

Implementing the new TB Diagnostic through proficiency testing program in Kenya

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Background

The Kenya National Tuberculosis Reference Laboratory (KNTRL), in partnership with USAID Kenya, launched Truenat assay proficiency testing using dry tube samples. A pilot in 24 facilities confirmed the quality of in-country panels in 2024. By the end of 2025, 78 facilities were enrolled in Round 2, which used an integrated online system for site enrollment and result reporting. The program aims to strengthen TB diagnosis, improve rifampicin-resistance surveillance, and align with the strategic plan to enroll all molecular testing facilities in proficiency testing.

Objectives

Strengthening both laboratory performance and patient outcomes through proficiency testing.

Methods

National Tuberculosis Reference Laboratory (NTRL), in collaboration with Smart Spot Quality (PTY) LTD, enrolled 38 Truenat testing facilities in a proficiency testing (PT) program between 2022 and 2023. Each facility received four dried card samples (DCS) per cycle, with expected results of either MTB detected, MTB detected with rifampicin resistance, or MTB negative, across six PT cycles. To sustain PT services, NTRL initiated in-house PT production in 2024 by validating Xpert dried tube specimens (DTS) on the Truenat platform. We analyzed result submission and satisfactory performance across eight PT cycles.

Results

PT enrollment increased from 38 in 2022 to 78 in 2025. Results submission rate ranged from 72% to 100%, with the lowest during the 2024 expansion. Satisfactory performance exceeded 80%, ranging from 82% to 94% (lowest in the first 2022 cycle). Sensitivity exceeded 80% and improved over time, indicating better diagnostic accuracy. Gains were likely due to system strengthening, including training, increased familiarity with PT processes, and adaptation to the expanding network.

Table 1 : Enrolment and feedback summary over time

Year	Provider	No of sites enrolled	Cycle no.	No. of sites returning results
2022-1	SMART SPORT	38	1	38
2022-2	SMART SPORT	38	2	38
2022-3	SMART SPORT	38	3	37
2023-1	SMART SPORT	38	1	33
2023-2	SMART SPORT	38	2	38
2023-3	SMART SPORT	38	3	37
2024-1	NTRL-kenya	78	1	56
2024-2	NTRL-kenya	78	2	68
2025-1	NTRL-kenya	78	1	74
2025-2	NTRL-kenya	78	2	74

Conclusion

Initially, the satisfactory performance rate was low at 82%, but it improved over time to 94% as facilities became more used to PT participation. To enhance the quality of testing services, it is essential for all TB testing facilities to be enrolled in the Proficiency Testing programme.

Poster Size Guideline

