only. The HemoCue Hgb 201+ analyzer is only to be used together with the HemoCue Hgb 201+ microcuvettes.
2. The measurement needs to be started no later than 10 minutes after filling the microcuvette.
3. Mixing samples for an extended period can produce increased oxygen pressure and viscosity that may give false results.
4. If “HHH” is displayed, the result exceeds the measuring range of system.
5. Values above 20.5 g/dL must be confirmed using a suitable laboratory method.
6. The following substances have not been found to interfere. The highest concentration or percentages tested is referred to in brackets. Interference studies have been performed according to NCCLS Document EP-74.
   - Acetaminophen (20 mg/dL), ascorbic acid (3 mg/dL), conjugated bilirubin (40 mg/dL), unconjugated bilirubin (20 mg/dL), creatinine (30 mg/dL), ibuprofin (40 mg/dL), leukocytes (600 x 10^9/L), lipemia (intralipid 4000 mg/L), triglycerides approximately 1000 mg/dL0, salicylic acid (50 mg/dL), tetracycline (20 mg/dL), thrombocytes (2100 x 10^9/L), urea (500 mg/dL), uric acid (20 mg/dL).
7. pH values between 6.3-9.0 do not interfere with the system.
8. Sulfhemoglobin is not measured with this method.

M. **MAINTENANCE, CLEANING, TROUBLESHOOTING:**

Documentation is required on the Health Center Maintenance log.
1. Each use - clean/disinfect after each use. Wipe exterior with Clorox germicidal wipes.
2. Daily – (see reverse Health Care Maintenance log). The microcuvette holder should be cleaned after each day of use.
   a) Check that the analyzer is turned off. The display should be blank.
   b) Pull the microcuvette holder out to its loading position. Carefully press the small catch positioned in the upper right corner of the microcuvette holder.
   c) While pressing the catch, carefully rotate the microcuvette holder towards the left as far as possible. Carefully pull the microcuvette holder away from the analyzer.
   d) Clean the microcuvette holder with alcohol, Clorox Germicidal wipes or mild detergent. It is important that the microcuvette holder is completely dry before being replaced.
3. Unscheduled:
   - Contact POC 547-6728
4. **Troubleshooting Errors:**
   - Refer to HemoCue 201+ operating manual troubleshooting guide

N. **REFERENCES:**
HemoCue 201+ Operating Manual, Manufactured by HemoCue HB, Angelholm, Sweden.