□ SAFH □ SAH □ SDH □ SMCS ■ SRMC □ SMF □ SSMC	SH Valley Laboratory Service Procedure	Section/#: Immunology/ II.ANA.10.02-/-RV.02
	Title: **Performing OraQuick Advance Rapid HIV-1/2 Antibody Test**	Initiated/Owned by: SRMC Lab Director and Supervisor
	Effective Date: 06/30/17	Next Review Date: Biennial

Performing OraQuick Advance Rapid HIV-1/2 Antibody Test

Purpose

Define specific situations for which rapid HIV testing will be permitted and provide instructions for performing the OraQuick Advance Rapid HIV-1/2 Antibody test.

Policy

- Rapid HIV-1/2 antibody testing will be limited to the following situations only:
  - Testing of a source patient involved in an employee bloodborne pathogen exposure (BBPE).
  - Testing of obstetric patient presenting in active labor with no record of prenatal testing.
- Rapid HIV-1/2 antibody test (Test code: HIVRPD) is defined as a *critical test* to be performed STAT with result phoned to the contact designated in table below. Refer to procedure *Critical Test Response and Notification*.

If…	Then result is phoned to…
SRMC employee exposure	Administrative RN Supervisor
SMF (SS) employee exposure	The contact identified on the employee health form. If no contact information is provided or no response, then the PSC Area Supervisor will be called.
OB patient	RN or physician care provider.

- For reactive/positive rapid HIV tests, reflex confirmatory test **HIV4G** will be ordered (by Lab) and sent to SMCS.

Equipment

Timer

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Performing OraQuick Advance Rapid HIV-1/2 Antibody Test, Continued

Reagents

Reagents	Storage & Stability
OraQuick Advance Rapid HIV-1/2 Antibody Test Kit, includes: • Test pouch with Developer Solution Vial and Test Device. • Disposable Sample Loops • Reusable Test Stand	• Store at room temperature, may be stored at 2-27°C. • Do not open test pouch until ready to perform test. • Stable to manufacturer's expiration.
OraQuick Advance Rapid HIV-1/2 Antibody Test Kit Controls	• Store refrigerated (2-8°C). • **Open expiration**: 8 weeks. • Do NOT use if cloudy or discolored (should be clear to straw-color).

Specimen Requirements

- Whole blood from EDTA (purple top) or sodium citrate (blue top tube).
- Specimen may be stored up to five days at 2-30°C.

Method Limitations

- False negative results may be caused by:
  – Preventative treatment for HIV
  – Highly active antiretroviral therapy (HAART)
- A non-reactive result does not preclude the possibility of exposure to HIV or infection with HIV. An antibody response to recent exposure may take several months to reach detectable levels.
- Clinical data has not been collected to demonstrate performance of this test method in persons under 12 years of age.

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Quality Control

External Controls:

- Consists of three controls:
  - HIV-1 antibody positive
  - HIV-2 antibody positive
  - HIV-1/2 antibody negative
- External controls must be run:
  - By each new (untrained) operator prior to performing testing on patient specimens.
  - Every 30 days.
  - With each new kit lot/shipment.
  - If temperature of test kit storage area falls outside 2-27°C.
  - If temperature of testing area falls outside of 15-27°C.
- Follow *Procedure* steps to perform QC. QC must be acceptable prior to using test kit for patient testing.

Internal procedural controls:

- Positive: Complete, reddish-purple line of any intensity in the Control (C) area triangle.
- Negative: background color of the result window must not interfere with reading test result.

Procedure

Follow the steps below to perform test:

Note: Allow test materials, specimen, and controls to warm to room temperature prior to testing.

Step	Action
1	Remove the Developer Solution Vial (DSV) from test pouch and *label with patient or control identification*. *Note: a separate test pouch is needed for each patient or control sample to be tested.*
2	Carefully remove the cap from DSV.
3	Slide the open DSV into a slot on a test stand, making sure to push the vial all the way to the bottom of the slot.
4	For patient specimens, mix tube by gently inverting several times.
5	Remove cap from patient specimen or control vial.

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Procedure (continued)

Step	Action
6	Insert the rounded end of a disposable Sample Loop into the patient specimen or control vial, making sure the loop completely fills with sample.
7	Carefully remove the filled Sample Loop and immediately immerse the loop into the appropriate labeled DSV. Stir the loop in the solution a couple of times to mix.
8	Remove the Sample Loop and discard in appropriate biohazard container.
9	Remove the Test Device from pouch. *Do NOT touch the flat pad.* *Notes:* • *The Test Device pouch must have an absorbent packet inside. If no absorbent packet is present, discard the Test Device and open a new pouch to use for test.* • *Do NOT cover the two holes on the backside of the Test Device in any way as this may cause an invalid result.*
10	Insert the flat pad of the Test Device all the way to bottom of DSV with result window facing forward.
11	Set timer for 20 minutes. *Do NOT remove the Test Device from the DSV while test is in progress.*
12	Read results after 20 minutes (but not more than 40 minutes) in a fully lighted area.
13	Record result on the *Rapid HIV Log*. Log entry must include: • Date of test • Patient or Control ID • Test result • Results of internal procedural controls • Your initials/tech code
14	Discard used DSV and Test Device in appropriate biohazard container.
15	Phone result to the appropriate contact defined in the *Policy* section. Document phoned notification on Rapid HIV log and in LIS.
16	If result is reactive/positive, then take the specimen to Processing. Processing staff will order the reflex confirmation test **HIV4G** and ensure the appropriate specimen is sent to SMCS. *Note: One full white top PPT tube will need to be collected for HIV4G test.*

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Performing OraQuick Advance Rapid HIV-1/2 Antibody Test, Continued

Evaluating Results

Evaluate internal procedural control and result window appearance to determine test validity as follows:

If ...	Then test result is...
Complete, reddish-purple line displays in the Control (C) triangle with no background color interference.	• Valid and may be reported. • Proceed to *Interpreting Results* section.
• NO line displays in the Control (C) triangle, • Control (C) or Test (T) line is outside of the triangle area, • Incomplete Control (C) or Test (T) line (i.e. does not span entire width of the result window), or • Excessive background color makes it difficult to read the test result.	• Invalid and may NOT be reported • **Test must be repeated**.

Interpreting Results

Interpret a valid test as follows:

If Test (T) triangle displays ...	And Control (C) triangle displays…	Then test result is...
NO line.	Complete, reddish-purple line no matter how faint.	Non-reactive/negative - indicates HIV-1/2 antibodies were NOT detected.
Complete, reddish-purple line no matter how faint.	Complete, reddish-purple line no matter how faint.	Reactive/positive – indicates HIV-1 and/or HIV-2 antibodies were detected.

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Reporting Results

Enter result for **HIVRPD** test in Sunquest roll and scroll as follows:

Note: Default [Enter] at any prompt not defined in table below.

<table>
<tr><th>Prompt</th><th>Action/Enter</th></tr>
<tr><td>Function:</td><td>MEM</td></tr>
<tr><td>Worksheet:</td><td>RVHRPD</td></tr>
<tr><td>Test-1</td><td>HIVRPD (or default to include all tests on worksheet).</td></tr>
<tr><td>CAP Method Accept/ Modify</td><td>A to accept</td></tr>
<tr><td>Acc. No.:</td><td>Enter the appropriate patient accession number.</td></tr>
<tr><td>HIVRPD:</td><td>
<table>
<tr><th>If test result is…</th><th>Then enter….</th></tr>
<tr><td>Non-reactive/negative</td><td>NRHIV
(Non-Reactive for HIV-1 and HIV-2 antibodies)</td></tr>
<tr><td>Reactive /positive</td><td>PRHIV
(Preliminary Positive for HIV-1 and HIV-2 antibodies, confirmation to follow)</td></tr>
</table>
Note: The ETC LKHIV “This method detects antibodies to HIV-1 and HIV-2” will auto-append to the result.
</td></tr>
<tr><td>Accept/Modify/ Reject</td><td>• First, enter M to modify result and append free text comment with the phoned result documentation, include:
– Name of person called.
– Date/time called, and
– Your tech code

Example: NRHIV-LKHIV-;called to/readback J.Jones/RN Supvr 7/13/16 1200. 9899

• Then, enter A to accept the result.</td></tr>
<tr><td></td><td>Verify the accuracy of result entry by using inquiry function (IQ or GUI Laboratory Inquiry), or by printing a completed worksheet to review results. Confirm by writing RVS and your initials on the Rapid HIV log entry.</td></tr>
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Performing OraQuick Advance Rapid HIV-1/2 Antibody Test, Continued

Confirmation Testing Process

The process for confirmatory testing of patient with reactive/positive Rapid HIV-1/2 Antibody Test is defined below:

<table>
<tr><th>Activity</th><th>What Happens</th><th>Who's Responsible</th></tr>
<tr><td>1</td><td>Reflex HIV4G test is ordered by Lab and sent to SMCS.</td><td>SRMC Lab</td></tr>
<tr><td>2</td><td>HIV4G test is performed (7 days/week).
<table>
<tr><th>When HIV4G test is…</th><th>Then…</th></tr>
<tr><td>Non-reactive</td><td>Result is reported immediately.</td></tr>
<tr><td>Repeatedly reactive</td><td>• Specimen is sent to Shared Lab for confirmation and differentiation of HIV-1 vs HIV-2 antibodies.
• HIV4G test remains pending.</td></tr>
</table></td><td>SMCS Lab</td></tr>
<tr><td>3</td><td>Confirmation and differentiation testing is performed.
<table>
<tr><th>When confirmatory Testing is…</th><th>Then…</th></tr>
<tr><td>Positive</td><td>HIV4G is reported.</td></tr>
<tr><td>Negative or Indeterminate</td><td>• HIV4G is reported.
• Specimen is sent to Quest for PCR testing (TAT 2-5 days). PCR test is reported separately.</td></tr>
</table></td><td>Shared Lab/ SMCS</td></tr>
</table>

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Performing OraQuick Advance Rapid HIV-1/2 Antibody Test, Continued

Supporting Documents

- OraQuick Advance Rapid HIV-1/2 Patient Result Log
- OraQuick Advance Rapid HIV-1/2 Quality Control Log
- Critical Test Response and Notification

References

OraQuick *Advance* © Rapid HIV-1/2 Antibody Test Product Insert #3001-1215, OraSure Technologies Inc., 03/16B.

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