

Certificate of Analysis for NR-43814

Mycobacterium tuberculosis, Strain KT-0029

Catalog No. NR-43814

Product Description:

Mycobacterium tuberculosis (M. tuberculosis), strain KT-0029 was isolated in 2010 from a human in South Korea. Strain KT-0029 was deposited as an extensively drug-resistant (XDR) Beijing genotype strain with resistance to isoniazid, moxifloxacin, ofloxacin, pyrazinamide and rifampin.

Lot: 70021320¹ Manufacturing Date: 19FEB2019

TEST	SPECIFICATIONS	RESULTS
Phenotypic Analysis ²		
Cellular morphology	Gram-positive rods	Gram-positive rods
Colony morphology ³	Report results	Irregular, low convex, undulate, rough and cream (Figure 1)
Growth rate	≥ 7 days	7 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 ⁴	Positive	Positive
Nitrate reduction	Positive	Positive
Antibiotic Susceptibility Profile		
Sensititre™ System ^{5,6}		
Amikacin	Report results	0.25 μg/mL
Cycloserine	Report results	64 μg/mL ^{7,8}
Ethambutol	Report results	4 μg/mL ⁸⁻¹⁰
Ethionamide	Report results	2.5 µg/mL ⁹
Isoniazid	Report results	4 µg/mL ^{8,11}
Kanamycin	Report results	5 μg/mL ^{8,12}
Moxifloxacin	Report results	2 µg/mL
Ofloxacin	Report results	8 µg/mL
Para-aminosalicylic acid	Report results	≤ 0.5 µg/mL ⁹
Rifabutin	Report results	≤ 0.12 µg/mL ⁹
Rifampin	Report results	> 16 µg/mL
Streptomycin	Report results	≤ 0.25 µg/mL ⁹
Genotypic Analysis		
Sequencing of Heat Shock Protein 65 gene	≥ 99% sequence identity to	100% sequence identity to
(~ 1620 base pairs)	M. tuberculosis, strain KT-0029 (GenBank: JLNN01000005.1)	M. tuberculosis, strain KT-0029 (GenBank: JLNN01000005.1) ¹³
Purity (post-freeze)	(Schbank, Schroops, 1)	(COMBAIN: OLIVIVO 1000005.1)
Middlebrook 7H10 agar with OADC enrichment ¹⁴	Growth consistent with expected	Growth consistent with expected
Wild Colook 71110 agai with OADO elillollillellt	colony morphology	colony morphology
Tryptic Soy agar ¹⁵	Report results	Growth consistent with expected
Trypho 50, agai	1 toport roouto	colony morphology
Viability (post-freeze) ³	Growth	Growth
IND 42044 was medical by inscribition of the democited as	Acriclista Middlehmadt 7110 haath with ADC as	GIOWIII

¹NR-43814 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% CO₂ to produce this lot

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²Information 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, 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



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Slowly Growing Mycobacterium Species." Int. J. Syst. Bacteriol. 42 (1992): 315-323. PubMed: 1581193.

³22 days at 37°C in an aerobic atmosphere with 5% CO₂ on Middlebrook 7H10 agar with OADC enrichment

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

⁵Sensititre™ System *Mycobacterium tuberculosis* MIC Plate, Thermo Scientific™, catalog number MYCOTB

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

⁷Two MICs were observed for cycloserine (64 μg/mL and 32 μg/mL) under identical test conditions. The highest MIC is being reported as the test result.

⁸Variability in the MIC result by the Sensititre™ method has been demonstrated (Lee, J., et al. "Sensititre MYCOTB MIC Plate for Testing Mycobacterium tuberculosis Susceptibility to First- and Second-Line Drugs." Antimicrob. 11-18. PubMed: 24100497.), with the results for a single antibiotic typically within one doubling dilution.

⁹For 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.

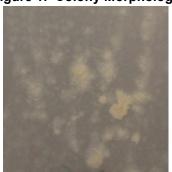
10 Two MICs were observed for ethambutol (2 μg/mL and 4 μg/mL) under identical test conditions. The highest MIC is being reported as the test result. 11Two MICs were observed for isoniazid (2 μg/mL and 4 μg/mL) under identical test conditions. The highest MIC is being reported as the test result.

12Two MICs were observed for kanamycin (2.5 μg/mL and 5 μg/mL) under identical test conditions. The highest MIC is being reported as the test

¹³Also consistent with M. africanum, M. bovis, M. canettii, M. caprae and M. microti

¹⁴Purity of this lot was assessed for 72 days at 37°C in an aerobic atmosphere with 5% CO₂. ¹⁵Purity of this lot was assessed for 22 days at 37°C in an aerobic atmosphere with 5% CO₂.





/Heather Couch/ **Heather Couch**

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Program Manager or designee, ATCC Federal Solutions

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