

To: All GeneXpert MTB/RIF Laboratories, Microbiology Laboratories, Clinical Microbiology Registrars and Pathologists, and Managers.

From: Farzana Ismail and Pedro da Silva

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Re: Interim guidance on the clinical management of suspected tuberculosis patients reporting MTB 'TRACE' DETECTED on pulmonary specimens tested using Xpert MTB/RIF Ultra.

The national Tuberculosis (TB) Diagnostic Programme transitioned from Xpert MTB/RIF (Xpert) to Xpert MTB/RIF Ultra (Ultra) by May 2018. Due to improved sensitivity, Ultra reports an additional category termed 'MTB trace detected' referred to as 'trace'. 'Trace' represents the lowest detectable amount of *Mycobacterium tuberculosis* (MTB) genetic material. However, when MTB is detected, the assay cannot distinguish organism viability, i.e., non-viable or remnant organisms may be detected in individuals with a history of previously diagnosed and/or treated TB and patients may not necessarily have active disease.

Depending on the Xpert MTB/RIF Ultra result, automated comments (approved by the TB directorate) are generated through the Laboratory Information System to guide clinical management. Particularly for a 'trace' result, the automated comment states: "*Mycobacterium tuberculosis DNA detected at the lowest limit (trace). The rifampicin testing was unsuccessful. Refer to the TB management guidelines.*"

The national TB Management Guidelines have been recently updated and include clinical management guidance for 'trace' results. However, due to delays with wider dissemination, approval has been given by the TB Directorate for an excerpt of the upcoming guidelines to be released as an interim guide.

In summary: Careful patient review should follow when Ultra testing reports 'trace' – for pulmonary specimens. This involves establishing an accurate TB history, re-evaluation of TB symptoms, further clinical assessment, and/or collection of additional specimens for testing, depending on findings. The decision tree is depicted as Figure 1.

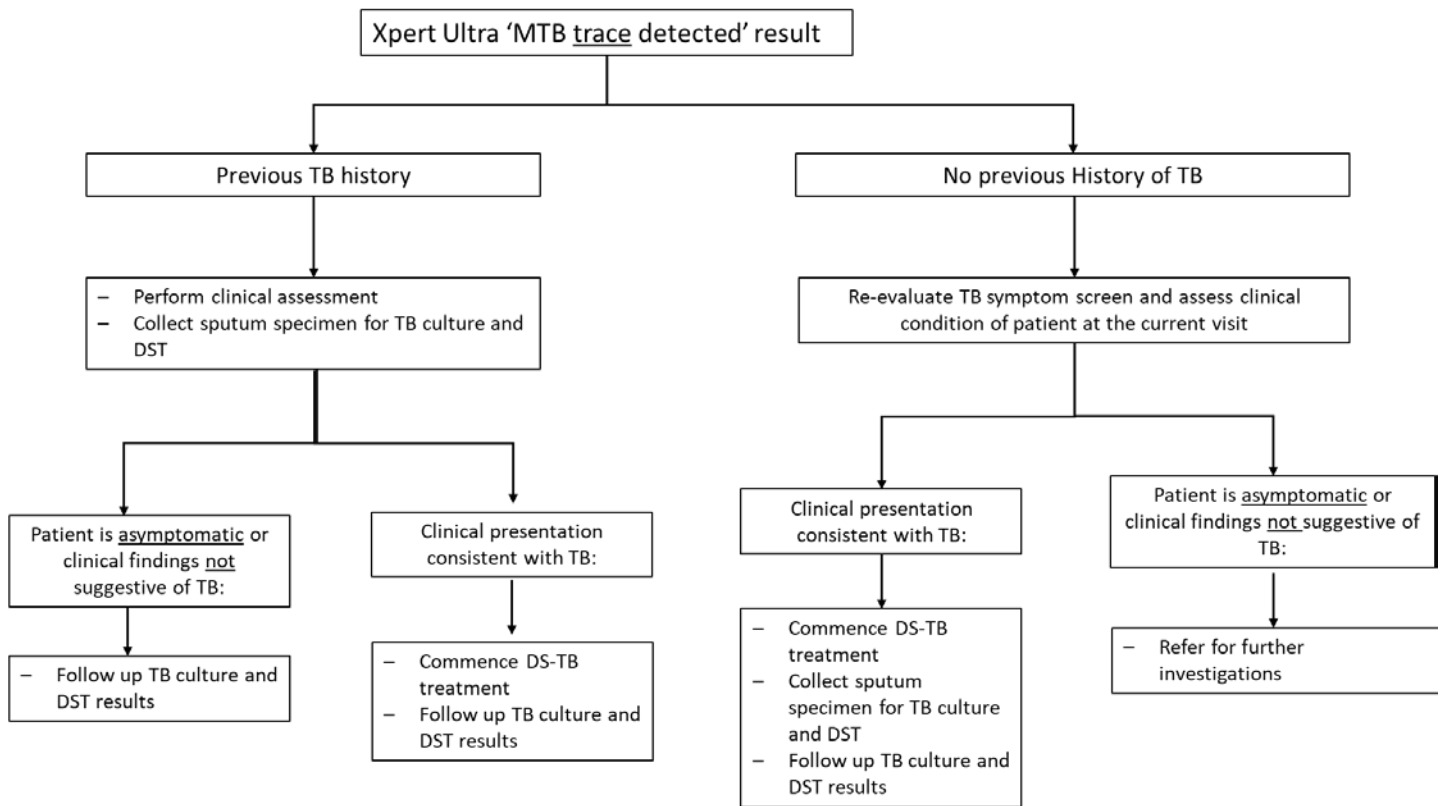


Figure 1: Clinical management algorithm for patients with 'trace' results. Algorithm reproduced from the upcoming TB Management Guidelines, with permission from the National Department of Health's TB Directorate. TB: tuberculosis; DST: Drug susceptibility testing; DS-TB: Drug-sensitive tuberculosis.

Wider dissemination of the TB Management Guidelines will follow in 2020.

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