FASTinov

Next Generation

Antimicrobial Resistance Technologies

Distributor Presentation

December 2023

Updated by George Skinner

FASTinov
Next Generation
Antimicrobial Resistance Technologies

PRODUCT

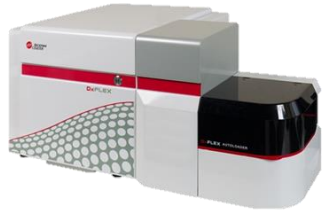
FASTinov workflow: AST from blood cultures in 2 hours

10 min | 60 min | 20 ~ 40 min | 2 min

Positive Blood culture

FASTinov prep

Panel incubation



Flow cytometry

FASTinov report

ID

FASTinov AST kits are CE-marked, approved for sale in the European Union under IVD Directive. They are not FDA-cleared and are not yet available for sale in the U.S. Availability in each country depends on local regulatory clearance.

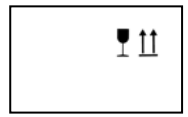
Kit configuration – current design

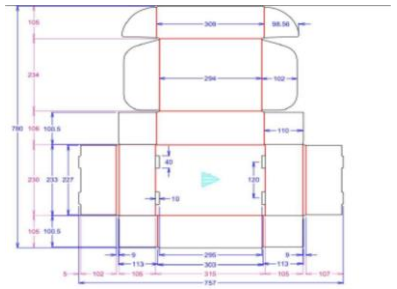
Documentation

IFU

Secondary box

Kit label





Tube A with Hemolytic agent X100

1x vials with flat base w/close cap 0.5ml X100

In paper box, labelled

AST panels*

8x FAST panels (v1, commercial) closed and with primary label attached

Plastic cuvettes

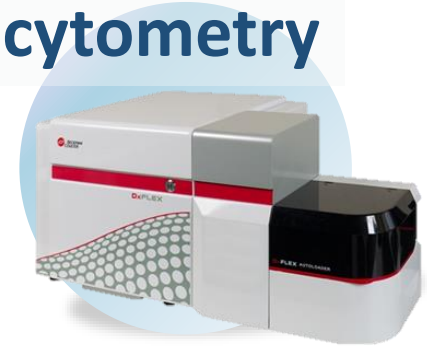
8x cuvettes

FASTinov technology: flow cytometry and phenotypic cell lesion study

FASTinov AST panels

+

Flow cytometry



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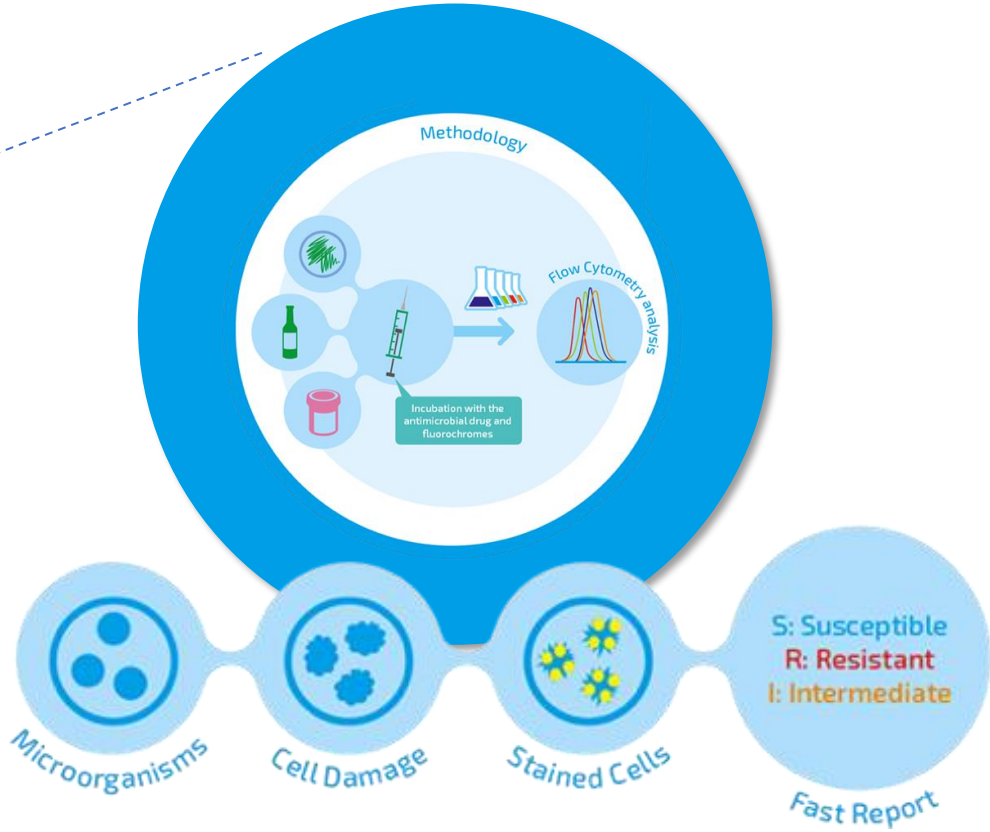
bioFAST software



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Antibiotic panel - FASTgramneg

Antibiotics FASTgramneg	*Enterobacterales*		*Pseudomonas* spp		*Acinetobacter* spp	
	EUCAST	CLSI	EUCAST	CLSI	EUCAST	CLSI
Ampicillin	√	√	-	-	-	-
Amoxacillin-clavulanic acid	√	√	-	-	-	-
Cefotaxime	√	√	-	-	-	-
Ceftazidime	√	√	√	√	-	-
Cefepime	√	√	√	√	-	-
Piperacillin-tazobactam	√	√	√	√	-	√
Ceftalozane-tazobactam	√	√	√	√	-	-
Ceftazidime-avibactam	√	√	√	√	-	-
Meropenem	√	√	-	-	-	-
Ciprofloxacin	√	√	√	√	√	√
Gentamicin	√	√	-	√	√	√
Amikacin	√	√	√	√	√	√

- Provides AST for 12 antibiotics for *Enterobacterales*, *Pseudomonas* and *Acinetobacter* spp.
- Detects main mechanism of resistance ESBL for EB Group 1
- Screens for presence of ESBL (for EB Group 2), pAmpC and carbapenemases

CE IVD

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Antibiotic panel - FASTgrampos

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

* Only for *S. aureus* according to EUCAST;
** Not aplicable to *S. epidermidis;*
*** Only for *S. epidermidis;* ****MIC value for *S. aureus* ;
# Only for *E. faecalis*

- Provides AST for 7 antibiotics for *Staphylococcus* and *Enterococcus* spp.
- Provides MIC for Vancomycin for *S. aureus*

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Test accuracy

	EUCAST							CLSI						
	N	EA%	CA%	mE	ME	VME	Reproducibility	N	EA%	CA%	mE	ME	VME	Reproducibility
FASTgramneg	2570	NA	98.9	0.0%	1.2%	0.9%	99.5%	2677	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%

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

	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%

Source: IFU

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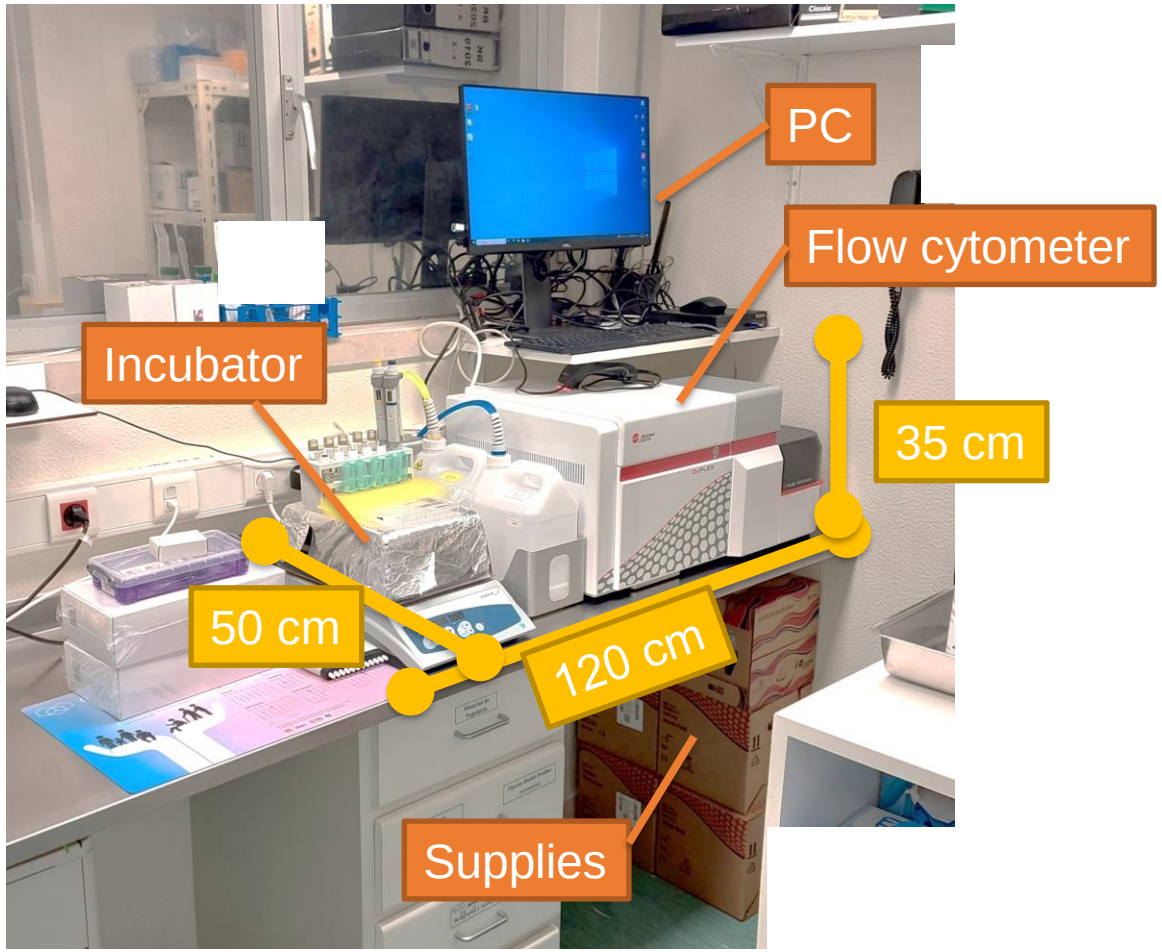
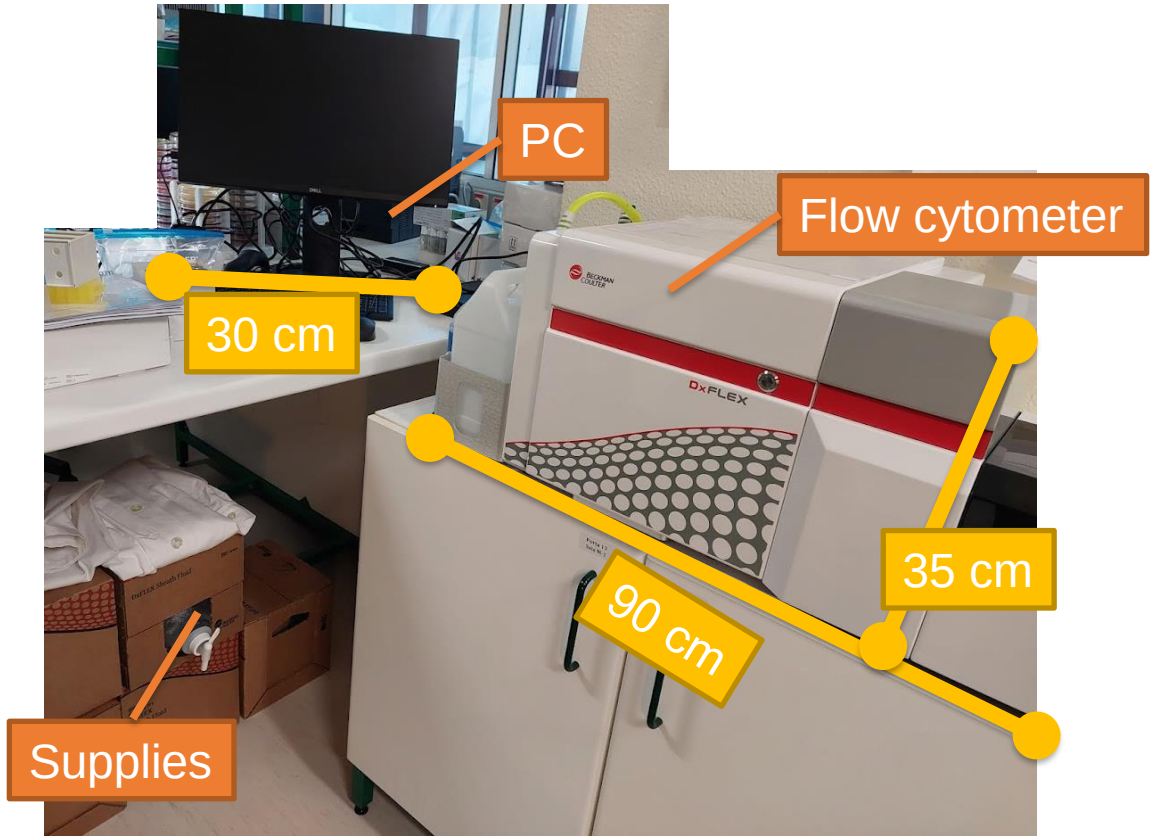
Space needed

Example A



Example B



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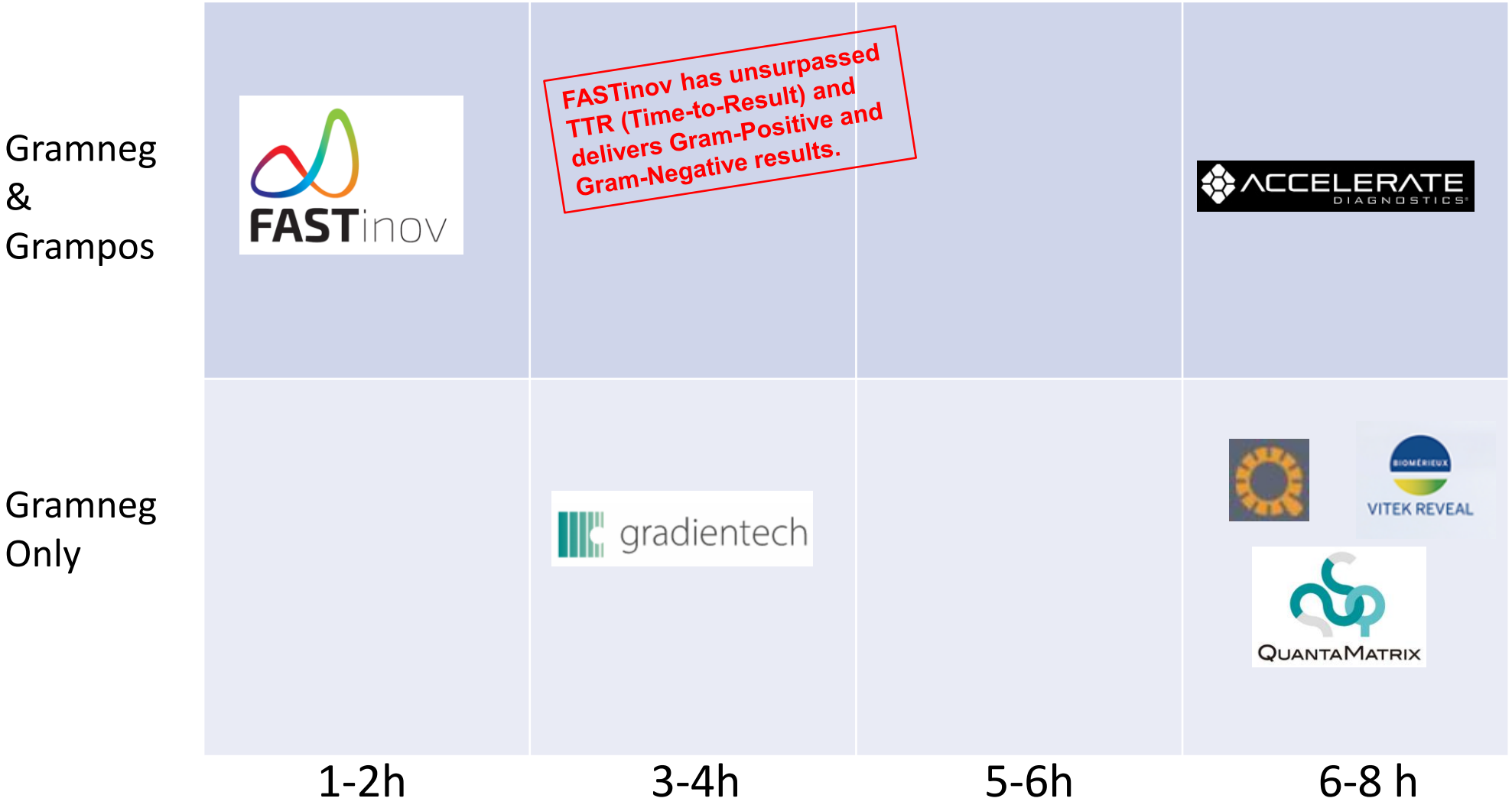
POSITIONING & PRICING

Competitive positioning – rapid AST



Competitor messages – Jul 2023

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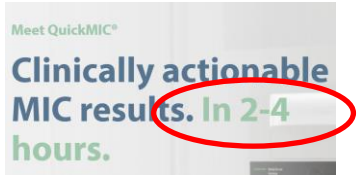
PHENOTYPIC AST IN 2H FROM BLOOD CULTURES

Speed

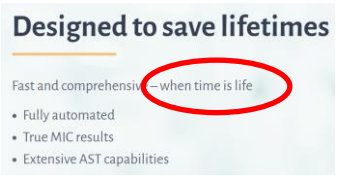
gradientech



Every competitor wants to claim "rapid result" ability

Speed

MIC



Speed

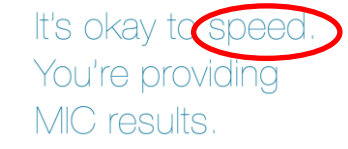
MIC

Automated

BIOMÉRIEUX

Speed

ACCELERATE DIAGNOSTICS



Fast

Fully Automated

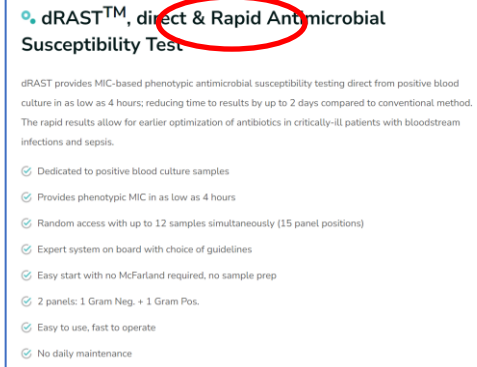
Actionable results

Speed

MIC

Automated

QuantaMatrix



Speed

MIC

Automated

Competitive positioning: rapid AST competitors

	FASTinov	Gradientech	Qlinea	SpecificDx	Accelerate Dx	Quantamatrix
Time to AST results	2h SUPERIORITY	2-4h ADVANTAGE	6-8h WEAKNESS	6-8 h WEAKNESS	6-8h WEAKNESS	6-8h WEAKNESS
Coverage of antibiotics panel	GN: 12 Abx GP: 7 Abx STRENGTH	GN: 13 Abx GP: - WEAKNESS	GN: 23 Abx GP: -- WEAKNESS	GN: Available GP: WEAKNESS	GN: 12 Abx GP: 5 Abx STRENGTH	GN: 12 Abx GP: 18 Abx STRENGTH
Throughput (1 instrument)	1 at a time 10-12 AST in 8h STRENGTH	1 at a time 10-12 AST in 8h STRENGTH	4 simultaneous 4 AST in 8h STRENGTH	4 simultaneous 4 AST in 8h WEAKNESS	1 at a time 1 AST in 8h WEAKNESS	16 simultaneous 16 AST in 8h STRENGTH
Usability	5-10' hands-on time PARITY	2'30'' hands-on time STRENGTH	2' hands-on time STRENGTH	2'30'' hands-on time STRENGTH	2' hands-on time STRENGTH	2' hands-on time STRENGTH

New category: "Ultra Rapid"

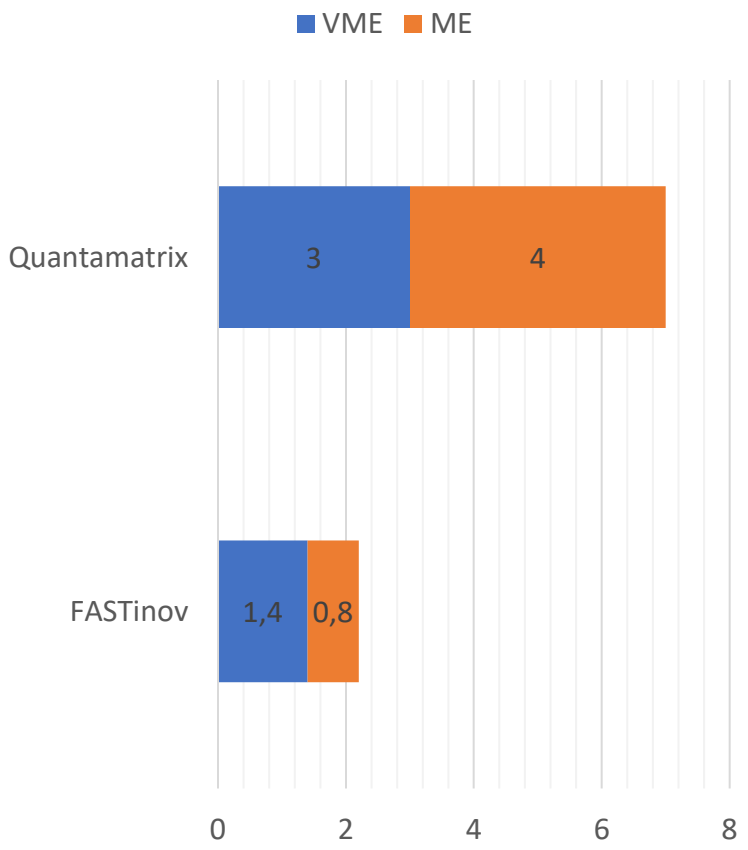
"rapid AST" category

AST with TTR 2h => *Same day*

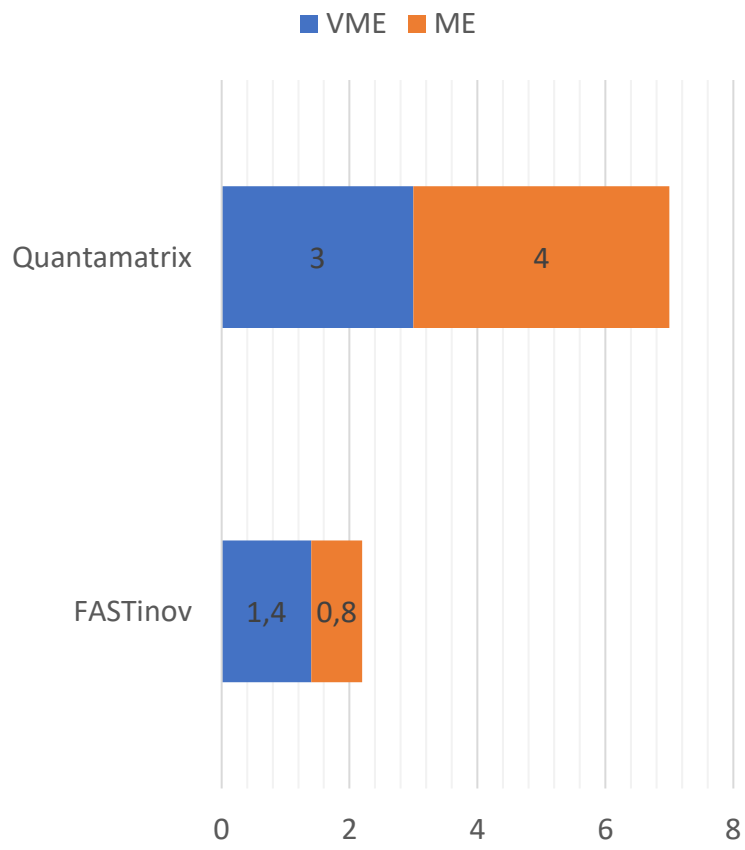
"Rapid" AST with TTR 6-8 hours => Most results delivered *next day*

Competitive positioning - accuracy

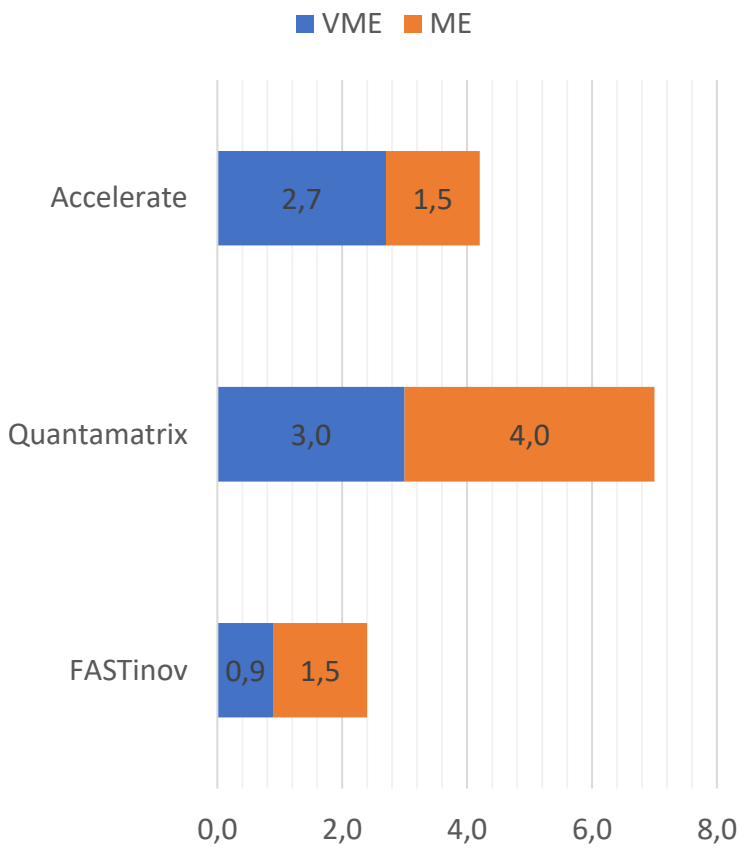
Gram-negative



Gram-positive



Total



Comparison of antibiotic panel – gram-negative

			FASTinov	Gradientech	QLinea	Accelerate	Reveal	Quantamatrix
Penicillins		Ampicillin	✓		✓		✓	✓
		Piperacillin					✓	✓
Cephalosporins	1st gen cephalosporins	Cefazolin			✓		✓	
	2nd gen cephalosporins	Cefuroxime			✓		✓	
		Cefoxitin					✓	
	3rd gen cephalosporins	Cefotaxime	✓	✓	✓		✓	✓
		Ceftazidime	✓	✓	✓	✓	✓	✓
		Ceftriaxone			✓	✓		
	4th gen cephalosporins	Cefepime	✓	✓	✓	✓	✓	✓
Penicillins+Beta Lactamase Inhibitor		Piperacillin/tazobactam	✓	✓	✓	✓	✓	✓
		Amoxicillin/clavulanic acid	✓		✓		✓	✓
		Ampicillin-Sulbactam				✓	✓	✓
Cephalosporin+Beta Lactamase Inhibitor		Ceftolozane/tazobactam	✓		✓		✓	
		Ceftazidime/avibactam	✓	✓	✓		✓	✓
		Ceftazidime/Clavulanic acid	✓				✓	✓
Carbapenems		Meropenem	✓	✓	✓		✓	✓
		Ertapenem			✓	✓	✓	
		Imipenem					✓	✓
Quinolones		Ciprofloxacin	✓	✓	✓	✓	✓	✓
		Levofloxacin			✓		✓	✓
Aminoglycosides		Gentamicin	✓	✓			✓	✓
		Amikacin	✓	✓		✓	✓	✓
		Tobramycin		✓		✓	✓	
Other	Antifolates	Trimethoprim/Sulfamethoxazole.					✓	✓
	Monobactams	Aztreonam			✓	✓	✓	
	Tetracycline	Tigecycline		✓			✓	
	Polymyxin	Colistin		✓				✓
			2h	**2-4h**	**6-8h**	**6-8h**	**6-8h**	**6-8h**

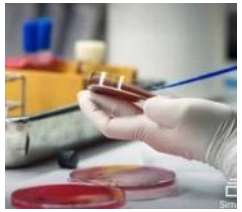
Comparison of antibiotic panel – gram-positive

Gram-positive			FASTinov	Gradientech	QLinea	Accelerate	Reveal	Quantamatrix
Penicillins		Ampicillin	✔			✔		
		Oxacillin	✔					
		Penicillin	✔					
Cephalosporins	2nd gen cephalosporins	Cefoxitin	✔					
	5th gen cephalosporins	Ceftaroline				✔		
Oxazolidinones		Linezolid	✔			✔		
Lipopeptides		Daptomycin				✔		
Glicopeptides		Vancomycin	✔			✔		
Aminoglycosides		Gentamicin	✔					
			2h	**2-4h**	**6-8h**	**6-8h**	**6-8h**	**6-8h**

While the Automated AST market grows with intense rivalry, new segment "**AST results that are actionable in the same shift**" is a unique and differentiated, high-value offer

Clinical value

Manual AST



2-4 days

Automated AST

1-2 days

"Rapid" AST

ACCELERATE

Next-day

2h AST

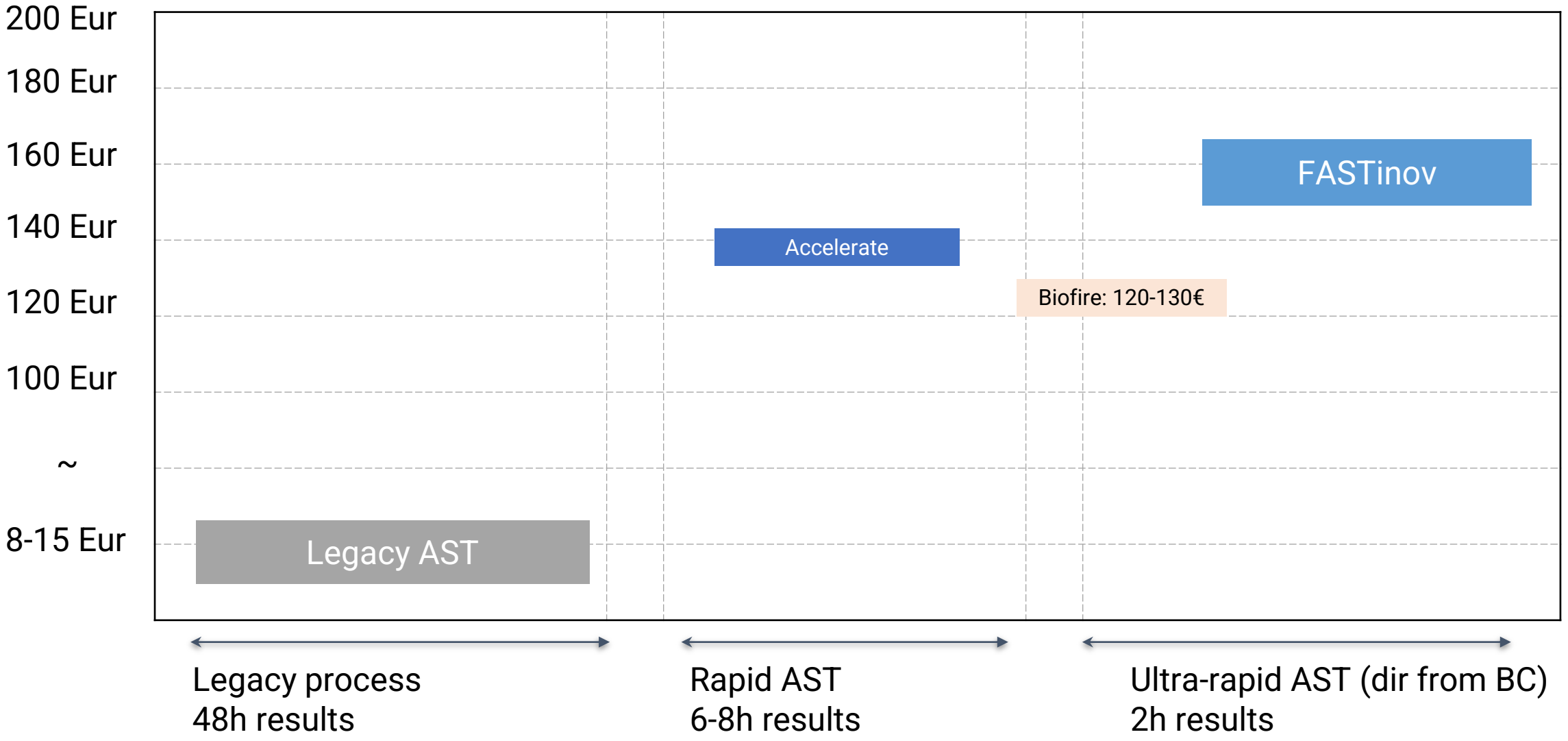
FASTinov Next Generation Antimicrobial Assays

2h AST

Speed

Competitive pricing: FASTinov intends to be price leader

Price per test



CUSTOMER TARGETS / SEGMENTS

Target Customer Segment

- Large and mid-size Hospitals with clinical pathology Dept.
  - Microbiology/Clinical pathology labs ★ budget ★ champion
  - Clinical departments ★ supporter
    - ICU, E&R, Int Medicine/Infecciology , AMR stewardship, Pediatric ICU
    - Oncology / Transplant departments
  - Purchasing / Administration ★ gatekeeper
- Group purchasers / Regional purchasers in tender regions ★ gatekeeper

Attitudinal:

- Wants to improve profile of pathology, especially post-covid
- Wants to be a partner to clinical services
- Believes in the importance of rapid AST to antibiotic stewardship

Primary target accounts – inclusion criteria

- Hospitals with rapid identification capability (Maldi-TOF / Mass spectrometry).
- Rapid Molecular ID and susceptibility systems in place indicated that customer has already obtained budget for rapid testing
- Infection control commission
- 500+ beds, or specialized hospitals in oncology, transplants, or pediatric & adult intensive units

Sales funnel – stages

Promotional stage > Demo stage > Commercial stage > Post-selling support

Stage 1

- Relationship building
- Promotion
- Business intelligence
- Tender management

Stage 2

- Evaluation planning
- Installation
- Certification
- Evaluation

Stage 3

- Proposal preparation
- Pricing approval
- Negotiation
- Activation

Stage 4

- Training
- Reorders
- Business intelligence

Gate 1

Evaluation agreed

Gate 2

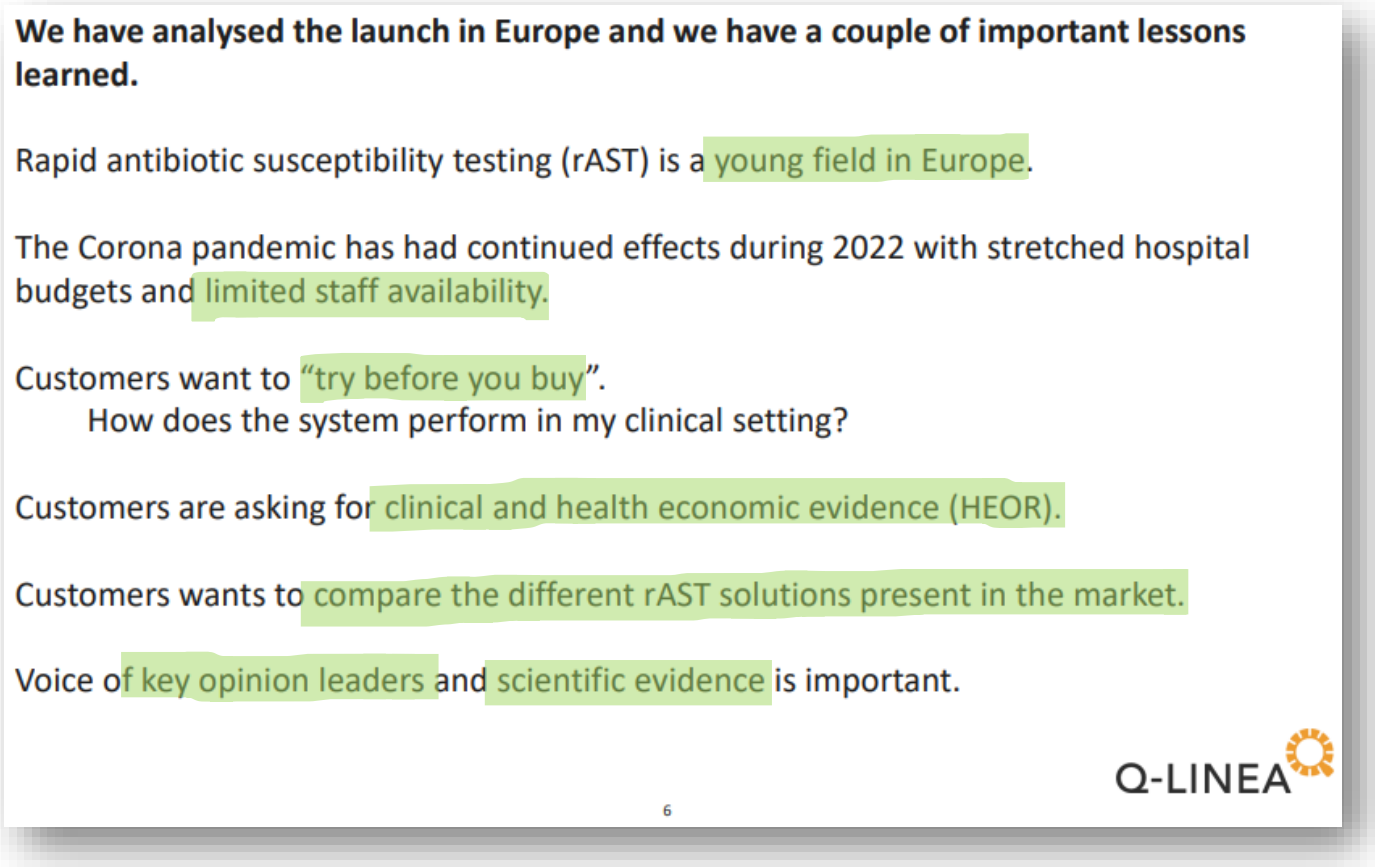
Negotiation/ tender started

Gate 3

Approval to start

MESSAGING & MARKETING MIX

QLinea market insights (Oct 2022)



We have analysed the launch in Europe and we have a couple of important lessons learned.

Rapid antibiotic susceptibility testing (rAST) is a young field in Europe.

The Corona pandemic has had continued effects during 2022 with stretched hospital budgets and limited staff availability.

Customers want to "try before you buy".
How does the system perform in my clinical setting?

Customers are asking for clinical and health economic evidence (HEOR).

Customers wants to compare the different rAST solutions present in the market.

Voice of key opinion leaders and scientific evidence is important.

Q-LINEA

6

This view of the market is from a competitor and highlights the situation that we all are facing, quite well.

FASTinov Brand message

- For the **critical infections** that require **immediate decisions**
- FASTinov AST provides the **world's fastest AST with results in less than 2h**
- For a **broad panel of species and antibiotics**
- AST results that are **Actionable within the Same Shift**

FASTinov

Next Generation
Antimicrobial Resistance Technologies

PHENOTYPIC AST IN 2H FROM BLOOD CULTURES

ULTRA RAPID

www.fastinov.com

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COMMERCIAL TOOLS

Pricing and discounting scheme – Recommended

Preferred discounting scheme based on **FOC.**

		Price per test, EUR, VAT excluded
List price (per test), EUR		**190.00**
Instrument discount	0.0%	0.00
Introductory offer discount	5.0%	9.50
Invoice price (per test), EUR		**180.50**

Instrument placement

2) Availability of cytometer

Cytometers already installed	Discount
Not installed	0%
Installed	10%

Free-of-charge system

Annualized panel consumption*	Nr of FOC tests	Final ASP at min
<= 300	0	**181**
301 - 600	8	**176**
601 - 900	32	**171**
901 - 1200	192	**149**
1201 - 1500	320	**143**
> 1500	540	**133**

Introductory offer: for hospitals starting with FASTinov AST

3) Introductory offer

	Discount
New client	8%
Existing customer	0%

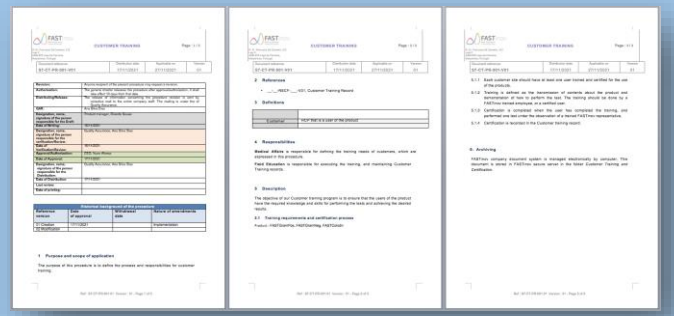
Estimated unit price after FOC, EUR**	**149**
corresponding to 192 tests offered free of charge plus 910 tests purchased	

Training and certification process

FASTinov provides on-site and off-site certification for operators of the technology.

- Product
- Training and certification
- Software update
- Lab workflow

SOP



Training

Certification

Introduction presentation

Step-by-step demo in lab

1st case observation

Certification

Commercial Start

Portugal - Background

- Jan-Jun 2023
- 6 demos completed in Portugal
  - POR_Porto_IPO Porto
  - POR_Almada_Garcia de Orta
  - POR_Coimbra_CHUC
  - POR_Vila Real_CHTMAD
  - POR_Amadora_Fernando Fonseca
  - POR_Porto_Santo António
- 139 tests performed

Portugal - Customer demos 2023

IPO Porto

26 Jan → 15 Feb, N=15

19 Apr → 2 May, N=29

6 Jun → 20 Jun, N=12

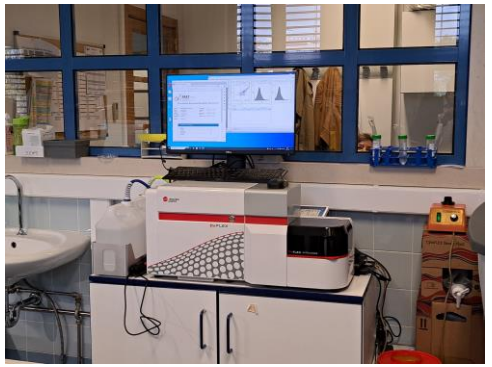
22 Mar → 12 Apr N=15

CHTMAD, Vila Real

HFF, Amadora

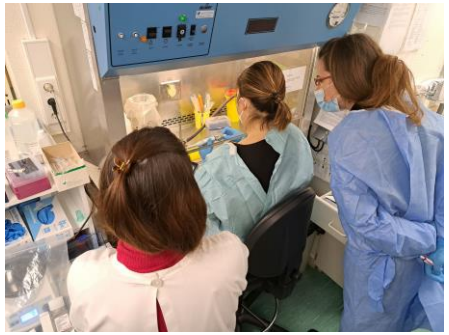
17 May → 2 Jun, N=30e

23 Feb → 15 Mar, N=49



CHUC, Coimbra

HGO, Almada



HGO, Almada

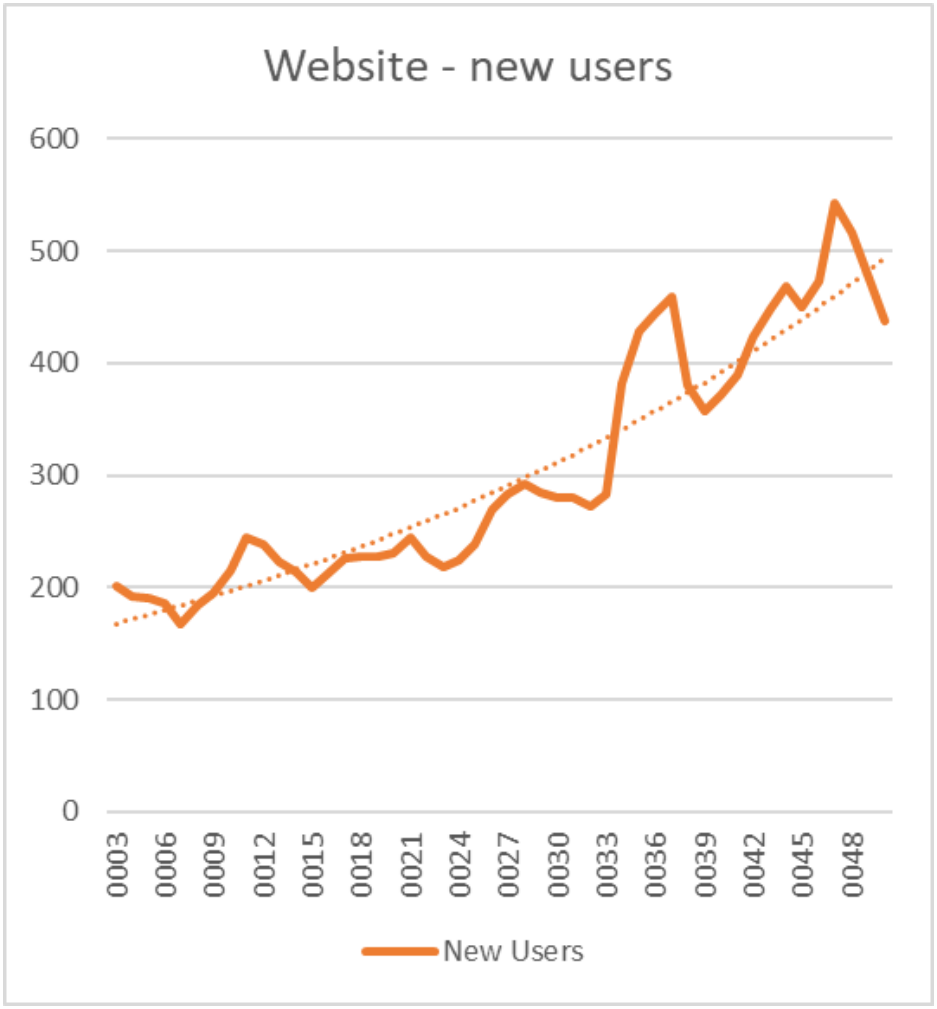
Events

- 2 – 4 March Figuera de Foz Portugal
- 8-11 March AMCLI Rimini Italy
- 27-30 April 2024 ECCMID Barcelona Spain
- 30 May - 1 June Zaragoza Spain
- ?? Sept Sepsis Update – Weimar, Germany

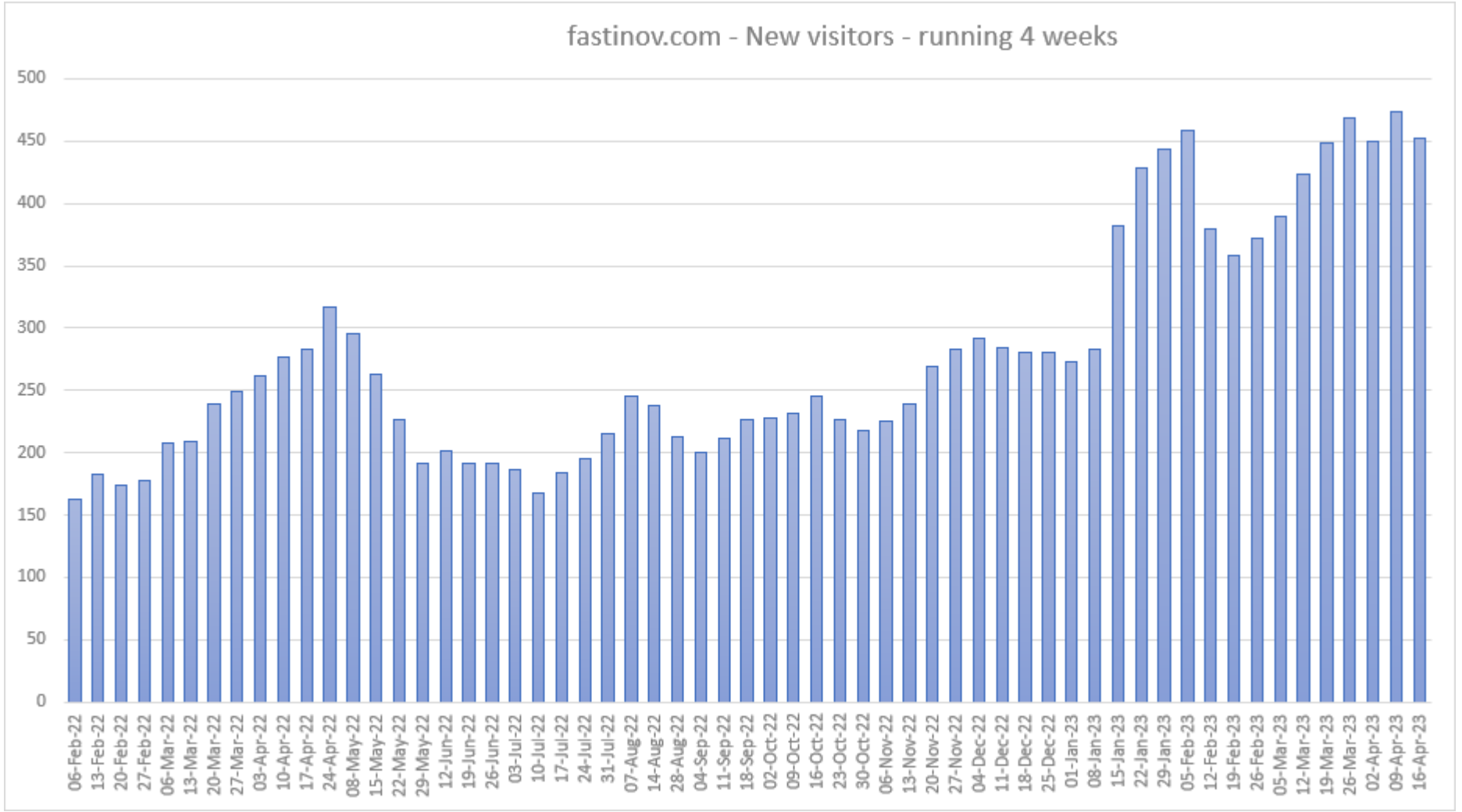
Online

Online marketing

- **Website**



Website visitors

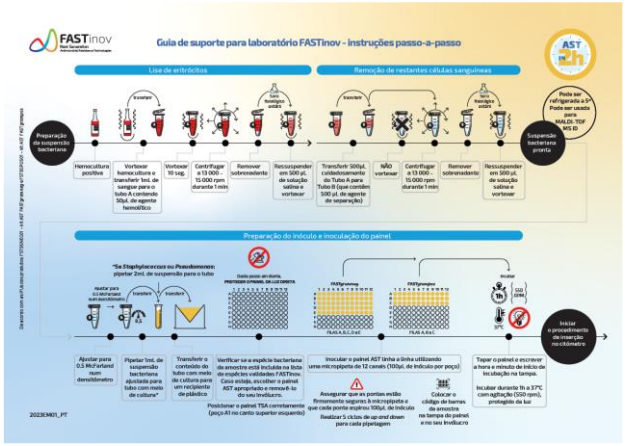


Field training

Field training

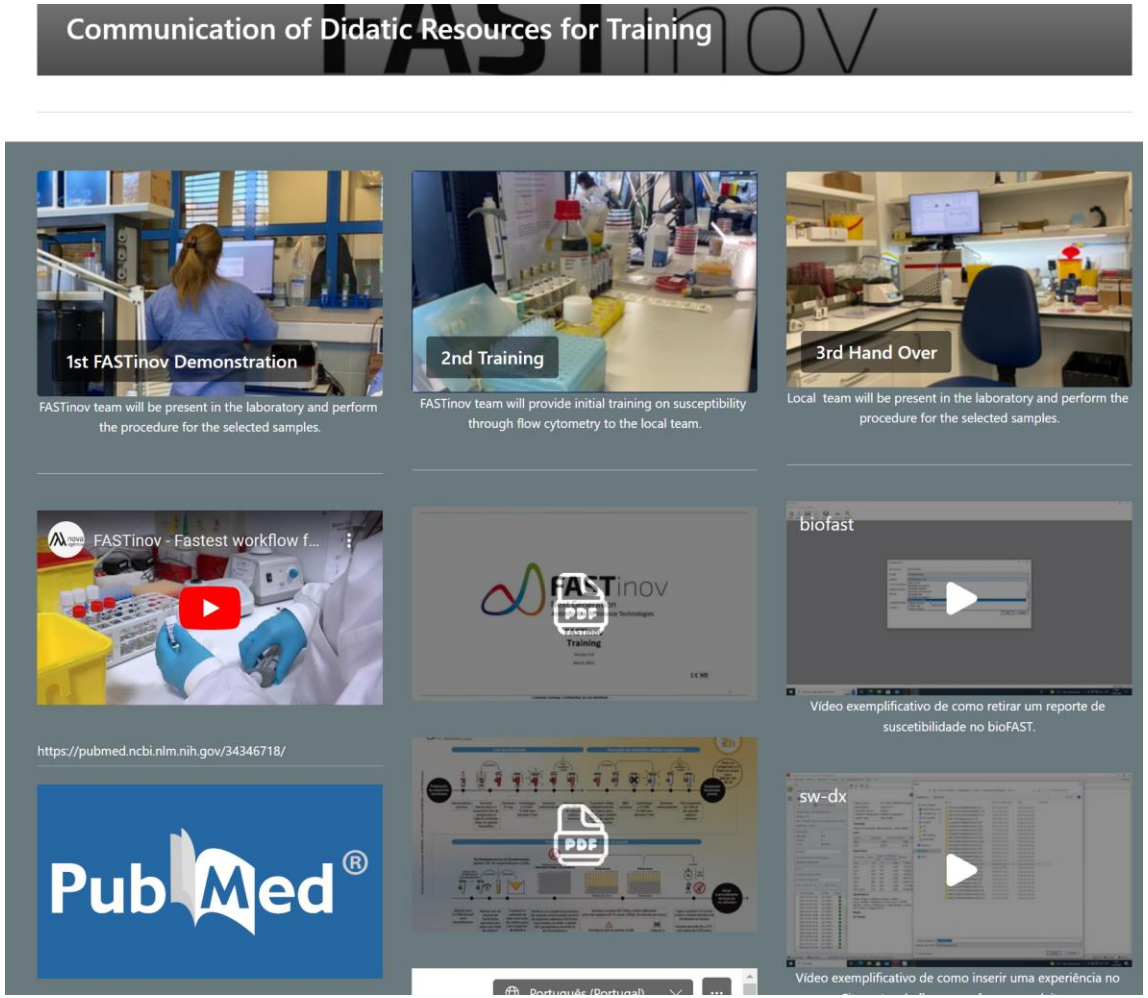
- **Sharepoint**

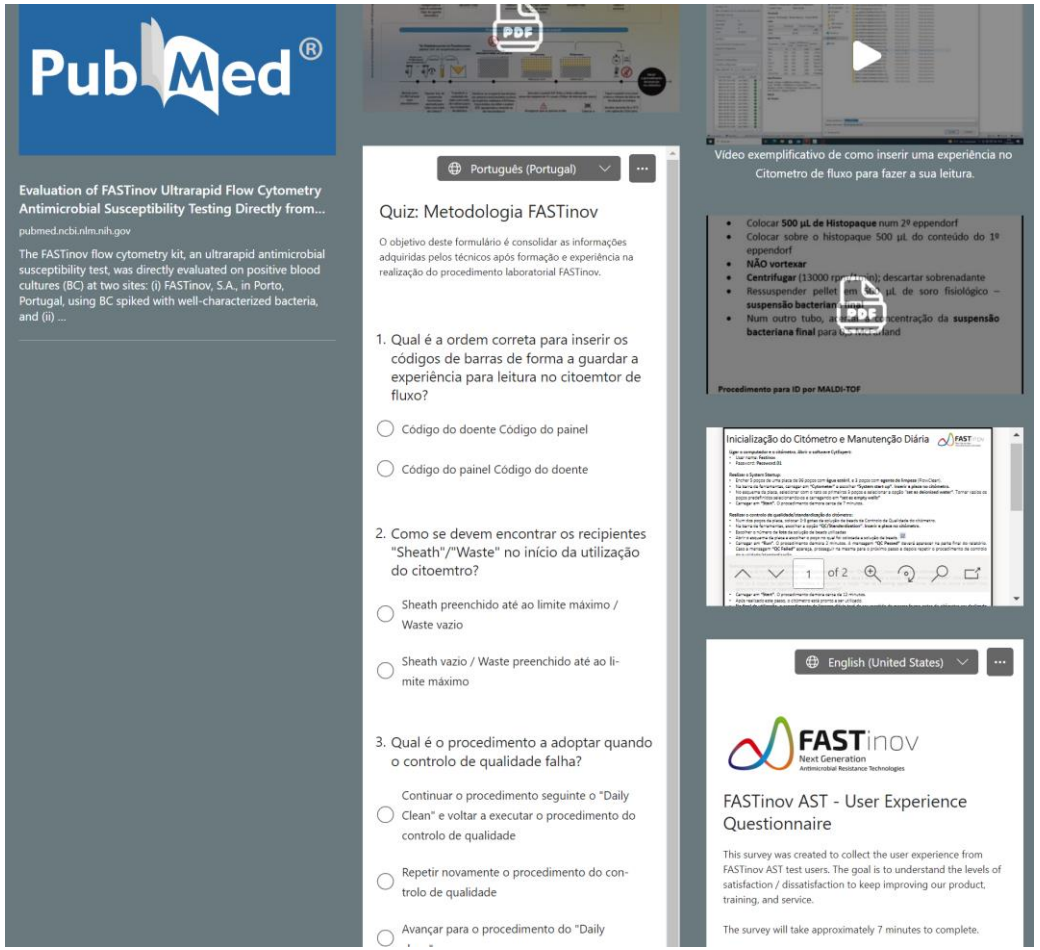
- **Materials**
- **Audiovisuals** (Video animation, loop presentation, mini-symposia)
  - Demostration reports
  - Training and **lab support materials**
  - Website and **online awareness** on the rise



Field training – sharepoint (June 2023)

https://fastinov.sharepoint.com/sites/FASTinov?OR=Teams-HL&CT=1689327212092&clickparams=eyJBcHBOYW1lIjoiVGVhbXMtRGVza3RvcCIsIkFwcFZlcnNpb24iOiIxNDE1LzIzMDYwNDAxMTYxIiwiSGFzRmVkZXJhdGVkVXNlciI6ZmFsc2V9





Clinical marketing

Disease burden and Empiric Antibiotic Therapy

Bloodstream infection (BSI)

Incidence:

200-220 episodes / 100,000 population[1,2]

(growing at 14% per year [1])

Case fatality rates:

25.6% at 30 days

46.4% at 1 year[2]

Empiric Antibiotic Therapy (EAT)

N = 5,715 patients with septic shock[3]

Appropriate 80%

Inappropriate 20%

*"antimicrobials with **in vitro activity** for the isolated pathogen(s) or appropriate for the underlying clinical syndrome"*

Survival 52%

Survival 10.3%

[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

[3] Kumar A Ellis P, Arabi Y, et al. ; Cooperative Antimicrobial Therapy of Septic Shock Database Research Group. Initiation of inappropriate antimicrobial therapy results in a fivefold reduction of survival in human septic shock. *Chest* 2009, 136:1237–48.

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Susceptibility Testing is necessary to inform appropriate therapy

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Ultra-rapid susceptibility → involvement in clinical decisions

Empiric Antibiotic Therapy

Espécie	Klebsiella oxytoca
Painel	FASTgramneg
Tipo de Amostra	Hemocultura
ID Amostra	EXP_20230313_123807137
Número do Lote	22C1122
Técnico	rita

Versão AST	2.1
Incubação Início	13/03/2023 12:10:49
Instrumento Início	13/03/2023 13:17:43
Relatório Final	13/03/2023 14:48:00

Suscetibilidade Antimicrobiana

Fármaco	
Ampicilina	R
Amoxicilina/Ácido clavulânico	S
Cefotaxima	S
Ceftazidima	S
Cefepime	S
Piperacilina/Tazobactam	S
Ceftalozane+Tazobactam	S
Ceftazidime+Avibactam	S
Meropenem	S
Ciprofloxacina	S
Gentamicina	S
Amicacina	S

Optimal Antibiotic Therapy

FASTinov
Next Generation
Antimicrobial Resistance Technologies

Thank You!