16 December 2024

The Global Laboratory Initiative (GLI) is pleased to share that the World Health Organization (WHO) announced prequalification of the first in vitro tuberculosis (TB) diagnostic test, Xpert MTB/RIF Ultra, on 5 December. The full announcement can be accessed by clicking on the image to the right or here. This is the first test for TB diagnosis and drug susceptibility testing that has met the WHO's prequalification standards.

Prequalification for TB diagnostics was announced by the WHO as a future change to the procedure to determine procurement eligibility of TB tests in a Public Announcement in 2021. WHO Prequalification, which has historically been used for HIV, Hepatitis B and C, malaria, HPV, and other disease programs, builds on disease program evidence assessment and class-based recommendations for diagnostic tests by evaluating each specific product brand for quality, safety, and performance within the product intended use setting.

Of interest, there are seven additional Nucleic Acid Amplification Tests (NAATs) that are WHO-recommended by the WHO Global TB Programme for detection of TB and drug resistance that are already undergoing WHO Prequalification assessment, including additional products from Cepheid, Molbio, Roche, BD, and Eiken Chemicals. The status of these assessments is publicly available and can be accessed here. In addition, the WHO Prequalification evaluation criteria for meeting prequalification requirements have now been established for Lateral Flow LAM (LF-LAM) tests and can be accessed here.

Readers can find GLI's resources for implementation of the prequalified Xpert MTB/RIF Ultra test and other WHO-recommended diagnostics on the **NEW** Global Laboratory Initiative website.