Introducing fast and accurate TB tests where patients seek care

Why we need new TB diagnostics
- Sputum microscopy is over 100 years old and fails to diagnose the majority of worldwide TB cases. It cannot detect drug-resistant or extra-pulmonary TB, and is particularly ineffective for diagnosis of TB in children and HIV-positive individuals.
- Lack of proper diagnosis costs patients and their families valuable time and money, delays treatment and leads to continued TB transmission.
- Mounting drug resistance and a growing number of patients co-infected with TB and HIV have highlighted the urgent need for more accurate and rapid diagnostic tests.

Our goal
To improve the accuracy, affordability and speed of TB diagnostic tests, and make them accessible throughout developing countries, at all levels of the health system.

Our approach
In our TB programme, we develop new technologies, and upgrade existing ones, taking into account MDR TB, XDR TB and HIV co-infection. We also ensure these technologies are optimized for low-resource settings and support roll-out in endemic countries.

Our successes so far
With our partners we have developed five WHO-STAG approved technologies in just seven years:
- **Liquid culture and drug susceptibility testing**
  Enables accelerated culture of sputum samples and visualizes TB bacteria directly, while simultaneously testing for drug susceptibility. Results are available within 14 days.
- **Rapid speciation test**
  Provides highly sensitive and specific detection of *M. tuberculosis* complex from liquid and solid cultured sputum samples and can confirm the presence of TB in just 15 minutes.
- **Fluorescence microscopy**
  Permits technicians to read slides more quickly and with greater accuracy.
- **Molecular line probe assay**
  Amplifies and visualizes *M. tuberculosis* DNA directly from smear-positive sputum samples and identifies genetic mutations that indicate drug resistance, all within six hours.
- **Automated nucleic acid amplification test**
  A cartridge-based fully automated technological platform for detection of TB and rifampicin resistance that is easy to use, requires very little training and gives results in under 2 hours.
**FIND negotiated prices**

FIND aims to provide endemic countries with cutting edge, innovative diagnostic products, making them available at affordable prices for low-income settings. To date, we have special price agreements with the five manufacturers with whom we developed these technologies or collected the evidence leading to WHO endorsement.

**Implementation**

FIND aims to increase access to rapid diagnostics in endemic areas by strengthening laboratory services at all levels of the health system and integrating WHO-STAG approved technology into TB control programmes. Over a span of five years, FIND and partners will transform TB diagnosis in 27 endemic countries, through the UNITAID-funded EXPANDx-TB project.

**Positioning of FIND-developed diagnostics in tiered health system**

![Diagram showing the tiered health system with FIND-developed diagnostics across different levels.]

**In the pipeline**

FIND is currently:

- Developing a simple molecular case detection test based on loop-mediated isothermal amplification (LAMP) technology that permits visual detection of positive TB samples within two hours.
- Working with partners to expand the GeneXpert platform and broaden its impact through innovations such as a new MTB/RIF cartridge with higher performance, an HIV viral load test, and a new assay for detection of extrapulmonary TB with potential for paediatric TB.
- Conducting biomarker research to accelerate the development of a “point-of-care” TB test – one that is simple, accurate, affordable, can be used anywhere and produces results on the spot.
- Expanding the number of diseases that can be diagnosed using the same technologies.
- Investigating how TB test platforms could be used to manage HIV infection and to detect other sexually transmitted diseases.
- Measuring impact to ensure that the right tools are put in the right place for the greatest impact on the community.

www.finddiagnostics.org