UPDATE - 2018

NEW JERSEY HOSPITAL ASSOCIATION

MAY 10, 2018

Eugene G. Martin, Ph.D
Professor of Pathology and Laboratory Medicine
Rutgers University – Robert Wood Johnson Medical School
New Brunswick, NJ
NJ HIV - Rapid Testing Support

RUTGERS - RWJMS

Eugene Martin, Ph.D.
Co-Director NJ HIV PI - DHSTS grant

Gratian Salaru, MD
Co-Director NJ HIV PI - DMHAS MOA

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Tom Kirn, MD, Ph.D.

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Rapid HIV Program Manager

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Moeen Ahmed BS,MT
Aida Gilanchi, BS,MT
Nisha Intwala, BS,MT (ASCP)
Franchesca Jackson, BS

DAS Mobile HIV Counselor
• Marianela Moreno

Administration:
• Lisa May
• Karen Williams

NJDOH/DHSTS

Christopher Menschner
Assistant Commissioner

Jihad Slim, MD
Medical Director, DHSTS

Steve Saunders, MS*
Director, HIV Prevention

Loretta Dutton
Director, HIV Care & Treatment

Barbara Bolden, Ph.D.
Surveillance

Greta Anschuetz
Gabrielle Ferrigno
Lisa Jones
Cynthia Mimmo
Rekha Damaraju
Shwetha Kamath
Kulpreet Kaur
Chelsea Betlow
Karen Robinson
Aye Maung Maung

NJ DHS/DMHAS

Adam Bucon, LSW
Office of the Medical Director
LEARNING OBJECTIVES

- NJ HIV Missions
- Rapid Testing Algorithm – New Jersey
  - A Discordant Case Study from last year
  - Review the discordant series and what it means for your clients
- PILOT PROJECTS
  - HIV/Syphilis Initiative
  - HIV/HCV Initiative
  - Pooled NAAT Quality Assurance Project. How are we doing?
  - INSTI Pilot
- What’s NEW in rapid diagnostics and what MAY BE coming to the US!
NJ HIV Missions

A Common Quality Assurance Platform for Rapid ID Screening in NJ

ASSESS New ID Screening Tests

DEVELOP & SUPPORT QA plan for Rapid ID Tests

TECHNICAL OVERSIGHT:
Site Visits, Competency Assessments, Proficiency Testing, Technical Support, Liaison

Inventory Management
Validate & Distribute 100,000 devices per year >1M since 2003

Review Performance

Data Analysis

IMPLEMENT STATEWIDE: New Rapid Tests

RAPID TRAINING:
HIV, STD Rapid Tests, QA
Last year: 36 Sessions: 238 trained

CDC Taskforces:
AHI, HIV Definition, HIV Confirmatory Algorithm

Publications/Abstr/Presentations
19/58/37

Evaluate and Strategize
TRACKING A DISCORDANT – AN RTA CASE STUDY
Initial Rapid HIV Screen
Determine Combo

HIV1/2 Ab +
P24 Ag +

Second Rapid HIV Screen
Trinity Unigold

CONFIRMED
“PRESUMPTIVE POSITIVE”

IMMEDIATE REFERRAL TO CARE

GOAL

POSITIVE SCREEN w/ CONFIRMATION:

DISCORDANT WORKUP:
CDC HIV DIAGNOSTIC ALGORITHM with NAAT

CONFIRMED "PRESUMPTIVE POSITIVE"
LINKED TO CARE DIAGNOSTIC & STAGING WORKUP

TRUE POSITIVE

FALSE POSITIVE

IMMEDIATE REFERRAL TO CARE

NJ RAPID HIV TEST ALGORITHM

FALSE

TRUE

GOAL

POSITIVE SCREEN w/ CONFIRMATION:
CONFIRMING AN HIV1 Antibody (Ab+)

LABORATORY-BASED

EIA or CIA

Biorad Geenius

RAPID TESTING [RTA]

Initial Rapid Test – Determine Combo

Different Rapid Test – Trinity Unigold

PRINCIPLE:

• ORTHOGONALITY: Using INDEPENDENT TESTS to confirm results

• TWO different manufacturer’s rapid HIV tests to verify (CONFIRM) an HIV+ ANTIBODY.

• StatPak followed by Trinity Unigold or Oraquick

• Determine Combo followed by Trinity Unigold/Oraquick/Insti
WHAT ABOUT HIV-1 p24 Antigen?

• What does it mean if you get a negative rapid second test? ➔
  ANSWER:
  • You might have a falsely negative second rapid antibody test; or
  • The initial DC Ab was falsely positive!

• BUT REMEMBER!
  • You can’t rule-out the possibility that you have an early infection with p24 Ag+ and an increasing titer of antibodies UNLESS YOU CHECK!

• LESSON LEARNED SINCE 2015-6
  • FINGERSTICK free p24Ag detection by Determine Combo is not very useful
Site # 1 – Initial Rapid HIV Screen Results – Determine Combo

Test 1 Reagent Lot #

Site # 2 - Second Rapid HIV Screen Results – Usually Trinity Unigold, occasionally Orasure Oraquick

Test 2 Reagent Lot #

NJ HIV picks up and refers specimen to reference lab (Quest) for CDC Laboratory based 4th gen screening PLUS an HIV quantitative viral load or we receive data from non-RWJ laboratory that follows on their own

Linkage information with Laboratory data if being reported to us
# Tracking Follow-up on an RTA Discordant Result

<table>
<thead>
<tr>
<th>Discrepancy ID</th>
<th>RTA Discrepancy Name</th>
<th>Client ID</th>
<th>Date of Test</th>
<th>Lab # 1 - Initial HCVVR Screening</th>
<th>Lab # 2 - Second HCVVR Screening</th>
<th>Altesa-1</th>
<th>Complement</th>
<th>Altesa-1 Recalibration</th>
<th>Screen</th>
<th>T</th>
<th>Product</th>
<th>Determine Combined (Confirm/Alert)</th>
<th>Test Code</th>
<th>Regulations</th>
<th>Apoptia HCV</th>
<th>Occurrence</th>
<th>HCV Genotype</th>
<th>Result</th>
<th>Red Flags</th>
<th>MS (MultiSystem)</th>
<th>EPA</th>
<th>FDA</th>
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<tbody>
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</tr>
</tbody>
</table>

**Table:**

- **RTA Discrepancy Name:** tracking follow-up on an RTA discordant result.
- **Client ID:** unique identifier for each client.
- **Date of Test:** date the test was performed.
- **Lab # 1 - Initial HCVVR Screening:** initial screening result.
- **Lab # 2 - Second HCVVR Screening:** second screening result.
- **Altesa-1:** result of Altesa-1 test.
- **Complement:** complement status.
- **Altesa-1 Recalibration:** recalibration result of Altesa-1.
- **Screen:** screening result.
- **T:** test result.
- **Product:** product information.
- **Determine Combined:** combined determine result.
- **Test Code:** code for the test.
- **Regulations:** regulations for the test.
- **Apoptia HCV:** apoptosis for HCV.
- **Occurrence:** occurrence of the event.
- **HCV Genotype:** genotype of HCV.
- **Red Flags:** red flags for the test.
- **MS (MultiSystem):** multi-system result.
- **EPA:** Environmental Protection Agency.
- **FDA:** Food and Drug Administration.

*Note: The table includes detailed data for tracking follow-up on an RTA discordant result, with specific values for each parameter.*
• We order two tests: A reflex (RFL) lab-based HIV screen AND a viral load assay looking for HIV-1 RNA. Provides internal check on the reference laboratory and gives us hints within a couple of days (IF POSITIVE).

HIV-1 RNA,QN,RT-PCR

HIV 1/2 AG/AB,4TH GEN RFL - Laboratory-based HIV screen (More Sensitive than any rapid test

• Should also be reactive if truly positive. Sensitive to both HIV p24 Ag AND HIV1/2 Ab.

• If reactive → a REFLEX TEST: HIV1/2 AB DIF,SUPPLEM USE is performed to confirm the presence of HIV antibodies

• If the confirmatory, differentiation assay is negative, the process moves to the only FDA approved diagnostic RNA assay: HIV-1 RNA,QL TMA.

• WHAT HAPPENED TO D17-18?
## Reference Testing – Important Notes

**TAKE NOTE:**

1. 5/12 was a Friday. It was not received at Quest until Tuesday. A partial result was back on Friday!
2. No HIPPA information was provided.
3. We knew by Tuesday that even though the differentiation couldn’t confirm it, the client was very likely infected and we could share this information.
4. The QL test took several more days!
Note:
1. It took until May 27 (15 days) to reach a final Report on the specimens from May 12\textsuperscript{th}! Why?

Answer: The TMA Qualitative RNA Assay, is ONLY performed in Chantilly, VA on split specimens sent from Teterboro, NJ on 5/15. Delays are substantial.

The Aptima assay is the only approved RNA assay For diagnosing HIV infection....

But, we’ve been asking the question for nearly a decade: How often a discordant ends up being truly positive or truly negative?
NJ RAPID HIV TEST ALGORITHM (1/2015 – 12/2016)

Initial Rapid HIV Screen
Determine Combo

If NEG, Results within 20-30 minutes

Second Rapid HIV Screen
Trinity Unigold

13.9% initial positive DC screens are discordant

DISCORDANT WORKUP:

CDC HIV DIAGNOSTIC ALGORITHM with NAAT

CONFIRMED “PRESumptive Positive”

LINKED TO CARE DIAGNOSTIC & STAGING WORKUP

88.7% are false positive (118)

7.5% are TP HIV infections (10)

120,796

961

P24Ag+ (21)

HIV1/2 Ab+

961

1

124

827

86% are confirmed by RTA

3.8% (5) were unresolved or refused follow-up

133

10
From January 1, 2017 through March 23, 2018

- 10 Non-RTAs:
  - 8 FP DC Ag+
  - 2 FP DC Ab = RT followed by a laboratory based screen [FALSE POS RTA]

- DC RTA Discordant: 56
  - 13 Rapid-2-Rapid (Two different sites/two different rapids): All 12 FP DC Ab+
    - 9 Determine/Unigold - 1 TP DC Ab+ (viral load: 140,494 copies/mL) - 8 FP DC Ab+
    - 4 Determine/Oraquick – 4 FP DC Ab+
  - 38 Rapid-Rapid (Both RTs performed at same site)
    - 35 Determine/Unigold –
      - 1 Lack confirmed evidence of HIV infection (Lab Based Ab+/Geenius DID NOT CONFIRM (viral load: < 20 copies/ML, Aptima -)
      - 5 TP DC Ab+ (All 5 were CIA Ag/Ab+, 3 Geenius Confirmed, 4 HIV-1 RNA + between 2701 copies/mL -> 2,149,048 copies/mL, 1 HIV-1 RNA < 20 copies/ML)
    - 1 FP Ag+
    - 28 FP DC Ab+
    - 3 Determine/Oraquick – 1 TP DC Ab+ (Lab Based Ab+/Geenius Confirmed (viral load: 72 copies/mL)

- FP Ag+: 6
RTA DISCORDANT FOLLOW-UP (2017-2018 YTD)

**January 1, 2017 Through March 15, 2018**

### Non-RTAs

<table>
<thead>
<tr>
<th></th>
<th>TP DC</th>
<th>FP DC</th>
<th>UNRESOLVED</th>
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</thead>
<tbody>
<tr>
<td>FP DC Ag+</td>
<td>0</td>
<td>8</td>
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</tr>
<tr>
<td>FP DC Ab+</td>
<td>0</td>
<td>2</td>
<td>0</td>
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</table>

### RTAs

#### Rapid-2-Rapid

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<th>TP DC</th>
<th>FP DC</th>
<th>UNRESOLVED</th>
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</thead>
<tbody>
<tr>
<td>DC Ab+/UG-</td>
<td>0</td>
<td>9</td>
<td>0</td>
</tr>
<tr>
<td>DC Ab+/OQ-</td>
<td>0</td>
<td>4</td>
<td>0</td>
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</table>

#### Rapid-Rapid

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<th>TP DC</th>
<th>FP DC</th>
<th>UNRESOLVED</th>
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<tbody>
<tr>
<td>DC Ab+/UG-</td>
<td>5</td>
<td>29</td>
<td>1</td>
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<tr>
<td>DC Ag+/UG-</td>
<td>0</td>
<td>1</td>
<td>0</td>
</tr>
<tr>
<td>DC Ab+/OQ-</td>
<td>1</td>
<td>2</td>
<td>0</td>
</tr>
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</table>

**Total**

<table>
<thead>
<tr>
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<th>FP DC</th>
<th>UNRESOLVED</th>
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</thead>
<tbody>
<tr>
<td></td>
<td>62</td>
<td>6</td>
<td>55</td>
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</table>
RTA DISCORDANT FOLLOW-UP (2017-2018 YTD)

**NJ RAPID SCREENING**
- 77,653 TESTED
- 609 POS
- 85 RTA DISCORDANTS

### RTA - Single Site (Rapid-Rapid)
- 84% (31/37) were False Positive Initial Determine Combo Ab+ screen after Laboratory based CIA w reflex confirmation (Geenius and or Aptima) with Quantitative HIV-1 RNA viral load (<20 copies detection limit)

<table>
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</thead>
<tbody>
<tr>
<td>DC Ab+/UG+</td>
<td>5</td>
<td>29</td>
<td>1</td>
</tr>
<tr>
<td>DC Ag+/UG+</td>
<td>0</td>
<td>1</td>
<td>0</td>
</tr>
<tr>
<td>DC Ab+/OQ-</td>
<td>1</td>
<td>2</td>
<td>0</td>
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</tbody>
</table>

### RTA - Two Sites (Rapid-2-Rapid)
- 100% (13/13) were False Pos Initial Determine Combo after Laboratory based CIA w reflex Confirmation (Geenius and/or Aptima with Quantitative HIV-1 RNA viral load (<20 copies)

- 70% DC Ab/UG; 30% DC Ab/OQ

<table>
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<th>FP DC</th>
<th>UNRESOLVED</th>
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<tbody>
<tr>
<td>DC Ab+/UG+</td>
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<td>0</td>
</tr>
<tr>
<td>DC Ab+/OQ-</td>
<td>4</td>
<td>0</td>
<td>0</td>
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DISCORDANT WORK-UP→ The Abbott/Alere Component

Questions that require specific information:
- Client information
  - Gender
  - If female, pregnancy status
  - Any therapies provided based on the result
  - Risk factors
Complaint Rates – NJ HIV vs. Overall

SUMMARY

• After the initial release DC has had a relatively stable pattern of False Positive complaints averaging .03-.04%
• NJ HIV reports every discordant to Alere Technical Support to assess whether a lot of reagent is potentially the issue.
Transition of the manufacturing process from Israel to Scarborough, ME was uneventful.

The complaint rate threshold to trigger a formal notice has never been approached.
Primary and Secondary Syphilis

Syphilis – Est. Rates Among MSM by State

Syphilis – Prevalence

* States reporting less than 70% of cases identified as MSM, MSW, or women in 2016 are suppressed.
Syphilis Project

• Healthy People Objective: Reduce sustained domestic transmission of primary and secondary syphilis
  • U.S. Target: 6.7 new cases per 100,000 male population and 1.3 new cases per 100,000 female population
  • NJ Target: 2.5 new cases per 100,000 population (male and female combined)

WHO DO WE WANT TESTED?

• NJ Target Population:
  • Primarily - Gay men
  • Female partners of known syphilis cases

• Clients from other states can be tested

• Referred clients from other agencies will be tested.
Syphilis Taskforce

- Joanne Corbo - Rutgers
- Rekha Damaraju – DHSTS
- Lisa B Jones – DHSTS
- Kulsoom Siddiqui – STD
- Steven Dunagan - STD

Pilot Sites:
- NJCRI: Ricardo Rodney; Moseale Coker
- VNA: Antoinette Joyner; Victor Vargas

HIV/Syphilis Screening available at:
- AAOGC
- Camden AHEC
- Hyacinth LOL in Jersey City
- Hyacinth Trenton
- SJAA – Oasis Drop In - Northfield
- NJCRI
- VNA
The Reverse Algorithm:

**Figure 1: Traditional Syphilis Serology Testing Algorithm**

1. **Qualitative Non-Treponemal**
   - Reactive
   - Non-reactive
   - **Quantitative Non-Treponemal**
   - Reactive
   - Non-reactive
   - **Treponemal**
     - Reactive
     - Non-reactive
     - **Consistent with current syphilis infection**
     - Syphilis infection unlikely; biological false positive likely
     - No laboratory evidence of syphilis infection

**Lab Interpretation**

*If either <1.4 consider these values associated with possible seroconversion.**

**Association of Public Health Laboratories**

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**Figure 2: Reverse Syphilis Serology Testing Algorithm**

1. **Treponemal (Immunoassay)**
   - Reactive
   - Non-reactive
   - **Non-Treponemal**
     - Reactive
     - Non-reactive
     - Supplemental Treponemal*
       - Reactive
       - Non-reactive
       - Consistent with current or past syphilis infection
       - Consistent with past syphilis infection
       - Inconclusive for syphilis infection; potentially early infection or false positive
       - No laboratory evidence of syphilis infection

**Lab Interpretation**

*The supplemental treponemal test should utilize a unique platform and/ or antigen, different than the first treponemal test. Other publications have tables comparing platforms and antigens in treponemal tests.*

**Association of Public Health Laboratories**
Syphilis Project Data

• **OPERATIONAL PILOT – FY 2017**
  
  VNA: 263 TESTED  18 SCREEN POSITIVE  3 FALSE POS
  
  NJCRI: 183 TESTED  20 SCREEN POSITIVE  0 FALSE POS – ALL HAD TPPA

  
  446 TESTED  38  3

• STD Taskforce: Significant changes to training, reporting, linkage processes

• Five ADDITIONAL SITES WERE ACTIVATED: 5/7/2018
  
  • AAOGC
  
  • Camden AHEC
  
  • Hyacinth LOL in Jersey City
  
  • Hyacinth Trenton
  
  • SJAA – Oasis Drop In - Northfield
HCV Pilot

**2017:** Beginning with 5 ARCH Nurse sites: (Camden AHEC, Hyacinth, NJCRI, Oasis (SJAA) and Well of Hope)
  - Tested: 339 identifying 47 positives (seroprevalence among sites (range 10% - 46.1%)

**2018:** 12 ARCH Nurse sites have been approved for HCV screening and are in various states of getting started.

NJCRI, St. Michaels, and Ocean County HD are offering expanded HIV/HCV testing.

CONFIRMATORY DATA WILL BE CRITICAL.

**Concerns:**

Nearly 60% of all testing devices HAVE BEEN used to satisfy manufacturer’s required internal quality control (54%) or to perform proficiency testing events (7%).

Follow-up results re: “not regularly reported” has been a problem!

**NJCRI:** Implemented a standing order to permit immediate phlebotomy and lab testing on initial HCV Positives

6/26/16
Pooled NAAT SUMMARY

HOW MANY DO WE MISS?

- Client willingness to have pooled NAAT marginal: <50%?
- Hospital recruitment PROBLEMATIC

- So Far:
  1. 145 pools of 27 specimens
  2. 3915 specimens
  3. 2 Positive (Not AHI – both missed HIV Ab+)
  4. Previous Study: 1 AHI/675 specimens

  EXPECTATION: 5.8 HIV +

- Differences from 2010: Collecting Architect data PLUS Pooled HIV1 RNA

- Why? How many are missed and why matters.

- TO DATE:
  1. In Essex County at the Community Based Sites participating, we have NOT identified a single case of acute HIV infection.
  2. We have observed only 2 cases of missed False Neg Determine Combo screens

QA effort: Evaluate the possibility that as many as 94 cases HIV infection are missed annually in screening 80,000 individuals by rapid HIV testing.

After rapid HIV testing, individuals are offered enhanced screening by a laboratory-based 4th generation screen (Abbott Architect) and pooled nucleic acid amplification testing (NAAT).

- Following sites are participating.
  1. Hyacinth Foundation, 100 Hamilton Place, Paterson, NJ
  2. NJCRI 393 Central Avenue, 3rd Floor, Newark, NJ
  3. Paterson Department of Health, 176 Broadway, Paterson, NJ
  4. Rutgers STOP Program, 65 Bergen Street, Room 177, Newark, NJ
  5. Trinitas Hospital, 654 E. Elizabeth, NJ Jersey Street, Plaza 1st Flr (Rm 161),

An NJ HIV QA activity supported by: IRB Protocol Number: 0220080007
SUMMARY STEPS 1 & 2: ADD SPECIMEN. MIX BY INVERSION. POUR into membrane. ADD developer.
INSTI PILOT SUMMARY

• WHY?
  • A 1 MIN TEST → MAY HAVE UTILITY IN APPROPRIATE VENUES.
  • REPORTEDLY NEARLY EQUIVALENT IN SENSITIVITY TO THE DC Ab marker

• CONCERNS:
  • Overall performance – Sensitivity/Discordant behavior/Potential for operator confusion

• WHERE/STATUS:
  • **INSTI (One Minute Test) Pilot:**
    • March Atlanticare began using the INSTI test in the ER in Atlantic City.
    • Jersey Shore Medical Center began testing in June
    • Our Lady of Lourdes began in July.
  • INSTI test as their first rapid test to screen for HIV in the emergency room. Positive screens are followed by a second rapid - Unigold

• Outcome (Jan 1, 2018): 4,745 clients tested with 15 positives, 1 Discordant.

• **Too early to decide:** Seroprevalence (0.295%) at these sites makes it difficult to reach any conclusions.
What’s on the Horizon

HOW LONG WILL IT TAKE??
## ABBOTT/ALERE – Strategic Decisions Remain

### Alere™ HIV/Syphilis Duo
- First and only WHO PQed multiplex test that detects HIV and syphilis simultaneously
- Suitable for Prevention of mother-to-child transmission screening program to meet WHO Dual Elimination targets
- Cost effective and easy to use

### Alere™ Pima CD4
- First commercial POC CD4 analyzer
- No sample handling required, results in 20 minutes
- Market leader for POC CD4 (>6000 analyzers placed)
- Connectivity enabled

### Alere™ q HIV-1/2 Detect
- Point of care molecular detection and differentiation of HIV type 1 and type 2 in 52 minutes
- No sample handling required
- Connectivity enabled
- Allows point of care EID testing

### Determine™ HIV ½
- Easy to use, fast results, high quality
- First line screening test in 80% of Low & Middle Income testing algorithms
- 4th generation rapid HIV tests enabling increased case findings
- FDA, WHO PQ and CE Marked

### ABON Tri-line™ HIV
- SD BIOLINE™ HIV 3.0
- Alere™ HIV Combo
- Determine™ HIV 1/2 Ag/Ab Combo
Today: US Screening for HIV & Syphilis

Determine Combo
- HIV Rapid
- Treponemal Rapid

Syphilis Health Check™?

Estimated 2- to 5-fold increased risk of acquiring HIV if exposed to that infection when syphilis is present. HIV and syphilis affect similar patient groups and co-infection is common.

Syphilis Testing currently utilizes both Treponemal Tests and Non-Treponemal Tests as part of a Testing Algorithm to fully assess the patient’s clinical condition.

Both Treponemal Tests and Non-Treponemal Tests are needed as each provide a part of the clinical picture. In essence, we are looking to find out...

- Has the patient been infected with Syphilis?
- Does the patient require treatment for Syphilis?

p24
HIV Abs

RPR
Tomorrow... Is there a market in the US?

INTEGRATED DUAL RAPID TESTS FOR HIV AND SYPHILIS:

SD BIOLINE DUO

DPP® HIV-Syphilis Assay

Syphilis Screen with RPR confirmation Built-In?

DPP® Syphilis Complete Assay

NONE OF THESE PRODUCTS ARE CURRENTLY APPROVED FOR USE IN THE UNITED STATES
NJ ASTHO “VISION” AWARDS – 1st Place

RAPID HIV TESTING PROGRAM
- 2006 -

PATIENT NAVIGATOR PROGRAM
- 2013 -
The End

THANKS FOR YOUR ATTENTION!