POTENTIAL AREAS TO EXAMINE IF A FALSE-POSITIVE OR CONTAMINATION IS SUSPECTED

Pre-Analytical

- [ ] Were specimens collected properly?
  - *Contact the TB clinic/hospital/healthcare provider for information*

- [ ] Were specimen containers labeled correctly?
  - *Contact the TB nurse/clinic/hospital*

- [ ] Were specimen requisition forms completed properly and matched to specimen container labels?
  - *Contact the laboratory accessioning department/TB clinic or compare form and container, if available*

- [ ] Were known MTBC positive patients' specimens collected on the same day in the same location?
  - *Inquire with the TB clinic/hospital*

Analytical

- [ ] Review patient's past and current test results
- [ ] Speak with TB program or healthcare provider to determine if patient symptoms are consistent with TB disease
- [ ] Review specimen processing logs (the day of the suspected contamination and days prior to and after potential contamination) for:
  - Clerical errors
  - Laboratory technologist who performed the testing
  - Order of patient specimens processed
  - Anything unusual with the specimen, equipment, safety, processing procedure, controls, etc. that may be annotated
  - Other known positive patient test specimens in the same processing batch
  - Whether controls or proficiency testing specimens were processed in the same batch or biological safety cabinet (BSC)
  - Amount of time it took for inoculated cultures to grow

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Job aids/templates can be modified for local use and should not be sent to CDC for data collection.

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- ☐ Review standard operating procedures (SOP) and workflow to rule out processes that could have led to contamination
- ☐ Ensure staff are following the SOP and/or observe technique for best practices
- ☐ Ensure identification testing passed appropriate quality control (QC)
- ☐ Review lot numbers of manufacturer reagents, media, kits, etc. and ensure all media have passed necessary sterility checks and QC
- ☐ Assess if pipettes/supplies used for specimen processing are also used with positive cultures and susceptibility testing
- ☐ Review laboratory cleaning/decontamination records
- ☐ Review BSC records to ensure BSC is operating properly
- ☐ Review autoclave records to ensure autoclave is operating properly
- ☐ Review nonconforming events (NCEs) for occurrences that may have caused a false-positive

Post-Analytical

- ☐ Review test results to ensure the correct result was reported for the correct patient
- ☐ Verify that the correct report was sent to the healthcare provider
- ☐ Determine whether laboratory results and associated reporting language were received and interpreted correctly by the healthcare provider
- ☐ Ensure that data entry or transcription errors did not occur when results were entered into the laboratory information management system (LIMS)
- ☐ Review negative specimen processing control results to ensure growth was not observed
- ☐ Ensure quality assurance procedures have been followed (e.g., secondary review)
- ☐ Cross-reference genotypes for specimens in question to any known positives processed the same day or to the H37Rv/Ra control strain