

***Mycobacterium tuberculosis*, Strain 11176-1**

**Catalog No. NR-49949**

**Product Description:** *Mycobacterium tuberculosis* (*M. tuberculosis*), strain 11176-1 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 11176-1 was deposited as a multidrug-resistant (MDR) strain with resistance to amikacin, capreomycin, ethambutol, isoniazid, kanamycin, rifampin and streptomycin.

**Lot<sup>1</sup>: 63950998**

**Manufacturing Date: 15JAN2016**

TEST	SPECIFICATIONS	RESULTS
<b>Phenotypic Analysis<sup>2</sup></b> Cellular morphology Colony morphology <sup>3</sup>  Growth rate Growth at 26°C Growth at 37°C Acid-fast stain Pigmentation in the dark (Scotochromogen) Photoinduction for 1 hour (Photochromogen) Nonchromogen (no pigment) Biochemical tests Niacin production <sup>4</sup> Nitrate reduction Pyrazinamidase	Gram-positive rods Report results  ≥ 7 days Negative Positive Positive (red colonies) Negative (no pigment) Negative (no pigment) Positive (no pigment)  Positive Positive Positive	Gram-positive rods Irregular, slight peaked, undulate, rough and cream (Figure 1) 21 days Negative Positive Positive (red colonies) Negative (no pigment) Negative (no pigment) Positive (no pigment)  Positive Positive Negative <sup>5</sup>
<b>Antibiotic Susceptibility Profile</b> Sensititre™ System <sup>6,7</sup> Amikacin Cycloserine Ethambutol Ethionamide Isoniazid Kanamycin Moxifloxacin Ofloxacin Para-aminosalicylic acid Rifabutin Rifampin Streptomycin	Report results Report results Report results Report results Report results Report results Report results Report results Report results Report results Report results Report results Report results	> 16 µg/mL 8 µg/mL 4 µg/mL <sup>8</sup> 2.5 µg/mL <sup>8</sup> > 4 µg/mL > 40 µg/mL 0.25 µg/mL 0.5 µg/mL ≤ 0.5 µg/mL <sup>8</sup> 0.5 µg/mL <sup>8</sup> 8 µg/mL 16 µg/mL <sup>8</sup>
<b>Genotypic Analysis</b> 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 <i>M. tuberculosis</i> type strain (GenBank: AL123456) <sup>9</sup>
<b>Purity (post-freeze)</b> Middlebrook 7H10 agar with OADC enrichment <sup>10</sup>  Tryptic Soy agar <sup>11</sup>	Growth consistent with expected colony morphology Report results	Growth consistent with expected colony morphology Growth consistent with expected colony morphology
<b>Viability (post-freeze)<sup>3</sup></b>	Growth	Growth

<sup>1</sup>NR-49949 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 28 days at 37°C in an aerobic atmosphere with 5% CO<sub>2</sub> to produce this lot.

<sup>2</sup>Information on Mycobacterium testing is available from Ribón, W. "Biochemical Isolation and Identification of Mycobacteria." *Biochemical Testing*, (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." *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>A 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*." *Tuberculosis (Edinb)*, 89 (2009): 109-113. PubMed: 19249243.).

<sup>6</sup>Sensititre™ System *Mycobacterium tuberculosis* MIC Plate, Thermo Scientific™, catalog number MYCOTB

<sup>7</sup>Minimum Inhibitory Concentration (MIC); No Clinical & Laboratory Standards Institute (CLSI) interpretations of the Sensititre™ System data for *M. tuberculosis* are currently available.

<sup>8</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>9</sup>Also consistent with *M. africanum*, *M. bovis*, *M. canettii*, *M. caprae* and *M. microti*

<sup>10</sup>Purity of this lot was assessed for 50 days at 37°C in an aerobic atmosphere with 5% CO<sub>2</sub>.

<sup>11</sup>Purity of this lot was assessed for 21 days at 37°C in an aerobic atmosphere with 5% CO<sub>2</sub>.

Figure 1: Colony Morphology



Date: 12 OCT 2017

Signature:

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