EARLY SEPSIS DIAGNOSIS

10x faster & **3x** more effective

Loop DIAGNOSTICS

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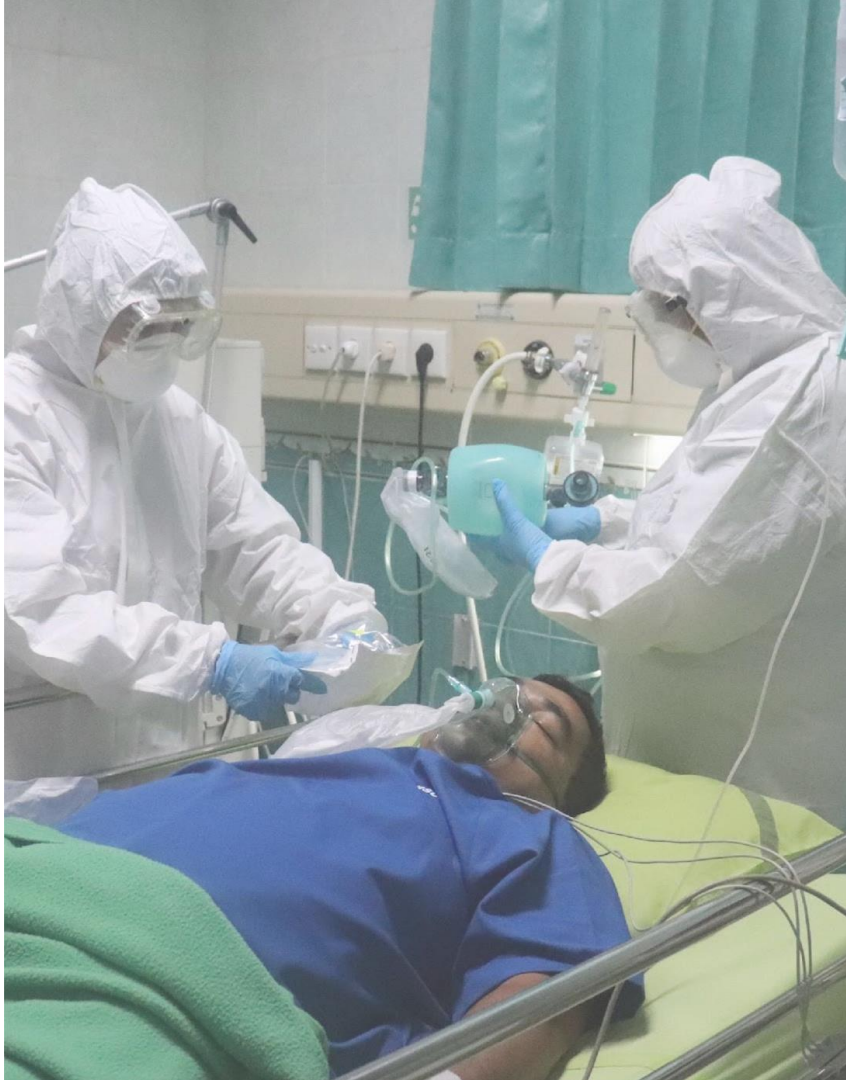
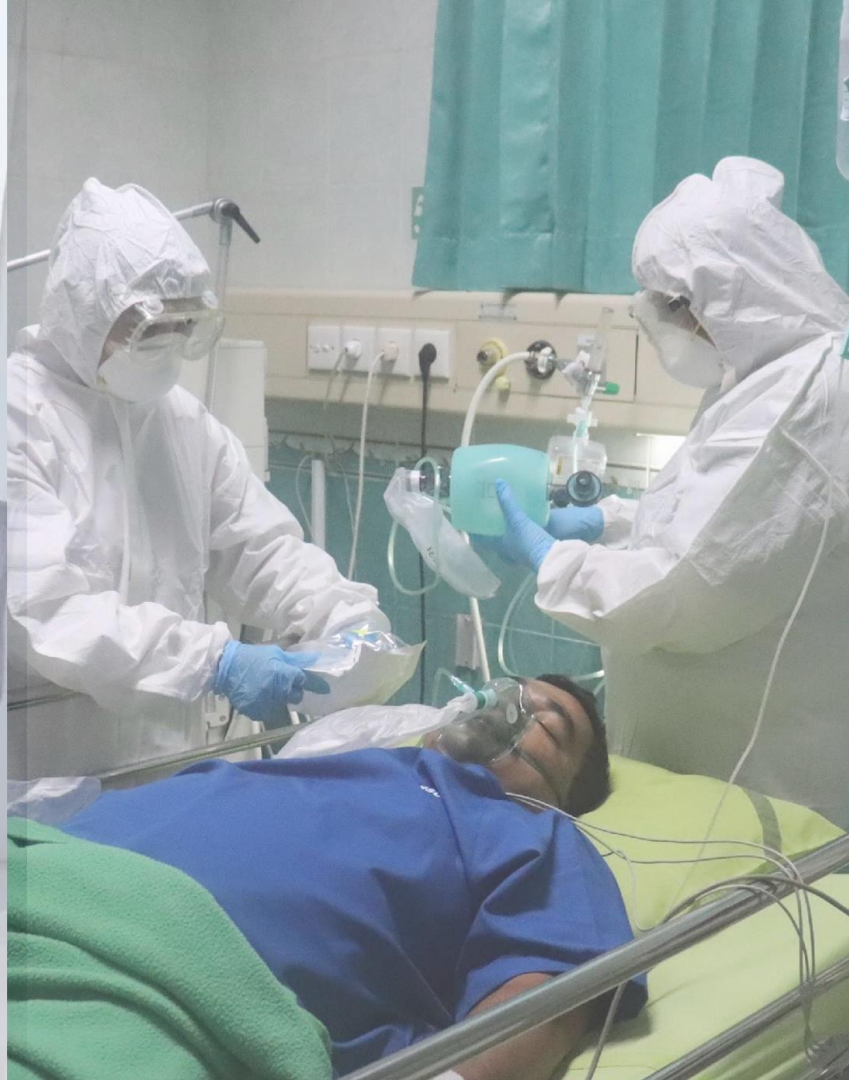


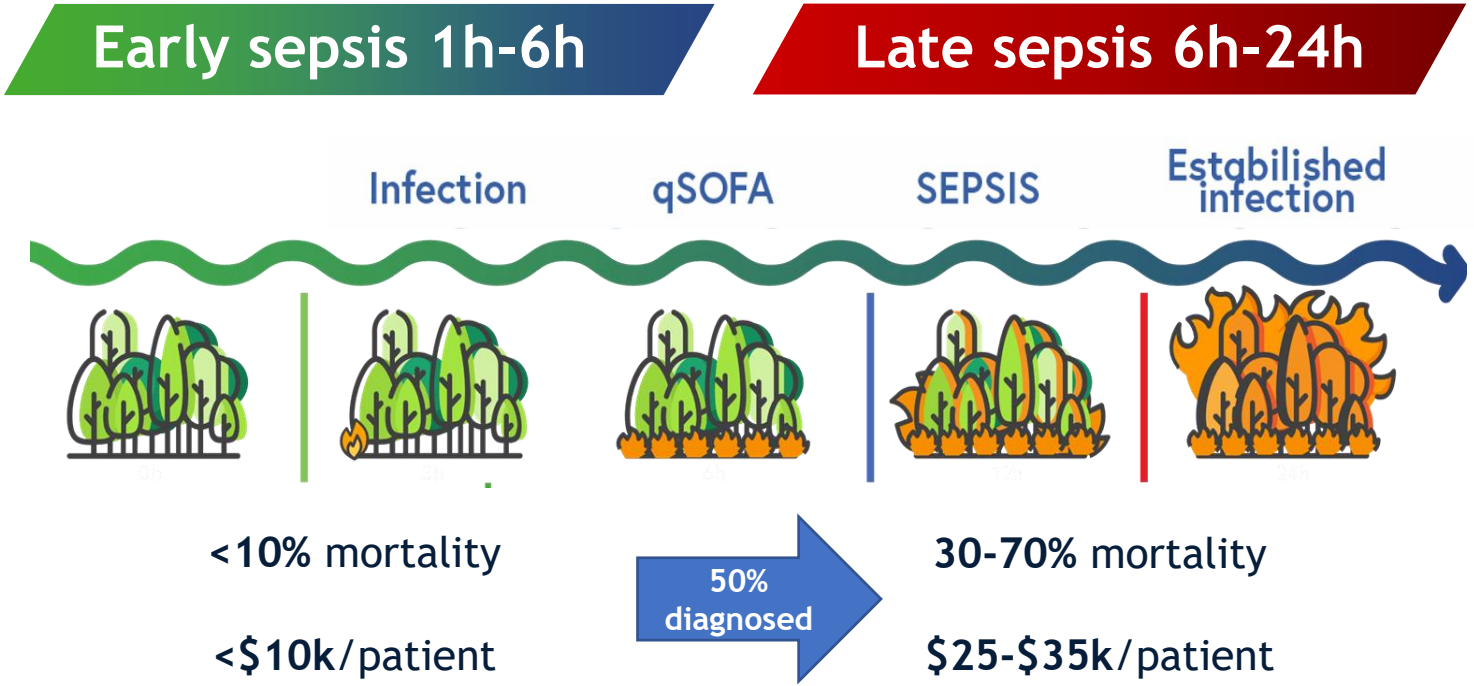
SEPSIS

50,000,000 Cases/year worldwide

11M deaths/year (globally)



EARLY DIAGNOSIS IS CRUCIAL



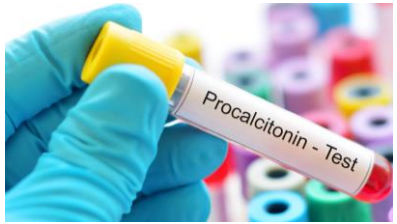
Liu, et al. Hospital Deaths in Patients With Sepsis From 2 Independent Cohorts. *JAMA*. 2014;312(1):90-92.

CURRENT TESTS NOT USEFUL FOR EARLY SEPSIS

CURRENT DIAGNOSTICS

PATHOGEN DETECTION AND SERUM BIOMARKERS

- **<30% SENSITIVITY**
- **18-72 HOURS DIAGNOSTIC WINDOW**



1 HOURS ----------DAMAGE TIME----------72 HOURS

CURRENT TESTS NOT USEFUL FOR EARLY SEPSIS

LOOP DIAGNOSTICS

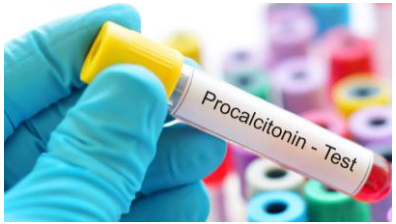
SEPTILOOP: Functional *ex vivo* response assay

- **>90% SENSITIVITY***
- **1-72 HOURS DIAGNOSTIC WINDOW**

CURRENT DIAGNOSTICS

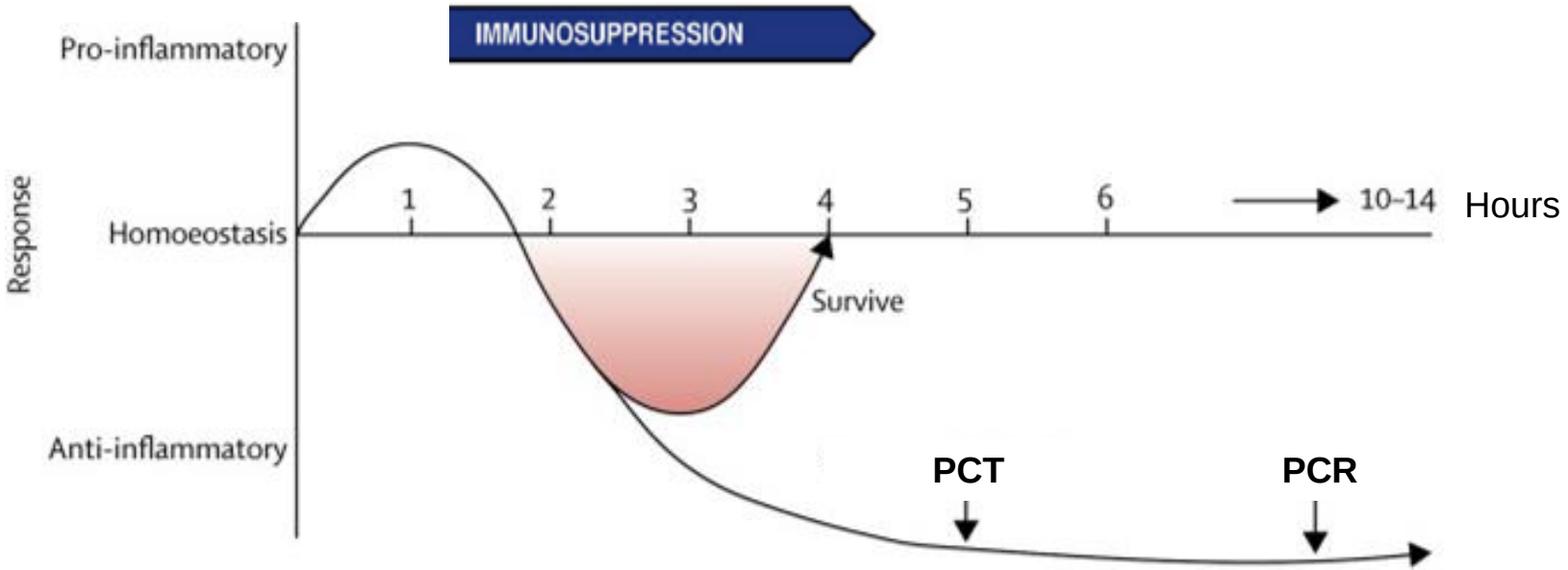
PATHOGEN DETECTION AND SERUM BIOMARKERS

- **<30% SENSITIVITY**
- **18-72 HOURS DIAGNOSTIC WINDOW**



1 HOURS ----------DAMAGE TIME----------72 HOURS

SCIENCE BEYOND LOOPDX

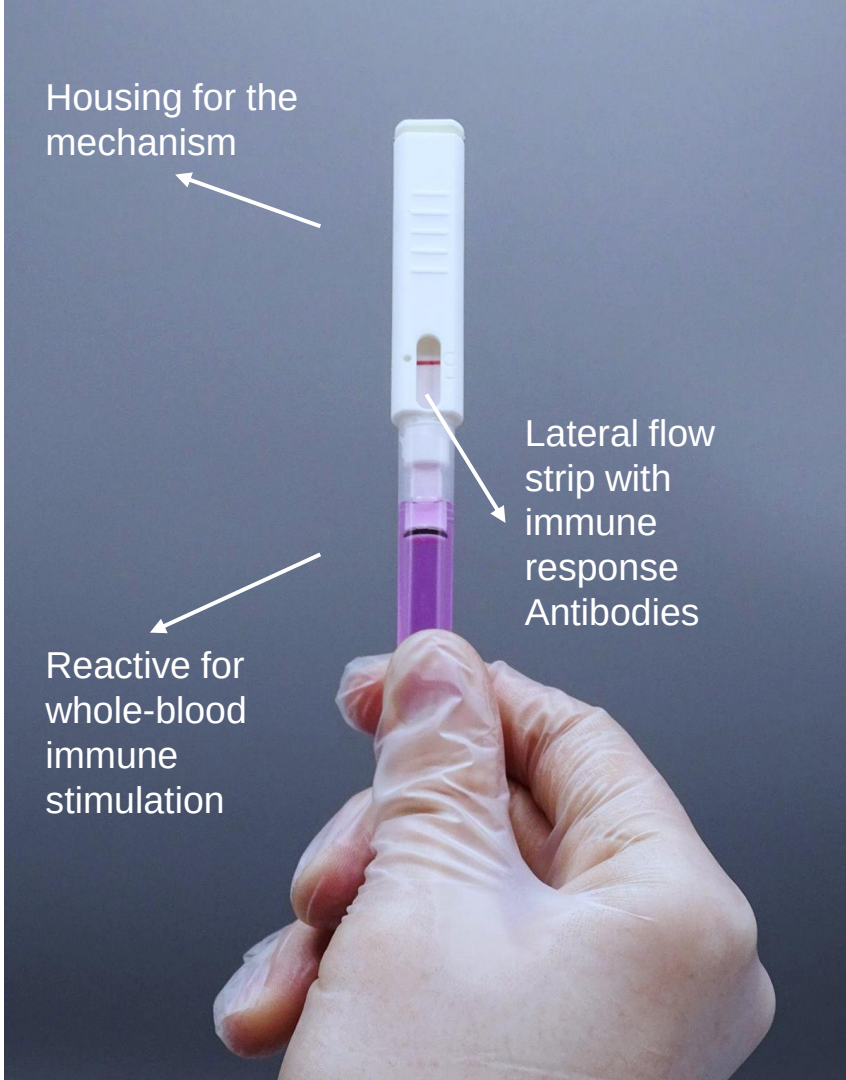


Lancet Infect Dis. 2013 March ; 13(3): 260–268.

PRODUCT: SEPTILOOP

Blood-based in vitro diagnostic test that identifies bloodstream infection *before* it progresses to sepsis.

Patent applied: WO/2021/245025, Method And Kit For The Early Detection Of Sepsis (PCT, June 2021)
Regulatory: Autocertification UKCA / Class C (IVDR) submitted



TECHNOLOGY PRODUCT PLATFORM

CLINICAL TRIAL STUDIES in 6 international Hospitals

>500 SEPSIS SUSPECTED PATIENTS TESTED

Suspected Sepsis patients tested with our device with the blood sample collection performed as they enter in the Emergency Unit. Tested for Emergency Department use.

2x Clinical Trials - 2019-2024. Hospital Universitari de Bellvitge (Barcelona, Spain)

3x Clinical Trials - 2022-2025. Hospital Universitari Parc Taulí (Sabadell, Spain).

1x Proof pilot study Clinical Trial- 2022. Hôpital Cochin (Paris, France)

1x Clinical Trial- 2023-2024. Hospital Universitario La Princesa (Madrid, Spain).

2x Proof pilot study Clinical Trial- 2022. Mechnikova Hospital and rivne Spinal rehabilitation Clinic (Dnipro and Rivine, Ucrania)

Regulatory performance clinical trials

Accuracy Clinical Trial- Jun 2022-Jan 2024 / IP: Dr. Antonio Artigas

Clinical, prospective, non-interventional, single-center, observational, descriptive study.

Parc Taulí Sabadell Hospital Universitari

Objective: To determine the diagnostic accuracy for bloodstream infection by SeptiLoop in the early diagnosis of sepsis.

SeptiLoop tested on: Sepsis suspected patients with NEWS>3 (**100** Sepsis-3 criteria and **50** Non-Sepsis-3 criteria).

Feasibility Clinical Study- Jun 2023-Jan 2024 / IP: Dr. Joan Sabater

Clinical, prospective, non-interventional, single-center, observational, descriptive study.

Bellvitge Hospital Universitari

Objective: To determine the diagnostic feasibility of bloodstream infection of SeptiLoop in the early diagnosis of sepsis

SeptiLoop tested on: 50 Controls from Healthy Donors and Cardiac Surgery Patients, & **50** Septic Patients

Sepsis & Blood culture (+)	Sensitivity*	Specificity	PPV
vs Non-Sepsis-3	81%	64%	73%
vs Controls	94%	80%	82%

***Note competitor biomarkers like CRP and PCT shown <30% SENSITIVITY**

B2B BUSINESS MODEL

*

**

Medical device distributor

disposables
€50-€100***

Per Hospital****

Sales (nª Tests):
20.800/year

Savings ICU Hospital:
$16 M/year

Sepsis Mortality reduction
10%-25%

*** Main revenue stream:** The disposable with COCGS [7-10]€

**** Medical device distributor** (6 LOIs from UK-EU): 30-40%

***** Price** will vary depending upon country of sale, public vs. private, and local insurance/regulatory conditions.

Based in more than 200 stakeholders.

****** Business case of a Hospital with** 50.000 emergency visits/year.

Based in more than 50 physicians.

COMPETITORS TECHNOLOGY

PoC device

Laboratory device

UCI sepsis stage

Emergency Sepsis Stage

MULTIDISCIPLINARY TEAM AND COMMITMENT

Immunologist and biomedical innovator

> 10 years leading innovation projects

Enrique Hernández, PHD
Chief Executive Officer

Business Pharmacist,

The 3rd startup project in Healthcare

Eduard Guerrero, MSC
Chief Operations Officer

Engineer and product Development,

> 5 years medical device development

Joan Vieyra, MSC
Chief Technology Officer

MDA and Scientific

>20 years leadering startups

Judit Cubedo, PHD
Chief Strategy Officer

>10 years as project management of innovative startups

Queralt Caus, MSC
R&D Manager

>3 years as Lab tecnician

Vanessa Roman,
Laboratory Technician

Physician Researcher,

> 15 years diagnosing in Emergency department

Erika Plata, PHD
Chief Medical Officer

Innovator and future entrepeneur

Gleb Morozov,
Market Research Intern

ROADMAP

2022
Functional device

-Regulatory activities Disposable – QMS

-Feasibility clinical trial

- Device design freeze and industrialization

€150k public grants
$30k Health Wildcatters

2023
Industrialization

- Regulatory activities Disposable applications – **ISO 13485**

- Accuracy clinical trials

- End of industrialization

€250k NEOTEC CDTI
€550k CDTI
€650k CAPITAL CELL
€300k ENISA

2024
Sales

- Submission under UKCA and CE mark-IVDR

- Regulatory Certification: **UK CA**

-Cost-effective clinical trial

-UK market access

€500k RETOS
€550k CDTI

2025
Scale up

- Regulatory Certification IVDR: **CE Mark**

-Launch EU commercialization activities

- European market penetration

Series A round: €5M

TOTAL FUNDING SINCE INCORPORATION
€1M Private
€3M Public

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Loop Dx