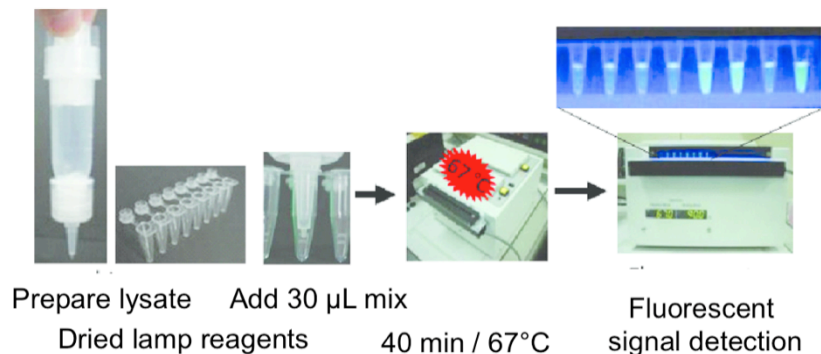


TB Loop-mediated isothermal amplification (TB-LAMP)

TB loop-mediated isothermal amplification (LAMP) is a manual NAAT. With LAMP, DNA amplification and detection of a gene can be completed in a single step. The test does not require sophisticated instruments and can be used at the peripheral health center level (closer to where people seek care, rather than a central laboratory), given biosafety requirements similar to sputum smear microscopy. The manufacturer of TB-LAMP is Eiken Chemical Company Ltd (Tokyo, Japan).

TB-LAMP requires less than one hour to perform and generates a result that can be detected with the naked eye under ultraviolet light. TB-LAMP detects the presence of *Mycobacterium tuberculosis* complex (MTBC) in a sputum sample.



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. Test implementation should be supported with training materials and technical guidance to ensure testing staff are proficient in performing the test.

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. TB-LAMP test kit storage temperatures should not exceed 30°C.

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.

In August 2016, the WHO recommended that LAMP might be used for the detection of TB as a replacement test for smear microscopy for the diagnosis of pulmonary TB in adults with signs and symptoms of TB. TB LAMP is a more sensitive test than smear microscopy, and 40% more patients are detected in smear-negative samples if TB LAMP is used as an add-on test once smear microscopy has been carried out. The WHO did not make a decision for or against the use of TB LAMP in the detection of TB in people with HIV due to the lack of evidence available. TB LAMP cannot replace smear microscopy for treatment monitoring.

Given the superior sensitivity and specificity and the ability to detect rifampin resistance up front by Cepheid's Xpert MTB/RIF test, and the anticipated POC platform Omni on the horizon that will have fewer training requirements, introducing TB LAMP does not appear to offer many benefits. Introducing a new test requires trainings, sorting out QA schemes and procurement, service and maintenance, etc. This is costly and time consuming, especially for settings with limited resources. LAMP equipment (about USD

730) is less expensive than GeneXpert, but the cost of Omni will be similar to the cost of the instruments necessary for TB LAMP, whereas the cost per test for TB LAMP is about the same as an MTB/RIF cartridge (EUR 7 or USD 9.7 per TB LAMP test, versus MTB/RIF at USD 10), which is not cost saving, especially considering that LAMP cannot detect rifampin resistance. Each run of six LAMP samples requires running a positive and negative sample (therefore adding the cost of two additional tests per run). Thus, it is not really worthwhile to invest in the introduction of TB LAMP.

TB LAMP ACTIVE TB DIAGNOSIS CANNOT DETECT DRUG RESISTANCE	
Advantages	Disadvantages
<ul style="list-style-type: none"> ▪ Fast—takes less than an hour to get results ▪ Low biosafety level, which is similar to microscopy ▪ Higher sensitivity than smear microscopy (by 15% more patients) ▪ Equipment more affordable than GeneXpert 	<ul style="list-style-type: none"> ▪ Cannot distinguish DR-TB from DS-TB ▪ Less specificity than smear microscopy—hence more false positive results (more people identified as having TB when they don't have TB) ▪ Worse than GeneXpert in terms of sensitivity ▪ Similar to GeneXpert, it CANNOT be used for treatment monitoring because it cannot distinguish between live and dead bacteria. Thus, sputum smear microscopy is still needed for treatment monitoring ▪ TB-LAMP requires several manual steps (around 10 steps) to perform the test and some of the steps are time and volume sensitive. Thus, it requires investments in terms of training and QA

Source: AN ACTIVIST’S GUIDE TO Tuberculosis Diagnostic Tools. Treatment Action Group, February 2017

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