Challenges and Success of Implementing the HIV Diagnostic Testing Algorithm: Reports from Four HIV Surveillance Programs

2016 HIV Diagnostic Conference

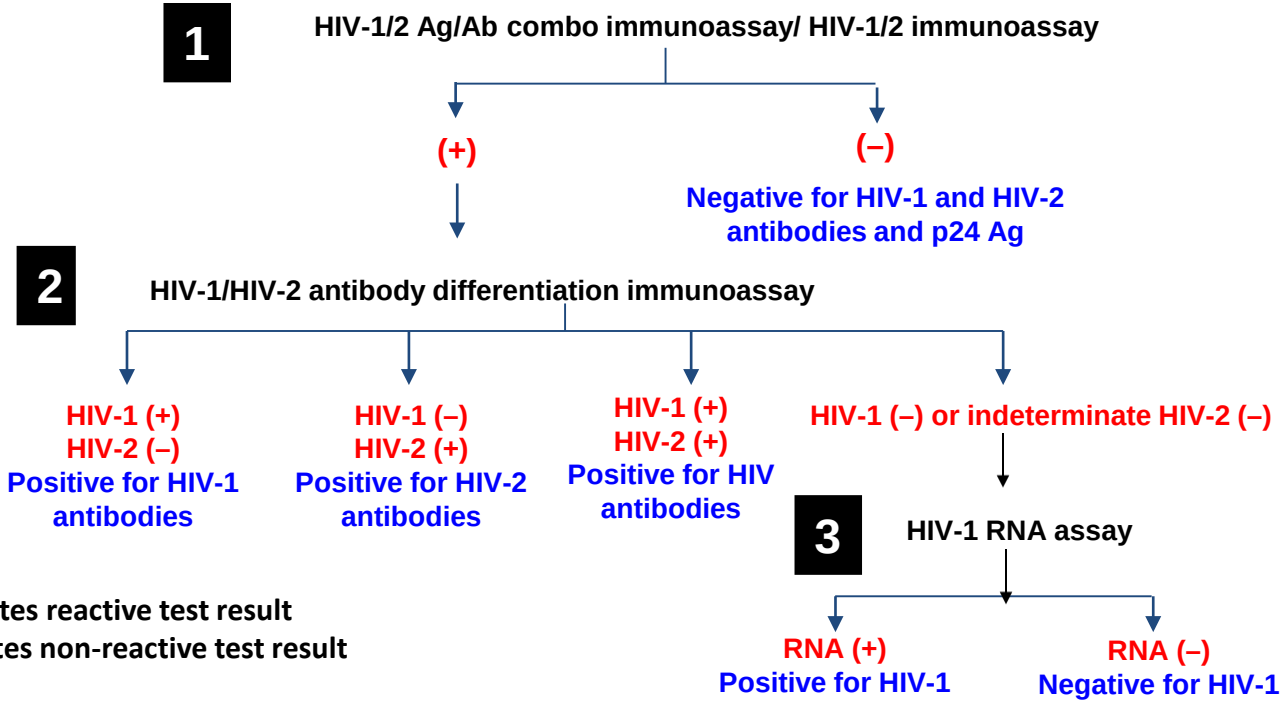
Outline

- Challenges of Implementing Public Health Reporting of the HIV Diagnostic Testing Algorithm

- Public Health Efforts and Successful Strategies
  - Educational efforts directed towards laboratories
  - Educational efforts directed towards clinicians
  - Roles of Health Department partner services and surveillance investigation

- Discussion

HIV Diagnostic Testing Algorithm



(+) indicates reactive test result
(-) indicates non-reactive test result

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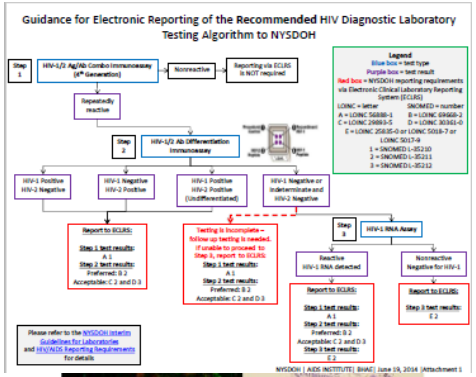
Main Challenges Related to Implementing Public Health Reporting of the Diagnostic Algorithm

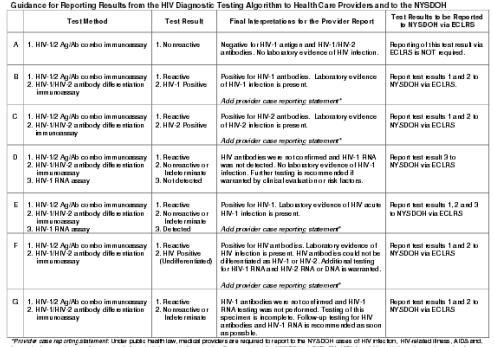
- Incomplete reporting of components of the algorithm is common
- Partial execution of the algorithm is common; reliance on specific clinician order
- Referral of specimen necessitates linking results to determine final test result
- Alternate algorithms and laboratory-specific reporting nuances
- Inconsistently used LOINC or laboratory proprietary coding
- Initial screening outside of the laboratory
- Not all reports represent newly diagnosed persons
- Unclear or nonspecific reports to the ordering clinician

Educational Efforts Directed Towards Laboratories (1)

Broad dissemination of clear and concise educational materials and official guidelines

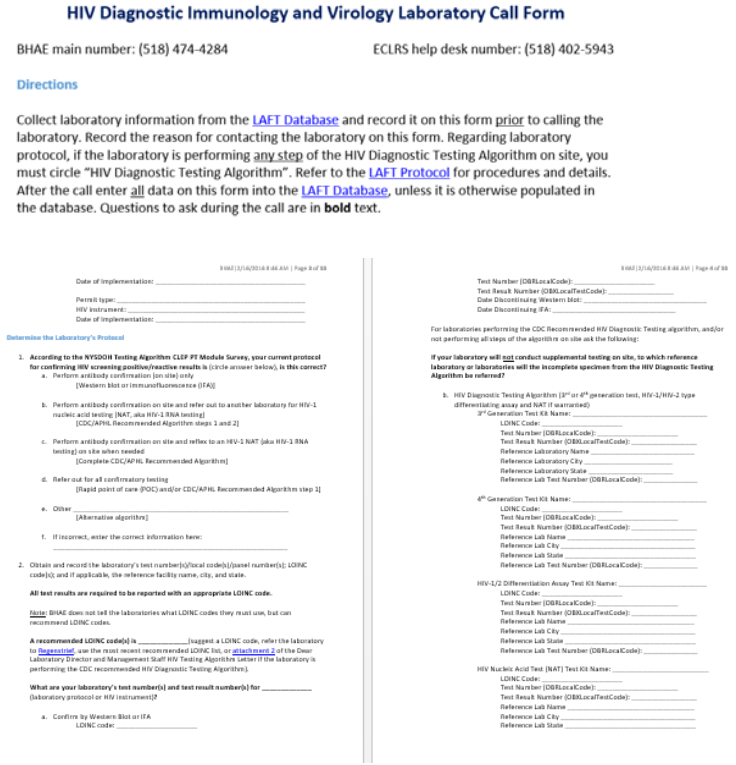
- New York State Laboratory Reporting of Communicable Diseases
- New York State HIV reporting guidelines, schematics and reporting grid
- CDC/APHL Laboratory Testing for the Diagnosis of HIV Infection





Educational Efforts Directed Towards Laboratories (2)

Comprehensive and standardized laboratory recruitment process with verification of permits, instruments, testing algorithms, LOINC, laboratory specific local codes, referral facility, review of NYS PHL reporting requirements, file format, anticipated testing volume



HIV Diagnostic Immunology and Virology Laboratory Call Form

BHAE main number: (518) 474-4284 ECLRS help desk number: (518) 402-5943

Directions

Collect laboratory information from the LAFT Database and record it on this form prior to calling the laboratory. Record the reason for contacting the laboratory on this form. Regarding laboratory protocol, if the laboratory is performing any step of the HIV Diagnostic Testing Algorithm on site, you must circle "HIV Diagnostic Testing Algorithm". Refer to the LAFT Protocol for procedures and details. After the call enter all data on this form into the LAFT Database, unless it is otherwise populated in the database. Questions to ask during the call are in **bold** text.

Date of implementation: _____

Permit type: _____
HIV instrument: _____
Date of implementation: _____

Determine the Laboratory's Protocol

1. **According to the NYSDOH Testing Algorithm CLEP PT Module Survey, your current protocol for confirming HIV screening positive/reactive results is** (circle answer below), **is this correct?**
   a. Perform antibody confirmation (on site) only
      [Western Blot or immunofluorescence (IFA)]
   b. Perform antibody confirmation on site and refer out to another laboratory for HIV-1 nucleic acid testing (NAT, aka HIV-1 RNA testing)
      [CDC/APHL Recommended Algorithm steps 1 and 2]
   c. Perform antibody confirmation on site and reflex to an HIV-1 NAT (aka HIV-1 RNA testing) on site when needed
      [Complete CDC/APHL Recommended Algorithm]
   d. Refer out for all confirmatory testing
      [Rapid point of care (POC) and/or CDC/APHL Recommended Algorithm step 1]
   e. Other _____
      [Alternative algorithm]
   f. If incorrect, enter the correct information here:

2. Obtain and record the laboratory's test number(s)/local code(s)/panel number(s); LOINC code(s); and if applicable, the reference facility name, city, and state.

All test results are required to be reported with an appropriate LOINC code.

Note: BHAE does not tell the laboratories what LOINC codes they must use, but can recommend LOINC codes.

A recommended LOINC code(s) is _____ (suggest a LOINC code, refer the laboratory to Regenstrief, use the most recent recommended LOINC list, or attachment 2 of the Dear Laboratory Director and Management Staff HIV Testing Algorithm Letter if the laboratory is performing the CDC recommended HIV Diagnostic Testing Algorithm).

What are your laboratory's test number(s) and test result number(s) for _____ (laboratory protocol or HIV instrument)?

a. Confirm by Western Blot or IFA
   LOINC code: _____

Test Number (DBXLocalCode): _____
Test Result Number (DBXLocalTestCode): _____
Date Discontinuing Western blot: _____
Date Discontinuing IFA: _____

For laboratories performing the CDC Recommended HIV Diagnostic Testing algorithm, and/or not performing all steps of the algorithm on site ask the following:

If your laboratory will not conduct supplemental testing on site, to which reference laboratory or laboratories will the incomplete specimen from the HIV Diagnostic Testing Algorithm be referred?

b. HIV Diagnostic Testing Algorithm (3rd or 4th generation test, HIV-1/HIV-2 type differentiating assay and NAT if warranted)
   3rd Generation Test Kit Name: _____
   LOINC Code: _____
   Test Number (DBXLocalCode): _____
   Test Result Number (DBXLocalTestCode): _____
   Reference Laboratory Name _____
   Reference Laboratory City _____
   Reference Laboratory State _____
   Reference Lab Test Number (DBXLocalCode): _____

   4th Generation Test Kit Name: _____
   LOINC Code: _____
   Test Number (DBXLocalCode): _____
   Test Result Number (DBXLocalTestCode): _____
   Reference Lab Name _____
   Reference Lab City _____
   Reference Lab State _____
   Reference Lab Test Number (DBXLocalCode): _____

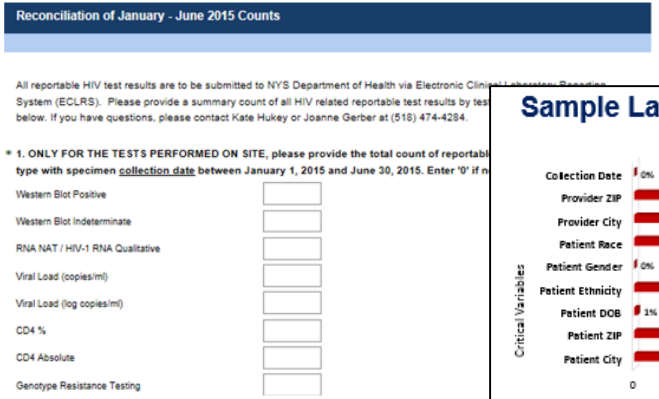
   HIV-1/2 Differentiation Assay Test Kit Name: _____
   LOINC Code: _____
   Test Number (DBXLocalCode): _____
   Test Result Number (DBXLocalTestCode): _____
   Reference Lab Name _____
   Reference Lab City _____
   Reference Lab State _____
   Reference Lab Test Number (DBXLocalCode): _____

   HIV Nucleic Acid Test (NAT) Test Kit Name: _____
   LOINC Code: _____
   Test Number (DBXLocalCode): _____
   Test Result Number (DBXLocalTestCode): _____
   Reference Lab Name _____
   Reference Lab City _____
   Reference Lab State _____

Educational Efforts Directed Towards Laboratories (3)

Twice annual count resolution and lab assessment distribution and reconciliation

Biennial permit renewal regulatory audit process

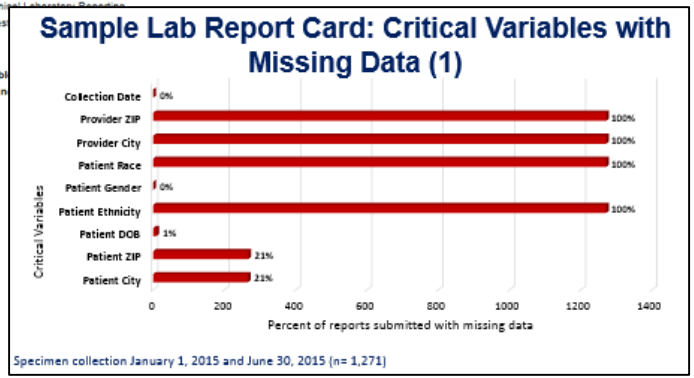

Reconciliation of January - June 2015 Counts

All reportable HIV test results are to be submitted to NYS Department of Health via Electronic Clinical Laboratory Reporting System (ECLRS). Please provide a summary count of all HIV related reportable test results by test below. If you have questions, please contact Kate Hukey or Joanne Gerber at (518) 474-4284.

* 1. ONLY FOR THE TESTS PERFORMED ON SITE, please provide the total count of reportabl type with specimen collection date between January 1, 2015 and June 30, 2015. Enter '0' if n

Western Blot Positive
Western Blot Indeterminate
RNA NAT / HIV-1 RNA Qualitative
Viral Load (copies/ml)
Viral Load (log copies/ml)
CD4 %
CD4 Absolute
Genotype Resistance Testing

Figure 1: Sample Count Resolution Survey



	Counts Received in SurveyMonkey	Counts Received in ECLRS	Difference
WB +	165	125	-40
WB Ind	4	3	-1
RNA NAAT	0	0	0
VL (copies)	2785	3071	286
VL (log copies)	0	0	0
CD4%	5306	5553	247
CD4 Abs	0	5562	5562
Geno	0	0	0
Step 1 Dx Alg (3rd/4th Gen Reactive)	14116	0	-14116
Step 2 Dx Alg (Multispot)	0	0	0
Total	22376	14314	-8062

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Educational Efforts Directed Towards Clinicians

1. The problems
2. What surveillance does to help
3. What labs could do to help

Problem 1: Confusion

- Physicians and testing sites confused about:
  - Proper/best HIV tests to order
  - Interpretation of HIV test results
  - Follow up process for discordant results
- Electronic ordering adds to confusion
  - Long lists of HIV tests
  - Type Differentiation tests looks like a screen
- Providers deal with multiple laboratories

Surveillance Helps

- Phone call to each physician/site when:
  - Improper tests ordered
  - NAT needed
- HIV Testing Guidance sent by email or fax following phone conversations
- Phone number listed above lab reporting section of case report
- Suggest attaching lab reports to case report
- Provide examples of how to report lab results in case report instructions

Case Report Instructions: How to Report Labs

2. Example of reactive rapid Ag/Ab 4th gen test (Determine) followed by standard lab algorithm:

HIV DIAGNOSTIC TESTS – please report all positive and subsequent negative tests											
Type of Test ***At least 2 Antibody Tests must be indicated for an HIV diagnosis*** IA = ImmunoAssay	Collection Date	Rapid Test	Positive or Reactive	Reactive for Ag	Reactive for Ab	HIV1 Ab Positive	HIV 2 Ab Positive	Indeterminate	Undifferentiated	Negative or NonReactive	Manufacturer
HIV-1/2 Ag/Ab **Lab** IA (4th Gen *Discriminating*)		N									
HIV-1/2 Ag/Ab **Rapid** IA (4th Gen *Discriminating*)	2/5/2016	Y			X						Alere Determine
HIV-1/2 Ag/Ab **Lab** IA (4th Gen)	2/5/2016	N	X								
HIV-1/2 Ab IA (2nd or 3rd Gen)		Y N									
HIV1/HIV 2 Type Differentiating IA	2/5/2016	Y				X					Multispot or Geenius
HIV-1 Western Blot		N									
HIV-1 RNA/DNA Qualitative NAAT		N									
OTHER:_____											
Last Negative Test (prior to HIV diagnosis)		Y N									
If HIV lab tests were NOT documented, is HIV diagnosis confirmed by a clinical care provider? ☐Yes ☐No ☐Unk IF YES, please provide date of documentation by care provider:_____/_____/_____											

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HIV Testing Guidance

SELECTING APPROPRIATE HIV DIAGNOSTIC TESTS

Guidance from the Michigan Department of Community Health/HIV Surveillance Program

With the release of improved HIV detection tests, we now have the ability to detect HIV infection earlier and identify patients in the acute phase when high levels of virus increase the likelihood of transmitting infection. Please follow the recommendations below for earlier detection of HIV and therefore the increased possibility of reducing transmission.

Key Points:

- Initial HIV screens should detect both antigen and antibody
- Two different reactive HIV tests may make an HIV diagnosis. If the second test is nonreactive or indeterminate, a third test must be run
- All initial reactive screening tests as well as all subsequent tests (regardless of the result) run must be reported to the health department

Testing Steps: (See generations of assays explained later in document)

Step 1: Initial screening test

- ✓ Best: 4th generation antigen/antibody assay. Performed in lab or rapid test
- ✓ Good: 3rd generation antibody assay that detects both IgG and IgM
- ✓ Acceptable: 2nd generation IgG antibody assay. Includes most rapid tests that do not detect HIV antigen or IgM antibody

Step 2: Supplemental test

- ✓ Best: HIV-1/HIV-2 antibody type differentiating assay (e.g. *Multispot, Geenius*)
- ✓ Good: Western blot or IFA (now being phased out)

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Problem 2: NAT Needed

- Reactive screen followed by negative supplemental test: need NAT
- Recommendation to submit fresh plasma often lost at bottom of lab report
- Labs should ideally reflex to FDA approved NAT, even if at another laboratory

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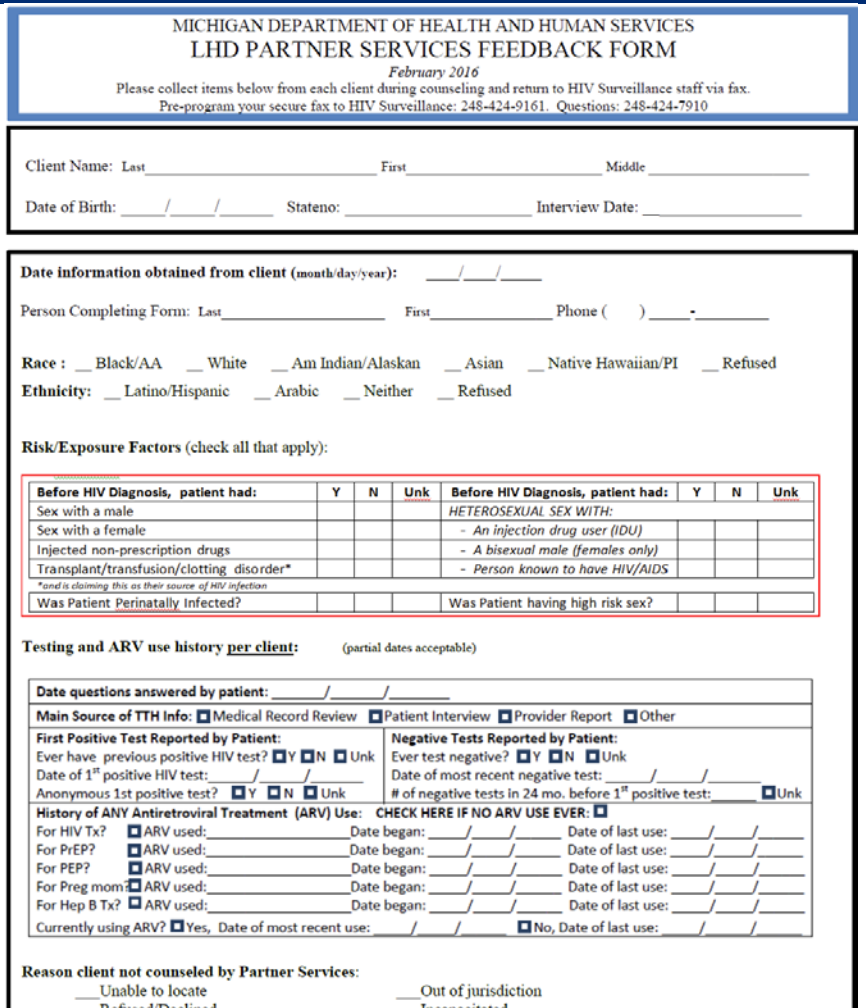

MICHIGAN DEPARTMENT OF HEALTH AND HUMAN SERVICES

LHD PARTNER SERVICES FEEDBACK FORM

February 2016

Please collect items below from each client during counseling and return to HIV Surveillance staff via fax.
Pre-program your secure fax to HIV Surveillance: 248-424-9161. Questions: 248-424-7910

Client Name: Last_____ First_____ Middle _____

Date of Birth: ____/____/____ Stateno: _____ Interview Date: _____

Date information obtained from client (month/day/year): ____/____/____

Person Completing Form: Last_____ First_____ Phone ( ) ____-____

Race : __ Black/AA __ White __ Am Indian/Alaskan __ Asian __ Native Hawaiian/PI __ Refused

Ethnicity: __ Latino/Hispanic __ Arabic __ Neither __ Refused

Risk/Exposure Factors (check all that apply):

Before HIV Diagnosis, patient had:	Y	N	Unk	Before HIV Diagnosis, patient had:	Y	N	Unk
Sex with a male				*HETEROSEXUAL SEX WITH:*			
Sex with a female				- *An injection drug user (IDU)*			
Injected non-prescription drugs				- *A bisexual male (females only)*			
Transplant/transfusion/clotting disorder*				- *Person known to have HIV/AIDS*			
**and is claiming this as their source of HIV infection*							
Was Patient Perinatally Infected?				Was Patient having high risk sex?			

Testing and ARV use history per client: (partial dates acceptable)

Date questions answered by patient: _____/_____/_____

Main Source of TTH Info: ☐ Medical Record Review ☐ Patient Interview ☐ Provider Report ☐ Other

First Positive Test Reported by Patient:	Negative Tests Reported by Patient:
Ever have previous positive HIV test? ☐ Y ☐ N ☐ Unk	Ever test negative? ☐ Y ☐ N ☐ Unk
Date of 1st positive HIV test: ____/____/____	Date of most recent negative test: ____/____/____
Anonymous 1st positive test? ☐ Y ☐ N ☐ Unk	# of negative tests in 24 mo. before 1st positive test: ____ ☐ Unk

History of ANY Antiretroviral Treatment (ARV) Use: CHECK HERE IF NO ARV USE EVER: ☐

For HIV Tx?	☐ ARV used: _____	Date began: ____/____/____	Date of last use: ____/____/____
For PrEP?	☐ ARV used: _____	Date began: ____/____/____	Date of last use: ____/____/____
For PEP?	☐ ARV used: _____	Date began: ____/____/____	Date of last use: ____/____/____
For Preg mom?	☐ ARV used: _____	Date began: ____/____/____	Date of last use: ____/____/____
For Hep B Tx?	☐ ARV used: _____	Date began: ____/____/____	Date of last use: ____/____/____

Currently using ARV? ☐ Yes, Date of most recent use: ____/____/____ ☐ No, Date of last use: ____/____/____

Reason client not counseled by Partner Services:

___Unable to locate ___Out of jurisdiction

Partner Services Feedback Form

Also used to request blood draws in discordant testing situations

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What Labs Could Do to Help

- Utilize specimen processing staff to follow up when submitters order questionable tests
- Restrict stand-alone supplemental tests by special arrangement only.
- Reflex to FDA approved NAT in discordant testing situations even if at another laboratory.
  - Worries about contamination from running NAT on original serum have not born out.
- Coordinate with other labs, governmental agencies to standardize ordering and messaging

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