TB-LAMP
It's time for a change

Detect TB more accurately and easily

Molecular DX
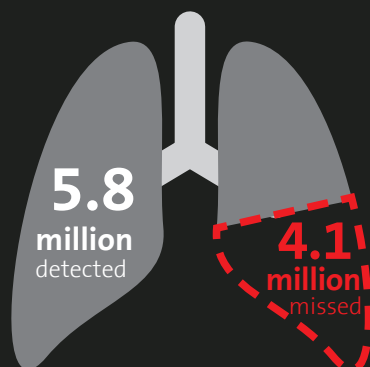
Smear microscopy misses nearly every second positive TB case

> *"We need new tests to rapidly diagnose people with TB; earlier, safer, easier and shorter treatment for infection and disease; and effective new vaccines."*
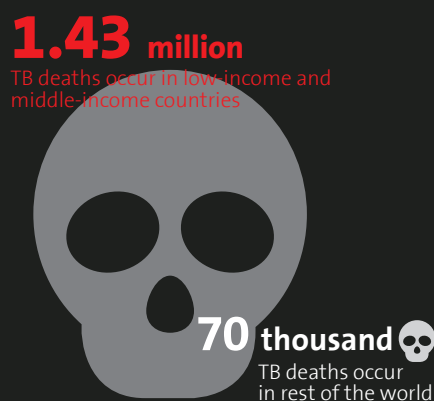>
> Ban Ki-moon, United Nations Secretary-General on World Tuberculosis day. March 2016

TB cases worldwide

5.8 million detected

4.1 million missed

> 9.9 million new cases in 2020 [1]
> 90 % of all cases were adults [1]
> The 2030 target is to reduce the TB incidence by 90 % [1]

TB deaths

1.43 million
TB deaths occur in low-income and middle-income countries

70 thousand
TB deaths occur in rest of the world

> TB is one of the top 10 causes of death [1]
> 0.21 million TB deaths among HIV-positive people [1]

Smear microscopy

50 % incorrect

50 % correct
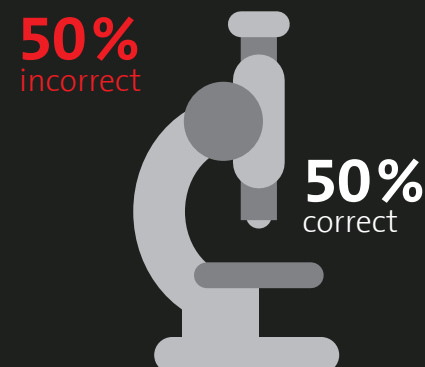
> In low-income and middle-income countries smear microscopy is the primary tool for diagnosing TB [1]
> Due to its poor sensitivity of 50 %, smear microscopy does not provide accurate test results (depending on staining method) [2,3]

These requirements are needed for sensitive, simple and accurate TB testing

Robustness
> Most laboratories have no access to air conditioning, safety cabinets or a good power supply

Performance
> Previous methods are not always reliable

Ease of use
> The processing or evaluation of results of previous methods is often complicated, well-trained personnel is missing

Cost effectiveness
> 95 % of the TB cases occur in low-income and middle-income countries

Speed
> Time to result and throughput are important in order to be able to treat the patient as quickly as possible

TB-LAMP
It's time for a change

"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; additionally, the technique is robust and can be used at peripheral health centers, where microscopy is performed."
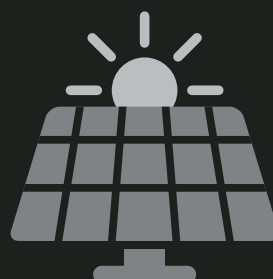
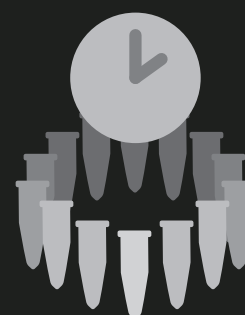WHO Policy Guidance. The use of TB-LAMP for the diagnosis of pulmonary tuberculosis. August 2016

+15 %
more detected

> 15 % more positive TB cases are detected by TB-LAMP than with smear microscopy [4]

> Simple and easy to learn workflow

> Robust reagents and equipment which can be operated with solar panel and battery

> High throughput with up to 14 samples in 1 – 2 hours

## WHO recommends TB-LAMP for replacing smear microscopy and several studies have shown its benefits [4]

Source	Sample number	Method	Sensitivity	Specificity
Reddy et al. (2018) [5]	705	Smear microscopy	45.4 %	99.0 %
		TB-LAMP	72.6 %	96.8 %
Donfack et al. (2018) [6]	527	Smear microscopy	53.6 %	99.0 %
		TB-LAMP	82.6 %	96.0 %
N'guessan et al. (2016) [7]	429	Smear microscopy	86.0 %	96.0 %
		TB-LAMP	92.0 %	94.0 %
Gray et al. (2016) [8]	1,777	Smear microscopy	63.8 %	—
		TB-LAMP	97.2 %	96.6 %
Kaku et al. (2016) [9]	472	TB-LAMP	99.1 %	98.4 %
Bojang et al. (2016) [10]	261	TB-LAMP	100.0 %	100.0 %
Ou et al. (2014) [11]	1392	TB-LAMP	92.1 %	98.3 %

Table 1:
Selected publications with TB-LAMP test performance in peripheral settings. Bacterial culture was used as gold standard

A comprehensive list of selected publications is available at:
www.human.de/lamp/pub

# Reliable, robust and proven worldwide Voices from the market
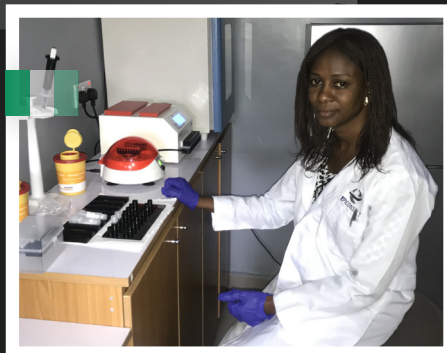
"TB-LAMP is a DNA-based method for quick TB diagnosis. It is fast, specific and has replaced microscopy because of its built-in heating block and UV light for reading sample results. It can be used in the remotest places because it's portable."

Chinyere Obiejemba,
Laboratory Technician,
EpiConsult Clinic & Diagnostic Centre Ltd.,
Abuja, Nigeria

"When I attended the training, I understood that TB-LAMP is beneficial for patients and technicians. Previously, the patient's first and second sputum was used in microscopy, but now, with the sensitivity of TB-LAMP, you only need to take the sputum once. With microscopy, it was difficult to handle 50 samples per day. This technique allows us to test 14 patients in one run and up to 70 in one day. For me, TB-LAMP is the best method for rapid detection of tuberculosis."

Joel Wepngong Tabah,
Laboratory Technician,
Baptist Hospital Mutengene,
Yaoundé, Cameroon
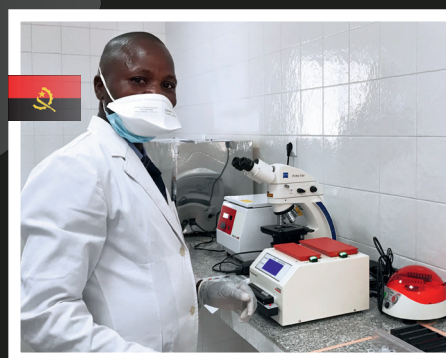
"I like the HumaLoop T and the easy handling very much. As a journey from the capital Luanda to my lab takes about 3 days by road, it is especially important for us to have a reliable device that requires only a minimum service every 12 months."

Tiago TxaVunda,
Laboratory Director,
HSC Nzagi,
Nzagi, Angola

Nigeria

Cameroon

Angola

India

"The high sensitivity, high throughput and the reliability of the assay, even under the challenging climate conditions, have convinced us. With this novel technology, we have the opportunity to find more tuberculosis cases than with traditional methods."

Anupam Kumar,
Dr. Lal PathLabs,
Delhi, India

Kenya

"We love using the new TB-LAMP technology: it is very quick and only takes about two hours for 14 samples per run. Thus a patient gets clarity on the same day whether he has TB or not. TB-LAMP provides very reliable results with a high sensitivity and specificity. Lastly, the HumaLoop T is a simple small machine which requires little infrastructure."

Anderson Mugendi & Simon Chege,
Laboratory Technicians,
Kangemi Health Center,
Nairobi, Kenya

Loopamp™ Systems
Solutions for various healthcare settings

Easy-to-use Loopamp™ technology for primary and peripheral laboratories

Specially designed as a consolidated platform for sample preparation, amplification and easy visual result reading, HumaLoop T facilitates sensitive and reliable detection of tuberculosis with the Loopamp™ MTBC Detection Kit.

> For small to medium throughput up to 16 tests per run or up to 70 samples per day

> Preinstalled and fixed incubation times and temperatures for Loopamp™ assays

> Consolidated processing: sample preparation, amplification and detection on a single instrument

> Perfect for use in remote areas with independent power solution by solar panel and battery system

> Explicit interpretation by visual reading of fluorescence signals

> Fast reporting: results in 1 – 2 hours

## Scalable Loopamp™ system for reference and regional laboratories

The HumaTurb system allows real-time detection of turbidity based upon magnesium-pyrophosphate which is generated during the amplification process. The entire system consists of HumaTurb C + A. The HumaTurb C for the setup and control of incubation time and temperature, necessary for amplification. The amplification itself takes place in the second part of the system, the HumaTurb A. The sample lysis is performed with the HumaHeat.

> For medium to high throughput: up to 96 tests per run if expanded with 6 HumaTurb A units

> Different Loopamp™ assays can be performed in one run

> Flexible data transfer via USB

> Built-in printer

> Automated result reporting

HumaLoop T

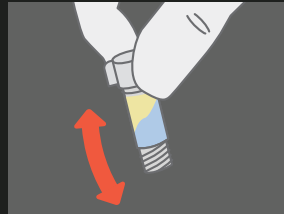Portable battery system with solar panel
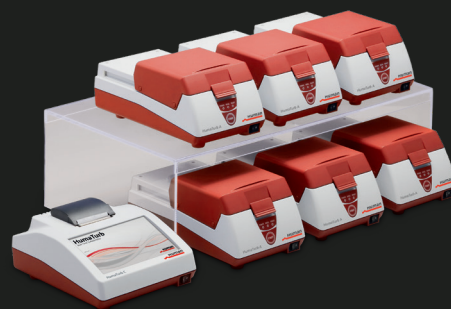
HumaTurb C with 6 HumaTurb A units

Simple and fast TB-LAMP workflow with HumaLoop T or HumaTurb C+A

1. Sample transfer and lysis
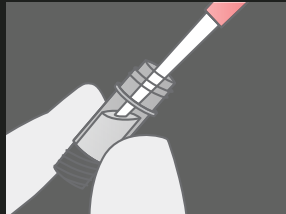
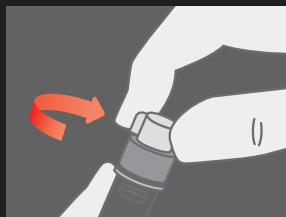Transfer 60 µl sputum with Pipette-60 into the heating tube.
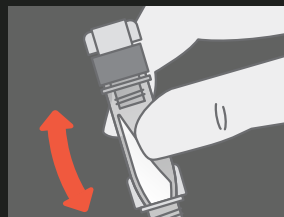

Mix well by shaking.

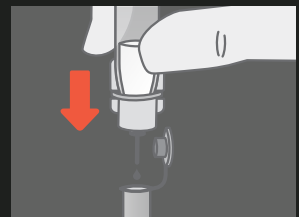Incubate the tube in the heating unit of HumaLoop T or HumaHeat for 5 min at 90° C.

2. Loopamp™ PURE DNA extraction

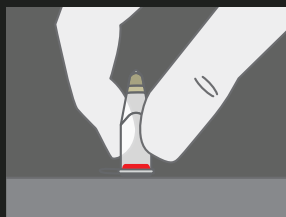Screw the heating tube onto the adsorbent tube.

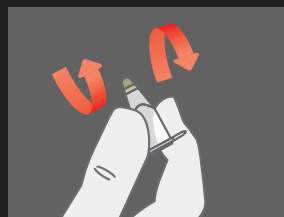Afterwards shake the tube until a milky solution is obtained.

Screw the injection cap onto the adsorbent tube. Extract the DNA into the reaction tube.

3. Loop-mediated isothermal amplification

Incubate the tube for 2 min at room temperature to reconstitute the reagents in the cap.

Mix the tube several times and tap until the reaction mix is collected at the bottom of the tube.
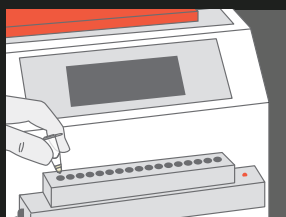

Incubate the reaction tube in the HumaLoop T reaction unit or HumaTurb A for 45 min at 67° C.
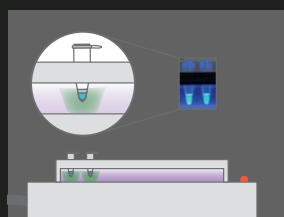
4. Result reading

HumaLoop T
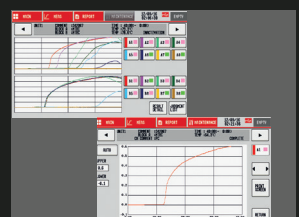

Insert the tubes into the detection unit and turn the UV light on.

Positive results light green, negative results show no fluorescence.

or

HumaTurb C

Turbidity measurement in real-time and automated result reporting.

Movie

TB-LAMP

Additional tools in cooperation with our partners

Mobile application for electronic result management

> Storing and sending the results obtained with HumaLoop T electronically by e-mail or SMS

> Highly professional patient management, even in remote areas

For more information
visit www.savics.org

External quality assurance program

> SmartSpot patented technology enables the packaging of inactivated MTB on a simple spot on a card

> Easy, safe and cost-effective to transport and stable for 24 months at ambient temperatures

To participate in the EQA programm
visit www.smartspotq.com

Ordering Information

HumaLoop T   REF: 961000
Incubator for sample processing, amplification and visual result reading

HumaTurb C + A   REF: 963200
C = Control unit displaying real-time turbidity measurements
A = Amplification unit

HumaTurb A   REF: 963100
HumaTurb C is connectable with up to six HumaTurb A units

HumaHeat   REF: 964000
Incubator for the sample lysis of the Loopamp™
PURE heating tubes. Mandatory for HumaTurb C + A

Pipette-60 Set   REF: 971000
Pipette to ease the transfer of sputum samples
1 x pipette and 4 x 96 filter tips

Loopamp™ PURE DNA Extraction Kit   REF: 970000
For the extraction of DNA of the sample. 90 tests

Loopamp™ MTBC Detection Kit   REF: 972000
For the qualitative detection of bacteria belonging to
Mycobacterium Tuberculosis Complex (MTBC) 2 x 48 tests

Solar Panel*   REF: 18965/100
Foldable solar panel for charging the battery system 100W

Portable Battery System*   REF: 18965/220
LAMP devices can be operated up to three runs

HuMax ITA*   REF: 980000
Benchtop centrifuge with preinstalled program for the incubation and mixing of Loopamp™ reaction tubes

* optional

Find more information about LAMP-related products on www.human.de/lamp or www.finddx.org

1. Global TB Report 2021, WHO.
2. Luelmo F. (2004) What is the role of sputum microscopy in patients attending health facilities?
    In: Frieden T, editor. Toman's tuberculosis: case detection, treatment, and monitoring – questions and answers. 2nd ed. Geneva: World Health Organization. pp. 7 – 13.
3. Perkins MD. (2000) New diagnostic tools for tuberculosis. Int J Tuberc Lung Dis. 4 (12 suppl 2): S182 – 8.
4. WHO Policy Guidance (2016) The use of loop-mediated isothermal amplification (TB-LAMP) for the diagnosis of pulmonary tuberculosis.
5. Reddy S. et al. (2017) Detecting Mycobacterium tuberculosis using the loop-mediated isothermal amplification test in South Africa. INT J TUBERC LUNG DIS 21(10):1154–1160.
6. Donfack VFD. et al. (2018) Comparative study of Loopamp™ Mycobacterium tuberculosis Complex Kit for Rapid Detection of Mycobacterium tuberculosis Complex in Cameroon. Biomed Biotechnol Res J 2018;2:46-52.
7. N'guessan K. et al. (2016) Clinical Performances of Pure TB-Lamp Kit for M. tuberculosis Complex Detection in Sputum Samples. Journal of Tuberculosis Research, 2016, 5, 129-138.
8. Gray CM. et al. (2016) Feasibility and operational performance of TB LAMP in decentralized setting. J Clin Microbiol; JCM-03036.
9. Kaku T. et al. (2016) Accuracy of LAMP-TB Method for Diagnosing Tuberculosis in Haiti. Jap J Infect Dis; 69(6): 488 – 492.
10. Bojang AL. et al. (2016) Comparison of TB-LAMP, GeneXpert MTB/RIF and culture for diagnosis of pulmonary tuberculosis in The Gambia. J Infect; 72(3): 332 – 33.
11. Ou X. et al. (2014) Diagnostic accuracy of the PURE-LAMP test for pulmonary tuberculosis at the country-level laboratory in China. PLoS One; 9(5): e94544.

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