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

Loopamp™ MTBC Detection Kit

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 to be used in professional laboratories and hospitals by adequately trained personnel. The result can be interpreted either by automated turbidimeter or visually under UV irradiation.

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 or automated detection possible.[3),4)]

The primers provided with this product are designed in the DNA gyrase subunit B (*gyrB*) and 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 the 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, a visual judgment under UV irradiation can be used instead of turbidity measurement. Before reaction, calcein in the reagent is in the 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 calcein becomes fluorescent.[4)]

KIT CONTENTS

Reagents are stable until the date on the label, assuming the container remains unopened at a storage temperature of 2–30 °C. The reagents are also confirmed stable after opening the container when adhered to these procedural directions.

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

*1: *Bst* DNA polymerase derived from *Bacillus stearothermophilus* is a strand displacement DNA polymerase that lacks 5′→3′ exonuclease activity.

*2: Primers designed in the *gyrB* and IS region of the MTBC genome DNA, purified from synthesized oligonucleotides by HPLC.

*3: 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

WARNINGS AND PRECAUTIONS

(1) For *in vitro* diagnostic use only.
(2) This product is designed only for clinical diagnosis of MTBC from sputum samples of human origin. Do not use it for 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 (sum of samples and controls) and re-seal the aluminium pouch immediately.
(12) Read the instruction manual and ensure that the required equipment (turbidimeter or incubator) is available before commencing the procedure.
(13) Sputum samples pose a potential risk for infection. Take all necessary preventive measures to avoid biohazard.[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 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.

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.

SPECIMEN COLLECTION

(1) Use the most purulent part of the sputum sample.
(2) Sputum samples should be used immediately after collection.
(3) 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.

MATERIALS REQUIRED BUT NOT PROVIDED

- Loopamp™ PURE DNA Extraction Kit
- Pipette-60 Set

For visual fluorescence detection
(For HumaLoop T)

- HumaLoop T

(For other incubator using UV 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)

PREPARATION OF REAGENTS

(1) MTBC detection reagent

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)

Flick (or spin) down the tube to collect the content to 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)

Flick (or spin) down the tube to collect the content to the bottom of the tube.

Note: The PC MTB should be measured every time.

MEASUREMENT PROCEDURE

DNA Extraction

To extract the DNA from 60 µL sputum sample, follow the instructions for the Loopamp™ PURE DNA Extraction Kit (sold separately). Dispense 60 µL of the sputum sample into the Heating Tube and load it into the HumaHeat or heating block preheated at 90 °C. Use the most purulent sputum whenever possible.

Reagent and Sample Mixing

(1) Turn on the HumaLoop T or the Real-Time Turbidimeter HumaTurb C+A.
(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 to 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 to 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 completion of polymerase inactivation (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 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 amplification reaction (for 40 minutes at 67.0 °C).
(3) After 40 minutes, inactivate the polymerase using the HumaHeat or 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).
(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). If any other situation occurs, however, 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.

Amplification plots

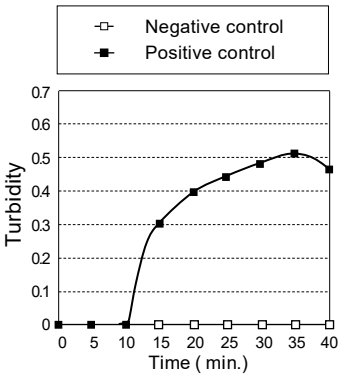

Fig. 1: Amplification plots for controls.

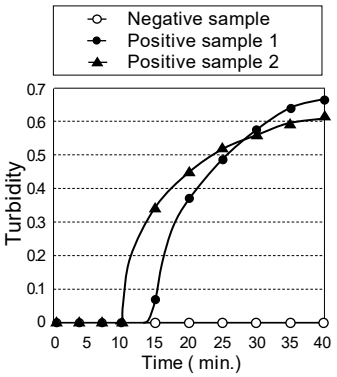

Fig. 2: Amplification plots for samples.

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) Do not use sputum samples containing a large amount of blood, as this may affect measurements. Refer to the "Manual of Clinical Microbiology, 12th edition"[6] in a case requiring sample pretreatment.

(7) The DNA solution should ideally be used immediately after preparation; if it is impossible, the DNA solution can be stored at room temperature and used within 72 hours.

(8) 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 inappropriate (over the upper line or under the lower line).

(9) **(For HumaLoop T or other incubator using UV light)**
If bubbles are present, flick (or spin) down the tubes to remove them.
(For Real-Time Turbidimeter HumaTurb C+A)
As bubbles in the reaction solution interfere with the turbidity measurement and cause false judgment, avoid causing any bubble when mixing reagent and sample solution. If bubbles are present, spin down or flick to remove the bubbles.

(10) 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.

(11) 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.

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

(13) When the HumaLoop T or the Real-Time Turbidimeter HumaTurb C+A is used, polymerase inactivation is automatically performed.

(14) 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.

(15) For other incubators, when UV light is used, do not stare directly at it. Instead, use a glass board or wear goggles or a protective eye mask whenever looking at UV light.

(16) 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.

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

INTERPRETATION OF RESULTS

For visual fluorescence detection

(For HumaLoop T)

Place each reaction tube in the Fluorescence Detection Unit, irradiate, and observe the tube from the side.

(For other incubator using UV light)

Irradiate the bottom of each reaction tube and observe from the side through goggles/glasses or a UV-blocking eye mask.

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

- 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

After confirming that the turbidity increases in the positive control but not in the negative control, evaluate samples per the following criteria (Figs. 1 and 2).

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

Notes:

(1) The minimum detectable sensitivity of this product is 0.38 genomes equivalent per test. Even with a negative test, patients with any persisting symptom indicative of infection by MTBC should undergo re-examination.

(2) 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.

(3) 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.

(4) 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.

INTERFERING SUBSTANCES

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).

PERFORMANCE CHARACTERISTICS

1. Accuracy

In testing the following samples:

- negative sample (concentration: 0 genome equivalent/test)
- positive sample 1 (1.875 genomes equivalent/test)
- positive sample 2 (125 genomes equivalent/test)

The negative sample should test negative, while the positive samples 1 and 2 should test positive.

2. Within-run Reproducibility

In testing five negative and positive samples simultaneously, the negative sample should test negative throughout, while the positive sample should test positive throughout.

3. Limit of Detection

0.38 genomes equivalent/test

4. Cross-reactivity

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*) (1.0×10^4 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)) (1.0×10^5 genomes equivalent per test), the measurement system tested negative for all bacterial species; no cross-reaction occurred.

5. Reactivity against MTBC

Reactivity against *Mycobacterium tuberculosis, Mycobacterium bovis*, and *Mycobacterium africanum* was confirmed.

6. Information about a Calibrator

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.

7. 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.[7] In Japan, 24,760 patients were newly registered as affected with tuberculosis in 2008, of whom 2,216 died.[8]

This product 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. Along with PCR and TRC, both of which had already been approved in Japan, this kit was used to test sputum samples collected for 2 days (320 samples from 160 subjects), and the results were compared between kits. Notably, testing based on this product included evaluations for the DNA extract solution obtained from the untreated sputum (hereinafter LAMP for untreated sputum) and those for the DNA extract solution obtained from the sputum pretreated by NALC-NaOH and some other processes (hereinafter LAMP for pretreated sputum).

As shown in the tables below, the overall concordance rate was favorable as follows: LAMP for untreated sputum vs. PCR: 91.5% (291/318 subjects); LAMP for pretreated sputum vs. PCR: 92.1% (293/318); LAMP for untreated sputum vs. TRC: 94.3% (230/244); LAMP for pretreated sputum vs. TRC: 93.0% (227/244). 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.

LAMP		PCR	
		Positive	Negative
Untreated sputum	Positive	196	7
	Negative	20	95
Overall concordance rate		91.5% (291/318)	
Diagnostic sensitivity		90.7% (196/216)	
Diagnostic specificity		93.1% (95/102)	
Positive predictive value		96.6% (196/203)	
Negative predictive value		82.6% (95/115)	
Likelihood ratio + (sensitivity/(1-specificity))		13.1	
Likelihood ratio - ((1-sensitivity)/specificity)		0.0999	

LAMP		PCR	
		Positive	Negative
Pretreated sputum	Positive	194	3
	Negative	22	99
Overall concordance rate		92.1% (293/318)	
Diagnostic sensitivity		89.8% (194/216)	
Diagnostic specificity		97.1% (99/102)	
Positive predictive value		98.5% (194/197)	
Negative predictive value		81.8% (99/121)	
Likelihood ratio + (sensitivity/(1-specificity))		31.0	
Likelihood ratio - ((1-sensitivity)/specificity)		0.105	

LAMP		TRC	
		Positive	Negative
Untreated sputum	Positive	163	5
	Negative	9	67
Overall concordance rate		94.3% (230/244)	
Diagnostic sensitivity		94.8% (163/172)	
Diagnostic specificity		93.1% (67/72)	
Positive predictive value		97.0% (163/168)	
Negative predictive value		88.2% (67/76)	
Likelihood ratio + (sensitivity/(1-specificity))		13.9	
Likelihood ratio - ((1-sensitivity)/specificity)		0.0451	

LAMP		TRC	
		Positive	Negative
Pretreated sputum	Positive	157	2
	Negative	15	70
Overall concordance rate		93.0% (227/244)	
Diagnostic sensitivity		91.3% (157/172)	
Diagnostic specificity		97.2% (70/72)	
Positive predictive value		98.7% (157/159)	
Negative predictive value		82.4% (70/85)	
Likelihood ratio + (sensitivity/(1-specificity))		32.6	
Likelihood ratio - ((1-sensitivity)/specificity)		0.0895	

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

NOTICE

In case of occurrence of 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.

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https://www.who.int/teams/global-tuberculosis-programme/data
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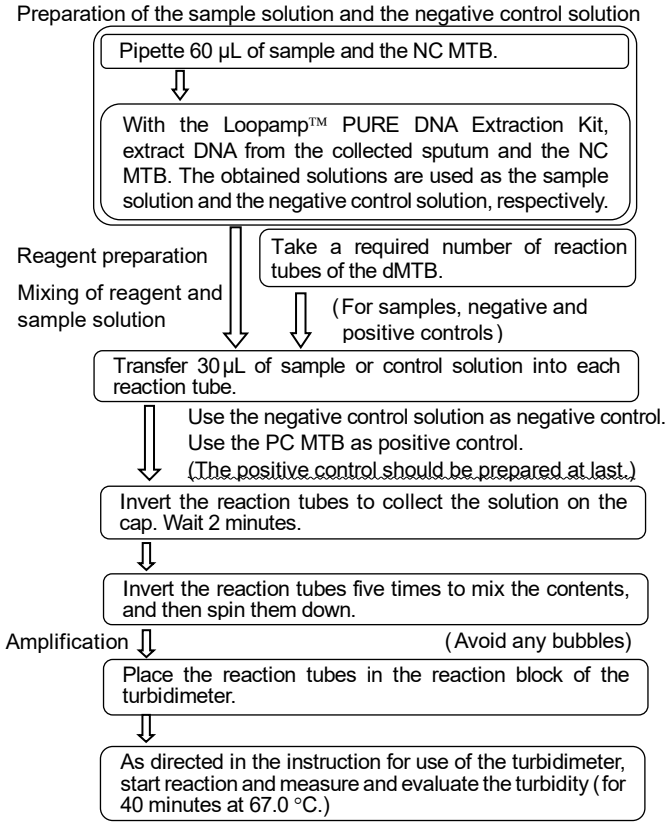
8) Kekkaku No Tokei 2009 (Statistics of TB 2009): Japan Anti-Tuberculosis Association

Flow chart

Operation procedure for real-time turbidity 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.

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

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