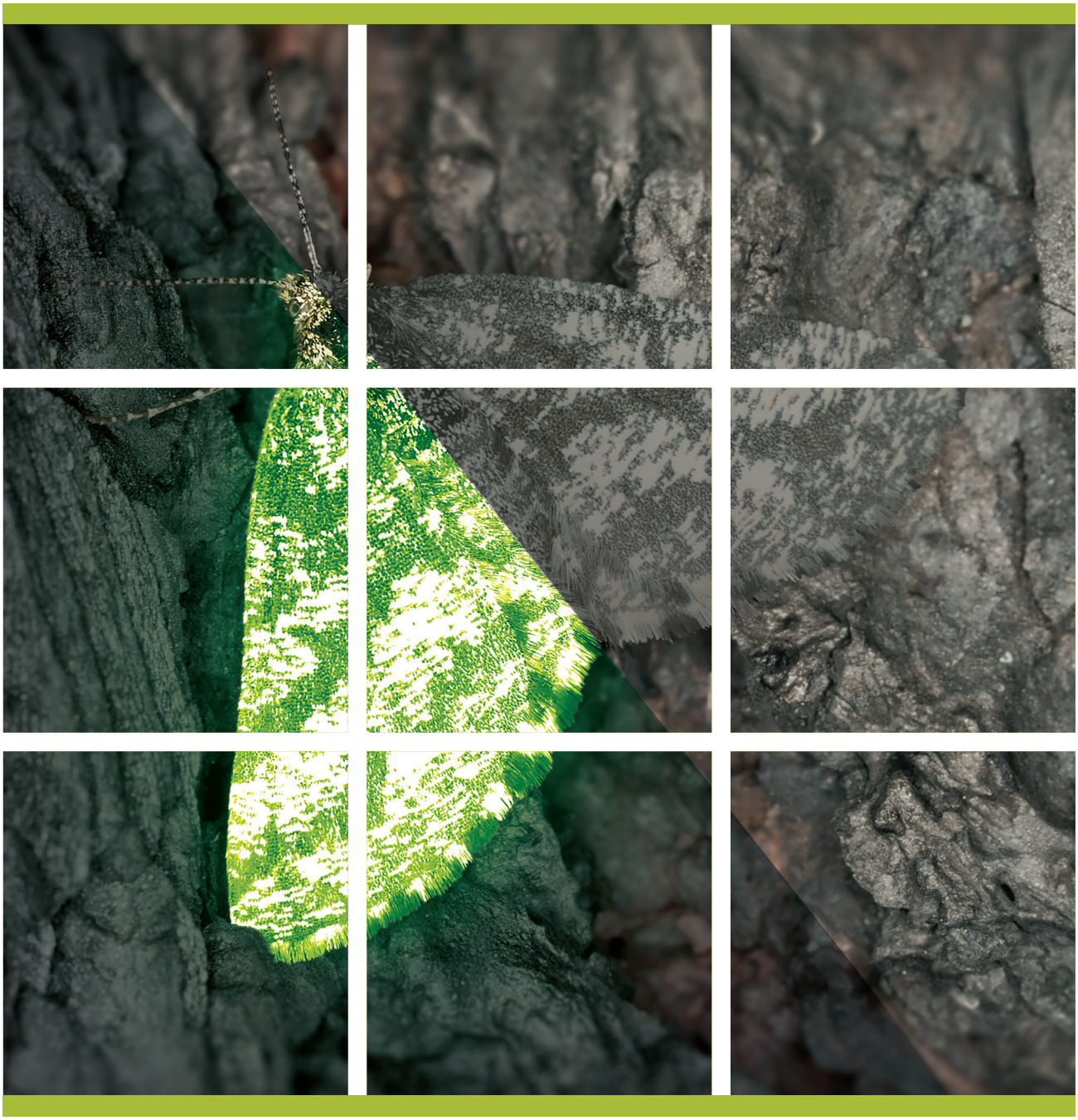
Frequently Asked Questions

TB-LAMP



EIKEN CHEMICAL CO.,LTD.

Human
Diagnostics Worldwide

Questions & Answers

This document is intended to give a comprehensive overview of important aspects of the TB-LAMP method, such as the storage, the handling or equipment characteristics. Only selected information from valid product documents is given. The instructions given in the valid versions of the applicable product documents (IFU, manuals, decontamination regulations) need to be followed when using the respective IVD products.

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LAMP Technology

What is the technology behind the Loopamp™ assays?
The LAMP or Loopamp™ technology bases on the amplification of genetic material at one temperature. The generation of a single strand by the DNA helicase, the binding of primer pairs and the generation of copies are optimized to work perfectly at one temperature. LAMP uses 4 primers that detect 6 distinct regions on the target DNA. During the amplification. process, copies are generated that contain loop or cauliflower similar structures. That's why the technology is called "loopamp".

What is the difference between LAMP technology and Real-time PCR?

Feature	Real-Time PCR	LAMP technology
Primers per target	2	4
Target numbers	1	6
Amplification	Exponential	Not exponential
Temperature steps for amplification	3	1
Time to result	1–3 h (depending on assay)	50–55 min
Equipment	Thermocycler	HumaLoop T/M or HumaTurb C+A
Results	Qualitative and quantitative	Qualitative
Result reading	Fluorescence curves (software)	Visual (green fluorescence) or real-time turbidity

Table 1: Side by side comparison of Real-Time PCR and LAMP technology

Is there already an External Quality Assessment for LAMP?
No, unfortunately there is no EQA system yet.

TB-LAMP

What is the difference of TB-LAMP compared to smear microscopy?

Similarities:
- Diagnostic tool for detecting tuberculosis
- Can be performed in each setting
- Requires the same bio-safety precautions
- Are easy to perform

Differences:
- TB-LAMP is a molecular method
- TB-LAMP is more specific
- TB-LAMP is more sensitive
- TB-LAMP does need less experience

Which equipment is needed to perform TB-LAMP?
The following items are needed:
- Gloves
- Pipette-60 set
- PURE rack set
- Timer (optional)
- Reaction tube stand
- Loopamp™ MTBC Detection Kit
- Waste bin
- Sputum container
- Loopamp™ PURE DNA Extraction Kit
- Squeezing device (optional)
- Marker
- HuMax ITA (optional, recommended)
- HumaLoop T or HumaTurb C+A with HumaHeat
- Pen

Does HUMAN provide also containers for sputum samples?
No. HUMAN doesn't provide sample containers.

Can TB-LAMP also be used as follow-up for patients?
No, a follow-up is always only possible with microscopy.

Which safety precautions are recommended for performing TB-LAMP?
To reduce the risk of DNA contamination, for molecular methods ideally two separate working areas are required. The transfer of sputum before sample processing is recommended to be performed in a biosafety bank if available. Due t the fact that the heating tube is just opened once for transferring the patient sample the risk of infection and contamination is minimized. But surely, before and after performing TB-LAMP the decontamination of the working surface with bleaching solution and further cleaning with alcohol should be part of the daily working procedure. Compared to the infrastructure required for smear microscopy, TB-LAMP has similar requirements and biosafety precautions but enables a cleaner working than dealing with the solutions of carbol-fuchsin and does not require any separated dark room like fluorescence microscopy.

How should the waste be handled?

- All potential infectious material should be placed and sealed in disposable plastic bags before being transported for incineration.
- Materials from TB laboratories should not be discarded in a landfill even after decontamination (for further recommendation, please refer to the Tuberculosis Laboratory Biosafety Manual).
- When using LAMP products, we recommend to handle all the material as potential infectious. Discard it as described above.
- Do not open the tubes after DNA amplification. Reaction tubes can contain very high concentrations of DNA after amplification (results in a very high risk of DNA contamination to work areas, posing a risk of subsequent false-positive LAMP results).
- Dispose of any other reagent, container, or lab ware in accordance with local regulations.

Is there a visualization of the TB-LAMP workflow?

The TB-LAMP training video is now published on the webpage of FIND in the Implementation Resources area (Tuberculosis and Training materials) and therefore accessible to everyone.
Please refer to: *https://www.finddx.org/implementation-resources/*

Reagents (General)

What is the shelf-life of the kits?
Loopamp™ PURE DNA Extraction Kit: 24 months after production
Loopamp™ MTBC Detection Kit: 14 months after production
The usage of the kit after the expiry date is not recommended and off label use (out of warranty).

What are the shipping conditions?
The kits can be shipped at room temperature (2-30°C).
The humidity should be between 0 –80%.

What are the storage conditions of the kits?
The kit should be stored at room temperature (2-30°C). If the room temperature is higher, it is recommended to store the kit in a refrigerator at 2-8°C.

How long does it take to perform a LAMP assay?
The average time from sample to result takes around one 1 h depending on the experience of the user and the sample number. The incubation times for all assays are 5 min for sample lysis using the Loopamp™ PURE DNA Extraction Kit, 40 min amplification and 5 min inactivation. Result interpretation takes around 2 min with the HumaLoop T.

How long does it take to perform different sample numbers?

Sample number	Time to result
1 + NC&PC	76 min
3 + NC&PC	77–78 min
7 + NC&PC	83–84 min
10 + NC&PC	87–88 min
14 + NC&PC	95–96 min

Table 2: Time to result with different sample numbers

What is included in the Loopamp™ Detection Kits?
The kits contain reaction tubes with dried reagents, liquid positive and negative controls, 30 µl plastic droppers and the instruction for use in 4 languages (GB, F, E, G).

How do you suggest using the droppers?
Use one dropper for each control. Do not use the same dropper for negative control first and then for transferring the positive control. This might dilute the control and could promote the transfer of contaminations.

Do I get quantitative or qualitative results with the Loopamp™ Detection Kits?
Based upon the LAMP technology, only qualitative results can be obtained.

Which LAMP tests are commercial available?
So far, assays for the detection of MTBC and Malaria Pan, Pf and Pv are available.

If the reagents are stored in the refrigerator, do they have to be equilibrated at room temperature before using them?
Yes, equilibrate them for 15 min at room temperature before start testing.

Why does the Loopamp™ Pure DNA Extraction Kit have 90 extractions but the Loopamp™ MTB Detection Kit has 96 tests?
A maximum of 16 reactions in one run of HumaLoop T can be performed. Of these 16 tests, 14 are samples and two are controls. The negative control will be processed identically as the samples while the positive control is pipetted directly in the amplification tubes. This means : 96 detection tests are needed for six runs of 16 tests, but only 90 Extraction kits are needed, as the positive control is not purified by the extraction kit.

How long are the results stable?
The fluorescence of the results is stable for up to two hours in light surroundings. Then it becomes weaker. They should be interpreted and documented immediately after the run is completed.

Reagents (Loopamp™ PURE DNA Extraction Kit)

How many extractions can be performed with one kit?
The kit contains enough material for 90 extractions.

What does the heating tube contain?
The heating tube contains sodium hydroxide for sample lysis. For a better recognition, the lysis buffer was colored.

Does it have any influence on the test performance, if the heating tube was longer than 5 min in the heating block?
After the 5 min lysis process, the heating block cools down.

How long can I store the dissolved powder-sample mix before the extraction?
It is not recommended to store the resolved powder-sample mix. The extraction should be performed immediately. Otherwise the mix dries quickly.

What is the content of the powder?
The powder contains chelating agents that removes the inhibitors from the lysed sample.

Some power came out when the adsorbent tube was opened. Is it dangerous or harmful?
No.

Is there a processing control for the lysis step?
No.

Can I start the extraction when the powder is not completely dissolved?
No. the power should be dissolved completely before starting the extraction.

A red color appears at the bottom of the adsorbent tube after mixing the powder with the lysed sample. What is the reason?
The reason for the color change is an insufficient mixing process. Mix through roughly until the powder was dissolved completely and the red color vanished.

Why should I perform the negative control with the PURE kit?
The negative control indicates if the lysis buffer, adsorbent tubes and injection cap are free of contaminations and the processing of the workflow was correct.

Can DNA extracted with the Loopamp™ PURE DNA Extraction Kit also be used for other methods?
In theory, the DNA solution extracted from the Loopamp™ PURE DNA Extraction Kit could be used for another PCR test. However, the performance of the Loopamp™ PURE DNA Extraction Kit has never been validated with any other PCR test as an IVD product. Therefore, such PCR tests would need to be tested before use.

Is it possible to store the extracted DNA?
The extracted DNA should be further processed in a timely manner.

Reagents (Loopamp™ MTBC Detection Kit)

How many tests can be performed with the Loopamp™ MTBC Detection Kit?
The kit contains reagents for 96 tests and 84 patient samples.

Which *Mycobacterium* species does the assay detect?
Loopamp™ MTBC Detection Kit detects *M. tuberculosis, bovis* and *africanum* that belong to the *Mycobacterium Tuberculosis Complex* (MTBC). With the kit, these species cannot be distinguished from each other.

What is the target sequence the assay detects?
The target sequences are located onto the gyrase B gene and in the insertion sequence IS 6110.

Which respiratory sample types are validated for the Loopamp™ MTBC Detection Kit?
Native and NalC-NaOH treated sputum are validated. There are preliminary data available, that bronchial lavage BAL can be also used as sample for TB-testing with for the Loopamp™ MTBC Detection Kit.

Is it possible to test also other sample materials?
Currently the assays are only validated (and CE-IVD marked) for sputum samples. Other samples materials have been tested in some studies but there are not enough data available yet.

What is the open vial stability of the positive and negative controls?
The open vial stability of the controls is the same as outlined onto the kit box. That means, there is no difference in the shelf life of opened and unopened controls.

How many positive/negative control tests can be performed with the material included in the kit?
The kit contains enough material for around 13 positive control tests and 100 negative control tests.

Can controls be skipped if more than 14 samples are performed in one run (e.g. use of HumaTurb C+A)?
No, this is not recommended.

Which substances interfere with the amplification reaction?
LAMP has a higher tolerance against inhibitory substances than other molecular methods. Although high amounts of blood (https://www.ncbi.nlm.nih.gov/pubmed/17011631)

What happens if Loopamp™ MTBC Detection Kit is performed with HumaLoop M?
They lysis and amplification temperature for the detection of MTBC are very specific. If HumaLoop M with different preinstalled temperatures is used, the cells are not lysed completely, there are unspecific primer bindings and the danger of generating non specific amplification products is quite high. Always use HumaLoop T for the detection of MTBC or program HumaHeat to 90°C and set up the corresponding program in HumaTurb C+A.

What do the detection tubes contain?
The detection tubes contain the dried reagents like the polymerase, primers or calcein as the fluorescence dye.

What is the test performance of TB-LAMP in new patients compared to smear microscopy?
The performance of PURE-TB LAMP with HumaLoop* in resource limited settings where smear microscopy is performed as preferred first-line test, has been evaluated with 3966 sputum samples. [1-4]

PURE-LAMP-TB	N	Sensitivity Smear +	Sensitivity Smear-	Specificity (Culture-)	Treatment Status
Ou et al. (2014)[1]	1329	92.1% (152/165)	53.8% (113/210)	98.3% (938/954)	Before (spot sputum)
		88.8% (333/375)		96.8% (924/954)	Before (spot/morning/ night sputum)
Kaku et al. (2016)[2]	472	99.1% (113/114)	51.2% (21/41)	98.4% (312/317)	Before (sample analysis)
	209	100% (47/47)	56.5% (13/23)	97.8% (136/139)	Before (patient analysis)
Gray et al. (2016)[3]	1745	97.2% (243/250)	62 % (88/142)	96.6% (1307/1353)	Before
Bojang al. (2015)[4]	261	100%	90.3%	100% (Smear+); 99% (Smear-)	Before
	156	100%	71.3%	63% (Smear+); 93% (Smear-)	Follow up

Table 3: Test performance of TB-LAMP published from 2014- beginning of 2016.

Summarizing this data, the obtained sensitivities of PURE-LAMP TB ranged from 92.1% up to 100% in smear+/culture+ sputum samples and from 51.2 up to 90.3% in smear-/culture+ samples from suspected TB patients. The specificities ranged from 96.6% up to 100% in new patients. Significantly lower specificities were detected in sputum samples from antibiotic treated patients. In all studies, PURE-LAMPTB had a significant better test performance than smear microscopy. Kaku et al. outlined that the use of the LAMP-TB test could increase the detection of TB by 18% in comparison to LED microscopy. These data correlate with their preliminary study result in Haiti[5].

The test performance of PURE-LAMP TB with HumaLoop in smear-/culture+ sputum samples is comparable to the GeneXpert system, a WHO endorsed test, which showed 67% sensitivity and 98% specificity in smear-/culture+ samples (based on 15 different reports).

Also Boehme et al. reported Xpert MTB/RIF, when implemented in urban and peri-urban health care labs, had a sensitivity of 96–100% in smear+ TB cases and 56–88% in smear- TB cases.

What is the test performance of TB-LAMP in HIV positive samples?
So far, there are only limited data available about the test performance of TB-LAMP in HIV patients. In the WHO policy guide, four of the thirteen included studies enrolled at least 10% HIV-positive participants, especially in Sub-Saharan Africa. Depending on the reference standards the pooled sensitivity varies from 63.8% with Standard 2 to 73.4 % with Standard 3. Pooled specificity was low with Standard 3 (95.0%) but high with Standard 2 (98.8%). The sensitivity of TB-LAMP in this population is around 10% lower as in patients without or unknown HIV status.

Reference Standard		Pooled sensitivity (%)	Pooled specificity (%)
TB negative defined as: two negative cultures on two different sputum specimens (Standard 1)	146	<4 studies	< 4 studies
TB negative defined as; two negative cultures on the same or different sputum specimens (Standard 2)	271	63.8 (49.0-76.4)	98.8 (85.1-99.9)
TB negative defined as at least one negative culture (Standard 3)	370	73.4 (51.9-87.6)	95.0 (64.0-99.5)

Table 4: Overall sensitivity and specificity of TB-LAMP in HIV patients compared to three culture-based references standards published in the WHO Policy Guide.

Further studies need to clarify and confirm these preliminary data.

What is the test performance of TB-LAMP in children?
So far, there are no data available that outline the test performance of TB-LAMP in children.

Do first-line antibiotics interfere with the reaction and influence the test performance?
It has been shown, that Isozianid (100 µg/ml), Rifampicin (100 µg/ml), Pyrazinamide (500 µg/ml), Ethambutol (20 µg/ml), Kanamycin (20 µg/ml) and Streptomycin (500 µg/ml) have no influence on the test performance of TB-LAMP.

In the WHO report was outlined that TB testing with TB-LAMP causes false-positive results when the room temperature is above 35°C. How can I avoid such results?
The study from Gray et al. reported false positive results when the room temperature is ≥ 37°C and with 25 µl negative control (4/192, false positive rate 2.1%). Keeping the room temperature (e.g. by a fan or air condition) lower than 37°C and the usage of more than 25 µl negative control will help to reduce the false positive rate.

How long can the heating tubes, containing the sample, be stored?
The heating tubes with the sample can be stored 4–5 hours (uncooled) or over the night (cooled).

The LOD of TB-LAMP is 0.38 genome equivalents/ test- what is that in CFU/ml?
It's very difficult to convert the genome equivalents into CFU/ml. TB-LAMP has an analytical sensitivity of around 100 CFU/ml.

Can latent TB be detected?
If the copies of target sequence are higher than LOD of MTBC kit, the results will show the posivites. Basically, latent TB has a short bacterial discharge, so such numbers of copy would be less than LOD.
http://www.who.int/tb/areas-of-work/preventive-care/ltbi_faqs/en/

Why is the positive control not handled exactly like the negative control to verify that the extraction was performed correctly?
The positive control is only designed for performance control of the reagent to avoid incorrect results due to quality degradation. NC is only purified water to control contamination in the test environment.

Instruments (General)

What is the warranty time of the instruments?
One year with option to extend it up to three years.

How often should the instruments be cleaned and maintained?
Once a year, depending on how often the instrument is used and how clean the environment is.

What is needed for maintain the instruments?
The required tools and materials are listed in each Maintenance checklist of the respective instrument. Detailed information will be given during the 'train the trainer' Training. Basically the engineer should be at least in possession of
- measuring temperature unit
- temperature measuring set
- Keypad/controller
- cover for heating chamber (HumaLoop)

What is the life expectancy of the instruments?
The life expectancy of all instruments is five years.

Do the instruments need a UPS?
A UPS should be used especially in areas where problems with sustained electricity supply appears. HUMAN provides UPS for 220 V countries and for HumaLoop T/M and HumaTurb. For all other countries, a UPS must be procured that meets all characteristics listed on the specification flyers.

Which time period can the UPS bridge?
The total duration of the 800VA UPS is 60-65 minutes, depending on the breaks between the different steps. The UPS should only be used for power failures up to one hour. The UPS does not serve to bridge an entire run.

Is it possible to operate the instruments with batteries?
Yes, HUMAN provides also a solution with a solar panel and battery

If the temperature exceeds the recommended tolerance of +/- 1 degree Celsius, will it have any impact on the LAMP reaction?
If the temperature of the reaction is out of range, the risk and actual rate of false-negative and false-positive results increases. Please control temperature properly.

If the measured temperature exceeds +/- 3 degrees Celsius, should the engineer still proceed to calibrate the instrument? If they proceed to calibrate the instrument, will "emoticons" be displayed?
If you can't adjust the temperature within the controllable range of +/- 3°C, please replace the instrument.

HumaLoop T/M or HumaTurb C+A need to be send back. What is the disinfectant procedure?

Precautions of LAMP related instruments

If you are returning the LAMP instrument from the customer's laboratory, you should thoroughly clean it using the following procedure to prevent infection or contamination (in the absence of customer instructions).

- **Materials required**
  1. Disposable lab coats ☐
  2. Disposable plastic gloves ☐
  3. Masks (N95 etc.) ☐
  4. 0.5% Sodium hypochloride ☐
  5. 70% EtOH ☐
  6. Paper towels (Kimwipes etc.) ☐
  7. Vinyl bags (for packing, bin bag etc.) ☐

Dispose of all used reagents, laboratory coats, gloves, masks, laboratory articles, etc. in accordance with local regulations!

- **Points to be checked before operation (confirm the experiment situation from the customers)**
  1. Has there been any problem with data or device during their experiment?

     ☐ No

     ☐ Yes What happened? _____

  2. Did they use DNA derived from clinical samples?

     ☐ No

     ☐ Yes What kind of samples did they use? _____

  3. Has a cap from a reaction tube been removed or have amplification products leaked from the reaction tube etc. after DNA amplification?

     ☐ No

     ☐ Yes How many times? _____

- **Decontamination procedure**
  1. Wear a disposable lab coat, a mask and gloves before operation. ☐
  2. Test the negative control included in the kit (N=3) and then confirm whether a DNA contamination occurs or not.* ☐
  3. Prepare the 0.5% Sodium hypochloride solution. ☐
  4. Confirm that no reaction tube etc. remains in the device. ☐
  5. Apply the solution from step 3 onto a paper towel (e.g. Kimwipes) and wipe the device with it. Then leave it at room temperature for 5 minutes. ☐
     → Refer to the separate sheet about cleaning the device.
  6. After 5 minutes, wipe the instrument with a paper towel soaked in 70% EtOH. ☐
  7. Test the negative control included in the kit (N=3) and make sure whether the DNA contamination has been removed or not.** ☐
  8. Seal the device with the vinyl bag and take it to a place where the packaging can be done (outside the laboratory). ☐
  9. Pack the sealed device into the storage box. ☐

**This step can be skipped if there is little possibility of contamination (from the customer information). In this case, however, you should confirm whether a contamination is detected at step 7 or not.*
***According to the situation, you can work elsewhere (e.g. your office) than in the customer's laboratory.*

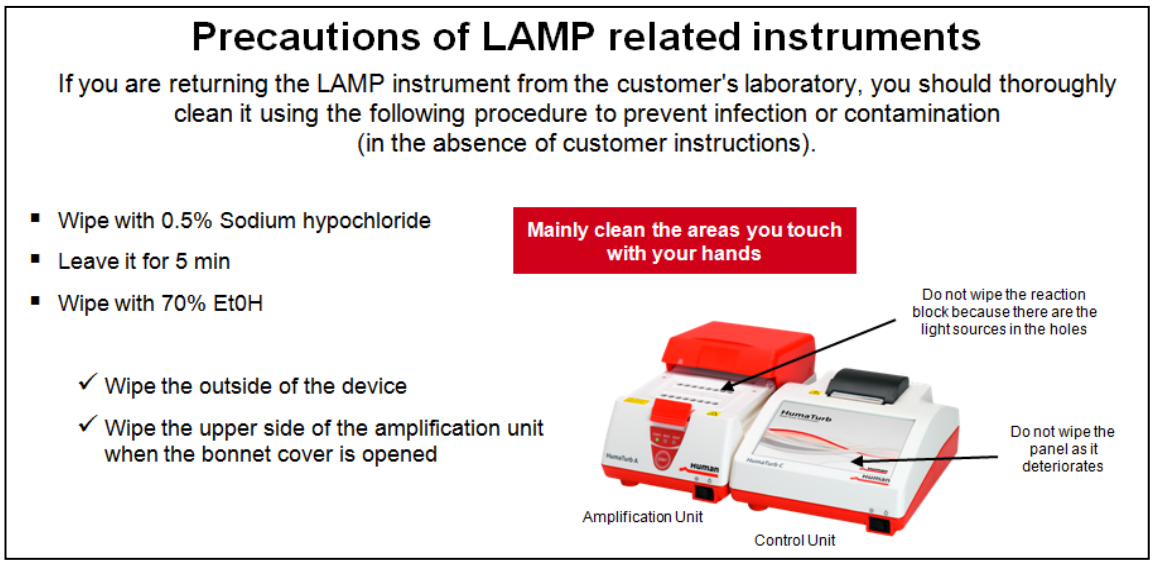

Figure 2: Checklist by Eiken Chemical Co., Ltd.

How long can the HumaLoop T/M and the HumaTurb C+A be operated with HUMAN's Solar Panel & Battery solution?

The performance of the battery is sufficient for about two complete runs with the LAMP instruments. The battery can also be charged directly with the solar panel and the time be extended. To charge a fully discharged battery with the solar panel, about 4-5 hours of sunlight are required when using a 100W solar panel.

Is it possible to connect a PC to the instruments?

No, unfortunately it is not possible to connect a PC. Results generated with the HumaTurb C+A system can be transferred to the PC using a USB stick.

How to interpret results which are LAMP negative but smear positive?

The most common reason for the discrepancy results between LAMP (-) and smear (+) is Nontuberculous mycobacteria. Also an inhibition to LAMP reaction from the specimen or uneven distribution of TB cells in the sample may cause false negative results.

Instruments (HumaLoop T)

What is the principle behind the detection of pathogens by reading green fluorescence?
The reagents of the Loopamp™ Detection Kits contain the fluorescent dye calcein which is initially combined with manganese ions to achieve the quenching effect. During the amplification of target DNA, pyrophosphate ions are generated that bind and remove manganese ions from calcein to irradiate fluorescence. The fluorescence is further intensified as calcein combines with magnesium ions. With a UV light source in the fluorescence detection unit, the fluorescence can be detected visually.

What is sample capacity of HumaLoop T?
With HumaLoop T, a maximum of 16 tests can be performed at the same time. For the amplification reaction, up to 14 patient samples can be tested. One positive and one negative control should be performed with each run.

What is the difference between the HumaLoop T and the HumaLoop M ?
Both instruments contain pre-installed heating profiles (incubation temperatures and times) for sample processing and amplification. The pre-programmed profiles support a failsafe operation of the instruments and the tests. HumaLoop T profile is dedicated to the detection of MTBC while HumaLoop M is dedicated to Malaria Pan and Malaria Pan/Pf (the instrument might be used in future for other parameters). Therefore, HumaLoop T should not be used for the detection of Malaria and HumaLoop M should not be used for the detection of tuberculosis.

Can the test results be printed out?
HumaLoop T does not contain a printer. The results should be documented separately in a written format.

What is recommended for cleaning HumaLoop T?
In order to ensure the normal operation, detection and use, the instrument needs to be cleaned regularly depending on the lab conditions and usage of the instrument. For cleaning outer surfaces, use a soft and dry cloth to wipe the shell of the device. In case of dirt that cannot easily be removed, use cloth soaked with a small amount of neutral detergent diluted with water. In case of a contamination with template DNA, wipe the instrument with 0.5% hypoclorite solution.

Instruments (HumaTurb System)

What is the HumaTurb system?
The HumaTurb system consits of an amplification unit (HumaTurb A) and a control unit (HumaTurb C). Up to six separate HumaTurb A units can be connected to one HumaTurb C. Each HumaTurb A unit contains two independ reaction blocks with a capacity of 2x8 tests. That means, two different parameters can be performed in one HumaTurb A unit simultaneously. For sample processing with the Loopamp™ PURE DNA Extraction kit, a separate heater with a specific insert for the heating tubes is required (HumaHeat; REF 964000). All available Loopamp™ Detection Kits can be performed with the HumaTurb system at the same time. The result reading is different from HumaLoop - turbidity is measured in real-time during the amplification process.

What is the principle of the real-time detection of turbidity with the HumaTurb system?
During the amplification process, in positive samples, magnesium pyrophosphate is generated that causes turbidity of the reaction mix.

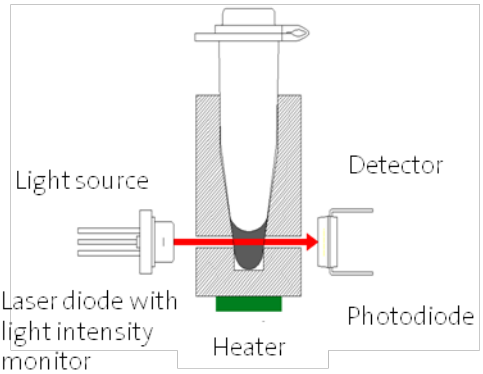

Figure 3: Principle of the real-time turbidimeter HumaTurb C+A.

Under each cavity, a photometer detects the specific absorbance in real-time which is displayed in the measurement screen of HumaTurb C. The interpretation of results is performed in correlation to the absorbances obtained from negative and positive controls and shown in colors (judgment card).

Card color	Judgment result
Pink	Positive (larger than the judgment value)
Green	Negative (lower than the judgment value)

Table 5: Judgment card for result interpetation with the HumaTurb system

Does the HumaTurb system provide quantitative results?
The HumaTurb system provides qualitative results.

What is the sample capacity of the HumaTurb system?
Depending on how many HumaTurb A units (up to six) are connected to HumaTurb C, the test capacity varies from up to 16 to 96 per run. One positive and one negative control should be performed for each assay and each unit.

Can the test result be printed out or transferred?
Yes, the HumaTurb system has a printer, USB and LIS connectivity for transferring the test results.

What is the difference between the test performance of TB-LAMP with HumaLoop T and HumaTurb C+A?
Both instruments are using the same kits. The test performance of these two instruments is comparable.

Instruments (HuMax ITA)

What is the advantage of using HuMax ITA?
HuMax ITA automates the 2 min incubation time and all mixing and spinning down steps during the generation of the reaction mix and reduces the manual steps during the LAMP workflow.

Do I have to use HuMax ITA?
No. All published data are generated without using HuMax ITA.

Instruments (HumaHeat)

What is the (sample) capacity of the HumaHeat?
The HumaHeat has a capacity for 16 heating tubes.

Which kind of tubes can I use for the sample lysis with the HumaHeat?
The inserts of the HumaHeat are specially adopted to the heating tubes of the Loopamp™ PURE DNA Extraction Kit.

Can I perform the sample lysis for Malaria and TB with the HumaHeat?
Yes, the incubation temperature can be set manually or with the software.

Advantages

- Usability -> Easy result interpretation
- Robustness -> Accurate pipetting is not mandatory
- Test Performance -> Comparable to other molecular methods
- Flexibility -> Adaptable to all sample throughputs
- Easy logistics -> Due to room temperature shipment & storage (2...30°C)

Notes

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