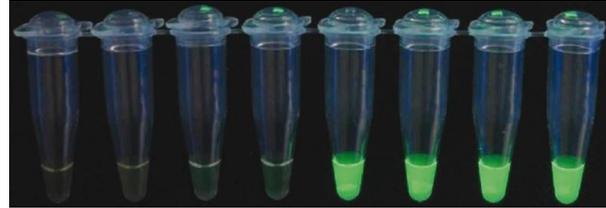


*30 September 2016:* In August 2016 the WHO Global TB Programme issued a policy recommendation on the TB-LAMP (loop-mediated isothermal amplification) test, indicating that it may be used as a replacement for smear microscopy for the diagnosis of pulmonary TB in adults with signs and symptoms of TB (i.e., with presumptive TB). The recommendation also states it may be used as a follow-on test to smear microscopy when further testing of smear-negative specimens is necessary.

TB-LAMP is a manual assay that requires less than one hour to perform. The test does not require sophisticated instrumentation and can be used at the peripheral health centre level, given biosafety requirements similar to sputum smear microscopy. The manufacturer is Eiken Chemical Company Ltd (Tokyo, Japan).



## Ordering and pricing

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 countries, and ways to order may be found on the [FIND website](#).

While TB-LAMP is rapid, has been shown to be more sensitive than smear microscopy<sup>1</sup> and may also be useful for differential diagnosis of nontuberculous mycobacteria (NTM), adoption of the test and its placement in laboratory networks and diagnostic algorithms should consider the following practical aspects:

1. TB-LAMP detects the presence of *Mycobacterium tuberculosis* complex (MTBC) in a sputum sample and therefore should not replace Xpert MTB/RIF, which simultaneously detects MTBC and rifampicin resistance.
2. Due to limited evidence, it is unclear whether TB-LAMP has additional diagnostic value over smear microscopy for the detection of TB in persons living with HIV.<sup>2</sup> **TB-LAMP may be a plausible alternative in settings with low prevalence of HIV and low prevalence of drug resistance, especially where environmental conditions may preclude implementation of Xpert MTB/RIF (e.g., unstable electricity, temperature, humidity, excessive dust).**
3. The TB-LAMP test procedure requires multiple hands-on steps. Training of technicians or other health care staff to perform the TB-LAMP test is similar to the amount of training for smear microscopy. More information on training and infrastructure requirements for TB-LAMP can be found [here](#). Test implementation should be supported with training materials and technical guidance to ensure testing staff are proficient in performing the test.
4. The TB-LAMP test procedure requires a heating block, and therefore electricity. Although short lapses or fluctuations in power should not significantly affect heating block temperatures, settings that experience frequent or lengthy outages may experience suboptimal test performance or service interruptions.
5. TB-LAMP test kit storage temperatures should not exceed 30°C.
6. Adoption of the TB-LAMP test does not eliminate the need for sputum smear microscopy, which should still be used for monitoring treatment of TB patients.
7. The TB-LAMP test is designed and evaluated to detect MTBC in sputum specimens. Other specimen types (e.g. urine, serum, plasma, CSF or other body fluids) have not been adequately evaluated and therefore are not currently recommended for use with the assay.

**The full WHO policy recommendations on TB-LAMP can be downloaded [here](#).**

<sup>1</sup> Using data from 1,810 persons with signs and symptoms consistent with TB in whom the most stringent reference standard was available, TB-LAMP had a pooled sensitivity 15% higher than smear microscopy (78% compared with 63%). Using data from 1,349 persons with signs and symptoms consistent with TB in whom the most stringent reference standard was available, TB-LAMP showed a 42% incremental yield in patients with culture-confirmed TB who had a negative sputum smear microscopy result.

<sup>2</sup> Data from 4 studies (271 participants) among HIV-positive adults with signs and symptoms consistent with pulmonary TB demonstrates sensitivity of TB-LAMP similar to sputum smear microscopy (64% and 62%).

See *The use of loop-mediated isothermal amplification (TB-LAMP) for the diagnosis of pulmonary tuberculosis: policy guidance*. Geneva: World Health Organization; 2016 (WHO/HTM/TB/2017.07)