

APHL/CDC Project for Referral of HIV Nucleic Acid Amplification Testing (NAT) for US Public Health Laboratories (PHLs)

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Project Objectives

- To provide PHLs access to HIV-1 NAT in a shared service model
 - in a timely manner and
 - to enable all PHLs to identify HIV-1 infection earlier



PHL Eligibility and Enrollment

- PHL performing 3rd or 4th generation immunoassays and supplemental testing
- 39 laboratories enrolled
 - 33 have submitted specimens
 - 10 no longer participating
- Yearly Denominator Data

“Submitting PHL”



Specimen Criteria

- 3rd or 4th Gen IA reactive with negative or indeterminate supplemental test result
- Data Submission Form
 - Date(s) of specimen collection, receipt at submitting PHL, time/temp for storage
- 997 specimens submitted
 - 980 (98.3%) analyzed

Referral Laboratories

- Established 2 PHL Referral Laboratories
 - NY and FL
- Test and Report HIV-1 NAT to Submitting PHL
- Bi-monthly data reporting to APHL
 - laboratory, reported to submitting laboratory



Monitoring and Evaluation

- Monitor proportion of specimens needing HIV-1 NAT that were tested by Referral Lab
 - 3rd or 4th Gen IA reactive with discordant IA
 - Submitting PHL data vs. Referral Laboratory Cumulative Data
- Monitor proportion of acute specimens
 - Denominator Data and Cumulative Data
- Monitor turnaround time

Summary of Project Specimens

Year (July-June)	Enrolled PHLs Submitting Specimens	Specimens Received at Submitting PHLs ^a	Specimens that require HIV-1 ^b NAT testing	Specimens Tested at Referral Lab	HIV-1 NAT Reactive (% Positive of Tested)
2012-2013 ^c	22	4,778	290	141 (49%)	12 (9%)
2013-2014	27	440,634	731	415 (57%)	62 (15%)
2014-2015	25	319,135	598	424 (71%)	56 (13%)
2012-2015^d	33^e	773,294	2372	980 (41%)	130 (13%)

a) Cumulative denominator data from submitting PHLs. b) Specimens that are 3rd or 4th Generation IA reactive with discordant supplemental testing c) 2012-2013 was from August 2012 through June 2013 d) 2012-2015 includes analysis of all specimens submitted during the project. e) Only 33 enrolled PHLs submitted specimens during the time frame.

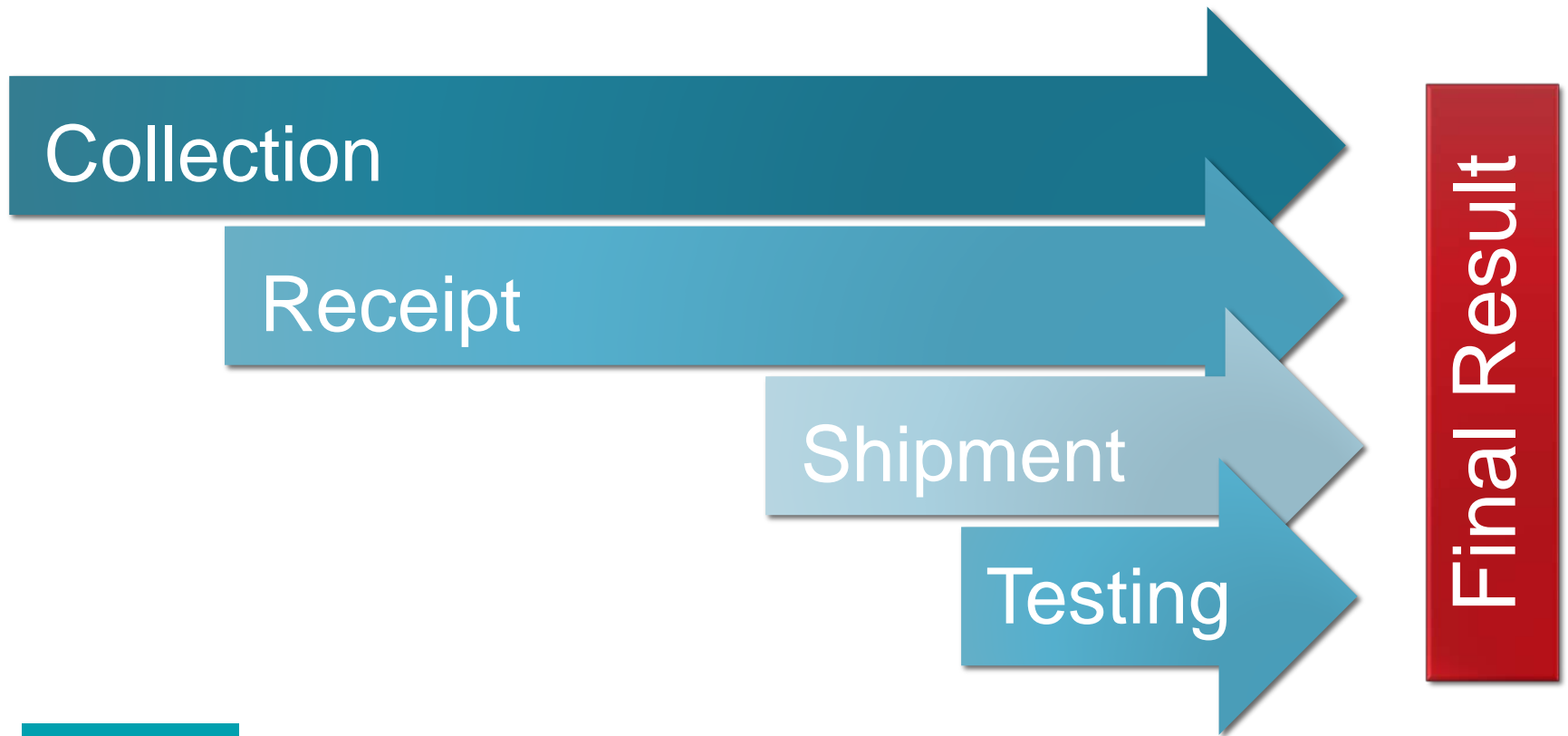
Why aren't labs sending all specimens?

- Insufficient quantity
 - 550uL minimum, 1.6mL ideal
- Pre-analytic requirements
 - Whole blood, plasma or serum stored for less than 72 hours at $\leq 25^{\circ}\text{C}$
 - Plasma or serum removed and stored up to 5 days at $2-8^{\circ}\text{C}$
 - Plasma or serum removed and stored at $\leq 20^{\circ}\text{C}$

How to keep your specimens within the requirements for HIV-1 NAT?

- Communicating with providers/submitters on specimen requirements
- Freeze specimen or aliquot to meet pre-analytic requirements
- Shipping
 - Prepare paperwork early
 - Training on proper packaging and shipping
 - Understanding the need to expedite shipment

What turnaround times are we monitoring?



Have turnaround times improved?

Monitored Intervals	Turnaround time Median (Mean) days		
	2012- 2013	2013- 2014	2014- 2015
Specimen collection to receipt in the submitting laboratory	1 (1.7)	1 (1.8)	1 (1.5)
Receipt in the submitting laboratory to shipment to referral laboratory	7 (15.6)	6 (8.1)	6 (7.1)
Receipt in referral laboratory to NAT test	2 (2.7)	1 (2.1)	1 (2.1)
Specimen collection to NAT result	13 (21)	11 (13)	10 (12)
Specimen collection to NAT test: <2 weeks	60%	75%	80%

How have submitting labs decreased turnaround times?

Collection to Receipt at Submitting Laboratory

- Communication about timely submission to the PHL
 - Send specimens as received, don't batch specimens to ship
- Using courier services to get specimens to the laboratory quicker than shipping

Analysis.
Answers.
Action.



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How have submitting labs decreased turnaround times? (cont.)

Receipt at Lab to Shipment to Referral Laboratory

- Modified testing
 - Condensed testing schedules
 - Removing set testing days
 - Increasing frequency of testing
- IQCP
- Shipping
 - Shipment on the same day as the result
 - Always have dry ice available

Analysis.
Answers.
Action.



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What is the Impact?

“... the HIV-1 NAT [project] has greatly helped their turn-around time to get people into care. If this was not an option, then they would have to track the person down and redraw in a month or so and start the process over again. They were very grateful for having this test available to them. ”

–from one submitting PHL

How can timely HIV testing impact linkage to care?

- 10 persons with reactive HIV-1 NAT
 - 9 of 10 enrolled and remain in care
 - 7 of 9 received baseline labs within 90 days of diagnosis
 - 6 of 9 patients have a suppressed VL<50 copies

What's next for the HIV-1 NAT Project?

- Improve number of specimens needing testing that are submitted
- Continue to provide timely testing and reporting
 - Working to improve TAT where possible
- Monitor HIV testing landscape & Adapt to Changing needs of PHLs
 - Role of newer/expensive supplemental testing

Thanks!

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**Please share any thoughts,
suggestions or success
stories**