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 saliva from presumptive TB cases for molecular analysis by Xpert and RT-PCR. ***Study design and methods*:** Consent for collection of an oral salivary specimen by flocked swab was obtained from 73 adult members during routine 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. Swabs were transferred to PrimeStore® Molecular Transport Medium (PS-MTM) and transported at ambient temperature for Xpert (V4) and RT-PCR (LightCycler) analysis. It was previously shown that PS-MTM samples can be successfully processed in Xpert MTB/RIF. All presumptive cases were also referred to the nearest clinic for routine investigation; however, only 6/73 actually presented. ***Results: RT-PCR detected *M. tuberculosis* DNA in 24 (32.9%) of 73 samples. In marked contrast, all samples tested negative by Xpert. A slight probability for an association between HIV-status and RT-PCR result was shown. In 27 persons with HIV status known, 12 (44%) were PCR-positive (7 HIV-positive, 5 HIV- negative). In 15 PCR-negatives, 12 were in HIV-negative and 3 in HIV-positive persons (Chi-square=4.20; P=0.0404)

RT-PCR result	TB risk category				Total
	Two or more symptoms only	Two or more symptoms plus previous TB	No symptoms but previous TB	TB case in the home	
Positive	18	1	1	4	24
Negative	42	2	0	5	49
Total	60	3	1	9	73
Chi-square=2.81; P=0.421; DF=3					

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 investigations.