

A reagent for detecting the *M. tuberculosis* complex

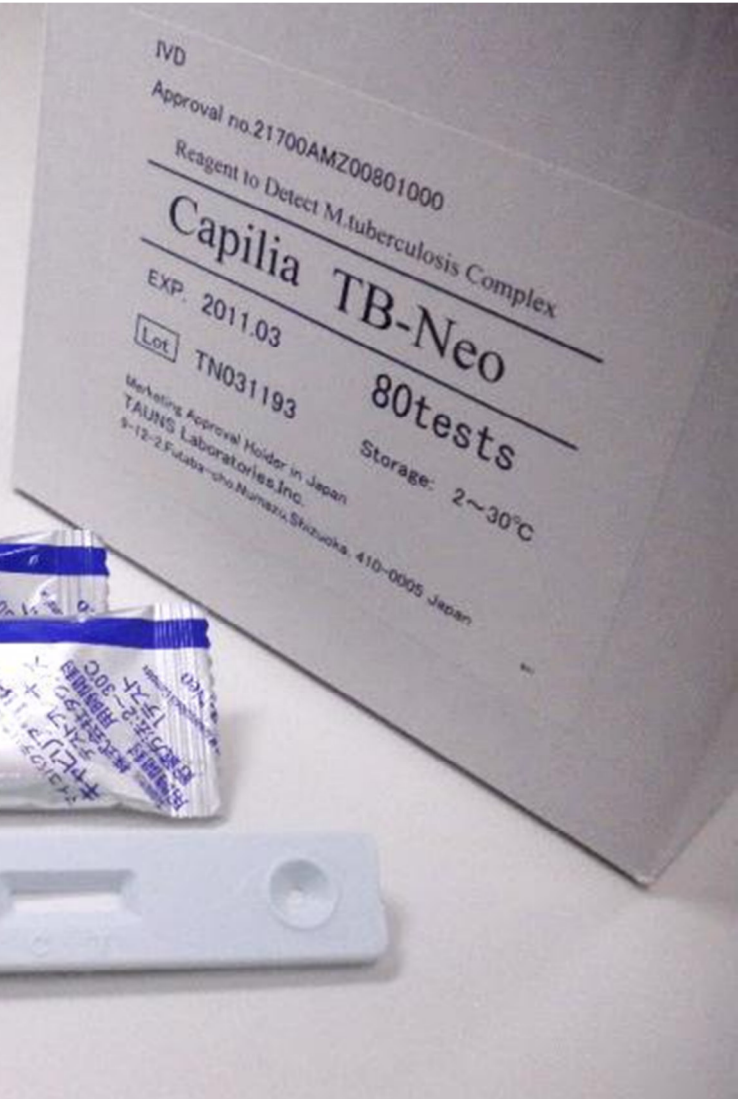
Capilia TB-Neo



Product Advantage

- ▶ Sensitivity and specificity are comparable to the nucleic-acid probe-based identification method.
- ▶ No special equipment required.
- ▶ Easy to operate.
- ▶ Test results obtained 15-minutes after the specimen is dispensed.

Capilia TB test is an official reagent for detecting the *M.tuberculosis* complex as described in the 2007 Japanese Inspection Guideline for *Tubercle bacillus*.



Capilia TB-Neo

Specimen 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 bacterial growth. 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 media in the incubator and use the media as a specimen.

■ 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 specimens.

Test procedure

■ Test procedure

1. Drip an 80~100µL specimen into the specimen placing area of the test plate.
2. Observe the reading area of the test plate after 15 min and interpret the result as follows.

■ Interpretation:

Positive, if a purple red line is observed in the reading areas of both [T] and [C]

Negative, if a purple red line is not observed in the reading area [T] but the color is observed in the reading area [C]

Reference data

■ Correlation with the conventional test methods

Clinical Isolate of *M. tuberculosis*

		Control kit (Capilia TB)		
		Positive	Negative	Total
Capilia TB-neo	Positive	46	0	46
	Negative	0	5*	5
	Total	46	5	51

Sensitivity: 100% (46/46)

Specificity: 100% (5/5)

Concordance rate: 100% (51/51)

As the above data show, positive results were also obtained with this kit for all of the 46 clinical isolates of *M. tuberculosis* for which positive results were obtained with the Control kit.

*) A gene analysis for five clinical isolates of *M. tuberculosis* for which negative results were obtained by the control kit (Capilia TB) as well as by this kit revealed that there was mutation in the base sequence of the MPB64 gene so that those isolates were mutants in which the expression of the MPB64 protein was incomplete.

■ The result of the cross-reactivity test

The reactivity with the following nontuberculous mycobacteria was checked and an absence of crossing has been confirmed with all of them.

M.kansaii, *M.simiae*, *M.asiaticum*, *M.scrofulaceum*, *M.gordonae*, *M.avium*, *M.intracellulare*, *M.nonchromogenicum*, *M.szulgai*, *M.terrae*, *M.xenopi*, *M.ulcerans*, *M.fortuitum*, *M.chelonae*, *M.abscessus*, *M.smegmatis*, *M.vaccae*, *M.flavescens*, *M.marinum* JATA22-01, *M.marinum* 351-2, *M.marinum* 329, *M. marinum* 60

Product summary

- Measuring principle: Immunochromatography
- Validity: 12 months
- Storage: store at 2-30°C
- Detection time: 15 minutes



Marketing Approval Holder in Japan
TAUNS Laboratories, Inc.

9-12-2, Futaba-cho, Numazu, Shizuoka, 410-0005, JAPAN
[HP] <http://www.tauns.co.jp/english/contact.php>