



## **INDIAN COUNCIL OF MEDICAL RESEARCH**

Department of Health Research – Ministry of Health & Family Welfare  
Government of India

### **Press Release**

#### **Molecular assay TrueNat recommended as initial test for TB and MDR-TB**

16th January 2020, New Delhi

In a significant development, WHO Global TB Programme has included an Indian Molecular assay TrueNat as initial test for TB and MDR-TB in view of its high diagnostic accuracy, in the rapid communication document on Molecular assays released by WHO's Global TB Programme. The TrueNat TB test is a new molecular test that diagnosis TB as well as testing for resistance to the drug rifampicin in about 90 minutes.

It is a matter of pride for Indian Council of Medical Research (ICMR), Department of Health Research (DHR) New Delhi as this was a long journey for promoting “Indigenous diagnostic technologies for diagnosis of TB and MDR/XDR-TB” developed by Indian scientists.

In an effort that was supported by DHR, Ministry of Health and Family welfare, Govt. of India and DBT, various indigenous technologies developed by Indian scientists/companies for detection of MDR/XDR TB were reviewed. Most promising kits were selected by the ‘Expert Group’ and were subjected to a double blind validation in comparison to standard tests at 4 national reference laboratories of the country.

After a stringent review and a series of validation and subsequent feasibility studies and continuous follow-up, the ‘TrueNat M.TB & Rif’ assay was found to be at par with the internationally recognized molecular assay Gene Xpert in terms of sensitivity and specificity and detection of rifampicin resistance. This was taken up by National TB Elimination Programme after recommendations from ICMR.

In a major effort as part of WHO pre-qualification process, ICMR funded Indian centres of the FIND-coordinated multi-central, prospective field evaluation study in four countries (India, Ethiopia, Peru, Papua-New Guinea). Based on the interim analysis of the data, WHO included TrueNat as test to diagnose TB (i.e. replacing sputum smear microscopy) and to

sequentially detect rifampicin resistance in view of its high diagnostic accuracy. The study has completed enrolment at all sites and the final analysis would be undertaken soon by FIND, Geneva.

The TrueNat assay kit is highly cost effective as compared to GeneXpert and can be used in peripheral centers without an AC lab and runs on battery which can be solar powered.

“Endorsement of the TrueNat by WHO would enable other low and middle income countries to procure TrueNat for TB and Rifampicin resistance thus supporting TB elimination in developing countries” said Dr. Balram Bhargava, Secretary DHR and DG ICMR.

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