

COUNTY OF SAN LUIS OBISPO PUBLIC HEALTH LABORATORY

Phone: (805) 781-5507 | Fax: (805) 781-1023

www.sloPublicHealth.org/Lab

LABORATORY TEST FACT SHEET

TEST: MALDI-TOF Mass Spectrometry ORDER CODES: 2460, 3660, 3950, 3960

TEST DESCRIPTION

The Bruker MALDI Biotyper is an instrument that uses matrix-assisted laser desorption/ionization-time of flight (MALDI-TOF) mass spectrometry (MS) to identify microorganisms from human specimens. MALDI-TOF MS technology analyzes the proteins, mainly ribosomal proteins, of a microorganism. The instrument converts the microorganism's proteins into a protein profile or fingerprint, termed mass spectrum. This protein profile is compared to the protein profiles of microorganisms in a reference library or database. An overall score is generated that signifies how closely the microorganism matches the protein profile of another microorganism in the database. The identity of the microorganism is confirmed when a close match is found. The Bruker MALDI Biotyper can be used to identify bacteria, mycobacteria, yeasts, and molds.

SENSITIVITY AND SPECIFICITY

The sensitivity and specificity of MALDI-TOF MS is related to the breadth of the library or database that serves as a comparator and varies for different classes of microorganisms. A review article indicated that the specificity for the MALDI-TOF MS ranges from 87.3% to 100% for genus level identification of clinical isolates. In addition, the detection limit is estimated to be 10⁴ to 10⁵ colony forming units for *Escherichia coli* (Hou et al. *Journal of Food and Drug Analysis* 2019).

For mycobacteria species, a validation study was performed to evaluate the Bruker MALDI Biotyper MBT Mycobacteria library. The overall sensitivity and specificity were found to be 99% (220/223) and 100% (109/109), respectively, when evaluating mass spectra from panels of mycobacteria, bacteria, and yeast. Separate validation studies were also performed for molds using the Bruker MALDI Biotyper MBT Filamentous Fungi library. The overall sensitivity when evaluating mold panels alone was found to be 100% (26/26), with a specificity of 100% (21/21).

LIMITATIONS

- Direct testing of patient specimens is not possible. Microorganisms must be isolated prior to testing.
- A microorganism will not be identified if the reference library or database does not include the genus and/or species.
- Some microorganisms can only be identified to the genus or systematic group level.
 - o In such cases, additional methods may be needed for final microorganism identification.
- This technology is not currently recommended to identify select agents, such as Bacillus anthracis.
- Taxonomy (name of microorganism) may reflect old nomenclature.
- Final results should be based on all relevant information, including specimen type, staining, colony morphology, growth characteristics, etc.

SPECIMENS ACCEPTED FOR TESTING

- 1. Two types of specimens will be accepted:
 - a. Patient specimens submitted for bacterial, mycobacterial, and fungal culture will be eligible for testing once a microorganism has been isolated from the specimen

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b. Bacterial, mycobacterial, and yeast isolates sent by the submitter

STORAGE AND TRANSPORT TEMPERATURE

Storage and transport should follow the requirements specific to the microorganism being cultured or identified.

CPT CODES

Bacterial identification: 87077Mycobacterial identification: 87118

Yeast identification: 87106Mold identification: 87107