Oklahoma State
Department of Health

# County Health Department Laboratory Procedures

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| Title: | HEMOCUE Procedure |
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# HemoCue® Hb 201 DM System


Hemoglobin testing is used as one of the initial steps in detecting or assessing anemia. The most common type of anemia is iron deficiency, which may result from inadequate iron intake, chronic blood loss, or increased need for iron, such as during pregnancy. Other causes of anemia, such as hemolytic disorders, acute blood loss or failure of erythropoiesis, may also result in a decrease in the hemoglobin concentration.

## PRINCIPLE

The HemoCue Hb 201 Data Management haemoglobinometer (HemoCue AB, Angelholm, Sweden) is a hand-held device (height 90 mm, width 160 mm, depth 210 mm, weight 250 g) that is used to measure hemoglobin concentrations [Hb] in whole blood samples. The microcuvettes used with the HemoCue device collect the exact amount of whole blood (approximately 10 µL) by capillary action, avoiding the formation of air bubbles, and mix the sample with reagents automatically. The microcuvettes contain the following dried reactants: sodium desoxylate to hemolyse red blood cells and release the hemoglobin; sodium nitrate to convert haemoglobin into methemoglobin; and sodium azide to convert the methaemoglobin into haemoglobinazide. To prevent decay of these reactants from exposure to the atmosphere, the cuvettes are kept in a sealed container. Excess blood is removed from the outside of the microcuvette, which must be placed in the cuvette holder of the HemoCue within 10 minutes. Light absorbance is measured at 570 nm and 880 nm to compensate for any turbidity in the sample, potentially caused by lipemia, leukocytosis or other sources. [Hb] is calculated using a programmed algorithm, and the result is displayed usually within 45 seconds.

An on-line training module showing aspects of specimen collection and processing and instrument operation and maintenance is available at the HemaCue website: www.hemocuelearningcenter.com

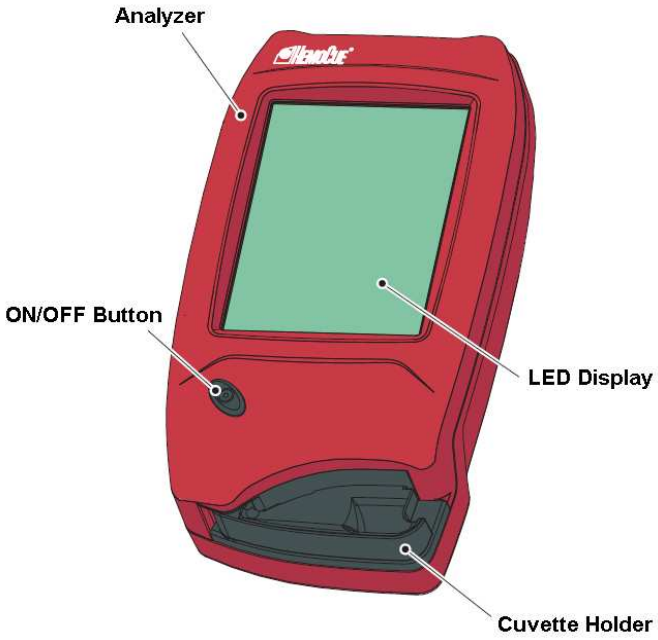
## SPECIMEN

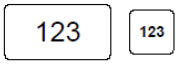
Fresh capillary blood, approx. 10 uL, is obtained from a finger stick or heel stick performed on adults or children aged 6 months and older. The puncture site must be dry and free from residual alcohol used to sterilize the site. The test is performed immediately, in the presence of the patient. Specimens are not stored and no batch testing is performed. Timing of specimen collection is not critical.

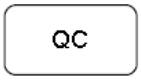
## EQUIPMENT AND SUPPLIES

- HemoCue® Hb 201 Data Management (DM) Analyzer
- HemoCue® Hb 201 DM (Primary and/or Secondary) Docking Station(s)
- Liquid Meter Trax™ Control

- HemoCue® Hb 201 Microcuvettes
- Fingerstick device or lancet
- Digital timer
- Alcohol wipes
- Kleenex™ or gauze
- Biohazard and sharps containers
- Non-absorbent, hydrophobic surface (e.g., Parafilm, plastic film or Scotch tape)



| Button | Designation | Function |
|---|---|---|
|  | Erase button | Erases the last input |
|  | Previous image button | Returns to the previous image<br>NOTE: Inputs/changes made in the current image will not be saved |
|  | Text mode button | Switches to text input mode |
|  | Numeric mode button | Switches to the numeric input mode |
|  | Barcode Scanner button | Switches to the Barcode Scanner mode |
|  | Scroll bar arrow (Up) | Scrolls upwards in a list of different options or in a text |
|  | Scroll bar arrow (Down) | Scrolls downwards in a list of different options or in a text |
|  | Next image button | Continues to the next image in the Help sequence |

| 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 |
|  | Verify/Duplicate sampling button | Allows for the performance of a second test, on the same patient, using a new Cuvette, without the need for re-entering the Patient ID and other information |
|  <br>  | Comment input button<br><br>Comment input button (dotted) | Allows a comment to be added to the current result<br><br>Button appearance confirms that comments have been added to the result |

**Reagent Preparation, Labeling, Storage, and Expiration**

All reagents are supplied ready-for-use and require no further preparation. All reagents and supplies are labeled with an Expiration Date by the manufacturer; however, this expiration date changes when the microcuvette container or Meter Trax Control bottle is opened. All laboratory supplies and reagents must be labeled with the Date Opened.

*Hemocue® Hb 201 DM Analyzer*

- The analyzer can be stored at 32-122°F (0-50°C).

*Hemocue® Hb 201 Microcuvettes*

- Use the microcuvettes prior to their expiration date. Once the container is opened the microcuvettes are stable for three months. (Microcuvette container should be marked with Date Opened).
- Store microcuvettes at room temperature 59-86°F (15-30°C) in a dry place. DO NOT FREEZE. A desiccant to control moisture is present in the lid of each container of microcuvettes. Keep container closed when not in use (moisture will damage the microcuvettes). If microcuvettes look clear, pinkish, or appear to be clumping, dispose of these microcuvettes and open a new container.

*Liquid Meter Trax™ Control*

- Store unopened Meter Trax™ upright at 34-46°F (2-8°C) in the refrigerator. DO NOT FREEZE.
- Unopened Meter Trax™ Control is stable until the manufacturer's expiration date (approximately 6 months) when stored refrigerated at 34-46°F (2-8°C).
- Opened Meter Trax™ Control is stable for up to 4 weeks (31 days) and must be stored at room temperature (64-86°F or 18-30°C).
    - Opened bottles must be dated with the Date Opened.
    - Discard Meter Trax™ Control if hemolysis occurs (i.e., the breakdown of red cell integrity); the Meter Trax™ Control will appear cherry red.

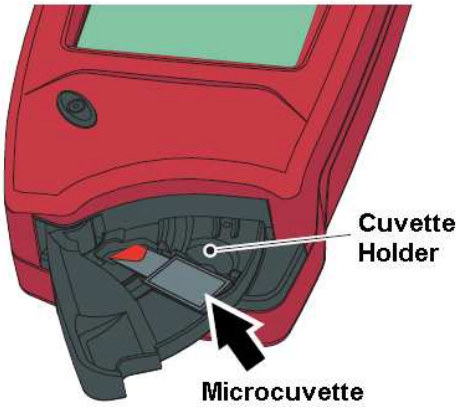
**QUALITY CONTROL**

**HemoCue® Meter Trax™ Control Procedure**

The HemoCue® Meter Trax™ Control procedure must be performed each day the instrument is used. This procedure should be rotated amongst all testing personnel at the site. These control data (downloaded from the analyzer daily when it is docked at the end of the day) are monitored by Field Laboratory Personnel remotely to determine if there are any issues in the function or operation of the analyzer.

1. Turn on the Hemocue® Hb 201 DM Analyzer by pushing the black button on the lower left side of the analyzer.
2. After the start-up menu, the HemoCue® Hb 201 DM Analyzer performs an internal electronic self-test, which takes about 20 seconds.

3. If using a fresh **unopened** Meter Trax™ Control, remove from the refrigerator and allow to warm to room temperature (a minimum of 15 minutes). If using a previously **opened** Meter Trax™ Control, this should already be at room temperature.
4. Once the Meter Trax™ Control has warmed to room temperature, mix the contents thoroughly by gently inverting the bottle until the sediment is fully resuspended (check the bottom of the bottle to make sure no sediment). **DO NOT SHAKE!** This will cause air bubbles and inaccurate readings. **Note:** Inadequate mixing will cause low hemoglobin values.
5. Remove the cap from the Meter Trax™ control bottle, and dispense one drop of the Meter Trax™ Control solution onto a non-absorbent, hydrophobic surface (e.g., Parafilm, plastic film or Scotch tape). **Do <u>not</u> dispense directly from bottle into the microcuvette.**
6. Holding the microcuvette at a 45° angle, place the tip of the microcuvette into the drop of Meter Trax™ Control solution until completely filled.
7. Place the microcuvette into the holder of the Hb 201 DM Analyzer. **DO NOT CLOSE.**




8. Start the digital timer (set for 2 minutes). **Note that the Meter Trax™ Control solution must be in the microcuvette for 2 minutes for optimal chemical reaction to occur to give an accurate reading.** Failure to do so may result in a failed control.
9. Wipe threads on the Meter Trax™ Control bottle and cap with a clean tissue then recap the vial tightly. Store opened Meter Trax™ Control bottle at room temperature.
10. On the Hemocue® Hb 201 DM Analyzer, touch the <<123>> button on the touch screen and enter Operator ID, then press <<QC>> button, followed by the <<Level 2>> button. Note: Level 1-5 refer to different concentrations of liquid controls.
11. Press the <<123>> and enter the Lot Number of Meter Trax™ Control.
12. **Wait for 2 minutes** (from time of filling microcuvette) **before closing the microcuvette holder.**
13. The control value will be displayed and will indicate whether “QC Pass” or “QC Fail”.
    - If the **control passes**, press <<OK>> on the touch screen and dispose of the microcuvette in the biohazard waste receptacle.
    - If the **control fails**, press <<OK>> on the touch screen and dispose of the microcuvette in the biohazard waste receptacle. DO NOT re-measure the same microcuvette.
        - Fill a <u>new</u> microcuvette and repeat steps above.

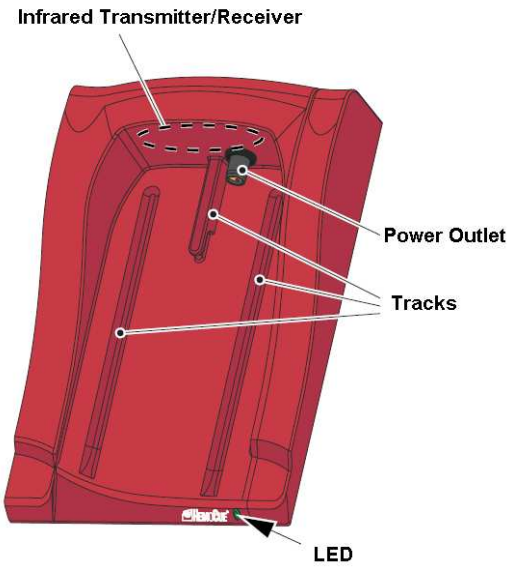
- If the new value is within the expected range, proceed to patient testing.
- If the new value is outside the expected range:
  - review all procedure steps to confirm the test is being performed correctly.
  - check the expiration date of the Meter Trax™ Control solution and microcuvettes.
  - check that the Meter Trax™ Control solution is adequately suspended before loading microcuvette.
- If no problems are found, fill a new microcuvette with Meter Trax™ Control solution and repeat steps above.
- If the new value is within the expected range, proceed to patient testing.
- If the new value is outside the expected range, contact OSDH Field Laboratory Operations at (405)271-5070.

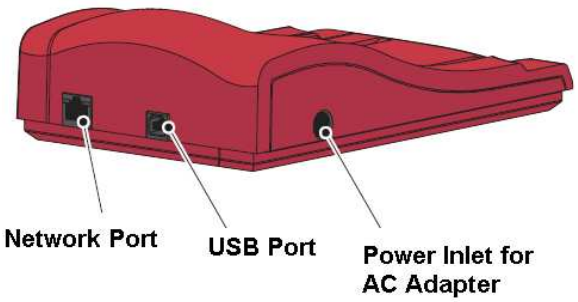
**Docking the Analyzer**

Analyzers should be docked each day (at the end of the working day) on a docking station to charge the battery of the analyzer and transmit/receive data (if a primary docking station is present). **Important:** Always slide the analyzer into and out of the docking station by means of its tracks.

- A **flashing green LED light** on the docking station indicates that the battery of the docked analyzer is charging.
- A **steady green LED light** on the docking station indicates that the docking station is receiving power and that the battery of the analyzer is fully charged.
- A **flashing red LED light** can only happen on a primary docking station and indicates an external communication error (problem with the internet connection). Reset the docking station by unplugging the power cord and plugging it back in after 60 seconds. The docking station light should turn green in 1-3 minutes.
- A **steady red light LED** on the docking station indicates the presence of an internal communication error within the docking station. If a red light is seen, reset the docking station by unplugging the power cord and plugging it back in after 60 seconds. The docking station light should turn green in 1-3 minutes.

Most facilities have a “primary” docking station that is connected to the internet and is able to transfer data from the analyzers to OSDH Field Laboratory Operations at the OSDH Central Office and receive updates for the analyzers (e.g., Meter Trax™ Control solution lot number, expiration date, and expected range, operator IDs, time/date, etc.). This Primary Docking Station can be connected to up to 5 secondary docking stations, which may also transfer/receive data if connected to a primary docking station. A few facilities do not have a primary docking station, but rather have only a secondary docking station, which does not have a network port and is used only for charging analyzers. For those facilities without a primary docking station, each analyzer must be taken to another facility with a primary docking station for transmission of QC data at least once per month (5 days grace period).



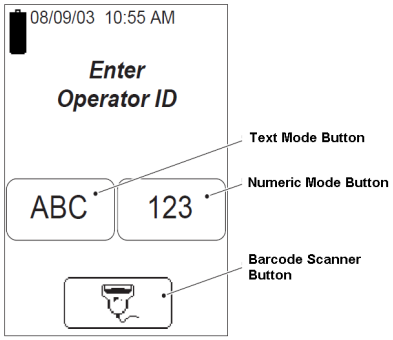




To upload data:

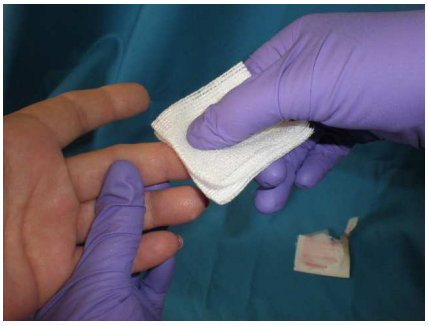
1. Prior to docking an analyzer, make sure the analyzer is ON and the LCD screen is displayed.
    - If the screen is not lit, touch the screen on the analyzer to display the LCD.
    - If the battery is low on the analyzer the screen will not light-up; if this is the case, dock the analyzer and use the power button to turn the analyzer ON. Make sure the LCD screen is lit.
2. Check for a green light on the docking station.
    - If a red light is observed on the primary docking station, reset the docking station by unplugging the power cord and plugging it back in after 60 seconds. The docking station light should turn green in 1-3 minutes.
3. Place the analyzer on the docking station.
4. Pull-out the microcuvette holder.
5. “Data exchange” will appear on the LCD screen during data transfer.

**PATIENT TEST PROCEDURE**

1. Press <<123>> on the Analyzer touch screen and enter Operator ID using the numbers on the number pad.



2. Press the <<Patient Test>> button (microcuvette with blood drop image) on the analyzer touch screen.
3. Enter Patient ID using the Text and Numeric mode buttons on the analyzer screen.
4. Make sure the patient's hand is warm and relaxed.
5. Cleanse the patient's ring or middle finger (avoid using fingers with rings, or ask patient to remove rings) with an alcohol wipe or isopropyl alcohol and Kleenex™. Do not cleanse the puncture site with a cotton ball; residual cotton fibers may interfere with hemoglobin measurements.
6. Wipe-off excess alcohol and allow to air-dry.



7. Using your thumb, lightly press the patient's finger while moving your thumb from the knuckle towards the tip of the patient's finger. This stimulates blood flow towards the sampling point.

8. While applying light pressure toward the fingertip, puncture the finger using a sterile, disposable lancet. (For best blood flow and least pain, puncture the skin at the side of the fingertip, not at the center.)

9. Wipe away the first two or three drops of blood with dry, sterile gauze or Kleenex™. **NOTE:** Do not use a cotton ball; excess cotton fibers may interfere with hemoglobin measurements.

10. Re-apply light pressure towards the fingertip until another drop of blood appears. If the flow is not strong enough to fill a microcuvette (10 µL of blood is required) in one continuous process, re-stick the patient.

11. When a large blood drop is present, place the open-end tip of the microcuvette into the blood drop and fill the microcuvette in <u>one continuous process</u>. The microcuvette must not be taken away from the drop of blood until it is full. Leave the microcuvette in the drop of blood for a few extra seconds after it looks full. If the microcuvette is under-filled, do <u>not</u> refill. Instead, discard the microcuvette and fill a new microcuvette using a fresh drop of blood.

12. Wipe-off excess blood from the outer surface of the microcuvette with lint-free tissue using a concise motion, being careful not to touch the open end of the microcuvette.
13. Look for any trapped air bubbles in the filled microcuvette.
    - If any air bubbles are present, fill a new microcuvette.
    - If a second sample is to be taken from the same finger stick, wipe away the remainder of the initial sample and fill a second microcuvette from a new drop of blood.
14. Place the microcuvette in the microcuvette holder of the analyzer.
15. **Wait for at least 2 minutes** (up to 10 minutes) for the blood to react with the reagents in the microcuvette, then close the cuvette holder and take the reading (displayed in grams per deciliter, g/dL). After 15 to 45 seconds, the result will be displayed and will remain on the display until the <<Confirm>> button has been pressed.


16. The following normal reference ranges for hemoglobin have been set by the World Health Organization for males, females and children and can be used to determine hemoglobin status of the patient:
    - Men (>15 years) 13.0-17.0 g/dL
    - Non-pregnant Women (>15 years) 12.0-15.0 g/dL
    - Pregnant Women (>15 years) 11.0-14.0 g/dL
    - Children (0.5 – 15 years) 11.0-14.0 g/dL

    The range of the Hemocue Analyzer is 0 to 25.6 g/dL; values falling outside this range will be displayed as “Overrange” and should be noted and verified by performing another capillary hemoglobin test.
17. Enter an appropriate Comment Code after accepting the hemoglobin reading by pressing the notepad on the bottom left of the analyzer screen.
18. Using the arrows on the right side of the analyzer, scroll down to the appropriate comment.
19. Press <<OK>> to save comment.
16. Dispose microcuvettes and blood-soiled gauze or tissues in biohazard trash.
17. The following information is entered on form ODH 303L, which is placed into the patient’s chart:

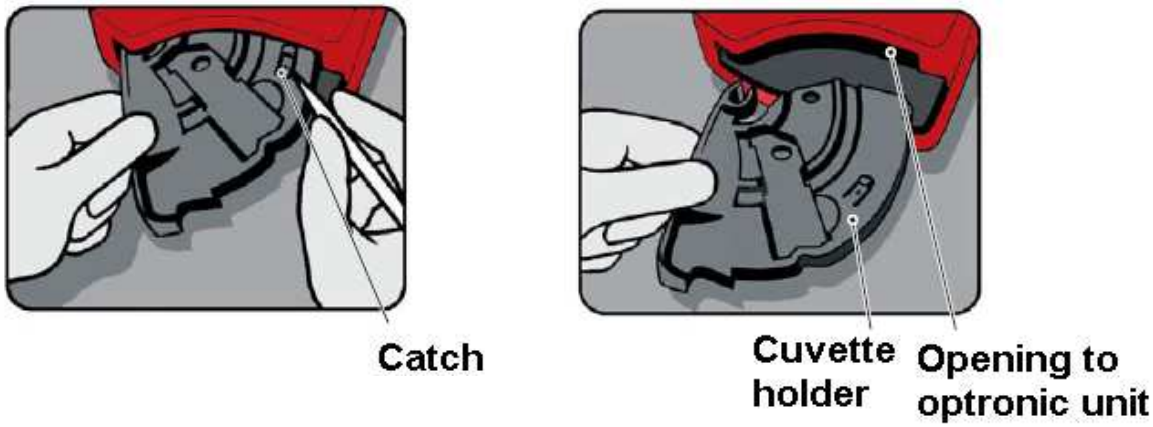
- HGB test result.
- Initials of person performing the test.
- Signature, credentials and initials (at bottom of form).

**PREVENTATIVE MAINTENANCE**

The Hemocue Hb 201 DM Analyzer is designed to work for a long period of time without any direct service. No preventative maintenance is needed for the electronic parts of the analyzer.

The microcuvette holder and photometric "eye" of the analyzer should be cleaned at least weekly (more frequently if high test volume is involved).

1. Check that the analyzer is turned off (display should be blank).
2. Pull the microcuvette holder out to the loading position. Using a pointed object, carefully press the small catch in the upper right hand corner of the microcuvette holder.




3. While pressing the catch, carefully rotate the microcuvette holder to the left as far as possible to the left then remove the holder from the analyzer.
4. Clean the microcuvette holder with alcohol or a dilute solution of mild detergent.
5. To clean the photometric "eye", push a long-tipped cotton swab, wetted with 70% alcohol, into the opening of the optronic unit and move from right to the left 5-10 times and then pull it out.
6. If the swab is stained, repeat until the swab comes out clean.
7. **Wait 5 minutes** before putting the microcuvette holder back into the analyzer. It is important that the microcuvette holder is completely dry before re-inserting it. Re-attach the microcuvette holder to analyzer and push back in place until you hear a click from the small catch in the upper right corner.
8. Document cleaning in the *HemoCue Maintenance and Function Checks Log*, which is specific for each analyzer.

The outside of the Hemocue Hb 201 DM Analyzer should be cleaned at least <u>once a month</u> unless there is a high volume of testing in which case the analyzer should be cleaned twice a month.

1. Make sure the analyzer is turned off.
2. Clean the outer case of the analyzer and the docking station with alcohol or a dilute solution of a mild detergent.

**PROBLEMS WITH OPERATION OF ANALYZER/DOCKING STATION**

**Troubleshooting**

Some of the common error messages are given in the table below. For a more complete list of error messages, refer to the Troubleshooting Section of the Hemocue Hb 201 DM Analyzer Reference Manual located in the Hemocue software\help\online help. Alternatively, call OSDH Field Laboratory Operations for help (405)271-5070 in troubleshooting problems. Document problems encountered with operation or function of the analyzer or docking station in the *HemoCue Maintenance and Function Checks Log*.

| Error Code | Description | Resolution |
|---|---|---|
| E01-E05 | Fault in the optics or electronics | Turn off analyzer and clean the optronic unit as described in the maintenance section or the analyzer needs service (contact OSDH Field Laboratory Operations to send analyzer for service) |
| E-11 | Hardware error | Analyzer needs service (contact OSDH Field Laboratory Operations to send analyzer for service) |
| E-26 | Patient test memory is full | Delete all or part of the patient tests stored in the analyzer |
| E-27 | QC memory is full | Delete all or part of the QC tests stored in the analyzer |

**Calibrating the Display**

If the touch screen is non-responsive, the screen may need to be recalibrated.

1. Make sure the Analzyer is turned off. The display should be blank.
2. Press the On/Off button for at least 10 seconds.
3. A plus sign will appear in the upper left corner of the display.
4. Gently press the center of the plus sign with a blunt object. Using the fingertip may not be precise enough.
   **NOTE:** This is the only occasion when anything other than the fingertips should be used to touch the display. Sharp edged objects can damage the display.
5. The first plus sign will disappear and 2 additional plus signs will appear in sequence.
6. Repeat according to instructions #3 and #4 above.
7. 2 more plus signs will appear to verify the calibration of the display.
8. Repeat according to instructions #3 and #4 above.
9. If the verification of the calibration is successful, the Analyzer will continue with the normal startup. If the verification fails, the display calibration procedure will start over again. If the procedure fails more than five times the normal startup procedure will continue, but the Analyzer probably needs service.

**HemoCue Repair**

Problems with operation of analyzers or docking stations should be addressed with OSDH Field Laboratory Operations at (405)271-5070. Generally, a loaner instrument will be supplied to the site while repair occurs. Document repairs in the *HemoCue Maintenance and Function Checks Log.*

## DOCUMENT RETENTION

QC documents, including the *HemoCue Maintenance and Function Checks Log,* should be retained for a minimum of two years.

## REFERENCES

Worldwide Prevalence of Anaemia 1993-2005: WHO Global Database on Anaemia.