Described Diagnostic Inconsistencies Were Observed with an Obsolete Version of the Xpert MTB/RIF Assay and Are Unlikely To Recur in the Current Version of the Assay

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The Xpert MTB/RIF assay (Cepheid, Sunnyvale, CA) detects the presence of Mycobacterium tuberculosis as well as mutations in the M. tuberculosis rpoB gene indicative of rifampin resistance. Somoskovi et al. describe a potential problem with this assay’s ability to detect mutations in codon 533 of rpoB (1). The authors note that their study was performed using the 3rd generation or “G3” version of the assay. We wish for readers to be aware that the G3 version of the assay has been obsolete since the release of the 4th generation of the assay in December of 2011. While we agree with the authors’ assessment that the performance that they observed with the G3 assay was cause for concern, their findings do not represent the current state of the assay. In fact, the G4 assay includes several modifications intended to improve codon 533 CCG detection performance, specifically, modifications to the PCR conditions and probe E signal detection parameters. These modifications were outlined in a report from the Foundation for Innovative New Diagnostics released in November of 2011 that also includes preliminary data from our lab demonstrating improved 533 CCG detection performance (2). We suggest that future reports of Xpert MTB/RIF assay performance should be viewed with caution if the G4 assay is not used.

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