## TB DIAGNOSTIC TEST DEVELOPED IN INDIA HAS HIGH ACCURACY, SAYS WHO

Relevant for: Developmental Issues | Topic: Health & Sanitation and related issues

According to WHO, the overall sensitivity of the Truenat MTB assay is 83% and specificity is 99%. | Photo Credit: <u>Special Arrangement</u>

In a Rapid Communication published on January 14, the World Health Organization (WHO) had mentioned that the India-made Truenat MTB, a molecular diagnostic test for pulmonary and extrapulmonary TB and rifampicin-resistant TB, has high accuracy.

Truenat MTB has "high diagnostic accuracy as initial test to diagnose TB and to sequentially detect rifampicin resistance", says the WHO Communication. It will be used as an initial test thus replacing sputum smear microscopy.

Truenat is developed by the Goa-based Molbio Diagnostics. The company was provided with technical assistance and resources by the Foundation for Innovative New Diagnostics (FIND) to help commercialise Truenat. ICMR had assessed and validated the diagnostic tool.

"Truenat will be cheaper per test than Xpert. The equipment and cartridges cost more in the case of Xpert," says Prof. Balaram Bhargava, Director-General of ICMR. "Truenat is robust and most suited for Indian conditions."

"With its better sensitivity, Truenat can be used as the initial tool for TB diagnosis," says Prof. Bhargava.

Besides other studies, a multi-centric, prospective field evaluation study was carried out in India, Ethiopia, Peru, Papua New Guinea involving 744 participants, with final results on bacteriological culture.

While sputum microscopy has only about 50% sensitivity, Truenat has been found to have higher sensitivity and specificity. According to WHO, the overall sensitivity of the Truenat MTB assay is 83% and specificity is 99%. In the case of Truenat MTBPlus, which uses two targets to diagnose TB bacteria, the sensitivity increases to 89% and the specificity is 98%.

In comparison, Xpert, which is also a molecular diagnostic test and has been widely used across the world, the sensitivity is 85% and specificity is 98%.

In cases where the sample is found to be positive, tests can be done to know if the TB bacteria are already resistant to rifampicin, a drug used as part of first-line treatment. Truenat MTB-RIF test for knowing the resistance has 93% sensitivity and 95% specificity.

According to WHO, the accuracy of Truenat and Truenat MTB Plus is comparable with Xpert and Xpert Ultra. Likewise, the accuracy to detect rifampicin resistance using Truenat MTB-RIF is comparable with Xpert and Xpert Ultra.

Based on data available from around 230 diagnosing units in the primary and community health centres in Andhra Pradesh, scientists at the Chennai-based National Institute of Epidemiology found Truenat had better ability to diagnose more TB positive cases. "Compared with smear microscopy, there was 30% more number of positive cases diagnosed after Truenat was

implemented in the 230-odd units," says Dr. Manoj V. Murhekar, Director of NIE.

"Instead of smear microscopy, Truenat can be used as an initial and point-of-care tool for diagnosing TB," he says. "Since not much expertise is needed to carry out the test, it can be used in peripheral units such as public and community health centres."

While Xpert needs reliable electricity supply and air-conditioning, Truenat is battery operated and portable, hence, it can be used in remote places. Truenat takes about 25 minutes to extract the DNA and another 35 minutes for diagnosis. Testing for rifampicin resistance takes an hour and is done only if the sample tests positive for TB. In the case of Xpert, it takes two hours to complete the diagnosis and test for rifampicin resistance.

Compared with a one ml of sputum sample required in the case of Xpert, only 0.5 ml sample is needed for Truenat. In the case of TB positive samples, the actual bacterial load in 1 ml of sputum sample is given, while Xpert provides only a qualitative result.

The main cost advantage while using Truenat will be in the manner the tests are carried out. Only when samples test positive will the test for rifampicin resistance be carried out in the case of Truenat. This is unlike Xpert where both TB diagnosis and rifampicin resistance test are done in one go. Hence the use of reagents may be reduced and will help make the testing cheaper when Truenat is used.

Also, a peripheral-level TB test using Truenat will reduce the delay in diagnosis and when combined with improved treatment initiation rates will fare better compared with district-level Xpert testing. After all, early diagnosis and treatment initiation will help reduce TB transmission and incidence.

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