

**Public announcement to TB in vitro diagnostics manufacturers, procurement agencies and national TB programmes: Extension of WHO GTB recommendation-based procurement eligibility for TB NAT assays until 31 December 2026**

18 December, 2025

The World Health Organization (WHO), through its Prequalification Unit and the Department for HIV, TB, Hepatitis, and Sexually Transmitted Infections (HTH), would like to announce that the transition period for WHO procurement eligibility of TB NAT assays based on the WHO endorsement mechanism has been extended from the previously communicated date (31 December 2025) until **31 December 2026**. Several prequalification applications are undergoing assessment, this additional time will allow to complete the ongoing assessments. This measure only applies to products that were previously endorsed through policy assessment and were then submitted and accepted for WHO prequalification assessment. After 31 December 2026 these products will have to be covered by both a WHO recommendation and prequalified for continued policy recommendation by WHO and to be eligible for procurement by WHO and other UN/International Procurement Agencies.

Please find below a summary of key dates:

<b>Q3 2022 - CLOSED</b>	<b>Q1 2023 - CLOSED</b>	<b>Q3 2026 - ONGOING</b>
PQ TSS-17 published, applications invited, and workshop held for manufacturers.	Deadline for previously endorsed TB NAT assay submissions for PQ assessment.	Deadline for PQ listing of currently endorsed TB NAT assays

Information on the [prequalification applications status](#) and the [list of prequalified IVDs](#) can be accessed on the WHO website.

This measure does not apply to new TB NAT assays without existing WHO policy recommendations. Manufacturers of new assays should contact the HTH Department for a class determination to inform the next steps for WHO policy and prequalification assessment. New products that undergo WHO policy assessment, are recommended, and for which an existing prequalification process is available will be required to achieve prequalification listing within two years of recommendation publication.