Process Mapping for Mycobacteriology Workflow Improvement in the New Jersey Public Health and Environmental Laboratories

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A snapshot of the TB unit in New Jersey

- We only operate from 8-4, 5 days a week (closed weekends and holidays)
- 2 ½ FTE staff
- Specimen volume ~2200/year
- Specimens come primarily from state TB clinics, large number of follow-up specimens
- Delivered in the afternoons by courier, on a pre-defined schedule
- Tests performed: Fluorescent smear, culture and identification, drug susceptibility testing, (no NAAT)

Project Conception

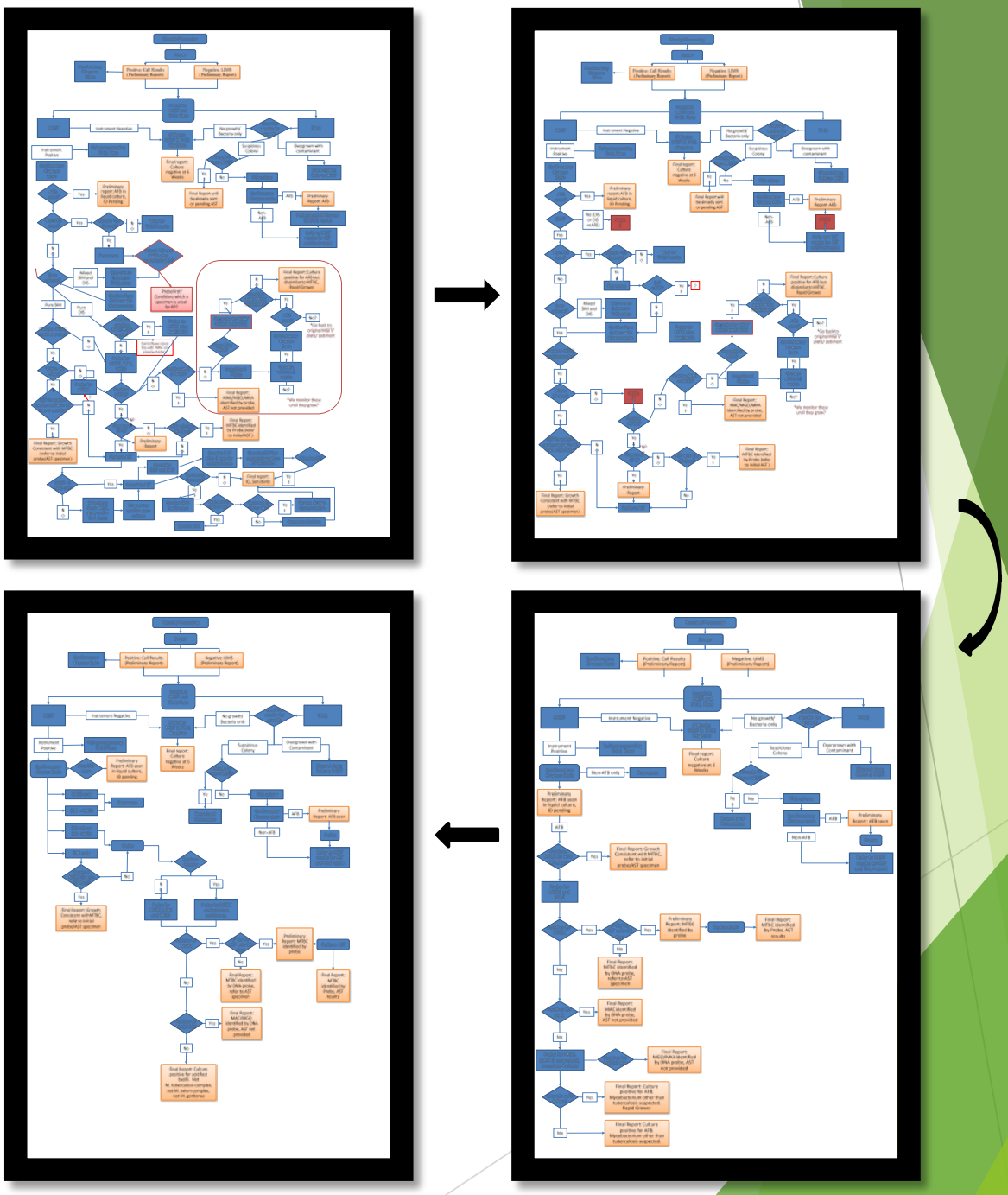
- **Staff turnover, lack of transfer of knowledge**
- **Trend of increasing turnaround times**

- **Goal 1: Improve Identification turnaround time**
- **Goal 2: Improve DST turnaround time**
- **Goal 3: Standardize paperwork and reporting, simplify workflow**

- **Overall goal to improve efficiency while decreasing stress on lab staff**

Process Mapping

- Flowchart diagrams of the entire TB workflow
- These were refined, simplified and edited over a course of discussions between lab staff, managers and the state TB program

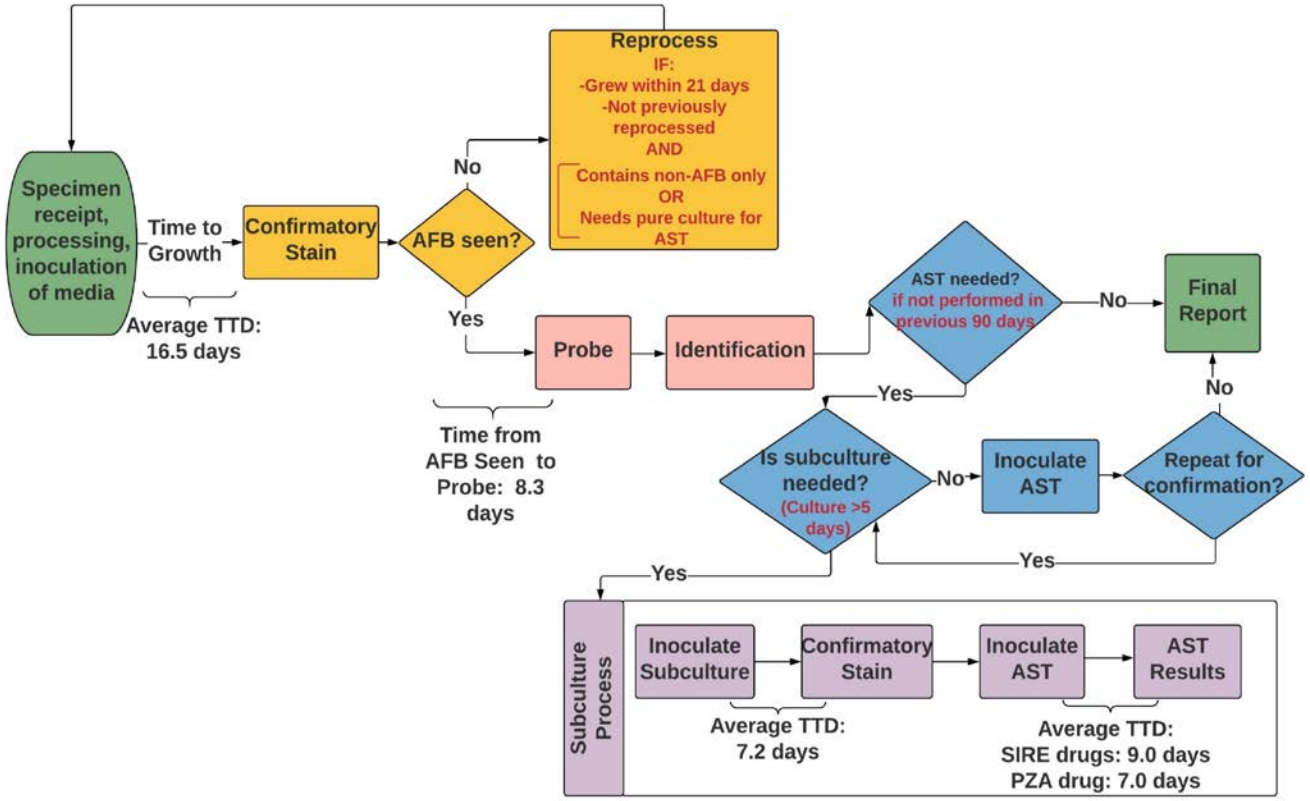


Data generation and analysis

- LIMS system mining for turnaround time
  - Each test result in LIMS is date stamped
  - Exported all results and corresponding dates that correlated to each step in the process map into Excel for analysis
- Analysis: averages and counts based on variables of interest
  - Filter results to look only at samples with specific qualities (e.g. all TB positive samples, met/unmet turnaround time goal, etc.)

	B	E	F	G	H	I	K	X	Y	Z	AJ	AK	AL	AN	AP	AQ	AR
1	Sample ID	Collection Date	Received Date	Process Date	MGIT off date	# Days TTD in MGIT	Reprocess Date	MM sub date	MM off date	MM TTD	MGIT off > probe date	Probe Date	Repeat Probe	ID Date	Probe>ID Date TAT	Rec>ID TAT	MET ID TAT
7	1610-139	10/25/2016	10/26/2016	27-Oct	14-Nov	15	15-Nov	12/6/2016	12/12/2016	6	32	16-Dec		16-Dec	0	51	No
18	1611-097	11/15/2016	11/17/2016	18-Nov	5-Dec	17	6-Dec	12/21/2016	12/29/2016	8	11	16-Dec	21-Dec	21-Dec	5	34	No
20	1611-099	11/16/2016	11/17/2016	18-Nov	12-Dec	24	19-Dec	1/6/2017	1/12/2017	6	4	16-Dec		20-Dec	4	33	No
103	1612-014	12/2/2016	12/2/2016	5-Dec	22-Dec	17		12/28/2016	1/5/2017	8	6	28-Dec		28-Dec	0	26	No
230	1612-147	1/5/2017	1/5/2017			7		1/24/2017	2/1/2017	8		12-Jan		17-Jan	5	12	Yes
234	1612-151	12/28/2016	12/29/2016	3-Jan	17-Jan	15	20-Jan	2/7/2017	2/14/2017	7	10	27-Jan		27-Jan	0	29	No
431	1702-015	2/1/2017	2/1/2017	2-Feb	28-Feb	26		3/7/2017	3/20/2017	13	6	6-Mar		6-Mar	0	33	No
551	1702-135	2/23/2017	2/24/2017	27-Feb	10-Mar	11		3/16/2017	3/22/2017	6	6	16-Mar		17-Mar	1	21	Yes
581	1703-007	2/28/2017	3/1/2017	3-Mar	21-Mar	18		4/5/2017	4/12/2017	7	1	22-Mar	5-Apr	5-Apr	14	35	No
606	1703-032	3/2/2017	3/3/2017	6-Mar	3-Apr	19		4/5/2017	4/12/2017	7	2	5-Apr		6-Apr	1	34	No
620	1703-052	3/7/2017	3/8/2017	3/9/2017	3-Apr	24		4/5/2017	4/12/2017	7	2	5-Apr		5-Apr	0	28	No
736	1703-169	3/27/2017	3/30/2017	3-Apr	12-Apr	12		4/19/2017	5/3/2017	14	7	19-Apr	4/26/17,	19-Apr	0	20	Yes
790	1704-020	4/5/2017	4/5/2017	6-Apr	21-Apr	15	10-May	5/3/2017	5/10/2017	7	12	3-May		3-May	0	28	No
862	1704-092	4/11/2017	4/19/2017	20-Apr	11-May	21	26-May	6/12/2017	6/19/2017	7	13	24-May	30-Jun	24-May	0	35	No
902	1704-132	4/27/2017	4/28/2017	1-May	15-May	14	16-May	6/5/2017	6/12/2017	7	18	2-Jun	22-Jun	2-Jun	0	35	No
910	1705-008	5/1/2017	5/2/2017	4-May	2-Jun	29		6/12/2017	6/20/2017	8	11	13-Jun	22-Jun	22-Jun	9	51	No
930	1705-029	5/4/2017	5/5/2017	8-May	19-Jun	37		6/22/2017	6/29/2017	7	2	21-Jun		21-Jun	0	47	No
979	1705-078	5/10/2017	5/15/2017	15-May	8-Jun	24		6/22/2017	6/29/2017	7	14	22-Jun		22-Jun	0	38	No

Data analysis



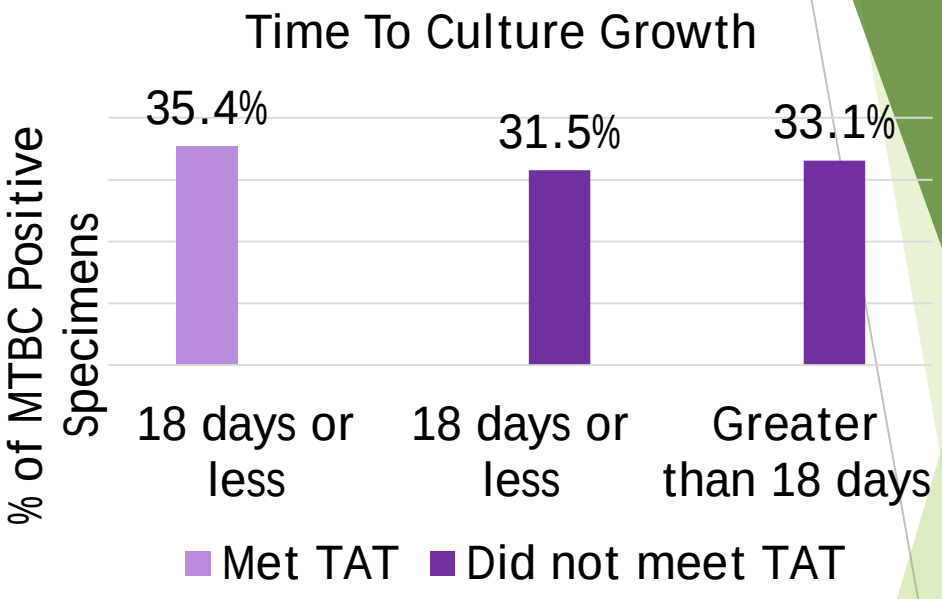
Three distinct steps identified

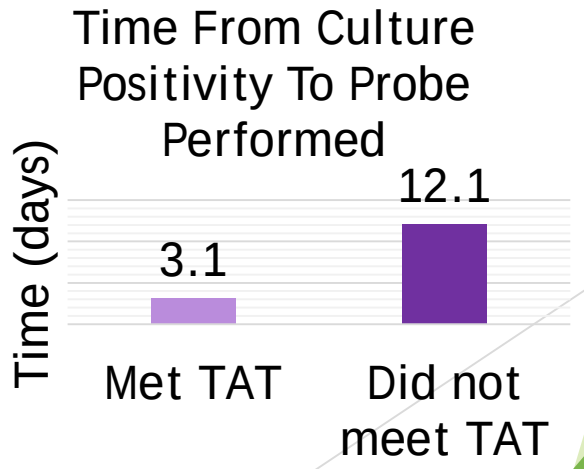
- Growth and identification of suspect AFB
- Complex identification by DNA Probe
- Inoculation of Antimycobacterial susceptibility testing
  - If DST is not inoculated within 5 days of positivity, specimens need to be subcultured to get a fresh culture

Average time to detection (TTD) highlighted for key processes

Results

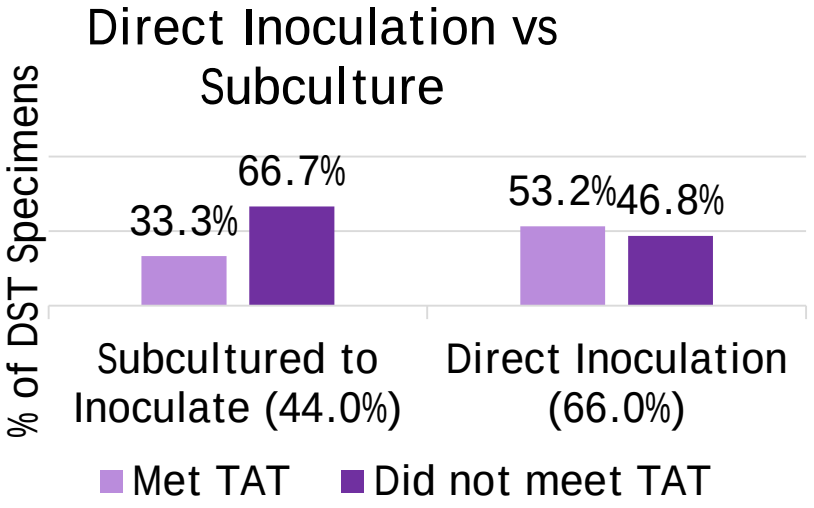
1. **Time to culture growth is a major barrier for 21 day identification TAT**
   - 18 days is the maximum time a specimen can grow and still achieve a 21 day turnaround
   - 35% of all positive specimens in 2017 took more than 18 days to grow to positivity
2. **There is a gap between when a culture becomes positive and when DNA probe testing is performed**
   - Due to multiple factors
     - day of the week the specimen becomes positive
     - testing volume, batching of specimens,
     - patient has previous history of positive cultures

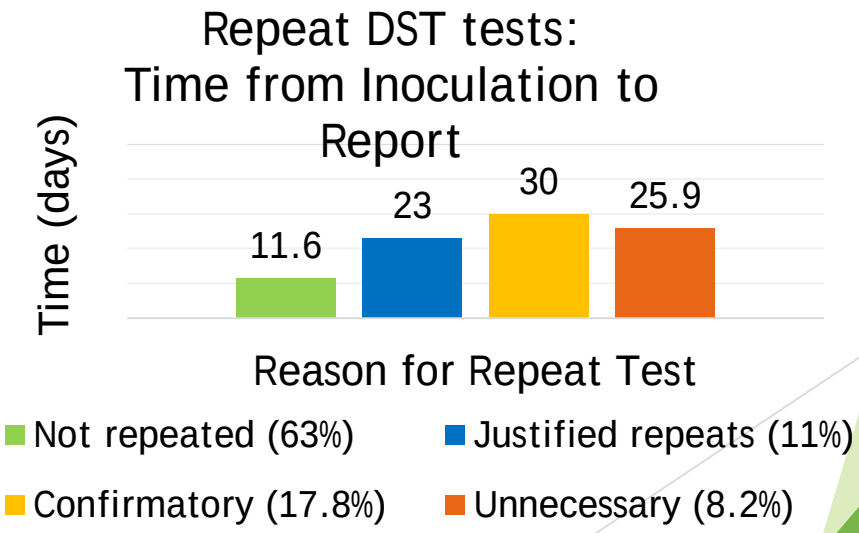




Results- continued

1. **Delaying probe testing causes specimens to need subculture prior to DST**
   - DST requires the culture to be within 5 days from initial positivity
2. **Subculturing adds ~10 days to the DST procedure**
   - 44% of all specimens needing DST in 2017 were subcultured prior to inoculating
3. **Repeating DST more than doubles the time to final report**
   - 47% of DST specimens in 2017 were repeated
   - Justified repeats include per protocol repeats due to unavoidable testing defects.
   - Confirmatory repeats are done to confirm when drug resistance is detected.
   - 8% of specimens overall were repeated in error or were not justified by standard protocols.





Recommendations and Actions

1. **Increase frequency of DNA probe testing to improve identification TAT and reduce the need for subcultures for DST turnaround**
2. **Simplify workflow and standardize probe criteria to reduce ambiguity about when a specimen should be tested**
3. **Inoculate DST directly from positive media as often as possible**
4. **Standardize criteria for when to repeat DST to reduce extra testing**

October 2017	- Eliminated extra testing to discriminate between subtypes of non-tuberculous mycobacteria - Wrote a document stating the standard criteria for performing DNA probe on a specimen - Simplified LIS test order list and report options
November 2017	- Ordered pre-made plates and buffer to reduce contamination and reduce variability
January 2018	- Increased frequency of genetic probe testing to twice weekly on standard days - Standardized criteria for repeating DST for per protocol and confirmatory results

Impact

1. **Time from positive culture to probe was reduced from 8.3 days to 6.2 days**
2. **Overall Identification turnaround time improved from baseline**
   - Still only 40% of specimens meet the 21 day goal
3. **Subculturing was dramatically reduced in 2018**
   - Only 17% of specimens had to be subcultured to inoculate (44% in 2017)
4. **Unnecessary Repeats were eliminated**
   - No unjustified or out of protocol repeats Jan-April 2018
   - Confirmatory repeats reduced from 17.8% to 13% due to stricter protocol
5. **No overall reduction in DST turnaround time observed (…yet!)**
   - Due to a troubleshooting issue in February 2018, the number of justified repeats increased dramatically (11% in 2017 to 39% in 2018 TD) for troubleshooting
   - Because of these extra repeats, there has not been any discernable change in DST turnaround times despite quicker inoculation times

Ongoing process

- Continued monitoring of turnaround time and other indicators
- Additional recommendations to improve workflow have been made but not yet implemented
- Identify and reduce the impact of additional trouble spots with measurable goals/outcomes for future quality improvement projects
  - E.g. Time from probe performed to identification reported: 90% of specimens should be reported within 1 day, no specimens with time to report greater than 1

Acknowledgments

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Using Process Mapping to Actively Improve Laboratory Processing in TB Contact Investigations

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Healthy People. Healthy Communities.

Background

- SC PHL validated QuantiFERON-TB Gold in July of 2015 for use in TB contact investigations.
- Advantages of QFT Gold
    1. Requires only one patient visit.
    2. Removes the risk of losing a patient to follow-up to read test.
    3. Reduces patient contact time.
- Considerations of QFT Gold
    1. Requires three tubes be drawn with strict filling requirements.
    2. Correct position of patient label in order to verify fill volume.
    3. Requirements for testing and incubation.

Background

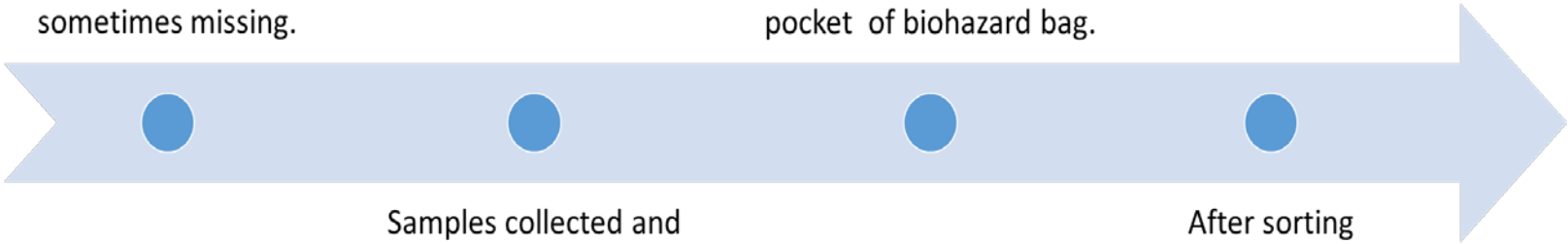
- QuantiFERON-TB Gold (QFT-Gold)
  - Performed in the Virology Laboratory at the South Carolina Public Health Laboratory (SC-PHL)
  - ~1,400 QFT-Gold tests per year
  - Accessions and logs in all patient samples for their laboratory section
  - In 2017 there was large scale TB contact investigation ~250 samples

Process Mapping

Sample submission forms are filled out by submitters. Information sometimes missing.

Specimen Submission:

Samples submitted in sets of three individually bagged and with submission form folded in pocket of biohazard bag.



Samples collected and sample volumes monitored at Laboratory after incubation

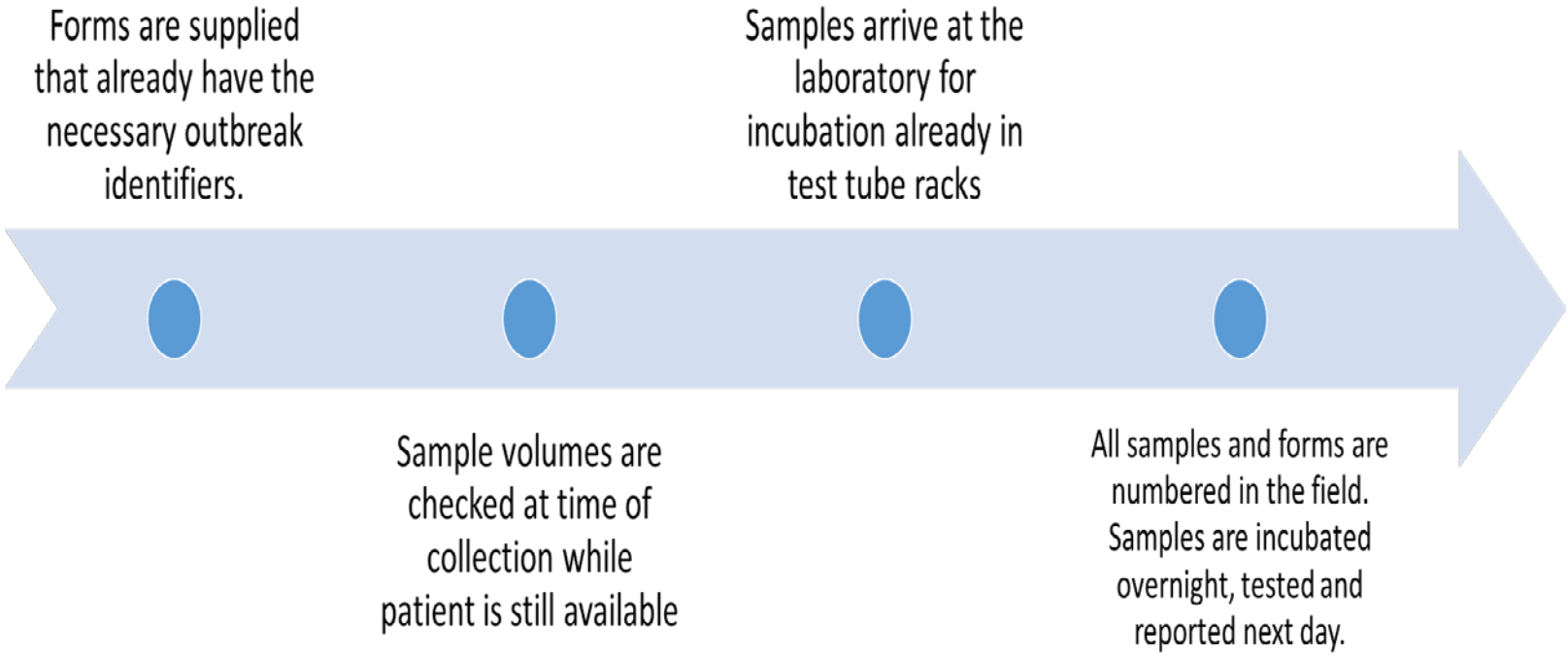
Two days from collection samples identified as incorrectly drawn

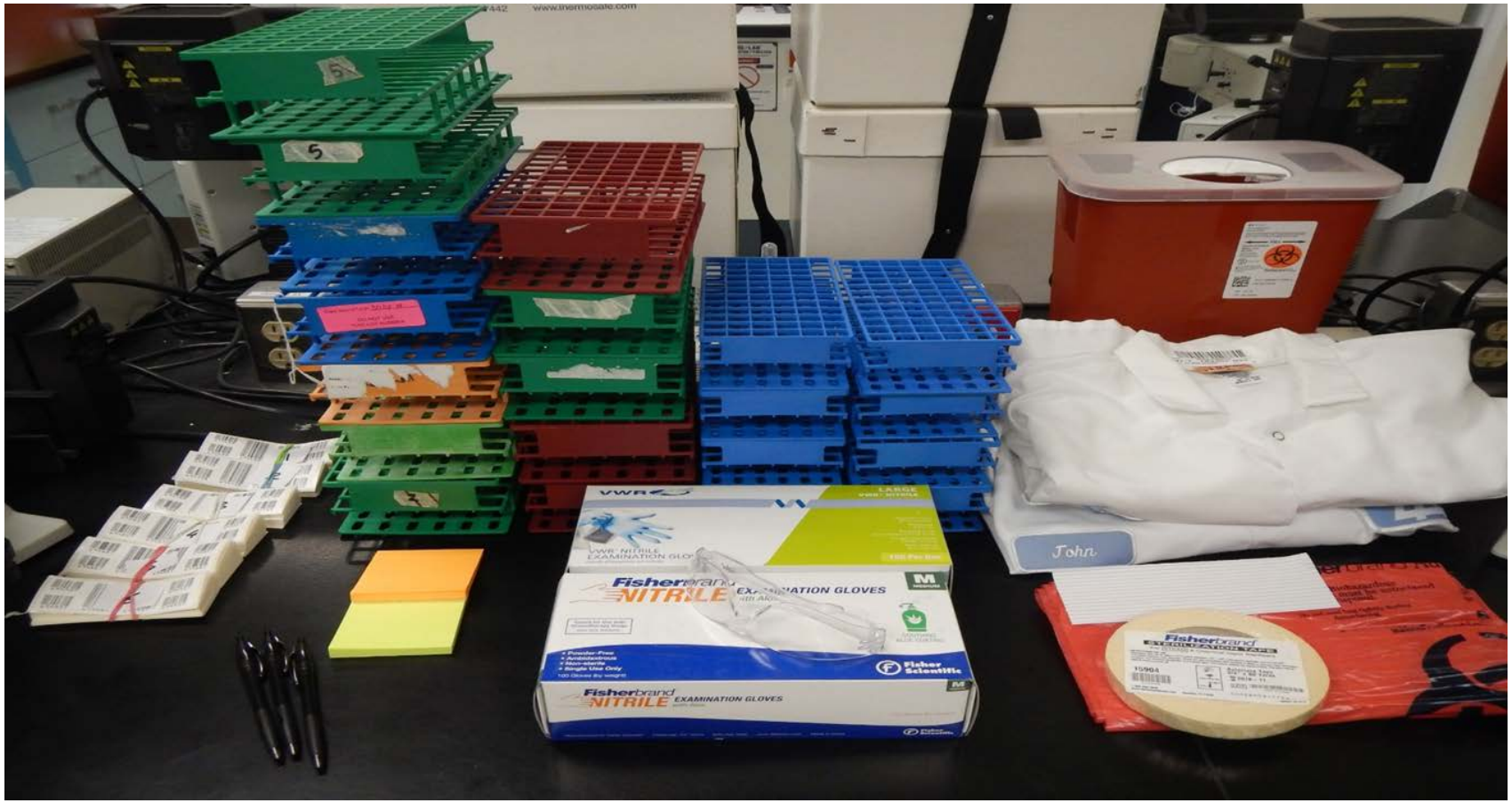
After sorting submission forms and samples, they are labeled with a lab ID number for processing.

Potential Impediments Identified

1. Correct fill volumes on all three tubes, prevents rejection of specimens and patient re-draws.
2. Sample labeling: both the position of the label and the numbering of samples upon submission of the samples.
3. Organization of samples and submission forms to improve workflow at the PHL.
4. Associating contact investigation samples from routine work to aid in reporting.

Process Mapping – Improvements!





Preparing for testing day

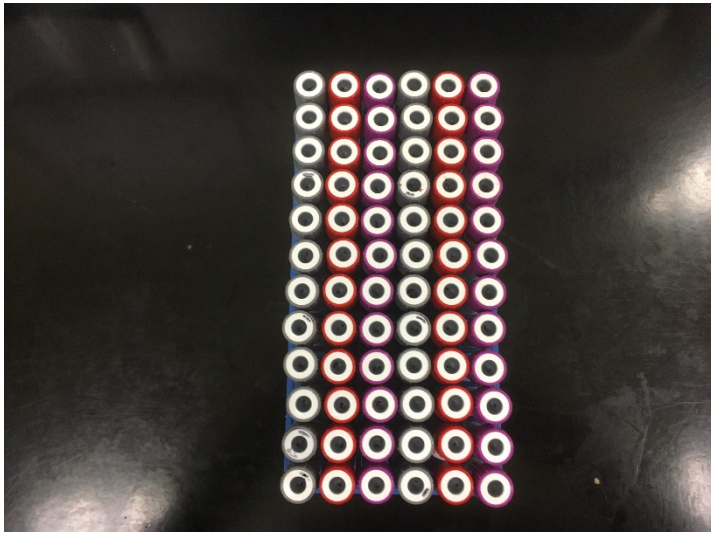
Accessioning setup at collection site

Verifying fill volume

Summary of Efficiencies Gained

- Faster identification of incorrectly drawn samples, providing the opportunity to recollect while the patient is still there
- Results reported faster, due to more efficient processing. (3-4 hours faster in a large investigation)
- Close to real-time results

Improved Processing



Unexpected Outcomes

- Improved communication between the PHL and SC TB Control Program
- Improved relationships between laboratory personnel and staff in the regions

Next Steps

- Evaluate workflow with 4-tube QFT test
- Work with TB Control Program to improve data exchange and identify improvements in all mycobacteriology testing
- Implementation of a new LIMS system and sample submission forms-opportunities for enhanced process flow
- Continually improve through process mapping, involving staff

Lessons learned

- Process review should include laboratory staff performing tests to correctly identify areas for process improvement
- Handling sample collection and submission differently in large scale investigations can improve testing outcomes
- Working closely during contact investigations supports better communication in general

Contact Information

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