

## TRAINING UPDATE

**Lab Location:** SGMC & WOMC  
**Department:** Core lab

**Date Distributed:** 1/22/2020  
**Due Date:** 2/22/2020  
**Implementation:** 2/5/2020

### DESCRIPTION OF PROCEDURE REVISION

<b>Name of procedure:</b>
<b>HIV External Quality Control Log    AG.F162.2</b>
<b>HIV Patient Result Log                    AG.F163.2</b>
<b>Description of change(s):</b>
<p>These logs are being revised due to a deficiency cited during CQA inspection.</p> <p><b>External QC Log</b></p> <ul style="list-style-type: none"><li>• Added prompt at top to record date of last ext. QC to better clarify that section</li><li>• Removed check boxes and replaced with spaces to record actual temperatures</li></ul> <p><b>Patient Result Log</b></p> <ul style="list-style-type: none"><li>• Removed requirement to document when next external QC is due. Replaced with instruction to verify its performance</li><li>• Added column to record ext. QC was verified (Y/N)</li><li>• Removed check boxes and replaced with spaces to record actual temperatures</li></ul> <p><b>These revised Logs will be implemented on February 5, 2020</b></p>

Document your compliance with this training update by taking the quiz in the MTS system.



## HIV EXTERNAL QUALITY CONTROL LOG

- Germantown Emergency Center
- Shady Grove Medical Center
- White Oak Medical Center

**Last external QC performed (date):** \_\_\_\_\_

Next external QC is due = *Month* \_\_\_\_\_ *Circle day below*

1 2 3 4 5 6 7 8 9 10 11 12 13 14 15 16 17 18 19 20 21 22 23 24 25 26 27 28 29 30 31

Internal Control must be documented each time a test is run.

**Results:**     **Acceptable**                      **External QC Lot:** \_\_\_\_\_

External QC must be performed with each new lot or shipment or every 30 days, whichever is more frequent.

**Unacceptable**    **Exp:** \_\_\_\_\_

Lot Status	OraQuick Rapid HIV-1/2 Antibody Test Kit Controls	Result Reactive / Non-reactive	Kit	Internal Control Purple reddish line Appears? Yes / No	Temperature of the test kit storage area (2 - 27°C)	Temperature of testing area (15 - 37°C)	Date / Tech code
			Lot # / Expire				
Lot Number  <input type="checkbox"/> New Lot Received  <input type="checkbox"/> New Shipment Received	HIV-1 Positive Control	<input type="checkbox"/> Reactive (expected) <input type="checkbox"/> Non-reactive***		<input type="checkbox"/> Yes (acceptable) <input type="checkbox"/> No (troubleshoot)**	Temp: _____ °C <input type="checkbox"/> Acceptable <input type="checkbox"/> Out of range*	Temp: _____ °C <input type="checkbox"/> Acceptable <input type="checkbox"/> Out of range*	
	HIV-2 Positive Control	<input type="checkbox"/> Reactive (expected) <input type="checkbox"/> Non-reactive***		<input type="checkbox"/> Yes (acceptable) <input type="checkbox"/> No (troubleshoot)**			
	Negative Control	<input type="checkbox"/> Reactive*** <input type="checkbox"/> Non-reactive (expected)		<input type="checkbox"/> Yes (acceptable) <input type="checkbox"/> No (troubleshoot)**			
Current Lot Number  <input type="checkbox"/> 30 day interval	HIV-1 Positive Control	<input type="checkbox"/> Reactive (expected) <input type="checkbox"/> Non-reactive***		<input type="checkbox"/> Yes (acceptable) <input type="checkbox"/> No (troubleshoot)**	Temp: _____ °C <input type="checkbox"/> Acceptable <input type="checkbox"/> Out of range*	Temp: _____ °C <input type="checkbox"/> Acceptable <input type="checkbox"/> Out of range*	
	HIV-2 Positive Control	<input type="checkbox"/> Reactive (expected) <input type="checkbox"/> Non-reactive***		<input type="checkbox"/> Yes (acceptable) <input type="checkbox"/> No (troubleshoot)**			
	Negative Control	<input type="checkbox"/> Reactive*** <input type="checkbox"/> Non-reactive (expected)		<input type="checkbox"/> Yes (acceptable) <input type="checkbox"/> No (troubleshoot)**			

\* If temperature is Out of Range, adjust the temperature first then repeat test. Refer to SOP section 6.3

\*\* If the purple-reddish line does not appear, repeat test using a new pouch. If the result is still invalid after repeat, refer to SOP section 10.5

\*\*\* If the QC result is Invalid, refer to SOP section 6.4

Lead Tech: \_\_\_\_\_ Date: \_\_\_\_\_

Supervisor: \_\_\_\_\_ Date: \_\_\_\_\_



## HIV PATIENT RESULT LOG

- Germantown Emergency Center
- Shady Grove Medical Center
- White Oak Medical Center

**Internal Control must be documented each time a test is run. Verify external QC was performed at required interval with acceptable results\*\*\***

Date	Patient Name & MR#	Patient Result Reactive / Non-reactive	Kit	Internal Control Purple reddish line Appears? Yes / No	Temperature of the test kit storage area (2 - 27°C)	Temperature of testing area (15 - 37°C)	Ext. QC verified Y / N	Tech Code
			Lot # / Expire		_____ °C <input type="checkbox"/> Acceptable <input type="checkbox"/> Out of range*	_____ °C <input type="checkbox"/> Acceptable <input type="checkbox"/> Out of range*		
		<input type="checkbox"/> Reactive <input type="checkbox"/> Non-reactive		<input type="checkbox"/> Yes (acceptable) <input type="checkbox"/> No (troubleshoot)**	_____ °C <input type="checkbox"/> Acceptable <input type="checkbox"/> Out of range*	_____ °C <input type="checkbox"/> Acceptable <input type="checkbox"/> Out of range*		
		<input type="checkbox"/> Reactive <input type="checkbox"/> Non-reactive		<input type="checkbox"/> Yes (acceptable) <input type="checkbox"/> No (troubleshoot)**	_____ °C <input type="checkbox"/> Acceptable <input type="checkbox"/> Out of range*	_____ °C <input type="checkbox"/> Acceptable <input type="checkbox"/> Out of range*		
		<input type="checkbox"/> Reactive <input type="checkbox"/> Non-reactive		<input type="checkbox"/> Yes (acceptable) <input type="checkbox"/> No (troubleshoot)**	_____ °C <input type="checkbox"/> Acceptable <input type="checkbox"/> Out of range*	_____ °C <input type="checkbox"/> Acceptable <input type="checkbox"/> Out of range*		
		<input type="checkbox"/> Reactive <input type="checkbox"/> Non-reactive		<input type="checkbox"/> Yes (acceptable) <input type="checkbox"/> No (troubleshoot)**	_____ °C <input type="checkbox"/> Acceptable <input type="checkbox"/> Out of range*	_____ °C <input type="checkbox"/> Acceptable <input type="checkbox"/> Out of range*		
		<input type="checkbox"/> Reactive <input type="checkbox"/> Non-reactive		<input type="checkbox"/> Yes (acceptable) <input type="checkbox"/> No (troubleshoot)**	_____ °C <input type="checkbox"/> Acceptable <input type="checkbox"/> Out of range*	_____ °C <input type="checkbox"/> Acceptable <input type="checkbox"/> Out of range*		
		<input type="checkbox"/> Reactive <input type="checkbox"/> Non-reactive		<input type="checkbox"/> Yes (acceptable) <input type="checkbox"/> No (troubleshoot)**	_____ °C <input type="checkbox"/> Acceptable <input type="checkbox"/> Out of range*	_____ °C <input type="checkbox"/> Acceptable <input type="checkbox"/> Out of range*		
Weekly review:			Weekly review:		Weekly review:			
Weekly review:			Weekly review:		Monthly review:			

\* If temperature is Out of Range, adjust the temperature first then repeat test with external quality control. Refer to SOP section 6.3

\*\* If the purple-reddish line does not appear, repeat test using a new pouch. If it stills fails, refer to SOP section

\*\*\* External QC required with every new lot or shipment, or every 30 days (whichever is more frequent) and if either temperature is out of range.