WHO Prequalification of In Vitro Diagnostics
PUBLIC ASSESSMENT REPORT

Product: Loopamp MTBC Detection Kit
WHO reference number: PQDx 10307-04545-00

The Loopamp MTBC Detection Kit, with product code 972000, manufactured by Eiken Chemical Co., Ltd., CE-mark regulatory version, was accepted for the WHO list of prequalified in vitro diagnostics and was listed on 18 December 2025.

Summary of the WHO Prequalification Assessment for the Loopamp MTBC Detection Kit

	Date	Outcome
Prequalification listing	18 December 2025	listed
Dossier assessment	27 May 2025	MR
Product performance evaluation	15 December 2025	MR

MR: Meets Requirements

Intended use

According to the intended use claim from Eiken Chemical Co., Ltd, *"The Loopamp MTBC Detection Kit is a qualitative in vitro diagnostic test to detect Mycobacterium tuberculosis complex (MTBC) DNA extracted from the sputum in patients with any symptom indicative of MTBC infection. The kit aids in the diagnosis of MTBC infection and is intended for use in patients older than 18 years of age. The kit is intended for use by healthcare workers who have received training on the use of this kit in laboratory and hospital setting. The test results can be interpreted either manually by visual fluorescence detection under UV or blue LED irradiation or automatically using a turbidimeter for turbidity detection."*

Test kit contents

Component	Description
Loopamp MTBC Detection Kit (product code 972000)	2 x 48 Tubes Positive control MTB (PC MTB) ……1 x 0.4 mL Negative control MTB (NC MTB) ……3 x 0.5 mL 30 µL dropper …… 1 x 18 droppers Instruction For Use ……1 copy

Items required but not provided:

- Loopamp PURE DNA Extraction Kit
- Pipette-60 Set
- Leak-proof, sterile, screw-capped flat bottom sputum collection containers
- PPE (at least 2 pairs disposable examination gloves per run, laboratory coat, mask etc.,)
- 0.5% sodium hypochlorite
- Water
- Indelible labelling marker
- Plastic bag with zip
- Paper
- Trash can

For visual fluorescence detection
(For HumaLoop T)

- HumaLoop T

(For other incubator using UV light or Blue LED Light)

- Incubator (temperature accuracy: ±0.5 ℃; with hot bonnet)
- HumaHeat or other heating block
- UV light or Blue LED light (wavelength: 240–260 nm and 350–370 nm)
- Goggles/glasses or a UV-blocking eye mask (optional)

For real-time turbidity detection

- HumaTurb C+A
- HumaHeat or other heating block
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For reagent and sample mixing

- Centrifuge for microtubes (optional)
- Centrifuge for eight connected tubes (optional)
- HuMax ITA, Micro Centrifuge (optional)

Storage Temperature and Stability

Parameter	**Condition**
Storage Temperature	2 to 30 °C
Shelf Life (from manufacture)[1]	14 months

[1] The assigned device shelf-life is based on stability data generated from the date of manufacture. The finished goods shelf-life, calculated from the date of packaging completion, may be shorter depending on the time elapsed between manufacture and final packaging of the device.

Dossier review

The manufacturer submitted a product dossier as per the "Instructions for compilation of a product dossier" (PQDx_018). The information (data and documentation) submitted in the product dossier was reviewed by WHO staff and external technical experts (assessors) appointed by WHO.

The manufacturer's responses to the discrepancies found during dossier screening and assessment findings were accepted on 27 May 2025.

Based on the product dossier screening and assessment findings, the product dossier for the Loopamp MTBC Detection Kit meets WHO prequalification requirements.

Manufacturing site inspection

The inspection of the manufacturing site(s) was conducted to assess whether the manufacturer's quality management system (QMS) and manufacturing practices are in alignment with:
(i) applicable international standards, such as ISO 13485 (Medical devices – Quality management systems – Requirements for regulatory purposes);
(ii) the manufacturer's own documented procedures and quality requirements; and
(iii) other relevant international standards and guidelines applicable to in vitro diagnostic (IVD) medical devices. The WHO's Public Inspection Reports are accessible at:

https://extranet.who.int/pqweb/vitro-diagnostics/who-public-inspection-reports

Product performance evaluation

Loopamp MTBC Detection Kit was evaluated by the Bacteriology Department at Indian Council for Medical Research - National Institute for Research in Tuberculosis (ICMR-NIRT), Chennai, India, on behalf of WHO in the 3rd quarter of 2024 and 1st quarter of 2025, according to protocol IVD/PR/4/P23, version 2.0.
The test was performed with the HumaLoop T instrument and read visually. The procedure for real-time turbidity detection using the HumaTurb C+A was not evaluated.

Clinical performance evaluation
In this limited laboratory-based evaluation of clinical performance characteristics, a panel of 314 sputum specimens was used. Specimens were characterized by fluorescence smear

microscopy, liquid culture (MGIT), and speciation, and by Xpert MTB/RIF Ultra, which was used as a comparator method.

Clinical performance characteristics in comparison with agreed reference standard			
	Overall	**Smear-positive**	**Smear-negative**
Sensitivity % (N=111)	87.4% (79.7-92.9%)	93.5% (85.5-97.9%)	73.5% (55.6-87.1%)
Specificity % (N= 203)	99.0% (96.3-99.9%)		
Invalid runs % (N= 32)	6.3% (2 out of 32 runs in the clinical evaluation)		
Difference in sensitivity with comparator method	-8.1% (Tango 95% CI: -15.4 to -2.0%)		
Difference in specificity with comparator method	+1.0% (Tango 95%CI: -1.8 to +4.1%)		

Analytical performance evaluation

Analytical performance characteristics	
Limit of detection (LoD) using the WHO International Standard for M. tuberculosis (H37Rv) DNA for NAT-based assays (NIBSC code: 20/152)	The LoD for *M. tuberculosis* detection was estimated at 2445 IU/mL (95% CI: 1365-4381) for *M. tuberculosis* detection.
Reproducibility	The hit rate for detection of *M. tuberculosis* (sensitive) at approx. 1000 CFU/mL was 67.5% (27/40) and hit rate for negative results was 100% (40/40) with negative specimen.
Inclusivity, exclusivity	The following mycobacteria (MTBC) were detected: *M. bovis*, *M. africanum.* The following mycobacteria (NTM) were not detected: *M. avium*, *M. kansasii*, *M. intracellulare*, in agreement with manufacturer's claim.
Cross-contamination / carry-over	No carry-over was observed when high positive and negative specimens were tested alternatively.

Operational characteristics and ease of use

This assay requires laboratory equipment and can be performed in laboratories with limited facilities. The instrument requires a stable source of electricity. Furthermore, training and implementation of good laboratory practice is essential to obtaining accurate results. Appropriate workflow for molecular testing including separation of rooms, careful manipulation of extracted DNA and adequate disinfection procedures are essential to avoid contamination.

Key operational characteristics	
Time to result for one run (14 specimens + 2 controls)	120 minutes
Operator hands-on time for one run	75 minutes (approx. 5 min pipetting and manipulation time per specimen)
Level of automation	Nil
Quality controls	QC including one positive and one negative control are provided by the manufacturer.
Operating temperature	5-40°C.
Result display and connectivity	Results are interpreted visually. If the test is performed with HumaLoop T, this is done by visual detection of fluorescence when irradiated under Blue LED light. If the test is performed with HumaTurb C+A, this is done by observing whether the amplification plots show increase in turbidity or not.
Power sources	Main power The use of a UPS is recommended, as stable electricity is required.
Biosafety *(outside of infectious specimen handling)*	Operators reported no biosafety considerations. (Equal to smear microscopy)
Waste	The volume of liquid is approx. 100 µL per test. The volume of solid waste is approx. 48 tubes (16 for lysing, 16 for extraction and 16 for reaction) per test/ run. Waste disposal requires no specific measures in addition to usual laboratory biohazard waste disposal procedures.
Calibration	Yearly calibration is recommended
Maintenance	Regular cleaning of the instrument is recommended. In addition, daily cleaning of surfaces and pipette with 0.5% bleach is required.

Based on these results, the performance evaluation of Loopamp MTBC Detection Kit was considered provisionally acceptable. However, the following deficiency was identified: the LoD claimed by the manufacturer (400 genome equivalent/mL, corresponding to approximately 430 IU/mL according to the manufacturer's conversion factor) was not verified. As a commitment to prequalification, the manufacturer is required to repeat the LoD assessment at the WHO Performance Evaluation Laboratory Centre For Tuberculosis, NICD, South Africa, according to the performance evaluation protocol shared by WHO.

Labelling review

The labelling submitted for the Loopamp MTBC Detection Kit was reviewed by WHO staff and external technical experts appointed by WHO. The review evaluated the labelling for clarity and consistency with the information submitted in the product dossier, alignment with international guidance and standards, and suitability for the intended users and settings in WHO Member States, including low- and middle-income countries.

The table below provides traceability of the labelling documents reviewed during the assessment, including document titles, version numbers, approval dates, and control identifiers.

Controlled Labelling References[2]

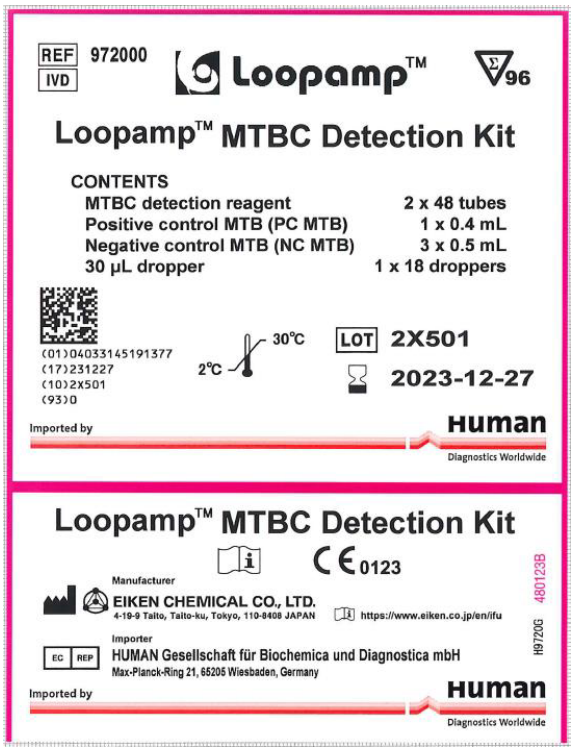
Document Type	Document Title	Version / Revision	Date Approved	Controlled Document No.
Outer box artwork	Loopamp MTBC Detection kit label	H9720G	2024-02-15	DHF-G005-000080
Pouch	Outer Package Label of the MTBC Detection Reagent	H97201D	2024-02-15	DHF-G005-000080
Reagent bottle labels	Outer Sleeve Case Label of PC MTB and NC MTB	H97202D	2024-02-15	[DHF-G005-000080]
Instructions for Use (IFU)	IFU Loopamp MTBC Detection Kit	380236-E	[to be updated]	[to be updated]

[2] Products reflecting the revised labelling are scheduled to begin shipment from September 2026.

Labels

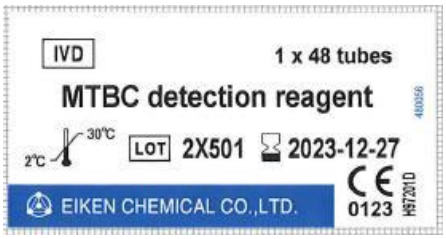
Outer box artwork

1.1 Outer Box Label of the Loopamp MTBC Detection Kit



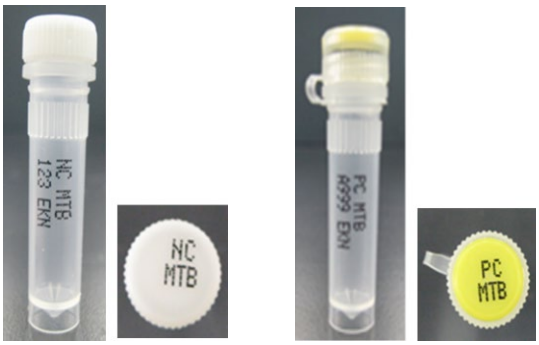
Pouch / Device label

2.1 Outer Package Label of the MTBC Detection Reagent



Reagent bottle labels

3.1 Label Printed on PC MTB and NC MTB Tubes

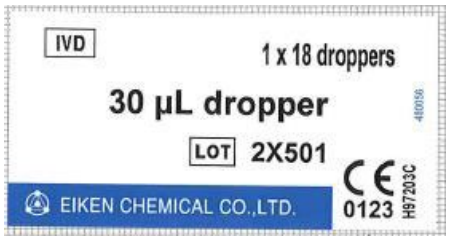


1.3-1: NC MTB (side and top) 1.3-2: PC MTB (side and top)

3.2 Outer Sleeve Case Label of PC MTB and NC MTB

Accessory labelling

4.1 Outer pouch label of 30 µL dropper



Instructions for Use[3]

[3] English version of the IFU was the one that WHO assessed. It is the manufacturer's responsibility to ensure accurate translation into other languages.

Instructions for Use
IFU on our website https://www.eiken.co.jp/en/ifu SSP available in EUDAMED
Human Diagnostics Worldwide
380236-E
English
REF 972000

Loopamp™ MTBC Detection Kit

1. INTENDED USE

The Loopamp™ MTBC Detection Kit is a qualitative *in vitro* diagnostic test to detect *Mycobacterium tuberculosis* complex (MTBC) DNA extracted from the sputum in patients with any symptom indicative of MTBC infection. The kit aids in the diagnosis of MTBC infection and is intended for use in patients older than 18 years of age. The kit is intended for use by healthcare workers who have received training on the use of this kit in laboratory and hospital settings. The test results can be interpreted either manually by visual fluorescence detection under UV or blue LED irradiation or automatically using a turbidimeter for turbidity detection.

2. TEST PRINCIPLES

This product is based on the nucleic acid amplification method, LAMP (Loop-mediated Isothermal Amplification), developed by Eiken Chemical Co., Ltd.

The characteristics of the LAMP method are as follows: (1) only one enzyme is required, and the amplification reaction proceeds under isothermal conditions;[1),2)] (2) it has extremely high specificity because of the use of four primers recognizing six distinct regions on the target; (3) it has a high amplification efficiency and can produce a high concentration of amplified product in a short time, which makes visual detection (manual) or automated detection based on turbidity possible.[3),4)]

The primers provided with this product are designed in the DNA gyrase subunit B (*gyrB*) and in the Insertion sequence *IS6110* (IS) region of the MTBC genome DNA, which has been confirmed by the alignment analysis of the selected base sequences of MTBC and nontuberculous mycobacteria to have a well-conserved base sequence in MTBC.

The DNA from untreated sputum or NALC-NaOH-treated sputum is extracted using the Loopamp™ PURE DNA Extraction Kit (sold separately). Then, the DNA solution is dispensed into a reaction tube. The strand displacement DNA polymerase, deoxynucleotide triphosphates (dATP, dCTP, dGTP, and dTTP), calcein, reaction buffers, and MTBC-specific primers are stored in dried form in the cap of the reaction tube. This dried LAMP reagent (MTBC detection reagent (dMTB)) is dissolved when the DNA solution is added. The reaction tube is then incubated at 67.0 °C, and the DNA is amplified through catalysis by the strand displacement DNA polymerase per the LAMP reaction.

The detection of amplified products is based on the turbidity measurement of a by-product, magnesium pyrophosphate (white precipitate).[3)] Alternatively, visual judgment under UV or blue LED irradiation can be used instead of turbidity measurement. Before reaction, the calcein in the reagent is in a quenched state because of manganese ions bound to it; however, once the LAMP reaction is started, pyrophosphate ions are generated and bind out the manganese ions, and the calcein becomes fluorescent.[4)]

3. KIT CONTENTS

The reagents are stable until the date on the label, assuming the container remains unopened at a storage temperature of 2–30 °C. The MTBC detection reagent is stable for 30 days at 2−30 °C after opening the pouch.

MTBC detection reagent····· 2 x 48 tubes
The following reagents in the dried form are contained in each reaction tube.
Bst DNA polymerase [a)]
Deoxynucleotide triphosphates
Magnesium sulfate
Calcein
Manganese chloride
Primers [b)]
Positive control MTB (PC MTB) [c)]····· 1 x 0.4 mL
Negative control MTB (NC MTB)····· 3 x 0.5 mL
30 µL dropper····· 1 x 18 droppers
Instruction For Use ····· 1 copy

a) *Bst* DNA polymerase derived from *Bacillus stearothermophilus* is a strand displacement DNA polymerase that lacks 5′→3′ exonuclease activity.
b) Primers designed in the *gyrB* and IS region of the MTBC genome DNA, purified from synthesized oligonucleotides by HPLC.
c) The PC MTB contains a product resulting from the *in vitro* amplification of a template genome DNA of *Mycobacterium tuberculosis* H37Rv (GenBank No. NC_000962) origin.

Abbreviations of the following reagents and Lot No., as well as manufacturer (EKN), are printed on the containers as shown below:

Reagents	Labelling on the tube	Code on the cap
Positive control MTB	PC MTB Lot No., EKN	PC MTB
Negative control MTB	NC MTB Lot No., EKN	NC MTB

*Metrological Traceability Information

The Positive Control is derived from the amplification product of genomic DNA originating from *Mycobacterium tuberculosis* H37Rv (GenBank No. NC_000962). The specific region of *Mycobacterium tuberculosis* H37Rv, which is the target of interest, serves as the template for the amplification of the PC MTB DNA fragment. This fragment is quantitated through photospectrometric analysis, and its DNA concentration of PC MTB is adjusted at 1,000 copies/µL.

4. MATERIALS REQUIRED BUT NOT PROVIDED

- Loopamp™ PURE DNA Extraction Kit
- Pipette-60 Set
- Leak-proof, sterile, screw-capped flat bottom sputum collection containers
- PPE (at least 2 pairs disposable examination gloves per run, laboratory coat, mask etc.)
- 0.5% sodium hypochlorite

・Water
・Indelible labelling marker
・Plastic bag with zip
・Paper
・Trash can

For visual fluorescence detection

(For HumaLoop T)

・HumaLoop T

(For other incubators using UV light or Blue LED Light)

・Incubator (temperature accuracy: ±0.5 °C; with hot bonnet)
・HumaHeat or other heating block
・UV light or Blue LED light (wavelength: 240–260 nm and 350–370 nm)
・Goggles/glasses or a UV-blocking eye mask (optional)

For real-time turbidity detection

・HumaTurb C+A
・HumaHeat or other heating block

For reagent and sample mixing

・Centrifuge for microtubes (optional)
・Centrifuge for eight connected tubes (optional)
・HuMax ITA, Micro Centrifuge (optional)

5. WARNINGS AND PRECAUTIONS

(1) For *in vitro* diagnostic use only.
(2) This product is designed only for clinical diagnosis of tuberculosis by detecting MTBC DNA from sputum samples of human origin when used in conjunction with other clinical findings. Do not use for any other purposes.
(3) When using this product, always follow these Instructions for Use.
(4) Do not freeze the reagents.
(5) Do not use any expired reagent.
(6) Do not mix different lots.
(7) Do not replenish any reagent.
(8) The performance of the Loopamp™ MTBC Detection Kit depends on the operator proficiency and adherence to procedural directions. Testing should be done by adequately trained personnel strictly according to the instructions provided.
(9) Remove the required number of reaction tubes from the packaging before using them and re-seal the aluminium pouch immediately.
(10) Do not remove the desiccant from the aluminium pouch. High-level humidity may deteriorate the dried LAMP reagent in the reaction tubes.
(11) Exposure to heat, humidity, and light might deteriorate the dMTB. Thus, remove only the required number of reaction tubes (the sum of samples and controls).
(12) Avoid contamination of the Reaction Tubes with hypochlorous acid, liquid hand soap, ethanol, or powder from the Adsorbent Tube (a component of the Loopamp™ PURE DNA Extraction Kit), as such contamination may lead to false results in LAMP reactions.
(13) Sputum samples pose a potential risk for infection. Take all necessary preventive measures to avoid biohazard. When collecting, handling, and disposing sputum and/or containers, wear the appropriate personal protective equipment (PPE) such as masks, laboratory coats and disposable gloves in accordance with a local regulation or WHO guidance [5].
(14) The PC MTB and the NC MTB contain a small amount of sodium azide as a preservative. As sodium azide is classified as toxic, avoid any contact with eyes, mouth, or skin.
(15) In case of accidental contact of any reagent with eyes, mouth, or skin, immediately rinse the affected site with running water and seek medical advice.
(16) Do not dilute or add the PC MTB to the samples. Instead, use the PC MTB only as described in this package insert to avoid DNA contamination.
(17) Store the PC MTB and any positive sputum samples separately from the other kit reagents.
(18) The cap of each reaction tube contains the dMTB in the dried form. Do not touch the inside of the cap.
(19) Before using the reaction tubes, check carefully if they have any cracks or scratches. Damaged tubes might give false results and lead to DNA contamination of the incubator and work area.
(20) Do not expose reaction tubes to UV light before the end of the LAMP reaction. Prolonged exposure to UV light might damage the tubes and lead to false results.
(21) When UV light is used for visual fluorescence judgment, do not stare directly at it. As UV light is harmful to the eyes, even watching for a short period can irritate eyes and cause symptoms similar to conjunctivitis. Instead, use a glass screen or wear protective goggles/glasses or a UV-blocking eye mask whenever looking directly at the UV light.
(22) Refer to the manual of the incubator. When the HumaLoop T or the Real-Time Turbidimeter HumaTurb C+A is used, remove the reaction tubes from the incubator carefully to avoid burns.
(23) All procedures using this product must be performed on a flat and stable surface to ensure proper operation and accuracy of results.

6. WASTE DISPOSAL

(1) Do not open the tubes after DNA amplification. Leave the cap closed and dispose of the used tubes as medical waste by incineration or after double bagging with sealable plastic bags.
(2) **Never autoclave or reuse the reaction tubes; else, amplified products will disperse and cause contamination.**
(3) The main material for the reaction tubes and reagent tubes is PP; for the reaction tube tray, PET; for the aluminium pouch, aluminium; and for the kit case, paper.
(4) Dispose of any used reagent, container, or labware per local regulations. Add a biohazard mark on the medical waste.

7. SPECIMEN COLLECTION TRANSPORT AND HANDLING

(1) It is recommended to collect one sputum specimen from the same patient in the early morning.
(2) Sputum specimens must be collected through deep coughing from the lower respiratory tract following the WHO standard [6].
(3) Use the most purulent part of the sputum sample. Saliva, nasal discharge, or oral secretions are not acceptable and must not be used for testing. Heavily blood-stained specimens are not acceptable, as the presence of excess blood may interfere with the performance of the assay.
(4) Untreated sputum can be stored at 2-8 °C or 35 °C up to 7 days. Untreated sputum should be transported to test site at 2-8 °C or 35 °C within 24 hours after sample collection. If storage at –20 °C is required, untreated sputum may be stored for up to 30 days and may undergo up to 3 freeze–thaw cycles without significant impact on assay performance.
(5) The DNA solution should ideally be used immediately after preparation; if it is impossible, the DNA solution can be stored at 35 °C and used within

72 hours.

(6) Collect sputum in a separate room from the LAMP amplification room. Aerosols containing the MTBC DNA can be generated during sputum collection and may cause contamination.

(7) For labelling and packaging during specimen transport, refer to the WHO Guidance[7] or applicable national and regional regulations.

8. PREPARATION OF REAGENTS

（1）MTBC detection reagent

After the DNA extraction step using Loopamp™ PURE DNA Extraction Kit (sold separately), remove the required number of tubes from the aluminium pouch and place them on the rack. (sum of samples and controls).

Note: After removing the required tubes, re-seal the aluminium pouch with any unused tubes immediately.

（2）Negative control MTB（NC MTB）

The NC MTB works as control to verify the performance of the entire assay process including DNA extraction. Flick (or spin) down the tube to collect the content on the bottom of the tube. Pipette 60 µL of the NC MTB into the Heating Tube provided in the Loopamp™ PURE DNA Extraction Kit. Follow the Instructions for use to process the NC MTB (hereinafter extracted NC MTB is called “negative control solution”).

Note: A negative control should be included every time.

（3）Positive control MTB（PC MTB）

The PC MTB is used to verify the performance of the amplification step only; it does not undergo the DNA extraction process. Before opening the tube, flick or centrifuge briefly to ensure that all contents are collected at the bottom.

Note: The PC MTB should be measured every time.

9. MEASUREMENT PROCEDURE

WARNING: Failure to follow the test procedure exactly as described may result in inaccurate results or test failure.

Before Testing

Before starting the test, users must carefully read the entire Instructions for use to fully understand the procedure. This is especially important to help prevent errors among inexperienced users.

DNA Extraction

Turn on the HumaLoop T or the Real-Time Turbidimeter HumaTurb C+A 20 minutes before starting an extraction. To extract the DNA from 60 µL sputum sample, follow the Instructions for use if the Loopamp™ PURE DNA Extraction Kit[8] (sold separately). **Whenever possible, select the most purulent portion of the sputum.** In summary, pipette 60 µL of the sputum sample into a Heating Tube and load it into the HumaHeat Incubator, Heating Unit of HumaLoop T or the heating block preheated to 90 °C. Incubate the sample at 90 °C for 5 minutes, followed by cooling at room temperature for 2 minutes.

Reagent and Sample Mixing

(1) Check that the temperature of the Heating Unit has reached 67°C.

(2) Dispense 30 µL of the sample solution into a reaction tube using the Loopamp™ PURE DNA Extraction Kit and close the cap.

Note: The volume between the two lines on the reaction tube corresponds to approximately 30 µL.

(3) Dispense 30 µL of the negative control solution into a reaction tube using the Loopamp™ PURE DNA Extraction Kit and close the cap.

Note: The volume between the two lines on the reaction tube corresponds to approximately 30 µL.

(4) Dispense 30 µL of the PC MTB into a reaction tube using the provided dropper and close the cap.

(5) Flick (or spin) down all tubes to collect the solution on the bottom of the tubes.

Note: Ensure that the liquid level is in the middle of the two lines on a reaction tube to ensure 30 µL of pipetting.

(6) Reconstitute the dried reagents in the cap by inverting the reaction tubes and collecting the DNA solution in the cap. Leave the tubes standing upside down for 2 minutes to reconstitute the dried reagents.

(7) Invert the reaction tubes five times to mix the content. Ensure that the dried reagents in the cap are fully dissolved.

(8) Flick (or spin) down all tubes to collect the solution on the bottom of the tubes.

Amplification

For visual fluorescence detection

（For HumaLoop T）

(1) Check that the temperature on the HumaLoop T is 67.0 °C.

(2) Place the reaction tubes in the HumaLoop T and press the green button to start the LAMP reaction (40 minutes at 67.0 °C). Refer to the HumaLoop T instruction manual for details on how to operate the incubator.

(3) Confirm the polymerase has been inactivated by heating at 80°C for 5 minutes (automatically completed by the HumaLoop T). Take all reaction tubes out of the HumaLoop T.

（For other incubator using UV light）

(1) Set the incubator temperature to 67.0 °C (with the hot bonnet temperature set to 10 °C above the reaction temperature or as near to this figure as possible – temperature accuracy: ±0.5 °C).

(2) Place the reaction tubes, and then start the amplification reaction (for 40 minutes at 67.0 °C).

(3) After 40 minutes, inactivate the polymerase using the heating block (for 5 minutes at 80 °C or 2 minutes at 95 °C) to terminate the reaction.

For real-time turbidity detection with HumaTurb C+A（see the flowchart of the procedure）

(1) Configure the Real-Time Turbidimeter HumaTurb C+A for detection with this product.

(2) Check whether the temperature displayed reaches 67.0 °C (allow the turbidimeter to warm up for 20 minutes before use).
If bubbles are present, spin down or flick to remove the bubbles in the reaction tube. As bubbles in the reaction solution interfere with the turbidity measurement and cause false judgment, avoid causing any bubbles when mixing reagent and sample solution.

(3) Place the reaction tubes and start measurement.

(4) Watch the turbidimeter display to check the positive and negative controls for any increase in the turbidity. If the turbidity increases in the positive control but does not in the negative control, the amplification reaction is proceeding correctly (Fig. 1). However, if any other situation occurs, the amplification reaction might be proceeding in the wrong way. In such a case, retest the affected samples.

(5) Confirm the completion of polymerase inactivation (automatically completed by the turbidimeter). Take all reaction tubes out of the Real-Time Turbidimeter HumaTurb C+A and discard them without opening.

10. INTERPRETATION OF RESULTS

For visual fluorescence detection

(For HumaLoop T)

If there are bubbles in the reaction tube, flick (or spin) down the tubes to remove them. Place each reaction tube in the Fluorescence Detection Unit, irradiate, and observe the tube from the side. It is recommended to read the results immediately after the reaction is completed. If this is not possible, the results should be read within 24 hours to ensure accuracy. During storage, be careful not to damage the reaction tube.

Pictorial representations of test outcomes in colour photos are available on the kit Instructions for use on electronic version on Elken Instructions for use website.

For a valid run, the following results must be obtained within 40 minutes:

- Positive Control: green fluorescent light is emitted.
- Negative Control: no fluorescent light is emitted.

The image of positive and negative control is shown on Fig 3

If any control is invalid, all samples in the run should be reported as invalid, and the test should be repeated.

After confirming that the run is valid, evaluate samples as follows:

- Positive sample: green fluorescent light is emitted.
- Negative sample: no fluorescent light is emitted.

(For other incubators using UV light)

Irradiate the bottom of each reaction tube and observe from the side through goggles/glasses or a UV-blocking eye mask. If there are bubbles in the reaction tube, flick (or spin) down the tubes to remove them.

For a valid run, the following results must be obtained within 40 minutes:

- Positive Control: green fluorescent light is emitted.
- Negative Control: no fluorescent light is emitted.

If any control is invalid, all samples in the run should be reported as invalid, and the test should be repeated.

After confirming that the run is valid, evaluate samples as follows:

- Positive sample: green fluorescent light is emitted.
- Negative sample: no fluorescent light is emitted.

For real-time turbidity detection with HumaTurb C+A

Turbidity is monitored in real time using the HumaTurb C+A device. Interpretation of the results is as follows:

- Positive Control: A clear increase in the turbidity curve (■ in Fig. 1) must be observed on the HumaTurb C+A screen within 40 minutes. The corresponding tube position will be displayed in pink, indicating a positive reaction.
- Negative Control: No increase in the turbidity curve (□ in Fig. 1) should be observed throughout the reaction period (i.e., the curve remains flat). The corresponding tube position will be displayed in **green**, indicating a negative reaction.

After confirming that the turbidity increases in the positive control but not in the negative control, evaluate samples per the following criteria (Fig. 2).

- Positive: some increase is observed in turbidity.
- Negative: no increase is observed in turbidity.

If either control result is invalid, all samples in the run must be considered invalid. For further instructions, refer to 13. TROUBLESHOOTING section. For further details on results interpretation and device operation, please refer to the HumaTurb C+A User Manual.

Amplification plots

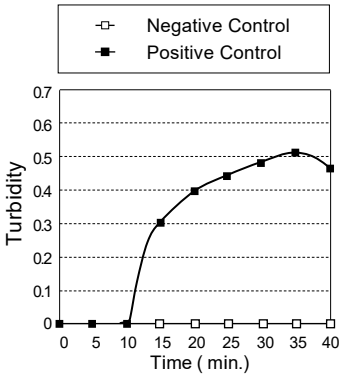


Fig. 1: Amplification plots for controls.

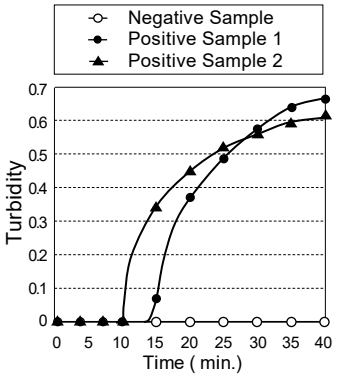


Fig. 2: Amplification plots for samples.

Pictorial image

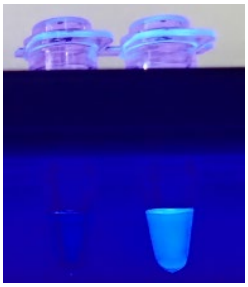


Fig. 3: Photograph of Negative Control (Left) and Positive Control (Right).under HumaLoop T blue LED

11. PROCEDURAL NOTES

(1) The LAMP reaction is very sensitive, and any contamination with even small amounts of the amplified product could lead to false-positive results.

(2) Separate the sputum collection and LAMP testing areas.

(3) Clean benches with over 0.5% sodium hypochlorite before and after performing the test.

(4) Take all necessary measures to avoid contamination, in particular, change gloves after transferring the sputum or if the gloves come into contact with the DNA solution.

(5) When handling this product, avoid microbial contamination and nuclease contamination. Even a small amount of DNase transmitted from sweat or saliva to the reaction tube might decompose DNA and cause a false result.

(6) When dispensing the solution into the reaction tube, avoid contact between the Injection Cap provided in the Loopamp™ PURE DNA Extraction Kit and the inner wall of the reaction tubes. Hold the tube rack upright and fill the tube until the level of the DNA solution is between the two lines (30 µL). It may influence the performance if it is incorrect (over the upper line or under the lower line.

(7) The dMTB should be fully dissolved. Any undissolved portion could influence the performance, such as decreasing the sensitivity. In particular,

keep the tubes standing upside down for 2 minutes.

(8) The PC MTB contains a high copy number of the control DNA. Avoid any contamination of other samples with the PC MTB. Dispense the samples and the negative control solution and close all reaction tubes before dispensing the PC MTB.

(9) Flick (or spin) down the PC MTB tube before opening it to collect the content on the bottom of the tube. Close the tube immediately after dispensing the PC MTB.

(10) For other incubators, when visual fluorescence judgment is chosen, inactivate the polymerase (for 5 minutes at 80 °C or 2 minutes at 95 °C) before judgment, or false judgment will be caused.

(11) **Never open the reaction tubes once the LAMP reaction has started or after completion. Be particularly careful when taking the reaction tubes out of the incubator to avoid opening the tubes accidentally.**

(12) Do not reuse any amplified product in the tubes for electrophoresis or other applications.

12. LIMITATIONS

(1) This product is a kit for qualitative detection; it is not designed for quantitative measurement. The intensity of fluorescent light observed, or the rise time of turbidity measured by the Real-Time Turbidimeter HumaTurb C+A does not correlate with the template DNA concentration or bacterial load in the specimen.

(2) This product has been validated for use at room temperature from10℃ to 35℃ and humidity from 20% to 80%, but has not been tested outside this range.

(3) The performance of this kit has not been established in individuals under 18 years of age or people living with HIV.

(4) Test results could be affected by specimen collection and transport, specimen preparation, inhibitors, and other laboratory procedural errors. A negative test does not exclude the presence of MTBC from the specimen. In making a clinical diagnosis, consider the patient's clinical condition and all other available laboratory results.

(5) Sputum can be stored at -20℃ for 30 days, but whether it can be stored longer has not been validated. It has been confirmed that sputum can be frozen and thawed up to three times, but no further validation has been done regarding frozen/thaw cycle.

(6) This device has not been validated for use with alternative specimen types such as induced sputum or gastric aspirates. Use with these specimen types is not recommended.

(7) The limit of detection (LoD) of this product is 300 CFU/mL for Mycobacterium tuberculosis (MTB). False-negative results may occur at concentrations near the LoD depending on specimen characteristics such as blood-stained or highly viscous sputum. Even with a negative result, patients with any persisting symptom indicative of infection by MTBC should undergo re-examination.

(8) This assay has clinical limitations. False-negative results may occur in patients with low bacterial burden or early-stage TB. A negative result does not rule out other diagnoses. Diagnosis of MTBC infection must be interpreted in conjunction with clinical symptoms, patient history, and other diagnostic findings.

(9) While the GyrB and IS regions targeted by this assay are specific to the MTBC, mutations in non-tuberculous mycobacteria (NTM) or other organisms may lead to false-positive results. Conversely, mutations within the target regions in MTBC may result in false-negative results. Although the primers have been designed to target a region containing a relatively small number of variations, MTBC might acquire further variations in this region and become less sensitive to this product. Hence, a negative test does not always rule out infection by MTBC.

(10) The number of IS element copies can vary by species and strain, which may influence the assay's detection limit.

(11) Contaminants such as cornstarch, soap, and powder from Loopamp™ PURE DNA Extraction Kit can cause false negative or false positive results.

13. TROUBLE SHOOTING

If invalid results occur despite correct use of the kit and adherence to the Instructions for Use, please refer to the Standard Operating Procedure and the detailed troubleshooting guide available at HUMAN Diagnostics Website[9]. In rare cases, invalid results may persist even when procedures are correctly followed. This may be due to factors such as sample quality, environmental conditions, or undetected contamination. In the event of repeated control failures or persistent indeterminate sample outcomes, please contact the HUMAN Diagnostics[10] for further assistance.

14. PERFORMANCE CHARACTERISTICS

14-1. Limit of Detection (LoD)

The limit of detection (LoD) was evaluated for the following analytes: *Mycobacterium tuberculosis* H37Rv strain, *Mycobacterium bovis* BCG, *Mycobacterium bovis*, and the First WHO International Standard for *M. tuberculosis* (H37Rv DNA for NAT-based assays, 20/152; hereinafter referred to as WHO IS). For each analyte, two dilution series were prepared in a matrix of MTB-negative human sputum, resulting in a total of nine concentration levels. Testing was performed using eight replicates per day over three consecutive days (n = 24 replicates per concentration) with two lots except for *Mycobacterium bovis*, which was tested using only one lot. The positive detection rate at each concentration was calculated and analyzed using probit analysis. Based on the probit analysis, the 95% detection thresholds were determined as shown on Table.

Microorganism/Analyte	LoD Estimate (CFU/mL)	Claimed LoD (CFU/mL)
Mycobacterium tuberculosis (H37Rv)	203 CFU/mL	300 CFU/mL
Mycobacterium bovis BCG	1,962 CFU/mL	2,000 CFU/mL
Mycobacterium bovis	1,626 CFU/mL	2,000 CFU/mL
WHO IS	336 genome equivalent/mL	400 genomes equivalent/mL

Mycobacterium tuberculosis (H37Rv)			*Mycobacterium bovis* BCG			*Mycobacterium bovis*			WHO IS		
CFU/mL	No. Detected	Percent Detection	CFU/mL	No. Detected	Percent Detection	CFU/mL	No. Detected	Percent Detection	genome /mL	No. Detected	Percent Detection
413	24	100%	4,013	24	100%	2,000	24	100%	725	24	100%
275	23	95.8%	2,006	24	100%	1,400	23	95.8%	363	23	95.8%
103	20	83.3%	1,605	23	95.8%	800	21	87.5%	181	22	91.7%
55	16	66.7%	803	19	79.2%	600	20	83.3%	91	18	75.0%
41	13	54.2%	535	13	54.2%	400	11	45.8%	45	13	54.2%
28	11	45.8%	401	10	41.7%	250	12	50.0%	23	14	58.3%
17	6	25.0%	161	5	20.8%	100	5	20.8%	11	10	41.7%
11	3	12.5%	67	3	12.5%	50	4	16.7%	6	5	20.8%
1	0	0%	2	0	0%	5	0	0%	3	2	8%

14-2. Reactivity (Inclusivity)

An analytical inclusivity study was conducted using contrived positive sputum specimens prepared by spiking MTB-negative human sputum with cultured strains of *Mycobacterium tuberculosis* lineages L1, L2, and L3, and *Mycobacterium africanum*, each at a concentration of ≥10^7 CFU/mL. Testing was performed with a single lot using 20 replicates per strain, and all samples yielded positive results (100%, 20/20) by both fluorescence and turbidity detection methods. These results confirm that the Loopamp™ MTBC Detection Kit is capable of detecting the tested MTBC strains.

Test Panel	Concentration	Fluorescence Detection	Turbidity
Mycobacterium tuberculosis Lineage 1	≥10^7 CFU/mL	100% (20/20)	100% (20/20)
Mycobacterium tuberculosis Lineage 2	≥10^7 CFU/mL	100% (20/20)	100% (20/20)
Mycobacterium tuberculosis Lineage 3	≥10^7 CFU/mL	100% (20/20)	100% (20/20)
Mycobacterium africanum	≥10^7 CFU/mL	100% (20/20)	100% (20/20)

* For *Mycobacterium bovis*, inclusivity was evaluated based on the results of LoD testing and further supported by in-silico analysis. The inclusivity of *M. africanum* was also assessed by in-silico analysis.

14-3. Cross-reactivity (Exclusivity)

In total, 26 different microorganisms were evaluated their cross-reactivity (exclusivity) to this kit. Regarding nontuberculous mycobacteria (*Mycobacterium asiaticum*, *Mycobacterium kansasii, Mycobacterium marinum, Mycobacterium simiae, Mycobacterium scrofulaceum, Mycobacterium szulgai, Mycobacterium gordonae, Mycobacterium xenopi, Mycobacterium avium, Mycobacterium intracellulare, Mycobacterium gastri, Mycobacterium haemophilum, Mycobacterium malmoense, Mycobacterium chelonae, Mycobacterium fortuitum, Mycobacterium flavescens*) (1.0 x 10^4 genomes equivalent per test) and respiratory disease bacteria (*Streptococcus pneumoniae, Staphylococcus aureus, Haemophilus influenzae, Moraxella catarrhalis, Klebsiella pneumoniae, Escherichia coli, Legionella pneumophila, Pseudomonas aeruginosa, Mycoplasma pneumoniae* (I), *Mycoplasma pneumoniae* (II)) (1.0 x 10^5 genomes equivalent per test), the measurement system tested negative for all bacterial species; no cross-reaction was observed.

14-4. Cross-reactivity (Co-infection Reactivity)

Cross-reactivity (Co-infection Reactivity) was evaluated using 26 different microorganisms (see Section 14-3. Cross-reactivity (Exclusivity)), each tested at a final concentration of at least 1.0 × 10^6 CFU/mL. MTB-negative sputum samples were spiked with MTB H37Rv at 3× LoD and combined with each microorganism. Each condition was tested in triplicate (n = 3). The measurement system tested positive for all bacterial species with no interference observed.

		Fluorescence	Turbidity
bacteria	*Streptococcus pneumoniae*	Positive	Positive
	Staphylococcus aureus	Positive	Positive
	Haemophilus influenzae	Positive	Positive
	Moraxella catarrhalis	Positive	Positive
	Klebsiella pneumoniae	Positive	Positive
	Escherichia coli	Positive	Positive
	Legionella pneumophila	Positive	Positive
	Pseudomonas aeruginosa	Positive	Positive
	Mycoplasma pneumoniae (I)	Positive	Positive
	Mycoplasma pneumoniae (II)	Positive	Positive
	Mycobacterium asiaticum	Positive	Positive
	Mycobacterium kansasii	Positive	Positive
	Mycobacterium marinum	Positive	Positive
	Mycobacterium simiae	Positive	Positive
	Mycobacterium scrofulaceum	Positive	Positive
	Mycobacterium szulgai	Positive	Positive
	Mycobacterium gordonae	Positive	Positive
	Mycobacterium xenopi	Positive	Positive
	Mycobacterium avium	Positive	Positive
	Mycobacterium intracellulare	Positive	Positive
	Mycobacterium gastri	Positive	Positive
	Mycobacterium haemophilum	Positive	Positive
	Mycobacterium malmoense	Positive	Positive
	Mycobacterium chelonae	Positive	Positive
	Mycobacterium fortuitum	Positive	Positive
	Mycobacterium flavescens	Positive	Positive
Mycobacterium tuberculosis H37Rv strain 3xLoD		Positive	Positive
Positive Control (PC MTB)		Positive	Positive
Negative Control (NC MTB)		Negative	Negative

14-5. Interfering Substances

The performance test for this product used the plasmid DNA containing the gyrB and IS region of the genome DNA of *Mycobacterium tuberculosis* H37Rv (GenBank No. NC_000962) as a calibrator. Our in-house studies have revealed that measurement was not affected by the presence of free bilirubin (91.0 mg/dL), conjugated bilirubin (101.0 mg/dL), chyle (formazine turbidity:7,300), and haemolytic haemoglobin (2,475 mg/dL).

Regarding drugs, our in-house studies have revealed that measurement was not affected by the presence of isoniazid (100 µg/mL), ethambutol (20 µg/mL), rifampicin (100 µg/mL), pyrazinamide (500 µg/mL), kanamycin (20 µg/mL), and streptomycin (500 µg/mL).

14-6. Precision (Repeatability)

An in-house repeatability study was conducted using one lot each of the Pipette-60 Set, Loopamp™ MTBC Detection Kit, and Loopamp™ PURE DNA Extraction Kit. A single operator performed testing over 20 consecutive days using sputum samples spiked with known concentrations of MTB and *Mycobacterium bovis*, as well as tuberculosis-negative sputum. The samples were included TB-negative sputum, MTB at 3× and 5× LoD, and M. bovis at 5× LoD. Each run included two replicates per sample. DNA extraction, amplification, and visual interpretation were performed using the HumaLoop T, following standardized procedures. Positive and negative controls were included in each run. The results demonstrated 100% agreement rate across all test conditions over the 20-day period.

Sample			Total No of Positive/ Total No of Tested	Positive rate(%)
TB-negative sputum			0/40	0
Mycobacterium tuberculosis	900 CFU/mL	3 x LoD	40/40	100
	1,500 CFU/mL	5 x LoD	40/40	100
Mycobacterium bovis	10,000 CFU/mL	5 x LoD	40/40	100

14-7. Reproducibility

A reproducibility study was conducted at three independent sites using contrived sputum specimens spiked with cultured *Mycobacterium tuberculosis* and *Mycobacterium bovis*. Specimens were prepared at concentrations of 3× LoD and 5× LoD for *M. tuberculosis*, and 5× LoD for *M. bovis*, using pooled MTB-negative sputum as the matrix. Testing was performed over five days, with each day comprising two runs. Each run included three replicates per sample. The four test samples were divided into two groups, as shown in the table below. Each group was tested twice daily over five days using three different reagent lots. DNA extraction, amplification, and visual interpretation were performed using the HumaLoop T, following standardized procedures. Positive and negative controls were included in each run. As summarized below, all analytes showed 100% agreement across the three testing sites.

Sample				Site 1	Site 2	Site 3	Total Agreement (%)
Panel 1	TB-negative sputum			0/30 (0%)	0/30 (0%)	0/30 (0%)	0/90 (100%)
	Mycobacterium tuberculosis	900 CFU/mL	3 x LoD	30/30 (100%)	30/30 (100%)	30/30 (100%)	90/90 (100%)
Panel 2	*Mycobacterium tuberculosis*	1,500 CFU/mL	5 x LoD	30/30 (100%)	30/30 (100%)	30/30 (100%)	90/90 (100%)
	Mycobacterium bovis	10,000 CFU/mL	5 x LoD	30/30 (100%)	30/30 (100%)	30/30 (100%)	90/90 (100%)

14-8. Clinical performance

To date, tuberculosis remains one of the world's largest infections. Globally, the total estimated number of new tuberculosis cases is about 10 million, and that of sputum smear-positive is about 4.3 million.[11] In Japan, 10,096 patients were newly registered as affected with tuberculosis in 2023, of whom 1,587 died.[12]

This kit was examined in two medical institutions designated for Class-2 infectious diseases (designated medical institutions that had beds exclusive for patients with tuberculosis) for performance in diagnosing patients suspected of tuberculosis. Comparator methods included culture as a gold standard, polymerase chain reaction (PCR), and transcription reverse transcription concerted reaction (TRC), the latter two of which are approved in Japan but are not considered gold standards. Sputum samples were collected for 2 days from 160 subjects (totaling 320 specimens). Notably, testing based on this product included evaluations for the DNA extract solution obtained from the untreated sputum and those for the DNA extract solution obtained from the sputum treated by NALC-NaOH. The comparative methods including culture were conducted using only treated sputum. Detection was performed using both visual fluorescence and turbidity observation methods and 95% Confidence Interval (95%CI) was calculated by Wilson's score method.

For untreated sputum, the overall concordance rate with culture was 82.0% (260/317) using visual fluorescence and 82.3% (261/317) using turbidity detection. One discrepancy was noted between visual fluorescence detection and turbidity detection, which occurred in a bloody sputum specimen that interfered with fluorescence detection. Excluding this sample, the results of both detection methods were consistent. Compared to PCR and TRC, the overall percent agreement was 91.5% (291/318 subjects) and 94.3% (230/244 subjects), respectively. Both detection methods showed identical agreement rates.

For treated sputum, the overall concordance rate with culture was 80.8% (256/317) for both detection methods. Compared to PCR and TRC, the overall concordance rates were 92.1% (293/318) and 93.0% (227/244), respectively. In addition, the evaluations made by real-time turbidity detection and visual fluorescence detection completely agreed, except for one sample (this sample was bloody sputum and tested false negative in visual fluorescence detection because of the disturbance by blood). Thus, we regard the two types of evaluations as identical to each other. The tables below show test results obtained by real-time turbidity detection. Of note, the results of visual fluorescence detection by the HumaLoop T were the same as those by the Real-Time Turbidimeter HumaTurb C+A

		Untreated sputum		Treated sputum	
		Culture			
		Positive	Negative	Positive	Negative
LAMP	Positive	196	8	191	6
	Negative	27	85	32	87
Clinical Sensitivity		87.9% (82.9–91.9%)		85.7% (80.4–90.0%)	

Clinical Specificity	91.4% (83.8–96.2%)	93.5% (86.5–97.6%)
Overall Concordance Rate	88.9% (84.9–92.2%)	88.0% (83.9–91.3%)
Positive Predictive Value	96.1% (92.4–98.3%)	97.0% (93.5–98.9%)
Negative Predictive Value	75.9% (66.9–83.5%)	73.1% (64.2–80.8%)
Likelihood Ratio +	10.2	13.3
Likelihood Ratio -	0.1325	0.1534

Note: The % in parentheses represent the 95% CI.

The likelihood ratio + for treatment sputum cannot be calculated.

		Untreated sputum				Treated sputum			
		PCR		TRC		PCR		TRC	
		Positive	Negative	Positive	Negative	Positive	Negative	Positive	Negative
LAMP	Positive	196	7	163	5	194	3	157	2
	Negative	20	95	9	67	22	99	15	70
Overall Percentage Agreement (OPA)		91.5% (87.9-94.3%)		94.3% (90.6–96.8%)		92.1% (88.6–94.8%)		93.0% (89.1–95.9%)	
Positive Percent Agreement (PPA)		90.7% (86.1-98.6%)		94.8% (90.3–97.6%)		89.8% (85.0–93.5%)		91.3% (86.0–95.0%)	
Negative Percent Agreement (NPA)		93.1% (86.4-97.2%)		93.1% (84.5–97.7%)		97.1% (91.6–99.4%)		97.2% (90.3–99.7%)	
Positive Predictive Value		96.6% (93.0–98.6%)		97.0% (93.2–99.0%)		98.5% (95.6–99.7%)		98.7% (95.5–99.8%)	
Negative Predictive Value		82.6% (74.4-89.0%)		88.2% (78.7–94.4%)		81.8% (73.8–88.2%)		82.4% (72.6–89.8%)	
Likelihood Ratio +		13.1		13.7		31.0		32.6	
Likelihood Ratio -		0.0999		0.0559		0.1050		0.0895	

Note: The % in parentheses represent the 95% CI.

15. ORDERING INFORMATION

Product Code	Product Name	Contents
972000	***Loopamp™ MTBC Detection Kit***	***96 tests***
980000	HuMax ITA	Micro Centrifuge
970000	Loopamp™ PURE DNA Extraction Kit	90 tests
964000	HumaHeat Incubator	Heating Block
971000	Pipette-60 Set	1 pipette; 4 x 96 tips
961000	HumaLoop T	1 Main unit 1 Fluorescence Detection Unit
963200	HumaTurb C+A	1 Control unit 1 Amplification Unit

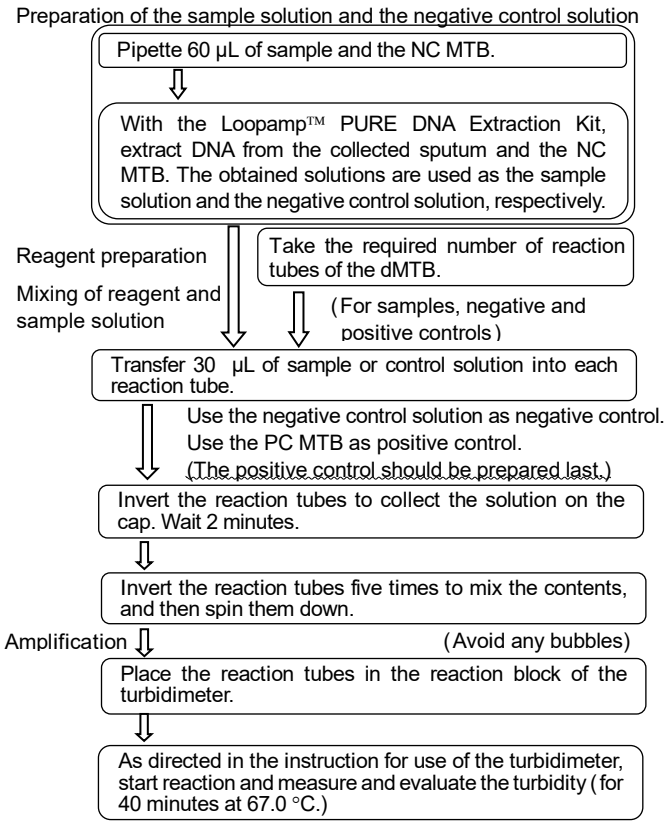
16. NOTICE

Any serious incident that has occurred in relation to the device shall be reported to the authorised representative, the manufacturer and the competent authority of the Member State in which the user and/or the patient is established.

17. Flow chart

Operation procedure for real-time turbidity detection

Please refer to TB-LAMP SOP[9] for florescence detection



Confirm the completion of polymerase inactivation (for 5 minutes at 80 °C or 2 minutes at 95 °C). Take all reaction tubes out of the turbidimeter and discard them without opening. Be careful not to damage the tubes.

18. REFERENCES

1) Notomi T., et al.: Nucleic Acids Research 28, No. 12, e63 (2000)
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7) World Health Organization. Guidance on regulations for the transport of infectious substances, 2023–2024 [Internet]. Geneva: World Health Organization; 2024 [cited 2025 May 26]. Licence: CC BY-NC-SA 3.0 IGO. Available from: https://www.who.int/europe/publications/i/item/9789240089525
8) Instructions for use for IVDR Certified Products for Loopamp™ PURE DNA Extraction Kit (Product Code: 970000) and Loopamp™ MTBC Detection Kit Available from: https://www.eiken.co.jp/en/ifu
9) TB-LAMP SOP Available from: https://www.human.de/training
10) HUMAN Diagnostics Worldwide Contact loopamp@human.de.

11) WHO global TB database:
https://www.who.int/teams/global-tuberculosis-programme/data
https://apps.who.int/iris/bitstream/handle/10665/336069/9789240013131-eng.pdf
12) Ministry of Health, Labour and Welfare JAPAN
https://www.mhlw.go.jp/content/10900000/001295037.pdf

19. TABLE OF SYMBOLS

REF Catalog number	Consult instructions for use	Expiration date
IVD *In vitro* diagnostic medical device	Manufacturer	Temperature limitation
LOT Batch code	Contains sufficient for <n> tests	EC REP Authorized Representative in the European Community

IVD CE 0123

Importer

EC REP **HUMAN Gesellschaft für Biochemica und Diagnostica mbH**
Max-Planck-Ring 21, 65205 Wiesbaden, Germany

EIKEN CHEMICAL CO.,LTD.
4-19-9 Taito, Taito-ku, Tokyo, 110-8408 JAPAN
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*Date of Revision: To be updated