Indicate Solutions

PRECISION MEDICINE PERSONALIZED

Presentation Deck

September 28th, 2021

This deck is for informational purposes only. An Emergency Use Authorization (EUA) has NOT been filed with the FDA for this product. EUA has NOT been granted and therefore the contents of this deck should not be viewed as a commercial promotion of this product.

The Indicate Project

2016- Indicate was formed by a multi-disciplinary team of scientists to detect actionable mutations in the blood of cancer patients in a rapid PoC test format

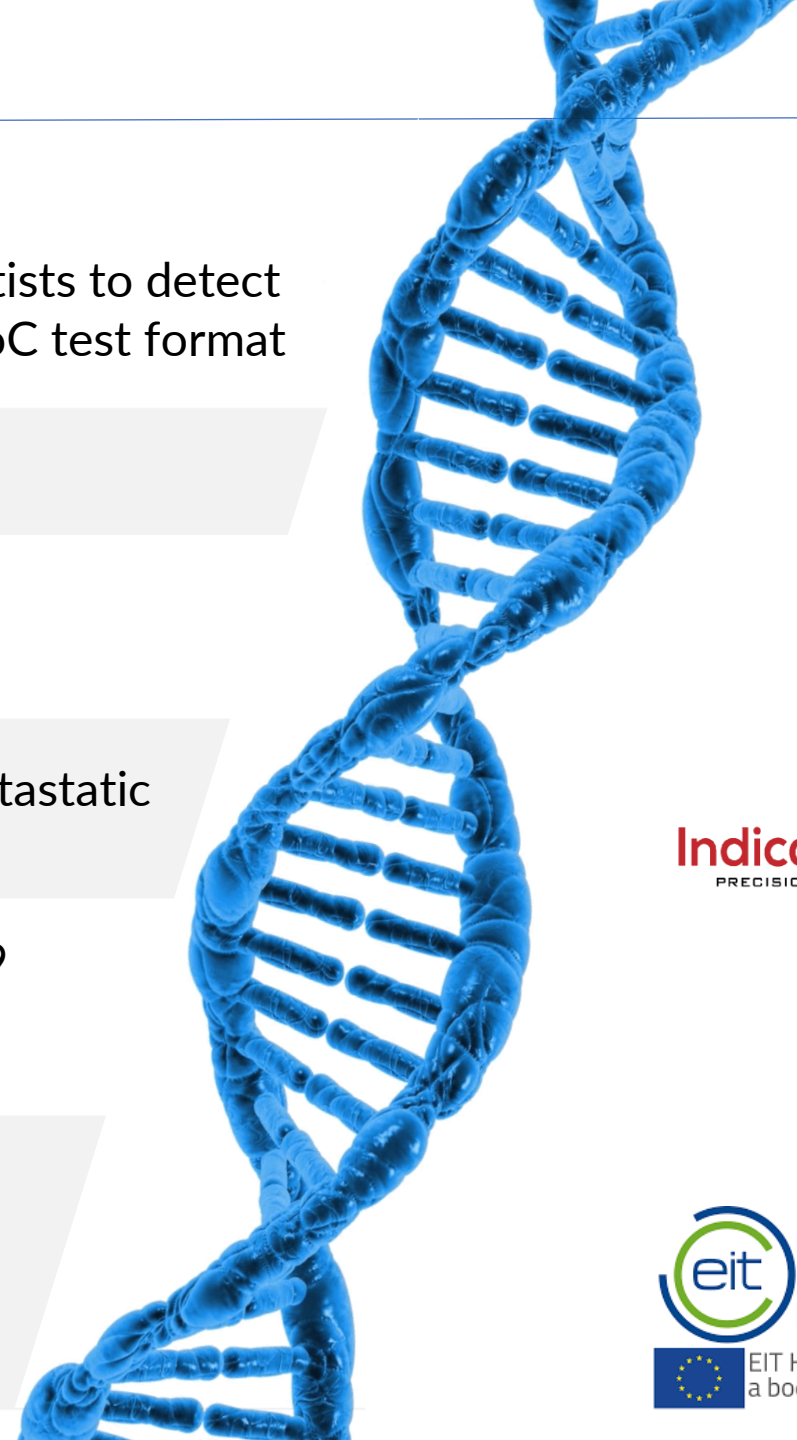
2017- EPO patent granted

2018- Detection of *EGFR* T790M and L858R mutations *in vitro* demonstrated (TRL4)

2019- Technology pipeline adapted to colorectal cancer and metastatic melanoma. Funds raised through investors and grants

2020- New platform technology developed to detect COVID-19 and other diseases in saliva in <15 mins. Patent filed. EIT Health grant awarded and EU H2020 ´Seal of Excellence´.

2021- Starting clinical validation of the REPViT Device. Repvit UK Ltd spun-out to develop infectious disease technology. Development of food pathogen test technology (SAFE).



European Commission
COVID 19 RESPONSE
SEAL OF EXCELLENCE

Indicate Solutions
PRECISION MEDICINE PERSONALIZED

eit Health

EIT Health is supported by the EIT, a body of the European Union

The Team

Anton Eratt Chief Executive Officer
Anton has >10 years experience in company executive roles and founded VPlus Networks and CCIE Advice

Kevin Walker-Curran (MSc) Chief Financial Officer
Kevin has degrees in commerce and international finance and >30 years commercial experience as senior management in Deloitte, PWC, Arthur Anderson and EY.

Prof. Charles Lawrie (DPhil, FRCPath) Chief Scientific Officer & co-founder
Charles did his doctorate in Institute of Virology (Oxford University). Author of >110 publications and books, he is a pioneer of cancer biomarkers in bodily fluids and viral diagnostics.

Javier Zubiria (MA) Chief Operating Officer
Javier did his Master in Deusto University and has >5 years comercial experience including in Tecnalia Ventures

Daniel Maitland, MA (Oxon)) Chief Technological Officer & Founder
Daniel has >20 years commercial experience having founded and exited two companies (Opus Energy and Seaglass cloud technology) >£600 million.

Advisory Board

Dr. María Armesto

Scientific Advisor in Virology

Prof. Luis Liz Marzán

Scientific Director of CIC-biomaGUNE

Prof. Adrian Harris

Chairman of Medical Oncology, Oxford

Prof. Peter Dobson (OBE)

Business and manufacturing Advisor

A revolution in diagnostic technology

Indicate Solutions
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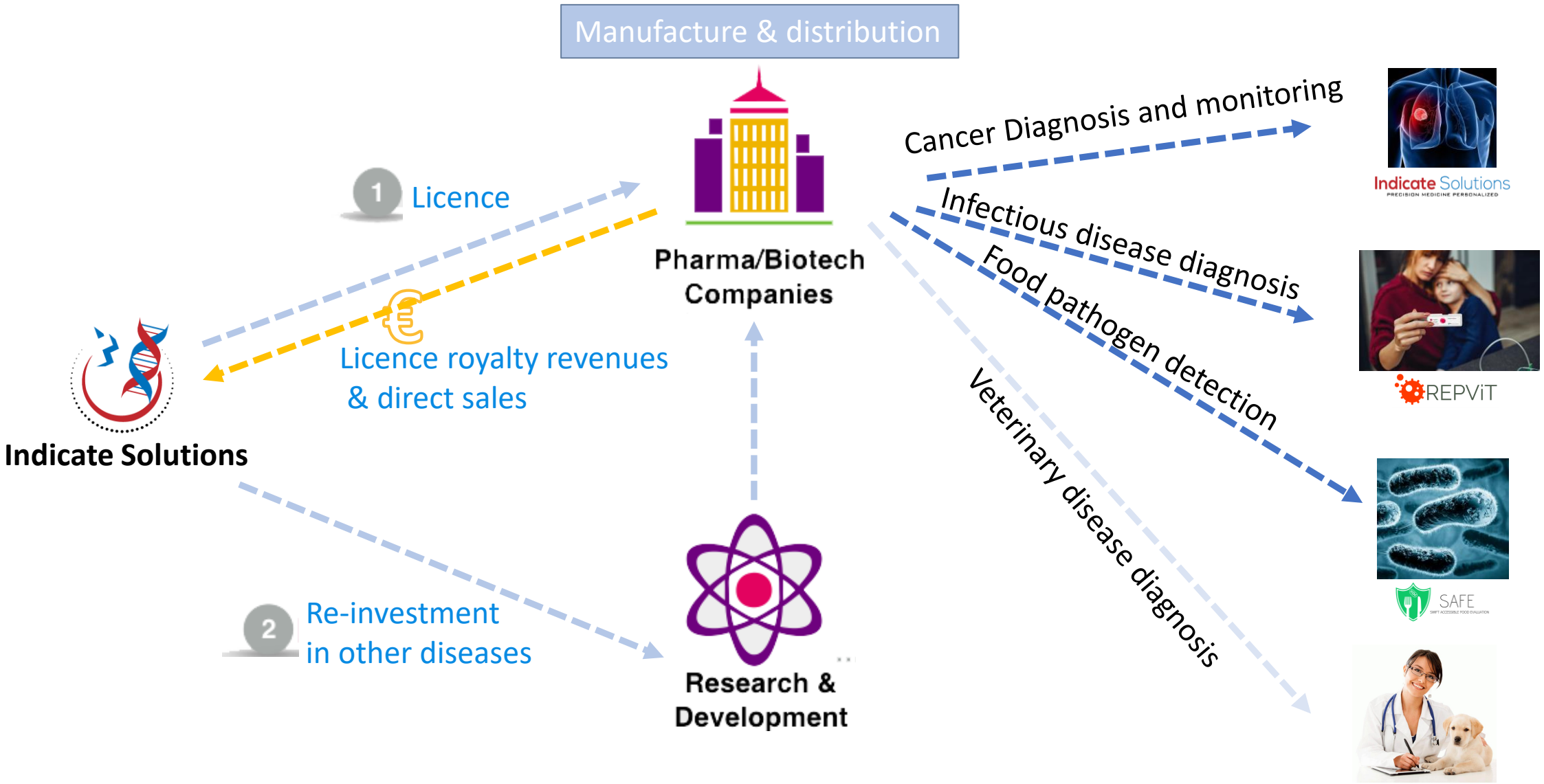
REPViT

SAFE
SWIFT ANYWHERE FOOD EVALUATION

Indicates´ diagnostic innovations powered by nanoparticles

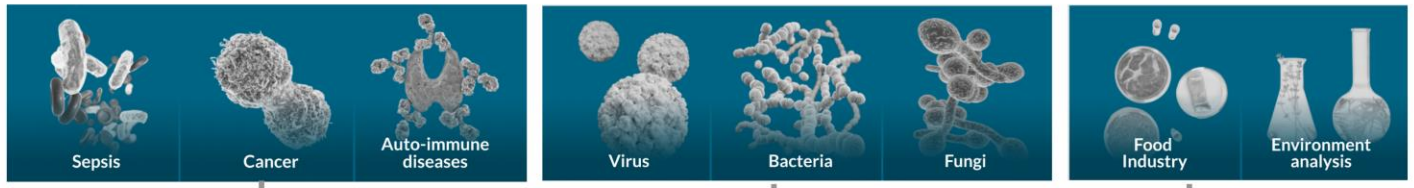
The technological opportunity represented by Indicate Solutions leverages our proprietary **nanoparticle-based biosensor technology** as **rapid, economic** and **highly-scalable** detectors of **nucleic acids** in cancer and infectious disease in a format similar to lateral flow assays allowing diagnosis whenever and wherever needed. The technology can revolutionize *in vitro* diagnostics by replacing PCR in health, food, environmental and veterinary fields.

Business Plan



Product pipeline

Disease areas



Indications

Non-small cell lung carcinoma (NSCLC)

SARS-CoV-2 / Influenza

Salmonella

Addressing unmet medical needs along the care continuum

Screening → Diagnosis → Risk stratification → Therapy selection monitoring

Clinical Indication	Biomarker Development	Feasibility Studies	Prototype assays	Analytical verification	Clinical validation	Regulatory approval	Commercialization
Infectious Diseases	SARS-CoV-2						
	Influenza						
Cancer	Non-small cell lung cancer						
	Melanoma						
Food Safety	Salmonella						
	Campylobacter						

Intellectual Property (IP)

Date	Title	Application no.	Territories	Status
2020	NP-colloidal sensor (SARS-CoV-2)	EP 20382499.0	EU Filings in USA, JP, CN and LatAm pending	**Filed**
2016	Diagnostic methods and devices	EP2016/077267	EU Pending in USA, JP & CN	**Granted**

Indicate Solutions has the exclusive global rights to exploit and commercialize the IP related to the diagnostic(s) for the lifetime of the patent(s) in return for minimal royalties.

Indicate Solutions

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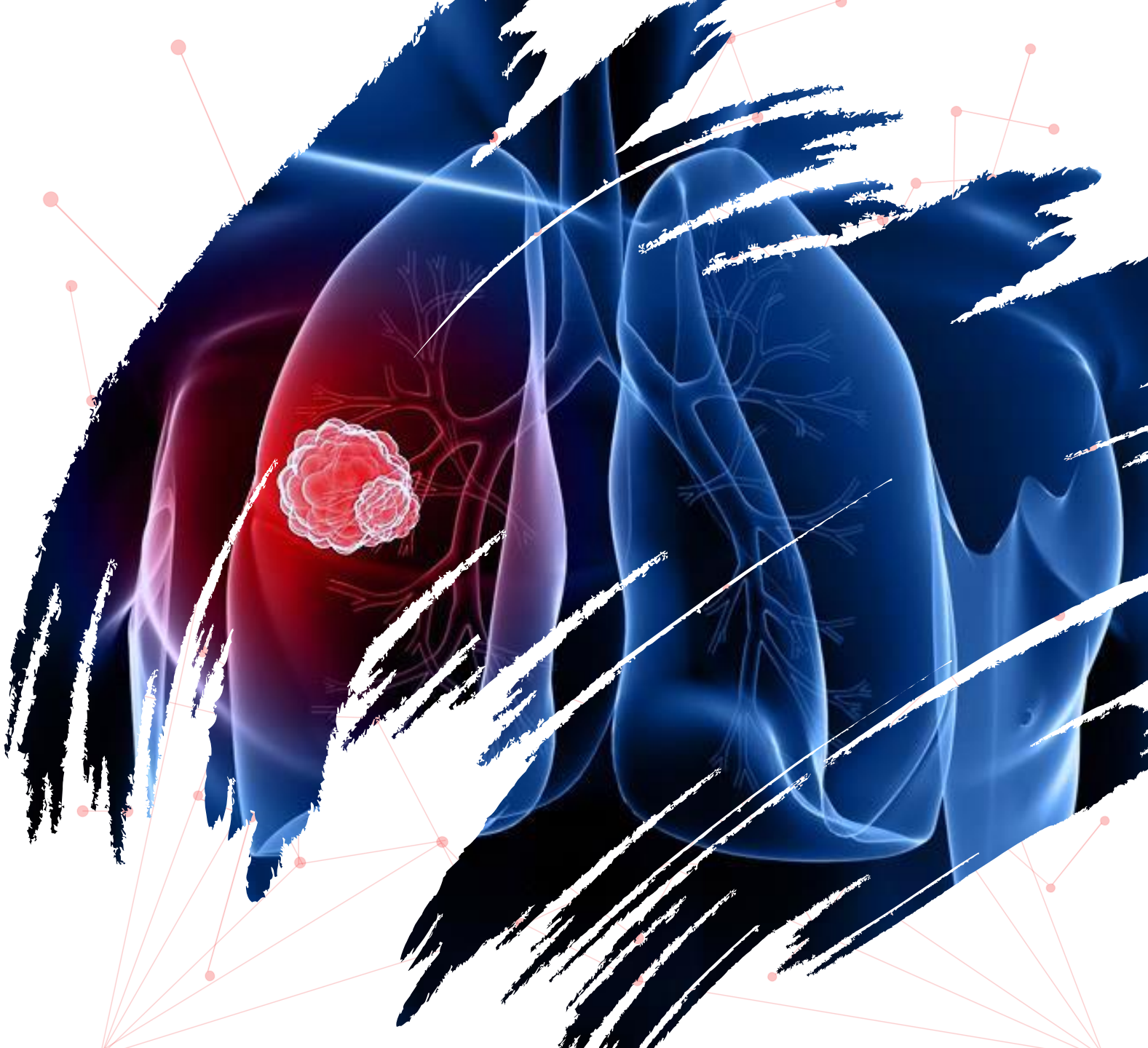


A REVOLUTION IN RAPID CANCER DIAGNOSTICS AT POINT-OF-CARE

eit Health

EIT Health is supported by the EIT, a body of the European Union

The Problem

Current cancer diagnostics are expensive & slow

Medical Diagnostic tests are always done in **laboratory**

COMPLEX

Lab tests performed by qualified technicians.

EXPENSIVE

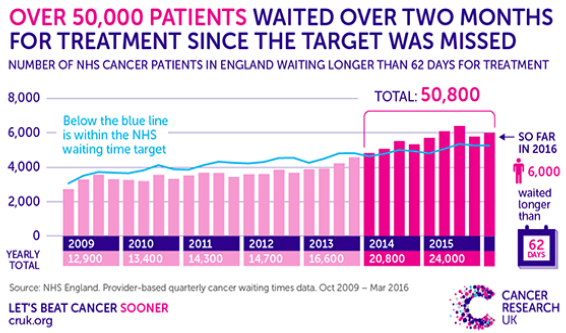
Off-site, extra resources, infrastructure and personnel

SLOW

Results 48-72hr, extra hospital appointment required→ treatment **delay** typically **3-4 weeks**

INVASIVE

Requires surgical biopsy or venous blood with high volumes



The Solution

Novel platform technology:

Lab-on a Chip

Rapid** (30 mins**) affordable**, **reliable** and **easy-to-use** blood diagnostic test when and where it is needed at **PoC

The Indicate rapid test allows test + treatment prescription in the same hospital appointment

DEVICE FEATURES:

- **Nanoparticle-based Solution**
- **Point of Need**
- **Precise**
- **Automated**
- **Not-invasive**
- **Fast (30 min)**

The Concept: Reader (Affordable) **+ Cartridge per Test** (disposable)

1. **Extract Sample**

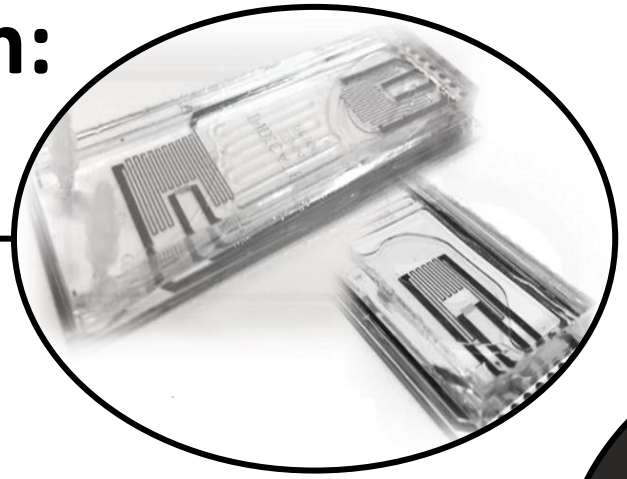
2. **Sample and cartridge in the Reader**

3. **Result in 30 minutes**

Technology

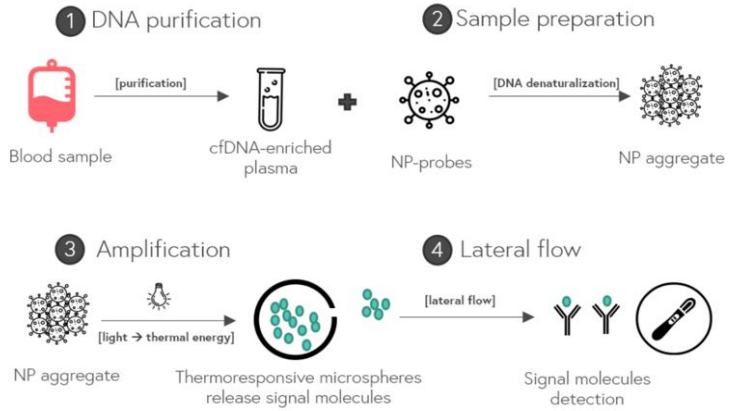
The Platform:

1 CARTRIDGE



2 READER

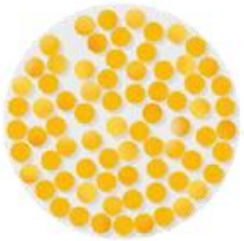
How it works:



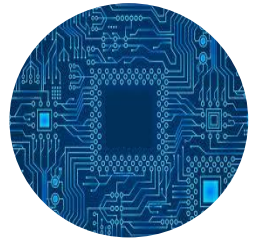
Based in:

Microfluidics

Nanoparticles



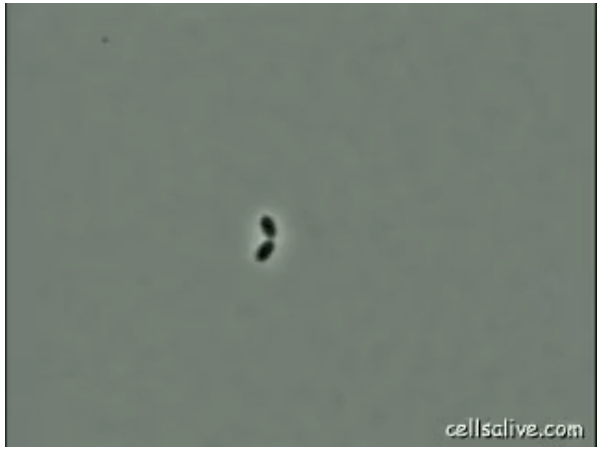
Microelectronics



Disruptive & Adaptable Platform Technology

1. **Patented** chemical amplification technology: **(EP2016/077267 (EU))**
   – also filed in **US**, **Japan** and **China**

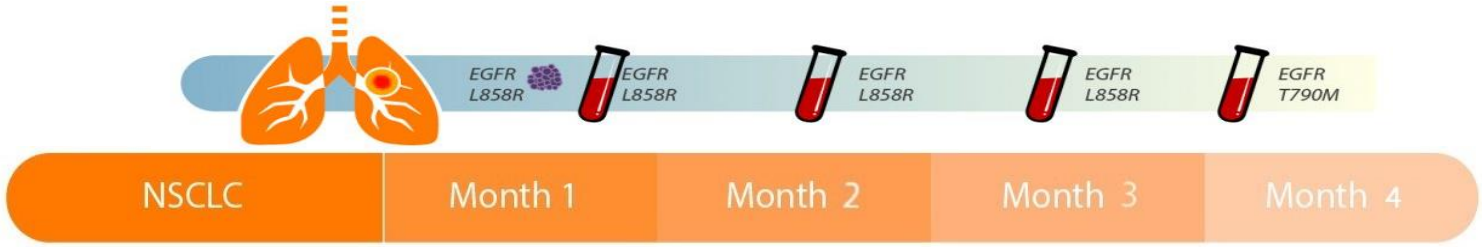
2. **PCR needs 30-40 cycles to get a signal**



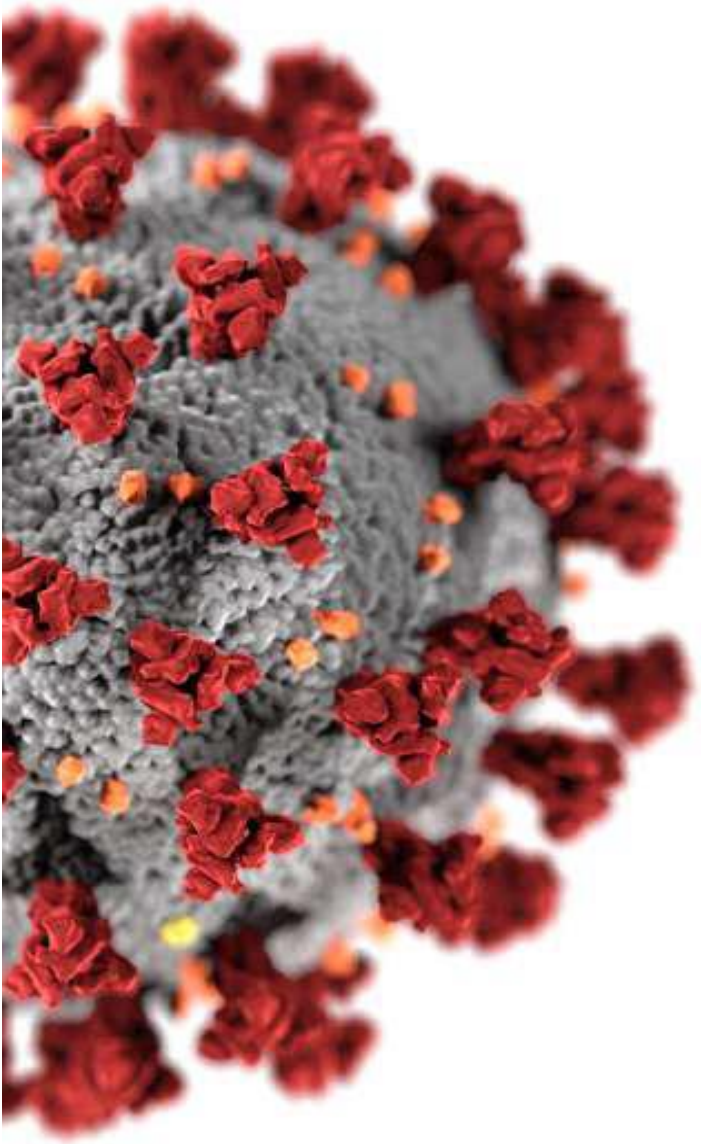
3. **Indicate offers an immediate signal amplification**

- Novel chemical amplification technology inspired by **signalling cascades in living cells** (and water balloons!)

- **Specificity**-Nanoparticle probes come together **only** when bound to mutated DNA sequence
- **Sensitivity**-Clustered nanoparticles turn light into heat releasing tens of millions of signal molecules
- **Easy-to-read result**- signal molecules form lines like pregnancy test
- **Adaptable**- platform technology for (m)any cancer types, infectious diseases (HIV, SARS, sepsis), veterinary, environmental etc.
- **Proof-of-concept indication:** *BRAF* V600E melanoma, *EGFR* L858R and T790M lung cancer



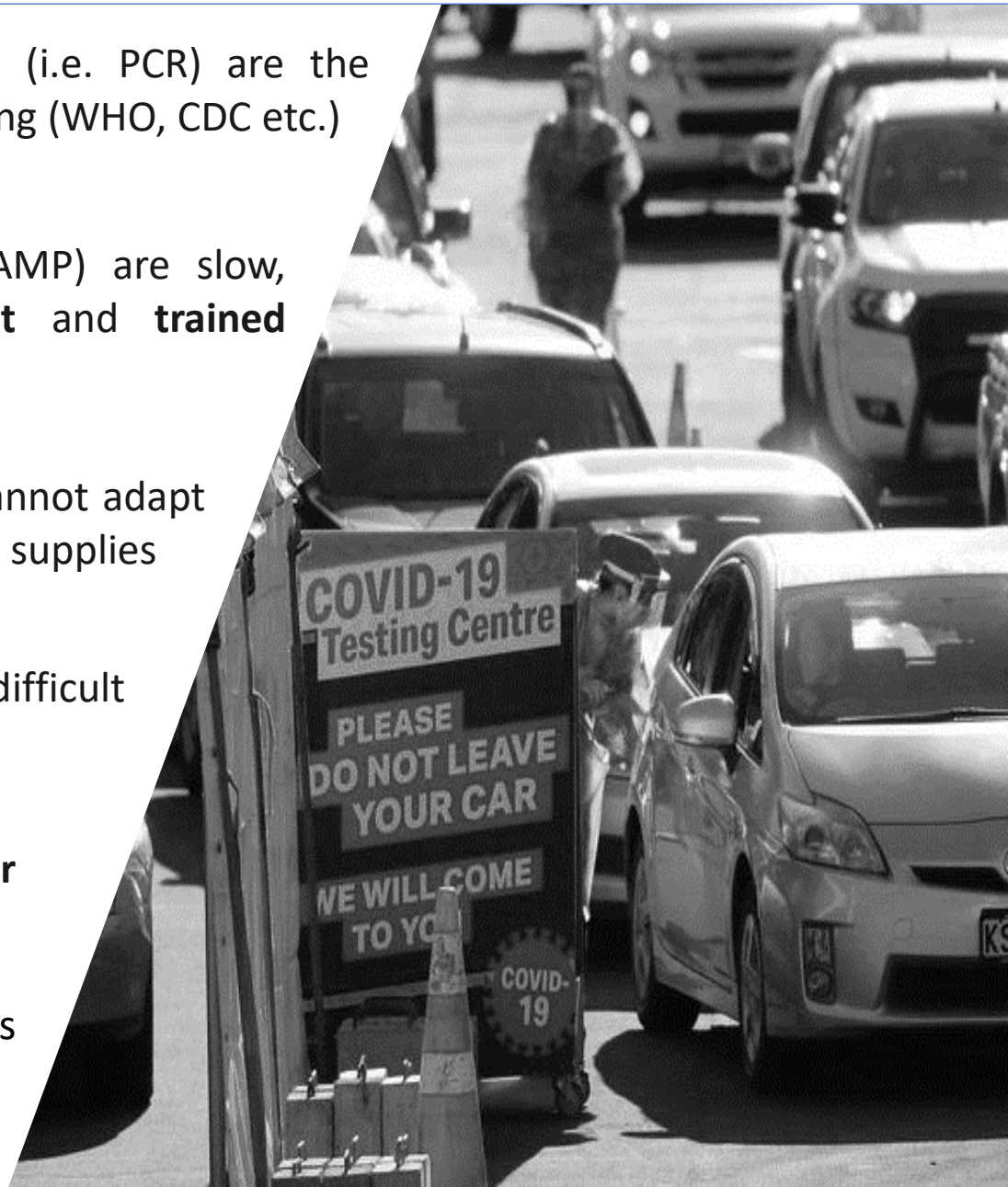
REPViT



Rapid, Economic, Easy-to-use, molecular nucleic acid test for infectious diseases from saliva samples

The Problem

- Molecular nucleic acid tests (i.e. PCR) are the **clinical gold standard** for testing (WHO, CDC etc.)
- **PCR** and PCR-based alternatives (e.g LAMP) are slow, **expensive**, **require complex equipment** and **trained personnel**
- Antigen/antibody rapid tests **suffer performance issues,** cannot adapt rapidly to viral mutations and rely on resources with limited supplies
- Current tests based on **nasal/oral swabs**, uncomfortable and difficult to administer effectively
- Even with wide-scale vaccination the **world-wide demand for testing massively outstrips supply**
- Covid-19 is now **endemic** and the global fear of infection is entrenched. Testing needs will exist for many years to come



The Solution

The REPViT test combines the home test capabilities of antigen/antibody rapid tests with the performance of PCR and is scalable beyond any competitor technology.

REPViT allows global daily testing of asymptomatic and symptomatic individuals, without economical or infrastructural restrictions

A simple saliva test, for use at home, at airports, in schools, in the workplace, before meetings- wherever and whenever is needed

A revolutionary alternative platform to PCR testing whenever and wherever needed.

"PCR in your pocket"

DEVICE FEATURES:

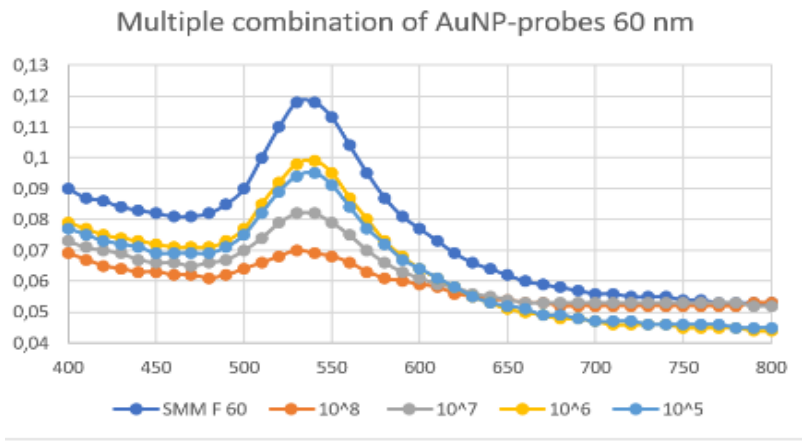
- **Scalable & Flexible**
- **Simple & Affordable**
- **PCR-like performance**
- **Platform Technology**
- **Only use Saliva**
- **Results in 15 min**

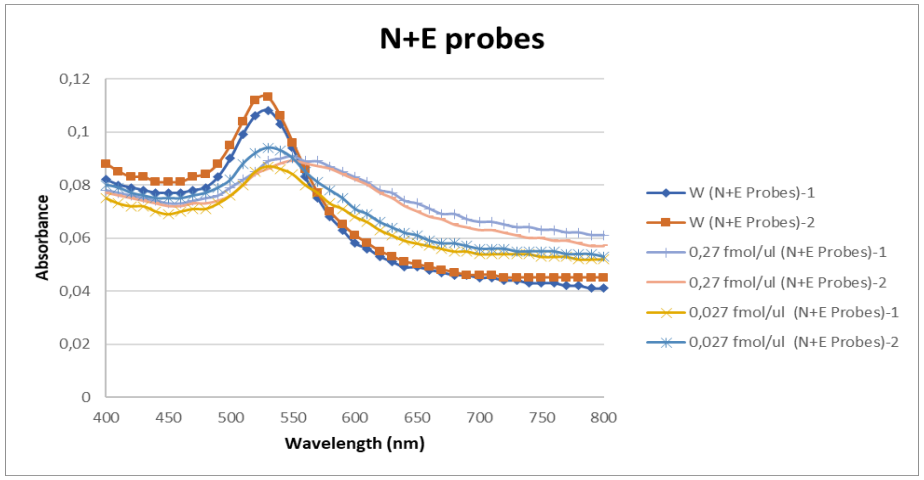
Disruptive & Adaptable Platform Technology

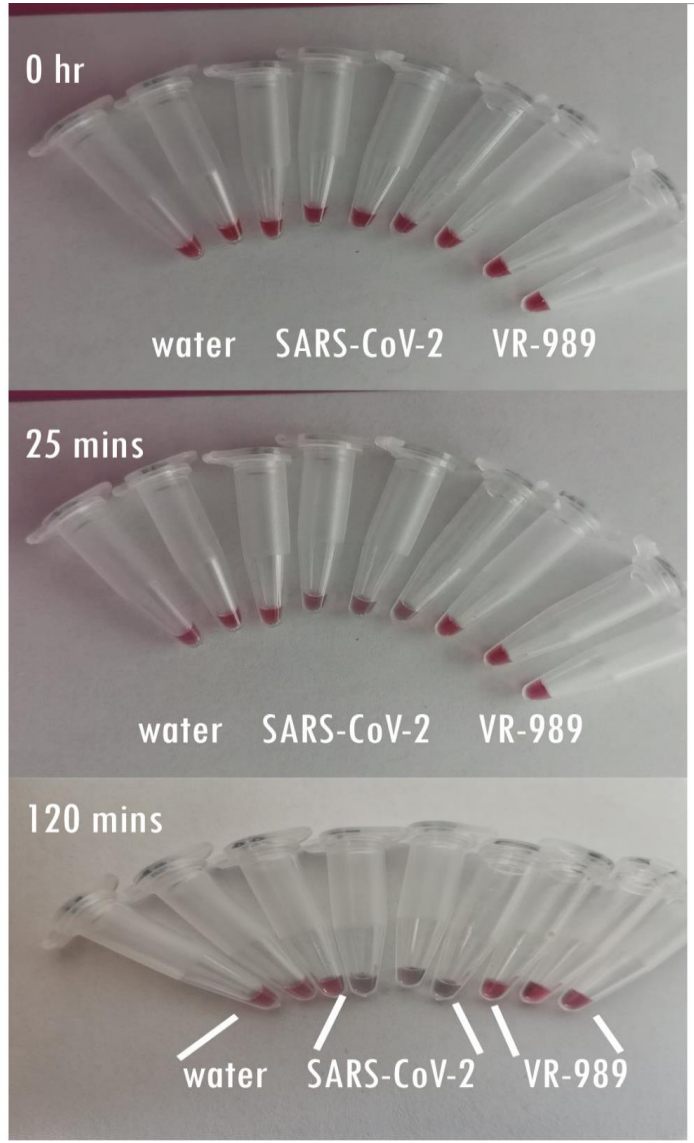
Experimental data

Current state of technology:

1. Limit of Detection (LOD) 0.026 fmol or ~10^4 copies (to be improved)
2. Specificity – no reactivity with closely related coronaviruses (e.g. VR-989, 229E etc.)
3. Functions with saliva or nasopharyngeal swabs- **no external RNA purification step needed**, **add sample direct to tube, shake and wait.**







Current performance data

Experimental data

1

Positive and negative clinical samples

Sensitivity based on 175 samples of known COVID – 19 status (PCR tested).

(95 CI: 82.71% to 98.02%)

2

Reference Method

RT-qPCR, symptomatic and asymptomatic individuals

Specificity, based on 175 RT-qPCR samples.

(95 CI: 89.03% to 99.19%)

3

Interference

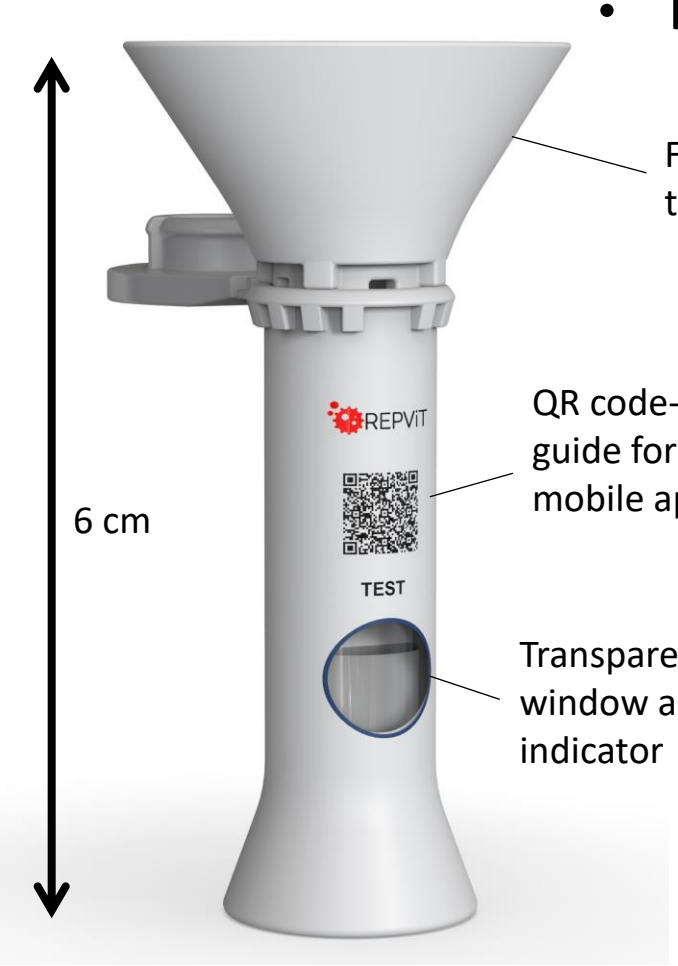
No cross-reactivity was observed for related pathogens, high prevalence disease agents and normal pathogenic flora

Accuracy, based on 175 samples.

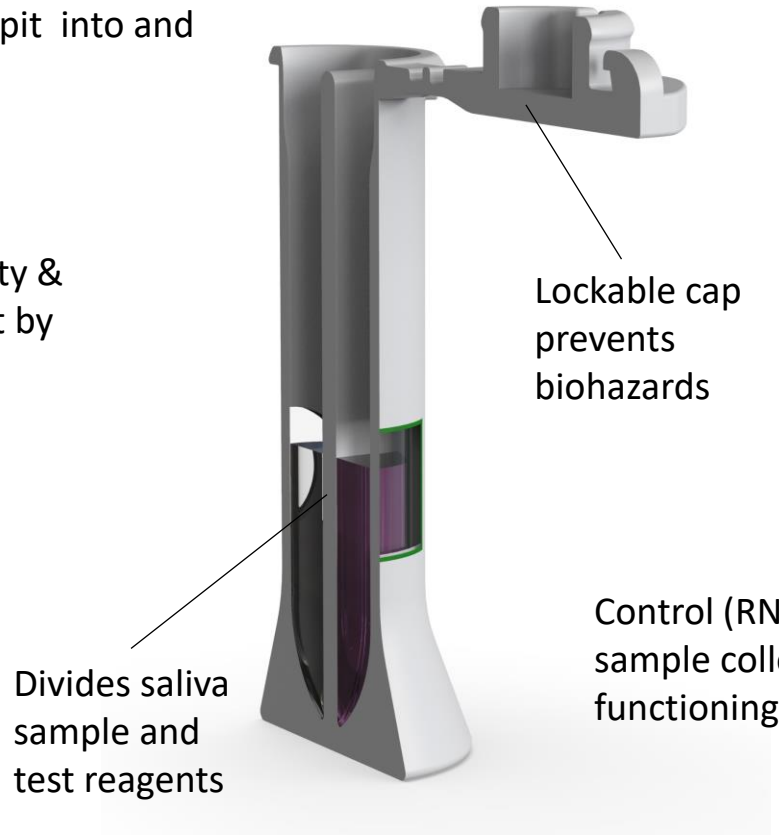
(95 CI: 89.46% to 97.86%)

Repvit all-in-one COVID-19 molecular test

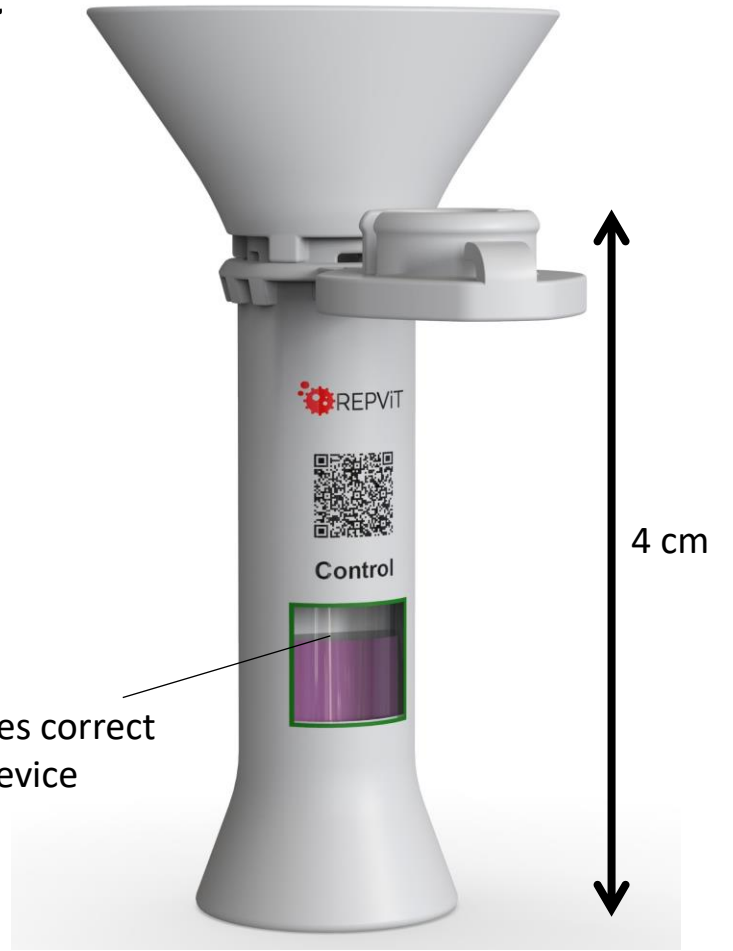
- **No user intervention other than spit → close → wait**



Front



Inside



Back

- **Two-piece polypropylene design for ease of manufacture**

Partnering to the market

COGS (€0.57 (10K-1 million tests))

Consists of nanoparticles (+other consumables) €0.12, injection molded plastics €0.10, assembly and packaging €0.15, transport, storage etc. €0.20. (costs based on conversations with manufacturers). >1 million tests COGS will fall significantly

Manufacture and regulatory

- **Manufacture and regulatory will be out-sourced**
- Agreement with major UK manufacturer to scale-up nanoparticle chemistry to equivalent 10 million tests daily- can be increased as required
- Agreement with EU-based IVD-specialist for third-party ISO1485 compliant verification
- Agreement with EU-based health service (Spanish) for clinical validation
- Agreement with regulatory consultants for FDA (EUA) and EMA CE regulatory pathway application

Distribution

- Distribution agreement signed for middle East
- Distribution agreement signed for China
- US-based global pharma negotiation for US/EU OTC market

Mobile app option

Optional off-the-shelf mobile phone app

- iOS/Android compatible app
- Unique QR code linked each specific test
- QR code enabling camera-based result confirmation and registering

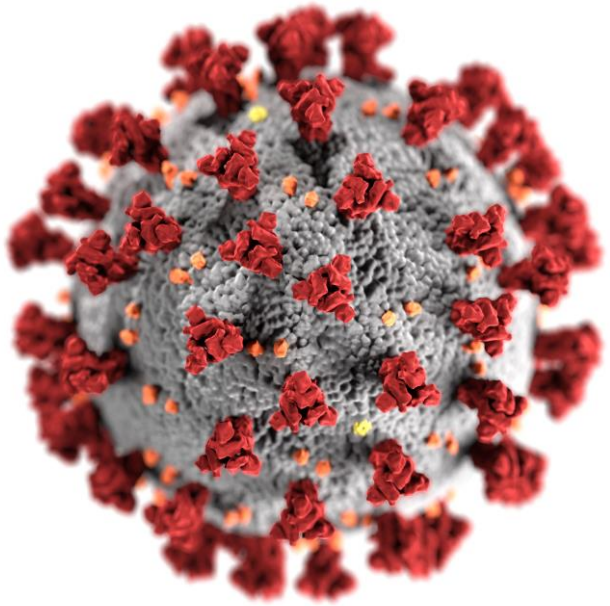
Outsourcing administration and data handling

- Offering tracing and reporting for use in schools, travel, immigration and etc.
- The user can decide the level of personal data entered and disclosed and to whom:
  - Passport number (for travel and immigration linked to proposed IATA system)
  - Health insurance number (for reporting to insurer)
  - For SARS-Cov-2, it could be linked to the national reporting apps
  - Result could also be reported automatically to national authorities using LOINC and SNOMED codes

The data could provide the long-term health profile of individuals and populations for Covid-19, Influenza and other diseases that could be tested by the platform

Adaptable Platform Technology

Platform-based Technology with many applications



Other Infectious diseases

Influenza, Enterovirus, Norovirus, Measles, Dengue, Dengue, Mumps, Herpes, Ebola, H1N1, HPV, HIV etc.

Market $40B (2020) CAGR 7%

Veterinary

Detection of pet and livestock disease. Lower barrier to market entry than medical diagnostics.

Market $6B (2020) CAGR 11.5%

Food Control

On-site rapid testing in farms, factories or point-of-sale. Allows disease control in livestock and immediate public health containment.

Market $13B (2017) CAGR 7.3%

SAFE

SWIFT ANYWHERE FOOD EVALUATION

Indicate Solutions
PRECISION MEDICINE PERSONALIZED

Walk away solutions for PCR analysis

*A revolutionary alternative platform for Food testing to use **whenever** and **wherever** needed.*

Standardization and harmonization of methods
- Reduction of errors and variability

Improved quality and performance
- Better reproducibility and repeatability
- Reduced contamination risk

Flexible
- Animal & plant DNA
- Bacterial DNA from enrichments
- Virus RNA

Real-time SAFE Workflow

Sample preparation

Food & feed samples, enriched bacteria cultures, virus samples

Nucleic acid preparation

Three protocols:
- Animal & plant DNA
- Bacterial DNA

Real-time PCR set-up

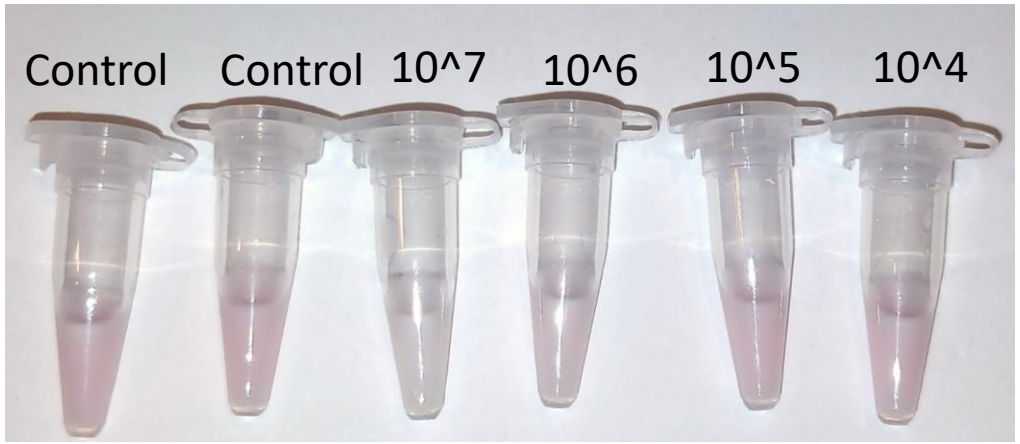
Broad range of kits:

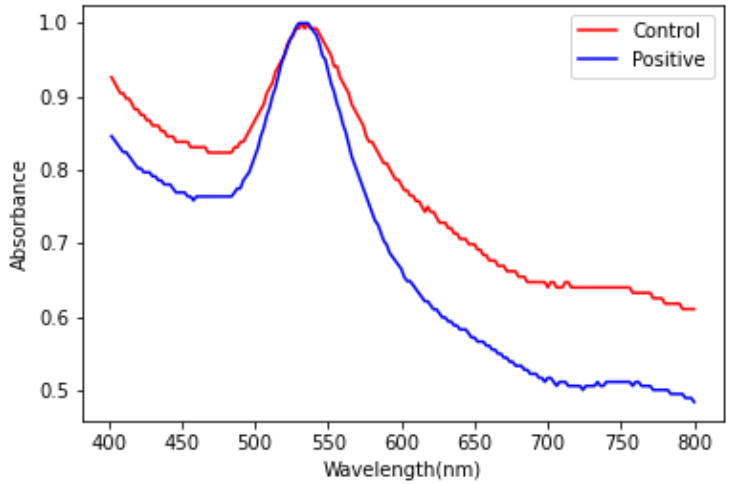
Disruptive & Adaptable Platform Technology

Experimental data

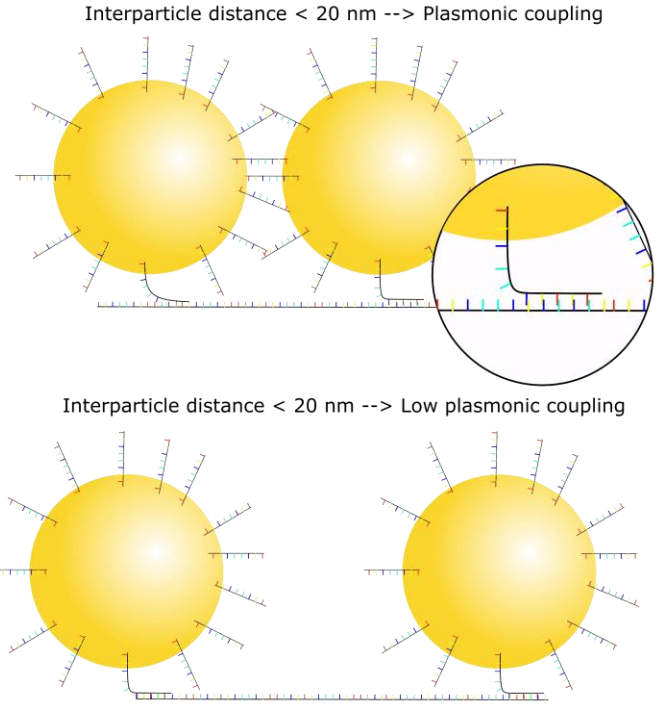
Current state of technology:

1. Limit of Detection (LOD) ~10^4 copies (to be improved)
2. Specificity and Sensitivity – Four different serovars of salmonella tested and detected from culture and from stool simples
3. Also tested in Campylobacter
4. Tested with milk and egg white- **<u>no</u> external RNA purification step needed, add sample direct to tube, shake and wait.**



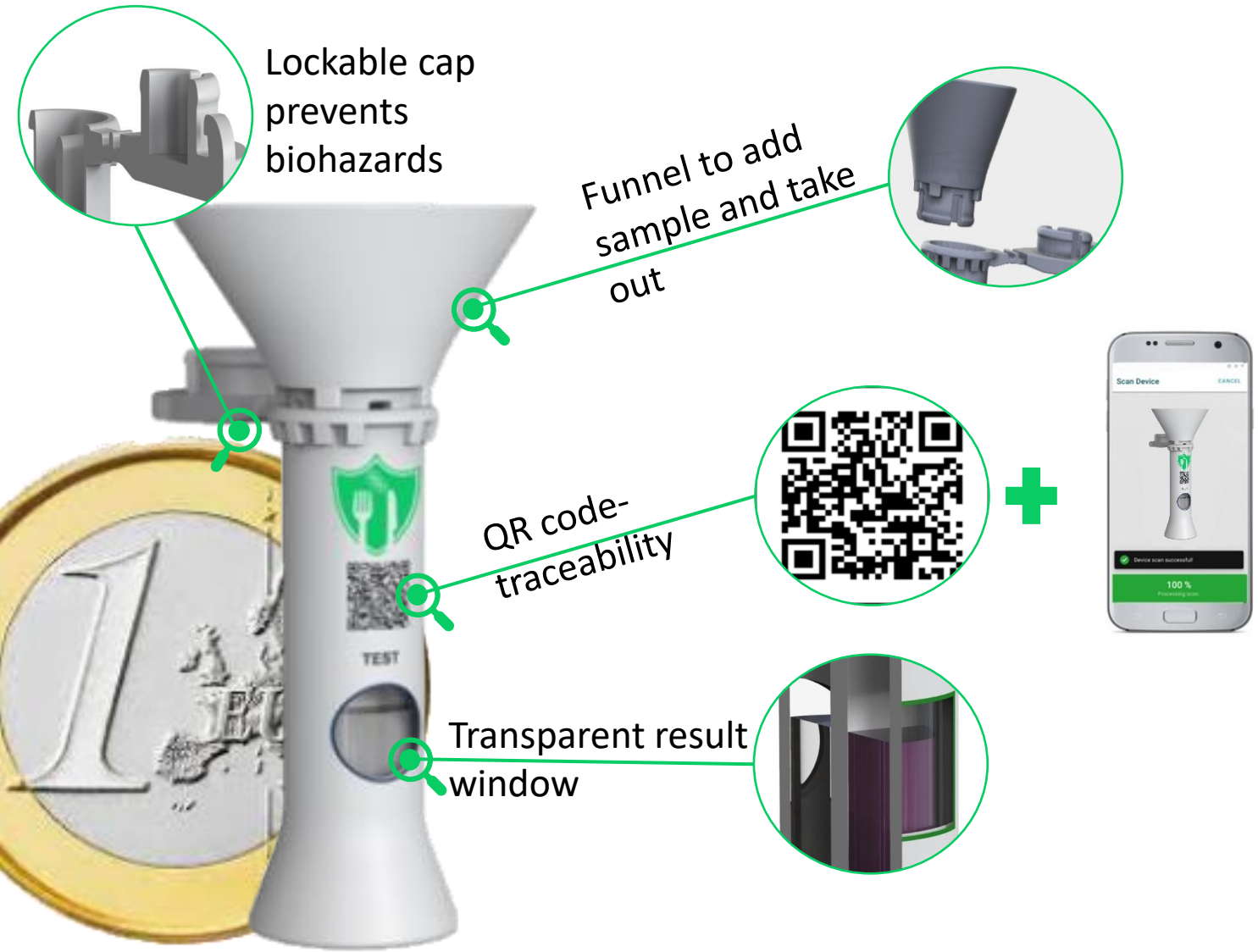


Control 10^7



SAFE all-in-one Food Safety molecular test

Working Prototype: No user intervention other than add sample → close → wait

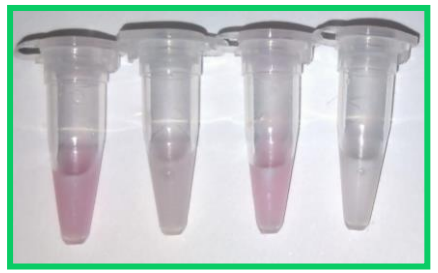


1. **Add sample in the tube with the funnel**

2. **Shake it 2 minutes**

3. **Result in 30 minutes**

Pink: Negative
Clear: Positive



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Indicate Solutions – Investing in the future of Diagnostics