A Successful HIV Testing Quality Assurance Program: New York State Experience

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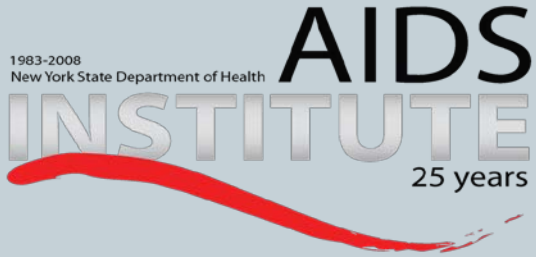

Anonymous Counseling and Testing (ACT) Program Overview

- Publicly funded HIV/STD prevention program, offers free, anonymous HIV counseling and testing as a dedicated service
- 35 skilled HIV counselors operate out of 6 regional offices
- CLIA waiver for multiple site testing. Lab Director from Wadsworth Center Laboratory
- Mobile testing program targets a variety of venues
  - Community-based testing sites
  - State/County correctional sites
  - Special initiatives at community events, mobile vans
  - Field testing for partner notification

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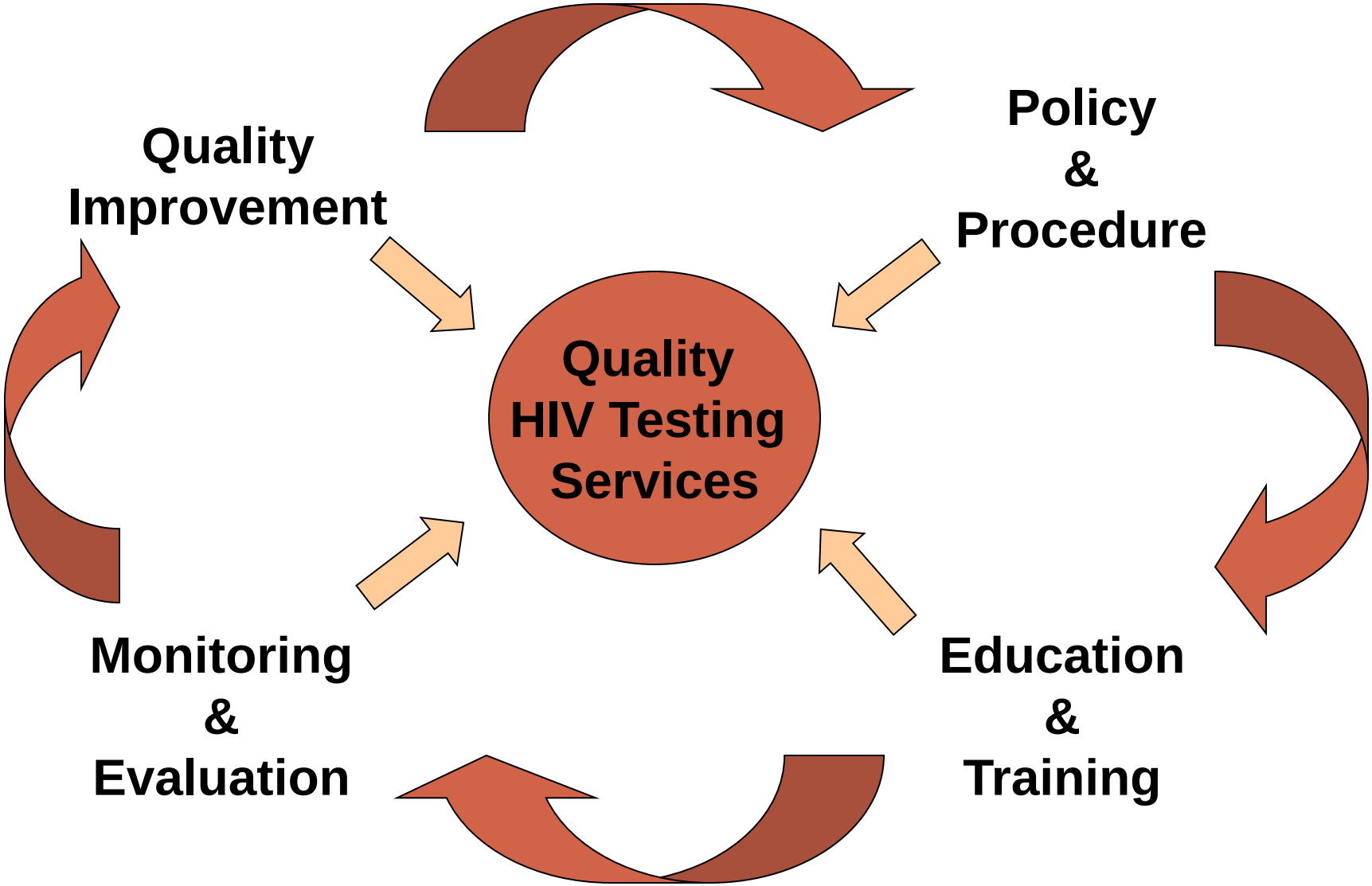
Testing Services Offered

- 3 rapid tests available
  - Uni-Gold Recombigen HIV, OraQuick ADVANCE HIV 1/2, and Clearview COMPLETE HIV 1/2
- 2-test algorithm used
  - All rapid reactive clients are offered a second rapid test
- Confirmatory testing
  - Venipuncture, dried blood spot collection, or oral fluid

Point of Contact Testing Challenges

- Multiple sites
- Staff dispersed to sites, work autonomously
- Varying environments
- Ensuring necessary supplies are on hand
- Staff are not licensed laboratorians
- Services are anonymous, limited ability to recall clients
- Main focus of staff is the client

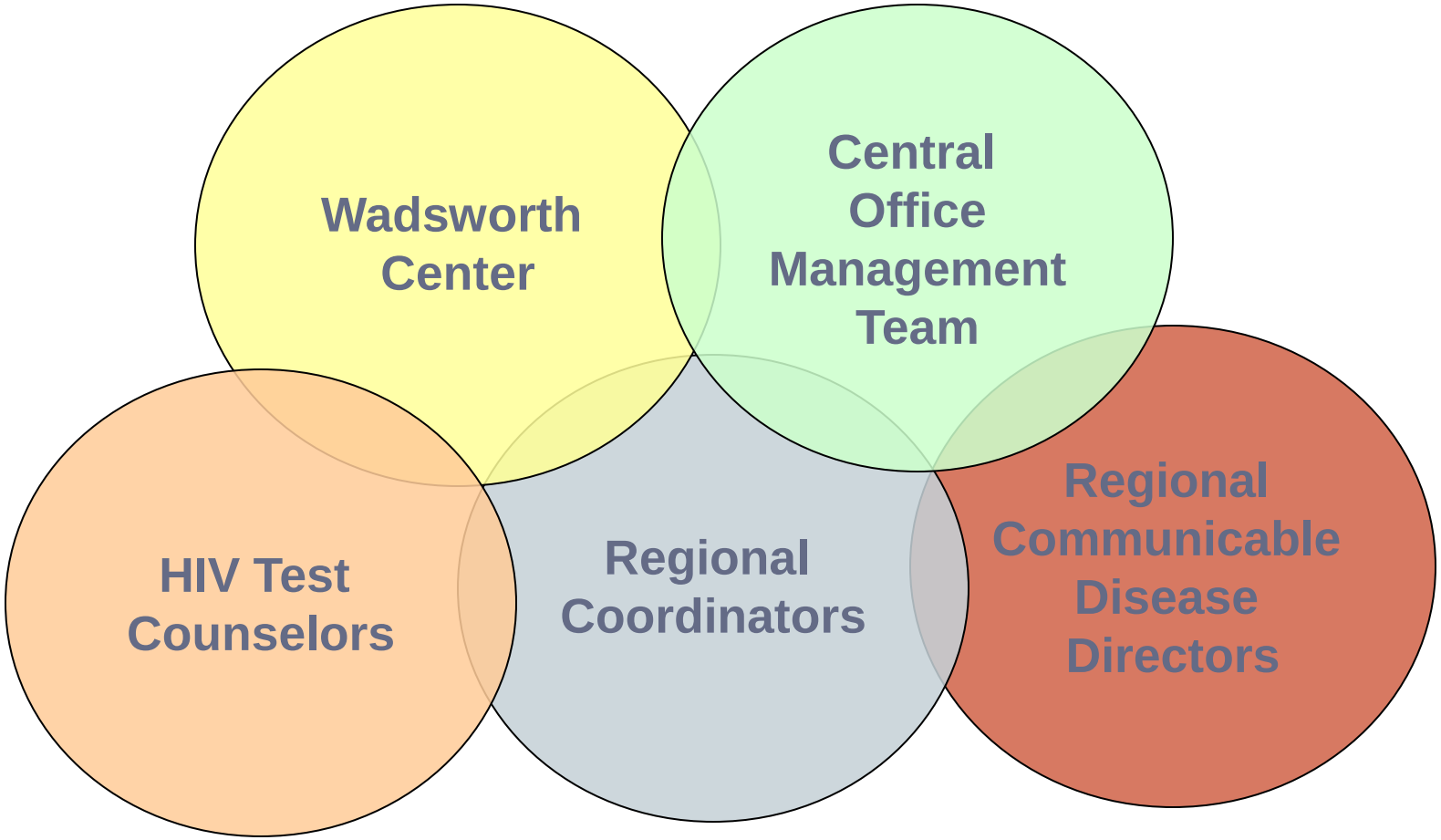
NYSDOH Approach to Ensure Quality



Partnership with Wadsworth Center

- New York State Department of Health Laboratory
- Bloodborne Viruses Laboratory Lab Director oversees ACT Program
- Reference laboratory for processing confirmatory specimens
- Lab plays an important role in ensuring quality:
  - Access to skilled laboratory staff with a high level of expertise
  - Assistance with HIV test counselor training
  - Creation of blinded proficiency test samples
  - Serves as a resource when unusual situations or questions arise related to test results (i.e. impact or influence of medical conditions on test results)
  - Direct communication: email, quarterly meetings, and as needed

Quality Testing



Involvement at All Levels

NYSDOH Approach to Ensure Quality

- Policy and Procedures
- Education and Training
- Monitoring and Evaluation
- Quality Improvement

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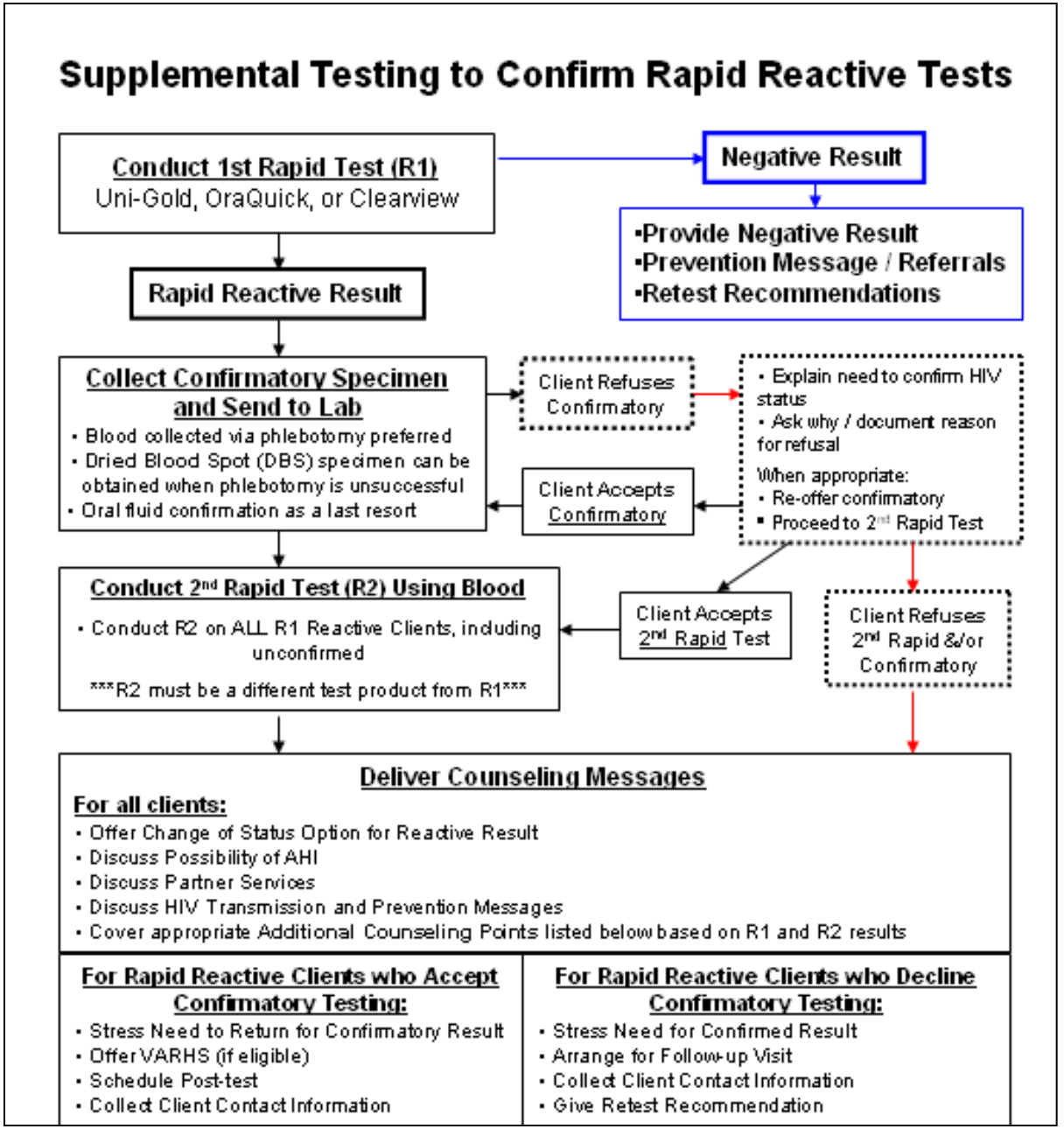
Policy and Procedures

- Policy/Guidance Manual – can be carried into field, each staff person receives a copy
  - Policies
  - Guidance Documents
  - Lab Protocols
  - Forms and Tools
- Reference Manual - one copy kept in office

Sample Field Guidance Tool



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RAPID REACTIVE SESSION CHECKLIST

Steps During Session:

_____ Complete Rapid Test Result Form and show result to client

_____ Conduct Enhanced Risk Assessment for clients not reporting high risk

_____ Conduct Acute HIV Infection assessment. Re-emphasize risk reduction for clients reporting symptoms

_____ Collect confirmatory specimen – Blood preferred, full lavender-top tube
- ___ Put client ID label with clinic code on specimen tube and requisition form
- ___ Enter Additional Client Info on Lab Requisition: "RR-_____" specifying rapid device(s) with which the client tested reactive. Enter time of blood draw.
- ___ Jointly verify with client that requisition and tube labels match

_____ Conduct supplemental rapid test and explain meaning of second result

_____ Encourage change of status from anonymous to confidential
- ___ Explain benefits of changing result to confidential status
- ___ Discuss names reporting

If client agrees to change status:
- ___ Verify identity
- ___ Complete Change of Status Form

_____ Offer referrals – Actively connect client with services when possible

_____ Discuss Partner Services

For clients who change status of reactive result:
- ___ Collect client information for Medical Provider Report Form
- ___ Elicit partner information

_____ Schedule tentative confirmatory post-test appointment
- ___ Inform client of incentive (CVS card) that they can get when they come for post-test
- ___ Obtain informal contact information for use in alerting client when the confirmed result arrives
- ___ Provide client with counselor contact information (business card, palm card, etc)

_____ Complete AIRS CTR Short Intake Form/Scannable CTR Form fully before leaving session

Sample Field Guidance Tool

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Policy and Procedure QA

- Management Team reviews and updates manual annually
- Lab Director reviews annually
- Staff are trained in new policies/procedures by Central Office Management Team
- Changes to existing policies/procedures are reviewed with staff
- Staff take responsibility for reviewing and presenting information to their peers at staff meeting
- Feedback is solicited for quality improvement – reality check from the field

Education and Training

- Education on laboratory requirements through partnership with Wadsworth Center
  - CLEP, proper lab practices, skills development
- Training on rapid test devices and laboratory practices

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Training/Orientation for New Staff

- Initial laboratory rapid test training
- Observe seasoned staff member conduct HIV test session (minimum of 10 clients)
- Conduct HIV test session with seasoned staff member observing (minimum of 10 clients)
- Sign-off by Coordinator to conduct HIV testing independently
- 3 month proficiency testing

Competency Assessment

- Annual Proficiency Testing for all staff
  - 30-item knowledge assessment
  - Observation of technical performance of each product in use
  - Test on reading interpretation panels for each product in use
  - Documentation of completion and performance evaluation

Rapid HIV Testing Technology and
Quality Assurance Knowledge Assessment

Name: _____ Date: _____

1. Rapid test quality assurance practices require a control to be run:
   (a) When the temperature in a clinic reaches 79 °F
   (b) Every morning and every evening
   (c) When a new test kit lot is opened

2. The acceptable storage of rapid HIV test kit **control** solutions should be:
   (a) Under refrigeration
   (b) Frozen
   (c) At room temperature

3. Which rapid HIV test device can **not** be refrigerated?
   (a) Uni-Gold ™ Recombigen HIV-1
   (b) Clearview COMPLETE HIV 1/2
   (c) OraQuick ADVANCE HIV 1/2

4. Three possible test result outcomes using HIV rapid tests devices are:
   (a) Reactive, non-reactive, indeterminate
   (b) Reactive, non-reactive, weakly reactive
   (c) Reactive, non-reactive, invalid

5. If the temperature in a clinic is 89 °F, the appropriate rapid HIV test to use is:
   (a) Clearview COMPLETE HIV 1/2 Test
   (b) OraQuick ADVANCE HIV 1/2 Test
   (c) Uni-Gold ™ Recombigen HIV-1 Test

Sample Knowledge Assessment

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Rapid Test Interpretation Panels

Rapid HIV Test Interpretation Panels for Patient Sample

Name: _____ **Date:** _____ **Score:** _____

Result: _____

Result: _____

Result: _____

Result: _____

Result: _____

Result: _____

Result: _____

Result: _____

Result: _____

Result: _____

Write the result for a patient sample on the line below each test device: Non-reactive (**NR**); Reactive (**R**); Invalid (**INV**) BDPO June 2009

Rapid Testing Proficiency Observation Tool

Clearview® COMPLETE Rapid HIV Testing Proficiency Observation Tool

OBSERVER NAME/DATE	COUNSELOR NAME
Temperature verified ≤86°	
Set Up	
Devices labeled to indicate specimen used	
Implements kept in pouch until used	
Verify presence of dessicant packet, absorbent pad and filter	
Buffer cap put in stand before specimen collection	
Work area set up to maintain efficient and safe workflow	
Technique	
Reagent sample collected to the first pipette gradation without bubbles	
One drop reagent put in weigh boat	
Reagent collected in device sample tip	
Device firmly seated in stand (3 clicks)	
Verification of seating (blue line in window)	
Timing	
15 minutes on timer	
Timer started when device fully seated	
Verification of pink/purple flow	
Result read when timer rings	
Sanitation/Disposal	
Gloves worn when testing	
Work done on protective barrier	
Appropriate waste disposal	
Hands cleaned after testing	

BDPO July 2009

Documentation of Proficiency Testing

New York State Department of Health - Bureau of Direct Program Operations

Summary of July 2009 Rapid HIV Proficiency Testing

First Name	Region	Date	Quiz Score (% correct out of 30)	Quiz Questions Missed	Interpreta-tion Panel Score (% correct out of 10)	Panels Missed	OQ Technique Pass/ Fail (P or F)	UG Technique Pass/ Fail (P or F)	CV Technique Pass/ Fail (P or F)	Blinded Sample Prof. Score (% correct out of 6)	Corrective Action
	Buffalo	7/31/09	100%		100%		P	P	P	100%	N/A
	Buffalo	7/31/09	93%	Q #13, 24	100%		P	P	P	100%	N/A
	Buffalo	7/31/09	100%		100%		P	P	P	100%	N/A
	Buffalo	7/31/09	97%	Q #30	100%		P	P	P/NI	100%	Additional observation
	Buffalo	7/31/09	100%		70%	Panel #4, 9, 10	P	P	P	100%	Clrvw panel retest
	Buffalo	7/31/09	100%		100%		P	P	P	100%	N/A
	Rochester	7/31/09	93%	Q #21, 24	100%		P	P	P	100%	N/A
	Rochester	7/31/09	97%	Q #21	100%		P	P	P	100%	N/A

Knowledge Assessment Scores

Result Interpretation Scores

Corrective Action/Training Needs

Monitoring & Evaluation

- System and schedule in place for all process control activities
- Before testing:
  - Inventory of kits
  - Recording storage temps
  - Running external controls
- During testing:
  - Processing of test and interpretation of result
  - Completion of Master Testing Log (Record clinic temp, lot number/expiration of test kit, test result)
- After testing:
  - Collection of confirmatory specimen (when needed)
  - Documentation of test result

Monitoring Activity	Daily	Bi-Weekly	Monthly	Annually
HIV Test Counselors				
Complete Temperature Logs (Clinic, Device Storage, and Control Storage)	X			
Complete Testing Master Log	X			
Run External Controls (rotating basis) and Document on Control Log		X		
Regional Coordinator				
Review Temperature Logs, Testing Master Logs, and Control Logs		X		
Observe Counselors Running Controls		X		
Complete Test Kit and Control Set Inventory			X	
Regional Communicable Disease Director				
Complete Regional Oversight QA Checklist			X	
Central Office Management Team				
Review Regional Inventory			X	
Conduct Regional Site Visits				X

Coordinator Checklist for Observation of External Controls

Coordinator Checklist for Observation of External Control Procedures

Counselor: _____ **Date**: _____

Preparation and Setup		
____ Cleans area and sets up workspace with protective barrier on a flat surface. Supplies: Timer, thermometer, gloves, hand sanitizer.		
Uni-Gold Recombigen	**Clearview Complete**	**OraQuick *ADVANCE***
____ Places 2 unopened test devices on the protective barrier.	____ Places the clear plastic test stand (wide end down) and control weigh boat on the protective barrier.	____ Places reusable test stand on the protective barrier.
____ Checks and records temperature to ensure it is within range to conduct testing. ____ **Uni-Gold**: 59 – 80.6 ° F ____ **Clearview Complete**: 64 – 86 ° F ____ **OraQuick *ADVANCE***: 59 – 99 ° F		
____ Puts on a clean pair of gloves. ____ Checks that device and control set being used has not expired.		
Uni-Gold Recombigen	**Clearview Complete**	**OraQuick *ADVANCE***
____ Opens 2 devices on workspace. ____ Checks for desiccant packet and if missing, discards the device.	____ Places 3 unopened devices on workspace. ____ Opens foil package, but doesn't remove device from pouch. If desiccant packet or absorbent pad (at the top of the device) or sample filter (at the bottom of the device) are missing, discards the device.	____ Places 3 unopened devices on workspace. ____ Checks for desiccant packet in the side of the pouch containing the device and if missing, discards the device and specimen vial.
Run Controls		
Uni-Gold Recombigen	**Clearview Complete**	**OraQuick *ADVANCE***
____ Labels the device or the protective barrier to identify each control. ____ For each control sample, with new pipette draws control sample to first gradation on the control pipette,	____ Labels the device or the protective barrier to identify each control. ____ For each control sample, with new pipette draws control sample to first gradation on the control pipette, ensures there are no air bubbles or air space, adds **one** free	____ Labels the developer vial or the protective barrier to identify each control. ____ Opens pouch containing the developer solution vial, removes vial from pouch and uncaps. Slide vial in the test stand ensuring vial is all the way to the

New York State Department of Health – AIDS Institute
Bureau of Direct Program Operations

ACT Program Regional Oversight QA Checklist

Program Area	Standard	No	Yes
Rapid Testing Quality Assurance (Refer to the Rapid Test Quality Control Guidance) Purpose: To maintain CLIA permit. Standard: 100% compliance	Rapid Test Temperature Logs updated daily: ❖ Control Storage Log ❖ Test Kit Storage Log ❖ Clinic Temp Log Temps recorded on logs are within acceptable range		
	Control logs reflect biweekly running of controls by staff on a rotational basis and review and sign-off by Coordinator		
	All completed logs are stored in a lab binder (current log can be posted)		
Hazardous Material Handling (Refer to the Biohazard Safety Guidance and Exposure Control Plan) Purpose: To prevent occupational exposure. Standard: 100% compliance	Up-to-date Exposure Control Plans are posted (dated within current year)		
	Waste disposal guidance is posted and conducted according to Policy		
	All biohazard bags and sharps containers include the program name and address before use		
Maintenance of Confidentiality (Refer to Client Confidentiality Policy) Purpose: To prevent confidentiality breaches. Standard: 100% compliance	Confidential material is kept under double lock when not in use		
Communication Purpose: To ensure staff receive appropriate, timely information. Standard: Staff aware of up-to-date information.	Monthly staff meetings are held; minutes produced		
	Minutes are distributed to staff with confirmation of receipt		
Comments:			

Regional Oversight QA Checklist

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Monitoring & Evaluation

- Regional Site Visits
  - Conducted annually by management staff
  - All documentation is reviewed
    - Master Logs, Control Logs, Temp Logs
    - Sampling of individual client charts reviewed for accurate test result documentation
  - Corrective action plans developed for sites that have deficiencies identified
  - Opportunity for management to get feedback on program policies

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Data Collection & QA

- Data Sources
  - Client level data collected and entered into AIRS (AIDS Institute Reporting System)
  - Weekly Activity Database
  - Individual client charts
  - Reactive and Positive Client Tracking Form
  - Wadsworth Center HIV Lab Reports
- All data sources are reviewed and compared to identify discrepancies or inaccuracies
- AIRS -Missing Information and Error reports assist with identifying reporting gaps

Wadsworth Center HIV Lab Reports

New York State Department of Health
Bloodborne Viruses Laboratory
Wadsworth Center

Rapid Test Confirmations: August 2009

Accession #	*CTS#*	*ELISA*	*Multispot HIV1/HIV2*	*p18*	*p24*	*p31*	*p40*	*gp41*	*p51*	*p55*	*p51/55*	*p65*	*gp120*	*gp160*	*Aptima*
RIL09216-6001	[redacted]	Positive	HIV-1 Positive	+	+	+	+	+			+	+	+	+	
RIL09217-6001		Negative	HIV-1/HIV-2 Negative	-	-	-	-	-			-	-	-	-	
RIL09219-6002		Positive	HIV-1 Positive	+	+	+	+	+			+	+	+	+	
RIL09224-6001		Positive	HIV-1 Positive	*	+	+	+	-			+	-	+	+	
RIL09225-6001		Positive	HIV-1 Positive	+	+	+	+	+			+	+	+	+	
RIL09226-6002		Positive	HIV-1 Positive	+	+	+	+	+			+	+	+	+	
RIL09226-6003		Positive	HIV-1 Positive	+	+	+	+	+			+	+	+	+	
RIL09230-6001		Positive	HIV-1 Positive	+	+	+	+	+			+	+	+	+	

Confirmed HIV Negative Result

Wadsworth Center HIV Lab Reports

New York State Department of Health
Bloodborne Viruses Laboratory
Wadsworth Center

Rapid Test Confirmations: December 2009

Accession #	*CTS#*	*ELISA*	*Multispot HIV1/HIV2*	*p18*	*p24*	*p31*	*p40*	*gp41*	*p51*	*p55*	*p51/55*	*p65*	*gp120*	*gp160*	*Aptima*
RIL09335-6001		Positive	HIV-1 Positive	+	+	+	+	+			+	+	+	+	
RIL09336-6002		Positive	HIV-1 Positive	+	+	+	+	+			+	+	+	+	
RIL09341-6004		Positive	HIV-1 Positive	-	+	-	+	-			+	-	-	-	D
RIL09344-6001		Positive	HIV-1 Positive	+	+	+	+	+			+	+	+	+	
RIL09348-6004			Not Done	-	+	+	+	+			+	+	+	+	
RIL09351-6001		Positive	HIV-1 Positive	+	+	+	+	+			+	+	+	+	
RIL09351-6002		Not	Not Done												

RNA+ Result

Communication

- Direct and ongoing
  - Immediate contact from regional staff to Central Office for unexpected situations (e.g. invalid results, storage temperatures out of range, etc.)
  - Statewide Regional Coordinator & Program Manager calls – monthly, email, and Supervisory monthly calls
  - Electronic reporting of lab results via CLIMS
  - Direct contact with HIV lab staff when unusual situations arise
  - In-person meetings with Lab Director – quarterly
- Very important to ensure quality testing services

Continuous Quality Improvement

Examples in the ACT Program:

- Cost considerations
  - Less frequent running of controls
- Test system considerations
  - Supplemental (2 test) rapid test strategy
- Determination of tests used
  - Review Sensitivity/Specificity/PPV
- Personnel Issues

Lessons Learned

- Ongoing effort is required
- Significant time investment
- Systems and a schedule need to be in place
- Everyone has a role, and involvement needs to occur at all levels
- Lab involvement results in better outcomes
- Communication is key

Acknowledgements

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Thank You!

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