



Every Step You Take; I'll be Watching You

Participants discussed in groups their recent experiences with CLIA inspections. Specifically, we will focus the questions (and discussion) on the pre-analytical processes in your laboratory.

Has your laboratory gone through the APHL TB Seld Assessment Tool, Mycobacterium Tuberculosis: Assessing Your Laboratory? Were there interesting findings or process improvements that came out of it?

No formal assessment, questionnaire, booklet	discussed about specimen rejection process (if difficult to obtain, might still process it)	Yes, used to overhaul department around safety/processing of reagents. Revisit every year for assessment.	ATCC Lot # needed on all stocks & subcultures
Lots of information and useful before CLIA (safety, QC, and documentation)	Maintain QA & QC checks for CLIA regulations. Reevaluate as needed, internal audits performed monthly	Lot numbers on all reagent aliquots	Not done recently - when done a while ago, lab added Neg Qcto processing run.
Specimen handling is out of our control, could be improved with more traceability and education	monitoring temperature of samples in transit - including storage prior to transit. Can use data loggers or temp gun. Some couriers need to make multiple stops	Yes - train staff, QC program, safety inspection (every 6 months or 2 years), review monthly	Beneficial for bench tech to be involved
	Have not or done years ago - evaluated on own - some people didn't know about tool kit - helpful for inspections as checklist	Not recently (is this an older tool kit?) or not at all (because new staff who hasn't has a chance to use) But this inspires us to revisit the toolkit!	

How was your last CLIA inspection? Any findings in your TB lab that you would like to share?

Annual smear tests	Expiration dates can be an issue with media. Inspections overall have been good.	BSL 2= lab = all PPE	Struggles with staff turnover and impact on training and expertise.	Verify in pairs, then supervisors review slides in CDC lab. All agree on the results and then report.
Focuses on: Competency, validation, stability testing, pre-analytical (e.g. temps)	smear reviewer - charts with AFB rating	Policy stating that media has to be inoculated by expiration date, not read by expiration date.	NAAT/5-6 Rare	turnover of staff an issue with training and review of slides.
Temperature ranges/stability around reagents and specimens	Validation plan was not signed before test was implemented	Dates missing on reagents and timer	Humidity levels	Some labs are making media in-house to plug gaps in supply chain if media expired, etc.
Annual competency assessments	Extended QC protocol to address media expiration.	Some small issues with temperature documentation	Ding for not including QC slide with every batch of stains	

How is your lab insuring you are meeting pre-analytical requirements?

E-tor/ lab online	Communicate only if reject specimen error on form (physician name missing, collection date/time) direction online.	Emails and pamphlets to remind submitters on specimen collection practices.	Issues with submitters completing proper paperwork and following submission guidelines.	Communicate via email to maintain record.	In case of rejection or other qualifiers - release report with comments or disclaimers
Reject samples if don't meet criteria	Update guideline from time to time.	Centrifugation and temperature requirements documented - needs to be detailed in paperwork.	Quarterly training to nurses	Work with submitters closely to avoid rejection.	courier service helps
Working with couriers and TB programs	Out of date forms - no test exists anymore - wrong specimen.	Communicate: scope tested on website - refer all submitters there	Monthly QA indicator to monitor	Collection of data(metrics) and focus on labs with reoccurring history.	Log for pre-analytical processing of quantiferon samples
some labs don't reject	Combining different sample types in one shipment is a problem.	When holidays are coming up, another reminder about specimen transport requirements.	Usually contact TB epi. to obtain clarification.	Some paperwork is difficult to read	website with specimen requirements
Calibrated probes for CO2.	send direct	Email submitter	Clear communication and routine reminders on submission details	Boxes that stay cold purchased.	Educational specialist hired to call on discrepancies.

What did you and/or your team do to celebrate after your inspection?

Provide breakfast - give a report for what needs to be fixed.	Made cupcakes	Had a beer with the team, after work.	Pizza
Food (on the record) Alcohol (off the record)	BBQ/pizza	Bought lunch for team.	Email from branch chief. Bureau chief comes personally to greet group.
Potluck	Celebrate everything - birthdays, holidays - potlucks	Nothing, back to work. Something to think about in the future.	sigh of relief.
	No time celebrating.		