

## Certificate of Analysis for NR-30941

## Mycobacterium tuberculosis, Strain 97-2001

## Catalog No. NR-30941

This reagent is the tangible property of the U.S. Government.

**Product Description:** *Mycobacterium tuberculosis (M. tuberculosis)*, strain 97-2001 was isolated between 1995 and 2000 from human sputum from an HIV-positive patient infected with pulmonary tuberculosis in North America.

Lot<sup>1</sup>: 70005805 Manufacturing Date: 16JUN2017

TEST	SPECIFICATIONS	RESULTS
Phenotypic Analysis <sup>2</sup>		
Cellular morphology	Gram-positive rods	Gram-positive rods
Colony morphology <sup>3</sup>	Report results	Irregular, low convex, undulate,
Colony morphology	1 topon roodile	rough and cream (Figure 1)
Growth rate	≥ 7 days	21 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	3 3 4	, ,
Niacin production <sup>4</sup>	Positive	Positive
Nitrate reduction	Positive	Positive
Pyrazinamidase	Positive	Positive
Antibiotic Susceptibility Profile		
Sensititre™ System <sup>5,6</sup>		
Amikacin	Report results	0.5 μg/mL
Cycloserine	Report results	8 µg/mL
Ethambutol	Report results	≤ 0.5 µg/mL <sup>7</sup>
Ethionamide	Report results	≤ 0.3 µg/mL <sup>7</sup>
Isoniazid	Report results	0.06 μg/mL
Kanamycin	Report results	2.5 µg/mL
Moxifloxacin	Report results	0.25 μg/mL
Ofloxacin	Report results	0.5 µg/mL
Para-aminosalicylic acid	Report results	≤ 0.5 µg/mL <sup>7</sup>
Rifabutin	Report results	$\leq 0.12  \mu \text{g/mL}^7$
Rifampin	Report results	≤ 0.12 µg/mL
Streptomycin	Report results	$\leq 0.25  \mu \text{g/mL}^7$
Genotypic Analysis		
Sequencing of Heat Shock Protein 65 gene	≥ 99% sequence identity to	100% sequence identity to
(~ 410 base pairs)	M. tuberculosis type strain	M. tuberculosis type strain
( Tro bass pane)	(GenBank: AL123456)	(GenBank: AL123456) <sup>8</sup>
Divitir (next frage)	,	,
Purity (post-freeze)	Crowth consistent with over seter	Crouth consistant with over seted
Middlebrook 7H10 agar with OADC enrichment9	Growth consistent with expected	Growth consistent with expected
Tryptic Soy agar <sup>10</sup>	colony morphology Report results	colony morphology Growth consistent with expected
Tryphic Suy agai	Vehou ieania	colony morphology
		Colorly Morphology
Viability (post-freeze) <sup>3</sup>	Growth	Growth
1ND 20044 was made and by inscribition of the democited made		wishes out. Dueth is a sulves was a dated to

<sup>&</sup>lt;sup>1</sup>NR-30941 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 21 days at 37°C in an aerobic atmosphere with 5% CO<sub>2</sub> to produce this lot.

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<sup>2</sup>Information 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, <a href="http://www.intechopen.com/books/biochemical-testing/biochemical-isolation-and-identification-of-mycobacteria">http://www.intechopen.com/books/biochemical-testing/biochemical-isolation-and-identification-of-mycobacteria</a> and Lévy-Frébault, V. V. and F. Portaels. "Proposed Minimal Standards for the Genus *Mycobacterium* and for Description of New Slowly Growing *Mycobacterium* Species." Int. J. Syst. Bacteriol. 42 (1992): 315-323. PubMed: 1581193.

<sup>3</sup>21 days at 37°C in an aerobic atmosphere with 5% CO<sub>2</sub> on Middlebrook 7H10 agar with OADC enrichment

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

<sup>5</sup>Sensititre™ System *Mycobacterium tuberculosis* MIC Plate, Thermo Scientific™, catalog number MYCOTB

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

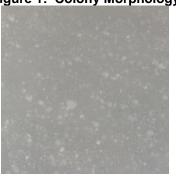
<sup>7</sup>For streptomycin, ethionamide, para-aminosalicylic acid, rifabutin and ethambutol, the endpoint for these drugs is determined by the well with approximately 80% inhibition of growth compared to the positive control well with no drug.

<sup>8</sup>Also consistent with M. africanum, M. bovis, M. canettii, M. caprae and M. microti

<sup>9</sup>Purity of this lot was assessed for 50 days at 37°C in an aerobic atmosphere with 5% CO<sub>2</sub>.

<sup>10</sup>Purity of this lot was assessed for 21 days at 37°C in an aerobic atmosphere with 5% CO<sub>2</sub>.





/Heather Couch/ Heather Couch

10 DEC 2018

Program Manager or designee, ATCC Federal Solutions

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