

RUTGERS

Robert Wood Johnson Medical School

Administrative Matters

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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

NJ HIV Rapid Testing Support Administrative Issues

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**

NJ HIV Rapid Testing Support Administrative Issues

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.**

NJ HIV Rapid Testing Support Administrative Issues

Proficiency Testing For RWJ Licensed Sites

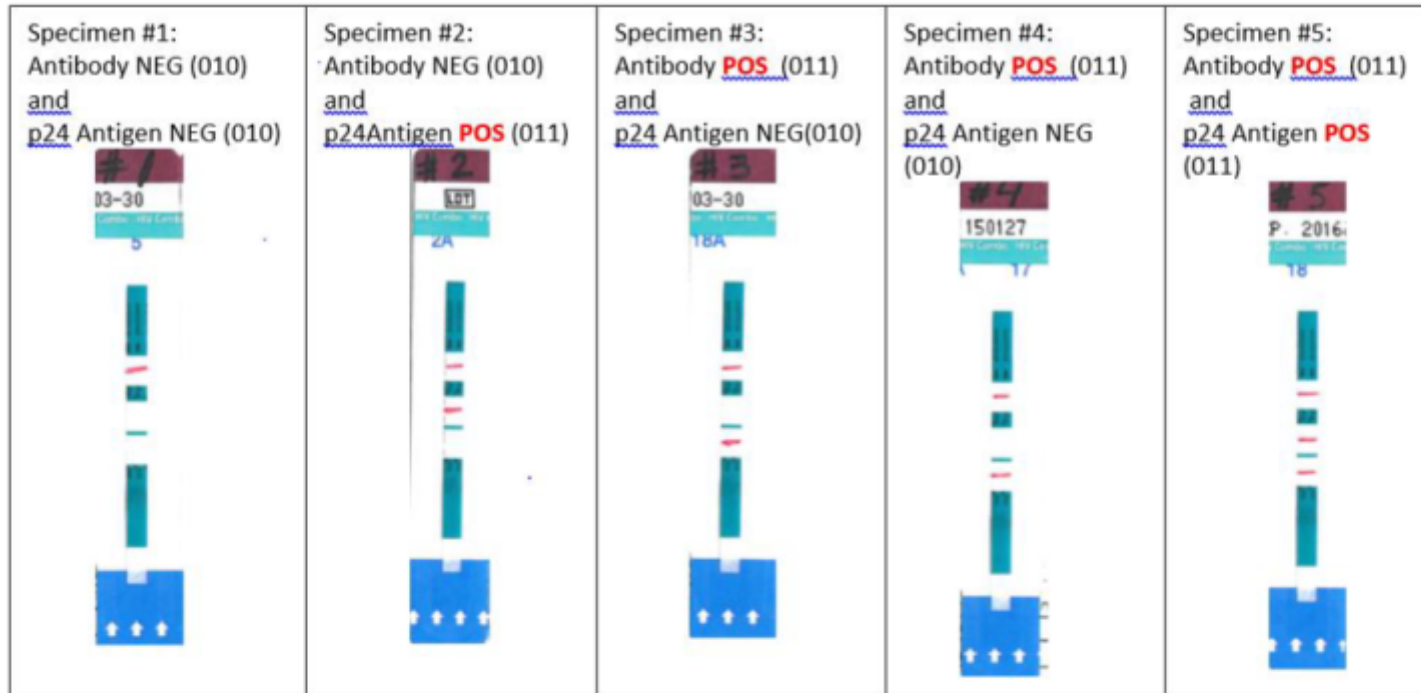
April 28, 2016
NJ HIV PROGRAM

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

DETERMINE COMBO – TEST STRIP RESULTS



A PROPERLY FILLED OUT AAB Proficiency Test Form showing Determine Combo results:

HIV MARKERS								
	CLIA number	State ID number	COLA number	LAP number	DATE RECEIVED	/ / 2016		
Procedure	Enter the NUMERIC code corresponding to your answer in the boxes to the right.		Specimen 1	Specimen 2	Specimen 3	Specimen 4	Specimen 5	Method Code
anti-HIV-1 or 1/2 Screening	010 Negative 011 Positive 020 Indeterminate	Enter Determine Antibody Result Here	010	010	011	011	011	3406
anti-HIV-1 Confirmation	010 Negative 011 Positive 020 Indeterminate 097 Pos for HIV1, Neg for HIV2 098 Neg for HIV1, Neg for HIV2 099 Pos for HIV1, Pos for HIV2 516 Neg specimens not confirmed	Enter Unigold Result Here						
HIV p24 Antigen	010 Negative 011 Positive	Enter Determine p24 Antigen Result Here	010	011	010	010	011	3406

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



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

DATE OF REQUEST:

DATE OF EVENT:

Name of Agency:

Street Address:

Contact:

State:

Zip Code:

Contact Phone No:

Cell No:

1.	Name or type of event:	
2.	Name and address of event location:	
3.	Zip Code(s) for the event:	(Zip code is in a high prevalence area per county maps)
4.	Start Time: AM End Time: AM	
5.	Has the event been advertized or marketed?	<input type="checkbox"/> Yes <input type="checkbox"/> No
6.	Is this event:	<input type="checkbox"/> Outdoor <input type="checkbox"/> Indoor
7.	Has the area been personally inspected?	<input type="checkbox"/> Yes <input type="checkbox"/> No
8.	Is the testing area temperature controlled?	<input type="checkbox"/> Yes <input type="checkbox"/> No
9.	If mobile van, is there a secure parking location with easy access for the mobile unit and those who wish to test?	<input type="checkbox"/> Yes <input type="checkbox"/> No

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

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).



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

Robert Wood Johnson Use ONLY

APPROVAL/NON APPROVAL

RWJ Oversight:

Non RWJ Oversight:

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		
Target Population	# Positive	# Negative
	0	0
	0	0
	0	0
	0	0
	0	0
	0	0
	0	0
	0	0
	0	0
TOTAL	0	0

* 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.

NJ HIV Rapid Testing Support Administrative Issues

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 Rapid Testing Support Administrative Issues

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.

NJ HIV Rapid testing Support Administrative Issues

SECOND Rapid HIV Test Result	
Date: _____	
NOT DONE BECAUSE: Client Walked OUT <input type="checkbox"/> Determined to be KNOWN POS <input type="checkbox"/> ALREADY IN CARE <input type="checkbox"/>	
Enter site information ONLY if Second Test Site Is different from First Test Site: <input type="checkbox"/> R2R <div style="float: right; border: 1px solid black; padding: 2px; font-size: small;">Check off ALL THAT APPLY</div>	
Second Test Site ID Number: _____	<small>Also enter in Local Field 2 in Evaluation Web</small> Second Test Site Name: _____
Second Test Site Counselor Number: _____	<small>Also enter in Local Field 2 in Evaluation Web</small> Second Test Site Counselor Name: _____
Second HIV Test Type: Rapid: <input type="checkbox"/> Unigold <input type="checkbox"/> OraQuick Result: Positive _____ Negative _____ Specimen (circle one): <input type="checkbox"/> Oral <input type="checkbox"/> Fingerstick <input type="checkbox"/> Venipuncture Test Kit Lot Number: _____	
Test Result: Fax to 732-235-9012. When Rapid HIV test result is part is completed DO NOT SEND the EvalWeb Form to this number	
<input type="checkbox"/> Check One <input type="checkbox"/> Both Tests Positive <input checked="" type="checkbox"/> Evaluation Web Result Form with client information mailed to Surveillance Date Mailed: _____ Mailed By: _____ <input type="checkbox"/> Discordant Result (First test is positive and second test is negative. Also for Antigen ONLY positives). Draw 2 serum separator tubes and 2 white top tubes & Call NJ HIV Program at 732-743-3624 or 732-743-3620 for pick-up. Process collected tubes according to instructions. <i>Discordant - Physician Line: 732-236-7013</i> <input type="checkbox"/> Second Test Not Done: Client refused - <i>Contact Partner Services and complete Partner Services Form</i>	
Client Referral to Treatment: Fax to 732-235-9012 when appointment information is completed	
Date client referred to treatment: _____	
Date of Appointment: _____	Appointment kept: <input type="checkbox"/> Yes <input type="checkbox"/> No
If No, Why? _____	
Patient Navigated By: _____	
CONFIRMATORY Laboratory Results or DISCORDANT Laboratory Results:	
Sent to Laboratory: <input type="checkbox"/> Blood drawn for antigen confirmation _____ 4 th gen Reflex: <input type="checkbox"/> POS <input type="checkbox"/> NEG; Biorad MultiSpot <input type="checkbox"/> HIV-1 <input type="checkbox"/> HIV-2 <input type="checkbox"/> NEG Aptima Qual HIV-1 RNA <input type="checkbox"/> POS <input type="checkbox"/> NEG	
Quantitative Viral Load: _____ copies/mL or < 20 copies/ML <input type="checkbox"/> NEG CD4 count: _____ <i>Please use assigned CTS number, de-identify and fax lab confirmation to: (732) 235-9012</i>	

NJ HIV Rapid testing Support Administrative Issues

Some Reminders

NJ HIV Rapid testing Support Administrative Issues

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

NJ HIV Rapid testing Support Administrative Issues

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](http://NJHIV.org))

NJ HIV Rapid testing Support Administrative Issues

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

NJ HIV Rapid Testing Support Administrative Issues

Standing Order Template

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

NJ HIV Rapid Testing Support Administrative Issues

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



Rapid HIV Testing Support Program Contact Information

Rutgers – RWJMS
 Department of Clinical Pathology & Laboratory Medicine
 NJ HIV Rapid Testing Support
 One World's Fair Drive
 Somerset, New Jersey 08873

732-743-3624 or 732-743-3630

732-235-9012 (fax)

732-236-7013 (Discordant Phone)

Website: njhiv1.org

Name	Position	Email	Telephone	Cell Phone
Eugene G. Martin, Ph.D.	PI and Co-Director	martneu@rwjms.rutgers.edu	732-743-3626	
Gratian Salaru, M.D.	PI and Director (DAS)	salarug@rwjms.rutgers.edu	732-743-3625	
Parisa Javidian, M.D.			732-743-3620	
Lauri Goodell, M.D.			732-743-3620	
Julie Cornett, M.D.			732-743-3620	
Joanne Corbo, MBA, MT(ASCP)	Program Manager	corbojo@rwjms.rutgers.edu	732-743-3620	
Latasha Adams BS, MT	Site Liaison POCT Coordinator	adamsli@rwjms.rutgers.edu	732-743-3236	732-669-2327
Moeen Ahmed, BS, MT	Site Liaison POCT Coordinator	ahmedmo@rwjms.rutgers.edu	732-743-3607	732-609-3425
Aida Gilanchi, BS, MT	Site Liaison POCT Coordinator	gilanchi@rwjms.rutgers.edu	732-743-3629	732-453-4704
Franchesca Jackson, BS, MT	Site Liaison POCT Coordinator	jacksonf@rwjms.rutgers.edu	732-743-3628	732-947-1015
Nisha Intwala Patel, MT (ASCP)	Site Liaison POCT Coordinator	intwain@rwjms.rutgers.edu	732-743-3612	732-947-1020
Marianela Moreno	Public Health Representative	morenom2@rwjms.rutgers.edu	732-743-3611	732-609-9136
Lisa May	Program Assistant	mayli@rwjms.rutgers.edu	732-743-3624	
Karen Williams	Administrative Assistant	Willak2@rwjms.rutgers.edu	732-743-3630	