TRAINING UPDATE

Lab Location:	SGMC & WAH	**Date Distributed:**	1/5/2016
Department:	Core	**Due Date:**	1/31/2016
		Implementation:	**2/1/2016**

DESCRIPTION OF PROCEDURE REVISION

Name of procedure:

Rapid HIV-1/2 Antibody Test SGAH.IM03, WAH.IM03 v1

HIV External Quality Control Log AG.F162.1

HIV Patient Result Log AG.F163.1

Description of change(s):

SOP:

Section	Reason
3.1	Remove plasma
6.3	**Change external QC frequency** *(new lot or shipment of test kits is received or every 30 days, whichever is more frequent.)*
11.3	Move report comment from 10.5
13	Add statements for those on treatment
16	Move logs from section 19

Forms:

Added 30 day frequency for external QC and prompt at top to document when next due (due date prompt also included on patient result log)

SOP & FORMs will be implemented on February 1, 2016

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

Approved draft for training (version 1)

Technical SOP

Title	**Rapid HIV-1/2 Antibody Test**	
Prepared by	Ashkan Chini	Date: 2/20/2012
Owner	Robert SanLuis	Date: 2/20/2012

Laboratory Approval	**Local Effective Date:**	
Print Name and Title	**Signature**	**Date**
Refer to the electronic signature page for approval and approval dates.		

Review		
Print Name	**Signature**	**Date**

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1. TEST INFORMATION

Assay	Method/Instrument	Order Code
Rapid HIV-1/2 Antibody Test	Qualitative Immunoassay/Manual	HIVRS2

Synonyms/Abbreviations
HIV-1/2 Antibody Test

Department
Core Lab/Immunology

Form revised 2/02/2007

2. ANALYTICAL PRINCIPLE

~~A venipuncture whole blood containing EDTA~~ An EDTA whole blood specimen is collected and transferred into the vial of developer solution, followed by the insertion of the test device. The developer solution facilitates the flow of the specimen into the device and onto the test strip. As the diluted specimen flows through the device, it rehydrates the protein-A gold colorimetric reagent contained in the device. As the specimen continues to migrate up the strip, it encounters the T zone. If the specimen contains antibodies that react with the antigens immobilized on the nitrocellulose membrane, a reddish-purple line will appear, qualitatively indicating the presence of antibodies to HIV-1 and/or HIV-2 in the specimen. The intensity of the line color is not directly proportional to the amount of antibody present in the specimen.

3. SPECIMEN REQUIREMENTS

3.1 Patient Preparation

Component	Special Notations
Fasting/Special Diets	N/A
Specimen Collection and/or Timing	Normal procedures for collecting and storing whole blood~~/plasma~~ may be used for samples to be analyzed by this method.
Special Collection Procedures	None
Other	N/A

3.2 Specimen Type & Handling

Criteria	
Type -Preferred **-Other Acceptable**	Whole blood (from EDTA tube only) None
Collection Container	EDTA (lavender top)
Volume - Optimum **- Minimum**	4.0 mL 3.0 mL
Transport Container and Temperature	Collection tube at room temperature
Stability & Storage Requirements	Room Temperature / Refrigerated (2 - 30 °C): 5 days as whole blood
	Frozen: Not recommended
Timing Considerations	N/A
Unacceptable Specimens & Actions to Take	Specimens that are unlabeled, improperly labeled, or those that do not meet the stated criteria are unacceptable. Request a recollection and credit the test with the appropriate LIS English text code for “test not performed”

Form revised 2/02/2007

Criteria	
	message. Examples: Quantity not sufficient-QNS; Wrong collection-UNAC. Document the request for recollection in the LIS.
Compromising Physical Characteristics	Prior to testing, mix the blood tube gently by inversion several times to ensure a homogenous sample.
Other Considerations	None

4. REAGENTS

Refer to the Material Safety Data Sheet (MSDS) supplied with the reagents for complete safety hazards. Refer to the section in this procedure covering "SAFETY" for additional information.

4.1 Reagent Summary

Reagents	Supplier & Catalog Number
OraQuick ADVANCE® Rapid HIV-1/2 Antibody Test Kit	OraSure Technologies, Inc. Cat. No. 1001-0079

4.2 Reagent Preparation and Storage

NOTES: Date and initial all reagents upon opening. Each container must be labeled with (1) substance name, (2) lot number, (3) date of preparation, (4) expiration date, (5) initials of tech, (6) any special storage instructions; check for visible signs of degradation.
Refer to the Material Safety Data Sheet (MSDS) for a complete description of hazards. If a specific hazard is present, it will be noted in this procedure when the hazard is first encountered in a procedural step.

Assay Kit	
Reagent	OraQuick ADVANCE® Rapid HIV-1/2 Antibody Test Kit, every Pouch contains one of following: Test Device, Developer Solution Vial and Absorbent Packet.
Container	Manufactured vial
Storage	Store at 2 - 27°C
Stability	Test Kit is stable until expiration date stamped on the cover. Once the Pouch is opened the Test Device must be inserted into the Developer Solution Vial within 60 minutes after introducing venipuncture whole blood. If refrigerated allow Test Kit to come to operating temperature before use (15 - 37°C).
Preparation	None

5. CALIBRATORS/STANDARDS

N/A

6. QUALITY CONTROL

6.1 Controls Used

Controls	Supplier
External Quality Control	OraQuick ADVANCE® Rapid HIV-1/2 Antibody Test Kit Controls

6.2 Control Preparation and Storage

NOTE: Date and initial all controls upon opening. Each container should be labeled with (1) substance name, (2) lot number, (3) date of preparation, (4) expiration date, (5) initials of tech, and (6) any special storage instructions; check for visible signs of degradation.

Assay Kit	OraQuick ADVANCE® Rapid HIV-1/2 Antibody Test Kit Controls
Reagent 1	HIV-1 Positive Control
Reagent 2	HIV-2 Positive Control
Reagent 3	Negative Control
Container	Manufactured vial
Storage	Store at 2 - 8°C
Stability	Control is stable until expiration date stamped on the reagent.
Preparation	None

6.3 Frequency

The kit has a built-in procedural (internal) control that demonstrates assay validity. It is run with each test performed.

The External Quality Control is run under the following circumstances:

- When a new lot or shipment of test kits is received or every 30 days, whichever is more frequent.
- If the temperature of the test kit storage area falls outside of 2 - 27°C.
- If the temperature of the testing area falls outside of 15 - 37°C.

6.4 Tolerance Limits

Internal Control:
The OraQuick ADVANCE® Rapid HIV-1/2 Antibody Test Kit has a built-in procedural control that demonstrates assay validity. A reddish-purple line in the

control ("C") area of the Result Window indicates that a specimen was added and that the fluid migrated appropriately through the test device. The control line will appear on all valid tests, whether or not the sample is reactive or non-reactive.

External Controls:
The HIV-1 and HIV-2 Positive Controls will produce a reactive test result and have been manufactured to produce a very faint test ("T") line.
The Negative Control will produce a non-reactive test result.

IF the QC result is …	**THEN…**
Invalid (refer to section 10.1)	Repeat the QC using a new Pouch
Invalid after repeat using a new Pouch	Repeat the QC using a new Pouch and set of External QC.
Invalid after repeat using External QC	Notify supervisor. Do not report patient results until acceptable QC results are obtained.

6.5 Review Patient Data

Review patient results for unusual patterns, trends or distributions, such as an unusually high percentage of abnormal results.

6.6 Documentation

Quality Control is documented on the HIV External Quality Control Log or HIV Patient Result Log as appropriate.

6.7 Quality Assurance Program

- Quality Control cross-checks must be done on each new batch of lot numbers received.
- The laboratory participates in CAP proficiency testing.

7. EQUIPMENT and SUPPLIES

7.1 Assay Platform

N/A

7.2 Equipment

Timer

7.3 Supplies

- Reusable Test Stands
- Specimen Collection Loop

8. PROCEDURE

NOTE: For all procedures involving specimens, buttoned lab coats, gloves, and face protection are required minimum personal protective equipment. Report all accidents to your supervisor.

The package insert for a new lot of kits must be reviewed for any changes before the kit is used. A current Package Insert is included as a Related Document.

8.1	Test Run
1.	Pick up an unused Specimen Collection Loop by the thick handle end. Put the rounded end of the loop into the tube of well mixed whole blood. Make sure that the loop is completely filled with blood with no bubbles.
2.	Immediately insert the blood-filled end of the loop all the way into the Vial. Use the loop to stir the blood sample in the Developer Solution. Remove the used loop from the solution. Throw the used loop away in a biohazard waste container.
3.	Check the Solution to make sure that it appears pink. This means that the blood was correctly mixed into the Solution.
4.	Remove the Device from the Pouch. Check to make sure that an absorbent packet is included with the Device. If no absorbent packet is present, discard the Device and obtain a new Pouch for testing.
5.	Insert the Flat Pad of the Device all the way into the Vial containing the blood sample. Make sure that the Flat Pad touches the bottom of the Vial. The result window should be facing towards you.
6.	Start timing the test. Do not remove the Device from the Vial during the test. Read the results after 20 minutes but not more than 40 minutes in a fully lighted area.

9. CALCULATIONS

None

10. REPORTING RESULTS AND REPEAT CRITERIA

10.1 Interpretation of Data

Test Results	Location	Appearance
Reactive	Triangle Labeled C	Reddish-Purple Line appears
	Triangle Labeled T	Reddish-Purple Line appears
Non-reactive	Triangle Labeled C	Reddish-Purple Line appears
	Triangle Labeled T	Blank
Invalid	Triangle Labeled C	Blank
	Triangle Labeled T	Blank or Reddish-Purple Line appears

10.2 Rounding

N/A

10.3 Units of Measure

N/A

10.4 Clinically Reportable Range (CRR)

N/A

10.5 Repeat Criteria and Resulting

Use function MEM to enter result. Worksheet: use WUR3 for WAH or SUR3 for SGAH.

IF the result is …	THEN…
Invalid	Repeat the test using a new Pouch
Invalid after repeat using a new Pouch	Request a new specimen and repeat. Also run the external QC with patient specimen to ensure proper performance of the test.

IF the result is …	THEN…
Non reactive	Report in LIS with code "NR"
Reactive	Report in LIS with code "REAC". Western Blot is reflexed, label prints (test code XHIV12)

11. EXPECTED VALUES

11.1 Reference Ranges

Non-reactive

11.2 Critical Values

None established

11.3 Standard Required Messages

Each result will have the following comment automatically added to the report by the LIS:

"The OraQuick HIV-1 and 2 assay is intended for use as a rapid SCREENING test for the presence of HIV-1 and 2 antibodies in whole blood. Positive results using OraQuick method must be tested by Western Blot and Western Blot must be positive to confirm the presence of HIV antibody. Repeat testing in 3-6 months is recommended in positive screening tests that are negative by Western Blot. Negative

screen tests indicate that no antibody to HIV-1 and 2 was detected. Patients exposed to high risk activity in the past three months may be falsely negative."

12. CLINICAL SIGNIFICANCE

Acquired Immune Deficiency Syndrome (AIDS), AIDS related complex (ARC) and pre-AIDS are thought to be caused by the Human Immunodeficiency Virus (HIV). The first AIDS-related virus, HIV-1 has been isolated from patients with AIDS and from healthy persons at high risk of AIDS. Genetic analysis of HIV-1 isolates has documented the existence of subtypes. Eight HIV-1 subtypes (A through H) have been identified world wide. HIV-2 has been shown to share a number of conserved sequences with HIV-1, but serological cross-reactivity between HIV-1 and HIV-2 has been shown to be highly variable from sample to sample.

13. PROCEDURE NOTES

- **FDA Status:** FDA Approved/Cleared (waived)
- **Validated Test Modifications:** None

- Clinical data has not been collected to demonstrate performance of OraQuick HIV 1/2 antibody test in persons under 12 years of age.
- Individuals infected with HIV-1 or HIV-2 who are receiving highly active antiretroviral therapy (HAART) may produce false negative results.
- Individuals undergoing preventive treatment for HIV may produce false negative results.

14. LIMITATIONS OF METHOD

14.1 Analytical Measurement Range (AMR)

N/A

14.2 Precision

N/A

14.3 Interfering Substances

To assess the impact of unrelated medical conditions or interfering substances on the sensitivity of the OraQuick ADVANCE Rapid HIV-1/2 Antibody Test, 200 serum/plasma specimens from a variety of medical conditions unrelated to HIV-1 infection and 125 specimens with interfering substances were spiked with an HIV-1 positive specimen to give a level of reactivity in the low positive range. All spiked specimens gave reactive results.

14.4 Clinical Sensitivity/Specificity/Predictive Values

Test Group	Total Specimen	OraQuick ADVANCE Reactive	Licensed EIA Repeatedly Reactive	True Positive
AIDS	40	40	40	40
Known HIV-1 positive	481	479	481	481
High-Risk	625	17	20	17
Total	1146	536	541	538

15. SAFETY

The employee has direct responsibility to avoid injury and illness at work. Nearly all harmful exposures to infectious substances and chemicals, and other injuries, can be avoided with effective training and consistent safe work practices.

Become familiar with the Environmental Health and Safety (EHS) Manual to learn the requirements on working safely and protecting the environment from harm. Although lab work typically focuses on the hazards of working with specimens and chemicals, we must also control other important hazards.

- Slips, trips, and falls cause many serious injuries. Please ensure that spills are cleaned quickly (to avoid slippery floors) and that you can see and avoid obstacles in your path.
- Ergonomic injuries result from performing tasks with too much repetition, force, or awkward position. Ergonomic injuries include strains and back injuries. Learn about ergonomic hazards and how to prevent this type of injury.
- Scratches, lacerations, and needle sticks can result in serious health consequences. Attempt to find ways to eliminate your risk when working with sharp materials.
- A Splash Guard or Splash Shield **MUST** be worn when performing this test.

Report all accidents and injuries immediately to your supervisor or the business unit Environmental Health and Safety Manager or Specialist.

16. RELATED DOCUMENTS

- Health Care Worker Exposure to Blood and Body Fluids, Infection Control Policy, Washington Adventist Hospital, policy # WAH.7036
- Health Care Worker Exposure to Blood and Body Fluids, Infection Control Policy, Shady Grove Adventist Hospital, policy # 101-02-026
- Admission to Labor and Deliver, Women's Services Policy, Washington Adventist Hospital, policy # WWS.9502
- Current package insert OraQuick ADVANCE® Rapid HIV-1/2 Antibody Test.
- HIV Patient Result Log (AG.F163)
- HIV External Quality Control Log (AG.F162)

17. REFERENCES

1. Package Insert, OraQuick ADVANCE® Rapid HIV-1/2 Antibody Test, Item # 3001-1215, revised 09/2012.

18. REVISION HISTORY

Version	Date	Section	Reason	Reviser	Approval
			Supersedes SGAH/WAH.IM02.000		
000	12/1/15	3.1	Remove plasma	L Barrett	R SanLuis
000	12/1/15	6.3	Change external QC frequency	L Barrett	R SanLuis
000	12/1/15	11.3	Move report comment from 10.5	L Barrett	R SanLuis
000	12/1/15	13	Add statements for those on treatment	L Barrett	R SanLuis
000	12/1/15	16	Move logs from section 19	L Barrett	R SanLuis
000	12/1/15	16	Update insert date	L Barrett	R SanLuis
000	12/1/15	Footer	version # leading zero's dropped due to new EDCS in use as of 10/7/13	L Barrett	R SanLuis

19. ADDENDA

None

~~HIV Patient Result Log (see Attachment Tab of Infocard)~~
~~HIV External Quality Control Log (see Attachment Tab of Infocard)~~

Quest Diagnostics

HIV EXTERNAL QUALITY CONTROL LOG

☐ Germantown Emergency Center
☐ Shady Grove Medical Center
☐ Washington Adventist Hospital

Next external QC is due = *Month* _____ *Circle day*

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** **Lot # / Expire**	**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 Number ☐ New Lot Received ☐ New Shipment Received	HIV-1 Positive Control	☐ Reactive (expected) ☐ Non-reactive***		☐ Yes (acceptable) ☐ No (troubleshoot)**	☐ (2 - 27°C) ☐ (Out of range)*	☐ (15 - 37°C) ☐ (Out of range)*	
	HIV-2 Positive Control	☐ Reactive (expected) ☐ Non-reactive***		☐ Yes (acceptable) ☐ No (troubleshoot)**			
	Negative Control	☐ Reactive*** ☐ Non-reactive (expected)		☐ Yes (acceptable) ☐ No (troubleshoot)**			
Current Lot Number ☐ 30 day interval	HIV-1 Positive Control	☐ Reactive (expected) ☐ Non-reactive***		☐ Yes (acceptable) ☐ No (troubleshoot)**	☐ (2 - 27°C) ☐ (Out of range)*	☐ (15 - 37°C) ☐ (Out of range)*	
	HIV-2 Positive Control	☐ Reactive (expected) ☐ Non-reactive***		☐ Yes (acceptable) ☐ No (troubleshoot)**			
	Negative Control	☐ Reactive*** ☐ Non-reactive (expected)		☐ Yes (acceptable) ☐ 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: _____

Quest Diagnostics

HIV PATIENT RESULT LOG

☐ Germantown Emergency Center
☐ Shady Grove Medical Center
☐ Washington Adventist Hospital

Next external QC is due = *Month* ____________________ *Circle day*

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.

Date	Patient Name & MR#	Patient Result Reactive / Non-reactive	Kit Lot # / Expire	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)	Tech code
		☐ Reactive ☐ Non-reactive		☐ Yes (acceptable) ☐ No (troubleshoot)**	☐ (2 - 27°C) ☐ (Out of range)*	☐ (15 - 37°C) ☐ (Out of range)*	
		☐ Reactive ☐ Non-reactive		☐ Yes (acceptable) ☐ No (troubleshoot)**	☐ (2 - 27°C) ☐ (Out of range)*	☐ (15 - 37°C) ☐ (Out of range)*	
		☐ Reactive ☐ Non-reactive		☐ Yes (acceptable) ☐ No (troubleshoot)**	☐ (2 - 27°C) ☐ (Out of range)*	☐ (15 - 37°C) ☐ (Out of range)*	
		☐ Reactive ☐ Non-reactive		☐ Yes (acceptable) ☐ No (troubleshoot)**	☐ (2 - 27°C) ☐ (Out of range)*	☐ (15 - 37°C) ☐ (Out of range)*	
		☐ Reactive ☐ Non-reactive		☐ Yes (acceptable) ☐ No (troubleshoot)**	☐ (2 - 27°C) ☐ (Out of range)*	☐ (15 - 37°C) ☐ (Out of range)*	
		☐ Reactive ☐ Non-reactive		☐ Yes (acceptable) ☐ No (troubleshoot)**	☐ (2 - 27°C) ☐ (Out of range)*	☐ (15 - 37°C) ☐ (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