

Overview of CLIA-Waived Rapid HIV Tests and the HIV Rapid Testing Algorithm (RTA) Project

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FDA Approved CLIA-Waived Rapid HIV Tests

Overview



FDA Approved CLIA-Waived Tests

Manufacturer	Rapid HIV Test	Specimen Type	Sensitivity	Specificity
OraSure Technologies, Inc. www.orasure.com	OraQuick Advance Rapid HIV-1/2	Oral fluid	99.3%	99.8%
		Whole blood (fingerstick or venipuncture)	99.6%	100%
Inverness Medical Professional Diagnostics http://www.invernessmedicalpd.com	Clearview HIV 1/2 STAT-PAK	Whole blood (fingerstick or venipuncture)	99.7%	99.9%
	Clearview HIV 1/2 COMPLETE	Whole blood (fingerstick or venipuncture)	99.7%	99.9%
Trinity Biotech http://unigoldhiv.com	Uni-Gold Recombigen HIV	Whole blood (fingerstick or venipuncture)	100%	99.7%



OraQuick Advance Rapid HIV-1/2



- Blood or Oral Specimen
- Store at room temperature
- Screens for HIV-1 and HIV-2
- Results read in 20-40 minutes
- Read window is 20 minutes



Clearview STAT-PAK HIV 1/2



- Blood Specimen Only
- Store at room temperature
- Screens for HIV-1 and HIV-2
- Results read in 15-20 minutes
- Read window is 5 minutes



Clearview COMPLETE HIV 1/2



- Blood Specimen Only
- Store at room temperature
- Screens for HIV-1 and HIV-2
- Results read in 15-20 minutes
- Read window is 5 minutes



Uni-Gold Recombigen HIV



- Blood Specimen Only
- Store at room temperature
- Screens for HIV-1
- Results read in 10-12 minutes
- Read window is 2 minutes



CLIA-Waived Tests Run Times

#1 ORAQUICK

Run Time
Min: 20 min
Max: 40 min.
Read Window
Between: 20-40 min.



#2 STAT-PAK and COMPLETE

Run Time
Min: 15 min.
Max: 20 min.
Read Window
Between: 15-20 min.



 Run Time
 Read Window

3 UNI-GOLD

Run Time
Min: 10 min.
Max: 12 min.
Read Window
Between: 10-12 min.



HIV Rapid Testing Algorithm (RTA)

Project Overview

CDC Funded Project



COUNTY OF LOS ANGELES
Public Health

RTA Project Objectives

- Evaluate feasibility and cost of implementing a RTA in public point-of-care HIV testing settings
- Validate use of a RTA to provide accurate diagnosis of HIV infection
- Assess the impact of same-day diagnosis of HIV on the linkage to medical care
- Develop written protocols and best practices for implementation of a RTA

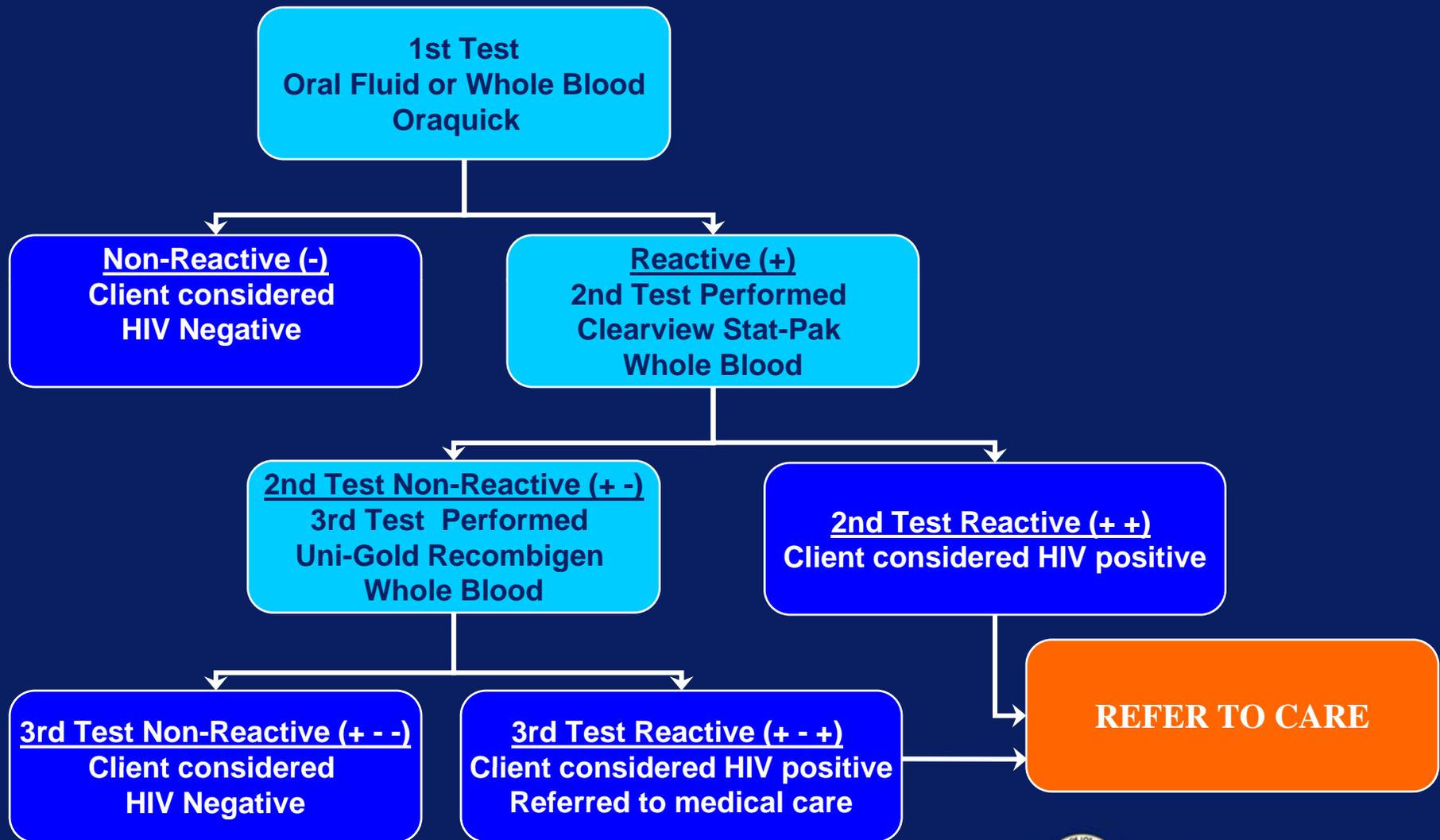


RTA Project Structure

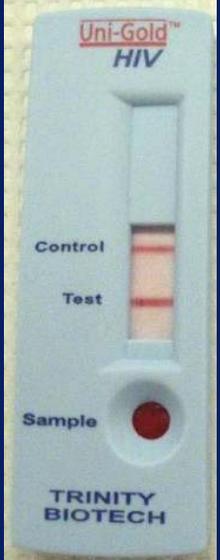
- Eligibility: All clients 12 years or older presenting for HIV rapid testing
- Locations:
 - Los Angeles Department of Public Health
 - San Francisco Department of Public Health
- Standard HIV testing consent forms
- RTA intervention Sites
 - 9 publicly funded point-of-care settings
 - Jails, mobile testing units, clinics, store fronts
- Comparison Sites
 - 23 publicly funded sites providing standard rapid HIV testing



HIV Rapid Testing Algorithm (RTA) – Intervention Sites

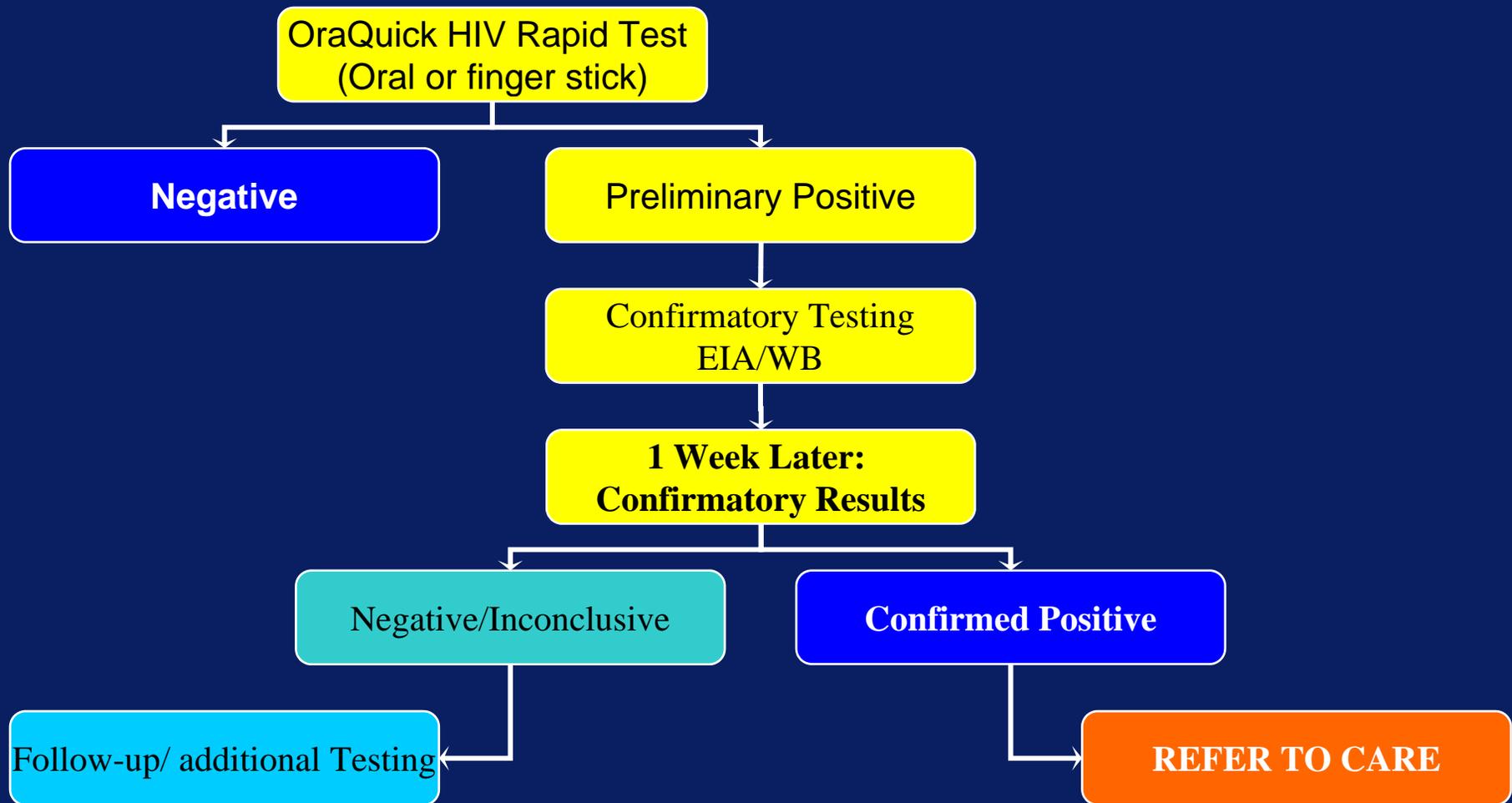


HIV Rapid Tests used in the RTA

OraQuick	Stat-Pak	Uni-Gold
 <p>#1</p>	 <p>#2</p>	 <p>#3</p>
Oral fluid directly or fingerstick with a loop	Collect blood from the vacutainer tube Using a loop (add 1 loop)	Collect blood from the vacutainer tube Using eye dropper (add only 1 drop)
Buffer in vial	3 drops of Stat-Pak buffer	4 drops of Uni-Gold buffer
Run for 20 – 40 min.	Run for 15 – 20 min.	Run for 10 – 12 min.
<u>Run temps</u> 59°F - 99°F	<u>Run temps</u> 64°F - 86°F	<u>Run temps</u> 59°F - 80°F
<u>Storage temps</u> 35°F - 80°F	<u>Storage temps</u> 46°F - 86°F	<u>Storage temps</u> 35°F - 80°F



Current Rapid HIV Testing Standard – Control Sites



RTA Intervention Site Results

	Los Angeles N (%) (8/15/07 – 9/1/08)	San Francisco N (%) (8/1/07 – 7/31/08)
# Tested	5,187	5,511
# Screened Reactive	127 (2.45%) ¹	104 (1.89%) ¹
# RTA Positive	39 (0.75%) ²	76 (1.38%)
# False Positive	4 (0.08%)	24 (0.44%)
Mean # Days Referred to Medical Care	0 days	0 days

¹ 84 clients from Los Angeles and 4 clients from San Francisco with reactive screening did not proceed to RTA due to refusal of confirmatory testing or reported prior HIV positive result.

² 1 Western Blot Result did not match RTA reactive Results (EIA/WB negative).



RTA Control Site Results

	Los Angeles N (%) (8/15/07 – 9/1/08)*	San Francisco N (%) (8/1/07 – 7/31/08)*
# Tested	16,495	7,829
# Screened Reactive	320 (1.94%)	145 (1.85%)
# False Positive	25 (0.15%)	27 (0.34%)
# Received Confirmatory Test Results	135 (42.2%)	87 (60.0%) [†]
Mean # Days Referred to Medical Care (range)	11.3 days (1 – 55 days)	7.6 days (7 – 21 days)

* HIV counseling and testing data are provisional due to reporting delays.

† Estimate due to reporting delays.



RTA Data Summary

- Intervention Sites
 - All clients received their test results on the same day
 - All RTA reactive clients were referred to medical care on the same day
 - 28 individuals had a false positive result resolved on the same day
 - The number of false positive OraQuick results are within the limits of the FDA approved package insert
 - Out of over 10,000 screening tests, one anomaly (RTA +/- WB result -) was observed



RTA Data Summary

- Control Sites
 - 42% – 60% of clients with initial reactive rapid HIV test returned for confirmatory test results
 - Intervention sites 100% of clients received final results
 - Mean 7.6 – 11.3 days before referred to medical care
 - Intervention sites mean 0 days



RTA Skills Required

Department of Public Health (DPH)

- Resources for start up
- Data systems in place
- Know your sites and assess site “readiness”

Agency/Testing Site

- Stable testing site
- Good track record with rapid testing
 - Adherence to quality assurance and testing protocols
- Great communication with DPH



RTA Skills Required – Continued

Agency/Testing Site Counselor

- Qualities needed for OraQuick
 - Ability to document
 - Attention to detail
 - Good eyesight, to see line
 - Good math skills
- Qualities needed for Stat-Pak & Uni-Gold
 - Need steady hand
 - Good eyesight to introduce control fluid into port



Lessons Learned

- Sites that had good history providing rapid testing were more successful with RTA
- RTA not for all sites
 - Sustaining phlebotomy capacity, staff turnover and training, adherence to RTA protocol
- The more Technical Assistance, the more successful
- Slow roll-out: staff and resources must be adequate
- A quality assurance plan and work flow plan must be developed and refined before implementation



RTA Next Steps

- Complete study period
- Link HIV counseling and testing data to HIV/AIDS surveillance data to determine:
 - If and when client entered into care
 - Differences between control and intervention sites
- Perform cost analysis of RTA
- Share best practices and lessons learned



Thanks!

Kevin Delaney

Project Officer

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Community Partners – Intervention Sites

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Community Partners – Intervention Sites



For More Information

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www.publichealth.lacounty.gov/aids

