

WHO includes an Indian diagnostic test in its global TB programme

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New Delhi, January 16: In a significant development, WHO Global Tuberculosis Programme has included an Indian molecular assay as initial test for detecting the disease and for identifying resistant strains of the TB bacteria.

The assay named TrueNet has been included in the rapid communication document on Molecular Assays released by WHO's Global TB Programme. It is a new molecular test that diagnosed TB as well as tests for resistance to the drug rifampicin in about 90 minutes.

The development is a fruition of efforts on the part of Indian Council of Medical Research (ICMR) to promote indigenous technologies for diagnosis of TB and multi-drug and extensively drug resistant TB (MDR/ XDR TB).

A team of experts reviewed various technologies developed by Indian scientists and companies for detection of MDR/XDR TB, with support from Department of Health Research in Union Ministry of Health and Family welfare, and Department of Biotechnology in Union Ministry of Science and Technology. The expert shortlisted most promising kits and conducted double blind validation in comparison to standard tests at four 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 assay was found to be on par with internationally recognized molecular assay Gene Xpert in terms of sensitivity and specificity and detection of rifampicin resistance. Subsequently, National TB Elimination Programme took it up, after recommendations from ICMR.

In another major effort, as part of WHO pre-qualification process, a multi-central, prospective field evaluation study was conducted in four countries - India, Ethiopia, Peru, and Papua-New Guinea. It was coordinated by Foundation for Innovative New Diagnostics (FIND), a global non-profit organisation driving innovation in the development and delivery of diagnostics to combat major diseases affecting the world's poorest population. ICMR funded the Indian centres of the study.

Based on the interim analysis of the data, WHO included TrueNat as test to diagnose TB, replacing sputum smear microscopy, and to sequentially detect rifampicin resistance. The study has completed enrolment at all sites and the final analysis would be undertaken soon.

Announcing the development, a press release from Indian Council of Medical Research said that the TrueNat assay kit is highly cost effective as compared to the globally accepted GeneXpert test and can be used in peripheral centres without an air-conditioned laboratory. It also runs on battery, which can be solar powered.

Secretary, Department of Health Research and Director General, Indian Council of Medical Research, Dr. Balram Bhargava, said, "Endorsement of TrueNat by WHO would enable other low and middle income countries to procure it for TB and Rifampicin resistance thus supporting TB elimination in developing countries".

Keywords: rifampicin, multi-drug resistance, MDR, extensively drug resistant, XDR, GeneXpert test, sputum smear microscopy