Reference Standards for Molecular Diagnostics

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Topics/Outline

• Standards for molecular tests that detect *M. tuberculosis* (active disease)
• Standards for molecular tests that detect drug resistance
Molecular Detection of TB

• Laboratory confirmation of TB
  • Liquid culture (usually of 3 specimens)
  • Solid culture (usually of 3 specimens)

• Clinical diagnosis of TB
  • Case review by panel of TB experts

Discrepant or discordant results

• Ensure that sample is from an untreated TB suspect and is an initial diagnostic specimen

• Consider all lab tests for the TB suspect
  • Investigate potential false-positive or false-negative results
  • Investigate potential lab contamination or labelling errors

• Clinical diagnosis
Molecular Tests for Drug Resistance

- Phenotypic tests
  - Liquid or solid media using critical concentrations
- Genetic tests
  - Sequencing of target genes
- Clinical outcome

Discrepant or discordant results

- Investigate possible labelling error or lab contamination
- Consider possibility of a mixed sample
- Repeat testing of patient sample
- Testing or retesting of isolate
- Sequencing of target gene(s)
- MICs using liquid or solid media
- Clinical outcome