

TB Shared Services – Missouri and Iowa

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Request for Proposal: Exploring Novel Approaches to Shared TB Laboratory Services

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Objectives of the Project

- Analyze the data
- Determine turnaround time comparing shared services vs. provided
- Calculate the cost of sharing the service
- Review successes and problems encountered
- Register satisfaction/dissatisfaction with sharing the service

Flowchart for Submitting Respiratory Sediment to IA for NAAT

Specimen must be part of the initial diagnostic set of three sputa or a Broncheal Alveolar

MO: is the specimen smear positive?

YES

NO

MO: Does the patient have a previous positive naat?

MO: Was a naat ordered?

YES

NO

YES

NO

Do not ship

MO: Does the patient have a previous positive naat?

YES

Do not ship

NO

Ship a 1mL aliquot of processed sediment to IA

IA: document date received
(this is automatically captured in our database)

IA: perform MTB/RIF test on GeneXpert

IA: is rpoB mutation detected?

YES

NO

IA: report the results as preliminary and ship to CDC for MDDR

IA: issue final report

Data Summary

Total # of MO specimens tested	117
Total # Specimens that were Smear positive	31
Smear positive/Mtbc culture positive	14
Smear positive/Mtbc culture positive, positive NAAT in Iowa (1 specimen unsat for testing in IA)	13
Smear negative	86
Smear negative, culture positive	4
Smear negative, culture positive, NAAT neg	3
Smear negative, culture positive, NAAT pos	1

72 Patients Tested

Specimens Submitted	# of Pt. N=72	Smear Neg N=46	Smear Pos N=29
1	41	17	24
2	17	15*	5*
3	14	14	0

*Three patients had two specimens each submitted with one positive AFB smear and one negative AFB smear and included in these counts.

Mtbc Culture Positive Patients n=17

Specimens Submitted	NAAT Positive	NAAT Negative
1	14	1
2	1	0
3	0	1

Interesting Findings

- Of the 117 tested (86 smear negative, 4 smear negative and culture positive)
 - Smear negative/culture positive specimen with positive NAAT in Iowa: 1
 - 3 smear negative/culture positive specimens with a negative NAAT in Iowa (represents 2 patients).
 - One of the patients had only one specimen submitted to Iowa since MO Public Health was notified that this patient had a BAL culture positive for Mtbcc at a hospital)

Interesting Findings cont.

- 29 specimens were smear positive:
 - Total # of smear positive/Mtbc culture positive specimens: 14
 - Total # of smear positive/Mtbc culture positive specimens with positive NAAT in Iowa: 13 (one was not satisfactory for testing due to transport issues with time and temperature)
- Diagnostic specimen that was first positive by NAAT: all were first specimens
 - # of specimens with discrepant results between MO MTD and IA NAAT: 0

Shared Services Project Enablers

- Electronic reporting and email notification when a result is ready to retrieve
- Web portal access to results (password protected)
- 6 day per week testing schedule in Iowa

The screenshot displays the State Hygienic Laboratory website. At the top left is the logo for the State Hygienic Laboratory at The University of Iowa. On the top right, there are navigation links for Home, Contact, Calendar, IT, and Jobs@SHL, along with a Google Custom Search box. The main content area features a large green banner with the text "TEST RESULTS" and a photograph of a person working at a computer. Below the banner, there is a sidebar with a list of services: "about the SHL", "environmental", "newborn and Maternal Screening", "disease Control", "education / Training", "certification Programs", "publications", and "news". The main content area includes a news item titled "Severe Combined Immune Deficiency (SCID) newborn screening pilot to begin in June - IDPH Announcement". Below this, there are four buttons for "OpenELIS", "Neonatal Screening", "PHIMS", and "ELIS". Further down, there are links for "Fillable PDF Forms", "Results Web Access Application", "Request for Paperless Result Delivery", "Web Access Application Manuals", and "OpenELIS Manual". At the bottom right, there is a link for "PHIMS Manual".

Turnaround Time: Missouri MTD

	Same Day	1 Day	2 Days
Smear Positive n=28	26 (93%)	2 (7%)	0
Smear Negative n=11	5 (46%)	3 (27%)	3 (27%)

Turnaround Time: Iowa NAAT

Once specimen is in Iowa

TAT	Number (%)
2.4 h	4 (3.4%)
4.8 h	49 (42.2%)
7.2 h	47 (40.5%)
9.6 h	6 (5.2%)
12.0 h	6 (5.2%)
14.4 h	2 (1.7%)
24 h	1 (.9%)
50.4 h*	1 (.9%)

From specimen receipt in Missouri

TAT	Number (%)
1.6 d	49 (42.2%)
1.7 d	30 (25.9%)
1.8 d	3 (2.6 %)
2-3 d	22 (19%)*
>3 d	12 (10%)* *

*9 delayed due to FedEx

** due to weather issues, holiday weekends, and inhibited specimens repeated

*Initial result invalid and repeated

Financial Impact –the cost of doing

- MTD Costs (Missouri)
 - Direct cost to test one specimen per day: \$224.17
 - With indirect costs added-one per day: \$311.15
 - Direct cost to do five per day (what we had as maximum batch at that time): \$125.55
 - With indirect costs added-five per day: \$174.27
- Cepheid Costs (Iowa)
 - Direct costs to do one: \$123.71
 - With indirect costs for one: \$171.71
 - Direct costs to do 4 per day (typical batch): \$116.04
 - With indirect costs for 4 per day: \$161.06
 - Direct costs to do 12 per day (max batch): \$106.93
 - With indirect costs for 12 per day: \$148.41

Financial Impact –the cost of sharing

- Fed Ex + Labor \$2,962.84
 - 57 shipments of 117 specimens
 - Average cost / shipment \$37.64
 - Average cost per specimen \$25.32
 - Missouri average savings to send to Iowa \$78.33
 - Reduction in cost per specimen to Iowa of 100-200 additional specimens per year \$1.25-\$2.25 per test

Cost of Shared Service

Item	Cost
MSPHL shipping cost/test	\$37.64
SHL test performance cost	\$121.43
Total cost of shared service/test	\$159.07
MSPHL cost of performing MTD	\$311.15
Savings per specimen*	\$152.08
At maximum batch size (5) savings (MSPHL \$174.27/test - \$159.07)**	\$15.20

* Assumes one test/day

** Assumes instrument is already purchased

Successes

- 5/3/2013 MO-96: Specimen submitted to IA laboratory for NAAT as requested by the physician. IA performed the test and it was NAAT positive for MTBC & RIF resistance not detected by the GeneXpert. MO did not perform the NAA test due to its current policy of testing only AFB smear positive specimens from patients exhibiting signs and symptoms of TB.
- This speaks to importance of performing NAAT on smear negative specimens.

Challenges

- Most challenges associated dealt with overnight transport of specimen sediment from Missouri to Iowa. Out of 57 shipments, 9 were delayed due to issues with the carrier or weather.
- No test is 100%, a smear negative specimen that was negative by MTD in Missouri and negative by the Cepheid GeneXpert test in Iowa but grew *M. tuberculosis* complex.
- One specimen was NAAT positive for Mtb with a result of “invalid” for the detection of potential rifampin resistance. Sediment was sent to CDC for MDDR testing and no mutations were detected. The conventional susceptibility testing displayed rifampin susceptibility.
- One smear negative specimen was NAAT positive for Mtb with a result of “detected” for a rifampicin mutation indicative of rifampicin resistance. Sediment was sent to CDC for MDDR. CDC reported no Mtb amplification detected. This specimen’s culture was no growth but the patient had a pleural fluid that grew Mtb at Quest Laboratories.

Continue sharing the NAAT?

- Question – does the data from the share service pilot for NAAT, demonstrate that the shared services should continue with either Missouri or Iowa submitting specimens and if there is capacity to expand the sharing of this service to other states.
 - By sharing the service you add one day or more to the turnaround time
 - There is substantial cost sharing (\$152/specimen)
 - It takes a dedicated staff to make it work

Customer Satisfaction - Missouri

- **Roy Tu'ua's Comments:**
 - *ELR was an immense benefit because results were easily accessible through the web any day of the week*
 - *Staff time was saved by not performing MTD*
 - *Shared services equates to less time spent maintaining competency of lab personnel but there is also a loss of skill and expertise*
- *“With the decrease in TB incidence in the US along with decreased funding, thinking outside the box and cultivating relationships with other State Laboratories is needed to ensure availability of TB testing services.”*

Customer Satisfaction - Iowa

- **Ryan Jepson's Comments:**
 - Weather delays for overnight shipping presented the biggest problem.
 - Testing aspect was very easy because MSPHL sent every thing correctly, pH'd and in 2 ml screw cap vials.
 - When CDC sent results on MDDR testing, the result was faxed to MSPHL
- *“Overall, it was very easy to incorporate Missouri's NAATs into SHL daily testing.”*

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