

POLICY & PROCEDURE – Rapid-2-Rapid HIV Testing

Protocol for Rapid to Rapid (R2R) HIV testing:

This Protocol/Procedure outlines the process for the Test to Treat Program being implemented by the Division of HIV, STD & TB Services (DHSTS) in order to link HIV screen positive clients into treatment as quickly as possible. Under this program, an individual who has tested positive by 2 different HIV testing methods can be immediately linked to care.

This process may differ slightly as to data handling and client linkage to treatment depending on which of three categories your site falls into:

Category 1: Rapid-Rapid Testing Site and Treatment Site:

Your testing site is a Rapid Rapid Testing site and is also a clinical treatment site. You use Clearview StatPak or Determine™ as the first Rapid HIV test and confirm the positive antibody result by using a second Rapid test (e.g., Trinity Unigold or OraQuick). The client is then referred to treatment within the organization on the same or next business day.

Category 2: Rapid Rapid Testing Site & Non Treatment Site-Client Will Be Transported to Treatment:

Your testing site is a Rapid Rapid Testing site, but is **not** a clinical treatment site. You use Clearview StatPak or Determine™ as the first Rapid HIV test and confirm a positive antibody result by using a second Rapid test (e.g., Trinity Unigold or OraQuick). Under this category, the client is referred for treatment to a clinical treatment site with which your organization has established a Memorandum of Agreement (MOA) permitting linkage to care within one business day. The initial testing site will be responsible for seeing that the screen positive client is transported to the treatment site on the same or next business day.

Category 3: Rapid Testing Site- Client Will Be Transported to Rapid Rapid Site For Second Test & Treatment:

Your testing site is **not a** Rapid Rapid Testing site. You use Clearview StatPak or Determine™ as the first Rapid HIV test and confirm the positive antibody result by sending the client to a Rapid Rapid Testing/Treatment site (Category 1) that performs a second Rapid test (Trinity Unigold or OraQuick) and links any positive client to treatment on the same or next business day.

The Category 1 site may elect to have certified staff travel and perform the second Rapid test at the Category 3 site's physical location, following the appropriate Mobile Travel Pack Policy. Testing records must be maintained according to the Travel Pack Policy. All record keeping and reporting requirements of this policy apply based on each counselor's primary location.

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PROCEDURES: RAPID TO RAPID (R2R) TESTING

Category 1- Rapid Rapid Testing Site and Treatment Site:

Your testing site is a Rapid Rapid Testing site and is also clinical treatment site. You use Clearview StatPak or Determine™ as the first Rapid HIV test and confirm a positive antibody result using a second Rapid test (e.g., Trinity Unigold or OraQuick). The client is referred to treatment within your organization, or a site of the client's choosing, within the same or next business day.

1. Client is tested using first Rapid HIV Test, Clearview StatPak, OraQuick or Determine™. If a positive antibody result is obtained using the Clearview StatPak, OraQuick or Determine™ Rapid test, follow the counseling message and perform a second Rapid HIV test to confirm the first positive result.
 - a. **Data:** Enter all the required information on the **NJ HIV Positive Tracking Form** for the First Rapid HIV test result. This information will also be entered into Evaluation Web and on the RAPID HIV Test Report.
2. Second Rapid HIV Test: A secondary Trinity Unigold Rapid HIV test or OraQuick Rapid HIV test is performed. If a positive result is obtained using the Trinity Unigold Rapid HIV test or OraQuick Rapid HIV test, the second test will verify the first positive antibody result. Follow the counseling message and navigate the client to a medical provider within your organization for treatment and any referrals for other services that may be needed.

If the first positive **result is only a positive** Antigen (Ag) line using Determine, follow the appropriate counseling message and navigate the client to a medical provider. Currently there are no Rapid tests available to an Antigen positive result, and the patient may be in the window phase of HIV infection. The medical provider will need to evaluate the patient. Call the NJ Rapid HIV Support Clinician at 732-236-7013 to report this result and report the case to the HIV Surveillance Program.

- a. **Data:** Enter all the required information on the **NJ HIV Positive Tracking Form** for the Second Rapid HIV test result. *It is not necessary to enter the site and counselor information unless it is different from the first result.* Check the box indicating both tests were positive. Be sure to fax the form to 732-235-9012. This information will also be entered into Evaluation Web and on to the HIV Test Report.
 - b. **Data:** Enter all the required information on the **NJ HIV Positive Tracking Form** for the Client Referral to Treatment. **Be sure to fax the form to 732-235-9012**
 - c. **The NJ HIV Positive Tracking form and the Rapid HIV Test Report must go with the client to the treatment site** (per your sites agreement with the treatment location you may be able to fax the form and report to ensure it is there for the client's appointment).
3. If the Second Rapid HIV Test is a negative result using the Trinity Unigold Rapid HIV test or OraQuick Rapid HIV test, you now have a **discordant result**. Call the NJ Rapid

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HIV Support Clinician at 732-236-7013 for guidance. Site staff should notify their medical director that a discordant has been identified and that additional testing will be done.

- a. Draw two 7 ml serum separator tubes and two 5 ml white top tubes (with at least 2 mls in the white top tube). Spin all the tubes down. Refrigerate the serum separator tubes and freeze the white top tube upside down.) Call NJ Rapid HIV Support Testing at 732-743-3624 to arrange for someone to pick up all the tubes.

Caution: *After collection, BD Vacutainer® SST™ Serum Separation Tubes should be inverted five times, allowed to rest for 30 minutes to clot, and centrifuged for 10 minutes. After collection BD Vacutainer® PPT™ Plasma Preparation Tubes (white top) should be inverted 8 times and centrifuged for 10 minutes. This can be done immediately or within 2 hours. The PPT tubes do not require any rest time as they do not clot.*
 - b. Follow the counseling message regarding a **discordant result**. One of the program doctors will work with the site regarding this discordant. NJ Rapid HIV Testing support will send you tubes for the blood draw if you do not have them. PLEASE make sure your site always has a couple of tubes available with valid expiration dates.
 - c. Upon arrangement, the NJ HIV Testing Support Program doctor will be available in person or by phone at the post-test counseling session to help answer any questions the counselor or the client may have about the indeterminate or inconclusive result.
 - d. **Data:** Enter all the required information on the **NJ HIV Positive Tracking Form** for the Second Rapid HIV test result. It is not necessary to enter the site and counselor information unless it is different from the first result. Check the box indicating the test result is discordant. Be sure to fax the form to 732-235-9012.
4. If the client refuses a second Rapid HIV test or refuses blood work if the result is discordant refer the client to Partner Services.
 - a. Upon arrangement the NJ Rapid HIV Testing Support Program doctor will be available in person or by phone to help answer any questions the counselor or the client may have about the false positive result.
 5. **Make sure the NJ HIV Positive Tracking Form is completed and faxed to NJ HIV Rapid Support Services at 732-235-9012.** This should be faxed once the first and second results are completed and again when the client has an appointment for treatment and the appointment is kept.
 6. All sites conducting Rapid-Rapid Testing are required to report all positive cases to the HIV Surveillance Program. The case may be reported to the state by submission of a printed copy of the completed Evaluation Web form. Identifying client information is to be provided on the back of the hard copy document. The needed information includes: Client Name; Client Address and Client Telephone Number, when available. The form can be sent to the Surveillance Program using a state supplied confidential envelope which is self addressed and postage paid. Envelopes or further

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guidance may be obtained by calling (609) 984-5940.

Category 2: Rapid Rapid Testing Site & Non Treatment Site- Client Will Be Transported to Treatment:

Your testing site is a Rapid Rapid Testing site and is **not** clinical treatment site. You use Clearview StatPak , Determine™ or OraQuick as the first Rapid HIV test and confirm the positive result by using a second Rapid test (Trinity Unigold or OraQuick). The client is referred to treatment to a clinical treatment site with whom you have an MOA, or a site of the client's choosing, within the same or next business day.

1. Client is tested using first Rapid HIV Test, Clearview StatPak, OraQuick or Determine™. If a positive antibody result is obtained using the Clearview StatPak, OraQuick or Determine™ Rapid test, follow the counseling message and perform a second Rapid HIV test to confirm the first positive result.
 - a. **Data:** Enter all the required information on the **NJ HIV Positive Tracking Form** for the First Rapid HIV test result. This information will also be entered into Evaluation Web and on the RAPID HIV Test Report.
2. Second Rapid HIV Test: A secondary Trinity Unigold Rapid HIV test or OraQuick Rapid HIV test is performed. If a positive result is obtained using the Trinity Unigold Rapid HIV test or OraQuick Rapid HIV test, the second test will verify the first positive result. Follow the counseling message and navigate the client to a medical provider within your organization for treatment and any referrals for other services that may be needed.

If the first positive **result is only a positive** Antigen (Ag) line using Determine, follow the appropriate counseling message and navigate the client to a medical provider. Currently there are no Rapid tests available to confirm an Antigen positive result, and the patient may be in the window phase of HIV infection. The medical provider will need to evaluate the patient. Call the NJ Rapid HIV Support Clinician at 732-236-7013 to report this result and report the case to the HIV Surveillance Program.

- a. **Data:** Enter all the required information on the **NJ HIV Positive Tracking Form** for the Second Rapid HIV test result. *It is not necessary to enter the site and counselor information unless it is different from the first result.* Check the box indicating both tests were positive. **Be sure to fax the form to 732-235-9012.** This information will also be entered into Evaluation Web.
 - b. **Data:** Enter all the required information on the Rapid HIV Positive Form for the Client Referral to Treatment. **Be sure to fax the form to 732-235-9012.**
 - c. **The NJ HIV Positive Tracking form and the Rapid HIV Test Report must go with the client to the treatment site** (per your sites agreement with the treatment location you may be able to fax the form and report to ensure it is there for the client's appointment).
2. If the Second Rapid HIV Test is a negative result is obtained using the Trinity Unigold Rapid HIV test or OraQuick Rapid test, you now have a **discordant result**. Call the NJ Rapid HIV Support Physician at 732-236-7013 for guidance, if needed. Site staff should

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notify their medical director that a discordant has been identified and that additional testing will be done.

- a. Draw two 7 ml serum separator tubes and two 5 ml white top tubes (with at least 2 mls in the white top tube). Spin all the tubes down. Refrigerate the serum separator tubes and freeze the white top tube upside down.) Call NJ Rapid HIV Support Testing at 732-743-3624 to arrange for someone to pick up all the tubes.

Caution: After collection, BD Vacutainer® SST™ Serum Separation Tubes should be inverted five times, allowed to rest for 30 minutes to clot, and centrifuged for 10 minutes. After collection BD Vacutainer® PPT™ Plasma Preparation Tubes (white top) should be inverted 8 times and centrifuged for 10 minutes. This can be done immediately or within 2 hours. The PPT tubes do not require any rest time as they do not clot.

- a. Follow the counseling message regarding a **discordant result**. One of the program doctors will work with the site regarding this discordant. NJ Rapid HIV Testing support will send you tubes for the blood draw if you do not have them (but PLEASE make sure your site always has a couple of tubes available with valid expiration dates).
 - b. Upon arrangement the NJ Rapid HIV Testing Support Program doctor will be available in person or by phone at the post-test counseling session to help answer any questions the counselor or the client may have about the indeterminate or inconclusive result.
 - c. **Data:** Enter all the required information on the **NJ HIV Positive Tracking Form** for the Second Rapid HIV test result. It is not necessary to enter the site and counselor information unless it is different from the first result. Check the box indicating the test result is discordant. Be sure to fax the form to 732-235-9012.
3. If the client refuses a second Rapid HIV test or refuses blood work if the result is discordant refer the client to Partner Services..
 - a. Upon arrangement the NJ Rapid HIV Testing Support Program doctor will be available in person or by phone at the post-test counseling session to help answer any questions the counselor or the client may have about the false positive result.
 4. **Make sure the NJ HIV Positive Tracking Form is completed and faxed to NJ HIV Rapid Support Services at 732-235-9012.** This should be faxed once the first and second results are completed and again when the client has an appointment for treatment and the appointment is kept.

All sites conducting Rapid-Rapid Testing are required to report all positive cases to the HIV Surveillance Program. The case may be reported to the state by submission of a printed copy of the completed Evaluation Web form. Identifying client information is to be provided on the back of the hard copy document. The needed information includes: Client Name; Client Address and Client Telephone Number, when available. The form can be sent to the Surveillance Program using a state supplied confidential envelope which is self addressed and postage paid. Envelopes or further guidance may be obtained by calling (609) 984-5940.

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Category 3: Rapid Testing Site- Client Will Be Transported to Rapid Rapid Site For Second Test & Treatment:

Your testing site is **not a** Rapid Rapid Testing site. You use Clearview StatPak, Determine™ or Oraquick as the first Rapid HIV test and confirm the positive result by sending the client to a Rapid Rapid Testing site in Category 1 who will use a second Rapid test (Trinity Unigold or OraQuick). The client is referred to treatment within the Category1 testing site organization within the same or next business day.

1. Client is tested using first Rapid HIV Test, Clearview StatPak, OraQuick or Determine™. If a positive antibody result is obtained using the Clearview StatPak, OraQuick or Determine™ Rapid test, follow the counseling message and perform a second Rapid HIV test to confirm the first positive result.
 - a. **Data:** Enter all the required information on the **NJ HIV Positive Tracking Form** for the First Rapid HIV test result. This information will also be entered into Evaluation Web and on the RAPID HIV Test Report.
2. Second Rapid HIV Test: A secondary Trinity Unigold Rapid HIV test or OraQuick Rapid HIV test is performed. If a positive result is obtained using the Trinity Unigold Rapid HIV test or OraQuick Rapid HIV test, the second test will verify the first positive result. Follow the counseling message and navigate the client to a medical provider within your organization for treatment and any referrals for other services that may be needed.

If the first positive **result is only a positive** Antigen (Ag) line using Determine, follow the appropriate counseling message and navigate the client to a medical provider. Currently there are no Rapid tests available to confirm an Antigen positive result, and the patient may be in the window phase of HIV infection. The medical provider will need to evaluate the patient. Call the NJ Rapid HIV Support Clinician at 732-236-7013 to report this result and report the case to the HIV Surveillance Program.

- a. **Data:** Enter all the required information on the Rapid HIV Positive Form for the Second Rapid HIV test result. **It is necessary to enter the second site's site and counselor information since it is different from the first result.** A copy of this form will be kept at the SECOND site and a copy can be forwarded to the treatment center if required for appointment. **The staff at the SECOND site will NOT enter data in Evaluation Web. The original form, now completed, should go back to the FIRST site. The first site will enter all the information into Evaluation Web.**
 - i. In order to document that the second result was done at a site other than testing site one, in Evaluation Web the second testing site number should be entered into local field 1 and the second counselor number should be entered into local field 2.
 - ii. Check the box indicating both tests were positive. Be sure to **fax the form to 732-235-9012**. This information will also be entered into Evaluation Web as usual.
- b. **Data:** Enter all the required information on the **Rapid HIV Positive Tracking Form** for the Client Referral to Treatment. Be sure to fax the form to 732-235-9012

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- c. **Data:** The staff at the SECOND site needs to enter the site number for the FIRST site on their test log so it can be referenced back to the first positive result. The FIRST site's number should be entered in the Testing type box and an S for second test should be in the control code box on the test log
2. If a negative result is obtained using the Trinity Unigold Rapid HIV test or OraQuick Rapid test, you now have a **discordant result**. Call the NJ Rapid HIV Support Physician at 732-236-7013 for further guidance, if needed.

- a. **SITE 2. Discordant protocol**

- i. Site staff should notify their medical director that a discordant result with previous rapid testing has been identified.
- ii. Draw two 7 ml serum separator tubes and two 5 ml white top tubes (with at least 2 mls in the white top tube). Spin all the tubes down. Refrigerate the serum separator tubes and freeze the white top tube upside down.) Call NJ Rapid HIV Support Testing at 732-743-3624 to arrange for someone to pick up all the tubes. Please let NJHIV staff know that the samples at your site are a discordant from **SITE 1**, so that NJHIV can link the case appropriately.

Caution: After collection, BD Vacutainer® SST™ Serum Separation Tubes should be inverted five times, allowed to rest for 30 minutes to clot, and centrifuged for 10 minutes. After collection BD Vacutainer® PPT™ Plasma Preparation Tubes (white top) should be inverted 8 times and centrifuged for 10 minutes. This can be done immediately or within 2 hours. The PPT tubes do not require any rest time as they do not clot.

- iii. Follow the counseling message regarding a discordant result. One of the program doctors will work with both sites regarding this discordant, as needed. NJHIV Testing support will replace used collection tubes.
- iv. Communicate discordant result to **SITE 1. The client will follow-up with SITE 1 for resolution of the discordant result.**
- v. **Data:** Enter all the required information on the **Rapid HIV Positive Tracking Form** for the Second Rapid HIV test result. It is necessary to enter the site and counselor information since it is different from the first result entry. Check the box indicating the test result is discordant. Keep a copy of the form. The original form, now completed will return to the first site. Do not enter data into Evaluation Web.

- a. **SITE 1. Discordant protocol.**

- i. Record discordant result and file the completed form in the client chart. Follow discordant protocol (as for a Rapid-Western Blot discordant) and arrange for client to return to your site for final resolution.

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- ii. If final resolution is POSITIVE, contact **SITE 2** and arrange client appointment to the treatment center of **SITE 2**.
 - iii. If final resolution is NEGATIVE (false positive first rapid tests), follow counseling messages, notify client of status.
 - iv. **Data:** Enter all required information in Evaluation Web.
3. If the client refuses a second Rapid HIV test or refuses blood work if the result is discordant refer the client to Partner Services.
 - a. Upon arrangement the NJ Rapid HIV Testing Support Program doctor will be available in person or by phone at the post-test counseling session to help answer any questions the counselor or the client may have about the false positive result.
4. Make sure the Rapid HIV Positive Tracking Form is completed and faxed to NJ HIV Rapid Support Services at 732-235-9012. This should be faxed once the first and second results are completed and again when the client has an appointment for treatment and the appointment is kept.
5. All sites conducting Rapid-Rapid Testing are required to report all positive cases to the HIV Surveillance Program. The case may be reported to the state by submission of a printed copy of the completed Evaluation Web form. Identifying client information is to be provided on the back of the hard copy document. The needed information includes: Client Name; Client Address and Client Telephone Number, when available. The form can be sent to the Surveillance Program using a state supplied confidential envelope which is self addressed and postage paid. Envelopes or further guidance may be obtained by calling (609) 984-5940.

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