

MPT64 Detection Kit

IP-TB

Instructions for use

[General notes]

- (1) Please read carefully the instructions and special notes before use.
- (2) Accurate results may not be obtained in case the test plate had absorbed moisture.
Use the kit for assessment immediately after opening.
- (3) Handle all samples with caution and regard them as contagious.

[Characteristics of the kit]

IP-TB is a research reagent that can detect easily MPT64 from solid or liquid culture.

- 1) Special training is not required.
- 2) No special equipment is necessary.
- 3) High sensitivity and accuracy.
- 4) Fast result: 15 minutes.

[Intended use]

Detection of MPT64 secreted by *Mycobacterium tuberculosis* complex in culture system.

[Contents of the kit]

- 1) Test plate
 - Anti-MPT64 antibody (Test line)
 - Anti-MPT64 antibody-conjugated gold colloid
 - Anti-mouse IgG antibody (Control line)
- 2) Diluent buffer
- 3) Sample collector
- 4) Instructions for use

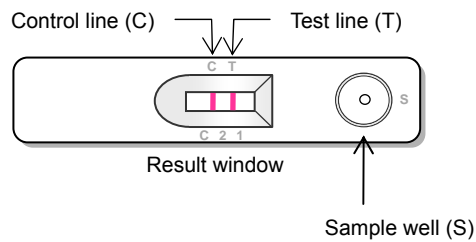
[Equipment required for pretreatment of sample or assessment]

- 1) Inoculation loop or micropipette
- 2) Timer

[Principle of assessment]

IP-TB is a lateral flow immunochromatographic assay for the qualitative detection of MPT64 antigen. MPT64 antigen forms a complex with the anti-MPT64 antibody conjugated gold colloid in the pad and moves onto the membrane by capillary action within the test plate. At this time, the complex reacts with the anti-MPT64 antibody coated on the test line to generate a reddish violet line. In absence of MPT64 antigen, test line does not emerge. Thus, the presence of MPT64 in the sample can be evaluated by appearance of the test line.

[Part of the test plate]



[Operational procedure]

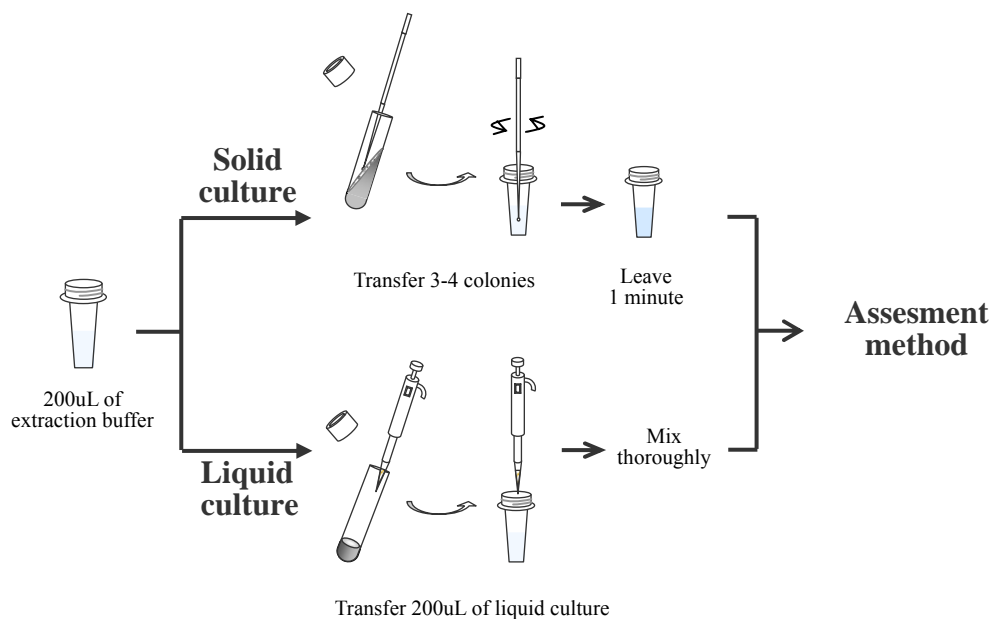
1. Sample preparation

Solid culture

- (1) Add 0.2mL of Diluent buffer to sample collector and transfer 3-4 colonies by inoculation loop.
- (2) Mix well and leave for 1 minute.

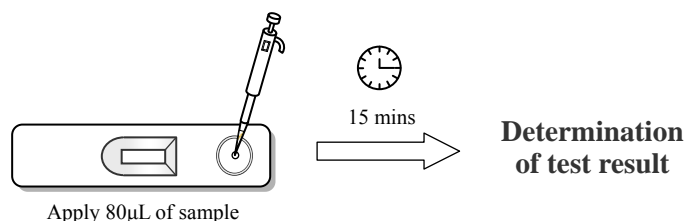
Liquid culture

- (1) Add 0.2mL of Diluent buffer to sample collector and add 0.2mL of liquid culture.
- (2) Mix well.



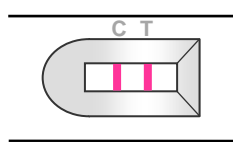
2. Assessment method

- (1) Transfer 80µL of supernatant into the sample well (S).
- (2) At 15 minutes, determinate by visual examination the test result. Do not determinate test result after 15 minutes.



[Determination of test result]

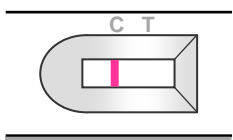
After reaction according to the operational procedure, determination of test result is based on the line that emerges on the result window at 15 minutes.



< **Positive** >

When lines are observed for the **control line (C)** and **test line (T)** on the result window, the sample is determined **MPT64 antigens positive**.

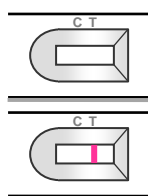
◆ The thickness of the line varies depending on the concentration of antigens in the sample. Even when a test line is pale, a sample with observable line by visual examination should be evaluated as positive.



< **Negative** >

When a line is observed on the control line (C) but not on test line (T) on the result window, the sample is determined negative.

◆ Negative result can be obtained by no presence of antigen in the sample or when antigen is inferior to limit of detection of the kit.



< **Invalid → re-measure** >

When a line cannot be observed on the control line (C) on the result window, the test is determined as invalid. The test should be performed again in a new test plate.

[Notes of assessment]

- (1) Bring the kit at room temperature prior to assessment.
- (2) Insufficient spread of the antibody conjugated gold colloid may vary the result. Please do not evaluate a sample within 15 minutes after applying the sample.
- (3) It is possible that accuracy result cannot be obtained after 15 minutes. Please do not evaluate a sample after 15 minutes.
- (4) Do not use reagents beyond expiration date.
- (5) Use reagents that are contained in the kit.
- (6) Do not reuse the test plate.

[Handling of sample]

- (1) Sample should be diluted and used for assessment immediately after collection.
- (2) Diluted sample cannot be store.
- (3) Handle all samples with the caution and regard them as contagious.
- (4) This kit was developed to detect MPT64 secreted by Mycobacterium tuberculosis complex in culture system. Do not use human humoral sample, organs, respiratory tract wash liquid as sample”.

[Performance]

1. Reactivity

IP TB detects MPT64 from *M. tuberculosis* and *M. bovine*.
Test line is not observable in the case of *M. avium*.

[Storage and available period]

Storage : 1 – 30°C

Useable period: expiry date is as described in the outer package.

◆ Avoid high temperature and humidity condition.

[Package unit]

		Name	
IP TB		Test plate	CODE: IPTBKT 20 tests/kit
		Diluent buffer	

Manufacturer:



Immuno Probe Co., Ltd.

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