Detect TB. Accurately. Easily.

Fast and robust test results with TB-LAMP
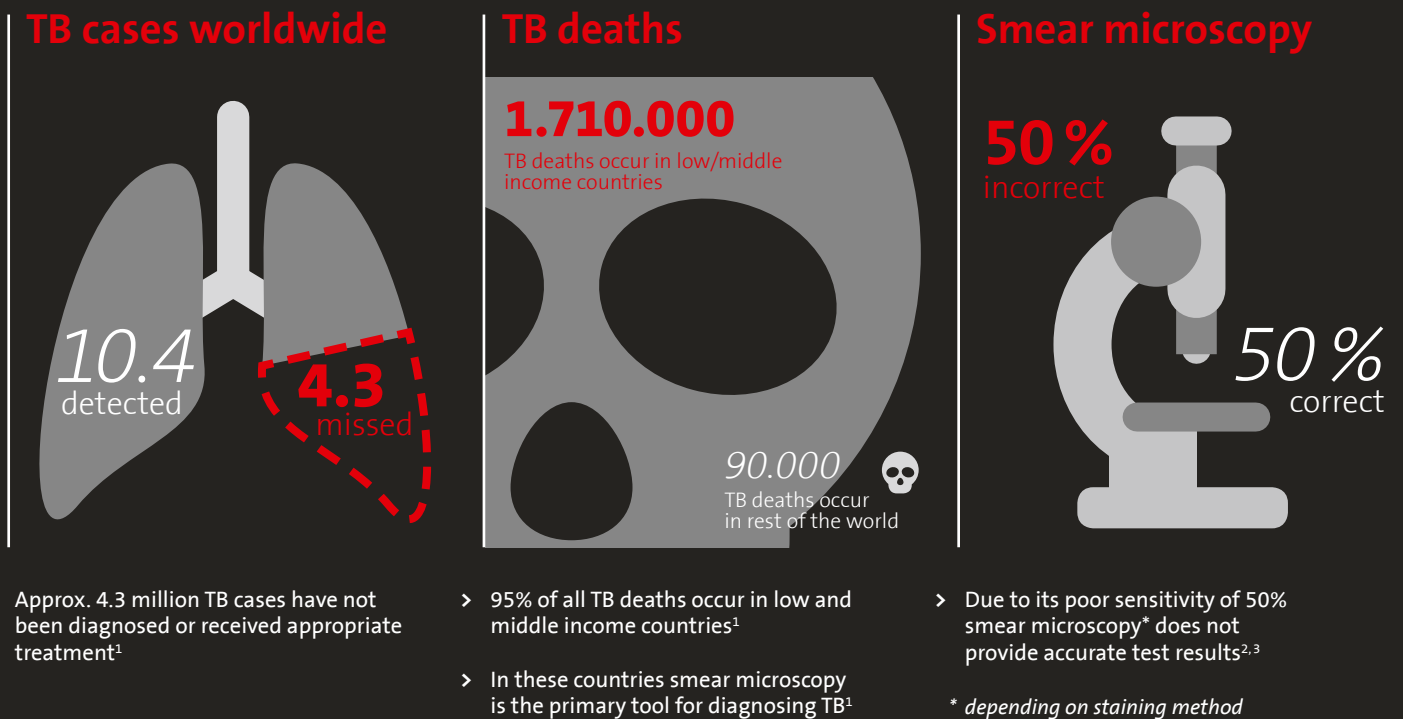
Molecular DX

HumaLoop T

EIKEN CHEMICAL CO.,LTD.

Human

Diagnostics Worldwide

Smear microscopy misses nearly every second positive TB case

TB cases worldwide

10.4 detected

4.3 missed

> Approx. 4.3 million TB cases have not been diagnosed or received appropriate treatment[1]

TB deaths

1.710.000 TB deaths occur in low/middle income countries

90.000 TB deaths occur in rest of the world

> 95% of all TB deaths occur in low and middle income countries[1]

> In these countries smear microscopy is the primary tool for diagnosing TB[1]

Smear microscopy

50% incorrect

50% correct

> Due to its poor sensitivity of 50% smear microscopy* does not provide accurate test results[2,3]

* depending on staining method

Sensitive and simple tools are required for accurate TB testing

Robustness

Performance

Ease of use

Minimum training

Speed

Cost effectiveness

TB-LAMP is a failsafe solution for peripheral microscopy centers

"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

WHO recommends TB-LAMP for replacing smear microscopy

> TB-LAMP detects > 15 % more positive TB cases

> Is also applicable to confirm smear negative results[4]

> Can be used as first line test for all patient groups
 when the GeneXpert system is not available[5]

TB-LAMP provides accurate results in smear+ and smear- patient samples

| TB-LAMP	Sample number	Sensitivity smear +	Sensitivity smear -	Specificity (culture -)
Ou et al. (2014)[6]	1392	92.1% (152/165)	53.8% (113/210)	98.3% (938/954)
		88.8% (333/375)		96.8% (924/954)
Kaku et al. (2016)[7,8]	472	99.1% (113/114)	52.1% (21/41)	98.4% (312/317)
	209	100% (47/47)	56.5% (13/23)	97.8% (136/139)
Gray et al. (2016)[9]	1745	97.2% (243/250)	62% (88/142)	96.6% (1307/1353)
Bojang et al. (2016)[10]	261	100%	90.3%	100% (smear +) 99% (smear -)

Table 1: TB-LAMP test performance in smear+ and smear- patient samples in peripheral settings. Bacterial culture was used as gold standard.
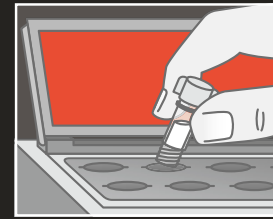
TB-LAMP is robust and easy to perform

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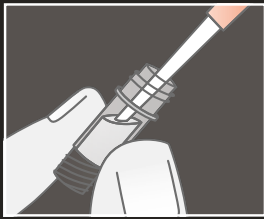
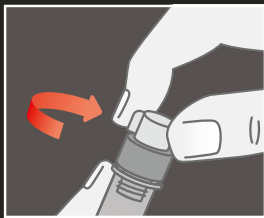Transfer 60µl sputum with Pipette-60 into the heating tube.
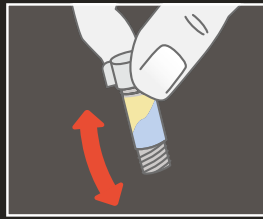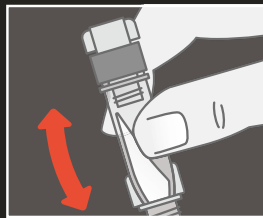
Mix well by shaking.

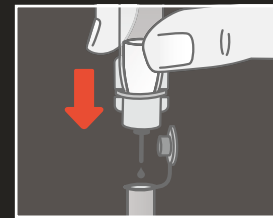Incubate the tube in the HumaLoop T heating unit for 5 min at 90°C.

2. Loopamp™ PURE DNA extraction
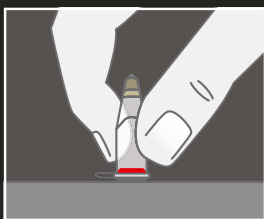
Screw the heating tube onto the adsorbent tube.

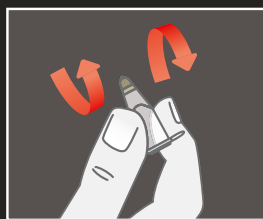Afterwards, shake the tube until a milky solution is obtained.

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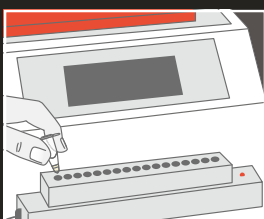
Mix the tube several times and tap until the reaction mix is collected at the bottom of the tube.

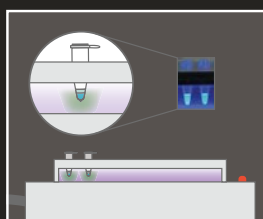Incubate the reaction tube in the HumaLoop T reaction unit for 45 min.

4. Result reading

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

Positive results light green, negative results show no fluorescence.

Features & Benefits

> Preinstalled incubation times and temperatures for a failsafe operation

> Dried reagents for a high robustness

> Solution for up to 70 samples/day

TB-LAMP requires minimum equipment and reagents

Pipette-60 Set *(1 pipette, 4 x 96 filter tips)*
REF: 971000

Loopamp™ PURE DNA Extraction Kit *(90 tests)*
Storage and shipment at 1 … 30°C
REF: 970000

Loopamp™ MTBC Detection Kit *(2 x 48 tests)*
Storage and shipment at 1 … 30°C
REF: 972000

HumaLoop T *(incubator for sample processing,
amplification and visual result reading)*
REF: 961000

HuMax ITA *(bench-top centrifuge with preinstalled program
for the incubation and mixing of Loopamp™ reaction tubes)*
REF: 980000

HUMAN's global distribution network

Local service and support

> For more than 45 years HUMAN provides IVD products for regions with limited infrastructure or remote areas.

> HUMAN has a well established distribution network in more than 160 countries.

> HUMAN offers solutions for all relevant areas of humanitarian aid, coordinated and controlled supply chains, local service and support.

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

1.   Global TB Report 2016, 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.   GLI model TB diagnostic algorithms *(2017) GLI global laboratory initiative advancing TB diagnosis.*
6.   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.*
7.   Kaku T. et al. *(2016) Assessment of accuracy of LAMP-TB method for diagnosing tuberculosis in Haiti. Jap J Infect Dis; Published online: March 18.*
8.   Kaku T. et al. *(2016) Accuracy of LAMP-TB Method for Diagnosing Tuberculosis in Haiti. Jap J Infect Dis; 69(6): 488−492.*
9.   Gray CM. et al. *(2016) Feasibility and operational performance of TB LAMP in decentralized setting. J Clin Microbiol; JCM-03036.*
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.*

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