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

- 3\textsuperscript{rd} or 4\textsuperscript{th} 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

<table>
<thead>
<tr>
<th>Year (July-June)</th>
<th>Enrolled PHLs Submitting Specimens</th>
<th>Specimens Received at Submitting PHLs</th>
<th>Specimens that require HIV-1 NAT testing</th>
<th>Specimens Tested at Referral Lab</th>
<th>HIV-1 NAT Reactive (% Positive of Tested)</th>
</tr>
</thead>
<tbody>
<tr>
<td>2012-2013&lt;sup&gt;c&lt;/sup&gt;</td>
<td>22</td>
<td>4,778</td>
<td>290</td>
<td>141 (49%)</td>
<td>12 (9%)</td>
</tr>
<tr>
<td>2013-2014</td>
<td>27</td>
<td>440,634</td>
<td>731</td>
<td>415 (57%)</td>
<td>62 (15%)</td>
</tr>
<tr>
<td>2014-2015</td>
<td>25</td>
<td>319,135</td>
<td>598</td>
<td>424 (71%)</td>
<td>56 (13%)</td>
</tr>
<tr>
<td>2012-2015&lt;sup&gt;d&lt;/sup&gt;</td>
<td>33&lt;sup&gt;e&lt;/sup&gt;</td>
<td>773,294</td>
<td>2372</td>
<td>980 (41%)</td>
<td>130 (13%)</td>
</tr>
</tbody>
</table>

- **a)** Cumulative denominator data from submitting PHLs.
- **b)** Specimens that are 3<sup>rd</sup> or 4<sup>th</sup> 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 ≤ 25°C
  – Plasma or serum removed and stored up to 5 days at 2-8°C
  – Plasma or serum removed and stored at ≤ 20°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?

Collection
Receipt
Shipment
Testing
Final Result
### Have turnaround times improved?

<table>
<thead>
<tr>
<th>Monitored Intervals</th>
<th>Turnaround time Median (Mean) days</th>
</tr>
</thead>
<tbody>
<tr>
<td>Specimen collection to receipt in the submitting laboratory</td>
<td>1 (1.7)</td>
</tr>
<tr>
<td>Receipt in the submitting laboratory to shipment to referral laboratory</td>
<td>7 (15.6)</td>
</tr>
<tr>
<td>Receipt in referral laboratory to NAT test</td>
<td>2 (2.7)</td>
</tr>
<tr>
<td>Specimen collection to NAT result</td>
<td>13 (21)</td>
</tr>
<tr>
<td>Specimen collection to NAT test: &lt;2 weeks</td>
<td>60%</td>
</tr>
</tbody>
</table>
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
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
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