TRAINING UPDATE

Lab Location:	SGMC & WOMC	**Date Distributed:**	2/25/2020
Department:	Core Lab	**Due Date:**	3/25/2020
		Implementation:	**2/27/2020**

DESCRIPTION OF PROCEDURE REVISION

Name of procedure:

Rapid HIV-1/2 Antibody Test SGAH.IM03 v3

Description of change(s):

Section	Reason
Header	Change WAH to WOMC
8.1	Added recording temperature on log
10.6	Removed calling charge RN from after-hours instruction
16	Updated hospital policies

This revised SOP will be implemented on February 27, 2020

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

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.		

TABLE OF CONTENTS

1. TEST INFORMATION

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

Synonyms/Abbreviations
HIV-1/2 Antibody Test

Department
Core Lab/Immunology

2. ANALYTICAL PRINCIPLE

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 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	Whole blood (from EDTA tube only)
-Other Acceptable	None
Collection Container	EDTA (lavender top)
Volume - Optimum	4.0 mL
- Minimum	3.0 mL

Criteria	
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" 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

NOTE: Labeling requirements for all reagents, calibrators and controls include: (1) Open date, (2) Substance name, (3) Lot number, (4) Date of preparation, (5) Expiration date, (6) Initials of tech, and (7) Any special storage instructions. Check all for visible signs of degradation.

4. REAGENTS

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.

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

Assay Kit	
Reagent	OraQuick ADVANCE® Rapid HIV-1/2 Antibody Test Kit, every Pouch contains one each 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.
Preparation	If refrigerated, allow Test Kit to come to operating temperature before use (15-37°C).

	Once the Pouch is opened the Test Device must be inserted into the Developer Solution Vial within 60 minutes after introducing venipuncture whole blood.

5. CALIBRATORS/STANDARDS

N/A

6. QUALITY CONTROL

6.1 Controls Used

Controls	Supplier
OraQuick ADVANCE® Rapid HIV-1/2 Antibody Test Kit Controls	OraSure Technologies, Inc. Cat. No. 1001-0077

6.2 Control Preparation and Storage

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	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 and Criteria for Acceptable QC

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 Documentation

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

6.6 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.

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. Record results on appropriate log; include storage and testing area temperatures.

NOTE: In the event that the test system becomes inoperable, notify supervision or designee for further direction. Patient specimens must be stored in a manner that maintains the integrity of the specimen.

9. CALCULATIONS

Not applicable

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 Review Patient Data

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

10.6 Repeat Criteria and Resulting

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…
Nonreactive	Report in LIS with code NR
Reactive	Report in LIS with code REAC. Confirmatory test is reflexed, label prints (test code XHIV4G)

Use LIS function **MEM** to enter results.

Enter Shift: (1, 2, or 3)
Worksheet: Use WUR3 for WOMC or SUR3 for SGMC
Test: <Enter>
Enter "A" (Accept)
Enter Accession number
Press <Enter> until Result screen is displayed

Enter Results using above codes

Note: Results of tests performed for exposures are called to Occ Health during business hours and after hours to the ~~charge nurse on the unit where the exposure occurred OR to the~~ nursing administrator.

11. EXPECTED VALUES

11.1 Reference Ranges

Nonreactive

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 plasma. Positive results must be confirmed with the CDC Recommended Laboratory HIV Testing Algorithm beginning with an HIV 1/2 antigen/antibody immunoassay. 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 worldwide. 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) / Precision

N/A

14.2 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.

14.3 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

Refer to your local and corporate safety manuals and Safety Data Sheet (SDS) for detailed information on safety practices and procedures and a complete description of hazards.

16. RELATED DOCUMENTS

- Health Care Worker Exposure to Blood and Body Fluids, Post Exposure Prophylaxis Policy, AHC Corporate Policy Manual, AHC 2.167
- HIV Protocol, Shady Grove Medical Center, Perinatal Services, policy 101-05-046b
- Blood and Body Fluid Exposure Orders, Laboratory policy
- 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 03/2016.

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

Version	Date	Section	Reason	Reviser	Approval
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
1	4/12/18	Header	Add WAH	L Barrett	R SanLuis
1	4/12/18	4,6	Remove individual section labeling instructions and add general one	L Barrett	R SanLuis
1	4/12/18	10.5	Review data moved from section 6	L Barrett	R SanLuis
1	4/12/18	10.6	Add detail for function MEM & calling, update confirmatory test information	L Barrett	R SanLuis
1	4/12/18	11.3	Update to match confirmatory test	R Master	R SanLuis
1	4/12/18	15	Update to new standard wording	L Barrett	R SanLuis
1	4/12/18	17	Update package insert date	L Barrett	R SanLuis
2	2/10/20	Header	Change WAH to WOMC	L Barrett	R SanLuis
2	2/10/20	8.1	Added recording temperature on log	L Barrett	R SanLuis
2	2/10/20	10.6	Removed calling charge RN from after-hours instruction	L Barrett	R SanLuis
2	2/10/20	16	Updated hospital policies	L Barrett	R SanLuis

19. ADDENDA

None