

FDA-cleared

MALDI Biotyper®

# MBT Sepsityper® Kit US IVD

For rapid microorganism identification direct from positive blood culture using the MALDI Biotyper® CA System

Innovation with Integrity

US-IVD



# 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.



## When every minute counts

### 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 turnaround time allows disease specific treatment which conserves healthcare 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



## 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

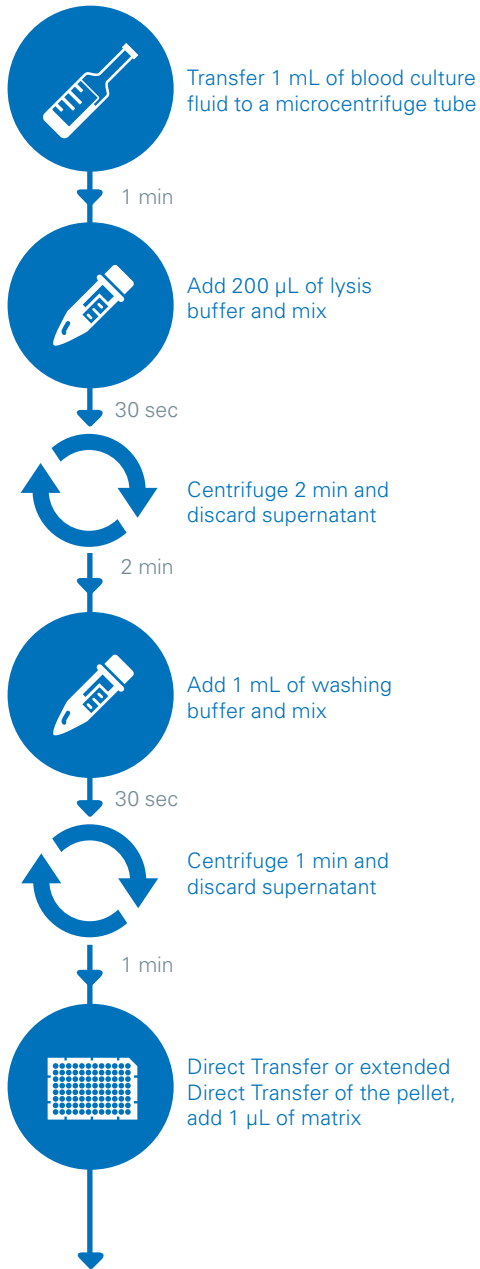
Medical Director, Antimicrobial Stewardship Miami Valley Hospital and Premier Health, Dayton, OH

"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."\*



\* All quoted early adopter customers have validated the research-use-only (RUO) version of the MBT Sepsityper kit as a laboratory-developed test (LDT) prior to the FDA-clearance of the MBT Sepsityper Kit US IVD.

# Fast and easy sample preparation



« Rapid Sepsityper Workflow »  
ID on MALDI Biotyper® CA System

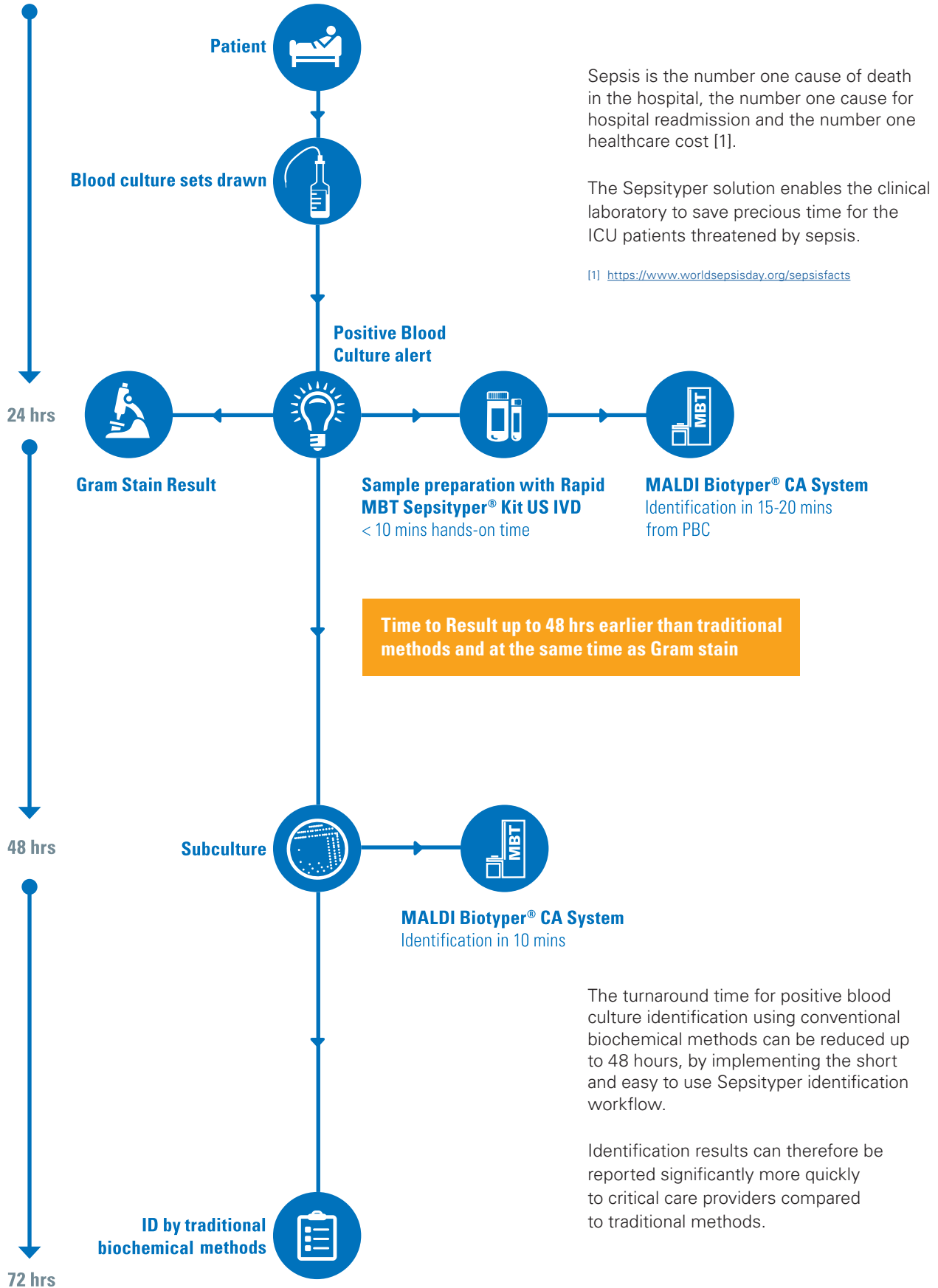
If no ID:  
Standard extraction,  
spot 1 µL of extract onto the  
MALDI target, add 1 µL of  
matrix

→ 10 min



ID on IVD MALDI Biotyper®  
CA System  
"Full Sepsityper Workflow"

# Saving precious time



# Efficient and 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: Corynebacterium argenteorotense (2.50)]	1.98
BTS1	bts (BTS)	<a href="#">Escherichia coli</a>	2.64
BTS2	bts (BTS)	<a href="#">Escherichia coli</a>	2.66

## Order information

### MBT Sepsityper Kit US IVD

Part No. 1867565

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

Only for sale in the USA and Puerto Rico.

IVD

Rx ONLY

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### Online information

[bruker.com/microbiology](http://bruker.com/microbiology)



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