European Commission

HERA HEALTH EMERGENCY PREPAREDNESS AND RESPONSE AUTHORITY

#HealthUnion

HERA Industry days

Health Emergency Preparedness and Response Authority

2 & 3 June 2025, Brussels

European Commission

Side session

Advancing diagnostics: scaling production, overcoming industry challenges, and addressing future needs in crises

European Commission

Advancing diagnostics: scaling production, overcoming industry challenges, and addressing future needs in crises

Cornelius SCHMALTZ
HERA 02

Jean-Paul MEIJNEN
Senior Director, Ginkgo Bioworks Netherlands

Irek ROSLON
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Jeroen NIEUWENHUIS
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DURABLE Project

European Commission

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#HealthUnion

Advancing diagnostics: scaling production, overcoming industry challenges, and addressing future needs in crises

3 June 2025

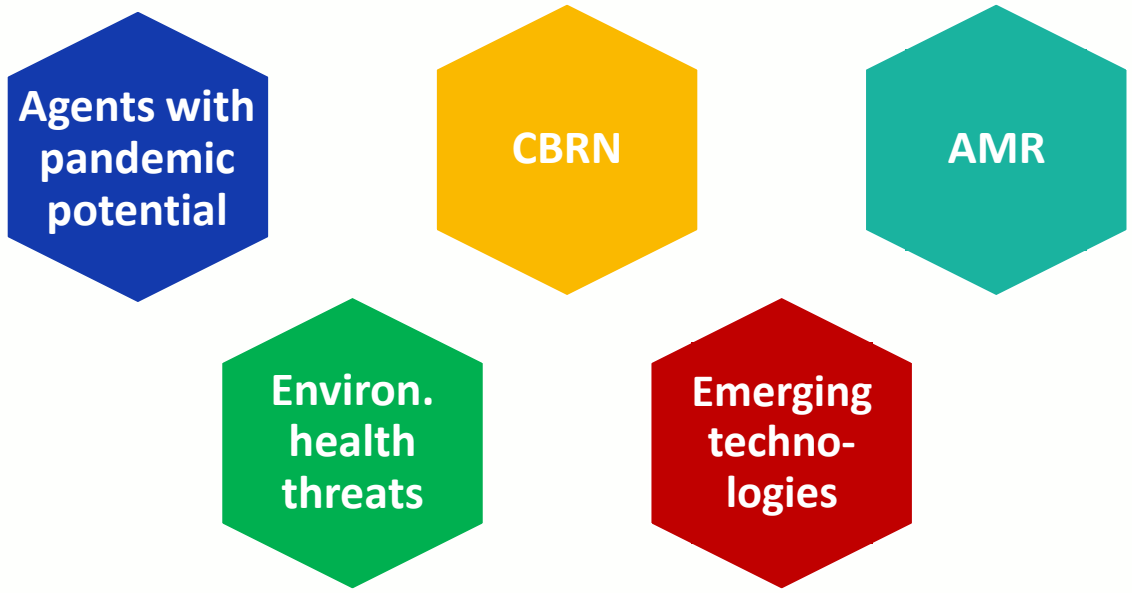
Cornelius Schmaltz, Head of Unit
HERA.02

HERA PRiorities

HERA
#HealthUnion

- In **2022**, HERA identified its 3 main serious cross-border health threat categories
- In **2023**, HERA identified 2 additional ‘threat subtopics’, to support the previously identified threat categories

→ **Diagnostics matter for all threat categories**



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HERA priorities

HERA
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- Diagnostics are core MCMs within HERA's mandate
- Enable critical decision-making across clinical care, surveillance, and outbreak response
- Bridge preparedness and response—linking threat identification to MCM deployment
- Investing in innovative diagnostic technologies for future threats

European Commission

Previous funding actions

HERA
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2022 (EU4Health):

- EUR 25 million: DURABLE lab network
  - Includes work on diagnostics

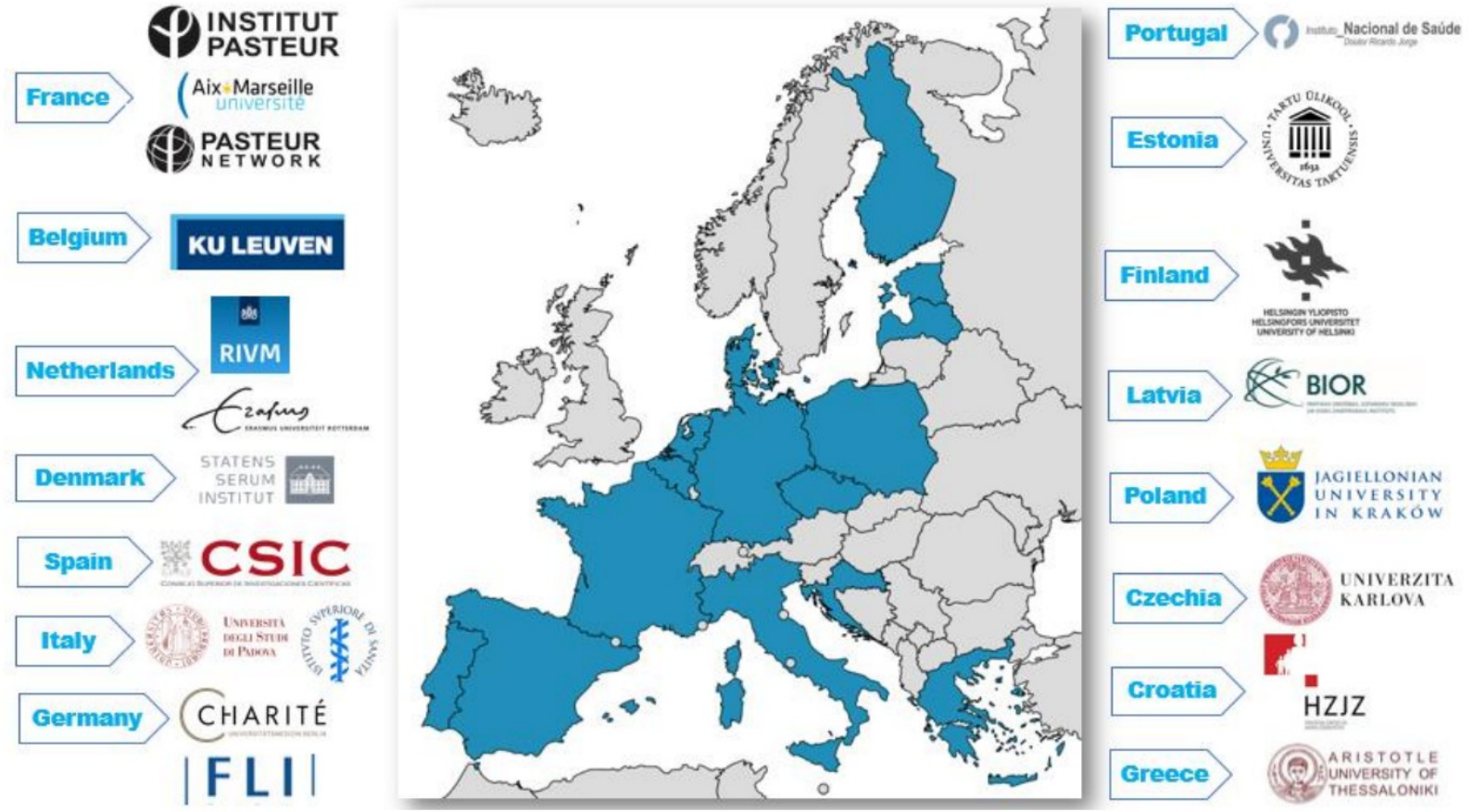

Figure 1: DURABLE consortium

European Commission

Previous funding actions

HERA
#HealthUnion

2023 (Horizon Europe):

- EUR 40 million: HORIZON-HLTH-2023-TOOL-05-08: Pandemic preparedness and response: In vitro diagnostic devices to tackle cross-border health threats
  - 6 projects funded (UniHealth, B-Path, DECIPHER, PREPARE-TID, PAIR, DRAIGON)

2024 (EU4Health):

- EUR 24 million: Point of care metagenomic sequencing for universal pathogen detection

2025 (EU4Health):

- EUR 12.86 million: Development of a rapid point-of-care antimicrobial susceptibility testing diagnostic medical device
  - Under evaluation

European Commission

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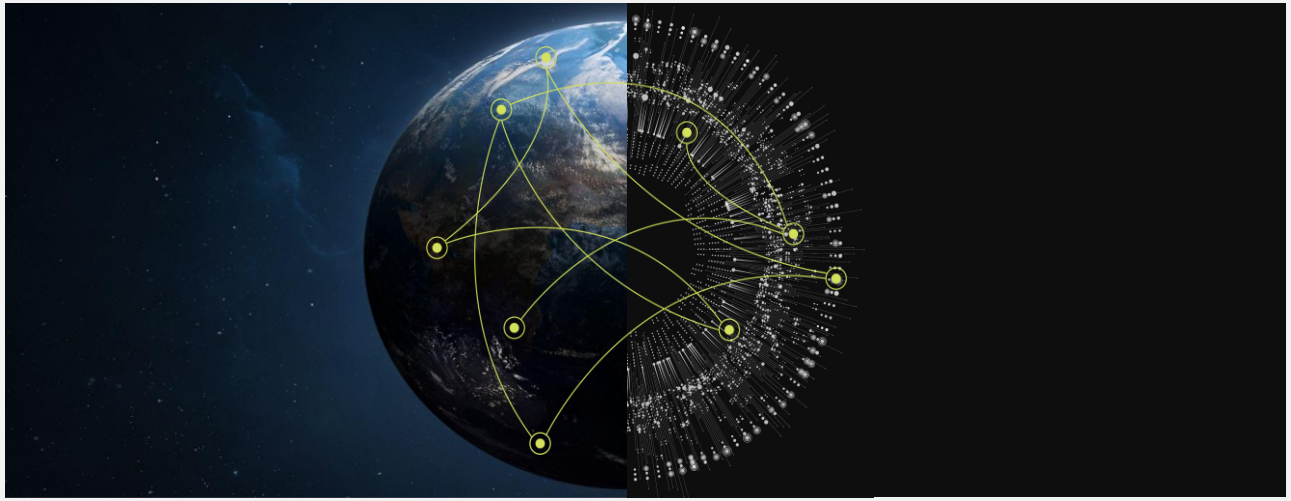
Ginkgo Biosecurity is powering global biosurveillance and rapid pathogen detection

Ginkgo Biosecurity is building **next-generation biosecurity infrastructure** and deploying the technologies global leaders need to **predict, detect, characterize, and respond** to a wide variety of biological threats.



Global Network

15,300,000+
Samples collected

96,000+
Samples sequenced

24,000+
Pathogen genomes sequenced

11
Key international airports (incl. 4 outside US)

44
Collection nodes (cumulative 2025)

Project RANGER: RApid Next Generation sequencing for Effective medical Response

What is Project RANGER?

A consortium of leading bioscience companies has been assembled to develop an innovative pathogen-agnostic diagnostic platform, led by the biosecurity division of Ginkgo Bioworks.

Project RANGER's Purpose:

This collaborative effort brings together industry leaders and cutting-edge technologies to create a comprehensive biosecurity network with global reach.

GINKGO BIOWORKS

JUMPCODE

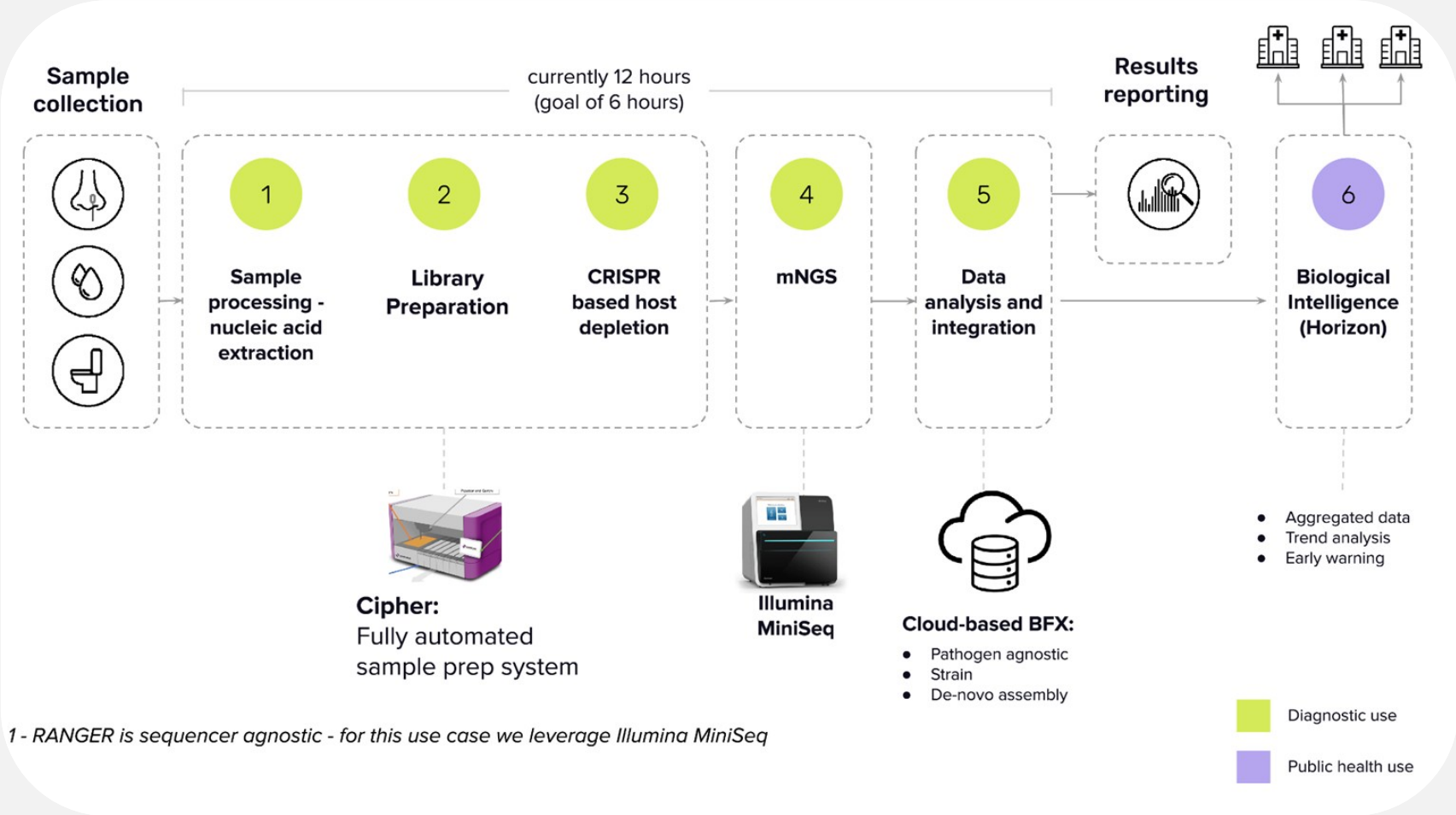
EUROIMMUN

BUGSEQ

tgen part of City of Hope.

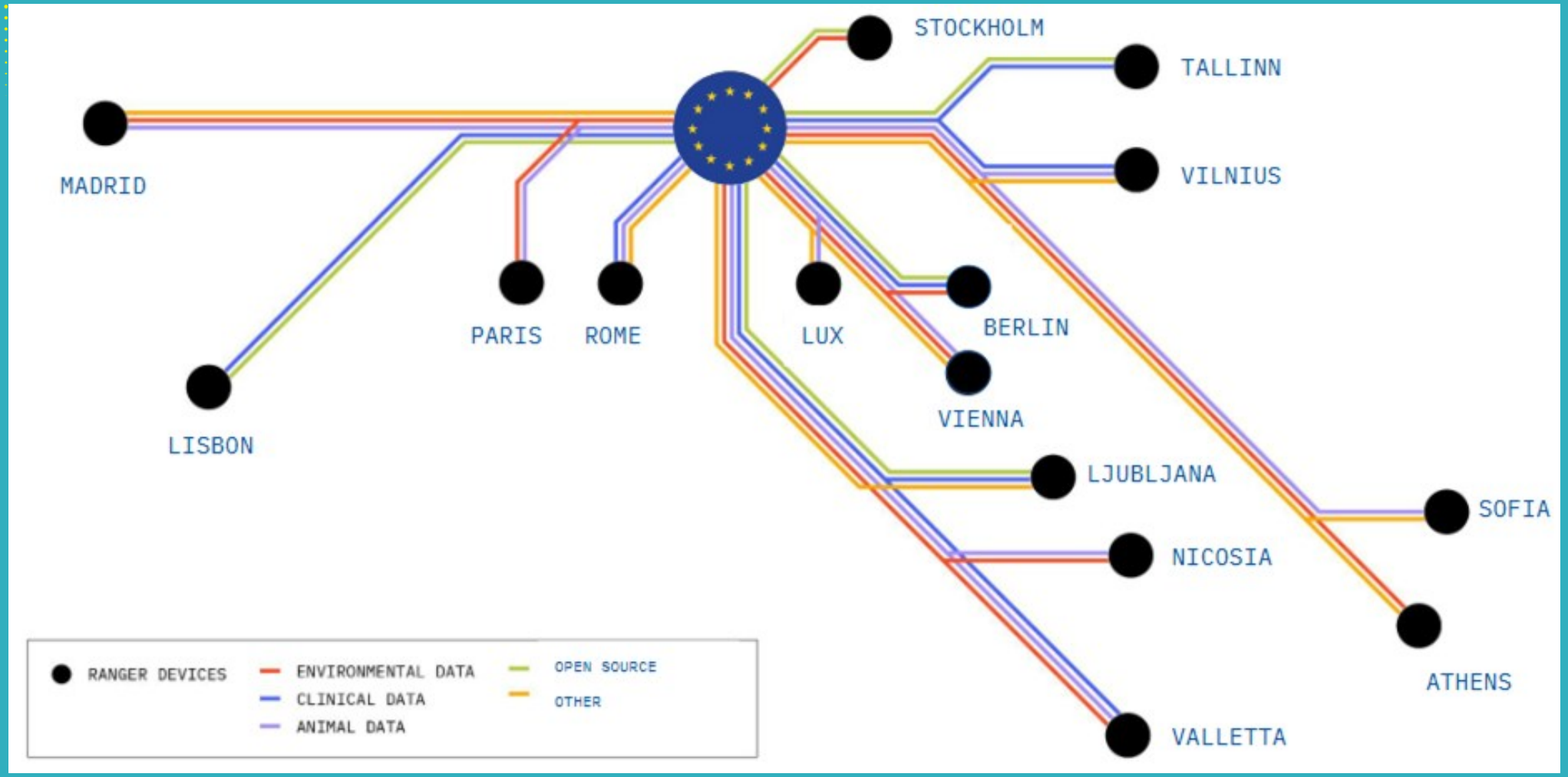
We are developing a system that combines rapid mNGS clinical system with public health data platform

RANGER's objective is to develop and validate a **fully automated, random-access sample preparation instrument** combined with an improved **metagenomic Next-Generation Sequencing (mNGS)** test as a pathogen-agnostic diagnostic for clinical and hospital laboratories.



This program is financed by the European Health and Digital Executive Agency (HaDEA) which implements EU funding programs for health and digital transformation, including EU4Health, Horizon Europe, and the Digital Europe Programme.

RANGER's implementation will allow for a widespread mNGS biosurveillance system for the EU



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Graphene single-cell sensors for antibiotic testing with 1hr results

dr. ir. I.E.Rosłoń

Rapid diagnostics. Today.

At SoundCell we developed the **MelodyOne**: a rapid AST platform that offers results in one hour.

The **MelodyOne** is our cutting-edge nanotechnology platform that detects bacterial resistance within just 1 hour—far faster than traditional methods. Using graphene-based sensors, it measures microscopic bacterial vibrations to determine if antibiotics are working in real time.

- **1-hour antibiogram from positive blood culture**
- **Compatible with bacteria and yeasts**
- **Process up to 10 samples a day**

EU collaboration towards a solution

SoundCell (NL) develops a novel Graphene based AST sensors with results <1h.

Optical readout systems & multi-cartridge

Graphene sensor chips mass manufacturing

Rapid AST Solution

Lambda-X (BE) designs high-tech optical instruments

Graphenea (SP) leader in graphene manufacturing

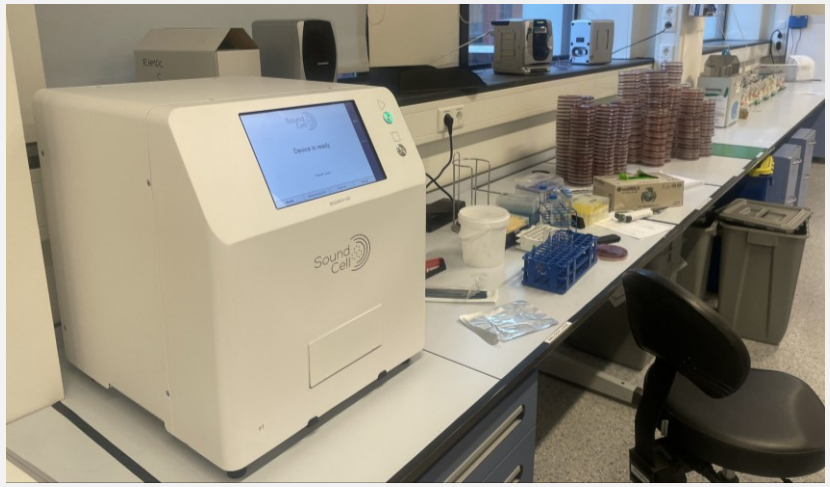
EIC TRANSITION

European Innovation Council

eurostars™

The missing piece of the AST puzzle

Reinier de Graaf
Je ziekenhuis voor het leven



"Microbiologists urgently need to solve 2 pieces of the puzzle:

- *What pathogen am I dealing with?*
- *What antibiotic is effective?*

The first part of the puzzle was solved >20 years ago. Now, SoundCell is solving the second part of the puzzle."

- **dr. Leo Smeets**, microbiologist at Reinier Haga Medical Diagnostic Centre (Delft)

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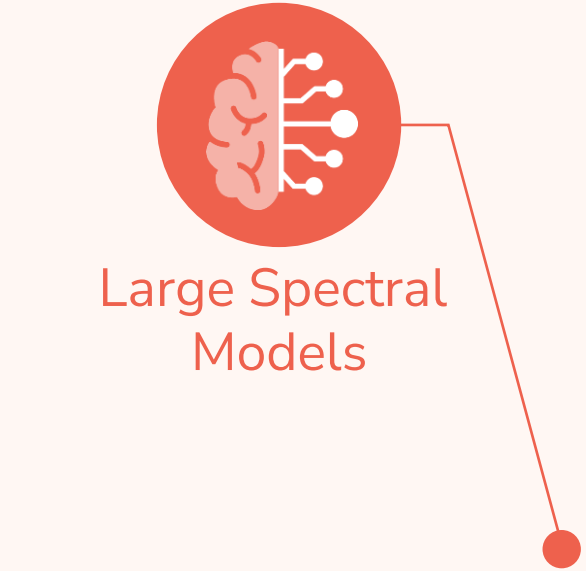
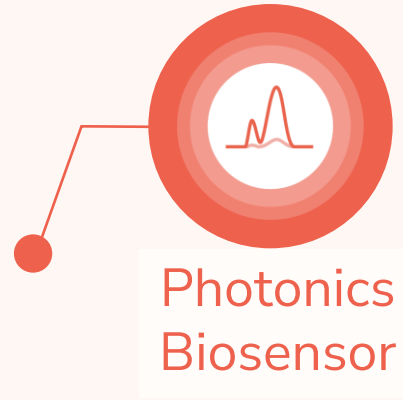
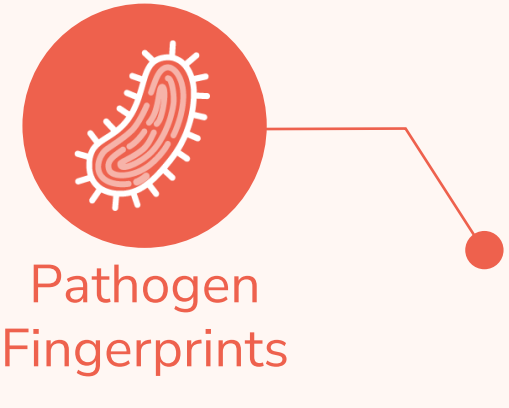
Nostics

Real-time fingerprinting of living microorganisms

for targeted treatment







Nostics B.V.
Amsterdam, NL

Nostics Inc.
Cambridge, USA

Certified B Corporation

Solution

Where others need days, we **confirm** infection and **identify** bacteria and fungi in **<10 minutes**

1. **Apply sample to cartridge**

Easy to use with minimal handling time

2. **Automated processing and AI analysis**

15 x 15 cm

Rapidly expandable menu by software update, no targets/labels in cartridge

3. **Actionable results**

Escherichia coli
Klebsiella pneumoniae
Enterococcus spp.
Staphylococcus saprophyticus
Proteus mirabilis
Streptococcus agalactiae
Staphylococcus aureus
Pseudomonas aeruginosa
Enterobacter cloacae

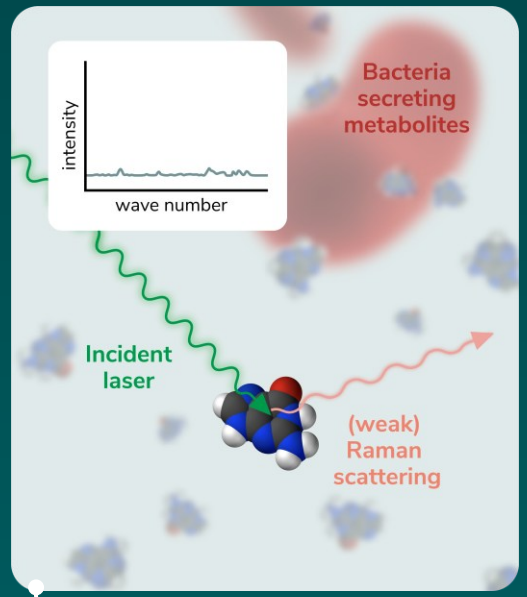
Nostics
guided treatment

Identification of active infections > living microorganisms

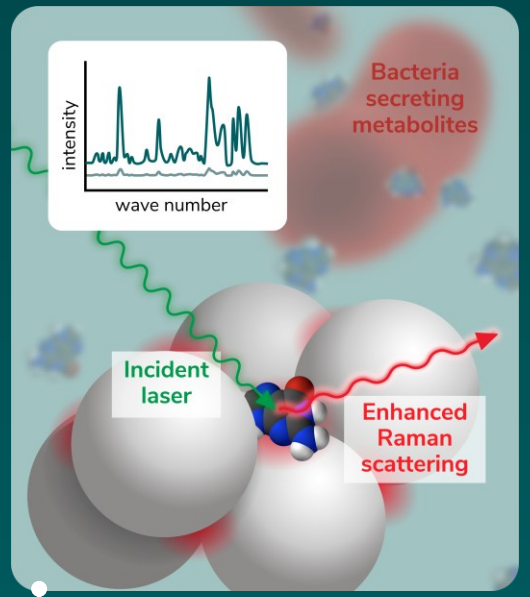
Nostics’ breakthrough technology

Reading biology as it could not be read before

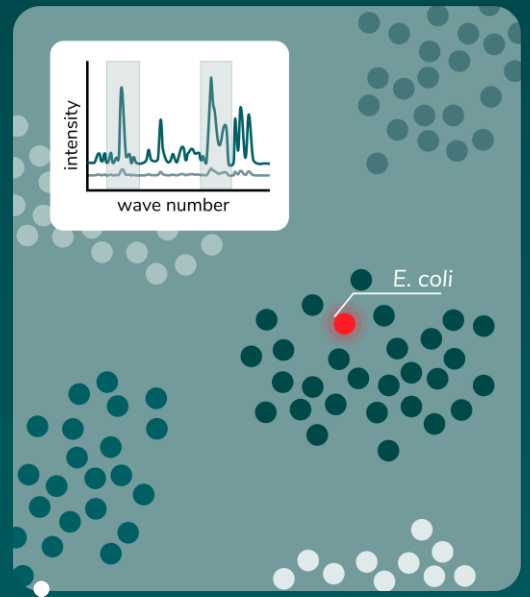
- <10 min directly from samples
- Identification of living microorganisms
- Menu expansion by software update
- Small footprint and battery-operated



Raman Spectroscopy
Viable pathogens secrete metabolites in a species-specific composition which serve as fingerprints for identification.



Nanomaterials
Nanosubstrate amplifies Raman signals, increasing sensitivity and enabling measurements without culturing.



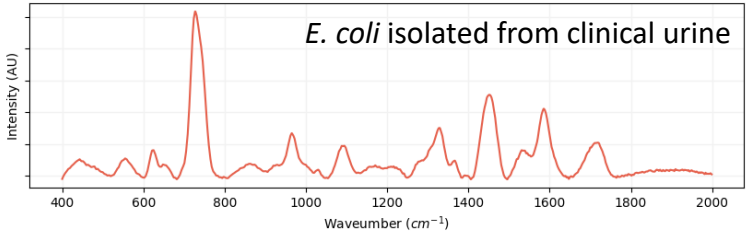
Artificial Intelligence
classification of pathogen fingerprints with proprietary algorithms trained using few-shot learning.

Launch application: Urinary tract infection

Demonstrated capability to expand to further sample types and pathogens

Launch application: Urinary tract infections

Urinary tract infections



UTI panel

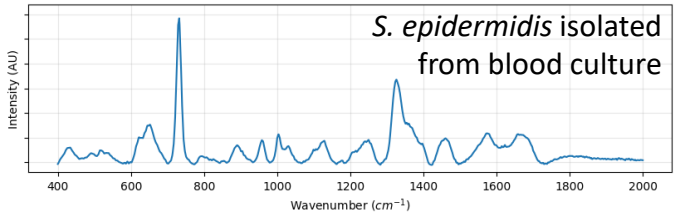
Escherichia coli
Klebsiella pneumoniae
Enterococcus spp.
Staphylococcus saprophyticus
Proteus mirabilis
Streptococcus agalactiae
Staphylococcus aureus
Pseudomonas aeruginosa
Enterobacter cloacae

Covering > 99% of all UTI cases in primary care

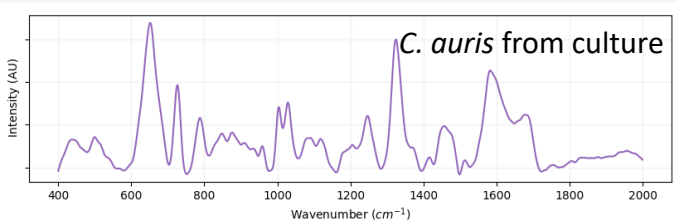
Existing CPT code expedites US launch

Examples of other platform applications:

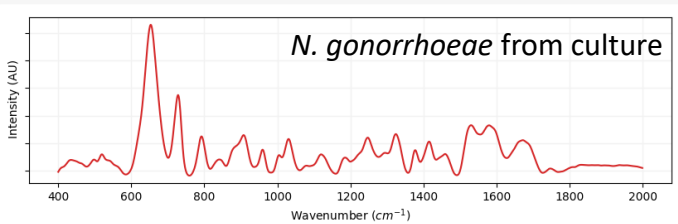
Blood stream infections



Fungal infections



Sexually trans-mitted infections

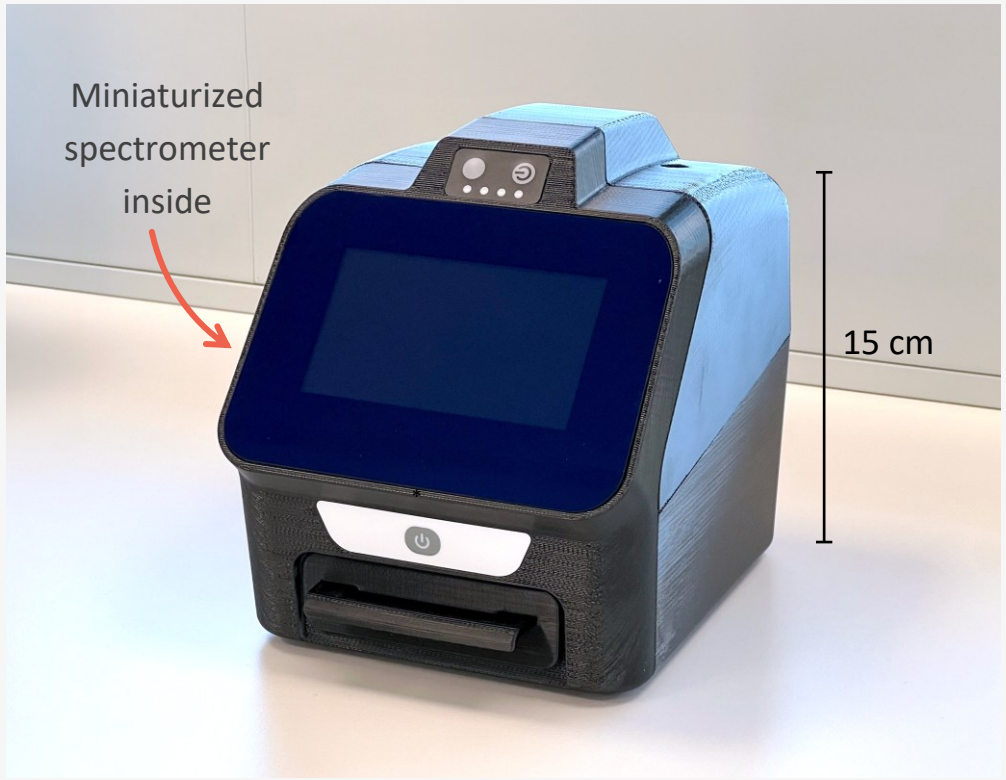


AST

Coming soon

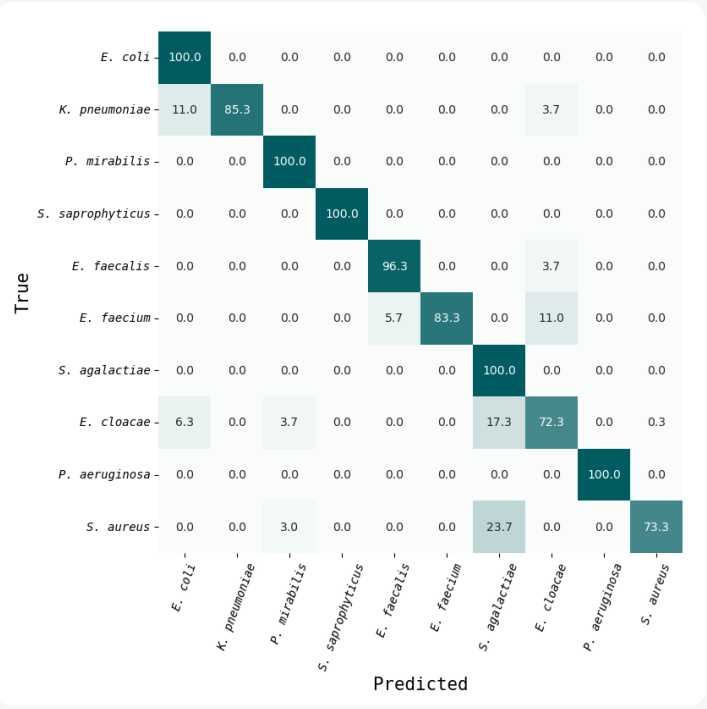
Functional model and high classification performance

Functional model with miniaturized low-cost spectrometer module



Excellent classification performance on UTI panel with independent datasets

Overall accuracy: 91%
Prevalence weighted: 97%



A decentralized solution to be used as a Medical Counter Measure when needed

Deployable at scale during pandemic

Detection and identification of emerging pathogens

Makes decentralized data transparent for surveillance

Rapid expansion to other clinical applications and pathogens

Rapid identification of pathogens and antimicrobial susceptibility

Easy to use, cost-effective and suitable for point-of-care

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DURABLE Project

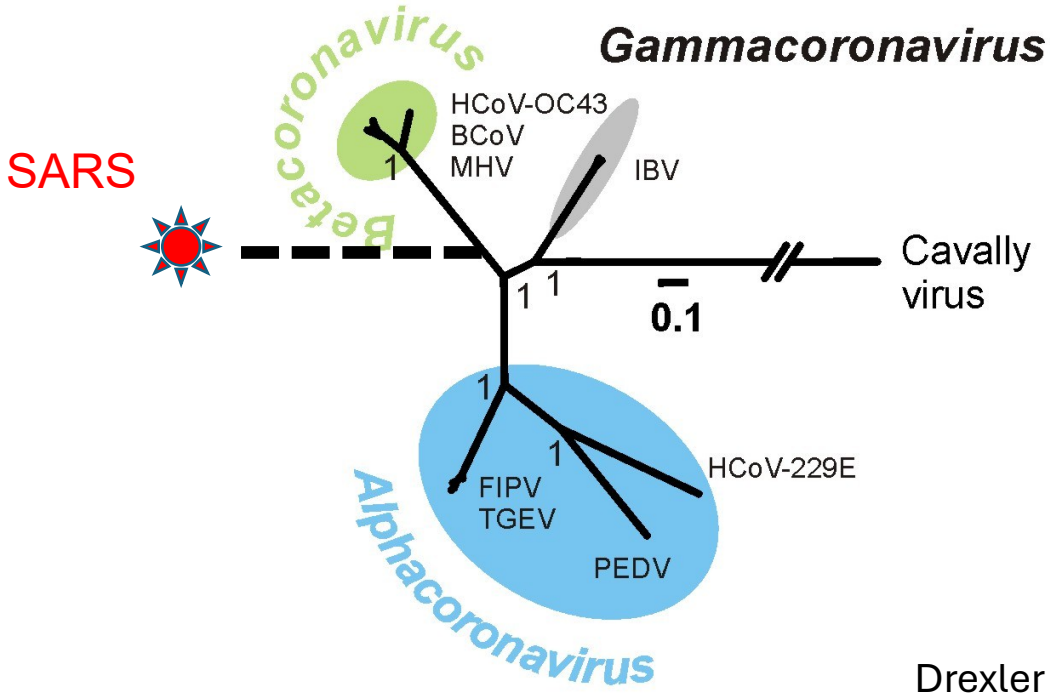
HERA/Durable:

Diagnostics as an immediate medical countermeasure

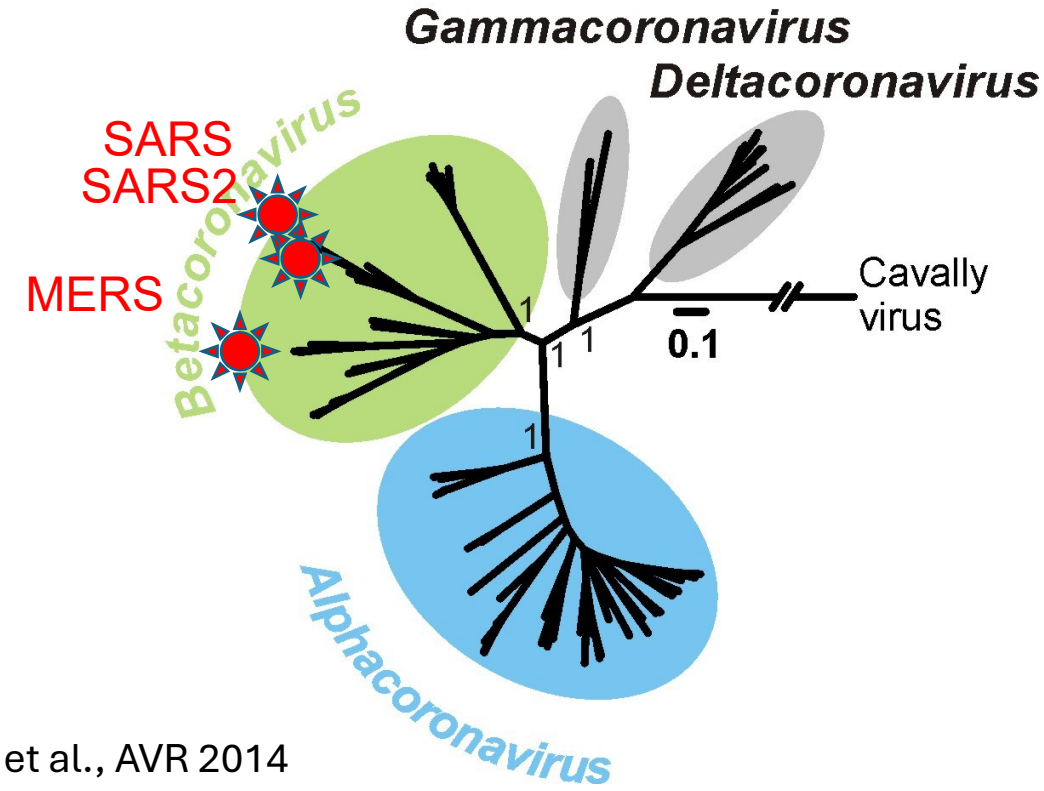
Christian Drosten, Charité, Berlin, Germany

Genomic data enables virus recognition

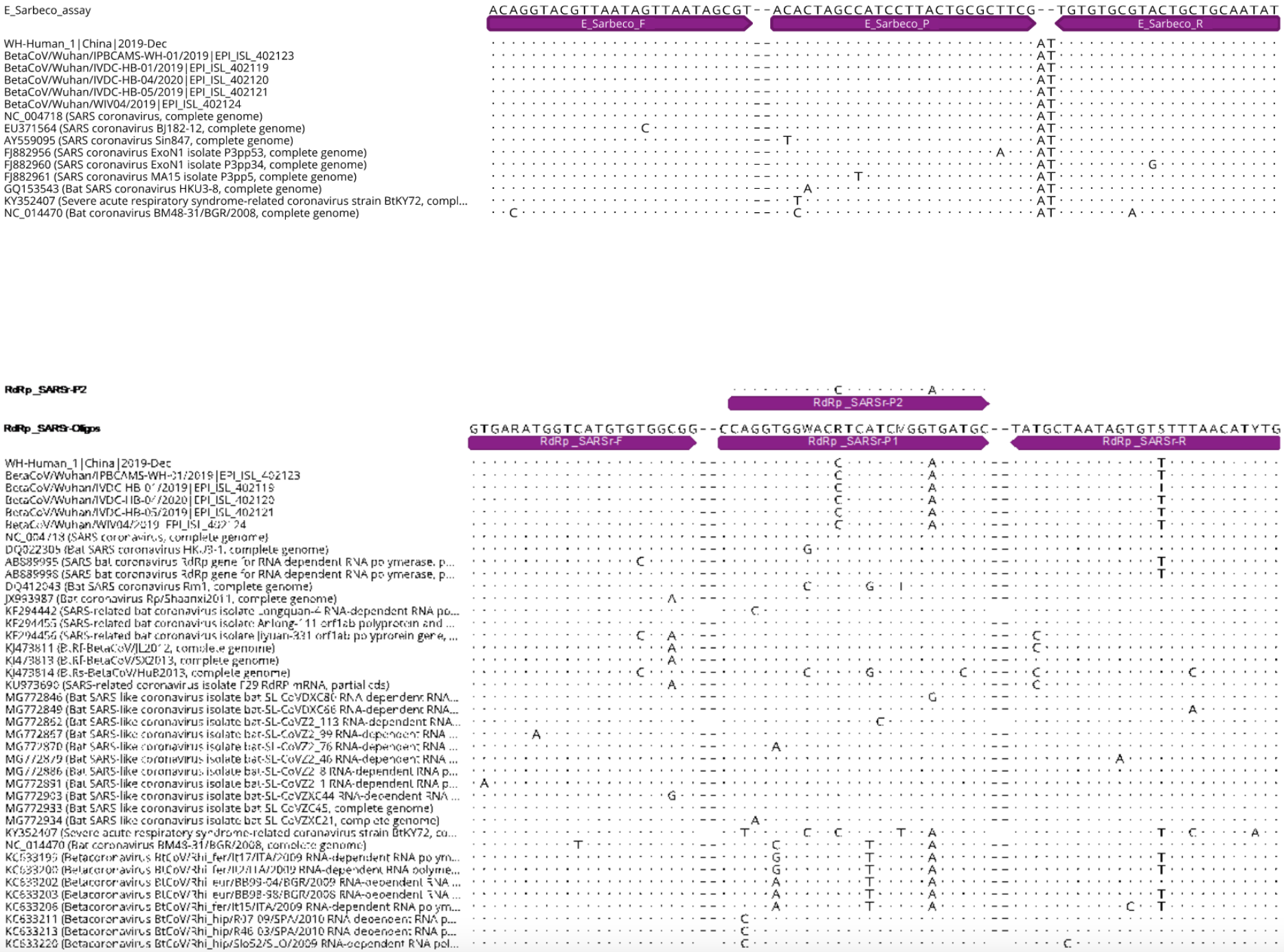
Before SARS



10 years after SARS



Drexler et al., AVR 2014

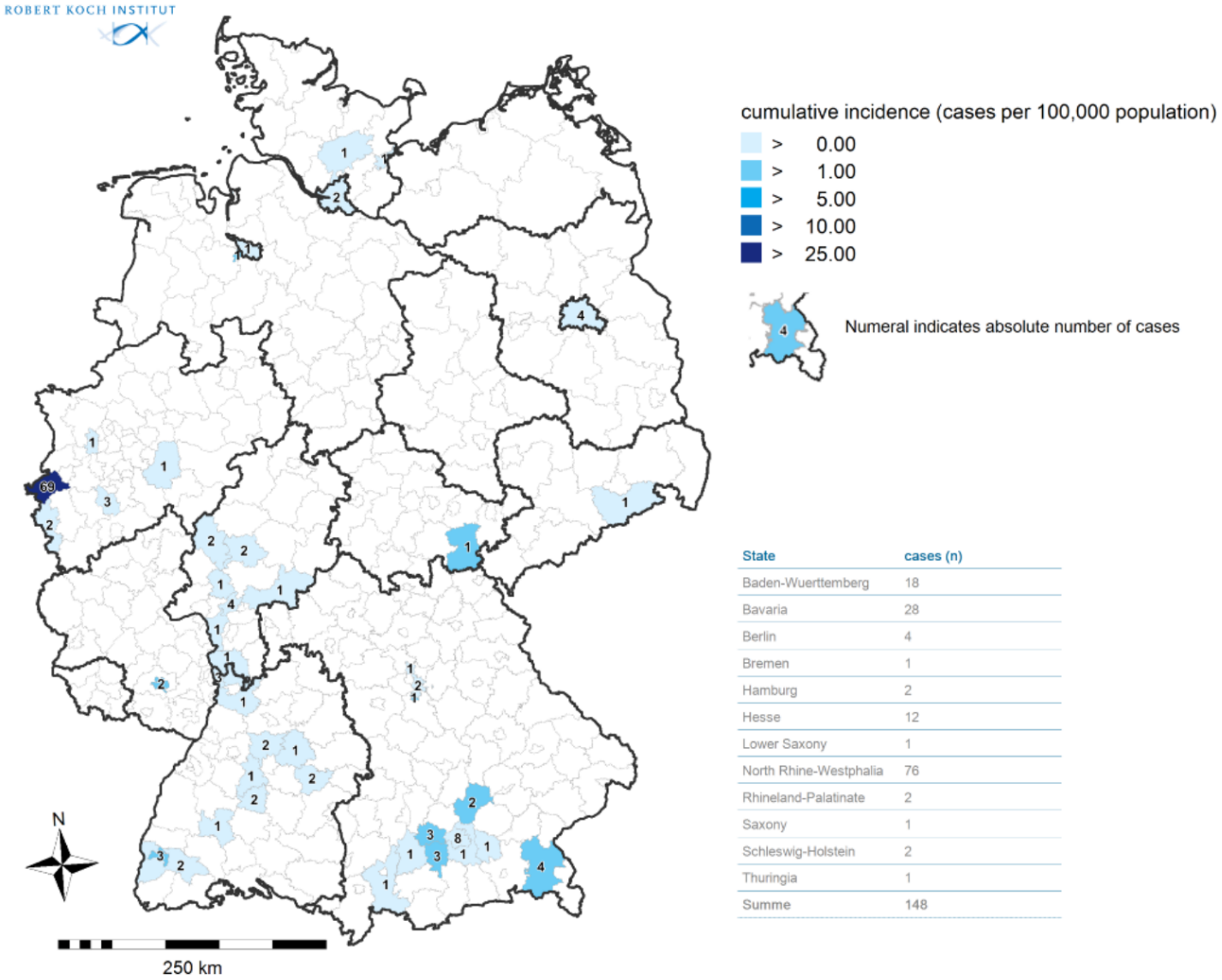


All variability relevant for PCR design was already known when SARS-CoV-2 emerged

Corman et al, Eurosurv 2020

Germany:

Very early, very broad availability of diagnostic testing



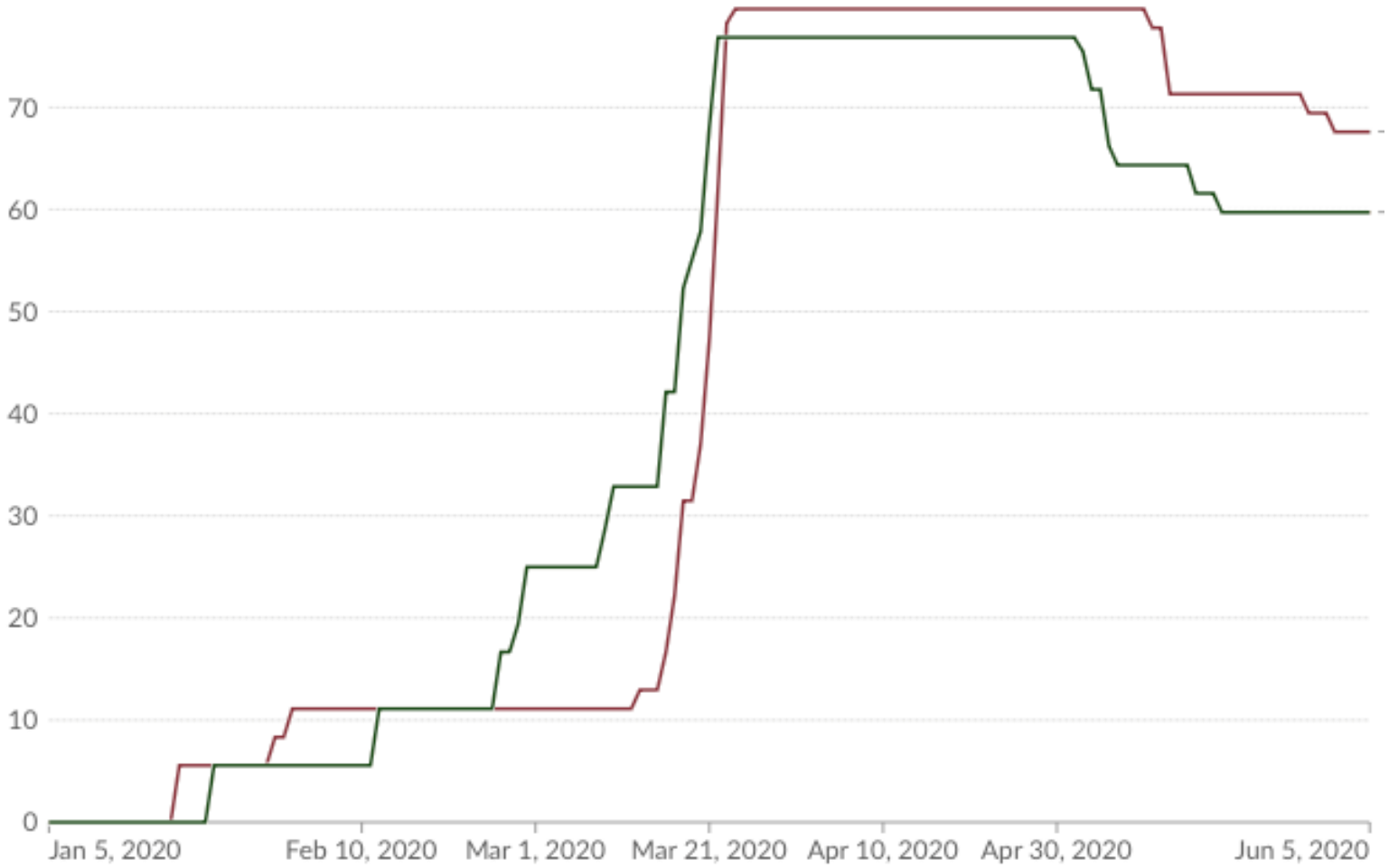
State	cases (n)
Baden-Wuerttemberg	18
Bavaria	28
Berlin	4
Bremen	1
Hamburg	2
Hesse	12
Lower Saxony	1
North Rhine-Westphalia	76
Rhineland-Palatinate	2
Saxony	1
Schleswig-Holstein	2
Thuringia	1
Summe	148

RKI situation report March 04 2020

COVID-19: Stringency Index

The stringency index is a composite measure based on nine response indicators including school closure travel bans, rescaled to a value from 0 to 100 (100 = strictest).

Table | Chart



UK vs D:
NPI later, stricter, longer

UK initiates contact measures ca. 3 weeks later than Germany (incidence rise from mid February, first fatal case 5th March, more than 100 confirmed cases by that time)

Ourworldindata.org; https://www.bbc.com/news/uk-51759602

Contact measures during 1st wave, D vs UK

COVID lethality, Germany First wave, Germany (COVID as primary cause of death, through July 2, 2020)	111.25 / million pop.
Same for UK	832.47 / million pop.
Absolute death toll in Germany (Lethality (per million) X 84 million population)	9345
Death toll assuming UK lethality	69927

European Centre for Disease Prevention and Control

An agency of the European Union

Evolution of Disease and Laboratory Networks

EVD-Labnet

COVID-19 and Influenza networks

EU Reference Laboratories for Public Health (EURL) mechanism

DURABLE
Research Network for Epidemics

HERA
HEALTH EMERGENCY PREPAREDNESS AND RESPONSE AUTHORITY

France
INSTITUT PASTEUR
Aix Marseille université
PASTEUR NETWORK

Belgium
KU LEUVEN

Netherlands
RIVM
Erasmus Universiteit Rotterdam

Denmark
STATENS SERUM INSTITUT

Spain
CSIC

Italy
Università degli Studi di Padova
Istituto Superiore di Sanità

Germany
CHARITÉ
FLI

Portugal
Instituto Nacional de Saúde Doutor Ricardo Jorge

Estonia
Tartu Ülikool Universitas Tartuensis

Finland
Helsingin yliopisto Helsingfors universitet University of Helsinki

Latvia
BIOR

Poland
Jagiellonian University in Kraków

Czechia
Univerzita Karlova

Croatia
HZJZ

Greece
Aristotle University of Thessaloniki

Preparedness research network of 20 leading scientific institutions

located in 15 EU countries

Challenges

Professional networks connecting research and public health laboratories

IVDR / validation efforts, requirement of formal clinical studies framework

Role for academic consortia in regulation and clearance processes (from samples to cohorts)

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Thank you