

## **2. Background**

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The first commercial TB NAATs were approved by the U.S. Food and Drug Administration (FDA) in the 1990s and have seen widespread use across the United States. In 2013, the FDA approved a new TB NAAT, Xpert MTB/RIF (Xpert), which can simultaneously detect *Mycobacterium tuberculosis* complex and mutations associated with rifampin resistance. In addition, many private and public health laboratories have developed their own NAATs, many of which utilize real-time PCR technology (similar to Xpert) to detect *M. tuberculosis* complex. These non-FDA approved NAATs need to be validated by their respective laboratories prior to clinical use.