



World Health
Organization

TUBERCULOSIS DIAGNOSTICS Automated DNA Test

WHO ENDORSEMENT AND RECOMMENDATIONS

The new DNA test for TB (see photo) is a fully-automated diagnostic molecular test that uses modern technology. It has the potential to revolutionize and transform TB care and control. The rapid test:

- simultaneously detects TB and rifampicin drug resistance (a reliable indicator for MDR-TB)
- provides accurate results in 100 minutes so that patients can be offered proper treatment immediately
- has minimal bio-safety requirements, training, and can be housed in non-conventional laboratories



- The rapid TB test was developed by FIND (the Foundation for Innovative New Diagnostics), Cepheid and the University of Medicine and Dentistry of New Jersey with funding from NIH (National Institutes for Health, USA) and the Bill and Melinda Gates Foundation.
- Scientific evidence has been reviewed by WHO, through firstly, an Expert Group and secondly, the WHO's Strategic and Technical Advisory Group for Tuberculosis. At a WHO Global Consultation more than 100 stakeholders agreed on key steps to operationalise the new tool in affected countries.
- FIND negotiated a 75% price reduction for the public sector of 116 low and middle income countries plus NGOs and other non-profit agencies recognised by the governments of these countries.

RECOMMENDATIONS

- **Strong recommendation:** the new automated DNA test for TB should be used as the initial diagnostic test in individuals suspected of MDR-TB or HIV/TB
- **Conditional recommendation:** the new automated DNA test may be used as a follow-on test to microscopy in settings where MDR-TB and or HIV is of lesser concern, especially in smear-negative specimens (recognising major resource implications)

EXPECTED IMPACT

- a three-fold increase in the diagnosis of patients with drug-resistant TB
- a doubling in the number of TB/HIV cases diagnosed in areas with high rates of TB and HIV (compared to microscopy diagnosis)

TIMELINE

- May 2006** – FIND partners with Cepheid to develop a new and novel TB test
- April 2009** – the new automated DNA test for TB receives CE IVD marking
- May 2009** – Demonstration studies underway
- September 2010** – New England Journal of Medicine publishes validation data; Expert Group issues strong recommendation to WHO based on scientific evidence; WHO's Strategic and Technical Advisory Group for Tuberculosis further reviews evidence and makes policy recommendations;
- November 2010** – WHO Global Consultation develops roadmap for implementation
- December 2010** – WHO endorses new automated DNA test for TB

ROLL OUT OF THE NEW AUTOMATED DNA TEST

- **Individual countries** (notably South Africa and India) have developed country plans for roll-out of the new automated DNA test for TB in selected settings at different tiers of the health services.
- **PEPFAR** has expressed interest to immediately implement the new TB test in HIV clinics in projects financed in priority countries
- **TB CARE**, the new USAID project to support TB control in countries, will actively promote the implementation of the new TB test as a key activity in increasing TB and MDR-TB case detection
- **EXPAND-TB**, implemented by WHO, FIND, the Global Laboratory Initiative and the Global Drug Facility, and funded by UNITAID and other donors, will include the new TB test as part of accelerated and expanded access to MDR-TB diagnostics in recipient countries
- **TB REACH**, an initiative of the Stop TB Partnership, financed by CIDA, will include the new TB test in their promoted interventions in Wave 2 (launched on 1 Dec 2010), to increase and accelerate TB case detection
- **The World Bank** has expressed interest in implementing the new TB test in countries covered by the East Africa Laboratory Strengthening project aimed at increasing access to TB and MDR-TB diagnosis
- **The Global Fund** - WHO and technical partners will encourage national programmes worldwide to seek additional resources from the Global Fund in support of the adoption of the new TB test in upcoming proposal rounds

COSTS AND FUNDING

Projected price reductions based on increases in the number of tests			
Year	2011	2012	2014
Number of Tests (million)	0.6m	1.7 m	3.7 m
Price per Test	\$16.86	\$14.00	\$10.72
Average Price Reduction	75%	79%	84%

THE GLOBAL PLAN TO STOP TB 2011-2015

For MDR-TB: The cost of testing all MDR-TB retreatment cases and 20% of all new MDR-TB cases is US\$14 million, requiring less than 1% of current funding for TB control.

For HIV-associated TB: The cost of testing all HIV-positive individuals suspected of having TB will cost US\$ 44 million, requiring 1-2% of current funding for TB control, and amounting to less than 1% of current expenditure on HIV care in several high TB-HIV burden countries.

WHY IS MDR-TB & TB/HIV DIFFICULT TO DIAGNOSE?

- The most widely used method to detect TB is the 125 year-old sputum smear microscopy test, which has a number of drawbacks, including low sensitivity (especially in HIV-positive individuals and children) and inability to determine drug-resistance.
- Conventional diagnosis of drug resistant TB relies on bacterial culture and drug susceptibility testing, a slow and cumbersome process. During this time patients may be inappropriately treated, drug-resistant strains may continue to spread, and resistance may become amplified.
- In contrast, the new DNA TB test is rapid, fully-automated and therefore not as susceptible to human error. It provides a highly accurate diagnosis in a single test that identifies both the presence of TB and drug-resistant TB. This means people can be offered the proper treatment immediately.