

# Certificate of Analysis for NR-43817

### Mycobacterium tuberculosis, Strain KT-0032

#### Catalog No. NR-43817

#### **Product Description:**

Mycobacterium tuberculosis (M. tuberculosis), strain KT-0032 was isolated in 2009 from a human in South Korea. Strain KT-0032 was deposited as an extensively drug-resistant (XDR) Beijing genotype strain with resistance to isoniazid, moxifloxacin, ofloxacin, pyrazinamide, rifampin and streptomycin.

Lot: 70021325<sup>1</sup> Manufacturing Date: 27FEB2019

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, 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	, ,	, , ,
Niacin production <sup>4</sup>	Positive	Positive
Nitrate reduction	Positive	Positive
Antibiotic Susceptibility Profile		
Sensititre™ System <sup>5,6</sup>		
Amikacin	Report results	0.5 μg/mL
Cycloserine	Report results	64 μg/mL <sup>7,8</sup>
Ethambutol	Report results	4 μg/mL <sup>9</sup>
Ethionamide	Report results	20 µg/mL <sup>8,9,10</sup>
Isoniazid	Report results	1 μg/mL <sup>8,11</sup>
Kanamycin	Report results	1.2 µg/mL
Moxifloxacin	Report results	4 μg/mL
Ofloxacin	Report results	16 μg/mL
Para-aminosalicylic acid	Report results	1 μg/mL <sup>9</sup>
Rifabutin	Report results	8 μg/mL <sup>8,9,12</sup>
Rifampin	Report results	> 16 µg/mL
Streptomycin	Report results	> 32 µg/mL <sup>9</sup>
Genotypic Analysis	·	
Sequencing of Heat Shock Protein 65 gene	≥ 99% sequence identity to	100% sequence identity to
(1620 base pairs)	<ul><li>M. tuberculosis, strain KT-0032</li><li>(GenBank: JLNL0100004.1)</li></ul>	M. tuberculosis, strain KT-0032 (GenBank: JLNL01000023.1) <sup>13</sup>
Purity (post-freeze)		
Middlebrook 7H10 agar with OADC enrichment <sup>14</sup>	Growth consistent with expected colony morphology	Growth consistent with expected colony morphology
Tryptic Soy agar <sup>15</sup>	Report results	Growth consistent with expected colony morphology
Viability (post-freeze) <sup>3</sup>	Growth	Growth
lability (poot-illocto)	0.000	Cional

NR-43817 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>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/intention-description-intentio

<sup>3</sup>21 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 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>Two MICs were observed for cycloserine (32 μg/mL and 64 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 ethambutol, ethionamide, para-aminosalicylic acid, rifabutin and streptomycin, 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>10</sup>Two MICs were observed for ethionamide (10 μg/mL and 20 μg/mL) under identical test conditions. The highest MIC is being reported as the test result

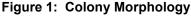
<sup>11</sup>Two MICs were observed for isoniazid (0.5 µg/mL and 1 µg/mL) under identical test conditions. The highest MIC is being reported as the test result.

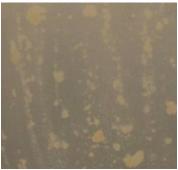
12Two MICs were observed for rifabutin (4 μg/mL and 8 μg/mL) under identical test conditions. The highest MIC is being reported as the test result.

<sup>13</sup>Also consistent with *M. africanum*, *M. bovis*, *M. canettii*, *M. caprae* and *M. microti* 

<sup>14</sup>Purity of this lot was assessed for 70 days at 37°C in an aerobic atmosphere with 5% CO<sub>2</sub>.

<sup>15</sup>Purity of this lot was assessed for 21 days at 37°C in an aerobic atmosphere with 5% CO<sub>2</sub>.





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Program Manager or designee, ATCC Federal Solutions

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