Technical Bulletin

UPDATE: Rapid Preliminary Identification from Positive Blood Culture Bottles

TO: Medical Staff and Clients

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SUBJECT: Preliminary bacterial identifications from blood culture by MALDI-TOF/MS is now FDA cleared

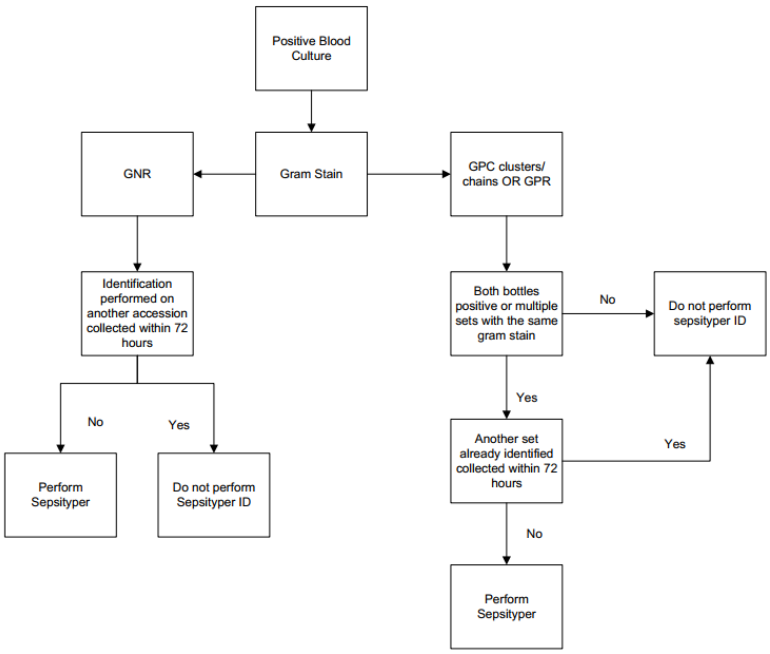
UPDATE: This test has been cleared by the U.S. Food and Drug.
DLS has been utilizing MALDI-TOF/MS Sepsityper for the preliminary identification of common bacteria directly from the positive blood culture bottles since 2020 and is pleased to announce a change in the regulatory status to IVD by FDA.

Detection of microbial pathogens in the blood of sick patients is one of the most critical services a clinical microbiology laboratory provides. Modern instrumentation can detect microbial growth quickly in true bacteremia, often less than 24 hours. The Gram stain provides the earliest information as to the etiology, however further identification relies upon isolation on solid media followed by matrix-assisted laser desorption ionization – time of flight / mass spectrometry (MALDI-TOF/MS). This normally requires overnight incubation.

Direct identification from the positive blood culture bottle will only be attempted when the Gram stain shows one organism morphology, as MALDI-TOF/MS cannot identify bacteria in polymicrobic cultures. For Gram positives, two or more positive bottles with the same Gram stain morphology are required to continue with a rapid identification.

These will always be preliminary identifications and will include the statement, “presumptive”.

The test should be used for clinical purposes with caution, and the results are not intended to be used as the sole means for diagnostic or patient management decisions.



Please refer any questions to Tori Enomoto, Manager - DLS Microbiology Laboratory at 441-5470, or DLS Client Services at 589-5101.