EPIDISEASE

Tomorrow´s health, today

GENETIC & EPIGENETIC IVD TOOLS AND BIOMARKERS

James Webb, Investor relations
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www.epidisease.com
January, 2026

EXEC TEAM

Socio-Founder & CEO
Dr. José Luis García

José Luis has spent nearly 25 years working on the forefront of the investigation of the genetic and epigenetic mechanisms of complex diseases.

He co-founded EpiDisease SL in 2014 to transform his pioneering scientific work into applied epigenetic and genetic biomarkers in the form of IVD tools that clinicians need to improve patient outcomes and save lives.

Socio-Founder & CSO
Dr. Salva Mena

With a track record of scientific leadership in innovative technologies and finance, Salva is now leveraging his expertise to help EpiDisease bring new ideas to the biotechnology market.

He's dedicated to driving growth and fostering innovation in a sector that is ripe for disruption.

COO
Dra. Eva García

As a seasoned manager of complex scientific projects, Eva has directed and helped many public innovations and scientific projects succeed.

With a deep understanding of the challenges facing biotech scale-ups she is committed to providing the operational leadership and guidance needed to transform EpiDisease´s entrepreneurial vision into reality.

CCO
James Webb

James is a skilled commercial leader with a focus on innovative and niche biotech sectors.

With 20 years of experience navigating the commercial landscape and launching multi million dollar franchises in the dynamic biotech sector, he fully understands the challenges facing the business in today's competitive landscape, and has the skills to succeed in it.

EMPLOYEES

Regulatory & clinical trial | Manufacture | Services
R&D | Commercial | Financial

ADVISORY BOARD

Prof. F. Pallardó, PhD, MD
Founder and Scientific Advisor
University of Valencia

T. Bas, PhD, MD
Scoliosis Medical Advisor
President of the Spanish Society of the Vertebral Column

N. Carbonell, PhD, MD
Sepsis Medical Advisor
Hospital Clínico de Valencia

P. de la Huerta
Partner and Advisor
HBA
+25y in biotechs

I. Ortea, PhD
MS Scientific Advisor
Superior Council of Scientific Investigations

A. Artigas, PhD, MD
Sepsis Medical Advisor
Member of the European Sepsis Alliance

ABOUT US

EpiDisease S.L. is *pioneering company focused on developing epigenetic biomarkers for the diagnosis and prognosis of human diseases*. We develop applied epigenetic IVD tests for commercialisation via exclusive and non-exclusive out-license agreements.

FOUNDED Valencia, Spain 2014

LOCATION PARC CIENTÍFIC VNIVERSITAT DE VALÈNCIA

INTELECTUAL PROPERTY

- **1 Patent granted EU, USA & Japon**
- **1 Patent granted in EU, USA, Canada, China & Hong Kong**
- **2 Industrial secrets**

PYME INNOVADORA
Válido hasta el 07 de junio de 2027
GOBIERNO DE ESPAÑA
MINISTERIO DE CIENCIA, INNOVACIÓN Y UNIVERSIDADES

Problem

Adolescent

Idiopathic

Scoliosis

3% of children 10 –17 yrs old

30 M

Suspected scoliosis cases annually

Clinical diagnosis made retrospectiveley via progression of spinal curve serverity

11 M

Confirmed cases anually

Cases are confirmed retrospectively after manual measurement of spinal curve progression

Solution

Genetic risk calculation tool

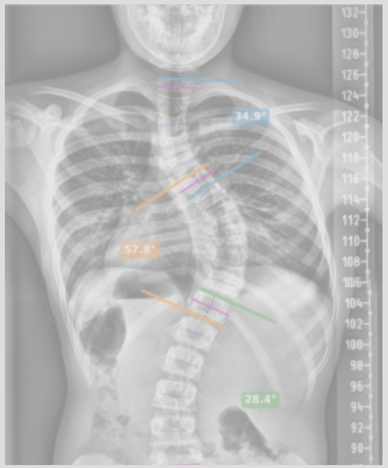
SCOLI GEN

(pre emptive)

AI image analysis tool for AIS radiographs

SCOLI VIEW

Automatic measurment of Cobb angle that removes users induced error



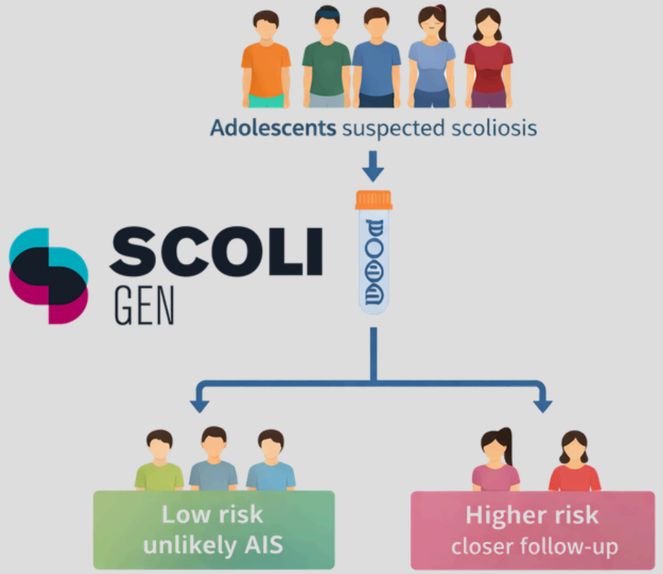
Genetic risk calculation tool in a saliva sample

SCOLI GEN

pre emptive

KEY FACTS

- **~ 25% of patients have familial scoliosis**
- **7–16% prevalence in first-degree relatives**
- **~15% of cases have at least one affected parent**
- **10–18% recurrence risk in siblings**
- **Family history identifies a population at increased genetic risk**
- **Enables targeted genetic risk stratification in adolescents**



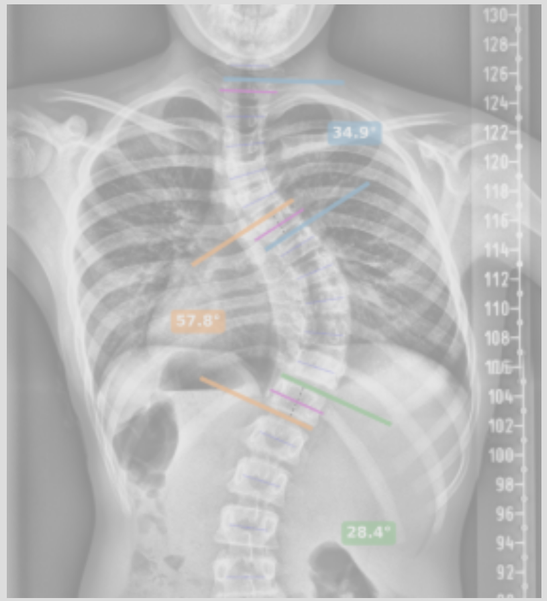
Genetic risk stratification based on >20 SNPs associated with AIS

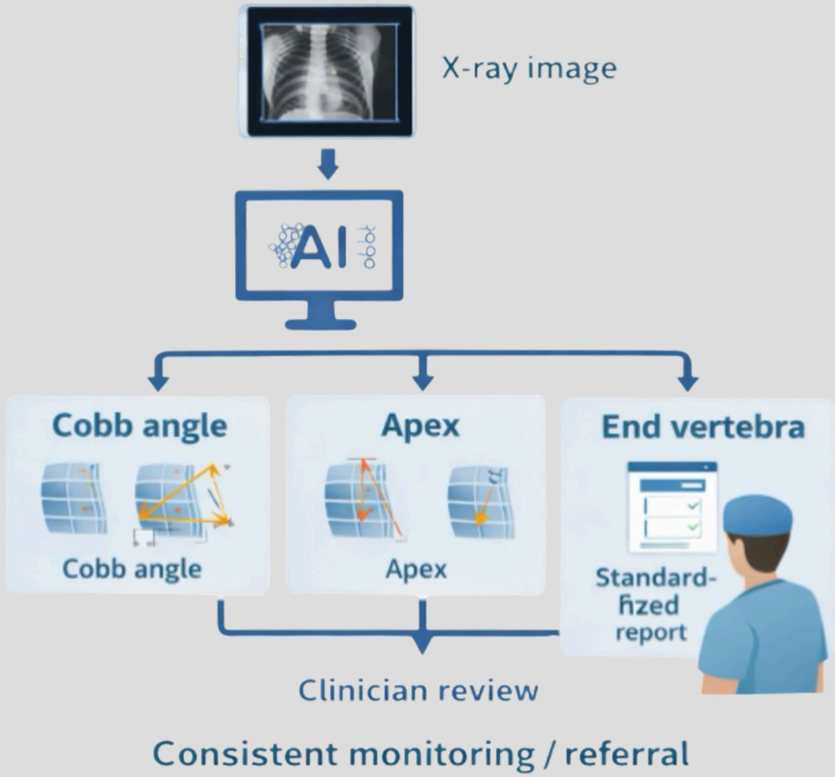
Metric	Value
Sensitivity (Sn)	90%
Specificity (Sp)	39%
Positive Predictive Value	56%
Negative Predictive Value	82%

Automated and standardized Cobb angle measurement from X-rays

SCOLI VIEW

Powered by the SPARC algorithm





KEY FACTS

- **3–7° variability in manual Cobb measurements performed by experienced specialists**
- **Clinical decisions rely on ≥10° diagnostic threshold**
- **Multiple measurements taken by multiple HCP leading to frequent repeat radiographs and delayed referrals**

Metric	Expert Manual Measurement	SPARC (ScoiVIEW)
Mean Absolute Error (MAE)	2.41º	3.01º
Standard Deviation (SD)	3.21º	2.71º
Intraclass Correlation (ICC)	-	97%
Error Range	-41.3º to 40.7º	-14.6º to 20.3º
Curve Dectection	Baseline	↑ Sensitivity

Market opportunity

There is a rising demand for **precision and predictive diagnostic tools**, allowing for planning and stratification of conservative treatment interventions.

Total Available Market (TAM)

2026 $ 1.7 Billion

Servicable Obtainable Market (SOM)

2026 $ 595 Million

No players currenlty in the AIS risk or diagnostic space

40% **peak mkt share**

F. Hoffmann-La Roche Ltd (Switzerland) Diagnostics market dominance

Value Proposition

stratification of patients at risk and robust spinal curve progression monitorisation

Improves

patient outcomes by allowing pre-emptive planning and resource use

Improves

conservative treatment monitorisation and reduces hospitilisation costs

Reduces

hospital waiting lists by allowing data-based patient stratification

Right patient - Right time - Right HCP

Reduces

exposure to uneccessary inionising radiation and the number of repeated X ray reports

Go-to-Market Strategy

B2B2C model combining hsopital adoption and pharma co-development

SCOLI GEN

LDT approval and commercially available

4Q 2025

SCOLI VIEW

Multicentre and mutlidisciplinary user validation trial completed

1Q2026

SCOLI VIEW

Submission of dossier to Notified body for CE-IVD certification

3Q2026

SCOLI VIEW SCOLI GEN

Scale-up and out-licensing agreement / distribution with established commercial player

4Q 2026-1Q 2027

Competitive Analysis

SCOLI GEN

No genetic test available

SCOLI GEN

Scoliometer

SCOLI VIEW

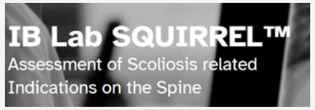


image biopsy lab

No published papers on its develoment or use

KPIs & Milestones

01

2025 Commercialition

ScoliGEN already in the market as LDT
ScoliVIEW will be commercilaised after CE certification.

02

2026 IVD CE certification

ScoliGEN for kit format to allow scale-up or distribution model
ScoliVIEW CE certifiation forecast in 2026

03

2027 FDA certification

Start discusions with the FDA after CE certification.
Look for out-licensing or IP sale.

Problem

Sepsis

Septic

Shock

DIC

500 M

Suspected sepsis cases annually

There is no clinically approved biomarker for the diagnosis and prognosis of sepsis

166 M

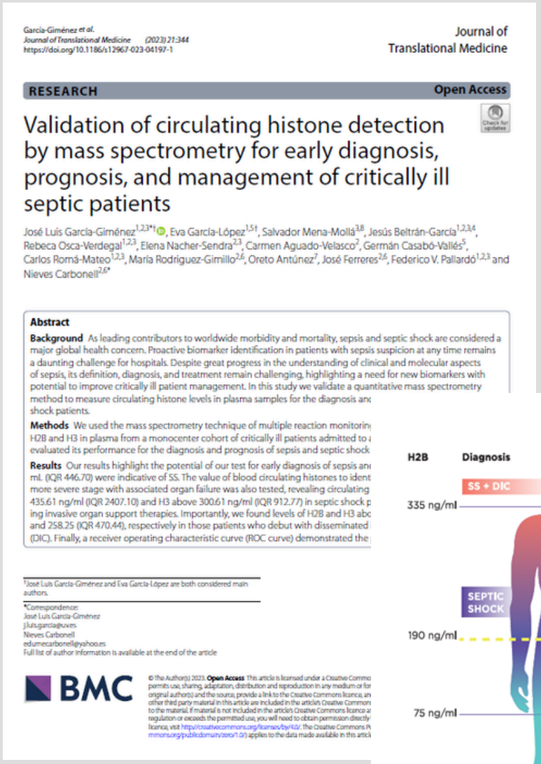
Confirmed sepsis cases anually

There is no clinically approved method for the measurement of the progression of sepsis

21 M

Deaths annually

- **Incorrect and late diagnosis**
- **poor management of sepsis and its progression**
- **lack of therapeutic options**



García-Giménez et al.
Journal of Translational Medicine (2023) 21:344
https://doi.org/10.1186/s12967-023-04197-1

Journal of Translational Medicine

RESEARCH Open Access

Validation of circulating histone detection by mass spectrometry for early diagnosis, prognosis, and management of critically ill septic patients

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Abstract

Background As leading contributors to worldwide morbidity and mortality, sepsis and septic shock are considered a major global health concern. Proactive biomarker identification in patients with sepsis suspicion at any time remains a daunting challenge for hospitals. Despite great progress in the understanding of clinical and molecular aspects of sepsis, its definition, diagnosis, and treatment remain challenging, highlighting a need for new biomarkers with potential to improve critically ill patient management. In this study we validate a quantitative mass spectrometry method to measure circulating histone levels in plasma samples for the diagnosis and shock patients.

Methods We used the mass spectrometry technique of multiple reaction monitorin H2B and H3 in plasma from a monocenter cohort of critically ill patients admitted to evaluated its performance for the diagnosis and prognosis of sepsis and septic shock

Results Our results highlight the potential of our test for early diagnosis of sepsis an mL (IQR 446.70) were indicative of SS. The value of blood circulating histones to ident more severe stage with associated organ failure was also tested, revealing circulating 435.61 ng/ml (IQR 2407.10) and H3 above 300.61 ng/ml (IQR 912.77) in septic shock p ing invasive organ support therapies. Importantly, we found levels of H2B and H3 abo and 258.25 (IQR 470.44), respectively in those patients who debut with disseminated (DIC). Finally, a receiver operating characteristic curve (ROC curve) demonstrated the

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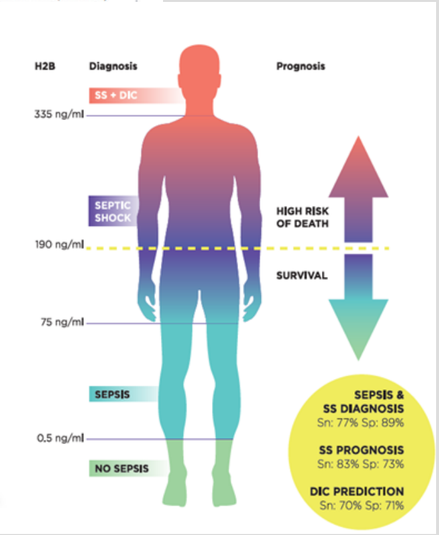


Solution

HIST SHOCK

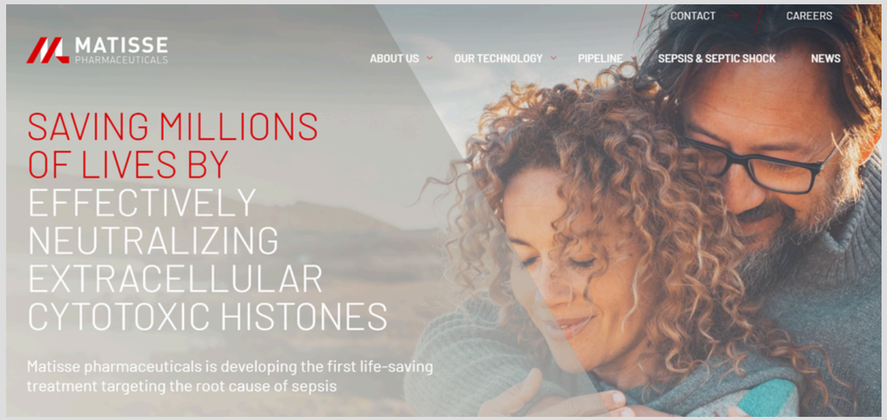
01 IVD LC–MS/MS assay in blood for histones H3 and H2B and recombinant activated C–protein (rhAPC) quantification

02 Already scientifically and clinically validated for the diagnosis and prognosis of sepsis in >600 ICU patients

03 Allows for the selection and segmentation of patients, diagnosis and prognosis of sepis, and the dynamic monitorization of their repsonse to anti–histone and and rhAPC therapies

HIST SHOCK CDx

A breakthrough companion diagnostic (CDx) test for sepsis



- LC-MS/MS TEST FOR DETECTING AND QUANTIFYING CIRCULATING HISTONES
- ENABLES EARLY AND PRECISE HISTONE LEVEL MONITORIZATION

HISTONE MEASUREMENT IN CIRCULATING BLOOD

PHASE I
PHASE II

MATISSE PHARMACEUTICALS

isopartub sodium (M6229)

Market opportunity growing

There is a rising demand for **targeted therapies**, where companion diagnostics help determine the most effective treatment for patients.

Pharmaceutical companies are increasingly integrating **companion diagnostics into drug development pipelines to improve the success rate of novel therapeutics**, further accelerating market growth.

Total Available Market (TAM)

2024 $ 160 Billion

Suspicion of Sepsis x10 confirmed sepsis cases

Sevicible Available Market (SAM)

$ >16 Billion

166M confirmed sepsis cases
No players as yet in the CDx sepsis space

40%

F. Hoffmann-La Roche Ltd (Switzerland) CDx market dominance

Value Proposition

measuring sepsis and sepsis progression biomarker,
not the (secondary) factors
that are associated with sepsis

Improves

patient outcomes
and ICU resource
use

Improves

management of
septic patient,
antibiotic missue and
reduces
hospitilisation costs

Reduces

clinical trial costs
and time to market
by providing a
quantitative marker

Improves

clinical trial outcomes
due thorugh correct
patient cohort selection
and segmentation

HIST SHOCK

establishing a troponin-like benchmark for sepsis diagnosis

SAVE Time **SAVE Lives** **SAVE Money**

Diagnostic precision

specific and quantifiable biomarker evidence to confirm, or rule out sepsis patients with high histone levels

Clinical impact

change clinical practice by allowing ICU physicians to detect and stratify those sepsis patients likely to responde to hisytone-removing therapies early and accurately

Prognostic power

pedicts disease serverity and mortality risk, guiding treatment intensity

Market potential

potential gold standard biomarker for sepsis diagnosis, prognosis and management, allowing for precison medicine and better targeting of therapies

Go-to-Market Strategy

B2B2C model combining hsopital adoption and pharma co-development

HIST SHOCK

Execution of RWE functional validation in 4 ICU in Spain

2025-2026

HIST SHOCK CDx

Matisse Pharmaceuticals Phase II trials M6229

2026-2027

HIST SHOCK

Submission of dossier to Notified body for CE-IVD certification

1Q2026

HIST SHOCK CDx

Scale-up and out-licensing agreement with established commercial player

2027-2028

Competitive Analysis

Market leader
20% share
$220M

Bacteria detection and antibiotic stewardship **NOT** sepsis detection

MeMed

FDA

CE

Bacteria vs Viral POC detection **NOT** sepsis diagnosis or prognosis

Immunexpress

SeptiCyte RAPID

FDA

CE

Host-response gene expression panel (mRNA signature) sepsis vs SIRS **NOT** sepsis prognosis

Volition

Nu.Q® NETs

ELISA **RUO** kits; nucleosome profiling

KPIs & Milestones

$1.1 Billion

Current global sepsis diagnostic market

20%

Market leader

BRAHMS PCT test

35%

New segment

Diagnosis + Prognosis biomarker.
Only in class
Same proce point as BRAHMS

01

2026 IVD CE certification

HistSHOCK clinical trial finished in 4Q2025.
Dossier submited to notified body 1Q2026.

02

2026-2027

Commercilaisation in ICU pilot centres that participated in clincial trial

03

2027 FDA certification

Start discusions with the FDA after CE certification.
Look for out-licensing or IP sale.

Thank you!

LET´S CHANGE THE WORLD TOGETHER!

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