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University of the Witwatersrand Faculty of Health Sciences School of Pathology Department of Clinical Microbiology and Infectious Diseases: Evaluation of new diagnostic methodology for the detection of second-line drug resistance in Mycobacterium tuberculosis clinical isolates.

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2016-12-06

Dear Joyce Mogale

Re: Implementation of the DR-TB Reflex testing including the MTBDR*s*l Line Probe Assay

The World Health Organization has provided policy recommendations for the adoption of the new shortened regimen for the treatment of RR/MDR-TB and linked to this has been the endorsement of the MTBDR*s*l Line Probe Assay for rapid detection of pre-XDR and XDR-TB. A decision has been taken to implement both the short regimen and the new test.

Several consultations have been held between clinicians, program and laboratory staff and a DR-TB reflex test set has been agreed on to facilitate the effective implementation of the new regimen and test. We thank the NHLS and NICD for the cooperation and support provide during these deliberations. The DR-TB reflex test algorithm is essential for the successful implementation of the shortened regimen and is shown below demonstrating the link with the clinical management:

The DR-TB reflex uses existing test methods available in the NHLS in a streamlined manner and now includes the addition of the MTBDR*s*l assay. This will require the implementation of the new test by NHLS and we are happy to be informed that designate sites in the NHLS have already undertaken verification procedures and the algorithm above has gone through the NHLS's microbiology expert committee.

We request the NHLS to introduce the DR-TB reflex test algorithm and the MTBDR*s*l with effect from 1 January 2017. The existing tests should be billed with the current price structures in place and the same would be true for new MTBDR*s*l assay (i.e. use of the MTBDR*plus* pricing). The tests should be billed against the CCMT grant unless individual provinces choose to use funds from their equitable share.

Kind regards

Dr Yogan Pillay
DDG: MCWH
Date: 8 December 2016

Cc: Provincial HODs, Provincial TB Managers