

# FUTURE PROOF HEALTHCARE

A sustainable healthcare for a new generation

## Company presentation

Life Science Investor Conference – 2023/04/19

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Q-LINEA 

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Headquarters, Marketing and demo lab, Consumable production in Uppsala

## Q-linea highlights



**Q-linea is developing disruptive solutions for faster infectious disease diagnostics, first product targeting sepsis**

**Planning & implementation of new commercialisation strategy**

Signed distribution agreements for the UK & Polish market

Building commercial organisation in the USA and Italy

Actively participating in several customer evaluations

**Progress toward US market**

Additional testing ongoing for the 510(k) application

Goal is to submit data in June

**Q-linea participates in several customer driven evaluation ASTar in Europe**

**Lead product ASTar®**



CE IVD

USD FDA  
Breakthrough device  
510k submitted in June



**EU-IVDR**

Q-LINEA 

# Q-linea facilities & staff

Headquarter, management, finance, HR & R&D



Commercial, training & demo



Consumable production and Instrument release





# Unique technology enables disruptive expansion pipeline & commercial opportunities

## Blood culturing

TRADITIONAL TECHNOLOGY



### Podler®



**Portable blood culturing and readout.** Equally fast as current state-of-the art stationary cabinets\*. But use transportation time for fastest TTR. **Next big leap in blood culturing...**

Q-LINEA TECHNOLOGY

## Identification

### Mass spec



### Molecular



### ASTrID®



**Highly multiplexed molecular ID analysis followed by AST**

Proof-of-principle: **>25 plex** pathogen analysis **direct** from venous blood. Patient study.

## Susceptibility testing



### ASTar®



CE-IVD, BC G-



### ASTrea™



POC

Proof-of-principle 45 min AST for urine analysis

Q-linea technology is covered by 24 patent families

## Urgent need for improved infectious disease diagnostics

### **Sepsis is the most common cause of death in our hospitals**

More common than lung + prostate + breast-cancer **combined**

Accounts for approximate 30% of all deaths in the hospital

Most expensive condition to treat in the US. >27B USD<sup>1)</sup>

### **Time to correct treatment is critical!**

7.6% decrease of survival rate for every hour of delay of effective therapy<sup>2)</sup>

Improved diagnostics needed today and for future generations

**Antimicrobial resistance is dramatically increasing**

Today treatment of infections is difficult due to bacterial resistance

**Treatment is based on assessments (empiric) not on diagnostics**

**Many treatments are ineffectual or unnecessary**

Has been presented as

**“Greatest threat to mankind”**

# ASTar – designed to save lifetimes

Developed together with our future customers

## Easy to use

- Fully automated
- ~2 min hands-on time
- Load-and go workflow

## Fast

- Results in ~6 hours
- High throughput
- 12 samples in parallel



## Comprehensive

- Large antibiotic panel
- Long concentration ranges
- Fastidious and non-fastidious bacteria
- Support additional samples (*e.g.* urine)

## Accurate

- True MIC results
- High reproducibility

**ASTar classified as a breakthrough device by the FDA**

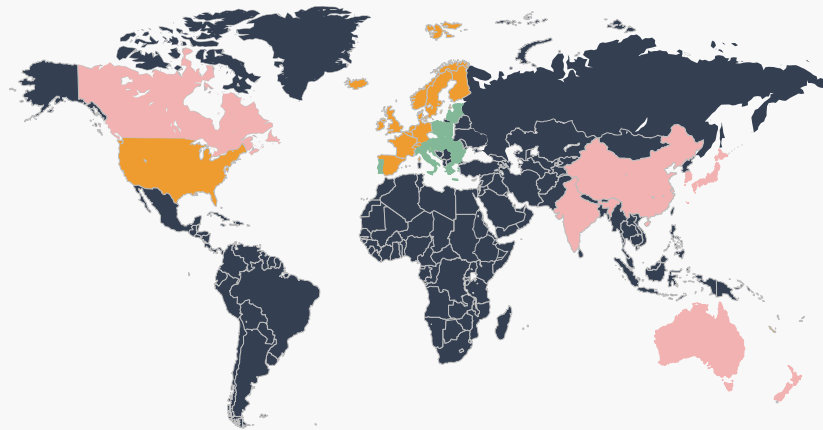


# Large addressable market for rapid AST diagnostics instruments

ASTar has several potential target markets

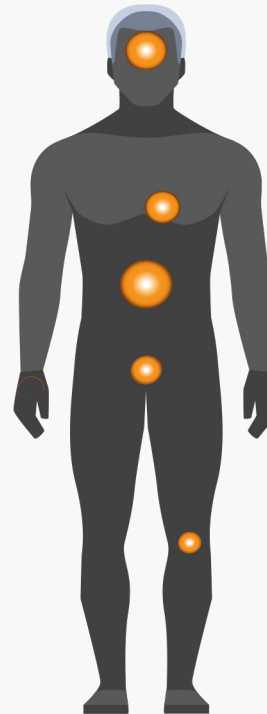


## Sepsis

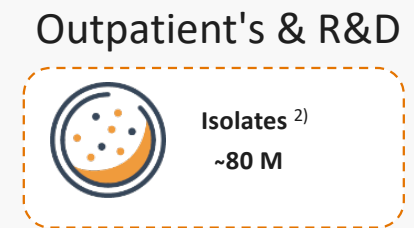
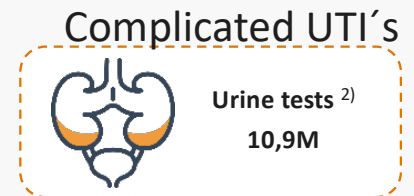


Key: ■ Primary markets ■ Other interesting markets ■ Markets recognizing CE/IVD marking

## Number of Antimicrobial Susceptibility Tests for *in vitro* diagnostics



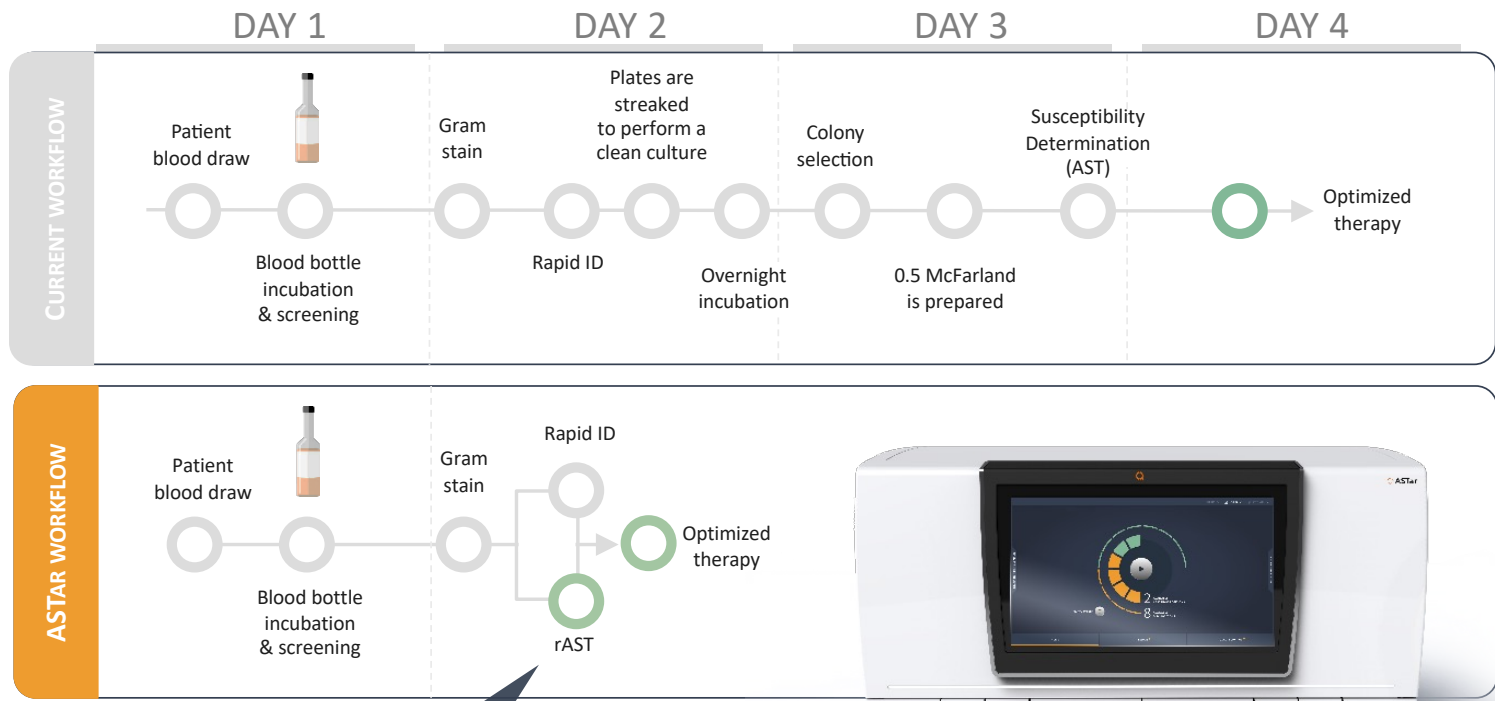
## LRTI



1) Blood from positive blood culture. Source: Management account on estimated annual addressable market volume, US + CE + APAC,

2) Management account on estimated annual addressable market volume, US + CE

# Up to 48 hours faster actionable results



Time to Actionable results is what matters for septic patients

A broad panel, >25 antibiotics  
Enable start of AST AND ID at the same time



# ASTar makes a difference in patient outcome

Patient-case from first commercial evaluation in Sweden

## Patient

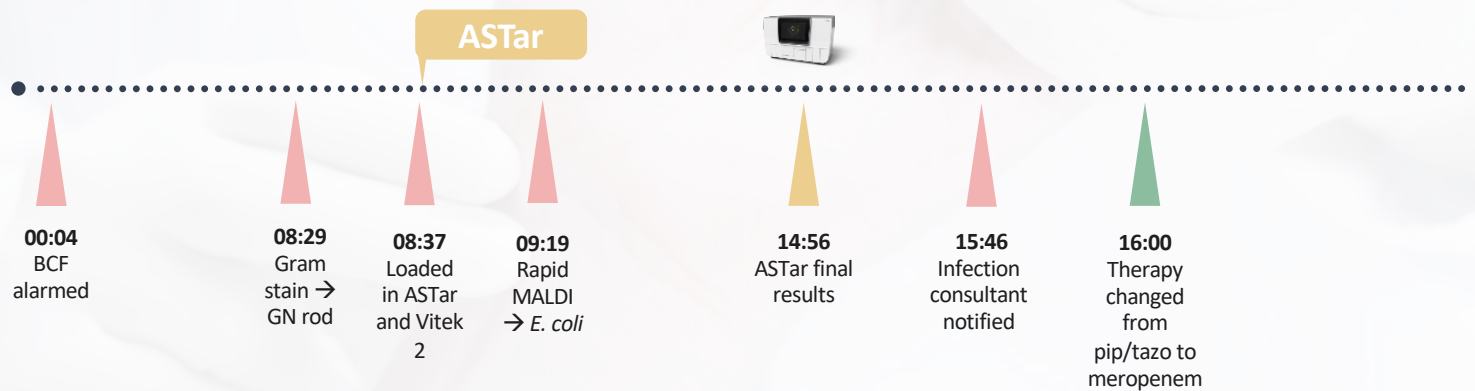
- Man, 64, surgery department
- Empiric treatment  
Piperacillin/tazobactam

## ASTar results

- ASTar results **at least 18 h earlier** than Std-AST.
- MIC results from **13 additional antibiotics**
- Resistant against initial treatment (pip/tazo)

## Timeline

Day 1



# Health economic benefits of faster **24 hours** faster diagnostics

## Lower mortality

Up to 40%  
lower mortality rates<sup>1)</sup>

## Less pressure for resistance and superinfections

Up to 25%  
reduction of *C. difficile*  
infections<sup>2)</sup>

## Cost savings

~\$2,500 – \$20,000  
cost savings per patient<sup>3)</sup>



ASTar can provide **up to 48 hours** faster diagnostics

Source: 1) Patel et al, *J Clin Microbiol.* 2017 Jan; 55(1): 60–67., ECCMID 2017, poster OS1033, Andreassen et al. Cost-effectiveness of MALDI-TOF and rapid antimicrobial susceptibility testing for high-risk patients, Huang et al. *Clin Infect Dis.* 2013 Nov; 57(9): 1237-45. 2) Fridkin et al, *MMWR*, 2014;63(9), 194-200. 3) Perez et al, *Arch Pathol Lab Med* 137:1247-1254, 2013, Perez et al *J Infect.* 2014 Sep;69(3):216-25, 2014, Bauer et al *Clin Infect Dis* 51:1074-1080, 2010. ) Patel et al, *J Clin Microbiol.* 2017 Jan; 55(1): 60–67.

## ASTar performance is strong and it is easy to use

*Evaluation of commercial systems for rapid antimicrobial susceptibility testing (rAST) of positive blood cultures: Comparison of susceptibility results*

View Sheffield Hospital's scientific poster presentation from ECCMID 2022, featuring the ASTar System.

***ASTar's panel covered 95,4% of all organisms included in the study.***

**“ASTar fits right into our processes and systems”**

Robert Price, Senior Biomedical Scientist, Whiston Hospital, UK



*Large multicentre evaluation in Germany and UK.*

*Covered 500 ASTar determinations on routine clinical samples. Compared against both Sensititre™, Vitek® and multipoint.*

***ASTar's panel covered 98,7% of all organisms included in the study.***

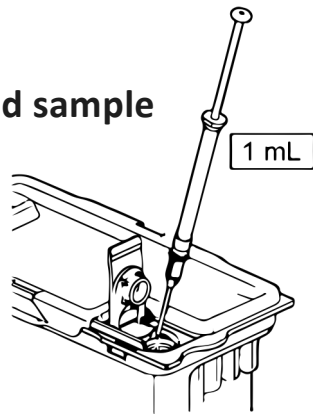
***Essential agreement (EA) >96,6%.***



# ASTar enables anyone at the lab to load samples anytime

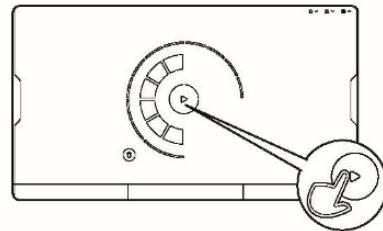
User friendly  
& 24/7 availability

Add sample

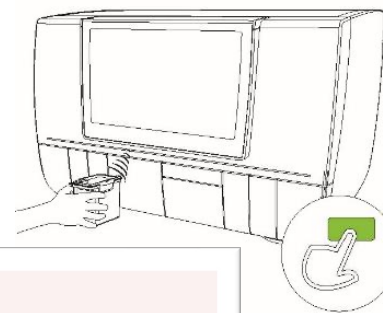


1 mL

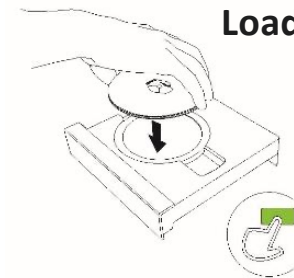
Click "start"



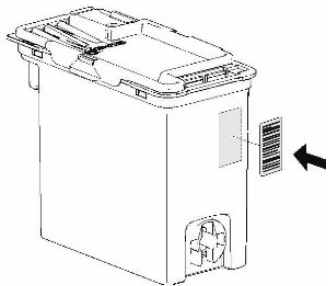
Scan barcode



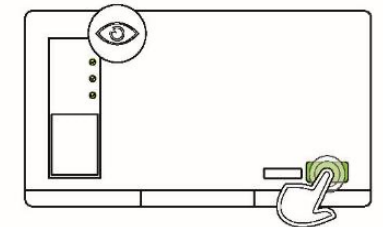
Load AST disc



Add sample  
barcode



**”**  
**User testimonial;  
How ASTar has helped  
save time in the lab**  
Listen to Ehsan Ghaderi, Head of Dept,  
and Sofia Persson, Consultant  
Physician, Bacteriology, Uppsala  
University Hospital, Sweden



Click "Start run"

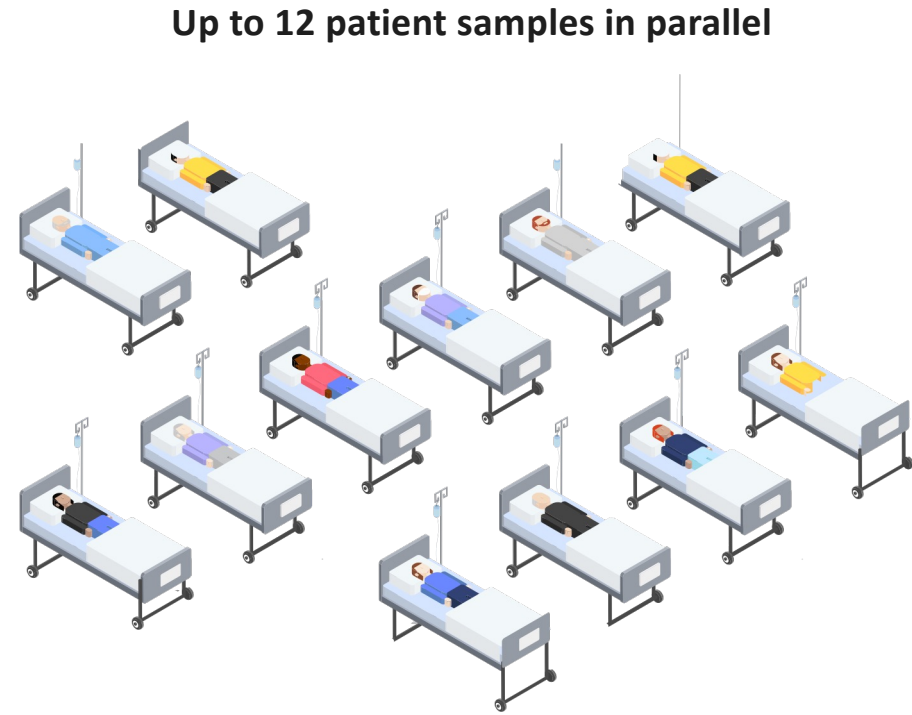
# High throughput and flexible solution

Our ambition was the most user friendly and capable system

High throughput & flexible



=



Fully automatic    Semi automatic






Consumables stored at room temp and a small insert at -20°C.

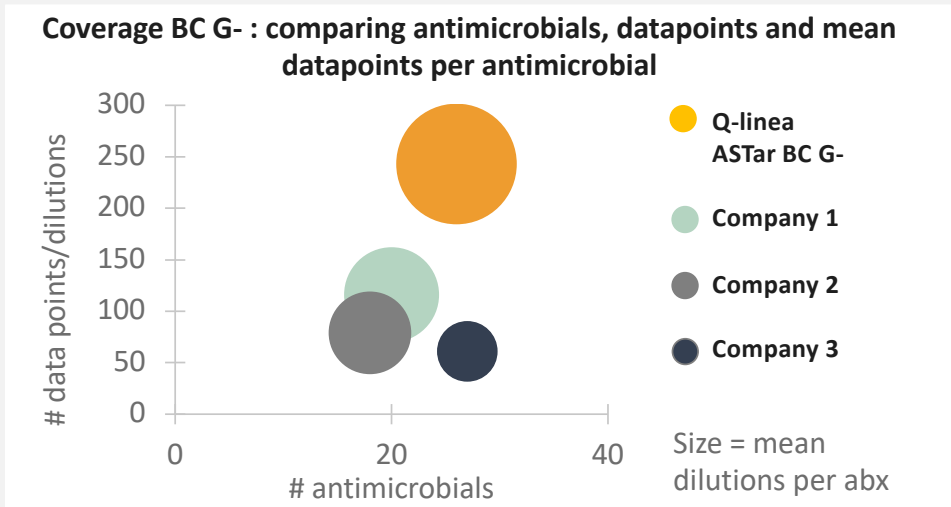
Compatible with small and large (e.g. urine) sample volumes, and to run isolates separately

# Excellent and accurate data from the CE-IVD clinical study

Broadest panel enabling actionable results

FDA and ISO requirements <sup>1,2)</sup>		
Essential agreement = Same MIC value as reference		
FDA	ISO	Q-LINEA 
89.9%	90%	<b>94.7%<sup>3</sup></b>
Categorical agreement = Correct treatment recommendation		
FDA	ISO	Q-LINEA 
89.9%	90%	<b>97.6%<sup>3</sup></b>
Reproducibility		
FDA	ISO	Q-LINEA 
95%	95%	<b>99.6%<sup>3</sup></b>

The ASTar<sup>®</sup> Instrument and ASTar<sup>®</sup> BC G- Kit offer the **broadest combination of antimicrobials and dilution ranges** in a single analysis for Gram-negative bacteria <sup>6</sup>. The analysis also **delivers true MIC results**.



16 Source: 1) ISO 20776-2, Clinical laboratory testing and in vitro diagnostic test systems — Susceptibility testing of infectious agents and evaluation of performance of antimicrobial susceptibility test devices: - Part 2: Evaluation of performance of antimicrobial susceptibility test devices 2) Guidance for Industry and FDA Class II Special Controls Guidance Document: Antimicrobial Susceptibility Test (AST) Systems, August 28, 2009, FDA document number 631.3) Company results from CE-IVD clinical study for BC G-, Gram negative antibiotic panel 2020-05-04 6) Based on commercially available systems market overview May 2021



# Updated commercialisation strategy – first stage in 2023

Initially focus on key geographies in Europe and East coast in the USA & at the same time manage costs

**Goal is to demonstrate ASTar commercially & Enable a strong ramp-up in 2024**



## USA – Q-linea Inc.

**Most important market due to size and demonstrated to be more mature for rAST than Europe**

**Pre-FDA evaluations in discussions with two hospitals**

**Will be approached using internal sales force & regional office**

## UK

**Important market due to size and sepsis awareness**

**Will be approached using distributor**



## Italy – Q-linea S.r.l

**Important market due to size and demonstrated interest of ASTar**

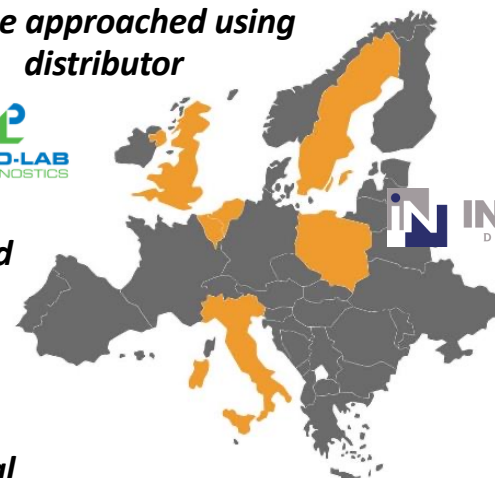
**Base for first HEOR study**

**Will be approached using internal sales force & regional office**

**Benelux**  
**Important market due to market leading KOL's**

**PK/PD driven antibiotic treatment**

**Will be approached using internal sales force, but no regional office**



## Poland

**Large focus on sepsis in 2023**

**Will be approached using distributor**



Time to actionable result is what matters for  
septic patients

What if time  
wasted could be  
time used?

Equal and better  
care for everyone

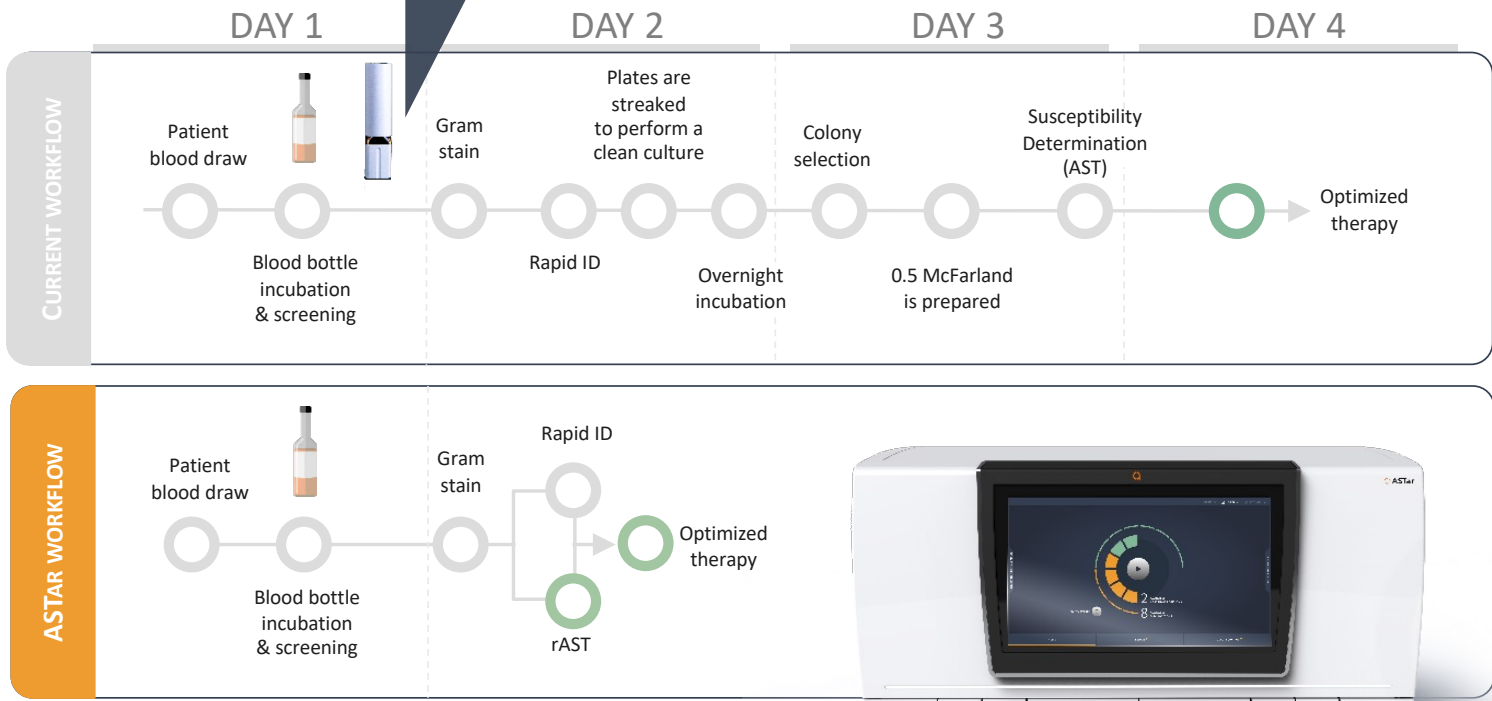
We aim to transform infectious disease  
diagnostics

Q-LINE



# Up to 48 hours faster actionable results

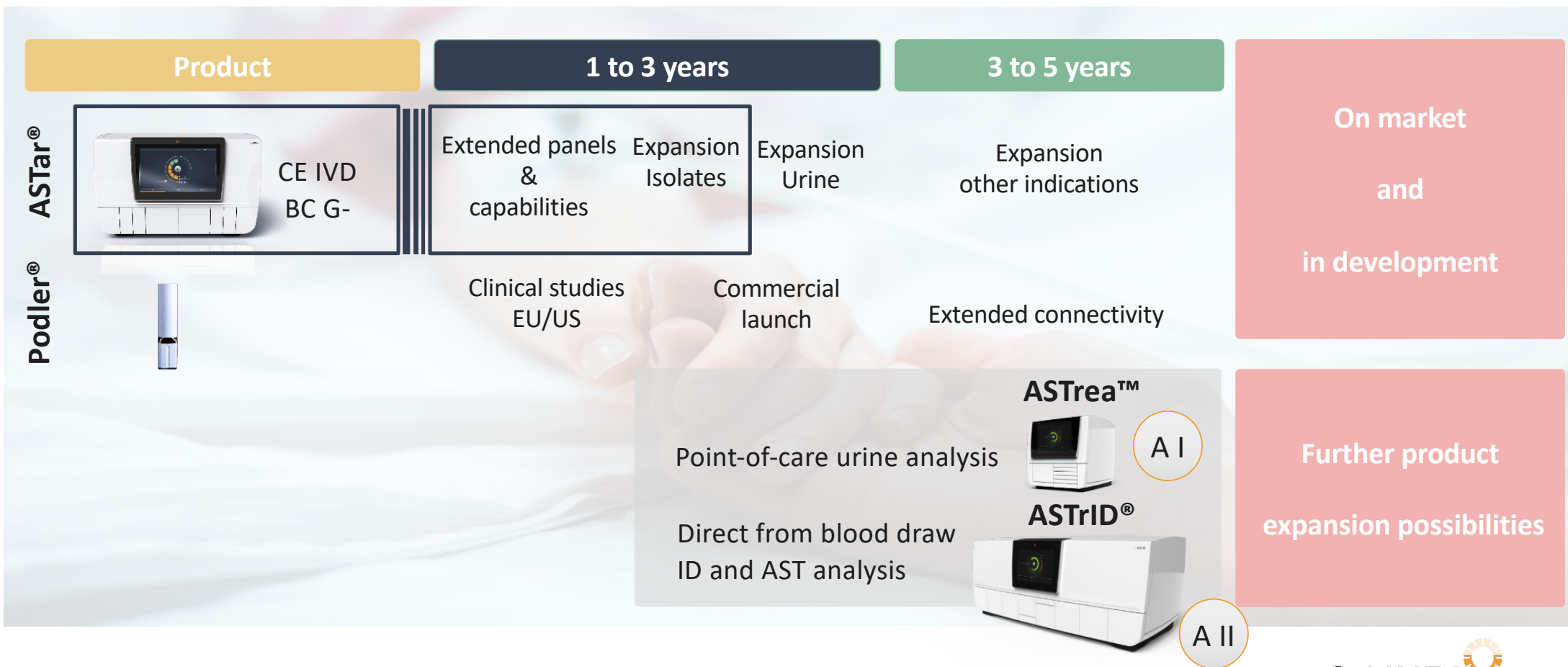
Transportation of blood culture from patient to laboratory:  
1 – 24+ hours

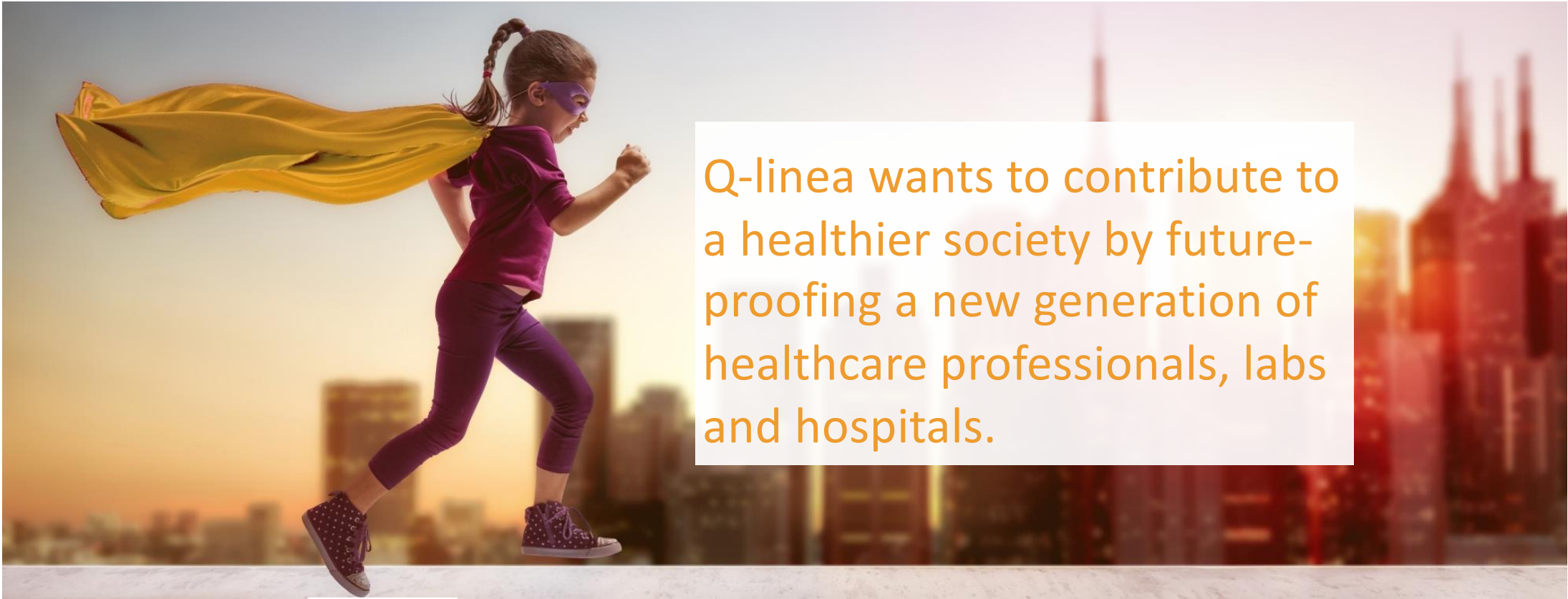


Time to Actionable results is what matters for septic patients



# Unique technology enables disruptive expansion pipeline & opportunities





Q-linea wants to contribute to a healthier society by future-proofing a new generation of healthcare professionals, labs and hospitals.

**Thank you**