

The Johns Hopkins Medical Institutions

**Hemoglobin Testing
using the
Data Management
HemoCue Analyzer**

A Self-Study Packet

for

**The Johns Hopkins Hospital
Point-of-Care Testing Program**

Revision: 12/02

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Upon completion of this self-study packet, the HemoCue Operator will be able to:

1. Perform daily cleaning and maintenance
2. Perform and verify a Red Control Cuvette Test.
3. Verify control lot numbers and expiration dates.
4. Verify microcuvette batch numbers and expiration dates
5. Perform and verify Low and High Control Tests.
6. Enter Operator ID numbers.
7. Enter Patient ID numbers.
8. Enter appropriate Comment Codes.
9. Perform and verify a Patient Test.
10. Troubleshoot HemoCue Lockout Mode.
11. Notify Johns Hopkins Medical Laboratories of Error Codes.

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Point - of- Care

Hemoglobin Testing

Test Principle for the Data Management HemoCue Analyzer

Blood is drawn into the microcuvette by capillary action and spontaneously mixed with the reagents inside the microcuvette. A direct reading of the concentration of hemoglobin is obtained within 1 minute and the value is indicated on the HemoCue Display Screen.

Limitations and Uses

- The HemoCue Hemoglobin test is used for the screening and ongoing management of patients
- The measurement of hemoglobin in blood is one of the most frequently performed tests. Blood hemoglobin concentration may be ordered as a screen for anemia blood loss, hemolysis, impaired blood formation, and polycythemia.

Linearity:

The DM HemoCue Analyzer will accurately read hemoglobin results between 0 and 23.5 g/dL. The hemoglobin value is read directly from the instrument.

Normal Ranges:

Adult Male: 13.9 - 16.3 g/dL

Adult Female: 12.0 - 15.0 g/dl

Critical Action Limits:

- < 5 g/dL or > 20 g/dL
- All critical action results must be reported to the physician, who will determine if additional follow-up is needed.

Abnormal Result Follow-up:

Physicians should utilize clinical judgment to determine the need for follow-up, i.e. submitting a venous sample to the central laboratory.

Interferences:

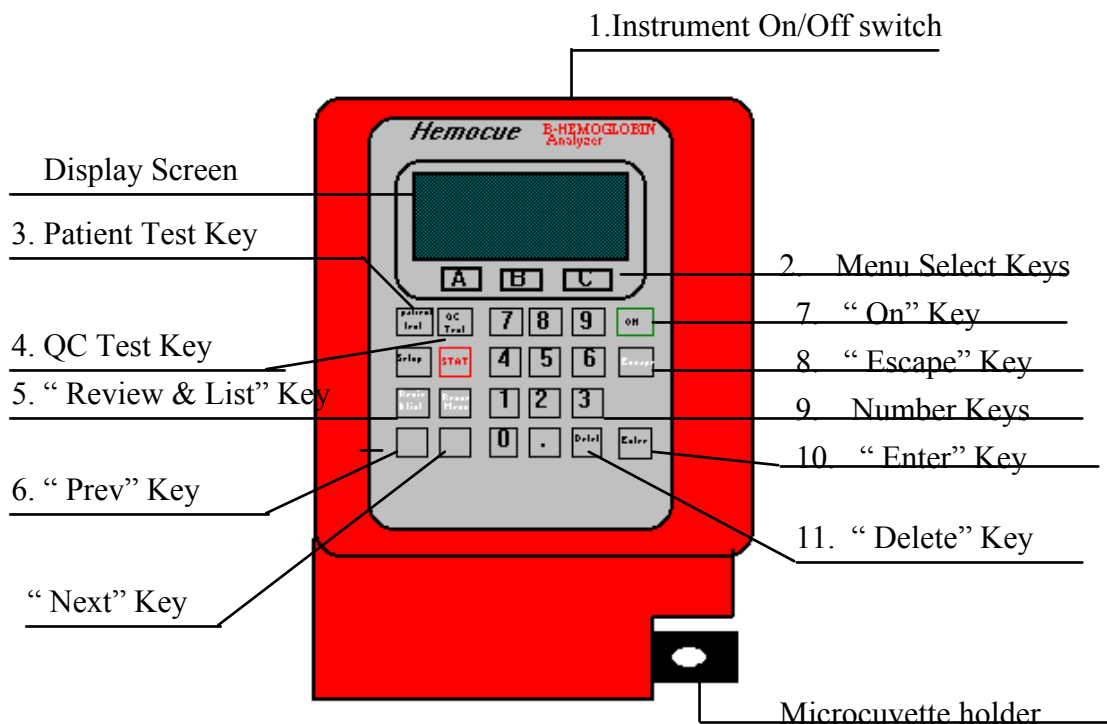
Interferences may be caused by dirty cuvettes / equipment.

Patient Test Result Documentation:

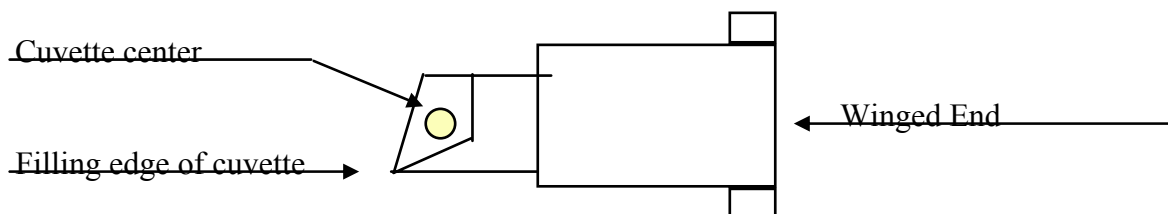
Record the HemoCue results in the patient's chart in a manner that will distinguish point-of-care results from central laboratory results. Record the collection date, time, operator initials and HemoCue instrument ID number with the patient's result.

HemoCue Data Management Analyzer

(Description of Keys on next page)



HemoCue Microcuvette for Patient Testing*



(*Note: Control Cuvette is red and should be kept in its storage box when not in use)

HemoCue Data Management Instrument Keys

1. Instrument On/Off: Turns the HemoCue on or off.
2. Menu Select Keys: Allows operator to choose a particular option on the Display Screen.
3. Patient Test Key: This key puts the HemoCue into the Patient Test mode.
4. QC Test Key: This key puts the HemoCue into the Quality Control mode.
5. Review and List Key: Operator can review previous patient and Quality Control results which are stored in reverse chronological order.
6. Prev.and Next Key: Allow the operator to move forward or backwards in the list of previous results.
7. On Key: Will light up the display screen after the HemoCue has gone into standby mode.
8. Escape Key: Moves the operator one step backwards through the test menu each time the key is pressed.
9. Number Keys: Used to manually enter Operator ID and Patient ID numbers.
10. Enter Key: May be used in place of the “ C” key.
11. Delete Key: Deletes any numbers entered and moves from right to left.

Johns Hopkins Hospital

Point-of-Care Testing Program

Quality Assurance Program

JHH Quality Assurance Program

The Johns Hopkins Hospital Point-of-Care Testing Program Quality Assurance Program for point-of-care hemoglobin testing has been developed to keep the Hospital in compliance with JCAHO and laboratory regulatory agency requirements.

The components of the JHH Quality Assurance Program are:

- I. Validation of Operator Skill
- II. Quality Control (QC)
- III. Laboratory Proficiency Check Samples

Each of these components is covered in more detail on the next several pages.

I. Validation of Operator Skill

- In order to be a DM HemoCue operator, an individual must pass the written test and successfully complete the skills competency checklist.
- Your operator ID will be the first six digits of your employee ID badge number and must be kept confidential.
- All staff performing hemoglobin testing must do QC at least once every six months.
 - ◇ QC test performance is stored in the DM HemoCue computer memory and is downloaded on a routine basis.
- Operator performance is reviewed every four to six months based on reports sent to the Nurse Manager by JHH Point-of-Care Testing Program Office.
- The computer reports show documentation of employee QC performance over the past four to six months.

I. Validation of Operator Skill (continued)

- An operator will not be able to continue testing with the meter if:
 - ◇ There is no record of QC performance in a 6 month period.
 - ◇ The operator's QC results are significantly different from all other operators.
- An operator who has not performed QC within the 6 month period or whose results are significantly different will need to be re-trained and re-tested.

II. Quality Control

- FREQUENCY:

All monitors at each patient testing site will have QC run once every 24 hours, analyzing two levels of control material (low and high).

- Quality control for the DM HemoCue consists of a Red Control Cuvette (QCC), Low Control (QCL), and a High Control (QCH).
- Quality control testing should be performed:
 - ◇ When cuvettes have been exposed to extreme heat, humidity, or cold.
 - ◇ When a bottle of cuvettes has been left opened.
 - ◇ If the DM HemoCue analyzer has been dropped.
 - ◇ If the DM HemoCue analyzer has been turned off.
- In order to ensure compliance, the operator who does QC should do all of the site's meters at the same time.
- Only one lot of cuvettes and controls will be in use at one time.
- The Red Control Cuvette is factory matched to the instrument. Do not switch Red Control Cuvettes between instruments. Lost or damaged Red Control Cuvettes need to be reported to the Johns Hopkins Medical Laboratories.

II. Quality Control (continued)

- If Quality Control is not performed every 24 hours, the HemoCue will lockout any patient testing until QC testing has been performed satisfactorily.
- Failed Quality Control will result in an instant lockout of patient testing until QC testing has satisfactorily passed.

Reagent Storage and Stability

- **Hematronix Meter Trax Controls**

- ◇ Unopened Hematronix controls are stable to the factory imprinted date on the label when stored refrigerated (2°- 8°C).
- ◇ Opened Hematronix controls are stable for 30 days at room temperature.
- ◇ Record the date “opened” and operator initials on each control bottle.
- ◇ Hematronix controls are derived from blood products. Use Standard Precautions when handling control specimens.

- **HemoCue Microcuvettes**

- ◇ Microcuvettes are stored at room temperature (18°-30°C) (64°-86°F).
- ◇ Unopened Microcuvettes are stable to the factory imprinted expiration date on the label.
- ◇ Opened Microcuvettes are stable for 90 days.
- ◇ Record the date “opened” and operator initials on each Microcuvette container.

The recording of the date “opened” on containers of microcuvettes and bottles of control solution is a Laboratory Regulatory Requirement!

Order of Activities

Quality Control samples (Hematronix) need to incubate in a filled cuvette 1 1/2 minutes prior to reading in the analyzer. To save time, the operator should perform the maintenance and quality control in the following sequence:

1. Perform routine maintenance and cleaning.
2. Perform hemoglobin control preparation
(fill two cuvettes with low and high control solutions).
3. Perform Red Control Cuvette optics check.
4. Run controls.

Routine Maintenance and Cleaning

- Maintenance and cleaning should be performed prior to running quality control and any time there is blood residue present.
- Turn the HemoCue off and remove the black cuvette holder by lifting while pulling straight out from the analyzer.
- Clean the cuvette holder by gently scrubbing with soap and water to remove any dried blood residue. Wipe holder with a 1:10 bleach solution or hospital approved germicide.
- Dry the holder thoroughly before placing it back into the HemoCue analyzer.
- Clean the exterior of the analyzer with 1:10 bleach solution or hospital approved germicide. *Do Not Use Iodine Solutions!*
- Place the cuvette holder back into the HemoCue and turn the analyzer back on.

Hemoglobin Control Preparation

1. Label a piece of parafilm with an “L” for the Low Control and “H” for the High Control, using a felt tip marker.
2. Check the open date and the manufacturer’s expiration date on the control vials. The controls are stable for 30 days at room temperature after opening. Discard the controls if they are more than 30 days old or past the manufacturer’s expiration date, then open and date new set of control vials.
3. Mix the vials of Hematronix Controls for a minimum of 2 minutes, alternating rolling the vials between the palms of the hands and inverting them.
4. Open the Low Control vial and squeeze a drop of sample onto the parafilm. Wipe any excess control from the cap of the vial and from the tip of the dropper using a Kimwipe.
5. Repeat Step# 4 using the High Control vial.
6. Check the open date and manufacturer’s expiration date on the cuvettes. Cuvettes are stable for 3 months after opening, if the bottle has been kept tightly capped and the manufacturer’s expiration date has not been exceeded. If the cuvettes have expired, discard, then open and date a new bottle.
7. Remove 2 cuvettes from the bottle and tightly replace the cap.
8. Holding a cuvette by the winged end, move the tip of the filling edge just into the low control drop. The cuvette will fill by capillary action.

Hemoglobin Control Preparation (continued)

9. Gently wipe any excess blood from the cuvette using a Kimwipe. Avoid touching the tissue to the open end of the cuvette as a small amount of sample will wick out of the cuvette.
10. Check for any bubbles in the cuvette. Tiny bubbles at the edge of the cuvette will not affect the test, but if any bubbles are noticed in the center of the cuvette, discard. Start again with a new cuvette.
11. Fill the remaining cuvette with the High Control.
12. Set the filled cuvettes flat on a pre-labeled piece of parafilm or on a Kimwipe. Set a timer for **1 1/2 minutes** and begin the Red Control Cuvette procedure.

Note: The cuvettes containing the Low and High Control must be read no later than 1 1/2 minutes after filling.

Red Control Cuvette Optics Check

- Press “QC Test” key. Select “QCC”.
- Remove the Red Control Cuvette from its protective box and check for dirt or smudges on the surface. Gently clean with a Kimwipe moistened with water to remove any dirt. Dry thoroughly with a Kimwipe.
- Place the Red Control Cuvette into the cuvette holder. The winged end should be pointed to the right with the tip up and to the left.
- Push the cuvette holder into the analyzer’s measuring position. After 10-15 seconds, the analyzer displays the value for the Red Control Cuvette and “Pass” or “Fail”.
- The acceptable range for the Red Control Cuvette result is ± 0.3 g/dL of the assigned / target value.
- If the Red Control Cuvette fails, pull the cuvette holder out. Enter a comment code for corrective action . Refer to the Troubleshooting Flow Chart in the HemoCue Policy and Procedure Manual for assistance.
- If the Red Control Cuvette passes, pull the cuvette holder out. Place the cuvette back into the protective box. Continue with control testing.

Hemoglobin Control Procedure

- Select “ QCL” for the low level control and “ QCH” for the high level control from QC menu.
- Place the cuvette containing the Low Control into the cuvette holder. The winged end should be pointed to the right with the sample to the left and the filling tip up.
- Push the cuvette holder into the analyzer into the measuring position. After approximately 45 seconds, the HemoCue will display the Low Control value and “Pass” or “Fail”.
- If the Low Control value fails, refer to the Troubleshooting Flowchart for the steps to be taken to correct the failed result. Enter the appropriate Comment Code for the corrective action into the analyzer.
- If the Low Control value passes, continue with the High Control following the above steps.
- When all Quality Control is successfully completed, patient testing may begin.

QC Failure Documentation

If QC fails, the operator will:

- Document the failed QC and corrective actions taken by entering comment code numbers into the DM HemoCue.
- Contact the Johns Hopkins Medical Laboratories (JHML) when troubleshooting techniques are unsuccessful or problems are encountered. Institute your site's contingency plan for when your DM HemoCue analyzer is not working.

Monday - Friday

8:30am - 4pm

JHML - 600 N. Wolfe:

410-955-2645

III. Laboratory Proficiency Check Samples

The Johns Hopkins Hospital Point-of-Care Testing Program Office periodically provides laboratory check samples to all patient testing sites for analysis. The purpose of these samples is to compare the accuracy of the meters at each site with a reference in the laboratory.

The Operator should:

- Use Standard Precautions in handling the laboratory check samples.
- Enter sample ID number found on side of tube when required, following the provided instructions.
- Test the samples on *each* meter within 24 hours.
- Laboratory Check Sample results are stored in the DM HemoCue computer memory.

Specimen Collection and Patient Testing

Specimen Collection

- Specimens immediately analyzed and reported without leaving the operator's possession do not need to be labeled.
- **If there is a delay in testing or an interruption between specimen collection and testing, specimens must be properly labeled with the patient's name, history number, and date and time of collection.**
- Sample Types

Capillary or arterial/venous blood are acceptable specimens for the Data Management HemoCue Analyzer and there are three methods for collection:

- ◇ Capillary Fingerstick
- ◇ EDTA Vacutainer tubes
(Venous or arterial blood)
- ◇ Lithium Heparin ABG Syringe
(Venous or arterial blood)

Specimen Collection (continued)

- **Capillary (Fingerstick):**
(Not recommended if the patient has peripheral vasoconstriction or is receiving pressors.)
 1. Lightly press finger from top knuckle to tip.
 2. Clean site with disinfectant and dry with sterile gauze.
 3. Perform puncture with lancet just off-center of finger tip.
 4. Wipe first 2-3 drops with a dry gauze (don't milk).
 5. Accumulate a large drop of blood and fill cuvette by moving the filling edge just into the blood.
 6. Gently wipe any excess blood from the cuvette using a lint-free tissue. Avoid touching tissue to the end of the cuvette.

- **EDTA Vacutainer Tube:** (Venous/arterial)
 1. Blood must be taken from an EDTA purple top tube.
 2. Invert tube 10 times. If there is a delay in testing, mix sample an additional 10 times.
 3. Remove the vacutainer cap and transfer a drop of blood to a square of parafilm using a disposable plastic pipette. Recap vacutainer.
 4. Move cuvette into blood to fill.
 5. Gently wipe any excess blood from the cuvette using a lint-free tissue. Avoid touching tissue to the end of the cuvette.

- **ABG Syringe:** (Venous/arterial)
 1. Collect blood in a lithium heparin ABG syringe.
 2. Pull back on syringe plunger slightly to allow approximately 1 cc. of air space.
 3. If sample is analyzed immediately, gently mix by inversion 10 times. If there is any delay, sample should be mixed an additional 10 times.
 4. Remove the syringe cap and squeeze a drop of blood onto a parafilm square.
 5. Move cuvette into blood to fill.
 6. Gently wipe any excess blood from the cuvette using a lint-free tissue. Avoid touching tissue to the end of the cuvette.

Data Management HemoCue Operation

The Data Management HemoCue operator is guided through the Quality control and Patient Test procedures by messages that appear on the display window.

A procedure is started by pressing the appropriate key in the leftmost group on the keypad when the analyzer is in the Standby or Lockout mode.

Standby mode display

HEMOCUE B-HEMOGLOBIN	
05/01/97	10:00 AM
MEM:999	FREE:981
READY	

A	B	C
---	---	---

Lockout Mode display

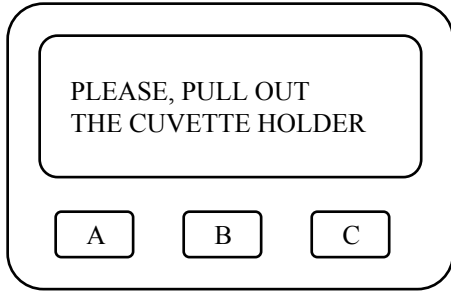
HEMOCUE B-HEMOGLOBIN	
05/01/97	10:00 AM
PAT.TEST.LOCKED OUT	
RUN QCC,QCL,QCH.....	

A	B	C
---	---	---

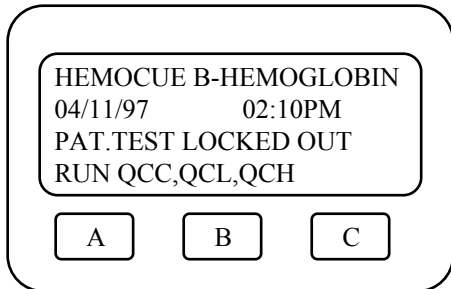
The keys A, B, and C are used to select from menus shown on the bottom of the display window. The menu will appear on the display directly above the letters A, B and C.

Operator and Patient ID numbers are entered by using either a barcode wand or the number keypad in the center of the HemoCue.

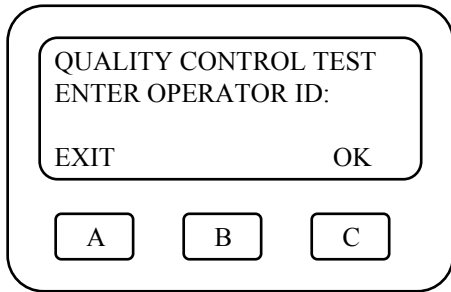
Display Screen Messages



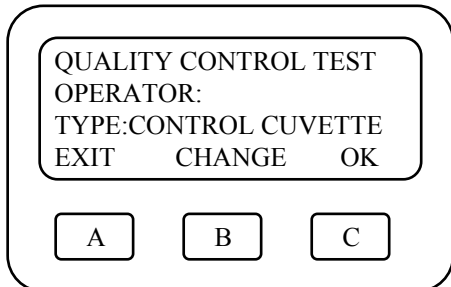
1. Turn on the HemoCue by pressing the On/Off switch to the On position. Pull out the cuvette holder.



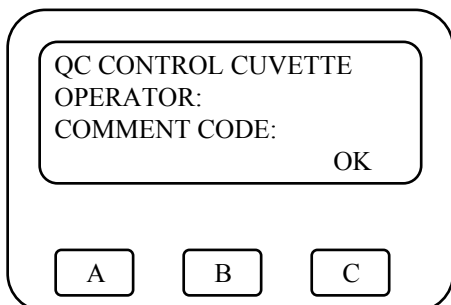
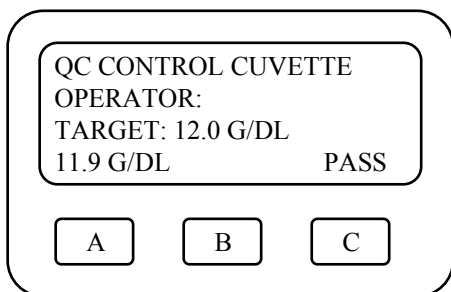
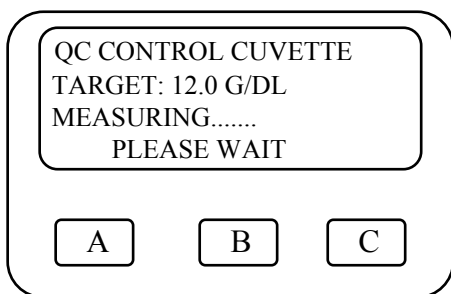
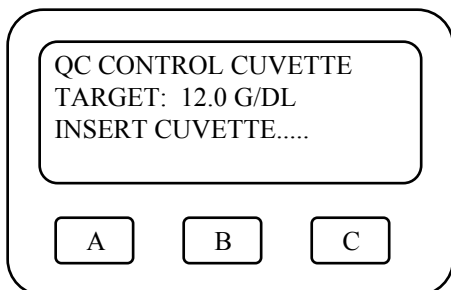
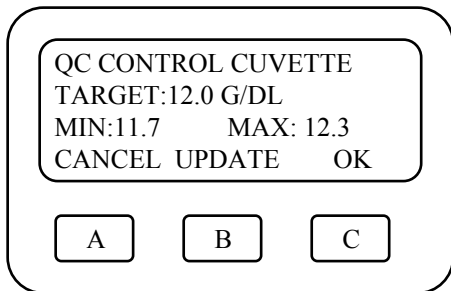
2. The HemoCue is in the lockout mode. Press the “QC Test” button located below the display screen and to the left of the number keypad.



3. Enter your operator ID number using the number keypad, then press “C” or “ENTER”. (If a barcode wand is being used, move the wand over the barcoded operator ID. The HemoCue will beep when the code is accepted).



4. Type: “Control Cuvette” is now displayed. Press “ C” (ok) to accept.



5. Verify the value and range for the Red Control Cuvette (QCC) against the value printed on the white card found in the red cuvette box. Press the “ C” key to accept the value. **Do not interchange red control cuvettes as they are factory matched to the individual HemoCue analyzer.**

6. Place the Red Control Cuvette into the cuvette holder and push in until a distinct click is heard.

7. The HemoCue display will show the word “ Measuring”. **Do not pull the cuvette holder out until the test is completed.**

8. The result is displayed until the cuvette holder is pulled out. If the result is within the acceptable range, “PASS” is displayed. If the result is not acceptable, “FAIL” is displayed and all patient testing is locked out until the fail is corrected. Refer to the Troubleshooting section of the Procedure Manual for the corrective action taken in the event of a Red Control Cuvette fail.

9. Enter a comment code, if needed, to document corrective actions from the list posted near the HemoCue. Codes are entered manually using the number keypad

Data Management HemoCue Comment Codes

If there are no problems with the instrument and the daily cleaning has been performed

1000 Daily Cleaning Performed

Comments for Red Control Cuvette Problems

1002 Repeat Red Cuvette Test

1003 Cleaned Red Cuvette

Comments for Low or High Control Problems

1004 Repeat Control Test

1005 Opened New Control

1006 Opened New Cuvettes

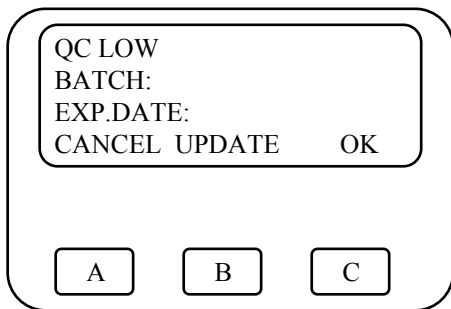
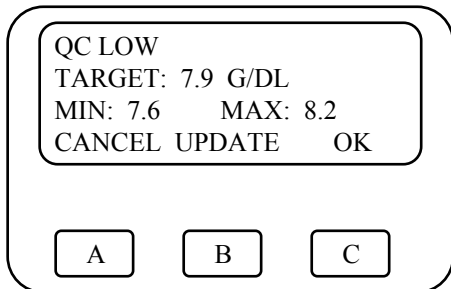
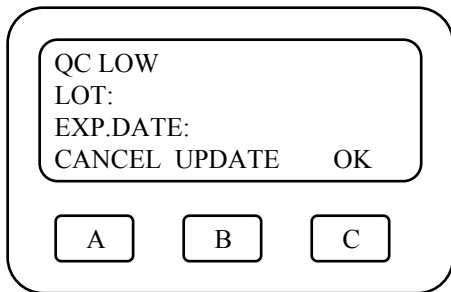
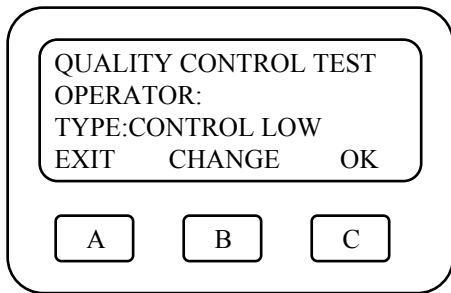
1007 Contacted Pathology

Comments for Patient Test Problems

1008 Operator Error - Repeat Test

1009 Abnormal Result - Repeat Test

The list of Comment Codes will be posted near the HemoCue for the operators to refer to during HemoCue operation.

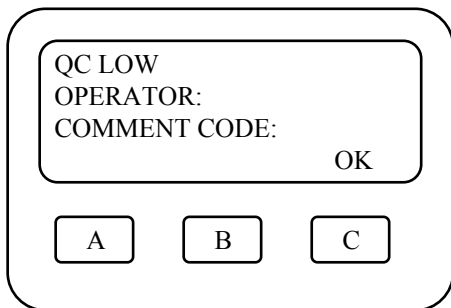
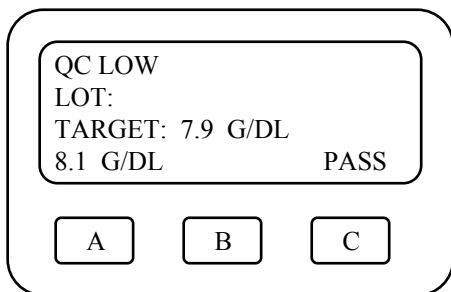
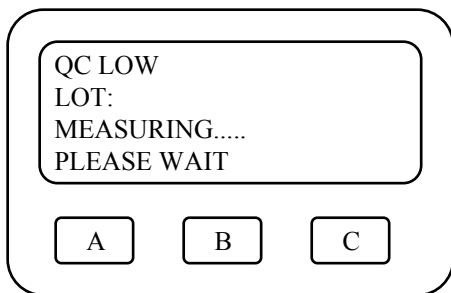
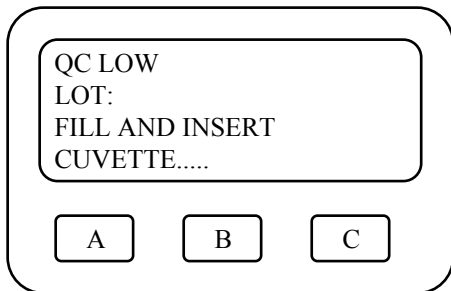


1. After the Red Control Cuvette test has been completed and passed, “ Type:Control Low” is displayed. To accept, press “ C” (ok).

2. Verify the Low Control lot number and manufacturer’s expiration date by pressing “ C” (ok). **If the lot number and/or manufacturer’s expiration date on the control vial do not agree with the information displayed in the meter, STOP TESTING and contact the Johns Hopkins Medical Laboratories for further assistance. If the handwritten open date is more than 30 days old, discard the control and open and date a new vial.**

3. The Low Control target value and range are displayed. Press the “ C” button to continue with the test.

4. Verify the microcuvette batch number and manufacturer’s expiration date printed on the side of the microcuvette vial with the numbers displayed on the meter. Press “ C” (ok) to accept. **If the batch number on the vial doesn’t agree with the number shown on the meter, press “B” to update. Enter password “9876” followed by the batch number and expiration date of the cuvettes. If the open date on the vial of cuvettes is more than 90 days old, or past the manufacturer’s expiration date, discard the vial . Open and date a new vial of microcuvettes and continue with the testing procedure.**



5. Place the prefilled cuvette containing the Low Control into the cuvette holder. Push into the meter until a distinct click is heard.

6. Wait while measuring. **Do not pull the cuvette holder out until the test is complete or the test will be aborted.**

7. The Low Control result is displayed until the cuvette holder is pulled out. If the result is within acceptable range, “PASS” is displayed on the screen. If “FAIL” is displayed, patient test lockout will occur and the control fail must be corrected. Refer to the Troubleshooting section of the HemoCue Procedure Manual for the corrective action taken in the event of a failed control result.

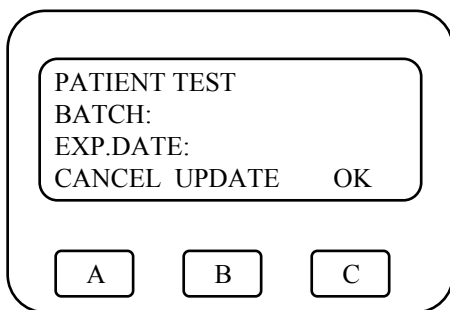
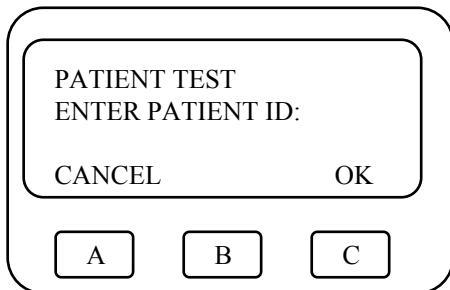
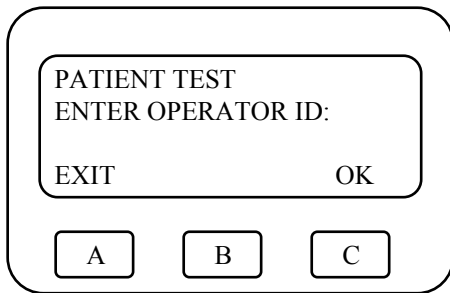
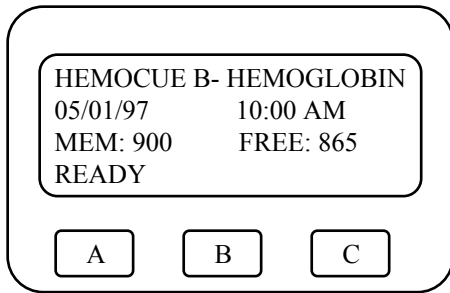
8. Enter the appropriate comment code by using the number keys.

9. Press “C” to continue with the High Control Test.

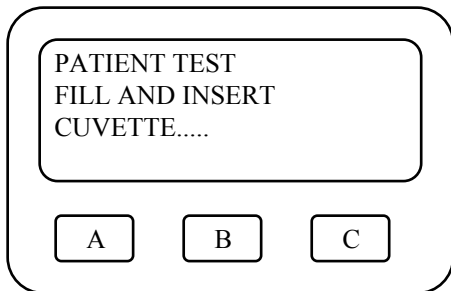
10. Repeat steps 2 - 8 using the prefilled cuvette containing the High Control.

11. When all the control tests are completed and passed, press the “A” key to exit the QC test mode. The HemoCue will go into the Standby mode.

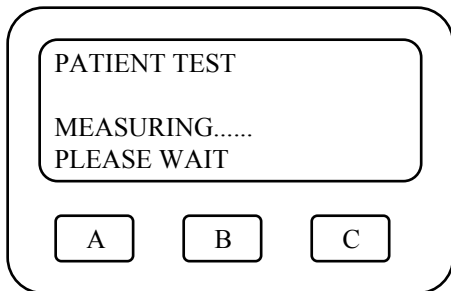
Display Screen Messages



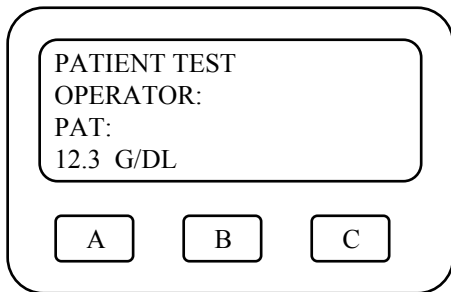
1. Press the “PATIENT TEST” key located below the display screen and to the left of the number keypad. This takes the HemoCue out of the Standby mode.
2. Enter Operator ID number and press “C” (If a barcode wand is being used, move the wand over the barcoded operator ID. The HemoCue will beep when the code is accepted).
3. Enter the Patient ID using the number keys in the center of the HemoCue.
4. Verify the microcuvette batch number and manufacturer’s expiration date printed on the side of the microcuvette vial with the numbers displayed on the meter. Press “C” (ok) to accept. **If the batch number on the vial doesn’t agree with the number shown on the meter, press “B” to update. Enter password “9876” followed by the batch number and expiration date of the cuvettes. If the open vial of cuvettes is more than 90 days old, or past the manufacturer’s expiration date, discard the vial. Open and date a new vial of microcuvettes and continue with testing.**



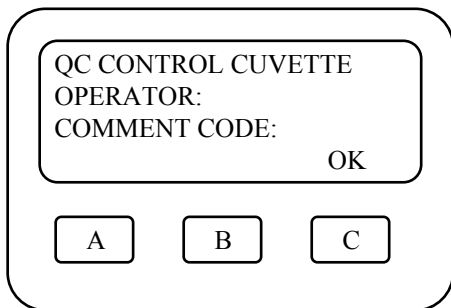
5. Fill cuvette and place in holder. Push into meter until a distinct click is heard.



6. Wait while measuring. **Do not pull the cuvette holder out until the test is completed or the test will be aborted.**



7. The patient result is displayed until the cuvette holder is pulled out.



8. Enter the appropriate Comment Code by using the number keys then press “C” .

Data Management HemoCue Error Codes

When the HemoCue instrument detects an internal error or malfunction, a message will be displayed on the screen, along with an error code. **These error codes are numbered from 900 - 999. The operator should stop testing immediately.** Notify the Johns Hopkins Medical Laboratories of the specific error code message and number so that the appropriate troubleshooting measures can be initiated.

If the “**Memory Full**” error message appears on the display screen, no test (QC or Patient) can be performed. Notify the Johns Hopkins Medical Laboratories immediately so that the memory can be cleared.

The Johns Hopkins Medical Laboratories' (JHML) Contacts :

Monday - Friday

8:30am - 4pm

- 1. JHML - 600 N. Wolfe: 410-955-2645**

Troubleshooting Flowchart for the DM HemoCue

