

Certificate of Analysis for NR-43810

Mycobacterium tuberculosis, Strain KT-0025

Catalog No. NR-43810

Product Description:

Mycobacterium tuberculosis (M. tuberculosis), strain KT-0025 was isolated in 2009 from a human in South Korea. Strain KT-0025 was deposited as an extensively drug-resistant (XDR) strain, with resistance to capreomycin, isoniazid, kanamycin, moxifloxacin, ofloxacin, pyrazinamide and rifampin.

Lot: 70021313¹ Manufacturing Date: 22JAN2019

TEST	SPECIFICATIONS	RESULTS
Phenotypic Analysis ²		
Cellular morphology	Gram-positive rods	Gram-positive rods
Colony morphology ³	Report results	Irregular, low convex, undulate,
		rough and cream (Figure 1)
Growth rate	≥ 7 days	22 days
Growth at 26°C	Negative	Negative
Growth at 37°C	Positive	Positive
Acid-fast stain	Positive (red colonies)	Positive (red colonies)
Pigmentation in the dark (Scotochromogen)	Negative (no pigment)	Negative (no pigment)
Photoinduction for 1 hour (Photochromogen)	Negative (no pigment)	Negative (no pigment)
Nonchromogen (no pigment)	Positive (no pigment)	Positive (no pigment)
Biochemical tests		
Niacin production ⁴	Positive	Positive
Nitrate reduction	Positive	Positive
Pyrazinamidase	Positive	Negative ⁵
Antibiotic Susceptibility Profile		
Sensititre™ System ^{6,7}		
Amikacin	Report results	≥ 16 µg/mL
Cycloserine	Report results	32 μg/mL
Ethambutol	Report results	2 μg/mL ⁸
Ethionamide	Report results	2.5 μg/mL ⁸
Isoniazid	Report results	> 4 μg/mL
Kanamycin	Report results	> 40 µg/mL
Moxifloxacin	Report results	8 μg/mL
Ofloxacin	Report results	16 μg/mL
Para-aminosalicylic acid	Report results	1 μg/mL ⁸
Rifabutin	Report results	> 16 µg/mL ⁸
Rifampin	Report results	> 16 µg/mL
Streptomycin	Report results	0.5 μg/mL ^{8,9}
Genotypic Analysis		
Sequencing of Heat Shock Protein 65 gene	≥ 99% sequence identity to	100% sequence identity to
(~ 1620 base pairs)	M. tuberculosis, strain KT-0025	M. tuberculosis, strain KT-0025
	(GenBank: JLNO01000023.1)	(GenBank: JLNO01000023.1) ¹⁰
Purity (post-freeze)		
Middlebrook 7H10 agar with OADC enrichment ¹¹	Growth consistent with expected	Growth consistent with expected
	colony morphology	colony morphology
Tryptic Soy agar ¹²	Report results	Growth consistent with expected
		colony morphology
Viability (post-freeze) ³	Growth	Growth
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¹NR-43810 was produced by inoculation of the deposited material into Middlebrook 7H9 broth with ADC enrichment. Broth inoculum was added to Middlebrook 7H10 agar with OADC enrichment kolles, which were grown for 27 days at 37°C in an aerobic atmosphere with 5% CO₂ to produce this lot.

BEI Resources

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²Information on *Mycobacterium* testing is available from Ribón, W. "Biochemical Isolation and Identification of Mycobacteria." <u>Biochemical Testing.</u> (2012) Jose C. Jimenez-Lopez (Ed.), InTech, http://www.intechopen.com/books/biochemical-testing/biochemical-isolation-and-identification-of-mycobacteria and Lévy-Frébault, V. V. and F. Portaels. "Proposed Minimal Standards for the Genus *Mycobacterium* and for Description of New Slowly Growing *Mycobacterium* Species." <a href="https://example.com/intention-description-intentio

³22 days at 37°C in an aerobic atmosphere with 5% CO₂ on Middlebrook 7H10 agar with OADC enrichment

⁴All mycobacteria produce niacin but only *M. tuberculosis* accumulates it, resulting in a positive test for *M. tuberculosis*.

⁵A negative result may indicate a low expression of pyrazinamidase activity or a mutation to the pyrazinamidase/nicotinamidase (*pncA*) gene conferring resistance to pyrazinamidase (Sheen, P., et al. "Effect of Pyrazinamidase Activity on Pyrazinamide Resistance in *Mycobacterium tuberculosis*." <u>Tuberculosis (Edinb).</u> 89 (2009): 109-113. PubMed: 19249243.).

⁶Sensititre™ System *Mycobacterium tuberculosis* MIC Plate, Thermo Scientific™, catalog number MYCOTB

Minimum Inhibitory Concentration (MIC); No Clinical & Laboratory Standards Institute (CLSI) interpretations of the Sensititre™ System data for M. tuberculosis are currently available.

⁸For ethambutol, ethionamide, para-aminosalicylic acid, rifabutin and streptomycin, the endpoint for these drugs is determined by the well with approximately 80% inhibition of growth compared to the positive control well with no drug.

⁹Two MICs were observed for isoniazid (0.5 μg/mL and 1 μg/mL) under identical test conditions. The highest MIC is being reported as the test result. Variability in the MIC result by the Sensititre™ method has been demonstrated (Lee, J., et al. "Sensititre MYCOTB MIC Plate for Testing *Mycobacterium tuberculosis* Susceptibility to First- and Second-Line Drugs." <u>Antimicrob. Agents Chemother.</u> 58 (2014): 11-18. PubMed: 24100497.), with the results for a single antibiotic typically within one doubling dilution.

¹⁰Also consistent with *M. africanum*, *M. bovis, M. canettii, M. caprae* and *M. microti*

¹¹Purity of this lot was assessed for 33 days at 37°C in an aerobic atmosphere with 5% CO₂.

¹²Purity of this lot was assessed for 22 days at 37°C in an aerobic atmosphere with 5% CO₂.





/Heather Couch/ Heather Couch

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Program Manager or designee, ATCC Federal Solutions

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