

Quality Control

LABORATORY TRAINING

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HemoCue 301: Instructional Videos

▶ <https://hemocueoncue.education/>



HemoCue 301 Liquid Controls: Eurotrol

- ▶ Tests the integrity of the microcuvettes, the HemoCue machine and the expertise of the lab tech.
- ▶ Liquid Controls are done weekly.
- ▶ Self-test is done daily (simply turning on the machine).



Storage of Controls

- ▶ Eurotrol Hb 301 Controls should be stored unopened in the refrigerator at 35-46°F (2-8°C).
- ▶ Closed shelf life: approx. 9 months at 2-8°C.
- ▶ This guarantees stability until the expiration date on the vial and the outer box.
- ▶ After opening, the vial is stable for **30 days** in refrigerator or at room temperature.

Liquid Controls Bottle Documentation

Be sure to document **Open Date** and **Expiration Date** on liquid control bottles.



WIC HEMOCUE QUALITY CONTROL (QC) LOG

Michigan Department of Health and Human Services

Site	Analyzer Type
Month	Control Manufacturer

QC Data: Quality Controls must be completed on a weekly basis. An extra line for cuvettes is available if a 2nd bottle is opened during the month. If a new microcuvette bottle with a new lot number is opened, controls must be completed prior to client testing. The package insert for liquid controls will specify open and closed vial expiration dates. Attach a copy of the liquid control insert to this log.

Liquid Controls	Lot Number	Date Opened	Closed Vial Expiration Date	Open Vial Expiration Date	Expected Range
Low Control					
High Control					

Microcuvettes	Lot Number	Date Opened	Expiration Date
Cuvette #1			
Cuvette #2			

Information from the LIQUID CONTROLS insert and MICROCUVETTES will be documented here.

WIC HEMOCUE QUALITY CONTROL (QC) LOG

Michigan Department of Health and Human Services

Site	North Clinic	Analyzer Type	Hb 301
Month	June 2020	Control Manufacturer	Eurotrol

QC Data: Quality Controls must be completed on a weekly basis. An extra line for cuvettes is available if a 2nd bottle is opened during the month. If a new microcuvette bottle with a new lot number is opened, controls must be completed prior to client testing. The package insert for liquid controls will specify open and closed vial expiration dates. Attach a copy of the liquid control insert to this log.

Liquid Controls	Lot Number	Date Opened	Closed Vial Expiration Date	Open Vial Expiration Date	Expected Range
Low Control	112223	6/23/20	8/20/21	7/22/20	6.4 - 7.1
High Control	112233	6/23/20	8/20/21	7/22/20	15.5 - 16.3

Microcuvettes	Lot Number	Date Opened	Expiration Date
Cuvette #1			
Cuvette #2			

HemoCue[®] Hb 301 Microcuvettes

- The microcuvette cavity containing dry reagent, holds **10 µL of blood**. The blood sample is drawn into the cavity by capillary action. The microcuvette serves as pipette, reaction vessel and as a measuring microcuvette.
- The filled microcuvette should be analyzed immediately or **within 40 seconds**.
- Close the lid immediately after taking the microcuvette out of the vial.
- Microcuvettes in an opened or unopened vial can be used until the **expiry date printed on the package** when stored at **10-40°C**.
- An unopened vial of microcuvettes can be stored for a shorter period of time (6 weeks) between -18–50 °C.



Microcuvettes

- ▶ Closed vial & Opened vial Expiration Dates will be the **SAME** for the microcuvettes.
- ▶ Upon opening the bottle, write the date opened on the bottle.
- ▶ Unusual circumstances:
 - ▶ If stored at extreme temperature: -18 to 50° C, microcuvettes will expire in 6 weeks.
 - ▶ This can occur during shipping/travel.
 - ▶ Manufacturer should label the microcuvette package with new expiration date.
 - ▶ For more information, call Technical Support: 1-800-426-7256



Microcuvettes

WIC HEMOCUE QUALITY CONTROL (QC) LOG

Michigan Department of Health and Human Services

Site	Analyzer Type
Month	Control Manufacturer

QC Data: Quality Controls must be completed on a weekly basis. An extra line for cuvettes is available if a 2nd bottle is opened during the month. If a new microcuvette bottle with a new lot number is opened, controls must be completed prior to client testing. The package insert for liquid controls will specify open and closed vial expiration dates. Attach a copy of the liquid control insert to this log.

Liquid Controls	Lot Number	Date Opened	Closed Vial Expiration Date	Open Vial Expiration Date	Expected Range
Low Control					
High Control					

Microcuvettes	Lot Number	Date Opened	Expiration Date
Cuvette #1	123456	6/19/20	5/10/21
Cuvette #2			

Expiration Date is the manufacturer's expiration date.

Storage outside of 50-100°F will decrease shelf life.

Document this data on the WIC Hemocue QC Log and WIC Client Log.

WIC CLIENT LOG: HEMOCUE

Michigan Department of Health and Human Services

Local Agency	Clinic
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	Lot Number	Date Opened	Expiration Date
Cuvette #1	123456	6/19/20	5/10/21
Cuvette #2			

Note: Mark a “2” in the client’s row in the Notes column when the 2nd bottle of microcuvettes has been opened.

Date	Client Name	Client ID Number	Hgb mg/dL	Notes	Initials
	Self-Test		<input type="checkbox"/> Pass <input type="checkbox"/> Fail		

Quality Control Procedure

- ▶ **Controls are a blood product and should be treated as such; wear gloves and follow lab rules for handwashing.**
- ▶ **Warm liquid control vials** to room temperature at least **15 minutes** prior to use.
- ▶ Hold the vial upright and roll the vial between the palms of your hands several times.
- ▶ Gently **invert vial 8-10 times** and **roll between the palms for 2-3 minutes.**
- ▶ Blood cells should not cling to the bottom of the vial.
- ▶ Never shake vials.

Quality Control Procedure Cont.

1. Place one drop on a non-permeable material such as tape, alcohol prep pad wrapper, or plastic.
2. Insert the tip of the microcuvette into the drop.
3. Wipe any residual control material from the sides of the microcuvette with a piece of gauze.
4. Check to see that there are no air bubbles.
5. Place microcuvette into the HemoCue machine and close.
6. Record the result on the QC Log.

Documentation

Liquid Controls	Lot Number	Date Opened	Closed Vial Expiration Date	Open Vial Expiration Date	Expected Range
Low Control	112223	6/23/20	8/20/21	7/22/20	6.4 -7.1
High Control	112233	6/23/20	8/20/21	7/22/20	15.5 - 16.3

Microcuvettes	Lot Number	Date Opened	Expiration Date
Cuvette #1			
Cuvette #2			

QC Results

Date	Low Control (Weekly)	High Control (Weekly)	Weekly Controls (Pass/Fail)	Initials	Cuvette #1 or #2
6-23-20	6.8	15.9	P	NE	#1

Quality Control Procedure Cont.

- ▶ Rotate staff to do weekly controls to ensure quality assurance.
- ▶ Attach liquid control insert to lab sheet (copies are acceptable if needed).
- ▶ Save for 3 years and 150 days.
- ▶ Lab sheets with controls can be removed from the lab after 2 months if desired and stored in another location.

Troubleshooting: Measurement of Control Materials are out of range

1. The microcuvettes are beyond their expiration date, damaged or have been improperly stored.
2. The optical eye of the microcuvette is contaminated.
3. The controls are beyond their expiration dates or have been improperly stored.
4. The control has not been mixed properly and/or is not at room temperature.
5. The microcuvette has not been placed in the analyzer within 40 seconds of filling.
6. Air bubbles in the microcuvette.
7. The optronic unit is dirty.
8. The control is not suitable for use with the HemoCue Hb 301 system.
9. The calibration of the analyzer has been changed.

1. Check the expiration date and the storage conditions of the microcuvettes.
2. Remeasure the control with a new microcuvette.
3. Check the expiration date and the storage conditions of the control. Remeasure the control with a new microcuvette. If the problem continues, contact the manufacturer of the control.
4. Make sure that the control is mixed properly and at room temperature. If the problem continues, contact the manufacturer of the control.
5. Remeasure the control with a new microcuvette.
6. Check the microcuvette for air bubbles. Remeasure the control with a new microcuvette.
7. Clean the optronic unit.
8. Contact the distributor for control information.
9. The analyzer needs service. Contact the distributor.

HemoCue Contact Information

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HemoCue America

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Questions?

