NEW YORK STATE | Department of Health | Wadsworth Center

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Guidelines For Submission of Validation Packages for Approval of MALDI-TOF Mass Spectrometry (MALDI-TOF MS) For Bacterial, Yeast and Mold Identification

These guidelines should be used in conjunction with and not in lieu of the existing microbiology molecular guidelines:
http://www.wadsworth.org/labcert/TestApproval/forms/Microbiology_NAAT_Checklist.pdf

General Guidance:

- Submit a detailed SOPM including all relevant quality assurance and proficiency testing details for this test. The SOPM must include appropriate controls including a negative and positive control, a testing algorithm, and all expected reporting and reflex testing scenarios. Specimen reports for each scenario must be included.

- If any alterations from the manufacturer's instructions or reporting guidelines (including acceptable score) are instituted, submission of additional validation data supporting this change would be required.

- All extraction methods that will be used in the laboratory must be included in the validation. At least 30 isolates for each extraction method must be included as part of the total number of representative isolates required in the validation.

- If lab-developed or acquired databases will be used in addition to the library databases provided by the manufacturer, submit the criteria for isolate selection (how isolates will be selected for library addition), confirmation method (how the organism was identified), spectral quality and number of spectra required for library creation.

For Blood Cultures:
The validation submission should include:

- For validation of bacterial identification from blood cultures, include data from at least 100 positive blood culture specimens. These positives should include at least 10 of the major bacterial species typically identified in blood culture specimens in the laboratory. For yeast identification, validation must include data from at least 50 positive blood culture specimens. These positives should include at least 5 of the major yeast species typically identified in blood culture specimens in the laboratory. In addition, 5 negative blood culture specimens

must be included in the validation study. A table of these results must include comparison identification information, identification score from MALDI-TOF MS, and final reporting information.

- The sample validation should utilize authentic clinical specimens. However, if the laboratory cannot acquire an adequate number of positive blood culture specimens within one month, then spiked specimens are acceptable to supplement the validation data. Minimum numbers apply as above for bacterial and yeast identifications. Please note that whole blood should be spiked with low numbers of yeast or bacterial agents before inoculating blood cultures. Blood cultures should include some representative samples with a high white blood cell count.

- Reproducibility studies must be performed. For inter-assay reproducibility, at least 3 authentic clinical samples or spiked clinical samples should be run on three different days. For intra-assay reproducibility at least 3 authentic clinical samples or spiked clinical samples should be run in triplicate.

For Bacterial, Yeast and Mold Isolates:

- Validation must include data from at least 200 representative bacterial isolates, 100 mold isolates or 50 yeast isolates including the most common species isolated from different sources in the laboratory. At least 30 isolates for each extraction method must be included as part of the total number of representative isolates. No negatives are required. A table of these results must include comparison identification information, identification score from MALDI-TOF MS, and final reporting information.

- Reproducibility studies must be performed. For inter-assay reproducibility, at least 3 clinical isolates should be run on three different days. For intra-assay reproducibility at least 3 clinical isolates should be run in triplicate.