

Certificate of Analysis for NR-48751

Mycobacterium tuberculosis, Strain 11862-0

Catalog No. NR-48751

Product Description: *Mycobacterium tuberculosis* (*M. tuberculosis*), strain 11862-0 was isolated in October 2012 from a subculture of a strain originally isolated from a patient with pulmonary tuberculosis in the Republic of South Africa. *M. tuberculosis*, strain 11862-0 was deposited as a multi-drug resistant (MDR) strain with resistance to amikacin, capreomycin, ethambutol, ethionamide, isoniazid, kanamycin, pyrazinamide, rifampin and streptomycin.

Lot¹: 63950970 Manufacturing Date: 11JAN2016

TEST	SPECIFICATIONS	RESULTS
Phenotypic Analysis ²		
Cellular morphology	Gram-positive rods	Gram-positive rods
Colony morphology ³	Report results	Irregular, raised, entire, rough and
colony morphology	T topon rooms	cream
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	1 Osluve (110 pigitietit)	1 ositive (no pigment)
Niacin production ⁴	Positive	Positive
Nitrate reduction	Positive	Positive
Pyrazinamidase	Positive	Positive
Pyrazinamidase	Positive	Positive
Antibiotic Susceptibility Profile		
Sensititre [™] System ^{5,6}		
Amikacin	Report results	> 16 μg/mL
Cycloserine	Report results	32 μg/mL
Ethambutol	Report results	8 μg/mL ⁷
Ethionamide	Report results	2.5 μg/mL ⁷
Isoniazid	Report results	> 4 µg/mL
Kanamycin	Report results	> 40 µg/mL
Moxifloxacin	Report results	0.5 μg/mL
Ofloxacin	Report results	1 μg/mL
Para-aminosalicylic acid	Report results	$\leq 0.5 \mu \text{g/mL}^7$
Rifabutin	Report results	0.5 μg/mL ⁷
Rifampin	Report results	> 16 µg/mL
Streptomycin	Report results	> 32 µg/mL ⁷
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Genotypic Analysis		1000/
Sequencing of Heat Shock Protein 65 gene	≥ 99% sequence identity to	100% sequence identity to
(~ 440 base pairs)	M. tuberculosis type strain	M. tuberculosis type strain
	(GenBank: AL123456)	(GenBank: AL123456) ⁸
Durity (post fronts)		
Purity (post-freeze)	Crowth consistent with avacated	Crowth consistent with expected
Middlebrook 7H10 agar with OADC enrichment9	Growth consistent with expected	Growth consistent with expected
To ontin Conserved	colony morphology	colony morphology
Tryptic Soy agar ⁹	Report results	No growth
Viability (post-freeze) ³	Growth	Growth

¹NR-48751 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 25 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." https://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." https://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." https://www.intechopen.com/biochemical-testing/biochemical-testing/biochemical-testing/biochemical-testing/biochemical-testing/biochemical-testing/biochemical-testing/biochemical-testing/biochemical-testing/biochemical-testing/biochemical-testing/biochemical-testing/biochemical-testing/biochemical-testing/biochemical-testing/biochemical-testing/biochemical-testing/biochemical-testing/biochemical-testing/biochemical-testing/biochemical-testing/biochemical-testin

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*.

⁵Sensititre™ System *Mycobacterium tuberculosis* MIC Plate, Thermo Scientific™, catalog number MYCOTB

⁶Minimum Inhibitory Concentration (MIC); No Clinical & Laboratory Standards Institute (CLSI) interpretations of the Sensititre™ System data for *M. tuberculosis* are currently available.

⁷For streptomycin, ethionamide, para-aminosalicylic acid, rifabutin and ethambutol, 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.

⁸Also consistent with *M. africanum*, *M. bovis*, *M. canettii*, *M. caprae* and *M. microti*

⁹Purity of this lot was assessed for 22 days at 37°C in an aerobic atmosphere with 5% CO₂.

Date: 11 JUL 2017

Signature:

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