

# Two-photon excitation technology enables complete solution for decentralized infection diagnostics

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*Emerging Antimicrobials and Diagnostics in AMR*



# Agenda

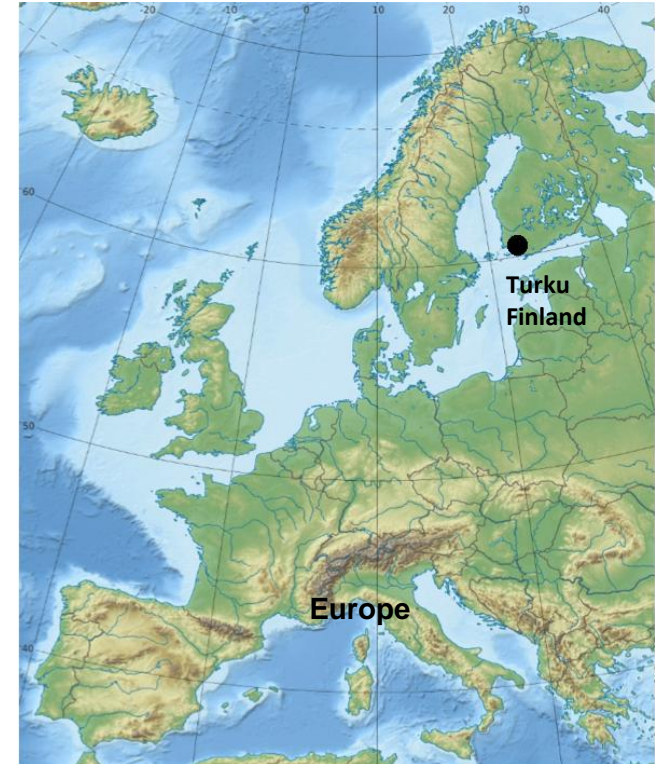
- ArcDia International Ltd
- ArcDia's three cornerstones in infection management
- ArcDia's resistance testing market vision
- mariAST® – world's fastest phenotypic resistance test



# ArcDia International Ltd

**ArcDia** is a fully integrated - privately-held company focusing on decentralized rapid and automated infection diagnostics

- **On the market since:** 2011
- **Head count:** 30
- **Location:** Turku, Finland
- **Quality system:** ISO-13485 certified by LRQA
- **Ownership:** VC, private investors and the management



# The turn-key solution for decentralized infection diagnostics



mariPOC<sup>®</sup> analyser for ID, AST  
and real-time surveillance

**mariPOC<sup>®</sup>**

A product line for rapid multianalyte  
identification of pathogens

**mariAST<sup>®</sup>**

A product line for rapid phenotypic  
antimicrobial resistance testing

**mariCloud<sup>™</sup>**

A cloud service for real-time  
epidemiological surveillance

# mariPOC<sup>®</sup> product line for multianalyte ID

## Currently available tests IVD CE

### mariPOC Respi

For influenza like illnesses

- Influenza A virus
- Influenza B virus
- Respiratory syncytial virus
- Adenovirus
- Human metapneumovirus
- Parainfluenza virus 1, 2, 3
- Bocavirus
- Coronavirus OC 43
- *Streptococcus pneumoniae*

### mariPOC Pharyn

For tonsillitis

- Adenovirus
- Group A Streptococci



### mariPOC Gastro

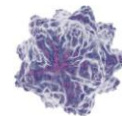
For acute gastroenteritis

- Norovirus GI
- Norovirus GII
- Adenovirus
- Rotavirus
- Campylobacter spp

### mariPOC CDI

For *C. difficile* infection

- *C. difficile* GDH
- Toxins A/B



# Future resistance testing market segmentation

mariAST® is applicable in all market segments

## CLINICS & Primary care AST - Therapy Guidance

Directly from clinical samples  
swabs, feces, abscesses

**Market size:** Currently small

**Growth rate:** Highest. The  
biggest market segment in  
future.

## HOSPITAL Screening & Infection control

Directly from clinical samples  
swabs, feces, abscesses

**Market size:** Currently big market

**Growth rate:** High

## CENTRAL LAB AST - Therapy Guidance

Pure cultured samples &  
positive blood cultures

**Market size:** Currently the  
biggest market

**Growth rate:** Small/moderate

Sweet spots of mariAST® show  
the highest growth potential

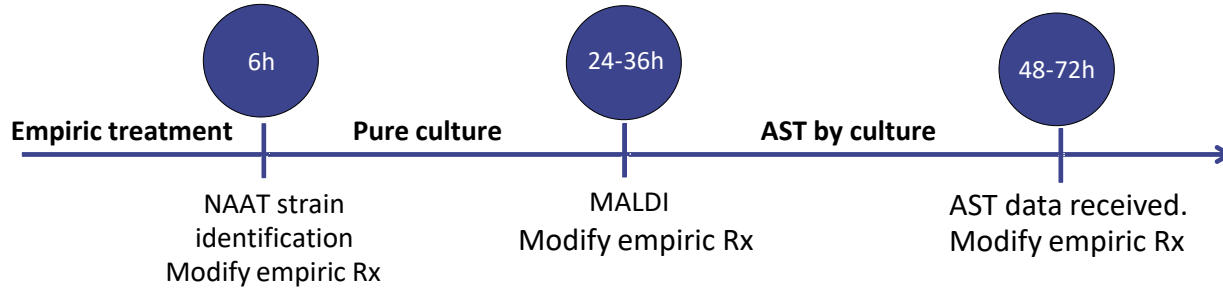
# **mariAST®** - Most promising platform for decentralized phenotypic resistance testing

- ✓ Rapid phenotypic AST without pure culture
- ✓ Directly from polymicrobial clinical samples
- ✓ Combines bacterial in-well culture & specific antigen detection with wash-free fluoroimmunoassay
- ✓ Real-time detection

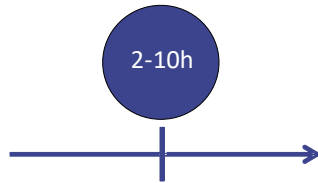


# mariAST<sup>®</sup> provides AST data directly from a clinical sample

## CURRENT PROCESS



## mariAST<sup>®</sup> PROCESS



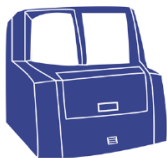
### 1 shift

- Strain identification and AST within 2 – 10 hours
- ✓ Directly from clinical sample
  - ✓ No pure culture needed





# mariAST<sup>®</sup> work flow



Directly from  
clinical sample

Automated  
analysis

Break-point resistance  
result within hours



- Initial ID in < 30 minutes
- AST for strong positives in 2 hours
- Negative results and AST for low positives in 10 hours
- Internal autoverification confirms results
- Connected to LIS & mariCloud<sup>™</sup>



More options

Date	Patient name	ID code	Test status
13.01.17	Taylor, Sarah	122-762-9255	Finished
13.01.17	Anderson, Victoria		Finished
13.01.17	Murphy, Sophie	010202A123F	Finished
13.01.17	Wagner, Lucas	050402	Finished
13.01.17	Martin, Jack	310709A6414	Finished
13.01.17	White, George	078-05-1120	Finished
13.01.17	Smith, Jessica		Finished
13.01.17	Meyer, William	12.5.2006	Finished
13.01.17	Green, Mike	AA 07 32 44 D	Finished
13.01.17	Garcia, Jane	19.11.2000	Finished
13.01.17	Jones, Mary		Finished
13.01.17	Law, Poppy		Finished

Ready for new sample in

0:00

Final result in

0:00

MSSA/MRSA

10



MSSA/MRSA diagnostic

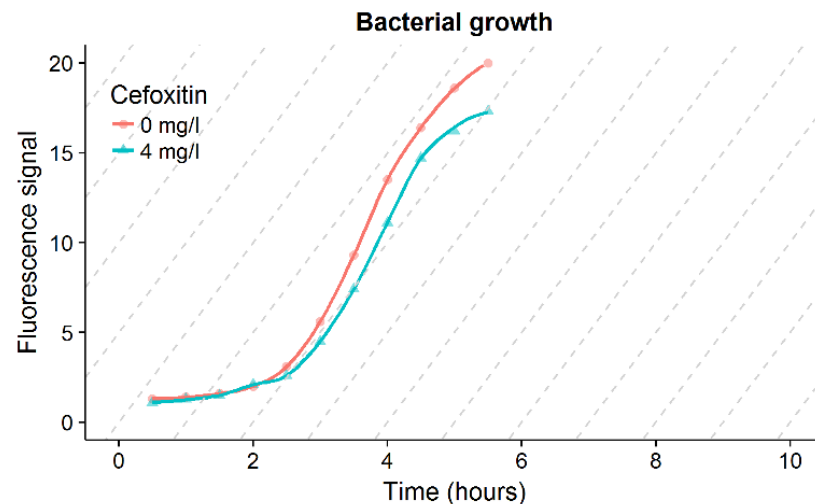
Finished

13.01.17 (16:08)

Green, Mike

Result Autoverification

MRSA OK



# Preclinical studies for MRSA test (RUO) show excellent performance

Proof of concept study	Performance figures
Sensitivity	88–100%
Specificity	91–94%
Median time to result	In hours

Antikainen et al. Preclinical evaluation of phenotypic mariAST MRSA RUO test against routine MRSA screening methods in hospital setting. ECCMID 2019, Amsterdam, the Netherlands. Abstract #2938 and poster #P2615.

Stenholm et al. Scand J Infect Dis. 2013;45:922-9,  
Eur J Clin Microbiol Infect Dis. 2011;30:1237-43

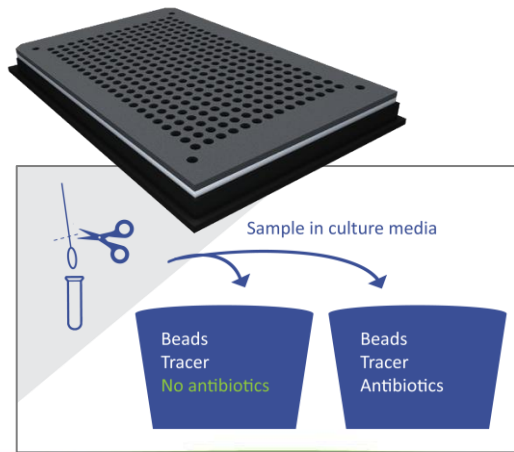
## Some key benefits

- Phenotypic methodology is not sensitive to genetic mutations
- Does not necessitate molecular and gene level information about the resistance mechanism
- Does not miss population diversity information as conventional polycolony pure culture AST does

# mariAST<sup>®</sup> technology

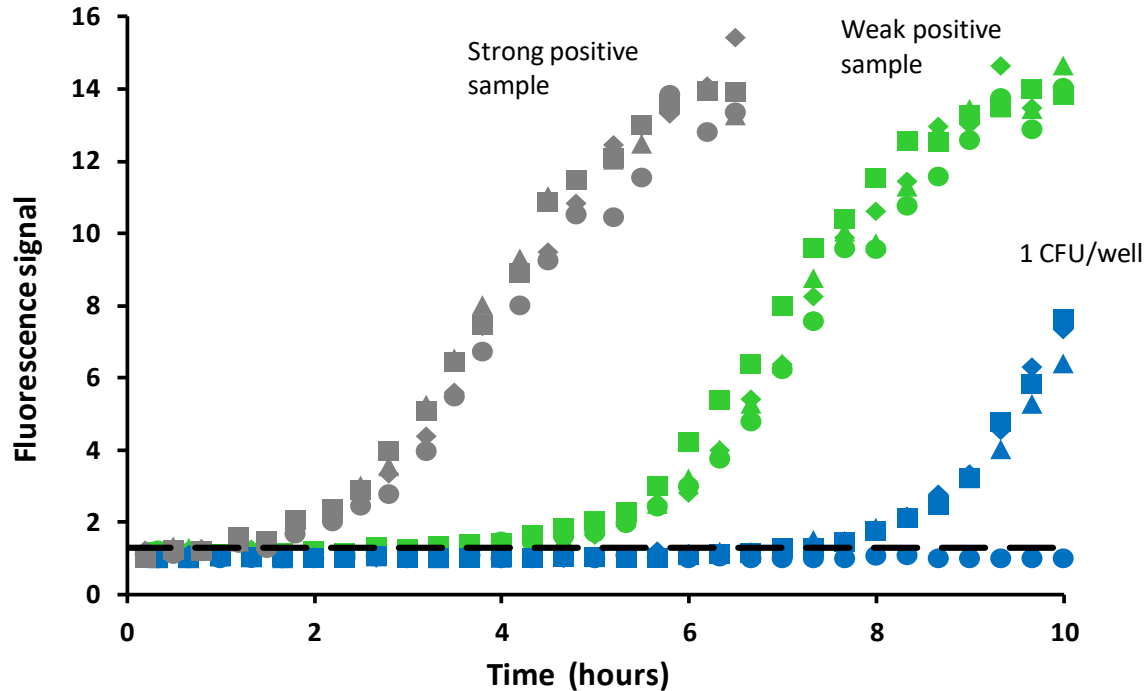
## Test cartridge

- Pathogen specific reagents & antibiotics are stored in hermetically sealed cartridge in the dry state
- 22-88 AST or multianalyte ID tests per cartridge



- **mariPOC<sup>®</sup> and mariAST<sup>®</sup>** are based on Nature-published fluoroimmunoassay of pathogen specific antigens
- The immunoassay binding reaction takes place on latex microbeads, which are detected by ***two-photon excitation fluorometry***
- This unique technique allows closed-tube detection of pathogen antigens without washing steps
- Reactions kinetics monitored in real time
- Repeated measurement provides species-specific bacterial growth curve

# mariAST® methodology enables species-specific detection directly from clinical samples down to 1 CFU/well





This figure shows growth curves for *S. aureus* in three different initial inocula using four replicates.

mariAST® methodology is a robust and sensitive approach for direct rapid phenotypic AST.

1) Antikainen et al. 2016. NSCMID 2016, Rovaniemi, Finland. Reference #0049.

2) Antikainen et al. ECCMID 2017, Vienna, Austria. Reference #P0172.

# mariAST® is the most advanced platform for rapid phenotypic AST

Technology platform	Directly from clinical samples	Real time detection	Random access	Peer reviewed articles	Applicable in decentralized market
mariAST® by 	✓	✓	✓	4	✓
Smarticles™ by GeneWEAVE™	✓	✗	✓	none	✗
Accelerate Diagnostics Inc. 	✗	✓	✗	Several	✗

mariAST® technology is industry validated by



# Most preferred application types for mariAST®

mariAST® enables identification and resistance testing in one shot for infections where

- the number of plausible pathogens is limited (3-4)
- common / high volume infections
- no need for MIC analysis, but a breakpoint concentration of the antimicrobial works

mariAST® is also technically suited for MIC determination\*

\* Antikainen et al. mariAST® methodology enables high precision MIC testing. 36<sup>th</sup> NSCMID, 2019. Reference # P-19, 67782.

## Therapy Guidance

Abscesses & skin infection  
Gonorrhea  
ESBL in UTI (*E. coli*)  
Pneumonia (pneumococci)  
Tonsillitis (GAS)  
*C. difficile* diarrhea

## Screening

MRSA  
CPE, VRE  
*C. difficile*

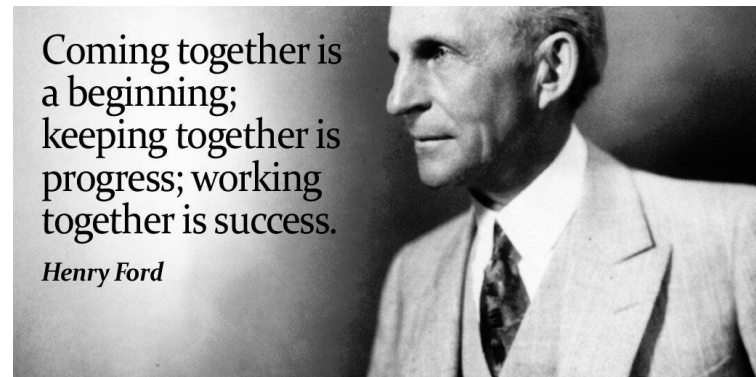


# Call for action!

- Successful tackling of AMR problem requires the best brains and most hard working individuals working on it
- Let's combine our strengths and take action
- Contact ArcDia for partnering opportunities

Coming together is  
a beginning;  
keeping together is  
progress; working  
together is success.

*Henry Ford*



[https://twitter.com/tim\\_fargo/status/1003384159509843970](https://twitter.com/tim_fargo/status/1003384159509843970)



# Thank you!

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