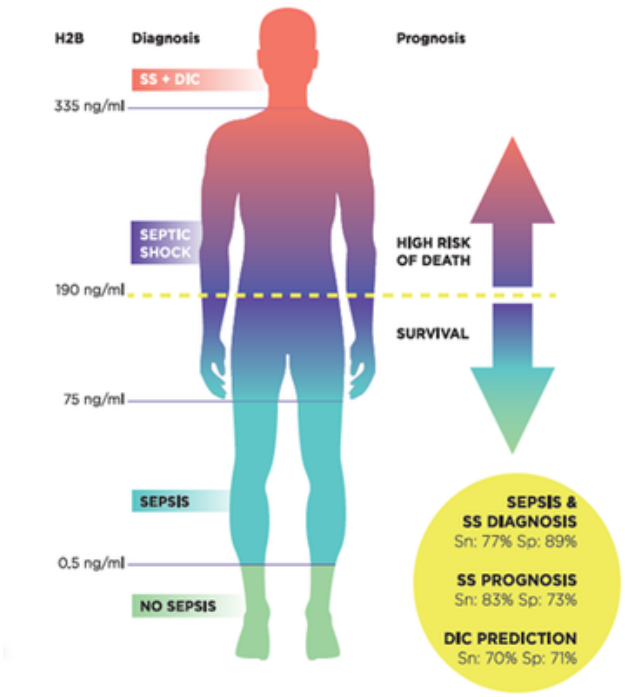
# HIST SHOCK

**HistSHOCK** is an IVD sepsis diagnosis and prognosis clinical test based on quantitative proteomics technology developed by EpiDisease SL, measured using the tandem mass analysis platform.

**HistSHOCK** uses a proprietary and patented histone signature identified in the blood of sepsis patients to **diagnose sepsis** (Sn 77%, Sp 89%) at a very early stage of the course of the infection, before overt clinical signs of sepsis are present [1].




**HistSHOCK** is also able to **predict** with a high degree of accuracy (Sn 83%, Sp 73%) which sepsis patients will progress towards **septic shock** and **disseminated intravascular coagulation** (Sn 70%, Sp 71%), a severe condition that sometimes appears in septic patients which is associated with mortality that ranges from 45% to 78% during hospitalizations [1].

Initial results of a proof of concept clinical trial of 89 ICU patients have been published and peer reviewed by the scientific and medical community [1].

A Clinical Performance Trial of **HistSHOCK** is currently on-going in four national reference centers for sepsis; Hospital University Clínico de Valencia, Hospital University Vall de Hebrón, Hospital University Parc Taulí and Consorcio Hospital General Universitario de Valencia. During the trial, which has both prospective and retrospective arms, a further 600 subjects will be tested with **HistSHOCK** in a real world intensive care unit setting.

1. García-Giménez, J.L., García-López, E., Mena-Mollá, S. et al. Validation of circulating histone detection by mass spectrometry for early diagnosis, prognosis, and management of critically ill septic patients. J Transl Med 21, 344 (2023). https://doi.org/10.1186/s12967-023-04197-1

The **HistSHOCK** project was awarded the **Seal of Excellence** from the European Innovation Council Accelerator Programme that led to it being awarded a €1.9M tranche of financing by the Spanish government´s CDTI (Centre of Technical Development and Innovation) Department.

These funds are being used to bring **HistSHOCK** to the European markets through the financing of a clinical performance trial in multiple sepsis reference hospitals in 2024. This trial will analyse a further 600 control and sepsis cases samples in prospective and retrospective cohorts to prepare the data necessary to obtain the IVDR-CE mark for the commercialization of **HistSHOCK** in the European Union in 2026.

The **HistSHOCK** technology is protected by a patent family extended to national phases. The patent has been granted in Europe (EP3535587), Japan (2019-546057), the USA (16/346,978), China (2017800822173) and Hong Kong (62020004691.5), all major markets for the commercialisation of **HistSHOCK**.

1. García-Giménez, J.L., García-López, E., Mena-Mollá, S. et al. Validation of circulating histone detection by mass spectrometry for early diagnosis, prognosis, and management of critically ill septic patients. J Transl Med 21, 344 (2023). https://doi.org/10.1186/s12967-023-04197-1


**140 subjects tested**

## DIAGNOSIS OF SEPSIS & SEPTIC SHOCK

**Sensitivity (Sn) 79%**

**Specificity (Sp) 89%**

## PROGNOSIS OF SEPTIC SHOCK

**Sensitivity (Sn) 83%**

**Specificity (Sp) 73%**

## PREDICTION OF DIC

**Sensitivity (Sn) 70%**

**Specificity (Sp) 71%**

# About Us

EpiDisease S.L. (EpiDisease, www.epidisease.com) is a biotechnology company that was founded in 2014 in Valencia (Spain) which develops and commercialises a pipeline of patented proprietary in vitro diagnostic (IVD) products and clinical software tools incorporating AI for complex human diseases.

EpiDisease has internationally recognised expertise in the analysis of epigenetic mechanisms such as DNA methylation, histone code/variants and miRNA, which are crucial for the study of gene expression. The Company has developed proprietary models for the development of novel epigenetic biomarkers and has characterized epigenetic drugs for public and private clients.

EpiDisease is a spin-off of the Centre for Biomedical Network Research (CIBER) of the Spanish National Institute of Health Carlos III (ISCIII), the Biomedical Research Institute INCLIVA, and the University of Valencia

EpiDisease has been certified as Clinical Diagnostic Center in Genetics and Microbiology by the Consellería de Salut Pública i Sanitat Universal-Generalitat Valenciana (Registry No. 22325).

The Company obtained recognition as support center for COVID-19 PCR testing by the Spanish Ministry of Science and Innovation through the Spanish Institute of Health Carlos III, and in July 2021 obtained the ISO 9001:2015 quality management certification as a COVID diagnostic laboratory.

EpiDisease has implemented the ISO 13485 standard for the management of the manufacture of medical devices, and ISO15189:2022, standard that establishes requirements for quality and competence in medical laboratory. The acrediation of both standards in expected in 2026.