

Simple and Affordable Testing for Multidrug-Resistant Tuberculosis

Health need

Tuberculosis (TB), a bacterial disease caused by *Mycobacterium tuberculosis*, is a major health problem in developing countries and is reemerging as a major health threat in the developed world. High prevalence in some developing countries is associated with HIV infection and AIDS. World Health Organization (WHO) statistics indicate there are 14 million cases of active TB worldwide, and approximately 9.4 million new cases occur each year. TB results in the highest mortality rate of any infectious disease in the world, approximately 1.7 million deaths annually. TB is a highly contagious disease that can be difficult to identify and diagnose accurately. Since it is curable with a course of antibiotic therapy, early diagnosis and treatment can curtail the spread of the disease within the general population. Some progress has been made in introducing new tools to achieve early diagnosis. However, early diagnosis of TB at the peripheral level remains a significant challenge since existing methods have low sensitivity (sputum smear), take a long time to produce results (solid culture), or are very expensive (automated liquid culture methods and automated nucleic acid amplification tests).

Technology solution

The microscopic observation drug susceptibility (MODS) test was first described by the TB working group at the Universidad Peruana Cayetano Heredia (UPCH), in Lima, Peru. This is an accurate, rapid, and inexpensive liquid culture-based method for determining TB positivity and resistance to first-line antibiotic therapies (isoniazid and rifampicin). It employs a simple, inexpensive tissue culture plate and commonly available culture media to provide results with a rapid turnaround from specimen collection to results dissemination (usually within seven days). The original platform has been validated in five countries with extremely high sensitivity and specificity. UPCH contacted PATH and asked for assistance in making the test easier and safer to use. PATH collaborated with Hardy Diagnostics (Santa Maria, CA) to develop the TB MODS Test Kit™. This kit includes everything that researchers and laboratory technicians need to perform the MODS test while providing test standardization and convenience to users. Additionally, it includes a PATH-designed silicone-based protective sealing lid for the culture plate to prevent cross contamination between samples and increase biosafety.

Current status and results

WHO endorsed the UPCH-designed MODS test in 2010. The TB MODS Test Kit™ has received a CE Mark and is for sale in European countries. With Hardy Diagnostics' commitment, the TB MODS Test Kit™ can be provided at low cost to low-resource countries. PATH carried out a landscape analysis in countries where PATH has offices in order to gauge the level of interest in the MODS test and the TB MODS Test Kit™. PATH also initiated a field evaluation of the kit in Peru to generate performance data in comparison with the UPCH-designed MODS test and reference tests. The results from this field evaluation will become available by the end of 2013.



Hardy Diagnostics

Hardy Diagnostics TB MODS Test Kit™

“Under these conditions, MODS and NRA [nitrate reductase assay] are recommended for direct testing of sputum specimens. Together with CRI [colorimetric redox indicat] methods, MODS and NRA are also recommended for indirect DST [drug susceptibility test] of *M. tuberculosis* isolates grown in conventional culture.” WHO Policy Statement *“Noncommercial culture and drug-susceptibility testing methods for screening patients at risk for multidrug-resistant tuberculosis.”*

Availability

For more information regarding this project, contact David Boyle at dboyle@path.org or Mutsumi Metzler at mmetzler@path.org.

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