

US-IVD

NEW • FDA-Cleared



When Every Minute Counts

MBT Sepsityper[®] Kit US IVD

- For Rapid Microorganism Identification Direct from Positive Blood Culture Using the MALDI Biotyper[®] CA System

Innovation with Integrity

MALDI-TOF

Engaging in the War Against Sepsis



It is crucial for the clinical microbiology laboratory to provide a rapid microorganism identification direct from positive blood culture due to the high mortality and morbidity rates associated with sepsis.

Early recognition, timely treatment, and reassessment of antibiotic therapy are critical actions necessary to improve outcomes for patients affected by sepsis.

Using the Sepsityper identification workflow reduces the turnaround time provided by traditional positive blood culture identification workflows by up to 48 hours, which will have a direct impact on patient outcomes.

MBT Sepsityper[®] Kit US IVD

The FDA-cleared MBT Sepsityper Kit US IVD is used in conjunction with the Bruker MALDI Biotyper CA System, allowing highly confident species level identification (ID) direct from positive blood culture (PBC). A rapid, accurate and cost-effective microorganism ID becomes available within 15-20 minutes after the blood culture alerts positive and requires only 10 minutes of hands-on-time to prepare the sample. When compared to traditional methods, ID results can be reported significantly quicker to critical care providers.



Key Features

Rapid Identification

- Less than 10 minutes hands-on-time eliminating the need for batching
- 15 -20 minutes overall identification time
- Complete identification in the same amount of time as Gram stain result



Dr. Elisabeth C. Shearon, Medical Director at Alverno Laboratories, Hammond IN

*"Rapid Sepsityper identification has been instrumental in terms of patient care. Especially in critically-ill patients, the improved turn-around-time allows disease specific treatment which conserves health-care resources and, most importantly, improves patient outcomes." **

Accurate, Specific and Efficient

- Analyzed using the world renowned MALDI Biotyper CA System
- Identifies all organisms contained within the current and future versions of the MALDI Biotyper CA System Reference Library, which includes bacteria and yeast
- Accuracy comparable to nucleic acid sequencing
- More cost-effective than molecular platforms



Ike Northern, CompuNet Clinical Laboratory, Director of Infectious Disease Testing and Immunology, Dayton, OH

"I think a lot of laboratories are realizing that they need to use MALDI-TOF MS technology for microbial identification. Many are now making this investment when they recognize the long-term cost benefits. The MBT Sepsityper® Kit US IVD will be the next step for a lot of clinical microbiology laboratories.

*Many are currently using multiplex PCR tests but once you have the MALDI Biotyper instrument, it's more cost-effective to use the MBT Sepsityper® Kit US IVD than large PCR panels." **

Improves Patient Care and Economic Benefits

- Complete ID available up to 48 hours earlier than traditional ID methods
- Rapid ID promotes Antibiotic Stewardship intervention
- Early confirmation of skin contaminants eliminates further unnecessary treatment and testing

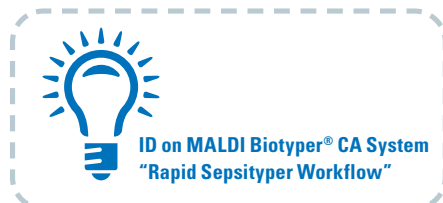
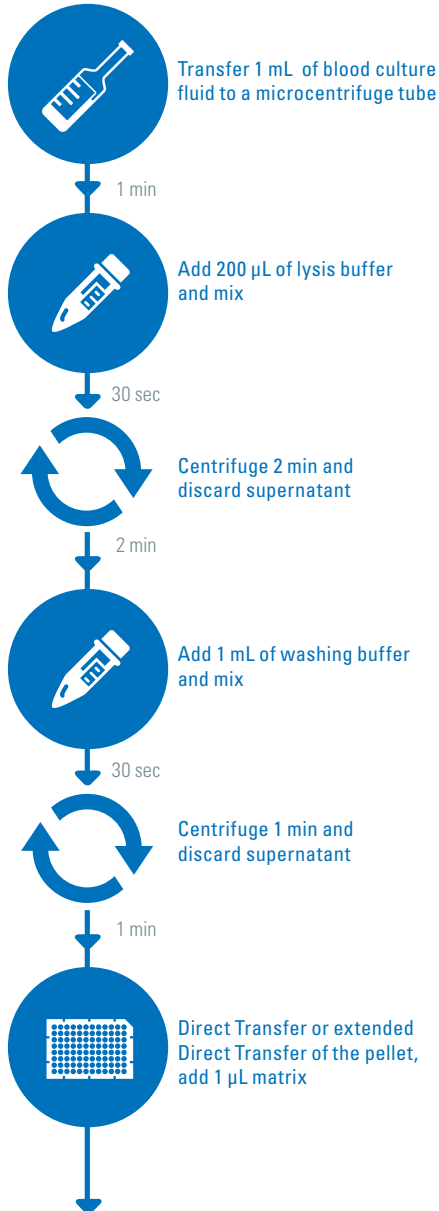


Dr. Steven D. Burdette, Medical Director, Antimicrobial Stewardship Miami Valley Hospital and Premier Health, Dayton OH

*"The MBT Sepsityper Kit data has allowed us to adjust antibiotic therapy according to our local antibiogram. This, at times, has allowed us to narrow or stop certain antibiotic treatments while in other cases, it has allowed us to escalate antibiotic coverage pending sensitivity data. It has become a crucial tool for our Antimicrobial Stewardship team." **

MBT Sepsityper Kit US IVD

Fast and Easy Sample Preparation



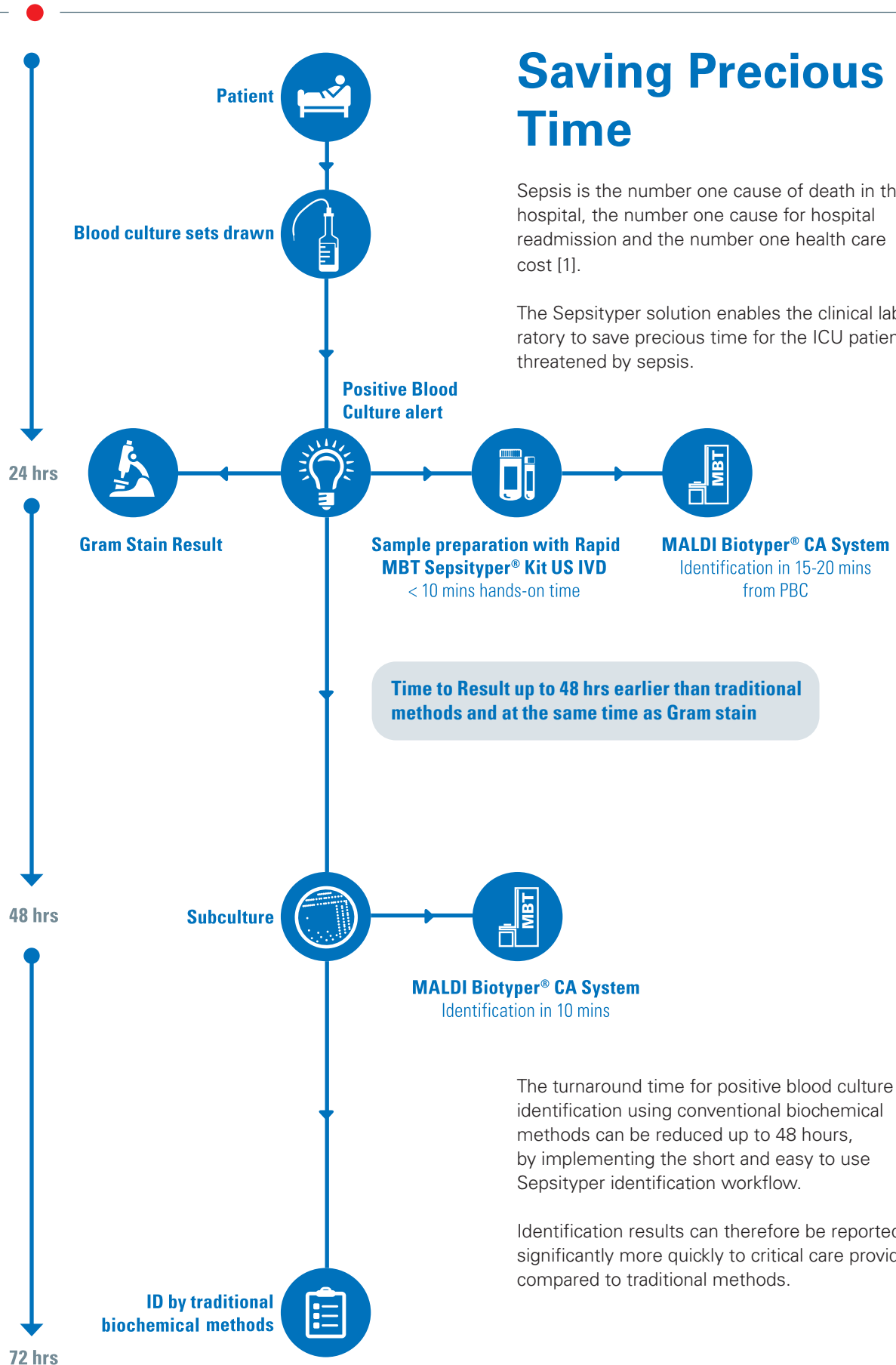
If no ID:
Standard extraction,
spot 1 μ L extract to the
MALDI target, add 1 μ L matrix
→
10 min



Saving Precious Time

Sepsis is the number one cause of death in the hospital, the number one cause for hospital readmission and the number one health care cost [1].

The Sepsityper solution enables the clinical laboratory to save precious time for the ICU patients threatened by sepsis.



The turnaround time for positive blood culture identification using conventional biochemical methods can be reduced up to 48 hours, by implementing the short and easy to use Sepsityper identification workflow.

Identification results can therefore be reported significantly more quickly to critical care providers compared to traditional methods.

Efficient & Easy Implementation

The MALDI Biotyper CA System, software and MBT Sepsityper Kit US IVD provide a complete and seamless solution. Standard ID and Sepsityper ID samples can be combined in one run with all results visible in one final report. Additionally, the software investigates whether the result may be a combination of two different microorganisms. If this is the case the software provides a mixed culture hint informing the user about a presumptive mixture, which needs to be confirmed by a pure subculture.

Target Position	Test Organism Label	Organism Identification	log(score) Value
A1	Sample 1 (Standard)	Candida auris Standard ID sample	2.35
A2	Sample 2 (Sepsityper)	Pseudomonas aeruginosa Sepsityper sample	2.24
A3	Sample 3 (Sepsityper)	Staphylococcus aureus [presumptive mixture with: <i>Corynebacterium argenteorotense</i> (2.50)]	1.98
BTS1	bts (BTS)	Escherichia coli	2.64
BTS2	bts (BTS)	Escherichia coli	2.66


Order information

Part No. 1867565 | MBT Sepsityper Kit US IVD


The MBT Sepsityper Kit US IVD contains all reagents and consumables required for microorganism isolation from 50 positive blood culture samples.

Read more

Expert Insights
Advanced Microbial Identification with MALDI Mass Spectrometry for Streamlined Therapeutic Treatment



Expert Insights
Advancing Infectious Disease Testing with MALDI-TOF Mass Spectrometry



References

[1] https://static1.squarespace.com/static/597f001fb3db2bde61e79d4a/t/5eb9a724784e22464687f293/1589225262675/Sepsis_Fact_Sheet_WSD.pdf

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IVD

Rx ONLY

As of May 2021, Bruker Daltonik GmbH is now Bruker Daltonics GmbH & Co. KG.



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