

## Certificate of Analysis for NR-48752

## Mycobacterium tuberculosis, Strain 11863-0

## Catalog No. NR-48752

**Product Description:** *Mycobacterium tuberculosis* (*M. tuberculosis*), strain 11863-0 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 11863-0 was deposited as a multi-drug resistant (MDR) strain with resistance to isoniazid, rifampin, pyrazinamide, ethambutol, streptomycin, kanamycin, ethionamide, capreomycin and amikacin.

Lot<sup>1</sup>: 63950973 Manufacturing Date: 11JAN2016

TEST	SPECIFICATIONS	RESULTS
Phenotypic Analysis <sup>2</sup> Cellular morphology Colony morphology <sup>3</sup> Growth rate Growth at 26°C Growth at 37°C Acid-fast stain	Gram-positive rods Report results  ≥ 7 days Negative Positive Positive (red colonies)	Gram-positive rods Irregular, raised, entire, rough and cream (Figure 1) 22 days Negative Positive Positive (red colonies)
Pigmentation in the dark (Scotochromogen) Photoinduction for 1 hour (Photochromogen) Nonchromogen (no pigment) Biochemical tests Niacin production <sup>4</sup> Nitrate reduction Pyrazinamidase	Negative (no pigment) Negative (no pigment) Positive (no pigment)  Positive Positive Positive	Negative (no pigment) Negative (no pigment) Positive (no pigment)  Positive Positive Positive
Antibiotic Susceptibility Profile  Sensititre <sup>TM</sup> System <sup>5,6</sup> Amikacin Cycloserine Ethambutol Ethionamide Isoniazid Kanamycin Moxifloxacin Ofloxacin Para-aminosalicylic acid Rifabutin Rifampin Streptomycin	Report results	> 16 µg/mL 32 µg/mL 8 µg/mL <sup>7</sup> 5 µg/mL <sup>7</sup> > 4 µg/mL > 40 µg/mL 0.5 µg/mL 1 µg/mL 1 µg/mL <sup>7</sup> 1 µg/mL <sup>7</sup> > 16 µg/mL > 32 µg/mL <sup>7</sup>
Genotypic Analysis Sequencing of Heat Shock Protein 65 gene (~ 430 base pairs)	≥ 99% sequence identity to <i>M. tuberculosis</i> type strain (GenBank: AL123456)	100% sequence identity to  M. tuberculosis type strain (GenBank: AL123456)8
Purity (post-freeze) Middlebrook 7H10 agar with OADC enrichment <sup>9</sup> Tryptic Soy agar <sup>9</sup>	Growth consistent with expected colony morphology Report results	Growth consistent with expected colony morphology No growth
Viability (post-freeze) <sup>3</sup>	Growth	Growth

<sup>&</sup>lt;sup>1</sup>NR-48752 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% 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." <a href="https://example.com/intended-com/inten

<sup>3</sup>22 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

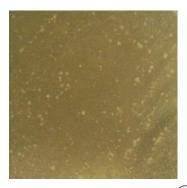
<sup>6</sup>Minimum Inhibitory Concentration (MIC); No Clinical & Laboratory Standards Institute (CLSI) interpretations of the Sensititre<sup>™</sup> System data for *M. tuberculosis* are currently available.

<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 22 days at 37°C in an aerobic atmosphere with 5% CO<sub>2</sub>.

Figure 1: Colony Morphology



Date: 14 JUN 2017 Signature:

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