

7. Decisions regarding airborne infection isolation

In February 2015, the FDA cleared the use of Xpert on sputum specimens to help clinicians make decisions regarding airborne infection isolation (AI) of patients suspected of having pulmonary TB. This expanded intended use of Xpert was based on preliminary results from a single study showing that two serial negative Xpert results predicted the absence of AFB smear positive, culture-positive TB 100% of the time. However, two serial negative Xpert results detected only 69% of AFB smear-negative culture-positive TB patients [7]. Therefore two negative Xpert results do not reliably rule out TB disease in smear-negative patients.

The FDA announcement also cautions that negative Xpert results “should not be the sole basis for infection control practices.” We are monitoring the performance of Xpert as it becomes increasingly implemented in LA County. Because of the serious consequences of missing a case of AFB smear positive TB (i.e. highly infectious TB), until operational data becomes available for review, **final decisions regarding airborne infection isolation should continue to be made based on all clinical, radiologic, and laboratory data, and not on the results of Xpert (or other NAAT) results alone.** See **Table 1** and **Table 2**.