Quality Assurance for Molecular Diagnostics

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Topics/Outline

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

• Internal Quality Controls
  • Negative controls – every test run
    • assess contamination of reagents
  • Positive controls – every sample kit
    • Limit of detection
    • Do not run with test samples

• Amplification control
  • Preferably test has an internal amplification control

External Quality Assurance

• Proficiency testing
  • mock specimens spiked with *Mtb*
  • detects major errors and contamination

• Performance indicators
  • % smear-positive detected (>99%)
    • assumes no AFB+ due to NTM
  • % *Mtb* culture positive detected
  • Contribution of molecular test to detection of TB in AFB-neg samples
  • Concordant samples
  • % indeterminate results
Molecular Tests for Drug Resistance

• **Internal Quality Controls**
  • Negative controls – every test run
    • assess contamination of reagents
  • Positive controls – every sample kit
    • Isolates with known mutations
    • Do not run with test samples

External Quality Assurance

• **Proficiency testing**
  • mock sputum specimens spiked with *Mtb* or isolates – wild type or known mutations

• **Rechecking**
  • Compare molecular result with phenotypic result (reference lab)
  • Compare molecular test result with sequencing result

• **Performance indicators**
  • % agreement molecular/phenotypic tests
  • Concordant samples
  • % indeterminate results