HIV Point of Care Testing Program

Alere Determine™ HIV-1/2 Ag/Ab Combo

Presented by:

Rutgers-RWJMS NJ Rapid HIV Support Staff

Acknowledgement – For multiple slides:
Thomas Knoble, MSW -
Capacity Building Program Manager
San Francisco Department of Public Health
GOALS FOR TODAY

• Background, Antibodies, Antigens
• Quality Assurance
  – Logging
  – Reporting
  – Proficiency Testing
  – QC Principles
  – Troubleshooting
• Details of Alere Determine
• Bloodborne Pathogen Overview
• Hands-on Testing
• Exam
What Do You Know About HIV Antibodies & Antigens?
Antigen - Ag
a pathogen or parts of a pathogen (virus, bacteria, fungi and parasites) that causes the body to produce antibodies (detected between 2 and 4 weeks)

Antibody - Ab
a Y-shaped protein created by your body in response to antigens (mostly within 3 months, but sometimes up to 6 months to be produced)
Determine Combo can detect BOTH antigens AND antibodies.

LAB-based antibody tests have been more sensitive than rapid antibody tests.

Earlier rapid antibody tests were much less sensitive.

VERY infectious BEFORE antibodies appear.
Antigens Levels Drop

Antibodies cover antigens and make them no longer detectable
What is an Acute Infection?

The Acute HIV infection refers to the first couple of months following HIV infection. During this time there is widespread dissemination of the virus and a person’s viral load can be very high. Usually around 6 weeks after infection, antibodies begin to fight the infection. Many people will not have any symptoms despite having a high viral load.

Studies have consistently shown that ~ 50% of new HIV transmissions are caused by onward transmission from an individual with AHI.
Intro to the Determine Combo Rapid Test

- One-step test
- Visual interpretation
- Can use fingerstick blood
- Looks for antibodies and antigen
- Results between 20 to 30 minutes
Test Accuracy

- We’re going to talk about how well the test works

- You do not need to memorize the details
  - Only need to know the test is very accurate

- There are two components of test accuracy:
  - Sensitivity
  - Specificity
Specificity

- When a test finds something, it should be the right thing
- Specificity tests the ability to detect a true negative
Sensitivity

- The ability of a test to find what it’s looking for and not miss it if it’s there
- Sensitivity test’s the ability to detect a true positive
Combining Specificity and Sensitivity

An ideal test would find the right thing (specificity) and not miss it when it’s there (sensitivity)
With Clients…

- Emphasize that the test is extremely accurate
- De-emphasize statistics and percentages
- For example “This test is highly accurate”
Because the Test is Highly Sensitive, (rarely misses a reactive) …

- We do not need to confirm non-reactive
- We do, however, always need to confirm reactive
Quality Assurance Requirements

- QA are practices and procedures which ensure that every client receives an accurate test result
- QA reduces human error as much as possible
Must Have...

Good eye sight

- Full/bright light, task light
- Do not use a flash light

Steady hand

Organizational skills
Central POCT QA Responsibilities

- Centralized procedures
- Inventory control
- Monthly visit:
  - Delivery of reagents and supplies
  - Review testing records
  - Competency review
  - Problem solving (additional visits as needed)
- Central monitoring
  - Completion of logs
  - Preliminary positive follow-up
- Discrepant (a.k.a discordant) result follow-up
Elements of Quality Assurance

1. **Competency Assessment and Operator Certification**
2. Quality Assurance/Performance Improvement
3. Proficiency Testing
4. Inventory control
5. Temperature logs
6. Quality Control
7. Test records (Patient, QC, PT)
8. Preliminary positive test monitoring
1. Training/Competency Assessment

- Review procedures  
  (we prepared them; you read them)

- Review QA (Quality Assurance) plan

- Run QC (Quality Control)

- Examiner observations

- Written test
Competency Reassessment

• Initial assessment
• 6 month reassessment
• Annual reassessment
• Quarterly QC
• Direct observation (at monthly visits)
• Written test
Coordinator Responsibilities

Training/Competency assessment

• Schedule counselors for training sessions
• Help keep track of counselors in need of recertification
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<tr>
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<th>Elements of Quality Assurance</th>
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</table>
2. **Performance Improvement**

- Periodic projects to monitor and improve performance
- Counselors and coordinators may be asked to gather data.
Elements of Quality Assurance

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8. Preliminary positive test monitoring
3. What is Proficiency Testing?

- External audit of performance
  - External unknowns are received from AAB 3 times a year
  - Results graded to national norms
  - AAB is reviewed by state for licensure.
- Analyzed by testing personnel as they would a patient specimen
- Unacceptable results require investigation and a written response
- RWJMS Internal Proficiency Testing
  - Part of monthly oversight visits
  - Part of operator recertification process
Proficiency Testing

• An email will be sent out just prior to shipment

• Specimens will be shipped by FedEx to you directly from AAB 3X a year
  – February
  – May
  – October

• These specimens should be tested promptly.

• Sign the Attestation Statement

• Fax the AAB results back to our office within 5 days (732-235-9012)

• Program Director will sign off on these centrally and we will enter results on AAB webpage.

• Successfully participating in a PT event is part of the operator recertification process and state licensure!
A disposable pipette will be provided with Determine controls to draw up sample from the proficiency sample vial.

Use one new disposable pipette with each sample.
Proficiency Testing

Do **NOT** use buffer when performing Proficiency testing.
## HIV MARKERS

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<tr>
<th>Procedure</th>
<th>Specimen 1</th>
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### Method Codes

- **Positive**
- **Negative**
- **Indeterminate**
- **Pos for HIV1, Neg for HIV2**
- **Neg for HIV1, Pos for HIV2**
- **Pos for HIV1, Pos for HIV2**
- **Confirmatory testing not performed**

### Instructions for Method Codes

- **Qualitative answers only**
- **Use reagent codes**
- **Avoid false results**
- **Use membrane-based methods**
- **Analyze specimens prior to testing**
- **Adhere to CMS guidelines**

### Special Safety Precautions

- **Biological safety cabinet**
- **Gloves**
- **Remove specimens from container**
- **Cover cuts**
- **Aseptic disposal**

### Analyst Attestation

- **Signatures**
- **Multiple analysts**
- **Signed by director or technical supervisor**
Coordinator Responsibilities

Proficiency Testing

• Unacceptable results require investigation and a written response

• RWJMS Internal Proficiency Testing
  – Part of monthly oversight visits
  – Part of operator recertification process
Elements of Quality Assurance

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4. Why Inventory Control?

- Standardization of reagents and supplies
- Validation of reagents
- Replacement of supplies and consumable
- Bulk purchasing (save $$)
Inventory Control
Coordinator Responsibilities

• You will notify your site liaison that you are in need of placing an order.

• Your supplies will be calculated based on the previous month’s usage & packaged by Rutgers-RWJMS staff.

• It will be delivered to you by your site liaison during your monthly site visit.

• You can fax your requests to 732-235-9012.
Elements of Quality Assurance

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5. Why Temperature Control?

- Reagents deteriorate
- Manufacturer validated storage conditions
  
  \(2 - 30 \degree C\) \(36 - 86 \degree F\)

- Corrective action if temperatures are out of range
New Jersey Rapid HIV Testing Support Program

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<td>Somerset, NJ 08873</td>
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<td>Fax: (732) 235-9012</td>
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<td>DIVISION:</td>
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Refrigerator Thermometer Expiration:

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<th>DATE</th>
<th>2°C-30°C (36°-86°F) ROOM (Storage) (Min/Max)</th>
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Please use a new sheet each month.

Please record the minimum to maximum temperatures recorded each day.

SECTION 27.5

Drafted: 11/11/2013
Temperatures to Know for Determine

• **Kit Storage** = 36-86 °F (2-30 °C)
  – If out of range, run controls

• **Testing** = 59 – 86 °F (15-30 °C)
  – If out of range, test elsewhere/fix problem

• **Controls** = 35-46 °F (2-8 °C)
  – If out of range, fix problem and document corrective action on back of temperature log.
Temperature Checks

• Record storage temperatures daily
  – Refrigerator (controls) and Storage room (Determine)
  – Reset Min/Max thermometers by pressing reset button

• If storage temperature out of range (<36 or >86°F), perform QC

• If testing area out of range (<59°F or >86°F), then TEST ELSEWHERE
# Patient Test Logs

## RAPID HIV TEST LOG

**Facility Name:**

**Box Lot #:**

**Expiration Date:**

**Testing Type Codes**
- DHSTS: STD-STD Svcs.
- FQHC: Federally Qualified Health Center
- TB/TB Svcs.
- PP/TP: Planned Parenthood/Family Planning
- OTE: One Time Event

| Testing Type | Date | ID Number | Room Temp | Control Line | Control 
|--------------|------|-----------|-----------|--------------|----------
| 1            |      |           |           |              |          |
| 2            |      |           |           |              |          |
| 3            |      |           |           |              |          |
| 4            |      |           |           |              |          |
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| 22           |      |           |           |              |          |
| 23           |      |           |           |              |          |
| 24           |      |           |           |              |          |
| 25           |      |           |           |              |          |

**Clients Positive:**

**Total Proficiency:**

**Supervisor Review:**

**Clients Negatives:**

**Total Controls:**

**NJHIVMT Review:**
POP QUIZ

• Can you test a patient?
• Can you store kits?
• Can you store controls?
POP QUIZ

• Can you test a patient?
• Can you store kits?
• Can you store controls?
POP QUIZ

• Can you test a patient?

• Can you store kits?

• Can you store controls?
• Can you test a patient?

• Can you store kits?

• Can you store controls?
Coordinator Responsibilities

Temperature Control:

- Review temperature logs weekly
- Ensure that corrective actions are documented
- Send temperature logs to us monthly
- Fax: 732-235-9012
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</table>
Determine External Controls

- Biohazards - Fluids made from human plasma
- Bring to room temperature (Approximately 20 min)
6. Determine External Controls

- HIV-1 Ab Reactive
- HIV-2 Ab Reactive
- HIV-1 p24 Ag Reactive
- Nonreactive
Why Quality Control?

- Does a new reagent lot perform properly?
  - Lot Validation (includes QC) – performed centrally
- Chemical reagents deteriorate.
  - Check with known QC specimens regularly (weekly)
- Do operators perform testing properly?
  - Run QC weekly by rotated staff
- Are transport and storage conditions satisfactory?
  - Run QC every shipment, and if storage temperature is out of range
- What happens if there is a problem?
  - Records permit follow-up by lot and by patient
Determine™ HIV-1/2 Ag/Ab Combo

A disposable pipette will be provided with Determine controls to draw up sample from the control vial.

Use one new disposable pipette with each sample.
Control Testing

Do NOT use buffer when performing Control testing.
Determine™ HIV-1/2 Ag/Ab Combo

Determine EXTERNAL Controls

- All 4 controls are run when performing External Quality Controls (they should be dated upon opening) – good until date on box
- Apply gloves and open foil pouch remove 4 test units from foil packet (check for absorbent desiccant packet – do not throw it away) & reseal pouch with absorbent desiccant packet in it.
- **Label each test devise with control ID**
- Peel desiccant strip off test device.
- Place test device in new ‘workstation’
Determine™ HIV-1/2 Ag/Ab Combo

- Using precision pipette draw up 50uL of control into pipette tip (use new tip for each control)
- Apply 50uL of control reagent to the Sample Pad – repeat for each control
- Do not use Chase Buffer with control reagents
- Start timer and read results between 20 and 30 minutes
- Dispose of pipette tip in bio hazardous waste.
<table>
<thead>
<tr>
<th>Code</th>
<th>Reason</th>
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<tbody>
<tr>
<td>QC 1</td>
<td>Weekly Control Run</td>
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<tr>
<td>QC 2</td>
<td>OUT OF RANGE Storage Temperature Control Check</td>
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<tr>
<td>QC 3</td>
<td>Other - Error (spilled solution, touched pad of device, not enough blood in port, etc)</td>
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<tr>
<td>QC 4</td>
<td>New Shipment Control Run</td>
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<tr>
<td>QC 5</td>
<td>Proficiency - Proficiency Testing (CAP, MPEP, AAB), Education, Training</td>
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<tr>
<td>QC 6</td>
<td>Invalid - Manufacturer Error (no solution in vial, no absorbent pack, no c-line, pink background, etc)</td>
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<td>QC 7</td>
<td>Expired</td>
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<td>QC 8</td>
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<td>QC 9</td>
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## Patient Test Log

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<th>Testing Type</th>
<th>DATE</th>
<th>ID NUMBER</th>
<th>ROOM TEMP</th>
<th>ONABLOOD CONTROL</th>
<th>Proficiency</th>
<th>CONTROL LINE</th>
<th>PRESENT</th>
<th>CONTROL CODES</th>
<th>P24 Ab</th>
<th>HIV Ab</th>
<th>Pos or Neg</th>
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<th>START END TIMES</th>
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<th>Clients Positive:</th>
<th>Total Proficiency:</th>
<th>Supervisor Review</th>
<th>NJHIVMT Review</th>
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<th>Clients Negatives:</th>
<th>Total Controls:</th>
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<th>Total Invalids:</th>
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Codes (cont’d)

“Reasons for Performing QC”

[1] – QC = Weekly Control Run
[3] – OTHER = Error (spilled solution, touched pad of device, not enough blood in port, etc.)
[6] – INVALID = Manufacturer Error (no absorbent pack, no c-line, pink background, etc.)
[7] – EXPIRED
Rapid Test QC checklist

1. Look at the temperature log. If it is not yet filled out for today:

- Record the reagent storage temperature and reset the thermometer. If out of range, proceed to STEP 5 and run quality control **(Reason 2)**

- Record the refrigerator temperature and reset the thermometer. If out of range, indicate on the back of the log what you did to fix the problem.

**REASON CODES**

[1] – QC = Weekly Control Run


[6] – INVALID = Manufacturer Error

[7] – EXPIRED
<table>
<thead>
<tr>
<th>DATE</th>
<th>TEST KITS</th>
<th>KIT CONTROL</th>
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<tbody>
<tr>
<td></td>
<td>2°-30°C (36°-86°F)</td>
<td>2.8°C (36°-46°F)</td>
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<td>ROOM (Storage)</td>
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Please use a new sheet each month.

Please record the minimum to maximum temperatures recorded each day.

SECTION 27.5

Drafted 11/11/2013
Rapid Test QC checklist

2. Look at the testing log
   - Were control samples run on the 1st day of the new testing week? If not, proceed to STEP 5 and run quality control tests (Reason 1)
   - Was the last test result in the log invalid? (STEP 7). If so, find out who's working on the invalid test, or proceed to STEP 5 and run quality control tests (Reason 6)

REASON CODES

[1] – QC = Weekly Control Run
[6] – INVALID = Manufacturer Error
[7] – EXPIRED
# RAPID HIV TEST LOG

<table>
<thead>
<tr>
<th>Testing Type Code</th>
<th>DATE</th>
<th>ID NUMBER</th>
<th>ROOM TEMP</th>
<th>Ctrl Blood Control</th>
<th>Ctrl Line Present</th>
<th>Ctrl Data</th>
<th>ONA/PA Pos or Neg</th>
<th>HIV Ab Pos or Neg</th>
<th>Intact Packaging intact</th>
<th>Positive/Repackaging Positive</th>
<th>START END TIMES</th>
<th>OPERATOR</th>
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**Clients Positive:**
**Clients Negative:**
**Total Invalids:**

**Total Proficiency:**
**Total Controls:**

**Supervisor Review:**

**NJHIVMT Review:**
Rapid Test QC checklist

3. Is this the first box of a shipment of reagents?
   – If yes, proceed to STEP 5 and run quality control tests (Reason 4)

REASON CODES

[1] – QC = Weekly Control Run
[6] – INVALID = Manufacturer Error
[7] – EXPIRED
4. Check reagent storage thermometer.

– If min or max temperature is out of range, run quality control tests (Reason 2).
– Do this every time you get a test kit from the box…not just the first time.

**REASON CODES**

[1] – QC = Weekly Control Run
[6] – INVALID = Manufacturer Error
[7] – EXPIRED
5. Running quality control:

- On the testing log, record that you are running control tests, and why you are running them.
- Put the control lot number in the Identification column.
- Don’t open a new box unless the old one is expired OR one of the control samples is depleted.
- Run the control tests and record the results. The three positive controls should have positive results (C and T lines). The negative control should have a negative result (C line, but no T line).
5. Running quality control (continued):

– If the control results are not what they should be, or if they are invalid, repeat the quality control tests:
  
  • Use the same box of controls
  • Use **reason #3 or 6** (Invalid) when you repeat the controls

– If controls didn’t work the second time, open a new box of controls (if available) and repeat controls. (use **reason #6; this is a manufacturer error.**) If the controls did work the second time around then the code would be **reason #3** for operator error

– If there isn’t a second set of controls, please call us.
5. Running quality control (continued):

- If the controls results did not work after opening the new box (this might be considered a third time but it is not), call us for help.

- You cannot test your client using Rapid Test and have them come back another time.

- OR draw two white top tubes and call our discordant phone number 732 236 7013 for pick up from Rutgers-Robert Wood Johnson Medical School.

- Further information and instructions will be given then.
Do you need to run controls?

- WHY?
Do you need to run controls?

- YES!
- The storage area has been too hot at some point (93 °F)
- Storage Temperatures: [36 - 86 °F] (2-30 °C)
- Testing Temperatures: [59 - 86 °F] (15-30 °C)
Elements of Quality Assurance

1. Competency Assessment and Operator Certification
2. Quality Assurance/Performance Improvement
3. Proficiency Testing
4. Inventory control
5. Temperature logs
6. Quality Control
7. Test records (Patient, QC, PT)
8. Preliminary positive test monitoring
7. Why Testing Logs?

- Control inventory (Are we almost out? Are tests missing?)
- Reagent recall (Need lot numbers! Can we call clients back?)
- QC monitoring (Was it done yet today? Did I run my required Control this week?)
- Monitor reasons for running QC
- PT monitoring (Competency assessment tool)
- Problem logs (What happened?)
- Logs will be reviewed centrally each month
## Testing Logs

- Check Expiration dates
- Check the storage temperature and testing logs before running a test, to see if QC is needed
- Record **Testing Type** – see codes at top of page.
- Record the **Date** of testing
- Record Control lot numbers, PT, HIV Test form label number as **ID Number**
- Record **Room Temperature** 18-30°C (64-86°F)
- Record Blood (**B**), Control (**C**) or Proficiency (**P**)
- Record a ‘Y’ or ‘N’ in the **Control Present** column.
- Record reasons for running QC in **Control Codes** column – **CHOOSE ONLY ONE CODE** though more than one may apply.
- Record **POS** (positive), **NEG** (negative) or **INV** (invalid) for **Results** column.
- Record **START** time after the three drops of buffer has been added to sample well. Please leave space for **END** time.
- Sign your initials legibly as **Operator**!
# Patient Test Log

## RAPID HIV TEST LOG

<table>
<thead>
<tr>
<th>Testing Time</th>
<th>DATE</th>
<th>ID NUMBER</th>
<th>ROOM TEMP</th>
<th>ORAL/BLOOD</th>
<th>CONTROL</th>
<th>PROFICIENCY</th>
<th>CURRENT</th>
<th>CONTROL</th>
<th>COV</th>
<th>PMA</th>
<th>PG/A</th>
<th>HVS</th>
<th>PHS</th>
<th>POS/PFS</th>
<th>START END TIMES</th>
<th>OPERATOR</th>
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Clients Positive: [ ]
Clients Negative: [ ]
Total Invalids: [ ]

Total Proficiency: [ ]
Total Controls: [ ]

Supervisor Review: [ ]
NJHIVMT Review: [ ]
How to Make Corrections to the Patient Test Log

- Use blue or black ink only on all forms
- Document any problems in the comments section on bottom of log page
- DO NOT USE WHITE OUT – EVER!
- Use one line to cross out error, footnote it, and write correction.

7:22pm  T.K. 12/15/2011
End time: 7:12pm
Coordinator Responsibilities

Testing logs:

- Review testing logs weekly:
  - Make sure it’s complete!
- Sign & date review:
  - Use the comments box to sign & date.
- Fax completed log sheet weekly:
  - Keep all logs for at least two years.
- Review QC rotation before quarter end:
  - Set up a calendar if necessary. Make sure EVERYONE rotates at least once every three months.
Elements of Quality Assurance

1. Competency Assessment and Operator Certification
2. Quality Assurance/Performance Improvement
3. Proficiency Testing
   • Inventory control
   • Temperature logs
   • Quality Control
   • Test records (Patient, QC, PT)
   • Preliminary positive test monitoring
8. **Why monitor Preliminary Positives?**

- Check Alere Determines performance
- Follow-up if confirmation is negative
  (part of CDC study)
Rapid 2 Rapid (R2R) HIV Testing

• In 2012, we were able to use a second HIV test to confirm an initial HIV screening test.

• Our goal is to move toward the Test to Treat or Rapid 2 Rapid testing.

• Therefore, your site should be making arrangements for a rapid confirmatory test if the first rapid test is positive and linking that client to care.

• The Patient Navigator Program can help make that happen.
R2R HIV Testing

There are three categories your site may fall under –

• Category 1. Rapid-Rapid Testing Site and Treatment Site
• Category 2. Rapid-Rapid Testing Site and Non Treatment Site
• Category 3. Rapid Testing Site
Category 1: Rapid-Rapid Testing Site and Treatment Site

- Your testing site is a Rapid-Rapid Testing Site (Initial test with a rapid HIV test device then confirm with a different type of rapid HIV test device)
- Clinical treatment is available onsite.
- Your client is referred to treatment within your organization within one business day.
Category 2: Rapid-Rapid Testing Site and Non-Treatment Site

- Your testing site is a Rapid-Rapid Testing Site (Initial test with one type of rapid HIV test then confirm with a different type of rapid HIV test device).
- Clinical treatment is **NOT** available onsite.
- Your client is referred to a 2nd clinical treatment site that your organization has a MOA permitting linkage to care.
- The initial site to arrange client transportation to 2nd clinical treatment site.
- Please utilize Navigator Program to link client to care.
Category 3: Rapid Testing Site, Only

- You use a rapid HIV test device as the first Rapid Test and confirm by sending client to a Category 1 site (R-R Testing and Treatment Site).
- Please utilize Linkage to Care Program to navigate client to care.
Patient Linkage to Care Locations:
(Please refer to contact sheets provided)

1. AtlantiCare Medical Center, Atlantic City, Atlantic County
2. Complete Care Health Network locations: Vineland, Glassboro & Bridgeton (see contact sheet for address and phone numbers)
3. Cooper University Hospital, Camden, Camden County
4. Eric B. Chandler Health Center, Middlesex County
5. Kennedy EIP Clinic, Burlington, Camden, Cumberland, Glouster and Salem Counties
6. Jersey City Medical Center, Jersey City, Hudson County
7. Jersey Shore Medical Center, Neptune, Monmouth County
8. Morristown Medical Center, Morris
9. Rutgers, NJ Medical School Newark, Essex County & Vicinity
10. St. Joseph’s Medical Center, Paterson, Passaic County
11. St. Michael’s Medical Center, Newark, Essex County
12. Trinitas Regional Medical Center, Elizabeth, Union County
13. Zufall Health Center, Morris, Sussex & Warren Counties
If you cannot reach a Navigator or are unsure of which Navigator to call, please contact the AIDS Hotline in NJ:

- 1-800-624-2377 (24/7)

Questions about what to do or you do not want to call the hotline or don’t feel comfortable calling the hotline please:

- Call Loretta Dutton – 609-892-6989 (cell)
  - DO NOT MAKE THIS YOUR FIRST OPTION.
Responsibilities of the Counselors

• Fill out NJHIV Positive Tracking Form for all positives

• Perform or arrange for a second test
  – On-site (different rapid test)
  – Arrange for Transport of client (Linkage to Care Coordinator can help)
  – Collect and send specimen (only if no other choice, i.e. Linkage to Care Coord. unavailable); must call Loretta Dutton for approval.

• Add second test information to the Tracking Form

• Send/fax Tracking Form to 732-235-9012

• First testing site fills out EvalWeb for all testing

• Send HIV Report Form to second test site or a treatment center ONLY. Do not send it to us!
Coordinator Responsibilities

Preliminary Positives:

• Make sure NJHIV Positive Tracking forms are completed and faxed to us

• Make arrangements for second test, and relationship with Linkage to Care Coordinator and treatment site

• Arrange for Phlebotomy services if needed
Counseling Message
Counseling Message: Non-Reactive for Antibody and Antigen

• Follow current Counseling Message
Using Determine, results are Preliminary Positive (whether HIV-1/2 Antibody or HIV-1 p24 Antigen):

• Perform a second rapid test using a different type of test device or navigate to a Category 1 site.

• If both are positive the first test has been confirmed therefore obtain partner notification information and navigate an appointment for medical provider immediately.
Counseling Message:

HIV 1/2 Antibody and HIV 1 p24 Antigen Positive

If the Determine HIV ½ Antibody and HIV-1 P24 Antigen are both reactive:

- Confirm using a different type of a rapid HIV test or navigate to a Category 1 site and
- Navigate an appointment for the client with a medical provider and obtain partner notification information.

- Antigens and Antibodies are both present early in an HIV infection. The presence of both HIV antigens and HIV antibodies is consistent with the development of an immune response to infection.
Counseling Message: HIV 1/2 Antigen Positive

Using Determine, results are Preliminary Positive (whether HIV-1/2 Antibody or HIV-1 p24 Antigen):

- **Do Not** perform a second rapid test
- **You should navigate an appointment for medical provider immediately.**
- **Draw blood** (same as for discordant result)
- **Call Discordant Hot Line** for guidance. (732) 236-7013
Determine™ HIV-1/2 Ag/Ab Combo

Overview

Kinetic of HIV Markers During Infection

The Alere Determine™ HIV 1/2 Ag/Ab Combo shortens the diagnostic window, helping to identify HIV from just 12 days after infection.
Discordant Analysis

• An infrequent event (Statewide ~ <50 X per year) which will require an individualized response
  – First result is PRELIMINARY POSITIVE, but the Second result is negative or indeterminate

• We wish to work directly with staff from any institution that experiences a discrepant result.

• Call our physician discordant phone:
  (732) 236-7013
Counseling Message—Discordant:
Using Determine, the results are Preliminary Positive for HIV-1/2 Antibody:

- Perform a second rapid test using a different type of a rapid HIV device or navigate to a Category 1 site

- If the second rapid HIV test is negative - follow current discordant procedures and notify discordant Hotline 732-236-7013 (if no answer leave a message – also call Program Manager or other member of NJ HIV Support Team).
Determine™ HIV-1/2 Ag/Ab Combo

Preliminary Positive Results

- **7**: Preliminary Positive for HIV-1 and/or HIV-2 antibodies and HIV-1 p24 antigen
  - Control line present
  - Ag and Ab test lines present

- **7A**: Preliminary Positive for HIV-1 and/or HIV-2 antibodies
  - Control line present
  - Ab test line present

- **8**: Preliminary Positive for HIV-1 p24 antigen*
  - Control line present
  - Ag test line present

*Control line present.
Discordant Follow-up

- Counseling issues – We are ‘on-call’ to come to your site at the time you have a follow-up meeting with your client
  - If scheduling permits, one of us can be present; or we can arrange to provide telephone consultation if this is preferred.
  - Make sure that your follow-up appointment is flexible!

- With every discordant, draw one white top and two yellow top tube and label with client ID and date, spin, & freeze upside down. RWJMS liaison will come and pick up tubes ASAP.

- Additional testing will be provided at no cost to the site or to the patient.
Notification

• Discordant Phone: 732-236-7013 (On Call Physicians)

• Office Phone: 732-743-3620 (Joanne Corbo, Program Manager)
  732-743-3624 (Lisa May)
  732-743-3630 (Karen Williams)

• Liaison #: 732-743-3628 (Fran Jackson) cell: 732-947-1015
  732-743-3612 (Nisha Intwala) cell: 732-947-1020
  732-743-3629 (Aida Gilanchi) cell: 732-453-4704
  732-235-6045 (Claudia E. Carron) cell: 732-947-1021
  732-743-3607 (Moeen Ahmed) cell: 732-609-3425
  732-743-3235 (Latash Adams) cell: 732-669-2327

• Mobile Tester 732-743-3611 (Marianela Moreno) cell: 732-609-9136

• Email: martineu@rwjms.rutgers.edu  salarugr@rwjms.rutgers.edu
  adamslj@rwjms.rutgers.edu
  corbojo@rwjms.rutgers.edu
  carronc1@rwjms.rutgers.edu
  gilancai@rwjms.rutgers.edu
  intwalni@rwjms.rutgers.edu
  jacksofn@rwjms.rutgers.edu
  ahmedmo@rwjms.rutgers.edu  morenom2@rwjms.rutgers.edu

• If you don’t need a response immediately email works best for all of us – it provides a record of the call and can’t get lost!
Alere Determine HIV-1/2 Ag/Ab Combo

Details of Testing
Personnel Protective Equipment (P.P.E.)
Universal Precautions

The practice of avoiding contact with patients' bodily fluids, by means of the wearing of nonporous articles such as medical gloves, and goggles.
Sharps: Handling & Disposal

- Sharps are medical instruments that are used to puncture the skin (syringes, lancets, needles)

- Dispose of sharps **immediately**, in a hard red plastic sharps container!

- Do **NOT** dispose of sharps in a red bio hazard bag
Biohazard Bags: Handling & Disposal

- Bandages, used cotton and gauze, and gloves with body fluids on them are biohazardous waste.

- Regulations say, if fluid cannot be squeezed out of the cotton, gauze, etc., the waste item can be disposed of in regular trash.
For Today’s Training

- Place pipettes and used test kits in the sharps container
- Place gloves and all other trash in the brown paper bag
Gloves

- Wear them when handling blood or blood products

- TODAY – whenever you touch the control fluid or proficiency sample!!!!

- With each new client change gloves
Alere Determine HIV-1/2 Ag/Ab Combo
Materials Provided in Determine Test Kit

1. Alere Determine™ HIV-1/2 Ag/Ab Combo Cards. Each Card consists of 5 or 10 Test Units
2. Desiccant Package
3. Chase Buffer
4. Quick Reference Guide
5. Package Insert
6. Subject Information Notices
7. Customer Letter
8. Disposable Capillary Tubes: For collection and transfer of fingerstick samples.
9. Disposable Workstations
Basic Materials

- Chase Buffer
- Absorbent Material (Chux)
- Capillary Tube
- Workstation
- Test Devices (card)
Determine™ HIV-1/2 Ag/Ab Combo

Materials that you will need for Testing:

1. Chux (cotton bench cover)
2. Shield/goggles (eye protection)
3. Thermometer
4. Timer
5. Disposable Capillary Tubes
6. Chase Buffer
7. Gloves
8. Sharpie marker
9. Gauze
10. Alcohol wipes
11. Biohazard/sharps container
12. Lancets
13. Band-Aids
14. Log sheets
15. Hand sanitizer
Prior to testing - Check **Quality Control** checklist

Expiration dates!!

External QC reagents opened are stable until expiration date as long as refrigerated!

Test devices are stable until expiration date on device and pouch!

Apply gloves and open foil pouch remove 1 test unit from foil packet (check for absorbent desiccant packet – do not throw it away) & reseal pouch with absorbent desiccant packet in it.

**Label each test devise with client ID**

Peel desiccant strip off test device.

Place test device in new ‘workstation’
Expiration Dates / Lot Numbers

The box, buffer, and test kit package, may not match
Use test kit package
Expiration date is formatted year, month, day
2015-12-17
Determine™ HIV-1/2 Ag/Ab Combo
Determine™ HIV-1/2 Ag/Ab Combo

Test Procedure

1. Prepare Test

Tear one strip from the right and remove cover.
Label with Client ID#
2 Place Test

Place one strip inside the workstation.

DO NOT REUSE WORKSTATION
Finger Stick Blood Collection

- Clean the finger of the person being testing with an antiseptic wipe, and allow it to dry.
- Spring-load the lancet, and puncture the finger a little off-center of the fingertip (toward the thumb).
- Hold the finger downward & apply gentle pressure beside the point of puncture.
- Avoid squeezing the finger to make it bleed – this may dilute the blood with excess tissue fluid.
- Wipe away the 1st drop of blood with sterile gauze pad & allow a new drop of blood to form.
- Take a clean, unused Specimen Collection pipette, and fill the pipette with blood up to the black line.
- Give the person gauze and have them squeeze to stop bleeding.
**Fingerstick Whole Blood**

3. **Add Sample**
Add 50 μL of whole blood to the Sample Pad. When all the blood is transferred from the capillary tube to the Sample Pad, wait 1 minute and add one drop of Chase Buffer to the Sample Pad.

*Caution: Do not lift the capillary tube from the Sample Pad before all the blood has been transferred.*

WAIT 1 minute

1 Minute

Then add Chase Buffer
Pipette Practice

- Depress bulb before inserting into control vial
- Hold vertically about 1 inch over sample pad
- Slowly depress bulb till a free flowing drop is produced
Alere Determine HIV 1/2 Ab/Ag Combo

- Start timing the test after you have added the specimen and waited 1 minute and then add one drop of buffer.
- Record the start time on the test log sheet.
- Read the results after 20 minutes have passed BUT LESS THAN 30 MINUTES!
- If the test is not read within 30 minutes, discard the test materials and start again. The test is INVALID.
Read the Test Result between 20 and 30 minutes after the addition of the Chase Buffer (for whole blood samples).

Do not read Test Results after 30 minutes.
Determine™ HIV-1/2 Ag/Ab Combo

4 Read Results

Read the Test Result between 20 and 30 minutes after the addition of the Sample.

Do not read Test Results after 30 minutes.

The control line should appear for all results. If it does not appear, the results are invalid and should be repeated.
Test Device

Notice the word “control”

Control area
Antigen Ag area
Antibody Ab area
Sample pad

Notice the abbreviations:
Ag↓
Ab↑
The control line should appear for all results. If it does not appear, the results are invalid and should be repeated.
The counselor will need to deliver an interpretation to the client. The choices (according to the package insert) are:

1. **ANTIBODY REACTIVE** (Two Lines - Control Line and Ab Line) - The test result is interpreted as *PRELIMINARY POSITIVE for HIV-1 and/or HIV-2 antibodies*.

2. **ANTIGEN (HIV-1p24) REACTIVE** (Two Lines - Control Line and Ag Line) - The test result is interpreted as *PRELIMINARY POSITIVE for HIV-1 p24 antigen*.

3. **ANTIBODY REACTIVE AND ANTIGEN (HIV-1 p24) REACTIVE** (Three Lines - Control, Ab and Ag Lines) - The test result is interpreted as *PRELIMINARY POSITIVE for HIV-1 and/or HIV-2 antibodies and HIV-1 p24 antigen*. 
4. **NONREACTIVE** (One Line – Control Line) - A NONREACTIVE test result means that HIV-1 or HIV-2 antibodies and HIV-1 p24 antigen were not detected in the specimen. The test result is interpreted as *NEGATIVE*

5. **INVALID** (No Control Line) - If there is no pink/red Control line in the Control Area of the Test Unit, even if a pink/red line appears in the Lower Test Area or the Upper Test Area of the Test Unit, the result is *INVALID* and the test should be repeated.
Reading Negative Results

- Line in Control Area
- No lines in Ab or Ag Areas
- HIV antibodies and antigens were not detected
Reading Reactive Antigen Results

- Line in Control Area
- Line in Antigen Area
- HIV antigens have been detected
Reading Reactive Antibody Results

- Line in Control Area
- Line in Antibody Area
- HIV antibodies have been detected
Reading Reactive Antibody/Antigen Results

- Line in Control Area
- Line in Antigens and Antibody Areas
- HIV antigens and antibodies have been detected
Invalid Results

- No Line in Control Area
- There was a problem running the test
- Cannot be interpreted
- Repeat test with new device
Determine™ HIV-1/2 Ag/Ab Combo

Invalid Results

- Invalid: No control line present
- Invalid: No control line present; Ag and Ab test lines present
- Invalid: No control line present; Ag test line present
- Invalid: No control line present; Ab test line present
INVALID RESULTS

• Means that there was an error running the test.
• Invalid results CANNOT be interpreted.
• Please repeat the test.
• If invalid twice, call us. DO NOT repeat the test a third time on a CLIENT.
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<th>Line</th>
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<th>Invalid</th>
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<td>Control</td>
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<td><img src="image2" alt="Nonreactive Control" /></td>
<td><img src="image3" alt="Invalid Control" /></td>
</tr>
<tr>
<td>Ag</td>
<td><img src="image4" alt="Reactive Ag" /></td>
<td><img src="image5" alt="Nonreactive Ag" /></td>
<td><img src="image6" alt="Invalid Ag" /></td>
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# RAPID HIV TEST LOG

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Clients Positives: Total Proficiency: Supervisor Review
Clients Negatives: Total Controls: NJHIVMT Reviews
Total Invalids:
Checklists/Summary

Testing & Daily Checklists
Testing Site Checklist I:

<table>
<thead>
<tr>
<th>Daily - Log Temperature checks:</th>
</tr>
</thead>
<tbody>
<tr>
<td>☐ Refrigerator</td>
</tr>
<tr>
<td>☐ Room</td>
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<tr>
<td>☐ Reagent Storage</td>
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<tr>
<td>☐ Check expiration dates</td>
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</table>

- Perform QC at a minimum:
  | ☐ Every Monday |
  | ☐ Whenever new shipments are received |
  | ☐ If storage temp was out of range |

- Check QC rotation schedule to insure that all are participating and on track

Perform testing (see Client Testing Checklist)

Fax all preliminary positives to Lisa May 732 235 9012
Checklist for Client Testing

- Client Testing:
  - Check Expiration dates
  - Make sure QC is current
  - Check room temperature
  - Use personal protective equipment
  - Check for desiccant pack
  - Label the test device
  - Read after 20 minutes, but less than 30 minutes
  - Record results in the testing log
Coordinator Responsibilities

- Inventory control
- Weekly
  - Review testing records
- Monthly:
  - Competency review
- Problem solving
- Call us if confirmatory test is not positive
Checklist for Coordinators

- **Daily:**
  - Review & Send logs to us as they are completed

- **Weekly:**
  - Review BOTH temperature logs and test records WEEKLY. Sign & date review.

- **Monthly:**
  - Review QC rotation before month-end or quarterly
  - Send logs to us
  - Check for recertification due

- **Periodically (per calendar):**
  - Expect Proficiency Testing samples
  - Make sure PT results are faxed in to us

- **As needed:**
  - Troubleshooting
When the state (CLIS) gives the go-ahead, you’re ready to test!
How We’re Doing?
– The Monthly Site Visit -

• Documentation tells the story – “An Open Book Exam”
  – Review the logs
    • Testing Log
    • Temperature Logs
  – Is everybody doing external QC periodically
  – Does the lab respond appropriately when corrective actions are needed (Temperature out of range, Reagents Expired)?
  – Is there evidence of supervisory review?
  – Is everybody certified… and is it current?
  – How is the laboratory performing on Proficiency Testing?
  – How about ongoing Competency Assessment?
The End