



Q-LINEA

Presentation for AGM 2022

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Q-linea 2021



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

146 beginning of 2021 to 173 employees & consultants at year end

Achieved CE-IVD for first application for ASTar, May 4th 2021

Thermo Fisher Scientific launched ASTar 15 October 2021

Very strong results from commercial evaluation of ASTar

Thermo Fisher Scientific has presented ASTar at two trade shows (KMIS, RICA) with good response

Large interest from customers

Positive development of the portable culturing technology

Excellent results on prototypes supports game-changing for blood culturing

Discussions with potential partners for Podler[®] started

Lead product ASTar[®]



Q-LINEA 

Q-linea facilities & staff

Consumable production and Instrument release

Headquarter, management, finance & R&D



Commercial, training & demo



Research, development & production in Uppsala Sweden

Why is improved infectious disease diagnostics important?

Sepsis

Leading cause of death in U.S. hospitals¹⁾
#1 hospitalization cost in the US with over \$24bn yearly³⁾

Kills >500,000 people yearly in the EU and US²⁾
Every 3 seconds someone dies of sepsis worldwide

~50% of all patients receive inappropriate treatment
~20% dies before current diagnostic provide results

Rapid diagnostics could reduce mortality with up to 40%⁴⁾

AMR

Antimicrobial Resistance

Has been presented as
“The biggest threat to mankind”

Rapid diagnostics would reduce unnecessary prescription
>65 % of all prescribed antibiotics for respiratory issues are unnecessary⁵⁾

Deaths due to AMR⁵⁾
In 2016, ~700 000 died
In 2050, 10 000 000 are expected to die if we do not act now

Source: 1. JAMA. 2014;312(1):90-92. 2. Clinical Infectious Diseases. ciy342, <https://doi.org/10.1093/cid/ciy342>, Fleischmann et al, Am J Respir Crit Care Med. 2016 Feb 1;193(3):259-72, Company estimates 3. <http://www.hcup-us.ahrq.gov/reports/statbriefs/sb204-Most-Expensive-Hospital-Conditions.pdf>. 4. 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. 5. Tackling drug-resistant infections: Final report and recommendations. Review on Antimicrobial Resistance. Web. 2016

An overview of 2021, accomplishments & achievements

Q1

Presented strong interim results from the CE-IVD study

**Essential agreement (EA) over 94%,
Categorical agreement (CA) over 97 %,
Overall reproducibility over 99%,**

First order from Thermo Fisher Scientific
Value of first order > 8 million SEK

Q2

**ASTar receives CE-IVD approval for first product
Gram negative bacteria in BSI**

Excellent data
Broad coverage
Strong usability feedback

US clinical study for ASTar started in June

Successful directed share issue
Gross proceeds of 301 million SEK

Thermo Fisher Scientific launched ASTar in Europe 15 October

**Q-linea performed ASTar evaluation at a Swedish Regional
Hospital**

ASTar outperformed traditional care by providing same
shift results

ASTar enabled rapid escalation on critically ill patient >
18 hours faster

ASTar changed therapy for a patient for the first time Q4

**Commercial evaluation study performed by Thermo
Fisher Scientific at several European sites**

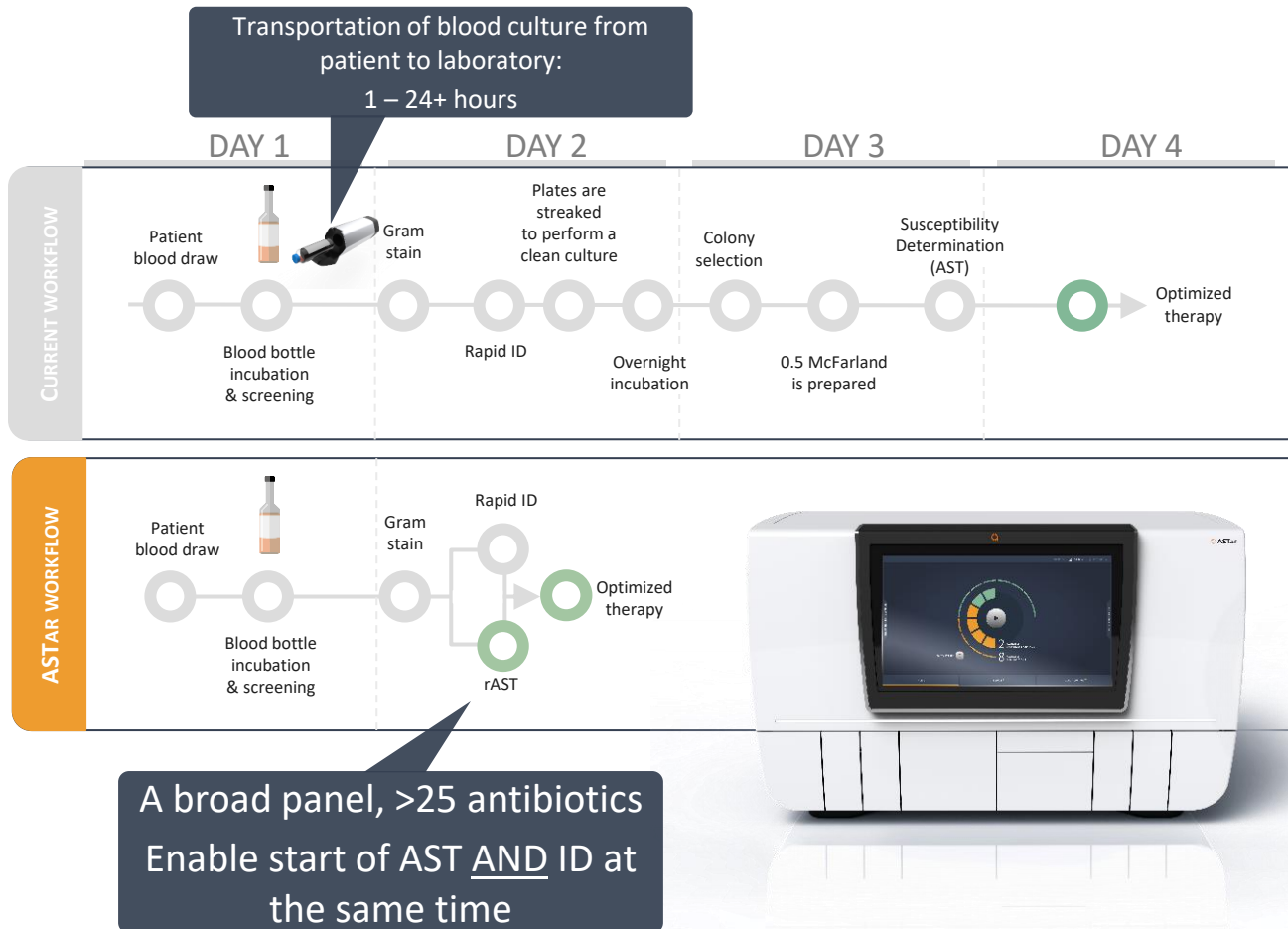
Results from the study were excellent in all key aspects:

System stability
Performance and
Customer feedback

Strong development of Podler
Excellent results of integrated prototypes

Q3

Up to 48 hours faster actionable results



Time to Actionable results is what matters for septic patients



Health economic benefits of 24 hour faster diagnostics

Lower mortality

Up to 40%
lower mortality rates¹⁾

Less pressure for resistance and superinfections

Up to 25%
reduction of *C. difficile*
infections²⁾

Cost savings

~\$2,500 – \$20,000
cost savings per patient³⁾



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 makes a difference in patient outcome

Patient-case from first commercial evaluation in Sweden

Patient

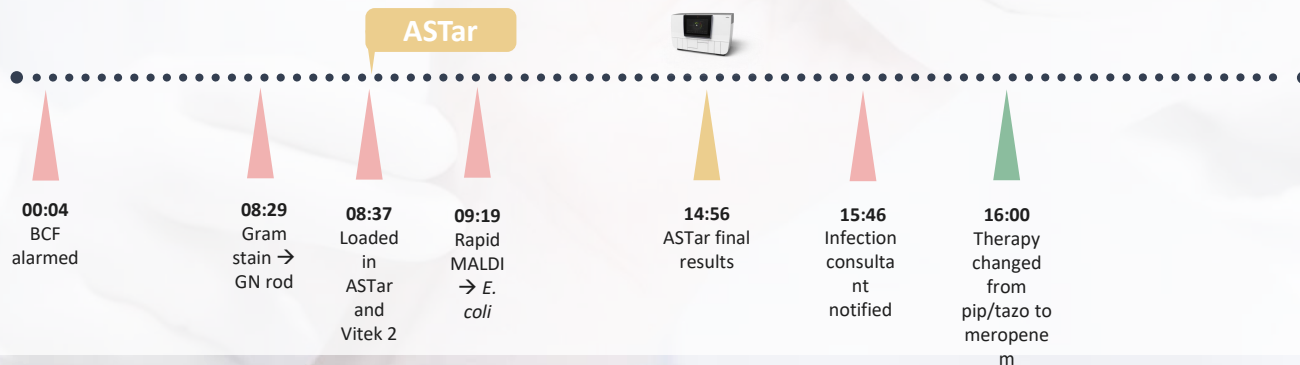
- Man, 64, surgery department
- Empiric treatment Piperacillin/tazobactam

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



AStar – a platform 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 simultaneous samples



Comprehensive

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

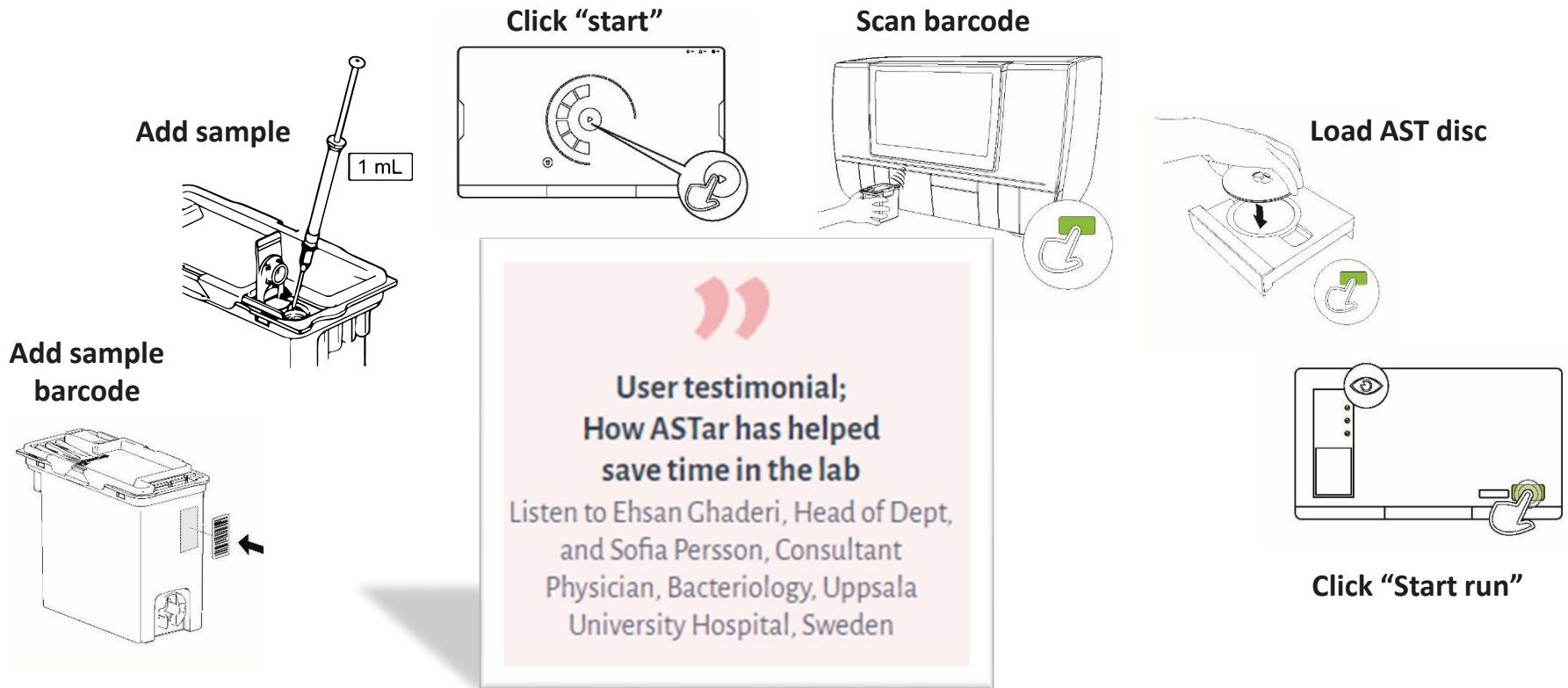
Accurate

- **True MIC results**
- High reproducibility

Easy to use

ASTar enables anyone at the lab to load sample anytime and enables lab personnel to do more in less time

User friendly
& 24/7 availability






Source: Company information and webpage

AS^Tar provides excellent performance

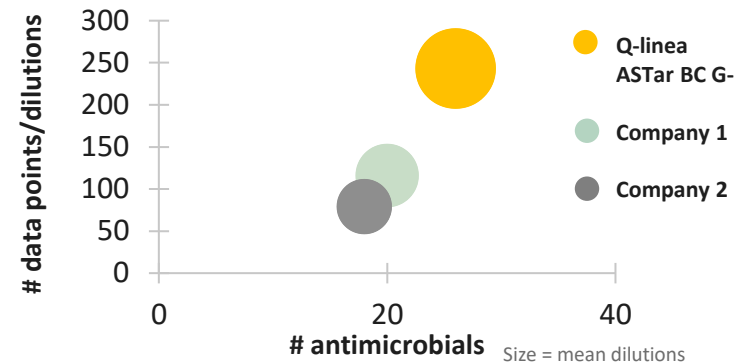
Broadest panel
enabling
actionable results

Excellent and accurate data from the CE-IVD clinical study

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

The AS^Tar[®] Instrument and AS^Tar[®] BC G- Kit offer the **broadest combination of antimicrobials and dilution ranges** in a single analysis for Gram-negative bacteria ⁶. The analysis also **delivers true MIC results**.

Coverage BC G- : comparing antimicrobials, datapoints and mean datapoints per antimicrobial



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

High throughput and flexible solution

Our ambition was the most user friendly and capable system

High throughput & flexible

Up to 12 patient samples in parallel

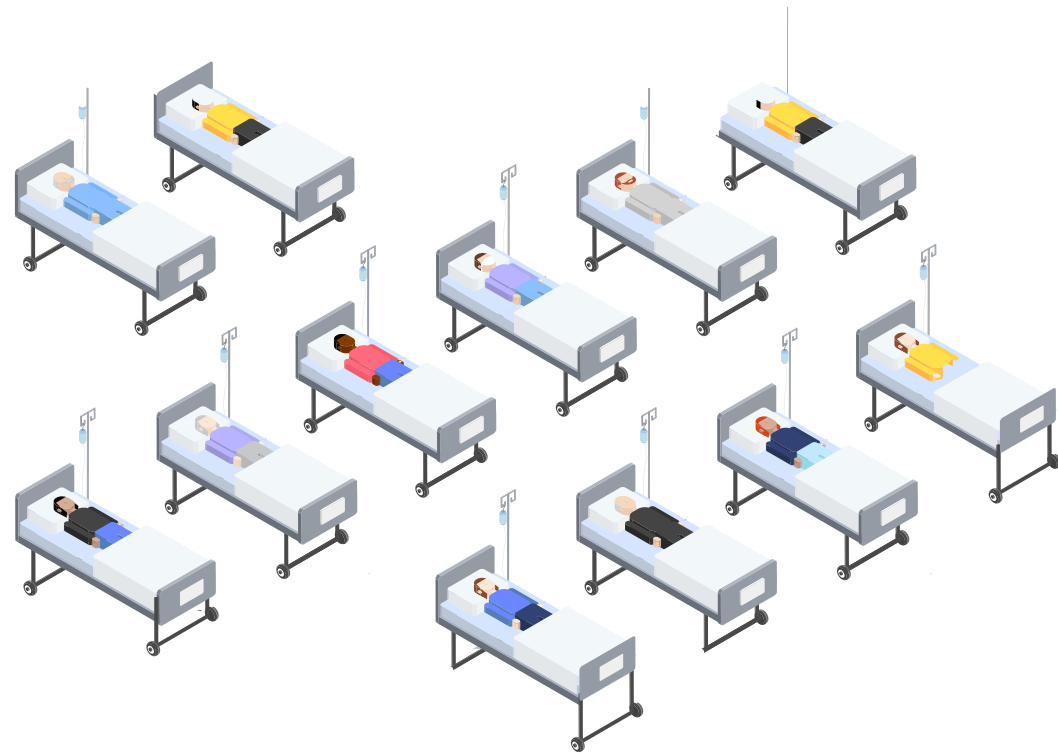


Fully automatic Semi automatic



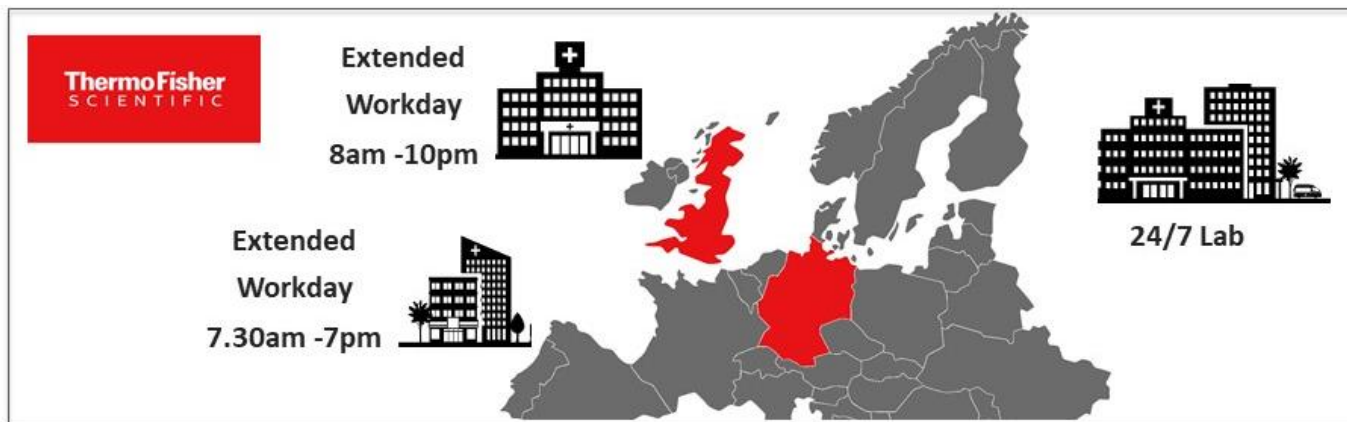
Consumables stored at room temp and a small insert at -20°C.

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



Excellent results from extensive commercial evaluation

AStar performed very well with great customer feedback



Evaluation performed by Thermo Fisher Scientific™ with support from Q-linea

Customer sites performed AStar testing on G- BC+ patient samples in parallel to their current testing

Almost 500 determinations using routine clinical samples

Comparison against Sensititre™ (CE claim) and In House Methos (Vitek® and Multipoint)

>96,6% Essential agreement across all sites compared to Sensititre

Database covered 98,7% of all G- organisms seen

System was robust. One service intervention across all sites during evaluation

2022 so far

ECCMID 2022, Lisbon

The interest in ASTar and other Q-linea products in developing was very strong

Both the Q-linea and Thermo Fisher Scientific booth were fully occupied with demonstrations of ASTar

A strong list of leads for both companies to follow up after ECCMID

Positive response on our development pipeline for ASTar

- Gram positive panel (including both fastidious & non-fastidious bacteria)
- Isolate testing using only the AST-disc

Podler went viral with a huge interest.

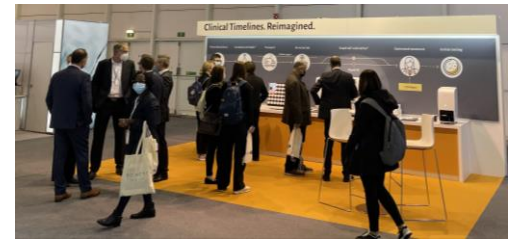
“Why have this not been developed before”, was a common comment

Commercial development

First ASTar customer – UK based hospital

Large interest to evaluate ASTar and positive about the future

Steady progress in 510k preparation to submit US clinical study to FDA



AStar – breakthrough technology

AStar classified as a breakthrough device by the FDA

Benefit for patients

- “breakthrough device” can be assigned to products that are considered to provide a more effective treatment of severe disease states”



US market approaching

- Breakthrough device designation enables **prioritized regulatory review** by the FDA
- Opens up the possibility to apply for unique reimbursement

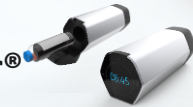
Unique technology enables disruptive expansion pipeline & opportunities

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

Source Company data. * In development. Podler is a registered trademark within EU

The effects of the Corona pandemic on Q-linea

Moving back to normal operation

Finally, we are now all moving back to the new normal after the pandemic

Our conclusion is that Q-linea and its personnel has managed the pandemic in a good way

- No identified spread within the company

- Rapid follow up and infection tracking to minimize further spreading

- Provided help in analysing Covid tests at the Uppsala University hospital

Future possible effects of the Corona pandemic

Depending on the development of the pandemic the primary risk is reduced access to customers and to perform customer evaluations

Shortage of components are still a risk, but Q-linea has provided long term orders of components to minimize the problem

Expense levels and financing strategy linked to possible delays in company activities.

We will follow the development carefully and although we see a positive development it is not over yet with new strains that may cause future escalation.

Full speed ahead with commercial activities



Strong interest from customers to evaluate ASTar

Ongoing activities

- Pre-market activities ongoing at full speed
- Training of personnel ongoing
- Marketing material in final preparation

Staged launch for long-term success

- First evaluation customers in the planning
- After evaluation of key customers, we aim to push for second stage launch