

PRELIMINARY POSITIVE FOLLOW-UP PROCEDURES FOR ORAQUICK

PRINCIPLE:

Some positive OraQuick results might be false. This is why for every result that is reactive by OraQuick (or preliminary positive), the test is followed by a confirmatory Western Blot test. If the Western Blot is negative, the OraQuick might be a false positive; but the OraQuick might be true and the Western Blot false negative if the client is in the conversion window phase.

If the confirmatory test is either negative or indeterminate, the best way to resolve the difference and figure out the correct answer is to collect a follow-up blood specimen at least 4 weeks after the initial reactive OraQuick result. The client should return for that extra blood work. After 4 weeks, a client in the window phase should now be clearly positive. If confirmatory testing is still negative after one month, the OraQuick was probably false positive.

PROCEDURE:

First visit:

1. If a preliminary positive result is obtained using the OraQuick rapid test, collect one completely filled 10ml red top vacutainer tube of blood and send it to the New Jersey State lab.
2. If no blood is drawn for a confirmatory test, refer the client to NAP. (# 1 on the OraQuick NAP Referral form.)
3. Either way, a preliminary positive report form needs to be completed and faxed to HIV Rapid Support Testing at 732-743-3632.

When the Western Blot result is returned by the state:

4. The confirmatory section of the original Preliminary Positive Report form needs to be completed and sent to NJ Rapid HIV Testing Support Program at 732-743-3632.
5. **If the Western Blot is Positive**, you may give the client the result on the "OraQuick Test Results" form that you received during your counseling training.
 - After you have given the client the result, complete the bottom portion of the Preliminary Positive Report form – client notification – and fax it to 732-743-3632.
 - If the client did not return to get the confirmed positive result
 - Refer the client to NAP (#2 on the OraQuick NAP Referral form.) and
 - Complete the bottom of the Preliminary Positive Report form and fax it to 732-743-3632.
6. **If the Western Blot is Negative**
 - a. Call NJ Rapid HIV Testing Support Program at 732-743-3624 and notify us of the result.
 - b. Site staff should notify their medical director that a discordant has been identified and that additional testing will be done.
 - c. The counselor should schedule an appointment with the client to give these results. Notify the NJ Rapid HIV Testing Support Program at 732-743-3624 of this appointment. One of the program doctors will work with the site regarding this discordant. The doctor will make every attempt to be available for the counseling visit, in person or by phone. (The information in the Principle section at the top of this page may be helpful.)

- d. If you can't reach the client, or the client does not come back to get the confirmatory result, refer the client to NAP. (#3 on the OraQuick NAP Referral form.) Complete the Preliminary Positive Report form and fax it to NJ Rapid HIV Testing Support Program at 732-743-3632.
- e. NJ Rapid HIV Testing Support Program will fax or email a Discordant Report Form, and will send you tubes for drawing blood.
- f. Complete as much information as possible on the Discordant Report Form and fax it to 732-743-3632.
- g. Same as C above.
- h. The counselor should arrange for the client to come back again, 4 weeks after the original OraQuick test. Let the client know that this is the best way to be sure of the correct result.
- i. At the return visit at 4 weeks, additional blood specimens should be collected: One red, gold or speckled-top; one purple-top, and one white top tube.
 - If possible, staff at the testing site should spin the white top tube, and freeze it upside down.
 - If you think the client will not return at 4 weeks, collect this blood at the time you are giving the client the negative Western Blot result.
 - Call HIV Rapid Support Testing at 732-743-3624 to arrange for someone to pick up the tubes.
 - Results of these tests will be forwarded to the CTS site when they are available.
 - If the client does not come back for this testing, try to get him or her back. If you can't, then refer the client to NAP (#4 on the OraQuick NAP Referral form.)
 - Complete the Preliminary Positive Report form and fax it to HIV Rapid Testing Support at 732-743-3632.

7. If the Western Blot is Indeterminate or Inconclusive

- a. Call NJ Rapid HIV Testing Support at 732-743-3624 and notify us of the result.
- b. Site staff should notify their medical director that a discordant has been identified and that additional testing will be done.
- c. The counselor will schedule an appointment with the client to give these results. Notify the NJ Rapid HIV Testing Support at 732-743-3624 of this appointment. One of the program doctors will work with the site regarding this discordant. We would also like someone from NJ Rapid HIV Testing Support to be present for this appointment.
- d. If you can't reach the client, or the client does not come back to get the confirmatory result, refer the client to NAP. (#5 on the OraQuick NAP Referral form.) Complete the Preliminary Positive Report form and fax it to HIV Rapid Testing Support at 732-743-3632.
- e. HIV Rapid Testing Support will fax or email a Discordant Report Form, and will send you tubes for drawing blood.
- f. Complete as much information as possible on the Discordant Report Form and fax it to 732-743-3632.
- g. At the post-test counseling visit (that you scheduled in step c), the NJ Rapid HIV Testing Support Program doctor will be available either in person or by phone to help answer any questions the counselor or the client may have about the negative western blot result. Someone from NJ Rapid HIV Testing Support will be present to take the tubes of blood from you.
 - At the post-test counseling session, blood specimens should be collected: One red, gold or speckled-top; one purple-top, and one white top tube.

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- Results of these tests will be forwarded to the CTS site when they are available.

Written by: _____ Sharon Holswade _____ Date: _____ 04/15/05 _____

Approved by: _____ Evan Cadoff, M.D. _____ Date: _____ 04/15/05 _____

Revised by: _____ Evan Cadoff/Franchesca Jackson _____ Date: _____ 5/4/06 _____

Revised by: _____ Sharon A. Holswade _____ Date: _____ 7/21/06 _____

Reviewed by: _____ Date: _____

Reviewed by: _____ Date: _____

OraQuick NAP Referral

Client CTS number _____

Site: _____

Today's date: _____

- Check the appropriate box to let NAP know why you are referring the client to them.
- Follow instructions in that box.
- Fax this form to NAP at 973-648-7384.
- Also fax a Preliminary Positive Report form to HIV Rapid Testing Support at 732-743-3632.

Counselor at site

NAP

<input type="checkbox"/> 1	Client did not have confirmatory specimen collected.	
	<ul style="list-style-type: none"> • Fax the Purple Bubble Sheet to NAP. • Send the Purple Bubble Sheet to NAP. • Does client know OraQuick was positive? <input type="checkbox"/> YES <input type="checkbox"/> NO 	<ul style="list-style-type: none"> • Do an OraSure (not OraQuick) to confirm the result.
<input type="checkbox"/> 2	Confirmed positive result, but the client did not return to get the positive Western Blot result.	
	<ul style="list-style-type: none"> • Fax the Purple Bubble Sheet to NAP. • Within 24 hours, Fax the lab result to NAP with this form (DO NOT include any patient identifiers other than the CTS number) 	<ul style="list-style-type: none"> • Perform post-test counseling session
<input type="checkbox"/> 3	Client has a positive OraQuick, and a negative Western Blot (discordant result), but the client did not return to get the Western Blot result.	
	<ul style="list-style-type: none"> • Fax the Purple Bubble Sheet to NAP. • Within 24 hours, Fax the lab result to NAP with this form (DO NOT include any patient identifiers other than the CTS number) 	<ul style="list-style-type: none"> • Tell the client that the results are discordant and that they might be HIV positive. • Refer the client back to the site for additional testing in 1 month.
<input type="checkbox"/> 4	Client had a positive OraQuick and negative Western Blot (discordant result). One month has passed, but client has not returned for their 1 month followup.	
	<ul style="list-style-type: none"> • Fax the Purple Bubble Sheet to NAP. • Within 24 hours, Fax the lab result to NAP with this form (DO NOT include any patient identifiers other than the CTS number) 	<ul style="list-style-type: none"> • Do an OraSure (not OraQuick) to confirm the result. • Refer the client back to the site for additional testing.
<input type="checkbox"/> 5	Client has a positive OraQuick with an indeterminate Western Blot (discordant result), but the client never returned to get the Western Blot result.	
	<ul style="list-style-type: none"> • Fax the Purple Bubble Sheet to NAP. • Within 24 hours, Fax the lab result to NAP with this form (DO NOT include any patient identifiers other than the CTS number) 	<ul style="list-style-type: none"> • Do an OraSure (not OraQuick) • Refer the client back to the site for additional testing immediately.

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For NAP use only:

Did you reach the client? ___ No ___ Yes (If Yes, Date _____)

Did you do an OraSure? ___ No ___ Yes (If Yes, Date _____)

Did you do an OraQuick? ___ No ___ Yes (If Yes, Date _____)

When the case is closed, Fax this form back to HIV Rapid Support Testing at 732-743-3632.

For Technical Assistance, call RWJ at 732-743-3624