



TB Ag

Capilia™ TB-Neo

WHO endorses "lateral flow immunochromatographic assay" for identification of *M.tuberculosis* complex.



- **Rapid test for identification of *M.tuberculosis* complex**
Detecting MPB64 protein, specifically produced by *M.tuberculosis* complex
- **Extremely high specificity to *M.tuberculosis* complex**
Equivalent accuracy to the nucleic-acid probe assay
- **Fast test results with one-step operation**
Reading time is 15 min. No special equipment required

Need Culture

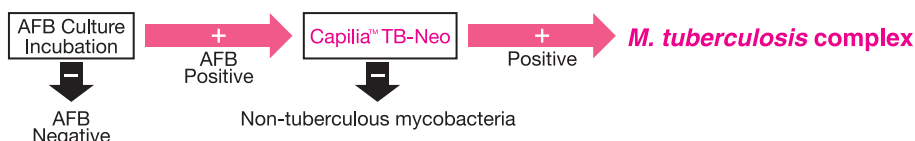
Both liquid medium and solid medium can be used as sample
For solid medium, Capilia™ TB-Neo Extraction Buffer (sold separately) is required



Capilia™ TB-Neo



Capilia™ TB-Neo Diagnosis Flow



Test Procedure

Sample preparation

■ Using a liquid medium for AFB (e.g. Middle Brook 7H9 broth)

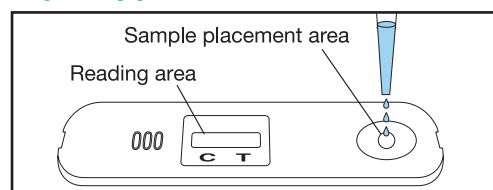
Incubate at 37°C for 1 to 3 weeks until the liquid medium becomes cloudy due to the growth of bacteria. In the event that MGIT is used, incubate until a positive interpretation is possible. In both cases, it is necessary to confirm the presence of AFB by acid-fast staining. Stir the liquid medium in the incubator and use the medium as a sample.

■ Using a solid medium for AFB (e.g. Ogawa medium)

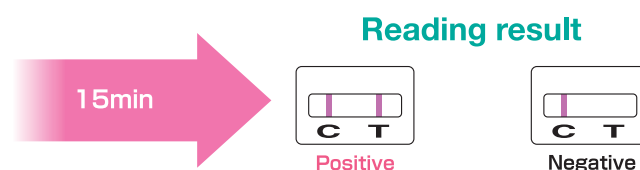
Incubate at 37°C for 2 to 4 weeks until the growth of bacterial colonies is confirmed on the solid medium, and then confirm the presence of AFB by acid-fast staining.

- (1) Dispense 0.2 mL of the extraction buffer (sold separately) into the tube.
- (2) Pick 1 µL of bacteria (equivalent to a 1mm-diameter platinum micro-loop) from the bacterial colony that has grown on the solid medium.
- (3) Suspend the collected bacteria in the buffer solution in the tube.
- (4) Close the tube with a stopper and fully suspend with a mixer. Then, use the bacterial suspension as a sample.

Sample application



Dispense 80-100 µL sample into the sample placement area at the test plate.



Reference Data

1.Sensitivity

Result	Clinical isolate of <i>M.tuberculosis</i> complex
Positive	497
Negative	3 ^{Note}
Total	500

Sensitivity: 99.4%

^{Note} 3 *M. tuberculosis* complex isolates that tested negative by Capilia™ TB-Neo

- 1 isolate: *M. tuberculosis* possessed a 63-bp deletion in the *mpt64* gene
- 1 isolate: *M. tuberculosis* possessed a 3,659-bp deletion from Rv1977 to Rv1981c, a region including the entire *mpt64* gene
- 1 isolate: *M. bovis* BCG Connaught lacked RD2 including the *mpt64* gene

2.Specificity

Clinical isolate of NTM	Number of strain	Number of negative result
<i>M.abscessus</i>	10	10
<i>M.avium</i> complex	15	15
<i>M.chelonae</i>	4	4
<i>M.fortuitum</i>	13	13
<i>M.gastri</i>	1	1
<i>M.gordonae</i>	8	8
<i>M.intermedium</i>	1	1
<i>M.intracellulare</i>	7	7
<i>M.kansasii</i>	15	15
<i>M.marinum</i>	1	1
<i>M.nonchurumogenicum</i>	3	3
<i>M.peregrinum</i>	2	2
<i>M.scrofulaceum</i>	5	5
<i>M.szulgai</i>	1	1
<i>M.xenopi</i>	4	4
Total	90	90

Specificity: 100%

Reference: Chikamatsu K, et al. Comparative evaluation of three immunochromatographic identification tests for culture confirmation of *Mycobacterium tuberculosis* complex. *BMC Infect Dis* 2014;14:54.

Product Summary

- **REF** CATB0870 (100 Tests)
Kit content: Test Plate × 100
- **REF** CATB0871 (10 Tests)
Kit content: Test Plate × 10
- Sold Separately : **REF** CATB0877 Capilia™ TB-Neo Extraction Buffer(20mL/Bottle)
- Validity: 27 months
- Storage: Store at 2-30°C
- Reading time: 15 minutes