Spotting Malaria reliably

Track down infections easily with highly sensitive Malaria-LAMP even in low-prevalent settings

Molecular DX

EIKEN CHEMICAL CO., LTD.

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Human

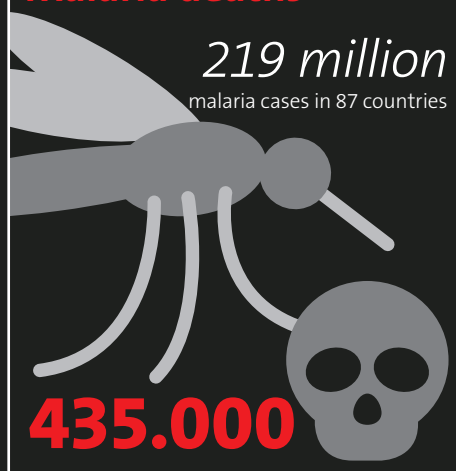
Diagnostics Worldwide

Microscopy and RDT's are not able to track down parasites in low-transmission settings

"Diagnostic testing and treatment Research is required to develop tools that can more readily detect low-level parasitaemia in asymptomatic carriers and ascertain the effectiveness of different screening strategies both at higher transmission levels, in order to appropriately target interventions, and when countries enter the elimination phase."[1]

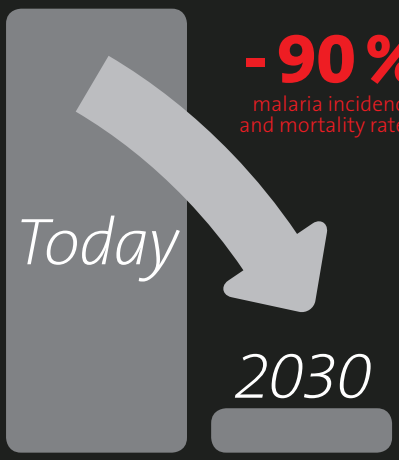
WHO, Global Technical Strategy for Malaria 2016–2030, 2015

Malaria deaths



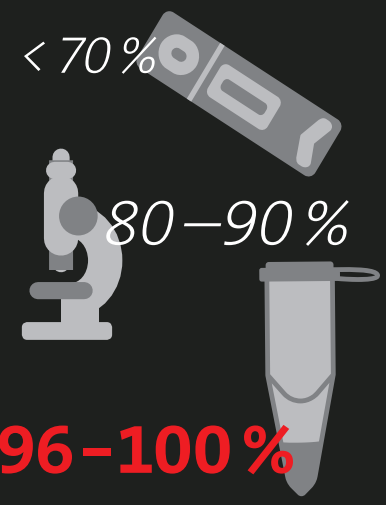
› Children aged under five years are the most vulnerable group. They accounted for 61% of all malaria deaths worldwide (2017)[2]

WHO Strategy



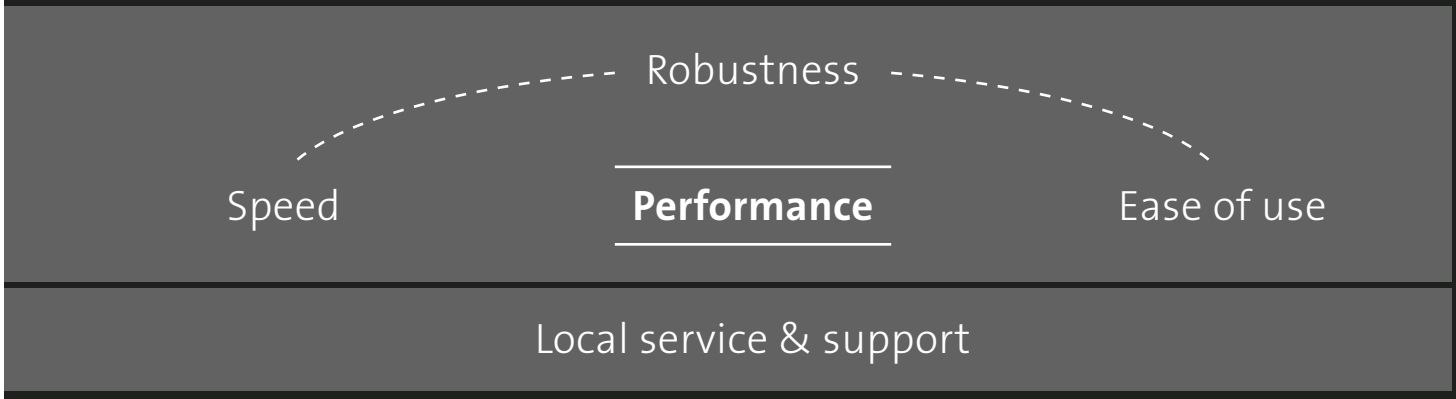
› The WHO Malaria strategy aims to reduce global malaria incidence and mortality rates by 90 % until 2030[2]

Sensitivity



› Due to their limited sensitivities of 80–90 % and < 70 %, microscopy and RDT's do not provide reliable results in low-transmission areas[3]

Diagnosis of malaria calls for a highly sensitive and fast method



Plasmodium vivax: A pathogen with significant challenges

"P. vivax malaria is difficult to detect and treat because the parasitaemia is typically low in comparison to that of P. falciparum, and current diagnostic tests cannot detect dormant forms residing in the liver."[4]

WHO (2015) Control and Elimination of *Plasmodium vivax* Malaria – A technical brief

Spread of *Plasmodium vivax*

- More than a third of the world's population, mostly in Asia and Latin America, is at risk of infection with *P. vivax* malaria[5]

Cases worldwide

- Despite tremendous progress in reducing *P. vivax* malaria since 2000, there were 8.5 million cases globally in 2016[5]

Predomination in elimination countries

- *P. vivax* predominates mainly in the approaching Malaria elimination countries defined by the WHO. The parasite is responsible for more than 70 % of malaria cases in countries with less than 5000 cases per year[5]

Challenges in the diagnosis of *Plasmodium vivax* Malaria

- *P. vivax* often has a lower parasite density (typically 10 times lower) than *P. falciparum*, making it difficult to detect *P. vivax* infections with Rapid Diagnostic Tests and microscopy.[5]
- The parasite also has a dormant liver stage that cannot be detected by current diagnostic tools.[5]
- Many Rapid Diagnostic Tests are unable to distinguish mixed Pf-Pv infections.[6]

Malaria-LAMP

Detection of asymptomatic, sub-microscopic infections

"Sub-microscopic P. falciparum and P. vivax infections are common in both low- and high-transmission settings. Use of NAA methods in malaria programmes should be considered for epidemiological research and surveys to map sub-microscopic infections in low-transmission areas. NAA methods might also be used for identifying foci for special interventions in elimination settings."[7]

WHO Policy brief on malaria diagnostic in low transmission settings, September 2014

High reliability and robustness by excellent test performance

- High sensitivity and specificity with a detection limit of 1 parasite / µl*
- Dried reagents: optimally suited for use in remote settings
- Patient friendly: only small sample volume (30 – 60 µl) is needed and differeent types of blood samples can be used
- **Test results for a differentiated diagnosis:** Differentiation between *Plasmodium pan* species, *Plasmodium falciparum* and *Plasmodium vivax*
- Recognized method: Listed in the WHO Policy brief on malaria diagnostic in low-transmission settings[4]

Malaria-LAMP as a valuable solution in low-transmission areas

Malaria-LAMP	Sample number	Sensitivity*	Specificity
González et al. (2012)[8]	705	Pan: 97.0 % Pf: 98.4 %	Pan: 99.2 % Pf: 98.1 %
Sattabongkat et al. (2014)[9]	1017	95.7 %	100 %
Aydin-Schmidt et al. (2014)[10]	1330	Fever patients: 91.5 – 98.3 % Asymptomatic patients: 90.7 – 97 %	100 %
Marti et al. (2015)[11]	205	100 %	100 %
Lau et al. (2016)[12]	201	100 %	100 %
Tambo et al. (2018)[13]	3151	95.5 %	99.92 %

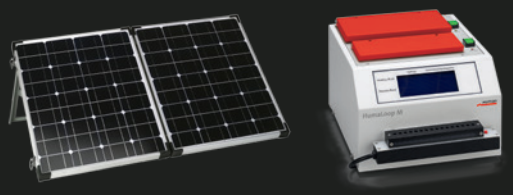
List of selected publications. A comprehensive list is available at : www.human.de/lamp/pub

* P. pan if not stated otherwise

Loopamp™ Systems

Two solutions for different fields of application

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 M facilitates sensitive and reliable detection for a variety of Loopamp™ tropic pathogens assays, e.g. Loopamp™ Malaria Pan, Loopamp™ Malaria Pf and Loopamp™ Malaria Pv.

- For small to medium throughput: up to 16 tests/run or up to 70 samples/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 h

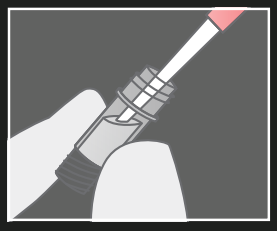
Scalable Loopamp™ system for reference and regional laboratories

HumaTurb system allows for the real-time detection of turbidity based upon magnesium-pyrophosphate which is generated during the amplification process. The entire system consists of Huma-Turb C and 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. In case of DNA purification with the Loopamp™ PURE DNA Extraction kit, sample lysis is performed with HumaHeat.

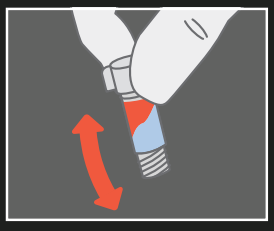
- For medium to high throughput: up to 96 tests/run (if expanded with 6 HumaTurb A units)
- Different Loopamp™ assays can be performed in one run
- Flexible data transfer via USB and LIS connectivity
- Built-in printer
- Result reporting

Simple and fast Malaria-LAMP workflow* with HumaLoop M / HumaTurb C+A

1. Sample transfer and lysis



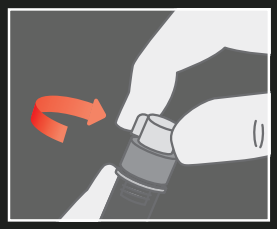
Transfer 30 µl blood and 30 µl 344 mM NaCl with a pipette into the heating tube.



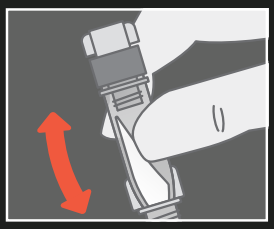
Mix well by shaking.

Incubate the tube in the heating unit of HumaLoop M **or** HumaHeat for 5 min at 75°C.

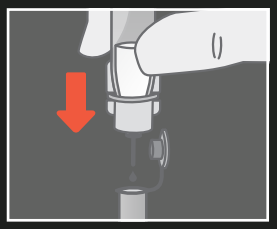
2. Loopamp™ PURE DNA extraction



Screw the heating tube onto the adsorbent tube.

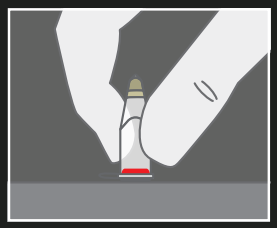


Afterwards, shake the tube until a milky solution is obtained.

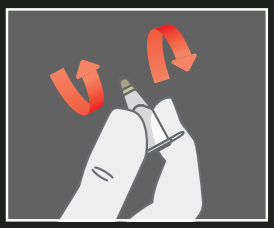


Screw the injection cap onto the adsorbent tube. Extract the DNA into the reaction tube.

3. Loop-mediated isothermal amplification



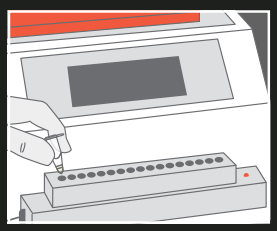
Incubate the tube for 2 min at room temperature to reconstitute the reagents in the cap.



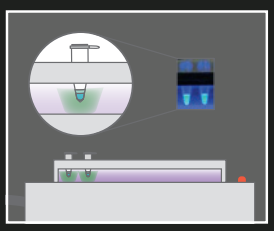
Mix the tube several times and tap until the reaction mix is collected at the bottom of the tube.

Incubate the reaction tube in the HumaLoop M reaction unit **or** HumaTurb A for 45 min at 65°C.

4. Result reading: HumaLoop M



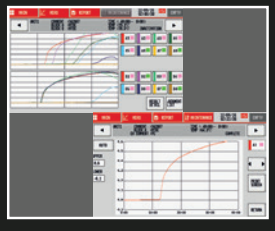
Insert the tubes into the detection unit and turn the UV light on.



Positive results light green, negative results show no fluorescence.

or

4. Result reading: HumaTurb C



Turbidity measurement in real-time.

*Also feasible with boil & spin method

Malaria-LAMP product overview

Loopamp™ Malaria Pan Detection Kit
for the qualitative detection of *Plasmodium pan species*
10 x 48 tests **REF: 974000** *2 x 48 tests* **REF: 977000**

Loopamp™ Malaria Pf Detection Kit
for the qualitative detection of *Plasmodium falciparum species*
2 x 48 tests **REF: 978000**

Loopamp™ Malaria Pv Detection Kit **New**
for the qualitative detection of *Plasmodium vivax species*
2 x 48 tests **REF: 975000**

Loopamp™ PURE DNA Extraction Kit
For the extraction of DNA of the sample
Specimens: Fresh blood, blood with heparin, blood spots on filter paper
90 tests **REF: 970000**

HumaLoop M
Incubator for sample processing, amplification
and visual result reading **REF: 962000**

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

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

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

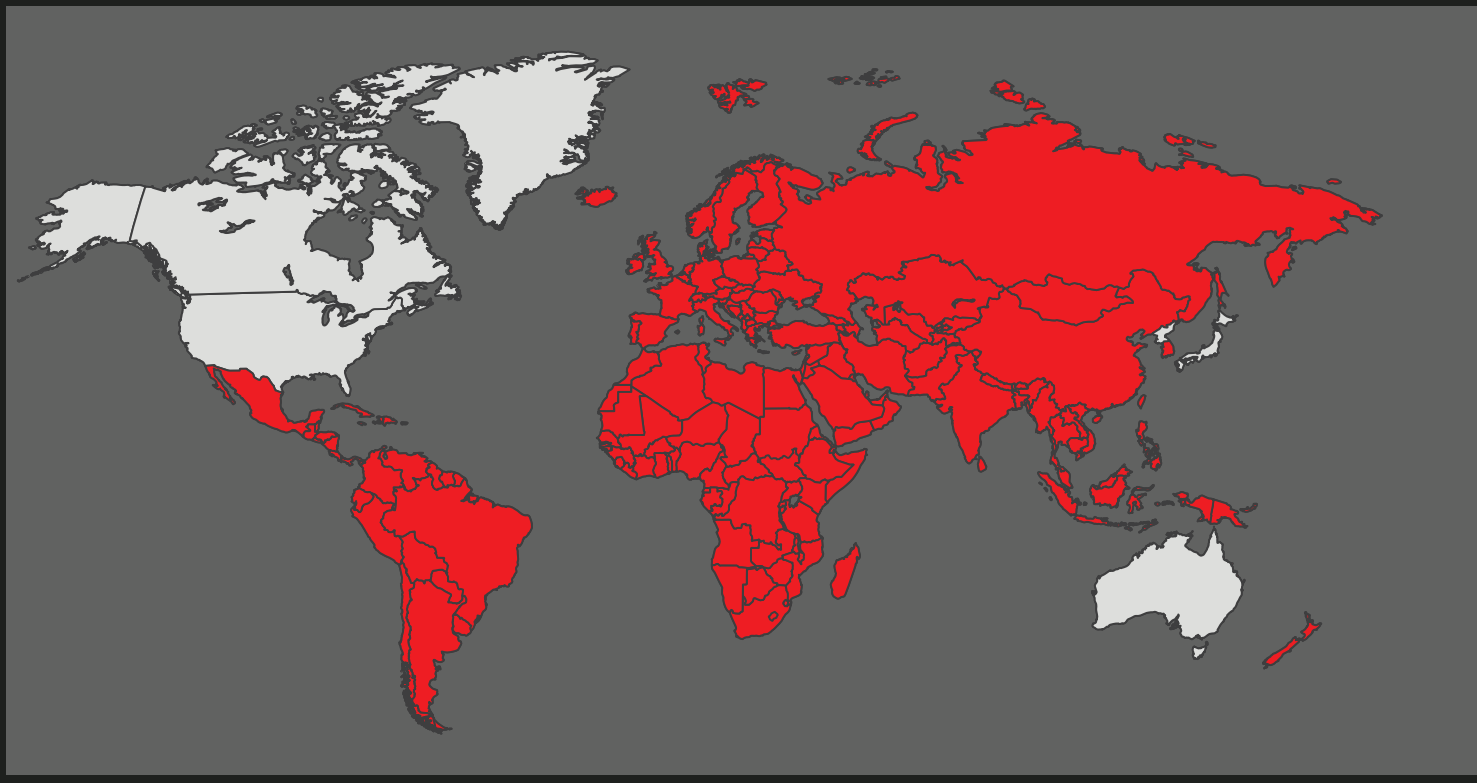
HuMax ITA
Bench-top centrifuge with preinstalled program for the incubation
and mixing of Loopamp™ reaction tubes **REF: 980000**

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

Portable Battery System (220V, 300W)
LAMP devices can be operated up to three runs **REF: 18965/220**

HUMAN's global distribution network

Local service and support



- Providing IVD products for regions with limited infrastructure or remote areas for more than 45 years
- Established distribution network in more than 160 countries
- Offering solutions for all relevant areas of humanitarian aid, coordinated and controlled supply chains, local service and support

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

1. WHO (2015) *Global Technical Strategy for Malaria 2016–2030.*
2. WHO (2018) *Global malaria report 2018.*
3. Cook J et al. *(2015) Loop-mediated isothermal amplification (LAMP) for point of care detection of asymptomatic low-densitiy malaria parasite carriers in Zanzibar. Malar; 14–43.*
4. WHO (2015) *Control and Elimination of Plasmodium vivax Malaria – A technical brief*
5. WHO (2015) *Confronting Plasmodium vivax Malaria*
6. Beeson JG. (2015) *Plasmodium vivax Malaria: Challenges in diagnosis treatment and elimination Malaria. The Pediatric Infectious Disease Journal; 34(5): 529 - 531.*
7. WHO (2014) *Policy brief on malaria diagnostic in low transmission settings, September 2014.*
8. Gonzalez IJ. et al. *(2012) Molecular diagnosis for screening and elimination of malaria: performance of the first commercially available malaria LAMP test. Malar J; 11:030.*
9. Sattabonkot J. et al. *(2014) Loop-mediated isothermal amplification assay for rapid diagnosis of malaria infections in an area of endemicity in Thailand J Clin Micorbiol; 52(5):1471–1477.*
10. Aydin-Schmidt B. et al. *(2014) Loop mediated isothermal amplification (LAMP) accurately detects malaria DNA from filter paper blood samples of low density parasitemias. PLoS One; 9 (8)e103905.*
11. Marti H. et al. *(2015) Diagnostic accuracy of a LAMP kit for diagnosis of imported malaria in Switzerland. Travel med. Infec Dis; 13(2):167–171.*
12. Lau YL. Et al. *(2016) Loop-mediated isothermal amplification assay for identification of five human Plasmodium species in Malaysia. Am J Trop Hyg; 94(2):336–339.*
13. Tambo et al. Malar J (2018) *17:255, Evaluation of loop-mediated isothermal amplification as a surveillance tool for malaria in reactive case detection moving towards elimination*

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