



## 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



## Molecular Detection of TB

### 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**



## **Molecular Tests for Drug Resistance**

### **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

