

Certificate of Analysis for NR-30900

Mycobacterium tuberculosis, Strain 98-3137

Catalog No. NR-30900

This reagent is the tangible property of the U.S. Government.

Product Description: *Mycobacterium tuberculosis (M. tuberculosis)*, strain 98-3137 was isolated between 1995 and 2000 from human sputum from an HIV-negative patient infected with pulmonary tuberculosis in North America.

Lot¹: 70004562 Manufacturing Date: 01JUN2017

| TEST | SPECIFICATIONS | RESULTS |
|--|-------------------------------------|---|
| Phenotypic Analysis ² | | |
| Cellular morphology | Gram-positive rods | Gram-positive rods |
| Colony morphology ³ | Report results | Irregular, slight peaked, undulate, |
| 3 3 3 7 3 3 3 7 | | 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 ⁴ | Positive | Positive |
| Nitrate reduction | Positive | Positive |
| Pyrazinamidase | Positive | Positive |
| Antibiotic Susceptibility Profile | | |
| Sensititre™ System ^{5,6} | | |
| Amikacin | Report results | 0.25 μg/mL |
| Cycloserine | Report results | 16 μg/mL ^{7,8} |
| Ethambutol | Report results | 2 μg/mL ⁹ |
| Ethionamide | Report results | 1.2 µg/mL ⁹ |
| Isoniazid | Report results | 0.06 μg/mL |
| Kanamycin | Report results | 2.5 μg/mL |
| Moxifloxacin | Report results | 0.25 μg/mL |
| Ofloxacin | Report results | 1 μg/mL ^{8,10} |
| Para-aminosalicylic acid | Report results | 2 μg/mL ⁹ |
| Rifabutin | Report results | ≤ 0.12 µg/mL ⁹ |
| Rifampin | Report results | 0.25 μg/mL |
| Streptomycin | Report results | 0.5 μg/mL ^{8,9,11} |
| Genotypic Analysis | | |
| Sequencing of Heat Shock Protein 65 gene | ≥ 99% sequence identity to | 100% sequence identity to |
| (~ 410 base pairs) | M. tuberculosis type strain | M. tuberculosis type strain |
| (110 5000 pano) | (GenBank: AL123456) | (GenBank: AL123456) ¹² |
| Divitor (no act fra acta) | (| (551125111111112120100) |
| Purity (post-freeze) | Crowth consistent with over a start | Growth consistent with expected |
| Middlebrook 7H10 agar with OADC enrichment ¹³ | Growth consistent with expected | Growth consistent with expected colony morphology |
| Truntia Say agar14 | colony morphology | Growth consistent with expected |
| Tryptic Soy agar ¹⁴ | Report results | colony morphology |
| | | Colorly morphology |
| Viability (post-freeze) ³ | Growth | Growth |
| | | |

¹NR-30900 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.

BEI Resources

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²Information on Mycobacterium testing is available from Ribón, W. "Biochemical Isolation and Identification of Mycobacteria." <u>Biochemical Testing.</u>



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(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." https://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." https://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." <a href="https://www.intechopen.com/biochemical-testing/bi

³21 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 (8 μg/mL and 16 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. Agents Chemother. 58 (2014): 11-18. PubMed: 24100497), with the results for a single antibiotic typically within one doubling dilution.

⁹For 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.

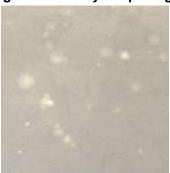
¹⁰Two MICs were observed for ofloxacin (0.5 μg/mL and 1 μg/mL) under identical test conditions. The highest MIC is being reported as the test result.
¹¹Two MICs were observed for streptomycin (≤ 0.25 μg/mL and 0.5 μg/mL) under identical test conditions. The highest MIC is being reported as the test result.

¹²Also consistent with M. africanum, M. bovis, M. canettii, M. caprae and M. microti

¹³Purity of this lot was assessed for 39 days at 37°C in an aerobic atmosphere with 5% CO₂.

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/Heather Couch/ Heather Couch

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Program Manager or designee, ATCC Federal Solutions

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