

TUBERCULOSIS DIAGNOSTICS

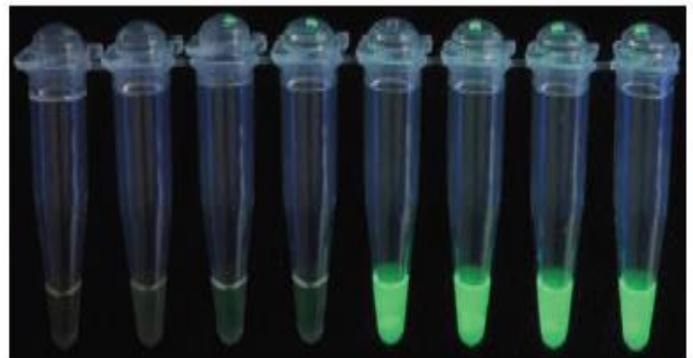
LOOP-MEDIATED ISOTHERMAL AMPLIFICATION FOR THE DETECTION OF *M. TUBERCULOSIS* (TB-LAMP)

BACKGROUND

- World Health Organization End TB Strategy calls for the early diagnosis of tuberculosis (TB) and for universal drug-susceptibility testing, highlighting the critical role of laboratories in the post-2015 era in rapidly and accurately detecting TB and drug resistance.
- Molecular assays based on nucleic acid amplification techniques, such as polymerase chain reaction, have been developed for rapid TB diagnosis and are being implemented in developing countries.

ABOUT THE TEST

- A commercial molecular assay to detect *Mycobacterium tuberculosis* complex that is based on LAMP techniques (TB-LAMP) has been developed by Eiken Chemical Company Ltd (Tokyo, Japan).
- TB-LAMP is a manual assay that requires less than 1 hour to perform and can be read with the naked eye under ultraviolet light.



BENEFITS OF TB-LAMP

- Loop-mediated isothermal amplification (LAMP) is a unique, temperature-independent technique for amplifying DNA that is simple to use, providing a visual display that is easy to read;
- The test is robust and does not require sophisticated instrumentation and can be used at a peripheral health centre level, under biosafety requirements similar to microscopy.
- LAMP methods have been used to detect malaria and several neglected tropical diseases. Similar training as for microscopy is required.

COSTS

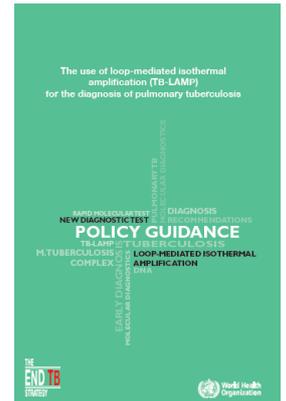
- Eiken is making the technology available at concessional prices for the public sector in 145 countries, and orders can be made through their distributor (HUMAN Gesellschaft für Biochemica und Diagnostica mbH).
- The price per test is 7 euros, and the available instruments allow for up to 16 or up to 96 samples per run.
- More information on the concessional prices negotiated by FIND, the list of eligible 145 countries, and ways to order may be found on the FIND website (<http://www.finddx.org/pricing/>);

WHO

RECOMMENDATIONS

ON THE USE OF TB-LAMP

http://www.who.int/tb/areas-of-work/laboratory/policy_statements



POLICY RECOMMENDATION

TB-LAMP may be used as a replacement test for sputum-smear microscopy for diagnosing pulmonary TB in adults with signs and symptoms consistent with TB (conditional recommendation, very low-quality evidence).

TB-LAMP may be used as a follow-on test to smear microscopy in adults with signs and symptoms consistent with pulmonary TB, especially when further testing of sputum smear-negative specimens is necessary (conditional recommendation, very low-quality evidence).

REMARKS

- These recommendations apply to settings where it is possible to perform conventional sputum-smear microscopy.
- TB-LAMP should not replace the use of rapid molecular tests that detect TB and resistance to rifampicin, especially among populations at risk of multidrug-resistant TB.
- Due to limited evidence, it is unclear whether TB-LAMP has additional diagnostic value over sputum-smear microscopy for testing persons living with HIV who have signs and symptoms consistent with TB.
- These recommendations apply only to the use of TB-LAMP in testing sputum specimens from patients with signs and symptoms consistent with pulmonary TB.
- These recommendations have been extrapolated to the use of TB-LAMP in children based on the generalization of data from adults, while acknowledging the difficulties of collecting sputum specimens from children.

IMPLEMENTATION CONSIDERATIONS

- TB-LAMP only detects TB, and therefore should not replace Xpert MTB/RIF, which simultaneously detects TB and rifampicin resistance and is automated.
- TB-LAMP may be a plausible alternative in settings with low prevalence of HIV and low prevalence of drug resistance, especially where environmental conditions ((unstable electricity, temperature, humidity, excessive dust) may preclude implementation of Xpert MTB/RIF.
- Several operational issues accompany the implementation of TB-LAMP: the needs for electricity, adequate storage and waste disposal, stock monitoring, and temperature control in storage settings where temperatures exceed the manufacturer's recommendation (currently 30 °C for TB-LAMP).
- TB-LAMP is designed and has been evaluated to detect *Mycobacterium tuberculosis* in sputum specimens. Its use with other samples (e.g., urine, serum, plasma, cerebrospinal fluid or other body fluids) has not been adequately evaluated.
- Adoption of TB-LAMP does not eliminate the need for smear microscopy, which should be used for monitoring the treatment of patients with drug-susceptible TB. However, the demand for conventional sputum microscopy may decrease in settings where TB-LAMP fully or partially replaces conventional sputum microscopy.