

## Certificate of Analysis for NR-48739

## Mycobacterium tuberculosis, Strain 11102-0

## Catalog No. NR-48739

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**Product Description:** *Mycobacterium tuberculosis* (*M. tuberculosis*), strain 11102-0 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 11102-0 was deposited as a multidrug-resistant (MDR) strain with resistance to amikacin, ethambutol, ethionamide, isoniazid, kanamycin, pyrazinamide, rifampin and streptomycin.

Lot<sup>1</sup>: 63950952 Manufacturing Date: 05JAN2016

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 Pigmentation in the dark (Scotochromogen) Photoinduction for 1 hour (Photochromogen) Nonchromogen (no pigment) Biochemical tests Niacin production <sup>4</sup> Nitrate reduction	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) 30 days Negative Positive Positive (red colonies) Negative (no pigment) Negative (no pigment) Positive (no pigment) Positive Positive Positive
Pyrazinamidase	Positive	Positive
Antibiotic Susceptibility Profile  Sensititre™ 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 <sup>7,8</sup> 32 µg/mL <sup>8,9,10</sup> 5 µg/mL <sup>9</sup> > 4 µg/mL > 40 µg/mL 1 µg/mL 1 µg/mL 4 µg/mL <sup>8,9,11</sup> 4 µg/mL <sup>9</sup> > 16 µg/mL > 32 µg/mL <sup>9</sup>
Genotypic Analysis Sequencing of Heat Shock Protein 65 gene (330 base pairs)	≥ 99% sequence identity to <i>M. tuberculosis</i> type strain (GenBank: AL123456)	100% sequence identity to  M. tuberculosis type strain (GenBank: AL123456) <sup>12</sup>
Purity (post-freeze) Middlebrook 7H10 agar with OADC enrichment <sup>13</sup> Tryptic Soy agar <sup>14</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-48739 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 22 days at 37°C in an aerobic atmosphere with 5% CO<sub>2</sub> to produce this lot.

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<sup>&</sup>lt;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-the-">http://www.intechopen.com/books/biochemical-testing/biochemical-isolation-and-identification-of-the-">http://www.intechopen.com/books/biochemical-testing/biochemical-isolation-and-identification-of-the-">http://www.intechopen.com/books/biochemical-testing/biochemical-isolation-and-identification-of-the-">http://www.intechopen.com/books/biochemical-testing/biochemical-isolation-and-identification-of-the-">http://www.intechopen.com/books/biochemical-testing/biochemical-isolation-and-identification-of-the-">http://www.intechopen.com/books/biochemical-testing/biochemical-isolation-and-identification-of-the-">http://www.intechopen.com/books/biochemical-testing/biochemical-isolation-and-identification-of-the-">http://www.intechopen.com/books/biochemical-testing/biochemical-isolation-and-identification-of-the-">http://www.intechopen.com/books/biochemical-testing/biochemical-isolation-and-identification-of-the-">http://www.intechopen.com/books/biochemical-testing/biochemical-isolation-and-identification-of-the-">http://www.intechopen.com/books/biochemical-testing/biochemical-isolation-and-identification-of-the-">http://www.intechopen.com/books/biochemical-testing/biochemical-isolation-and-identification-of-the-">http://www.intechopen.com/books/biochemical-testing/biochemical-isolation-and-identification-of-the-">http://www.intechopen.com/books/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/bi



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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>30 days at 37°C in an aerobic atmosphere with 5% CO₂ 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 tuberculosi*s 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>Two MICs were observed for cycloserine (16 μg/mL and 32 μg/mL) under identical test conditions. The highest MIC is being reported as the test result.

<sup>8</sup>Variability in the MIC result by the Sensititre<sup>™</sup> 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.

<sup>9</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.

10Two MICs were observed for ethambutol (16 μg/mL and 32 μg/mL) under identical test conditions. The highest MIC is being reported as the test result.

11Two MICs were observed for para-aminosalicylic (2 μg/mL and 4 μg/mL) under identical test conditions. The highest MIC is being reported as the test result.

<sup>12</sup>Also consistent with M. africanum, M. bovis, M. canettii, M. caprae and M. microti

<sup>13</sup>Purity of this lot was assessed for 55 days at 37°C in an aerobic atmosphere with 5% CO<sub>2</sub>.

<sup>14</sup>Purity of this lot was assessed for 30 days at 37°C in an aerobic atmosphere with 5% CO<sub>2</sub>.





/Heather Couch/ Heather Couch

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Program Manager or designee, ATCC Federal Solutions

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