Public announcement on the piloting of a novel parallel WHO Prequalification and TB policy assessment process for new TB in vitro diagnostics

Systematic evidence assessment, policy development, and prequalification processes are core functions of the World Health Organization (WHO) and essential for ensuring quality, evidence-based, and safe health interventions to benefit Member States. **To streamline and optimize WHO assessment of new in vitro diagnostics, the WHO Prequalification Unit (PQT) within the Department of Regulation and Prequalification (RPQ) and Department for HIV, TB, Hepatitis, and STIs (HTH) are pleased to announce a partnership to pilot a novel parallel assessment process.**

In 2025, HTH will assess evidence on a new, near point-of-care class of tuberculosis (TB) diagnostic technologies that will inform updated TB policy guidance, while PQT will simultaneously assess individual near point-of-care testing class products for possible prequalification. The molecular tests in this new diagnostic class are expected to expand access to needed testing services because they can be done using easy-to-collect tongue swabs as a new sample type for TB detection. PQ listing of prequalified IVDs will only occur if a near point-of-care class of TB diagnostic technologies is established by HTH and the products under assessment are confirmed to be recommended within the class. Per routine practice, the PQ listing will trigger WHO procurement eligibility. This parallel process is envisioned to speed WHO assessment of the impact, quality, and safety of near point-of-care tests with the potential to expand access to needed TB diagnostic services.

WHO PQT and HTH are working closely to ensure that the pilot assessment process for near point-of-care TB diagnostics is as streamlined as possible. The HTH evidence assessment process for a new, near point-of-care class of TB molecular diagnostics recently launched with announcement and completion of the Public call for data to inform WHO policy updates on new TB diagnostic samples, tests, and testing strategies. In response, PQT will publish a Call for Submissions for near point-of-care testing products by 30 August 2025. Manufacturers are encouraged to monitor PQT announcements and review existing Technical Specification Series and PQ guidance for TB Nucleic Acid Tests (NATs) to best prepare for PQ submission and assessment.