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New rapid molecular TB test to detect drug resistance

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XpertÃ?Â® MTB/XDR cartridge enables expanded drug-resistance tuberculosis (TB) profiling in less than 90 minutes



The Foundation for Innovative New Diagnostics (FIND) and US based Cepheid, Inc, have announced the launch of the new Xpert® MTB/XDR* test, which enables expanded drug-resistance tuberculosis (TB) profiling in less than 90 minutes. Xpert MTB/XDR can be used to empower clinicians to quickly prescribe treatment regimens for extensively drug-resistant TB (XDR-TB).

Able to detect TB that is resistant to multiple first- and second-line TB drugs, the test could help fill a critical gap that is currently jeopardizing global TB elimination targets. By contrast, current methods for identifying drug-resistance profiles for XDR-TB are very complex to perform, can take up to 16 weeks to deliver results, and as a result, are often completely unavailable to patients.

XDR-TB is the most complicated form of TB, with the worst outcomes. Mortality has been reported as high as 41% in some cohorts. The WHO recommends rapid molecular testing and detection of drug-resistant TB as an essential condition for the implementation of new treatment regimens.

"Rapid diagnosis and fast test results in just a few hours by Xpert MTB/XDR test will save lives," saysCatharina Boehme, CEO of FIND.

Xpert MTB/XDR leverages Cepheid's new 10-colour technology, which enables the detection of multiple mutations across several genes, from a single sample. Xpert MTB/XDR can detect resistance to isoniazid, ethionamide, fluoroquinolones, amikacin, kanamycin and capreomycin. Access to testing that can reliably identify resistance towards isoniazid as well as to fluoroquinolones and amikacin will help enable clinicians to quickly select the most appropriate MDR-TB treatment for each individual patient.

"Rapid testing of resistance to isoniazid and fluoroquinolones is a critical step towards ensuring those who are ill with drug-resistant TB, and in particular XDR-TB, can access treatment and care early – in line with the latest WHO guidelines on the treatment of drug-resistant TB," said Tereza Kasaeva, Director of the WHO Global TB Programme. "WHO is looking forward to receiving all relevant data on the GeneXpert MTB/XDR cartridge from Cepheid and partners to rapidly proceed with an evaluation of the new test."

The test runs on Cepheid GeneXpert® systems equipped with 10-colour multiplexing modules. GeneXpert 10-colour modules are capable of processing the already widely used Xpert MTB/RIF^ and Xpert MTB/RIF Ultra* tests for diagnosis of TB and rifampicin resistance."This test is the first to leverage 10-colour homogeneous detection within the GeneXpert system.

The team has demonstrated the ability to detect a wide array of TB drug resistance mutations directly from clinical specimens with a high level of accuracy comparable with standard testing. A study conducted by Cepheid showed promising results for the detection of mutations associated with first- and second-line drug resistance.

Data from the FIND evaluations will form part of the dossier now being prepared for WHO review at the end of this year. If the test is recommended for use by WHO, countries could include it in their national policies and accelerate its scale-up – particularly in high-burden TB countries such as India and China.

Reflex testing of MDR-TB patients, to rapidly and accurately diagnose XDR-TB within 2 hours and minimum expertise needed, has the potential to be the cornerstone in the rapid initiation of tailored treatment.

"It is great to have the Xpert MTB/XDR test that can be deployed in the peripheral laboratories and greatly improve access to diagnosis of drug-resistant TB and selection of the most appropriate treatment regimens," said Lucica Ditiu, Executive Director of the Stop TB Partnership.

***Image Caption**: Cepheid's Xpert® MTB/XDR cartridge enables expanded drug-resistance profiling in less than 90 minutes*