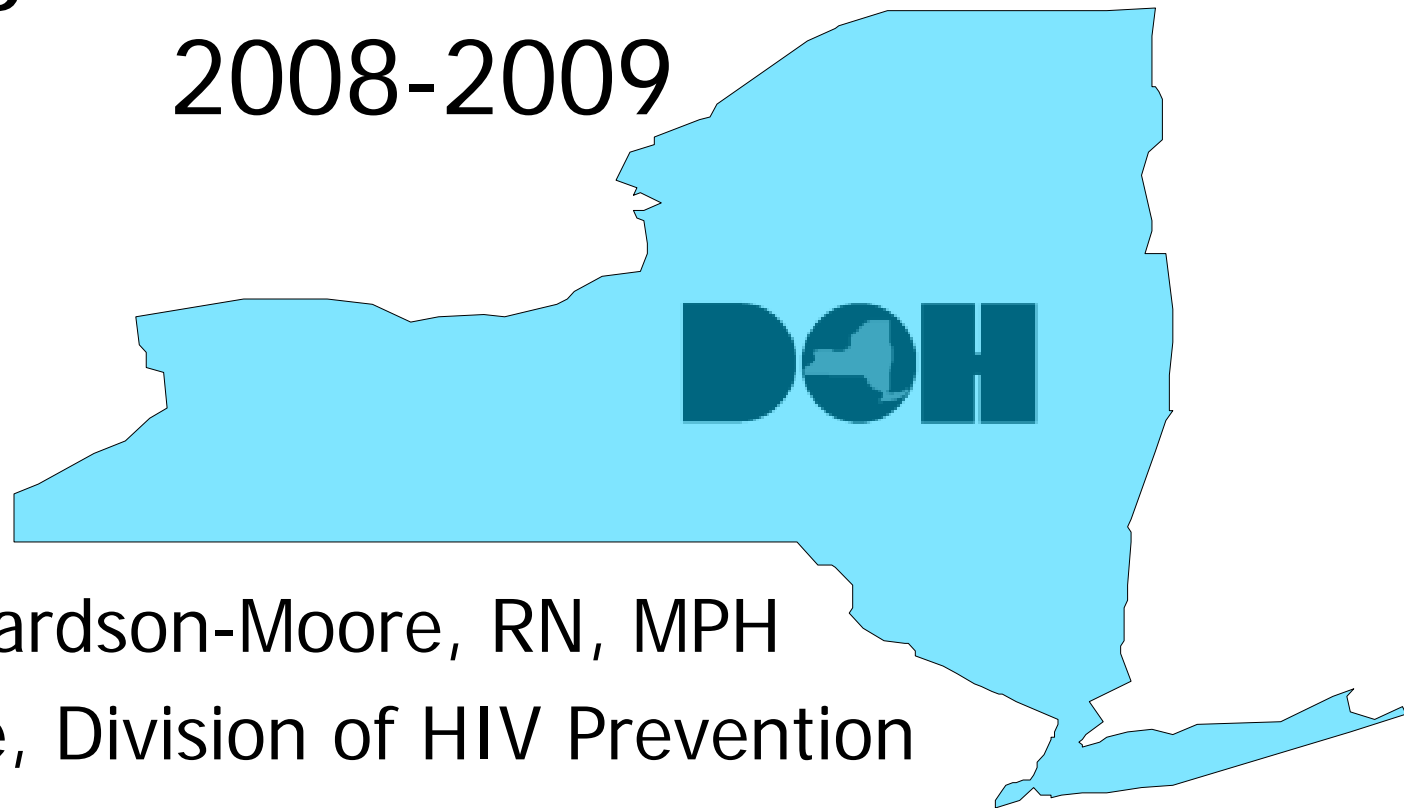


# Two-Rapid Test Strategy in Anonymous HIV Counseling and Testing Sites in New York State 2008-2009



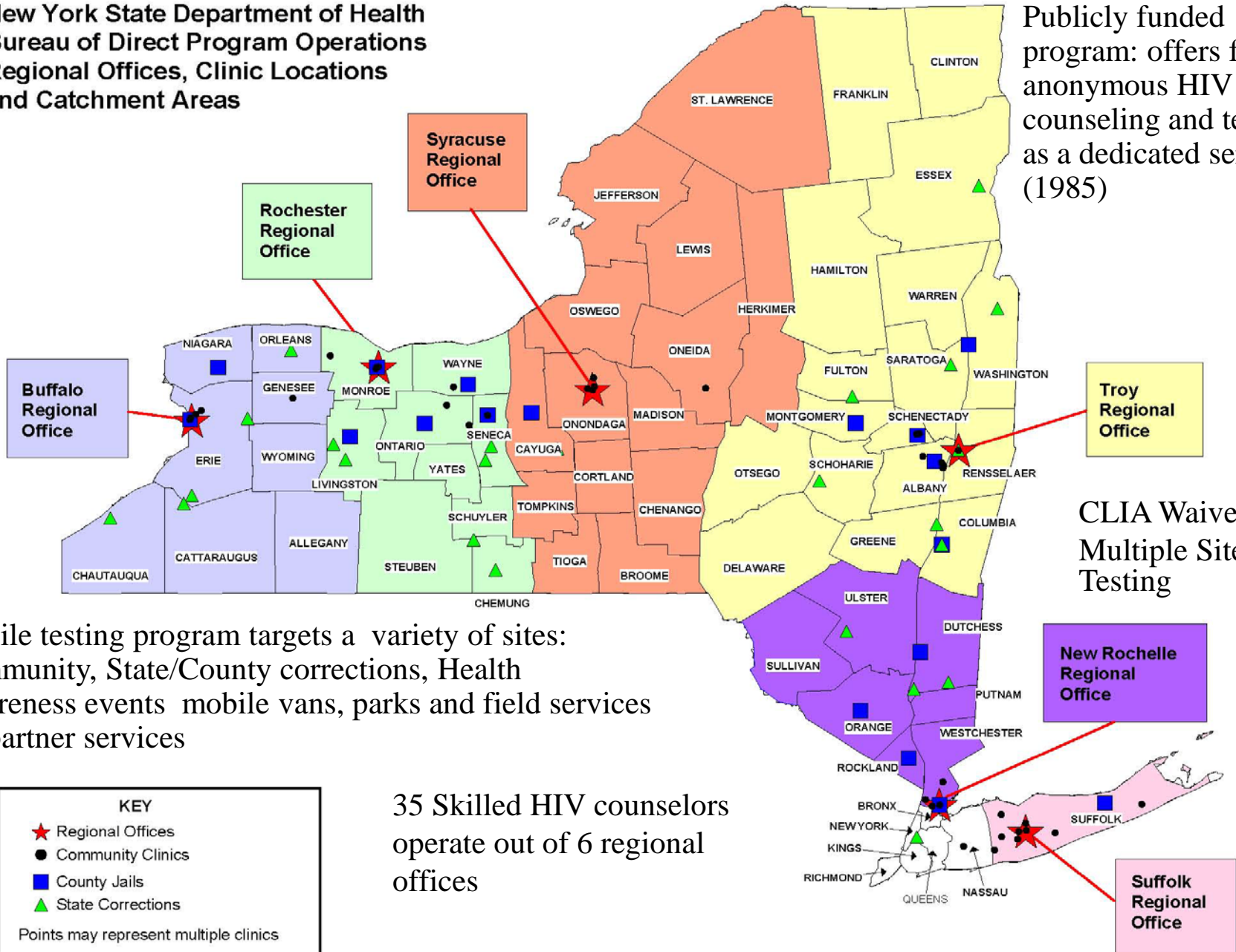
April Richardson-Moore, RN, MPH

AIDS Institute, Division of HIV Prevention

2010 HIV Diagnostics Conference

New York State Department of Health  
Bureau of Direct Program Operations  
Regional Offices, Clinic Locations  
and Catchment Areas

Publicly funded program: offers free, anonymous HIV counseling and testing as a dedicated service (1985)



CLIA Waiver for Multiple Site Testing

35 Skilled HIV counselors operate out of 6 regional offices

Mobile testing program targets a variety of sites: Community, State/County corrections, Health Awareness events mobile vans, parks and field services for partner services

# ACT Program Description

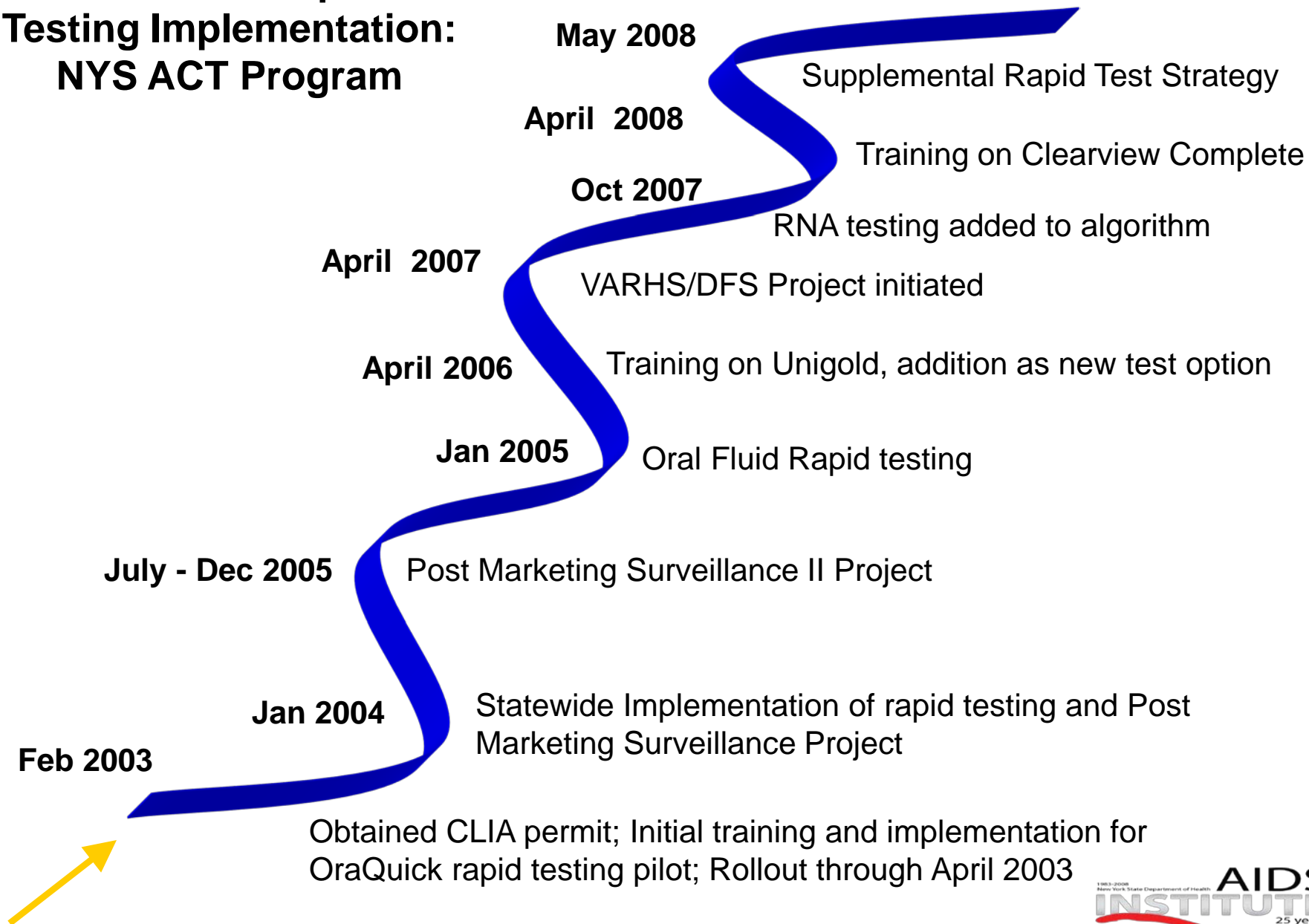
- **Program Mission**
  - HIV prevention and access to care
- **Guidance provided through NYS Public Health Law**
  - Article 27F requires Informed Consent
  - Article V outlines laboratory requirements
  - Article 21 directs HIV Reporting and Partner Notification

# ACT Program Policy

**Steps taken to get HIV infected clients into care include:**

- Change anonymous test results to confidential
- Provide active referrals to medical services
- Conduct follow-up visits (in addition to post test) to ensure referral complete and offer Partner Services
- Offer participation in Variant Atypical Resistance HIV Surveillance (VARHS/DFS) Project (ended October 2009)

# Milestones in Rapid HIV Testing Implementation: NYS ACT Program



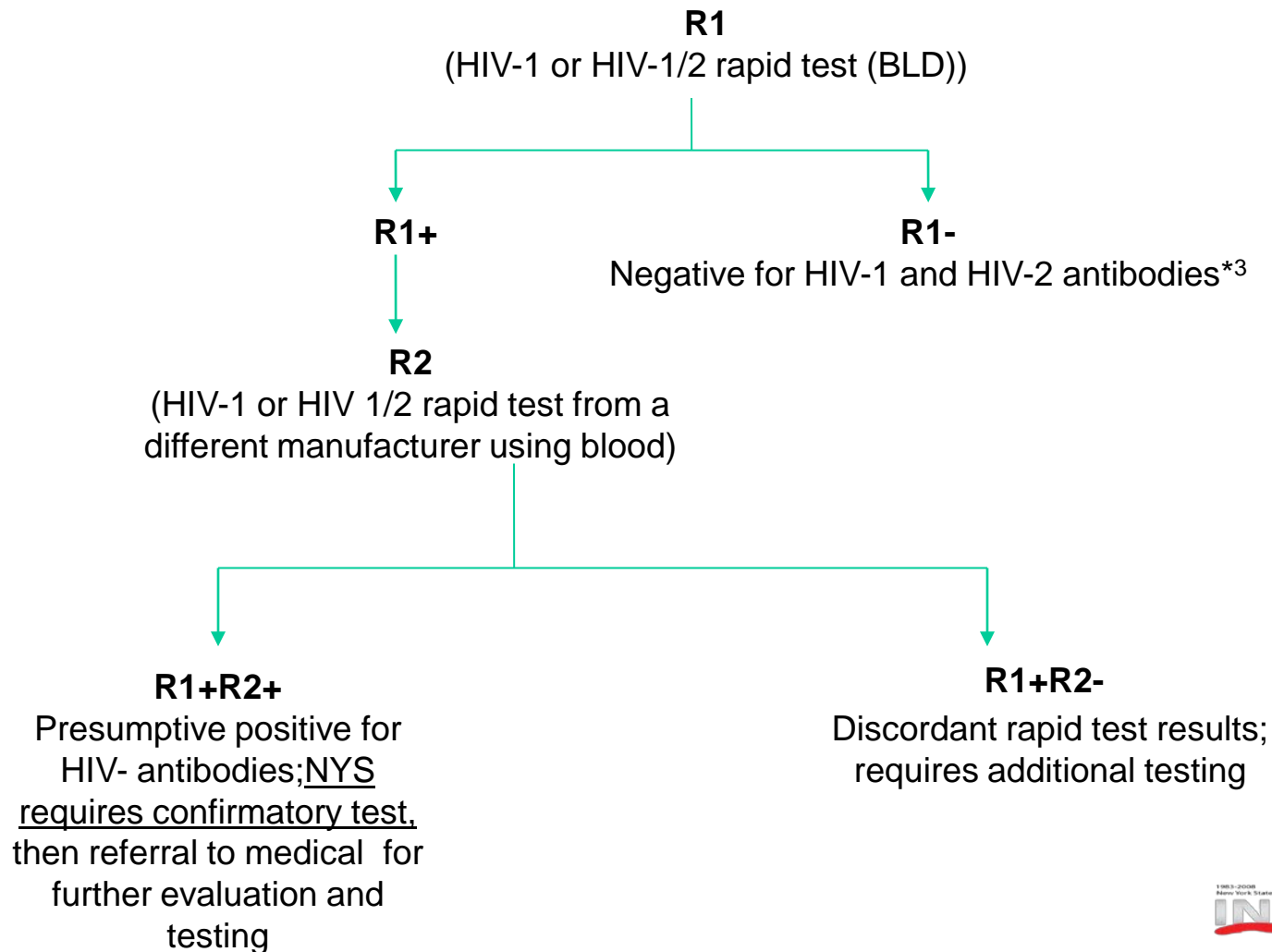
# Data: Rationale for New Strategy

- Rapid Reactive results May 2007 to April 2008
  - 113 of 17,973 rapid tests were rapid reactive
    - 15 declined confirmation
    - 82 confirmed positive of 113 RR (7 Acute HIV Infections\*)
    - 2 WB Indeterminate (prior to RNA availability)
    - 14 False Positive
  - 75% (63/84) return for test result (includes 2 standard positives)
    - 63.1% (53/84) self or provider reported in care
  - 70.2% (59/84) changed to confidential test result
    - 86.4% (51/59) self or provider reported in care
  - PPV = 85.4.% (82/96) \*\*




\*RNA testing 10/07

\*\* 2 WB Indeterminate

# Strategy: Two Rapid Tests (R1/R2) Performed in Sequence (R1/R2 are different rapid tests)

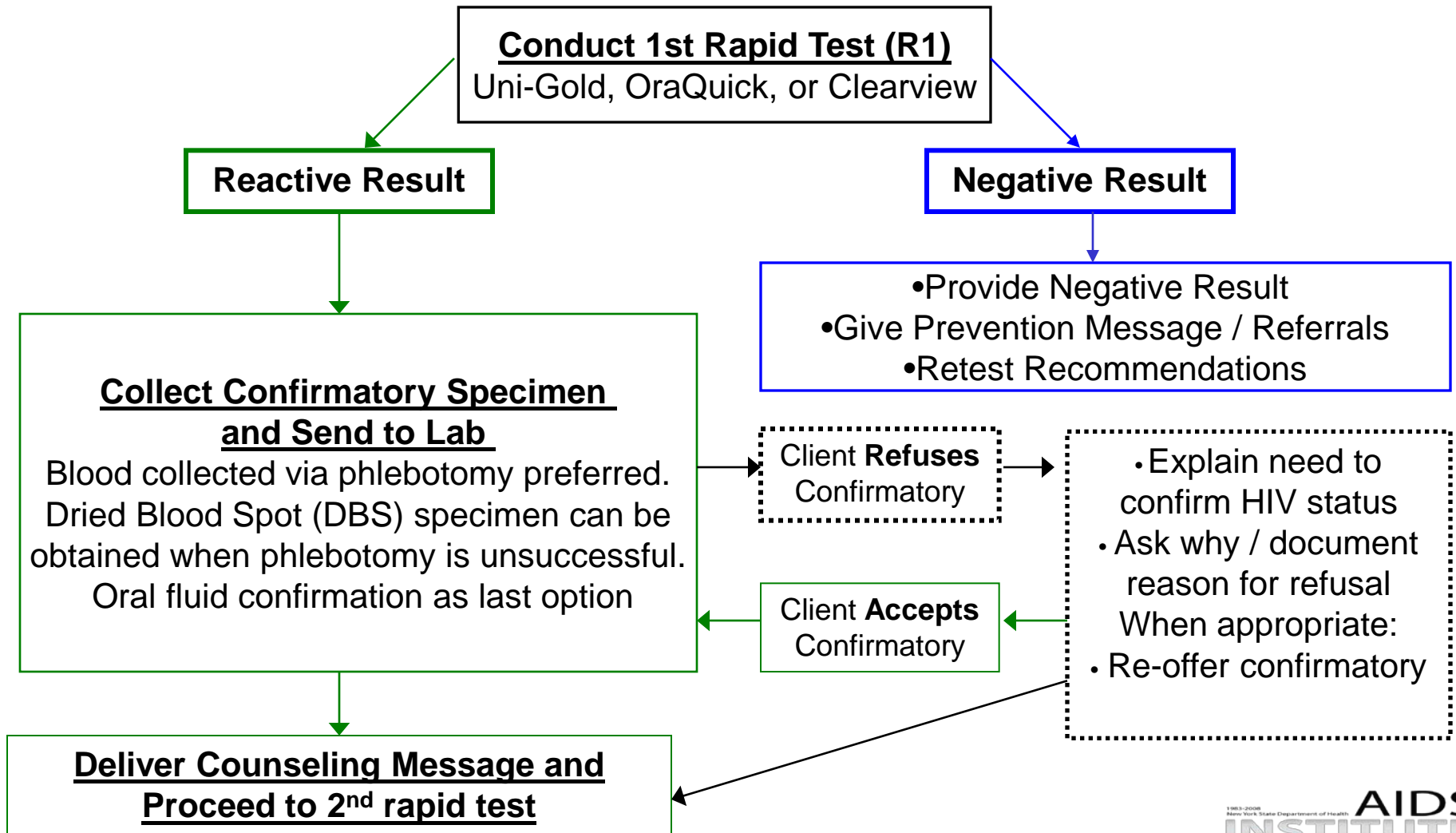


# Three Rapid Tests

Uni-Gold	Clearview Complete	OraQuick
<p>#1</p> 	<p>#2</p> 	<p>#3</p> 
<p>Policy guidance directs staff to use device as R1 due to run time, though situation and client preference can impact R1 choice</p>	<p>Product insert: reactive test maybe observed and read earlier than 15 minutes (Line observed in Control and Test area)</p>	<p>Oral fluid available for clients who do not want a finger stick PPV issues in past Must use blood if 2<sup>nd</sup> test</p>
<p><b>Run time 10-12 min. Read window 2 min.</b></p>	<p><b>Run time 15-20 min. Read window 5 min.</b></p>	<p><b>Run time 20-40 min. Read window 20 min.</b></p>
<p><b><u>Run Temps</u> 59 °F -80 °F</b></p>	<p><b><u>Run Temps</u> 59 °F -99 °F</b></p>	<p><b><u>Run Temps</u> 59 °F -99 °F</b></p>



# Supplemental Test Strategy with Counseling Messages



# Counseling Message for Initial Rapid Reactive Result

R1: Reactive

*“Your first rapid screening test is reactive.”*

*Your test result is reactive. This is a screening test, and as discussed, further testing is needed before we know for sure whether or not you are infected with HIV.*

*Though tests are highly accurate, a second rapid test and a confirmatory test are needed. A second rapid test will better indicate your HIV status while you wait for the results of a confirmatory test.*

# Supplemental Testing Strategy (Continued)

## Conduct 2<sup>nd</sup> Rapid Test (R2) Using Blood

Conduct R2 on All R1 Reactive Clients

\*\*\*R2 must be a different test product from R1\*\*\*

Client **Declines**  
2<sup>nd</sup> Rapid Test

### Deliver Counseling Messages

R1 Reactive	R2 Reactive	R1 Reactive	R2 Negative	R1 Reactive	R2 Refused
<b>Discuss:</b> - Likelihood of Positive Result - Low Probability of False Positive with 2 Reactive Results - Elicit Partners - Offer Medical / Other Referrals		<b>Conduct Risk Assessment</b> <b>Discuss:</b> - Possibility of False Reactive Result from R1 - Possibility of AHI - Offer Referrals		<b>Review Risk Assessment</b> <b>If High Risk Discuss:</b> - Likelihood of Positive Result - Offer Referrals <b>If Low Risk Discuss:</b> - Possibility of R1 False Reactive - Offer Referrals	
<b><u>For all clients:</u></b> <ul style="list-style-type: none"> <li>• Offer change of status option for reactive result</li> <li>• Stress need to return for confirmatory result</li> <li>• Collect informal client contact information</li> <li>• Discuss HIV transmission and prevention messages</li> <li>• Offer VARHS (if eligible)</li> <li>• Schedule post-test</li> <li>• Discuss Partner Services</li> </ul>					

# Counseling Message for Second Test Rapid Reactive Result

R2: Reactive

*“Your second rapid screening test is reactive.”*

*“You have had 2 reactive rapid HIV tests indicating you are likely HIV infected. The confirmatory specimen will confirm that you are HIV infected. We need to discuss medical care, how you can prevent transmission and how to notify your partners...”*

# Counseling Message for Second Test Rapid Non-Reactive Result

R2: Non-Reactive

*“Your first screening test was reactive and your second test was negative.”*

*“It is possible that the test may have reacted to some underlying health condition, or it may have been a false reaction with the rapid test. Based on our discussion you may not be infected with HIV. \**

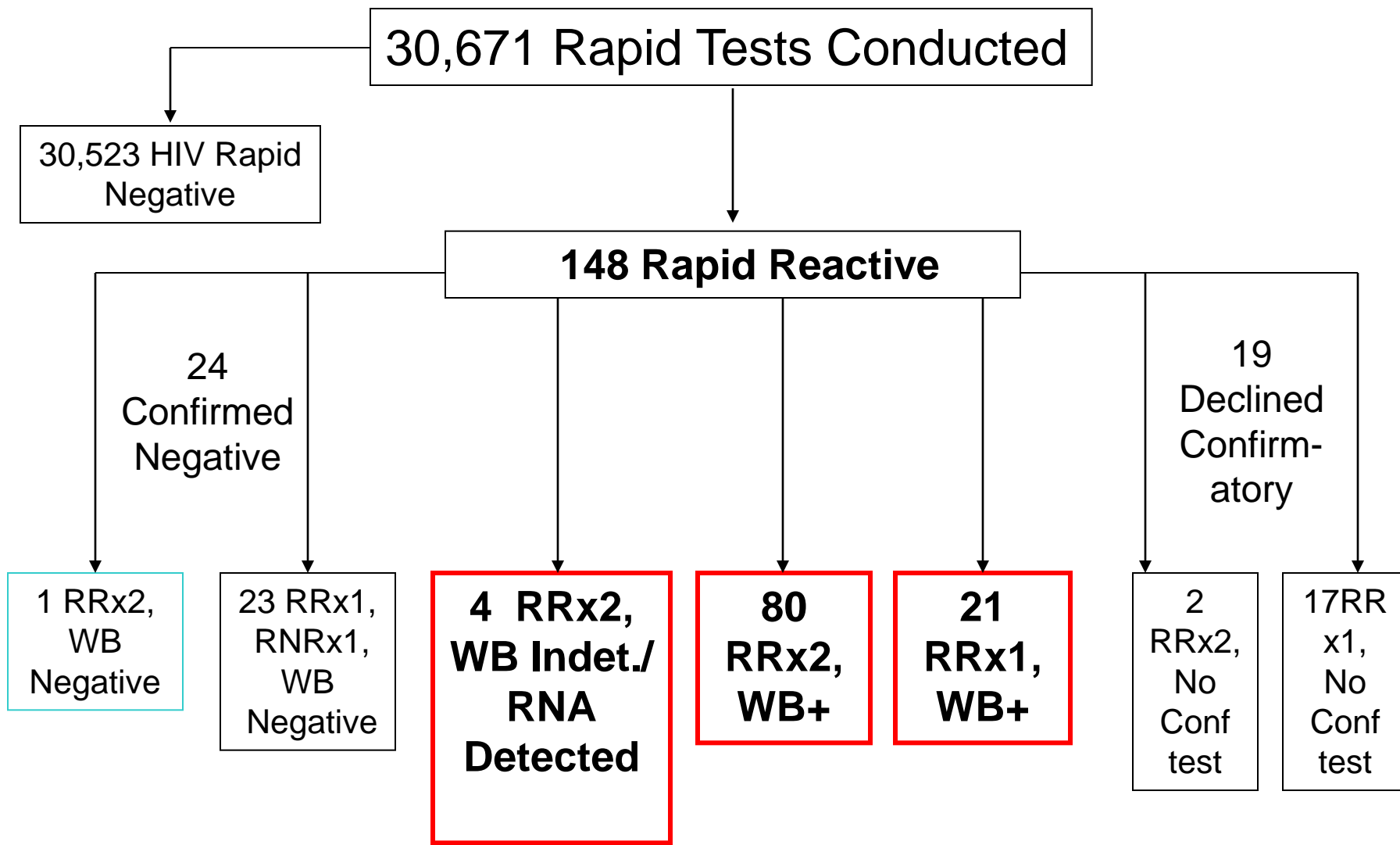
*It is necessary to get the results of the confirmatory test to know your HIV status “*

*\* Message for low risk client: If high risk indicated, AHI is discussed*

# Supplemental Testing Strategy Questions

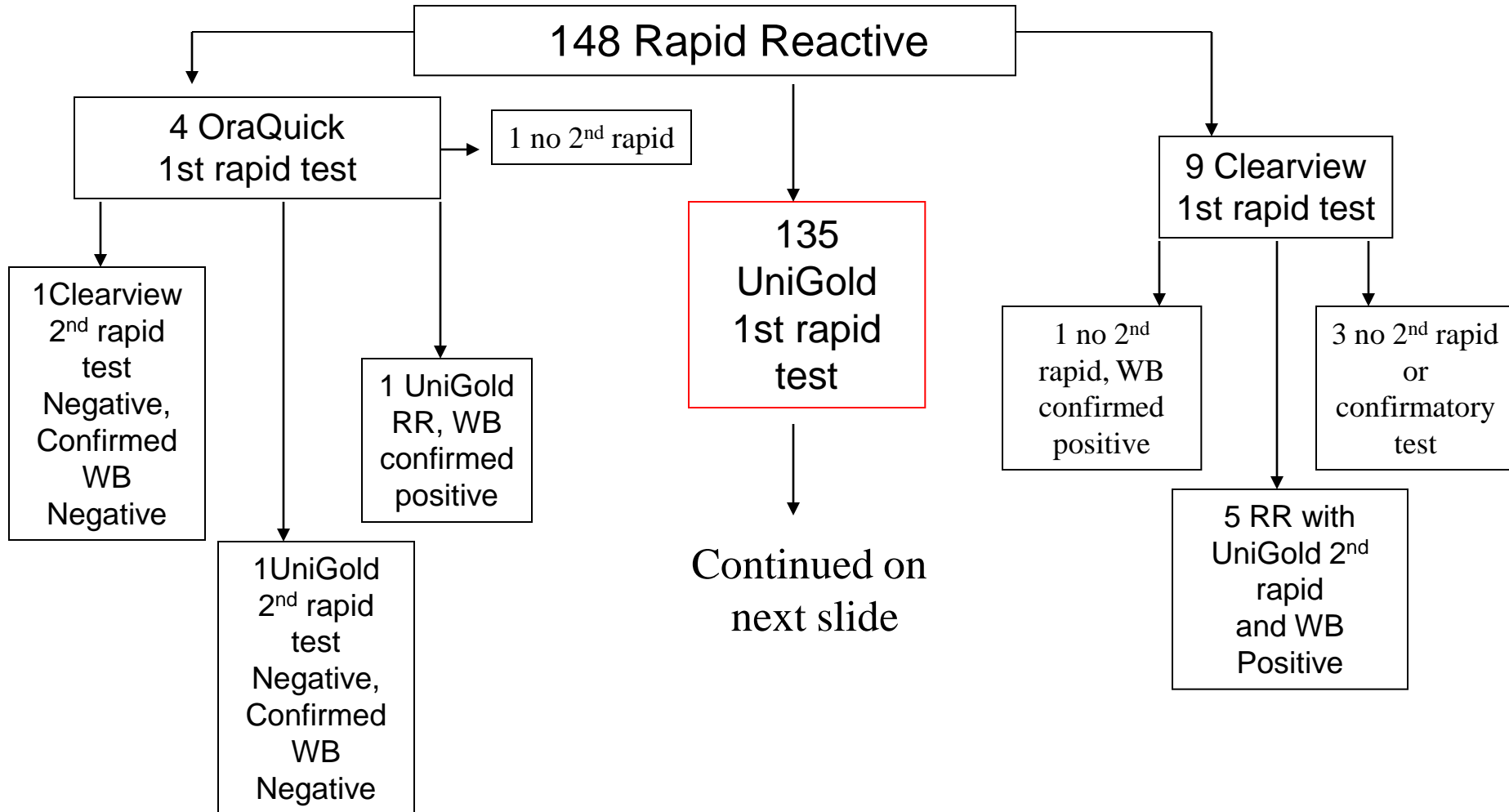
- Does this strategy increase the number of positive clients who know their test result?
- Does this approach get clients linked to medical care?
- Does it improve predictive value of rapid testing?

# NYSDOH Rapid Testing Data May 2008 - December 2009



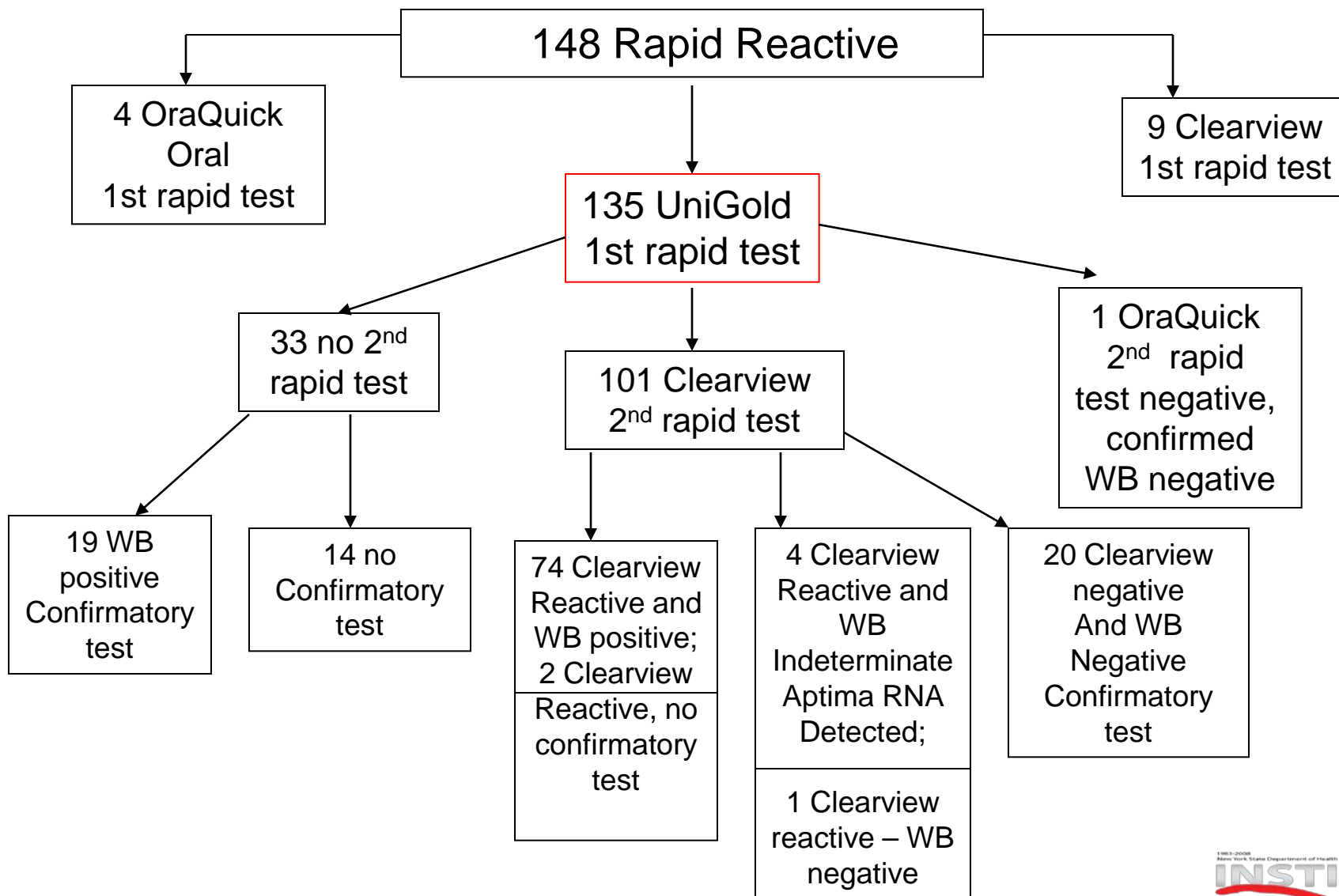
**105 Confirmed Positive**

# NYSDOH Rapid Testing Detail by Test Type May 2008 to December 2009





# NYSDOH Rapid Testing Detail by Test Type May 2008 to December 2009 (continued)



# Confirmed Positive Status

- 89 of 105 returned for post test counseling (84.8%)
  - 16 did not return for post test
- 88 of 89 changed to confidential status (98.9%)
  - 1 did not convert
- 84 of 89 self-reported or physician reported in care (94.4%)

# Positive Predictive Value

- 148 total rapid reactive
  - 19 did not accept confirmatory testing
- 129 Reactive tests with confirmation
  - 105 confirmed positive
  - 24 Rapid Reactive/Negative WB
    - 23 False Reactive (RR1 reactive/RR2 non-reactive)
    - 1 False Positive on 2 rapid tests (only true FP)
      - $PPV = TP / (TP + FP) = 105 / 106 = 99.1\%$

# Program Outcomes

<u>Activity</u>	<u>Before</u>	<u>After</u>
Post Test Counseled	75%	84.8%
Changed to Confidential	70.2%	98.9%
Accessed Care (confidential)	86.4%	94.4%
PPV	85.4%	99.3%

# Future Program Directions

- Based on Two-Test Algorithm Results:
  - Link clients to care prior to receiving confirmatory test results
  - Utilize knowledge for public health benefit, i.e., partner services, prevention messages

# Staff Acknowledgements

- Bureau of Direct Program Operations Central and Regional Offices
- Wadsworth Center Laboratory

## Contact Information:

**Email:** April Richardson-Moore      alr02@health.state.ny.us

Mara SanAntonio-Gaddy      mls07@health.state.ny.us

**Phone:** 518-474-3671