

FDA Approval of GeneXpert in making Airborne Isolation Decisions



September 2015

Background

- February 2015- FDA approved change in package insert for Cepheid Xpert
 - “either one or two sputum specimens
 - Used as alternative to serial smear results for release from All
 - Concern for premature release of individuals from respiratory isolation
- NTCA convened panel of experts to provide consensus guidance

Proposed guidance

- Xpert MTB/RIF – positive
 - Continue respiratory isolation
- 1st Xpert MTB/RIF - negative
 - Repeat Xpert MTB/RIF
 - If 2nd specimen positive, continue respiratory isolation
 - If 2nd specimen negative, infectious TB not likely.
 - Consider release from isolation if clinically indicated.
- 3 negative sputum smear results collected at least 8 hours apart
 - Infectious TB not likely
 - Consider release from isolation if clinically indicated.

Use caution!

- Waiting for final consensus statement
- Virginia likely to adopt consensus statement

