



NANOTECHNOLOGY COMMITTED TO HEALTH



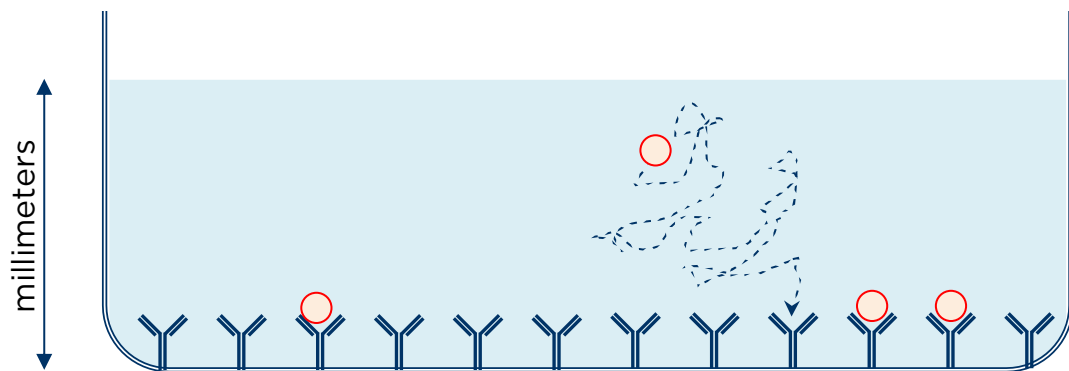
# 5 minutes to save lives

## World's most rapid sepsis test

Dr. Nicolas Durand, May 17, 2019

# Abionic's technology revolutionizes ELISA tests

## Standard ELISA technology - Microtiter plate



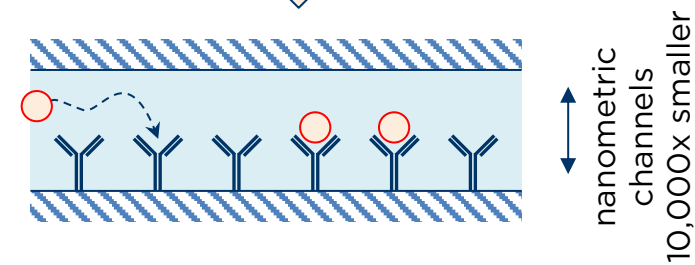
○ Molecule to be detected

- Average traveling distance to capture antigen: 5mm
- Incubation time: Minimum 3 hours
- Intensive washing steps needed to avoid measuring non-specific molecules in the bulk

In a standard ELISA immunoassay, antigens have to travel millimeters to get contact with antibodies, requiring **hours**

## Abionic's nanofluidic-based Fluorescent Immunoassay (FIA)

Abionic nanofluidic technology



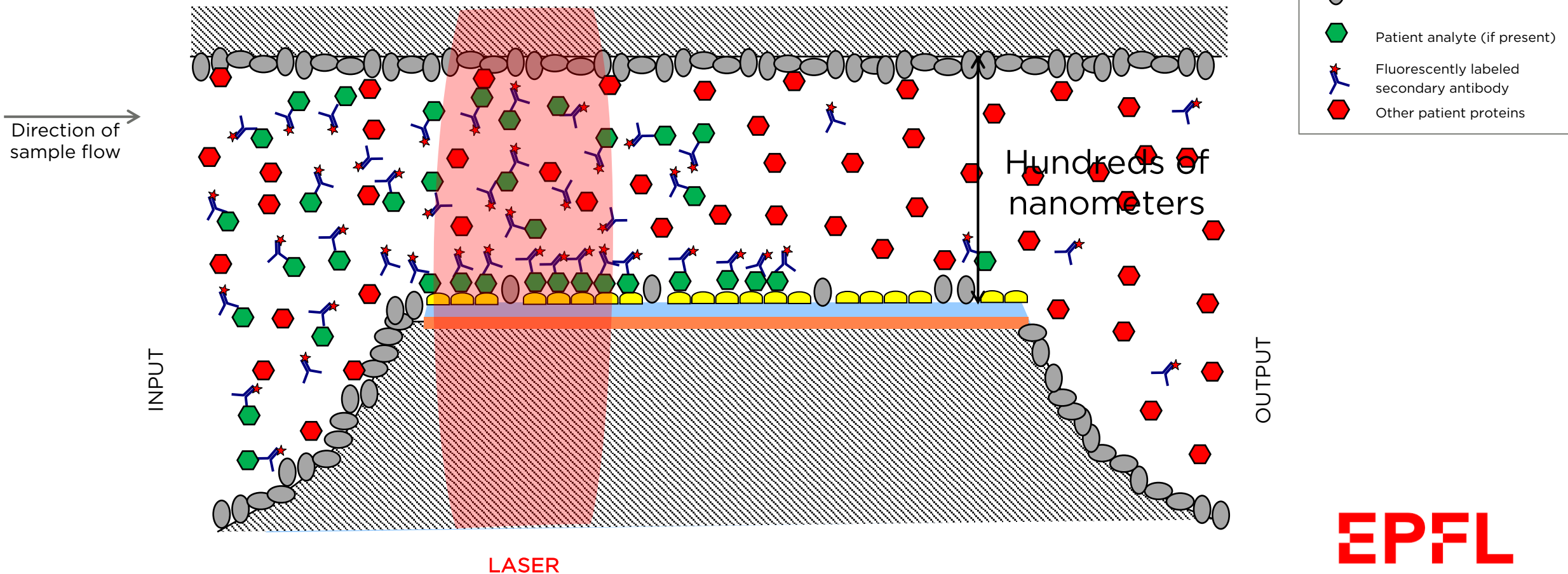
○ Molecule + Secondary fluorescent antibody

- Average traveling distance to capture antigen: 500nm<sup>(1)</sup>
- Incubation time: 2 minutes
- No washing step thanks to a patented confocal & photobleaching signal processing

In Abionic's FIA, antigens are forced into nanochannels, reducing travel distance and incubation time to **2 minutes**

# Abionic's technology revolutionizes ELISA tests

## Nanofluidic biosensor lateral view:



# Our products: The abioSCOPE and its capsules



# WHO's ASSURED Challenge

Diagnostics should be:

- **A**ffordable by those at risk of disease
- **S**ensitive
- **S**pecific
- **U**ser-friendly
- **R**obust and rapid
- **E**quipment-free
- **D**eliverable



World Health  
Organization

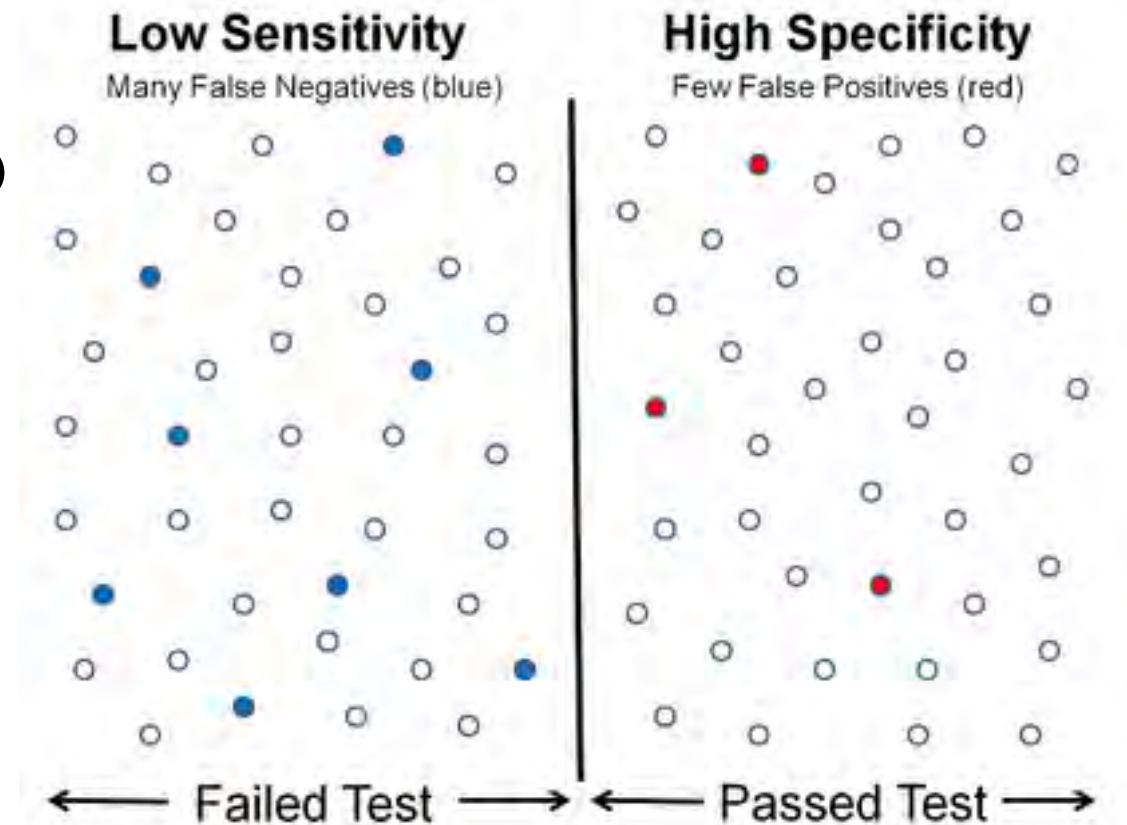




# WHO's ASSURED Challenge

Diagnostics should be:

- **A**ffordable
- **S**ensitive (few false-negative results)
- **S**pecific (few false-positive results)
- **U**ser-friendly
- **R**obust and rapid
- **E**quipment-free
- **D**eliverable



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# WHO's *ASSURED* Challenge

Diagnostics should be:

- **A**ffordable
- **S**ensitive
- **S**pecific
- **U**ser-friendly (simple to perform with little training)
- **R**obust and rapid
- **E**quipment-free
- **D**eliverable



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Organization

# WHO's *ASSURED* Challenge

Diagnostics should be:

- **A**ffordable
- **S**ensitive
- **S**pecific
- **U**ser-friendly
- **R**obust and rapid (<30min)
- **E**quipment-free
- **D**eliverable



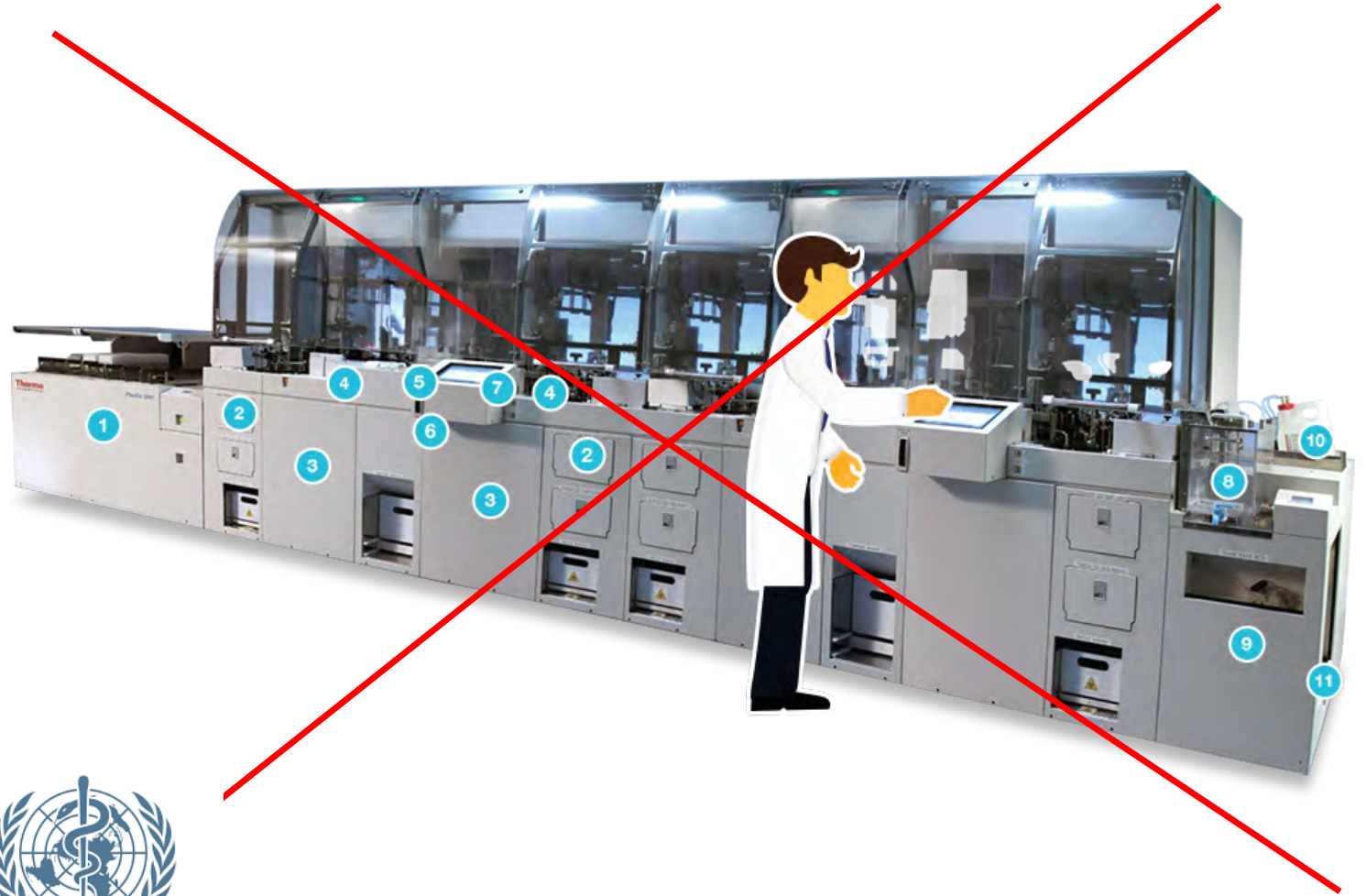
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# WHO's ASSURED Challenge

Diagnostics should be:

- **A**ffordable
- **S**ensitive
- **S**pecific
- **U**ser-friendly
- **R**obust and rapid
- **E**quipment-free
- **D**eliverable



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# WHO's *ASSURED* Challenge

Diagnostics should be:

- **A**ffordable
- **S**ensitive
- **S**pecific
- **U**ser-friendly
- **R**obust and rapid
- **E**quipment-free
- **D**eliverable to those who need them



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# WHO's *ASSURED* Challenge

Diagnostics should be:

- **A**ffordable
- **S**ensitive
- **S**pecific
- **U**ser-friendly
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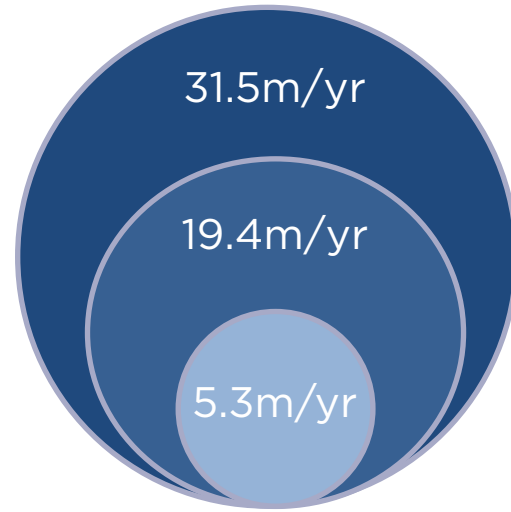
That's our  
objective at  
 abionics



World Health  
Organization

# ☾ The abioSCOPE: a life-saving device

**Sepsis:**  
Right  
treatments  
but too late



- There are 31.5m sepsis cases per year
- Of which, 19.4m severe sepsis cases per year
- Resulting in 5.3m fatalities per year

**Abionic's solution  
impacts millions of  
lives worldwide**

☾ **abionic**

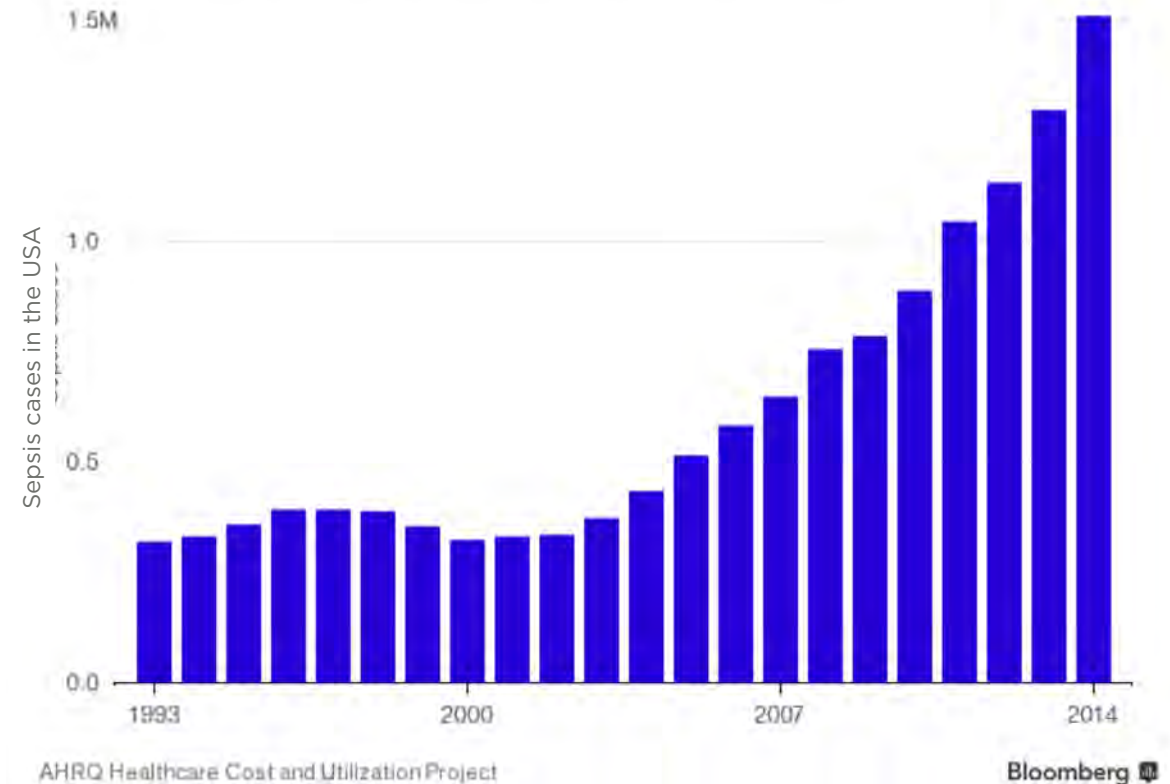




# ☾ Sepsis market

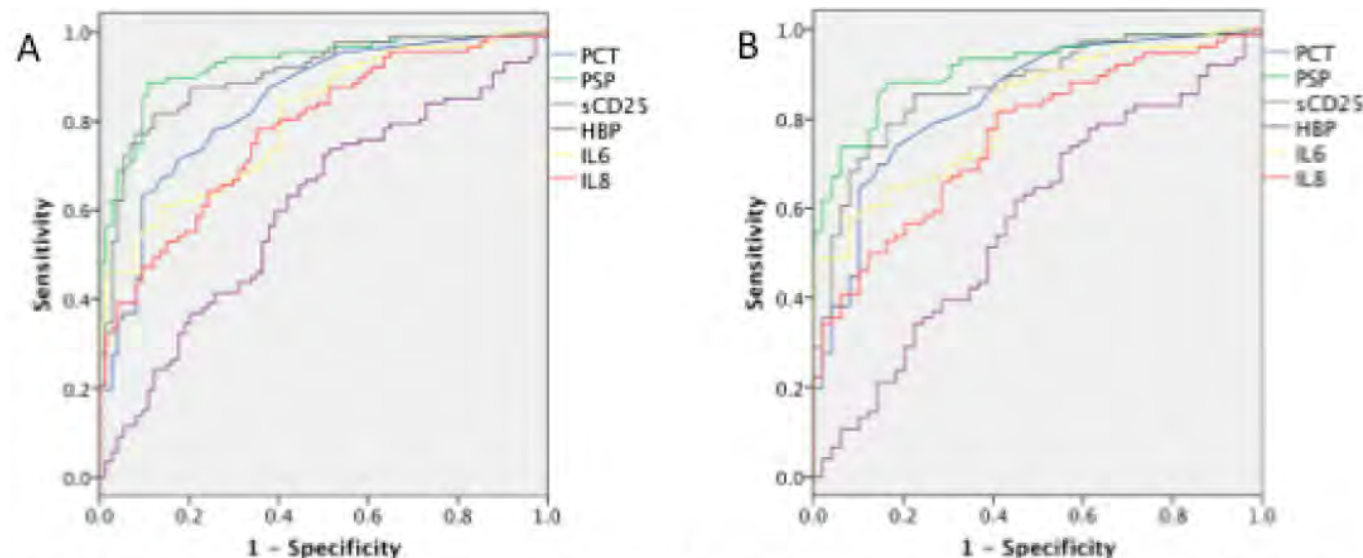
- Every **3 seconds** someone dies from sepsis
- Mortality increases **8% every hour** that the treatment is delayed.
- Sepsis causes more deaths than prostate cancer, breast cancer and HIV/AIDS combined.
- If diagnosed with sepsis and treated in the 1st hour, the patient has more than 80% survival rate.

**Hospital Stays for Sepsis Appear to Be Rising Dramatically**  
Experts say cases of sepsis may have been undercounted for years



# What are the best biomarkers to identify sepsis?

PSP is slightly better than the other biomarkers



**Table 3 Diagnostic performance of biomarkers.**

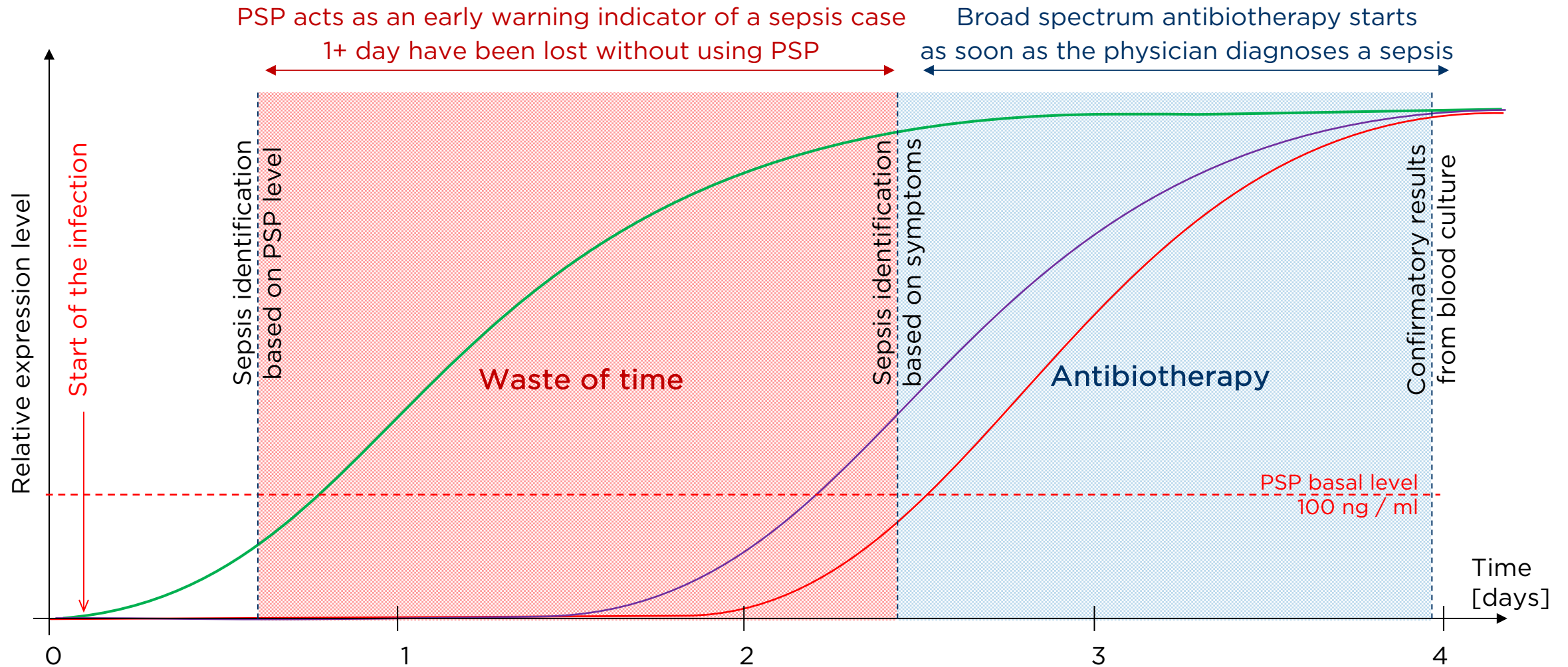
Marker	AUC (95% CI)	Cut off	Sensitivity	Specificity	PPV	NPV
PCT	0.84 (0.78 to 0.90)	1.0 ng/ml	71%	82%	83%	71%
→ PSP	0.93 (0.89 to 0.97)	30 ng/ml	90%	83%	86%	87%
sCD25	0.90 (0.85 to 0.95)	2.5 ng/ml	83%	83%	85%	81%
HBP	0.60 (0.52 to 0.69)	50 ng/ml	78%	36%	59%	59%
IL6	0.81 (0.74 to 0.87)	200 pg/ml	68%	68%	71%	65%
IL8	0.78 (0.71 to 0.85)	80 pg/ml	78%	63%	71%	71%
IL1 $\beta$	0.76 (0.69 to 0.84)	1.0 pg/ml	61%	88%	86%	69%

Biomarker performance is shown for 162 patients in distinguishing sepsis ( $n = 87$ ) from SIRS without an infective aetiology ( $n = 75$ ) Data for GMCSF and TNF $\alpha$  are not shown as only a minority of patients had detectable levels of these markers.





# PSP is raising 1+ day before the other biomarkers



# European sepsis observational impact study



Dr. Marlies Ostermann, London

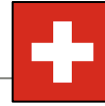
Guy's & St  
Thomas' Hospital

Dr. Ben Creagh-Brown, Guildford

Royal Surrey  
County Hospital

Dr. David Brealey, London

University College  
London Hospitals



Dr. Jérôme Pugin, Geneva

HUG  
Hôpitaux  
Universitaires  
Genève

Dr. Jean-Luc Pagani, Lausanne



Dr. Yok-ai Que, Bern

INSELSPITAL



Dr. Thomas Daix, Limoges



Dr. Pierre-François Dequin, Tours



Dr. Alain Lepape, Lyon



Dr. Christophe Guitton, le Mans



Dr. Giuseppe Nardi, Rimini

Ospedale  
Infermi

Dr. Alberto Garelli, Ravenna

Santa Maria  
delle Croci

Dr. Daniela Silengo, Torino

Ospedale San  
Giovanni Bosco

Dr. Angelo Giacomucci, Perugia

Santa Maria  
della Misericordia



Principal Investigator:  
Dr. Bruno François  
(CHU Limoges, France)

# Immunoassays (PSP) vs Molecular tests

## Examples:

PSP level is pointing out a severe sepsis situation in 5 minutes at the Emergency Department.



Patient will receive large-spectrum antibiotics and will be sent to ICU.



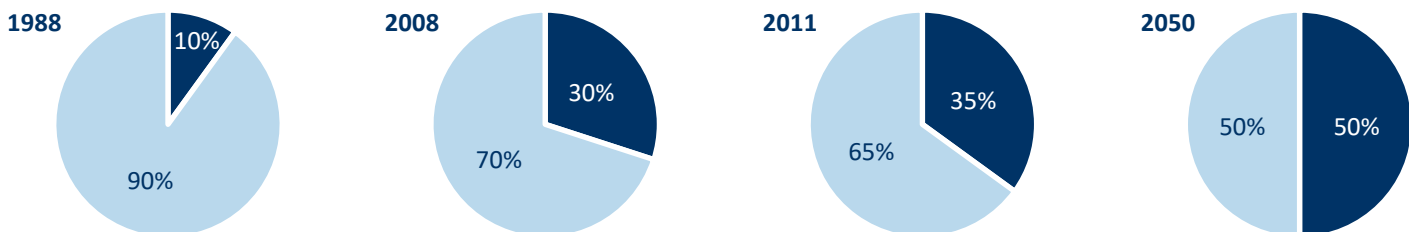
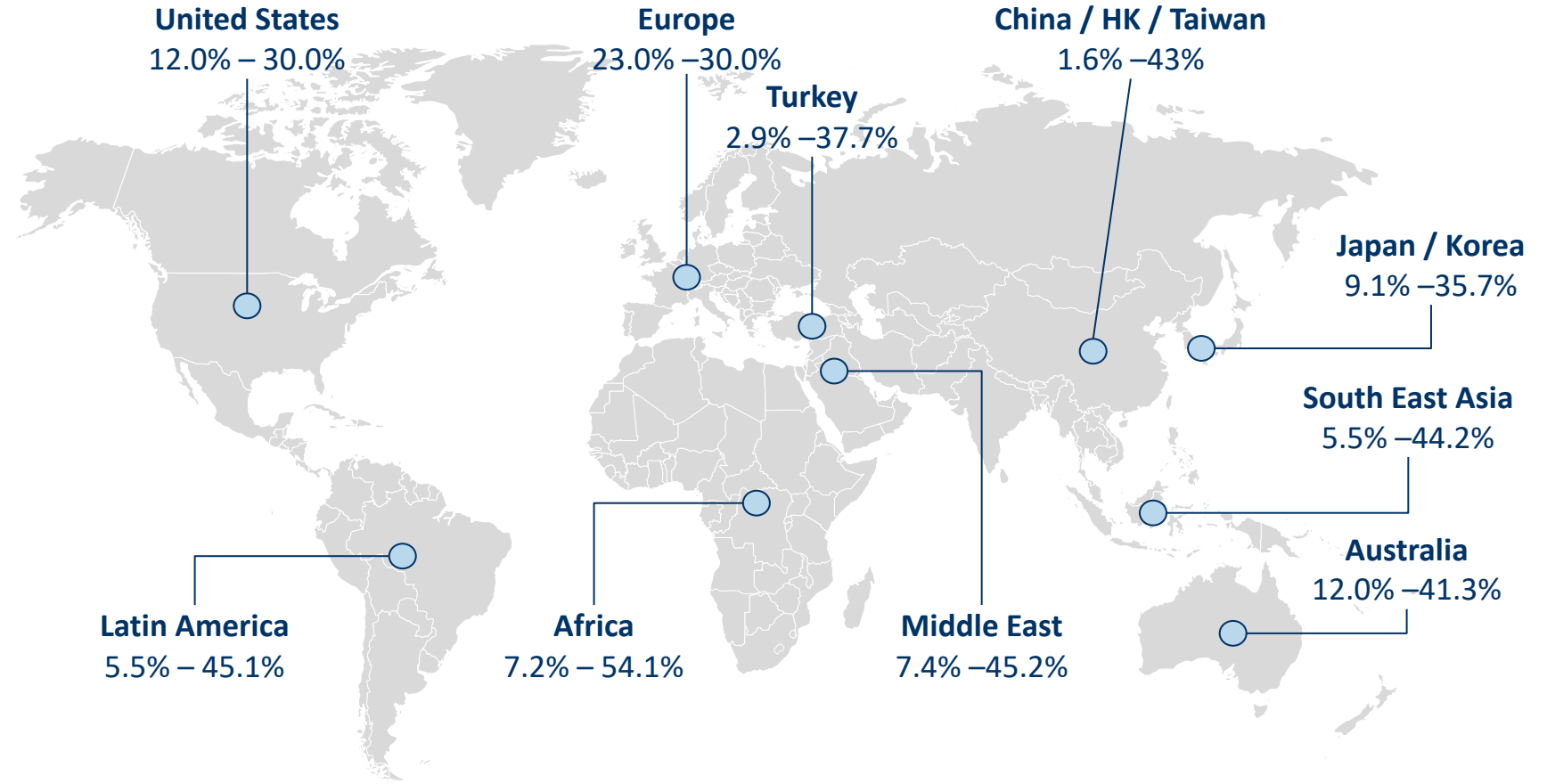
Molecular test will identify the pathogen in 6 to 8 hours at the laboratory.



Antibiotherapy will be narrowed according to the pathogen.

**MDs need both information**







# Increasing allergy prevalence rates worldwide



Source: World Health Organization



# abioSCOPE gathers all positive features from skin prick tests and immunoassays

	 Skin prick test	 Immunoassay	 abioSCOPE
Location	Point of care	Central laboratory	Point of care
Volume of blood	In vivo test	10ml	One single blood drop (50µL)
Ease of use	Test performed by physician	Skilled operators required	Test performed by assistants
Nature of results	Qualitative / Binary	Quantitative	Quantitative
Reliability	Poor accuracy	Gold-standard level	Similar to Immunoassay
Time to results	Within a single visit	Days	< 5 minutes
Cost per test	Low	High	In line with reimburs. policies
Physician's margin	High but need time	Zero-margin operation	High margin captured
Customization	1 test required per allergen	Highly customizable	Highly customizable
Throughput	Low	High if significant volumes	High
	 Most frequent approach, allowing physicians to perform a complete diagnostic and a drug prescription within 1 visit, while capturing the margin, despite risk of misdiagnosis	 Gold-standard test, but limited market penetration given significant time to results (patient has to plan a second visit) and low profit margins for physicians	 Abionic's platform is ideally suited to address the technology gap currently faced by physicians, outperforming immunoassay and skin tests

# CHUV clinical diagnostic comparison

	n	P	N	D	% Agreement
Cat dander	105	36	68	1	99.1
Grass pollen	105	52	50	3	97.1
Birch pollen	105	41	59	5	95.2
Dog dander	105	10	87	8	92.4
House dust mite	105	30	67	8	92.4
<b>Overall</b>					<b>94.6</b>

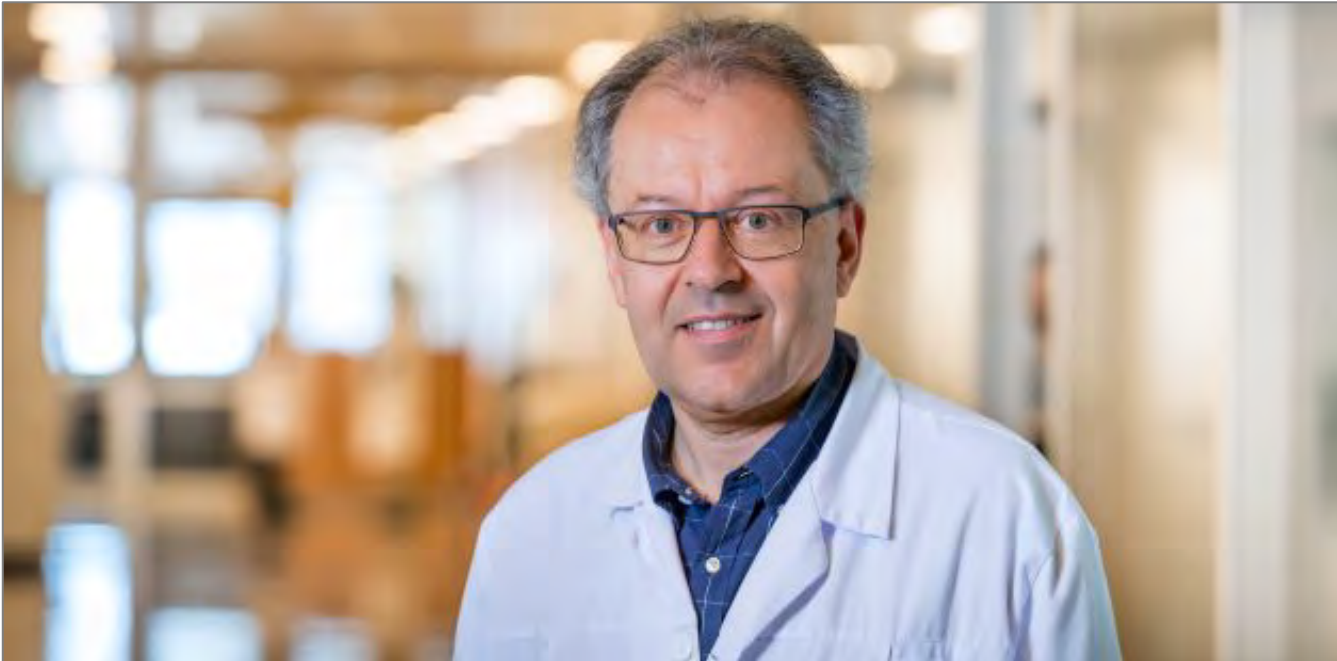
**Table 2.** Positive and Negative Percent Agreements (PNA, NPA) calculated in function of diagnostic made by Expert panel who had nanofluidic assay (NFA) sIgE or reference method (RM) sIgE. Number of patients for who the Expert panel agreed that the patients was sensitized (P) or not sensitized (N) to a given allergen. Diagnostic discrepancies within expert panel is represent by D. Total number of patients was 105

- The overall agreement in clinical diagnosis decision taken by the Expert panel was 94.6% (ranging from 92.4% to 99.1% depending on the test)
- This clearly highlights that using the abioSCOPE results in similar clinical decision-making process compared to using the reference method.



## Principal investigator statement

“The abioSCOPE offers immediate access to molecular allergology, thus providing an aid to the diagnosis of allergies and faster access to the right treatment. The tests my team and myself have performed on the abioSCOPE convince me that its performance fills an unmet need”.





**Prof. Dr. François Spertini**

Head of Allergology and Immunology  
department

State Hospital Vaud (CHUV),  
Switzerland

# Diagnostic devices registration



abionic		Switzerland 	USA 
Regulation	International regulation & norms	CE, Class I, II, III, IVDR (Directive 98/79/EC)	CFR 866.5750
		ISO 13485	CFR 21 Part 820
	Audit by notified body and competent authority	SGS, SQS, Tüv, BSI, etc. + Swissmedic	Food and Drug Administration (FDA)
Market access	National registration by competent authority	Swissmedic	Food and Drug Administration (FDA)
	Reimbursement	Swiss government & insurances	Medicare, Medicaid, private sector, etc.

Very long complex process...



# ☾ Diagnostics in France



# Scandals prevention



2011

2010

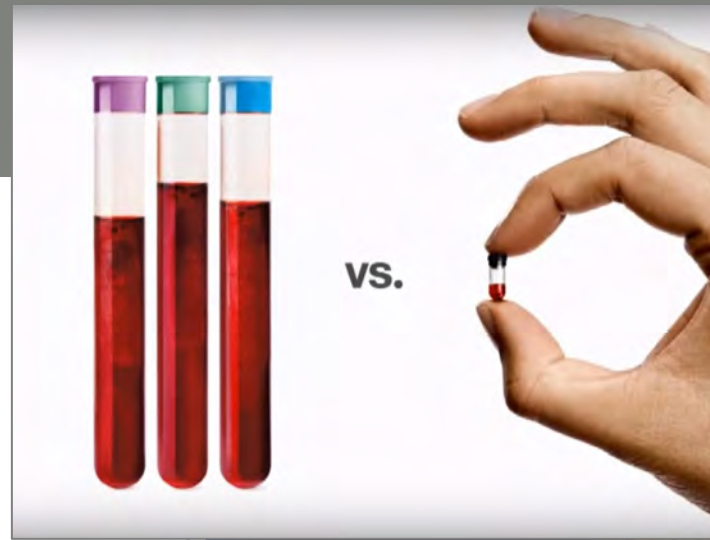




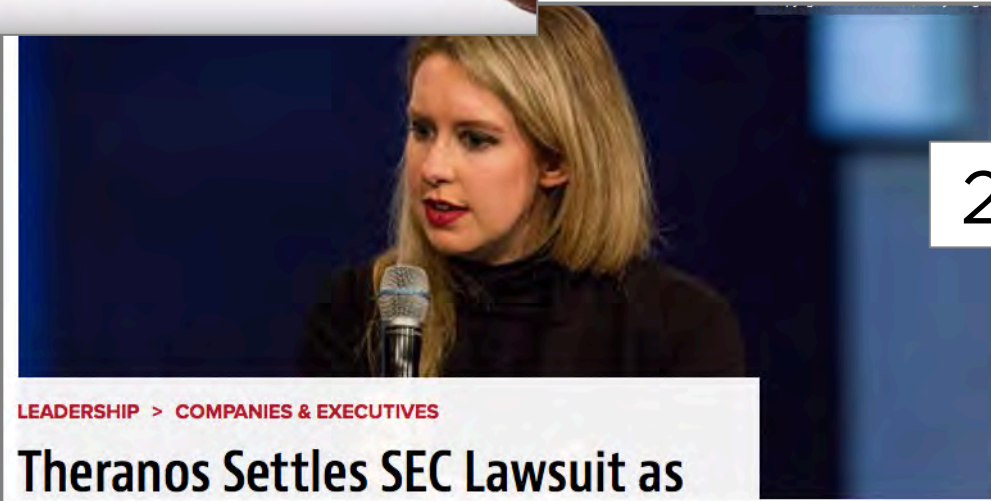
# Scandals prevention

theranos

2013



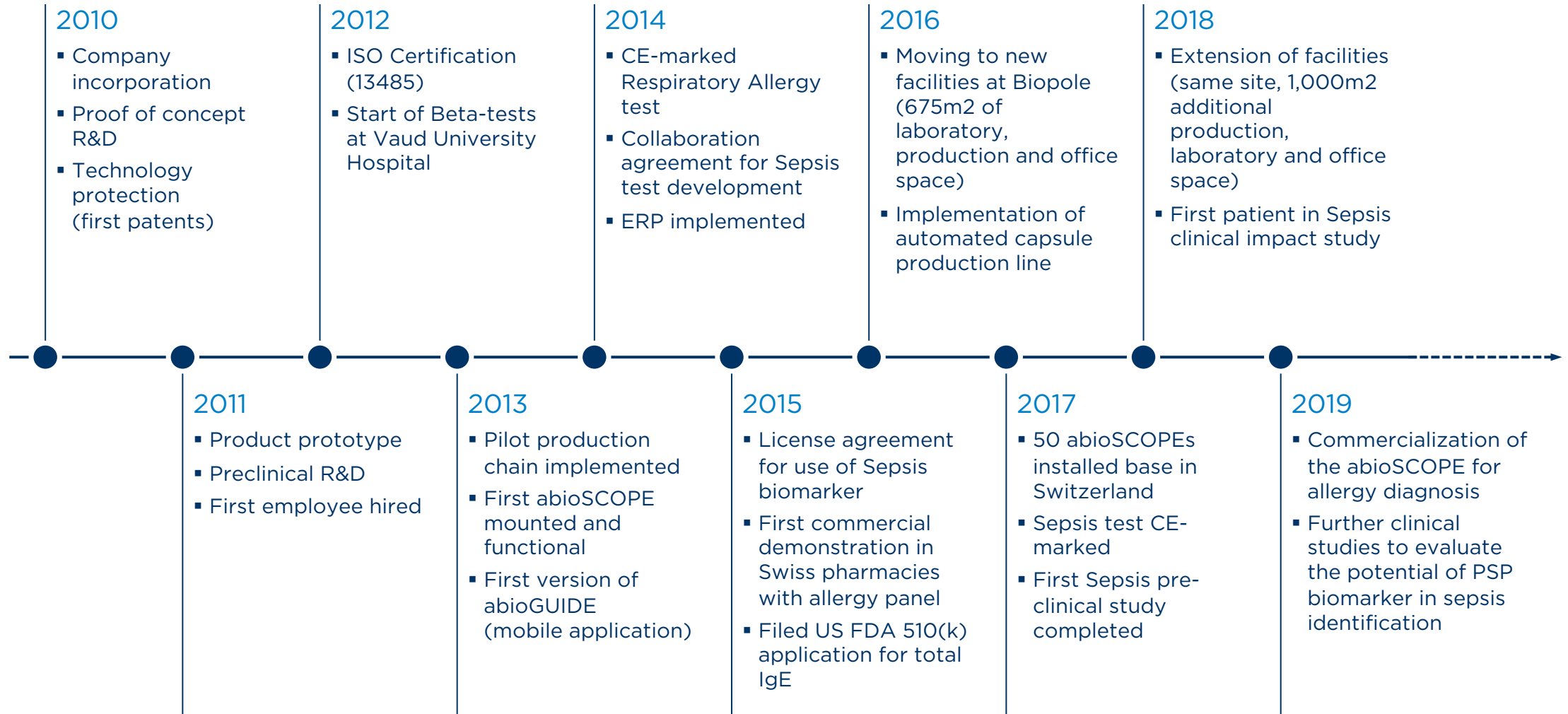
2018



LEADERSHIP > COMPANIES & EXECUTIVES  
**Theranos Settles SEC Lawsuit as CEO Holmes Stripped of Control**

Elizabeth Holmes, CEO of Theranos, agreed to pay a \$500,000 penalty to resolve the case, surrender voting control of Theranos, and be barred from serving as an officer of a public company for 10 years.

# Abionic's journey





# Conclusion

The future of diagnostics is a hi-tech Patient-centered medicine





NANOTECHNOLOGY COMMITTED TO HEALTH

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