Administrative Matters

Joanne Corbo, MT(ASCP, MBA
HIV PROGRAM MANAGER
Rapid HIV Test Support

Rutgers – Robert Wood Johnson Medical School
New Brunswick, NJ
NJ HIV Rapid Testing Support Administrative Issues

Website for NJ HIV Rapid Testing Support: njhiv1.org
SUPPLY ORDERS

• SUPPLY ORDERS For ALL Sites are based on average monthly test volume (basically a Standing Order)

• SUPPLY ORDERS For ALL Sites Not Under the RWJ License
  – Will be filled based on average testing volume
  – Will be delivered the last two weeks of the month
  – If anything is need above the normal or if you need to decrease your order let us know prior to the 15th.
  – We pay for each delivery so please help us be cost efficient

• Call Lisa May at 732-743-3624 or Karen Williams at 732-743-3630 for any additional items or special situations requiring additional supplies. All orders must be approved by management before delivery
Proficiency Testing For RWJ Licensed Sites

• Proficiency Tests must be completed by the due date in the email
• Do not enter results online. Fax results to your liaison at 732-235-9012
• Take care when filling out results form. Look at the test strips when entering results. Avoid cross outs on the results form.
• We know the form is confusing. Please call us with questions. We have developed a guide to assist you.
• Proficiency tests are critically important. Failure of Proficiency testing could result in your site not being able to test.
Proficiency Testing For RWJ Licensed Sites

April 28, 2016
NJ HIV PROGRAM

FILLING IN THE AAB PROFICIENCY TEST FORM CORRECTLY

- **DO NOT** USE THE RESULTS IN INTERPRETATION COLUMN ON YOUR LOG SHEET TO ENTER RESULTS ON THE SURVEY FORM.
- ENTER THE RESULTS YOU SEE ON THE TEST STRIPS – See below for an example!

1) Determine Combo Antibody results are recorded on the AAB Proficiency Test Form in the row labelled: anti-HIV-1 or 1/2 screening.
2) Unigold results (at sites approved for Unigold testing) are entered in the box labelled **anti-HIV-1 Confirmation** because they are confirming the presence of antibody detected by the initial Determine Combo screen.
3) Determine Combo p24 Antigen results are reported in the row labelled HIV p24 Antigen
A PROPERLY FILLED OUT AAB Proficiency Test Form showing Determine Combo results:

<table>
<thead>
<tr>
<th>Procedure</th>
<th>Specimen 1</th>
<th>Specimen 2</th>
<th>Specimen 3</th>
<th>Specimen 4</th>
<th>Specimen 5</th>
<th>Method Code</th>
</tr>
</thead>
<tbody>
<tr>
<td>HIV p24 Antigen</td>
<td>010 Negative</td>
<td>011 Positive</td>
<td>010 Negative</td>
<td>011 Positive</td>
<td>010 Negative</td>
<td>3406</td>
</tr>
<tr>
<td>HIV-1 or HIV-2</td>
<td>010 Negative</td>
<td>011 Positive</td>
<td>010 Negative</td>
<td>011 Positive</td>
<td>010 Negative</td>
<td>3406</td>
</tr>
</tbody>
</table>

Enter Determine Antibody Result Here

Enter Unigold Result Here
NJ HIV Rapid Testing Support Administrative Issues

One Time Events

Procedure for One Time Events:

- Need to clearly documented where testing at a One Day Event location occurs
- DHSTS will need to approve One Day Event Request
- One Day Event request Form is still required
- New OTE Results form will document where testing was done
NJ HIV Rapid Testing Support Administrative Issues

- Requests should be sent 10 business days in advance (No exceptions)
- Must use current form (electronic version on NJ HIV1.org)
- Send to Sonya Thompson/copy to Joanne Corbo,
- Use new email address for Sonya: Sonya.Thompson@doh.nj.gov
- Approvals done by Sonya/PMO based on strict criteria for target population/prevalence (Criteria: zip code etc.)
- Results for One Day Events must be sent to Sonya Thompson/copy to Joanne Corbo within three business days of the event (electronic version on NJ HIV.org)
- Results form must also go to your site liaison by email/fax to document where testing was done
NJ HIV Rapid Testing Support Administrative Issues

DIVISION HIV, STD AND TB SERVICES
ONE-DATE TESTING EVENTS

INSTRUCTIONS FOR ELIGIBILITY

1. All agencies receiving kits and supplies from Robert Wood Johnson are required to submit this application approval

2. The request for approval is to be received by email only 10 (ten) business days prior to the event to:
   Sonya Thompson at sonya.thompson@doh.state.nj.us with cc to (corbojo@rwjms.rutgers.edu).

3. Testing venue/geographic area is considered a high prevalence location based on the County Zip code maps provided by DHSTS.

4. The target population is considered high risk for HIV as defined in the DHSTS HIV and Care Services Plan
   See Web Site at: http://hpcpsdi.rutgers.edu/NJHPG/downloads/2012-16PCplan.pdf

5. Pre—event planning has occurred to assure the above criteria has been met.
NJ HIV Rapid Testing Support Administrative Issues

```
<p>| | |</p>
<table>
<thead>
<tr>
<th></th>
<th></th>
</tr>
</thead>
<tbody>
<tr>
<td></td>
<td></td>
</tr>
<tr>
<td></td>
<td></td>
</tr>
<tr>
<td>---</td>
<td>---</td>
</tr>
<tr>
<td></td>
<td></td>
</tr>
<tr>
<td></td>
<td></td>
</tr>
<tr>
<td></td>
<td></td>
</tr>
<tr>
<td></td>
<td></td>
</tr>
<tr>
<td></td>
<td></td>
</tr>
<tr>
<td>---</td>
<td>---</td>
</tr>
<tr>
<td></td>
<td></td>
</tr>
<tr>
<td></td>
<td></td>
</tr>
<tr>
<td></td>
<td></td>
</tr>
<tr>
<td>---</td>
<td>---</td>
</tr>
<tr>
<td></td>
<td></td>
</tr>
<tr>
<td></td>
<td></td>
</tr>
<tr>
<td></td>
<td></td>
</tr>
<tr>
<td></td>
<td></td>
</tr>
<tr>
<td></td>
<td></td>
</tr>
</tbody>
</table>
```
<table>
<thead>
<tr>
<th>Question</th>
<th>Yes</th>
<th>No</th>
</tr>
</thead>
<tbody>
<tr>
<td>10. Is there sufficient lighting and space for performing a rapid test and reading the result</td>
<td>☐</td>
<td>☐</td>
</tr>
<tr>
<td>11. If not a testing van, do you have a confidential area for testing?</td>
<td>☐</td>
<td>☐</td>
</tr>
<tr>
<td>12. If not a mobile van, do you have suitable cooling equipment and a stable testing area?</td>
<td>☐</td>
<td>☐</td>
</tr>
<tr>
<td>13. What is the number of anticipated HIV tests?</td>
<td></td>
<td></td>
</tr>
<tr>
<td>Number of Tests:</td>
<td></td>
<td></td>
</tr>
<tr>
<td>14. Do you have a plan for acquiring more kits if you run short?</td>
<td>☐</td>
<td>☐</td>
</tr>
<tr>
<td>15. Is this a targeted testing event</td>
<td>☐</td>
<td>☐</td>
</tr>
<tr>
<td>16. If targeted, what is your target population?</td>
<td></td>
<td></td>
</tr>
<tr>
<td>17. Target population consistent with DHSTS’s high-risk target populations?</td>
<td>☐</td>
<td>☐</td>
</tr>
<tr>
<td>18. Is the target area in the high incidence areas (refer to zip code maps)</td>
<td>☐</td>
<td>☐</td>
</tr>
<tr>
<td>19. Is this event for the general public?</td>
<td>☐</td>
<td>☐</td>
</tr>
<tr>
<td>20. Is this event a national testing day or other event day?</td>
<td>☐</td>
<td>☐</td>
</tr>
<tr>
<td>21. Will other services be offered?</td>
<td>☐</td>
<td>☐</td>
</tr>
<tr>
<td>Please explain:</td>
<td></td>
<td></td>
</tr>
</tbody>
</table>

Please **email request** within **10 (ten)** business days **prior to event** to:
Sonya Thompson at sonya.thompson@doh.state.nj.us with cc to corbojo@rwjms.rutgers.edu
(Note: DO NOT FAX OR MAIL REQUEST).

Please **email results** within **3 (three)** business days of the event to:
Cynthia Mimmo at cynthia.mimmo@doh.state.nj.us with a cc to Sonya Thompson at sonya.thompson@doh.state.nj.us, corbojo@rwjms.rutgers.edu and the RWJ site liaison (Note: Only cc to RWJ site liaison if the site is under the RWJ license).
<table>
<thead>
<tr>
<th>RWJ Oversight:</th>
<th>Non RWJ Oversight:</th>
</tr>
</thead>
<tbody>
<tr>
<td>Yes</td>
<td>No</td>
</tr>
</tbody>
</table>

Request Approved:  Yes [ ]  No [ ]  Approval Date: 

If denied please state the reason: ____________________________

Special Instructions: ____________________________
NJ HIV Rapid Testing Support Administrative Issues

One-Day Event Results Report
Submit one form per event within three business days of event

Date of Event:
Sponsoring Agency:
Testing Agency (if different than sponsoring agency):
Site Number of Testing Agency:
Name of testing Location:
Address of testing Location:
Zip code of testing location:

Test Results

<table>
<thead>
<tr>
<th>Target Population</th>
<th># Positive</th>
<th># Negative</th>
</tr>
</thead>
<tbody>
<tr>
<td></td>
<td>0</td>
<td>0</td>
</tr>
<tr>
<td></td>
<td>0</td>
<td>0</td>
</tr>
<tr>
<td></td>
<td>0</td>
<td>0</td>
</tr>
<tr>
<td></td>
<td>0</td>
<td>0</td>
</tr>
<tr>
<td></td>
<td>0</td>
<td>0</td>
</tr>
<tr>
<td></td>
<td>0</td>
<td>0</td>
</tr>
<tr>
<td></td>
<td>0</td>
<td>0</td>
</tr>
<tr>
<td></td>
<td>0</td>
<td>0</td>
</tr>
<tr>
<td>TOTAL</td>
<td>0</td>
<td>0</td>
</tr>
</tbody>
</table>

* General Population is any non targeted group

Please complete the entire form. Totals will automatically add for you. "SAVE AS" naming the file with your agency name and date of event.

Email to Joanne Corbo at corbojo@RWJMS.rutgers.edu
and Sonya Thompson at sonya.thompson@doh.state.nj.us within three business days.
If you are under the RWJ license please email/fax this form to your liaison.
• NJHIV Positive Tracking Form
• Discordant Workup
NJ HIV Rapid Testing Support Administrative Issues

Rapid To Rapid Protocol

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.
NJ HIV Rapid Testing Support Administrative Issues

Discordant Work Up in Rapid to Rapid Protocol

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 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.
Discordant work up/ procedure:

- If second rapid or confirmatory does not match first rapid the result is discordant

- Draw blood for work up:
  - Two white top tubes (must be spun down and frozen upside down)
  - Two serum separators (must be spun down and refrigerated)

- You must report all discordant results to RWJ

- Call 732-236-7013. Leave a message with contact information so RWJ pick up samples and process.
• NJHIV Positive Tracking Form

• Use new form included in packet (available on NJ HIV.org)
• Must be sent in as completed to RWJ
• Fax to 732-235-9012 or 732-743-3632
• Do NOT Fax Evaluation WEB Forms to RWJ. WE can only accept de-identified information
NJ HIV Positive Tracking Form

First Rapid HIV Test Result

Client ID # ______________________
Date: ______________________

First Test Site ID Number _______  First Test Site Name: ______________________________________________________

First Test Site Counselor Name: __________________________  First Test Site Counselor Number: ______________________

First Rapid HIV Test Type:  □ OraQuick  □ Clearview STAT-PAK  □ Determine  □ Other

Result:  Positive HIV 1/2 Antibody □  Positive HIV Antigen (Determine ONLY) □
Specimen (circle one):  □ Oral  □ Fingerstick  □ Venipuncture  Test Kit Lot Number: ______________

Positive ANTIGEN ONLY (Determine): No rapid tests can validate this result. Collect discordant work-up samples for confirmation, call NJHIV support for assistance and REFER client to care IMMEDIATELY. This may represent an acute HIV case; confirmation may take 7-10 days. ENTER CONFIRMATORY RESULTS BELOW.

For Single Rapid Test Sites and Non Clinical Rapid-Rapid Test sites, this form MUST ACCOMPANY the patient to test site where second test will be performed and must go to the treatment site. The form must be returned to the first test site to capture the positive result and referral to care.
Some Reminders
Test logs:

• RWJ test logs due the 10th of the month
• May also be sent as they are completed
• Please make sure logs are complete
  • Site Number, Contact Information, shipment number
  • Test information complete: Pos, Neg, Temperature, Start Time End Time, Operator Initials
  • If doing second test for another site indicate second test and site number of first site

• Fax to 732-235-9012 or 732-743-3632
**RWJ License renewals:**

- License renewals sent with a checklist
- Coordinator must sign checklist to indicate all items necessary for regulatory compliance are in place at the site
- Send copy of standing order indicating it has reviewed and is current must be included
- Copy of standing order template included in packet (available on NJ HIV.org)
Checklist for License Renewal:

Site Name ____________________________

☐ We have the current signed RWJ NJ Rapid HIV Testing Support Program Policy Manual available at our testing location.

☐ We are using the current signed Exposure Control Plan provided in the RWJ NJ Rapid HIV Testing Support Program Policy Manual.

☐ We have a current signed Exposure Control Plan available at our testing location if we are not using the plan provided in the RWJ NJ Rapid HIV Testing Support Program Policy Manual.

☐ We have a copy of the standing order for performing Rapid HIV Testing signed by our current Medical Director or Authorized Physician at our testing location. The standing order has to be reviewed this year; We have documented that it is current and that the medical director (who signed it) has not changed.

☐ We have attached a copy of the standing order with our license application for RWJMS records.

Signed by:

________________________________________________________

Site Testing Coordinator
To Whom It May Concern:

This standing order shall constitute a request for rapid HIV testing for screenings performed at:

Name of Testing Site:
Address of Testing Site:

In cases where a client receives a preliminary positive result using a rapid HIV test, this authorizes:
HIV Western Blot and/or a second Rapid HIV test (for all preliminary positives);
and follow-up testing as appropriate to the clinical setting—which may include:
Additional HIV serology
HIV nucleic acid testing

Signature

Print Name
Medical Director
New Initiative

• CDC has asked us to assess capability of sites to bill for HIV Testing
• RWJ will be working with Ciccatelli Associates Inc. to do a needs assessment for NJ testing sites
• You will be contacted to do an online survey to start the process
• More information to come
NJ HIV Rapid Testing Support Administrative Issues