Stool NAAT for paediatric TB detection

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Reference ID:
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Technology Domain: Diagnostics

Disease Area (Broad):

Communicable Diseases (bacterial, viral, fungal, parasitic) – Tuberculosis

Need and utility of the Technology from Public health perspective:

There is an urgent need for non-sputum-based MTB testing to improve paediatric TB diagnosis and management. While the current technology, Xpert Ultra, is used only for MTB and its rifampicin resistance detection, this protocol's utility would extend beyond MTB to include the detection of resistance to both first- and second-line drugs using Line probe assay (LPA).

Technology Readiness level (TRL):

- TRL5: Pivotal study completed

Validation Status and outcome:

Out Of 513 patients, 29 (5.6%) were positive for MTB in both stool and respiratory samples using either test. Additionally, eight other patients were positive for MTB in stool alone (7.2%). The findings indicate the validity of the standardised protocol with an additional yield of 1.6%. Validation with a larger sample size is completed.

Market Potential:

The standardized stool concentration protocol addresses a critical gap in pediatric TB diagnosis by enabling non-invasive detection of MTB and broader drug-resistance profiling beyond what current Xpert Ultra offers. Its compatibility with NAATs and culture-based methods, combined with demonstrated additional MTB yield (1.6%) in a 513-patient validation, positions it as a valuable tool for improving case detection in high-burden, resource-limited settings. With TRL-5 readiness and published clinical evidence, the protocol has strong uptake potential across national TB programs and diagnostic laboratories focused on enhancing paediatric TB outcomes.

Publication:

- Rajendran et al. Standardization of a stool concentration method for Mycobacterium tuberculosis detection in the paediatric population. Int J Mycobacteriol. 2022 Oct-Dec;11(4):371-377. doi: 10.4103/ijmy.ijmy_126_22. PMID: 36510920