Detection by RT-PCR of *Mycobacterium tuberculosis* from oral swab specimens using PrimeStore® molecular transport medium

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Background

GeneXpert-based Xpert MTB/RIF (Xpert) assay has largely replaced smear-microscopy as entry point for investigation of presumptive tuberculosis cases. However, the WHO target product profile for new rapid tests for TB prioritizes non-sputum-based approaches. We investigated an oral swab technique for collecting oral samples from presumptive TB cases for molecular analysis by RT-PCR (***Figure 1***).

Study design and Methods

- Consent for collection of an oral salivary specimen by flocked swab was obtained from 73 adult members during household visits in a TB-HIV high-prevalence urban setting in South Africa.
- Persons with at least 2 typical symptoms of TB, a recent TB episode, or living with a confirmed case of TB were included. All presumptive cases were also referred to the nearest clinic for routine investigation.
- Swabs were transferred to PrimeStore® Molecular Transport Medium (PS-MTM) and transported at ambient temperature for RT-PCR (LightCycler) analysis. By comparison, PS-MTM samples were also processed in Xpert MTB/RIF (V4) as per procedures previously reported (Daum LT, et al. IJTLD 2016; 20:1118-1124).

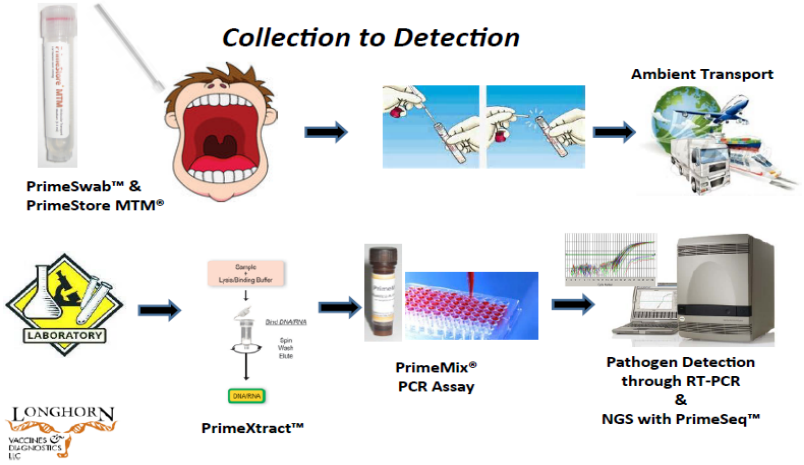

Figure 1. **The PrimeSuite™ Process**

Results

- RT-PCR detected *M. tuberculosis* DNA in 24 (32.9%) of 73 samples (***Figure 2***).
- An association between HIV-status and RT-PCR result is suggested.
- All PS-MTM samples tested negative by Xpert.
- All 73 presumptive cases were also issued with referral letters to the nearest clinic for routine investigation; however, only 6/73 actually presented. Non-responders quoted lack of funds to travel, stigma

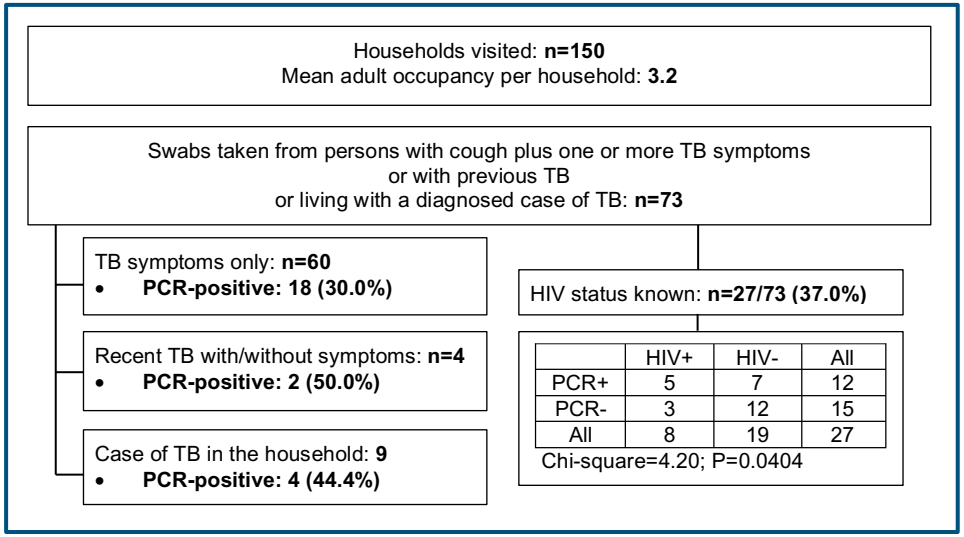

Figure 2. **RT-PCR results in swab specimens from persons with presumptive TB**

Conclusions

- Swab-collection of saliva from persons with two or more typical TB symptoms and storing/transporting these samples in PS-MTM with subsequent analysis by RT-PCR holds promise as an easy-to-perform, safe and patient-friendly procedure for triaging presumptive TB at the household level.
- This approach detected *M. tuberculosis* DNA in about one-third of persons that would otherwise not be picked-up by currently used first-line diagnostic methods and provides a solid basis for targeted patient follow-up investigation.

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