

***Mycobacterium tuberculosis*, Strain 11862-1**

Catalog No. NR-49950

Product Description: *Mycobacterium tuberculosis* (*M. tuberculosis*), strain 11862-1 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 11862-1 was deposited as a multidrug-resistant (MDR) strain with resistance to amikacin, capreomycin, ethambutol, ethionamide, isoniazid, kanamycin, rifampin and streptomycin.

Lot¹: 63951001

Manufacturing Date: 15JAN2016

| TEST | SPECIFICATIONS | RESULTS |
|---|--|--|
| Phenotypic Analysis² Cellular morphology Colony morphology ³ 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 ⁴ 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 Negative⁵ |
| Antibiotic Susceptibility Profile Sensititre™ System ^{6,7} 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 32 µg/mL 8 µg/mL ⁸ 2.5 µg/mL ⁸ > 4 µg/mL 40 µg/mL 0.25 µg/mL 0.5 µg/mL ≤ 0.5 µg/mL ⁸ 0.5 µg/mL ⁸ 16 µg/mL 32 µg/mL ⁸ |
| Genotypic Analysis 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) ⁹ |
| Purity (post-freeze) Middlebrook 7H10 agar with OADC enrichment ¹⁰ Tryptic Soy agar ¹¹ | Growth consistent with expected colony morphology Report results | Growth consistent with expected colony morphology Growth consistent with expected colony morphology |
| Viability (post-freeze)³ | Growth | Growth |

¹NR-49950 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% CO₂ to produce this lot.

²Information 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.

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*.

⁵A 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.).

⁶Sensititre™ System *Mycobacterium tuberculosis* MIC Plate, Thermo Scientific™, catalog number MYCOTB

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

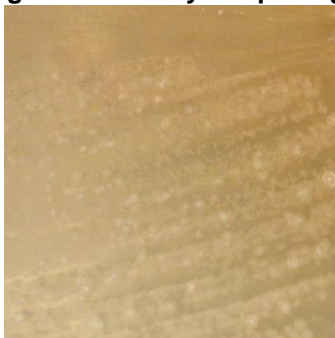
⁸For streptomycin, ethionamide, para-aminosalicylic acid, rifabutin and ethambutol, the endpoint for these drugs is determined by the well with approximately 80% inhibition of growth compared to the positive control well with no drug.

⁹Also consistent with *M. africanum*, *M. bovis*, *M. canettii*, *M. caprae* and *M. microti*

¹⁰Purity of this lot was assessed for 50 days at 37°C in an aerobic atmosphere with 5% CO₂.

¹¹Purity of this lot was assessed for 21 days at 37°C in an aerobic atmosphere with 5% CO₂.

Figure 1: Colony Morphology



Date: 15 SEP 2017

Signature:

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