

FASTinov AST – Product Overview

Bloodstream infections

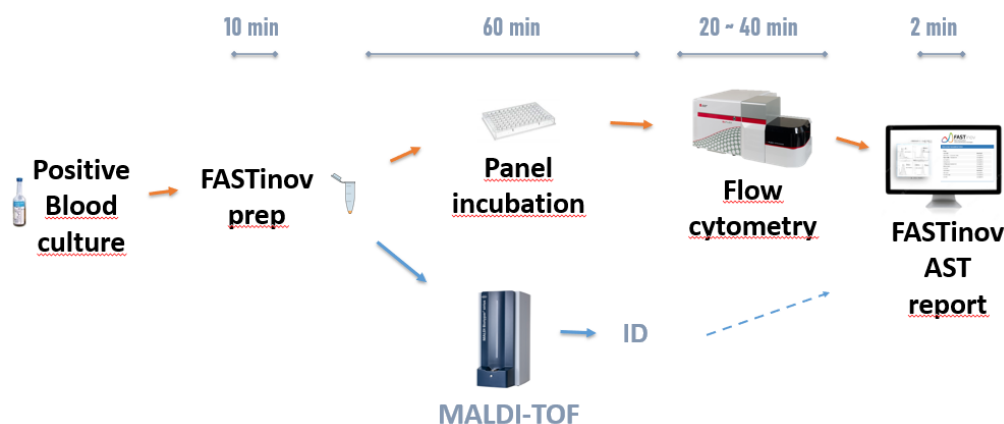
Bloodstream infections (BSI) have an incidence rate of approximately 200/100 000 population and present case fatality rates of approx. 25.6% in 30 days^{1,2}. Both sepsis and BSI are severe life-threatening conditions that require an appropriate, timely response to provide optimal treatment. This is becoming increasingly difficult because of antimicrobial resistance (AMR).

Without knowledge of the pathogen, the available treatment option is Empirical Antibiotic Therapy (EAT). Since there is no information on the resistance profile of the pathogen, some studies estimate that as much as 20% of the treatments are not appropriate³. One study with septic shock patients has shown that in such case, survival was 10.3% for the patients that received inadequate EAT. Therefore, rapid determination of antimicrobial susceptibility (AST) enables fast therapy optimization.

FASTinov Technology

FASTinov offers a **phenotypic AST that can provide susceptibility results (antibiogram) in 2 hours, directly from positive blood cultures** (Figure 1). The blood culture is processed to isolate the pathogen in the form of a bacterial suspension, and the FASTinov AST panel is inoculated. Bacteria in contact with antibiotics suffer lesions when susceptible. Specific fluorescent probes are then activated, staining susceptible cells. After 1 hour of incubation, the panel is analysed by a flow cytometer. High-speed cell-by-cell multiparametric analysis delivers data that is analysed by FASTinov's proprietary software bioFAST, which **generates the antibiogram in less than 2 hours from the processing of the blood culture**. Rapid identification of the pathogen by MALDI-TOF MS can also be performed directly from the same bacterial isolate obtained after processing the blood culture.

With one instrument, one result can be delivered in 2h, and up to 5 antibiograms can be delivered in 4h.



¹ Buetti N, Atkinson A, Marschall J, et al Incidence of bloodstream infections: a nationwide surveillance of acute care hospitals in Switzerland 2008–2014 *BMJ Open* 2017;7:e013665. doi: 10.1136/bmjopen-2016-013665

² Schechner, Vered et al. One-year mortality and years of potential life lost following bloodstream infection among adults: A nation-wide population based study The Lancet Regional Health – Europe, Volume 23, 100511

FASTinov AST kits – details

FASTgramneg kit (Gram negative) -- CE-IVD

AST for 12 antibiotics

Antibiotics FASTgramneg	Enterobacterales		Pseudomonas spp		Acinetobacter spp	
	EUCAST	CLSI	EUCAST	CLSI	EUCAST	CLSI
Ampicillin	✓	✓	-	-	-	-
Amoxicillin-clavulanic acid	✓	✓	-	-	-	-
Cefotaxime	✓	✓	-	-	-	-
Ceftazidime	✓	✓	✓	✓	-	-
Cefepime	✓	✓	✓	✓	-	-
Piperacillin-tazobactam	✓	✓	✓	✓	-	✓
Ceftazone-tazobactam	✓	✓	✓	✓	-	-
Ceftazidime-avibactam	✓	✓	✓	✓	-	-
Meropenem	✓	✓	-	-	-	-
Ciprofloxacin	✓	✓	✓	✓	✓	✓
Gentamicin	✓	✓	-	✓	✓	✓
Amikacin	✓	✓	✓	✓	✓	✓

Enterobacterales, Pseudomonas spp. and Acinetobacter spp

Detects main mechanism of resistance ESBL for EB group 1

Screens for the presence of ESBL (for EB group 2), pAmpC and Carbapenemases

FASTgrampos kit (Gram positive) -- CE-IVD

AST for 7 antibiotics

Antibiotics FASTgrampos	Staphylococcus spp		Enterococcus spp	
	EUCAST	CLSI	EUCAST	CLSI
Penicillin*	✓	✓	✓	✓
Ampicillin	-	-	✓	✓
Cefoxitin**	✓	✓	-	-
Oxacillin***	✓	✓	-	-
Vancomycin****#	✓	✓	✓	✓
Linezolid	✓	✓	✓	✓
Gentamicin	✓	✓	-	-
Gentamicin high level#	-	-	✓	✓

Staphylococcus spp. and Enterococcus spp

Provides MIC for vancomycin for S. aureus

Accuracy (Clinical validation study)

The clinical validation study was conducted in 2022 in Porto, Portugal and Madrid, Spain (Ramon y Cajal hospital, Prof Rafael Cantón), with the following results:

	EUCAST									CLSI							
	N	EA%	CA%	mE	ME	VME	Reproducibility		N	EA%	CA%	mE	ME	VME	Reproducibility		
FASTgramneg	2,570	NA	98.9	0.0%	1.2%	0.9%	99.5%		2,677	NA	97.9	1.3%	0.8%	0.7%	99.3%		
FASTgrampos	857	91.5	97.8	0.2%	2.8%	0.4%	99.4%		931	91.5	97.9	0.3%	2.6%	0.3%	99.8%		

		Detection of mechanisms of resistance			
		N	Sensitivity	Specificity	Accuracy
Screening	ESBL(EB group I)	45	95.7%	100%	99.3%
	ESBL(EB group II)	17	100%	100%	100%
	pAmpC	37	100%	100%	100%
	Carbapenemases	52	92.2%	95.1%	94.1%

N - number of strains
 EA (%) - Percentage of Essential agreement (only for colistin and vancomycin)
 CA (%) - Percentage of Categorical Agreement
 mE- minor Error; ME- Major Error; VME- Very Major Error
 NA- not applicable

Summary

FASTinov's antimicrobial susceptibility technology establishes phenotypic susceptibility in 2 hours directly from blood cultures. Our flow cytometry-based test can provide accurate susceptibility for both gram-negative and gram-positive pathogens, and its very short time-to-results allows for same-day results, which is unprecedented in the industry, making currently it the world's fastest antibiogram.