Detect TB. Accurately. Easily.

Fast and robust test results with TB-LAMP
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, 24. March 2016

Sensitive and simple tools are required for accurate TB testing

TB cases worldwide
- Approx. 4.3 million TB cases have not been diagnosed or received appropriate treatment

TB deaths
- 1,710,000 TB deaths occur in low and middle income countries
- 95% of all TB deaths occur in low and middle income countries
- In these countries smear microscopy is the primary tool for diagnosing TB

Smear microscopy
- Due to its poor sensitivity of 50% smear microscopy* does not provide accurate test results
- 50% correct
- 50% incorrect

S. due to its poor sensitivity of 50% smear microscopy* does not provide accurate test results

* depending on staining method

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 recommends TB-LAMP for replacing smear microscopy

- TB-LAMP detects > 15% more positive TB cases
- Is also applicable to confirm smear negative results
- Can be used as first line test for all patient groups when the GeneXpert system is not available

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

<table>
<thead>
<tr>
<th>TB-LAMP</th>
<th>Sample number</th>
<th>Sensitivity smear +</th>
<th>Sensitivity smear -</th>
<th>Specificity (culture -)</th>
</tr>
</thead>
<tbody>
<tr>
<td>Ou et al. (2014)</td>
<td>1392</td>
<td>92.1% (152/165)</td>
<td>53.8% (113/210)</td>
<td>98.3% (938/954)</td>
</tr>
<tr>
<td></td>
<td></td>
<td>88.8% (333/375)</td>
<td></td>
<td>96.8% (924/954)</td>
</tr>
<tr>
<td>Kaku et al.</td>
<td>472</td>
<td>99.1% (113/114)</td>
<td>52.1% (21/41)</td>
<td>98.4% (312/317)</td>
</tr>
<tr>
<td>(2016)</td>
<td></td>
<td>100% (47/47)</td>
<td>56.5% (13/23)</td>
<td>97.8% (136/139)</td>
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<tr>
<td>Gray et al.</td>
<td>1745</td>
<td>97.2% (243/250)</td>
<td>62% (88/142)</td>
<td>96.6% (1307/1353)</td>
</tr>
<tr>
<td>(2016)</td>
<td></td>
<td>100%</td>
<td>90.3%</td>
<td>100% (smear +) 99% (smear -)</td>
</tr>
<tr>
<td>Bojang et al.</td>
<td>261</td>
<td>100%</td>
<td></td>
<td></td>
</tr>
</tbody>
</table>

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
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