



Precision Medicine for Acute Care

**Your healthcare should be  
tailored to your biology.**

Computer-aided Triage and Notification Software for Measurement of Biomarkers

ICD-10 Coordination and Maintenance Committee Update  
March 2025

Sepsis causes a huge financial and quality burden to hospitals that is unaddressed with current solutions.

\$29,118

Average Hospital **Loss** per  
Septic Patient in the U.S.<sup>1</sup>

>50%

of Septic Cases are in  
Violation of CMS Sepsis  
Guidelines Across the U.S.

Limited  
Benefit

of Sepsis Alert Systems on  
Mortality, Length of Stay, and  
Compliance

GE Healthcare and Roche Diagnostics, 2020.  
Assumes 1.7M annual sepsis cases at 5000 Hospitals  
<https://www.hfma.org/topics/financial-sustainability/article/sepsis-poses-a-cost-containment-challenge-in-the-face-of-the-cov.html>

"National Performance on the Medicare Sep-1 Sepsis  
Quality Measure," CCM 2020.  
<https://www.ncbi.nlm.nih.gov/pmc/articles/PMC6588513/>


Makam AN, Nguyen OK, Auerbach AD. Diagnostic accuracy and effectiveness of automated electronic sepsis alert systems: A systematic review. J Hosp Med. 2015 Jun;10(6):396-402. doi: 10.1002/jhm.2347. Epub 2015 Mar 11. PMID: 25758641; PMCID: PMC4477829.




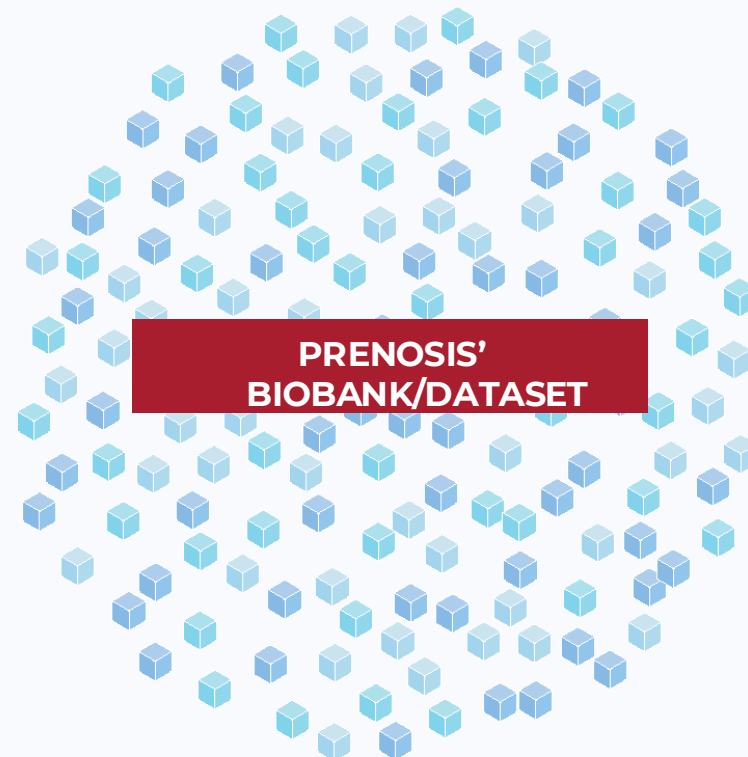
Heterogeneity in patient presentation remains a challenge. Prenosis built a biological and clinical dataset to identify biological signatures in sepsis.

**11**   
HOSPITAL SITES  
AND GROWING

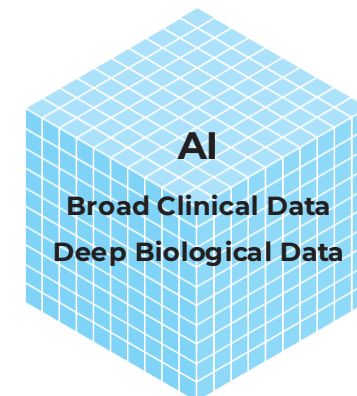
**> 29K**   
PATIENTS

**> 40**   
PROPRIETARY  
BIOMARKERS MEASURED  
PER SAMPLE  
Produced by the  
Prenosis BSL2 Lab

**> 115K**   
SPECIMENS  
COLLECTED  
Linked to deep  
clinical data



**IMMUNOSCORE  
DIGITAL DIAGNOSTICS**



# Biological insights from thousands of patients inform better diagnosis and care management.

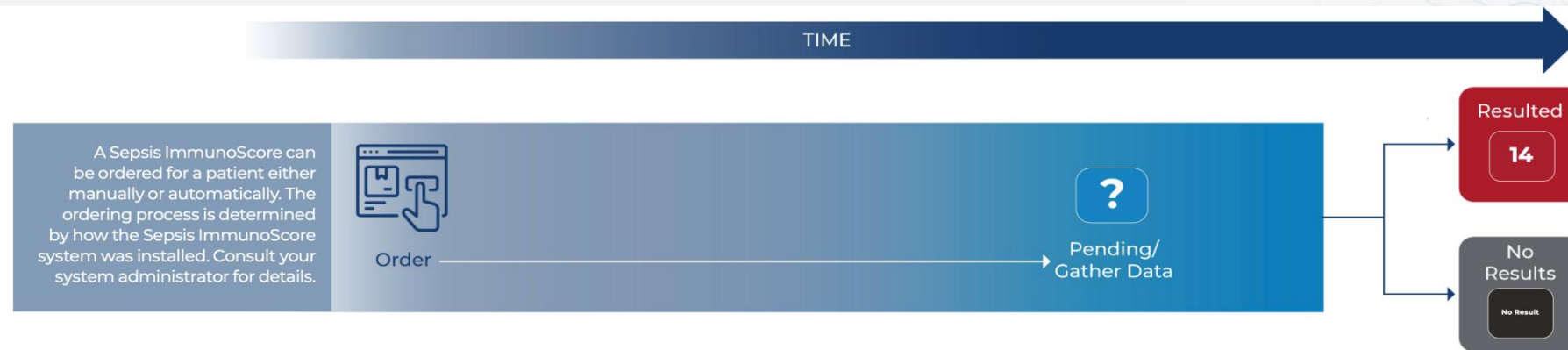
The Sepsis ImmunoScore™, the first FDA-Authorized Artificial Intelligence/Machine Learning (AI/ML)-based software as a medical device, identifies patients at risk for having or developing sepsis as well as the prediction of key parameters important to health systems.

- Hospital length of stay
- In-hospital mortality
- ICU transfer within 24 hours
- Mechanical ventilation within 24 hours
- Vasopressor usage within 24 hours

The Sepsis ImmunoScore is intended to be used in conjunction with other laboratory findings and clinical assessments to aid in the risk assessment for presence or progression to sepsis within 24 hours of patient assessment. It is intended to be used for patients **admitted to the Emergency Department or hospital** for whom sepsis is suspected, and a blood culture was ordered as part of the evaluation for sepsis.



# Sepsis ImmunoScore™ Workflow – Drives Provider Awareness



## PENDING

When a Sepsis ImmunoScore is first ordered for a patient, the state of the test is "Pending". This period is used to gather all necessary information for the algorithm. In some cases, it is necessary to order labs if they have not been ordered. The software will inform the user of the orders to be placed and their status on the Pending Screen.



## RESULTED

When there is enough information to generate a result, the status changes to "Resulted," and the result is displayed.



## NO RESULT

If the Sepsis ImmunoScore is still pending 3 hours and 30 minutes after it is ordered, then the status will change to "No Result," and a result will never be generated for this order of the Sepsis ImmunoScore.



Sepsis ImmunoScore is part of the clinical workflow utilizing existing clinical data available in the EHR to provide a sepsis risk stratification.

**22 Total Parameters –  
12 required**

- Systolic Blood Pressure
- Diastolic Blood Pressure
- Temperature
- Respiratory Rate
- Heart Rate
- Blood Oxygen Saturation
- White Blood Cell Count
- Platelet Count
- Creatinine
- Blood Urea Nitrogen
- Procalcitonin
- C-Reactive Protein



Risk Stratification Category	Diagnostic Interpretation	Sepsis Risk Score Range
Low	Sepsis unlikely	0 – 12.2 <sup>1</sup>
Medium	Sepsis possible	12.2 – 30.6 <sup>1</sup>
High	Sepsis likely	30.6 – 87.2 <sup>1</sup>
Very High	Sepsis very likely	87.2 – 100 <sup>1</sup>

Pending Result provides insight into pending biomarker and clinical data needed.

?

score for sepsis within 24 hours

Result Pending

Order Time

12/05/2024 12:18

Result Time

—

?

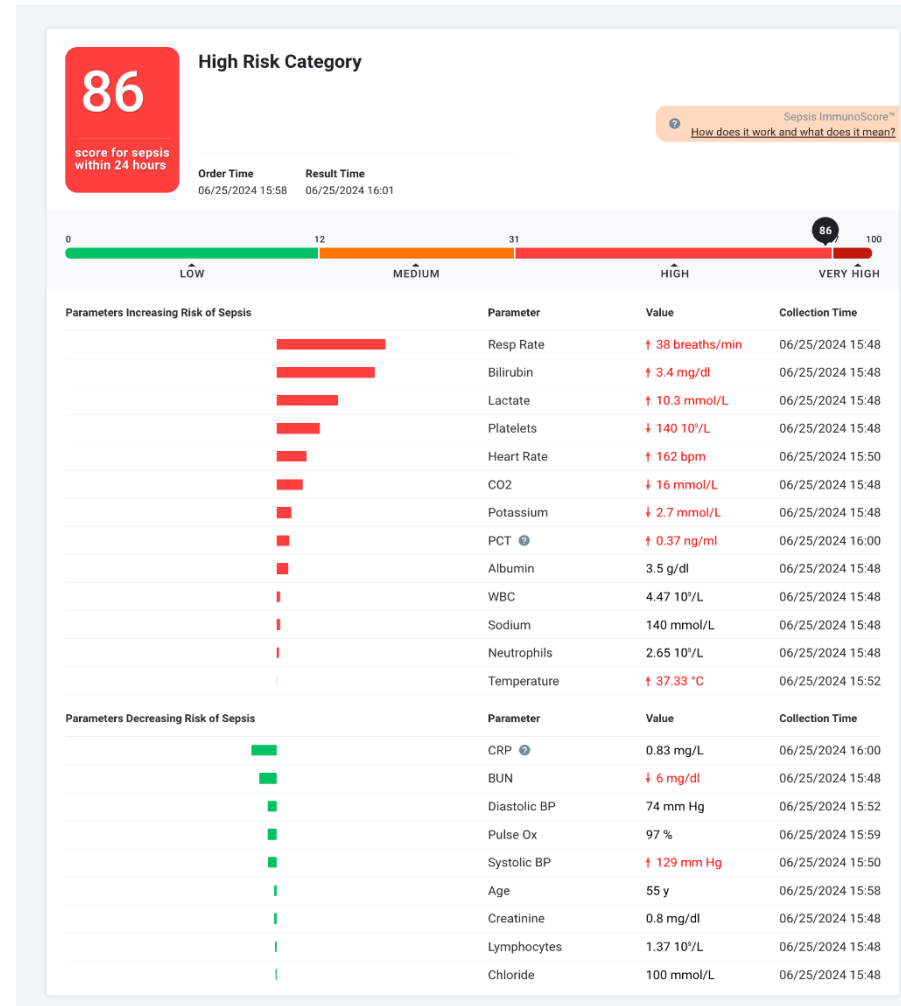
Sepsis ImmunoScore™  
How does it work and what does it mean?

Measurements to Order	CRP	! Required for ImmunoScore	No results within 24 hours
	PCT	! Required for ImmunoScore	No results within 24 hours
	WBC	! Required for ImmunoScore	No results within 24 hours



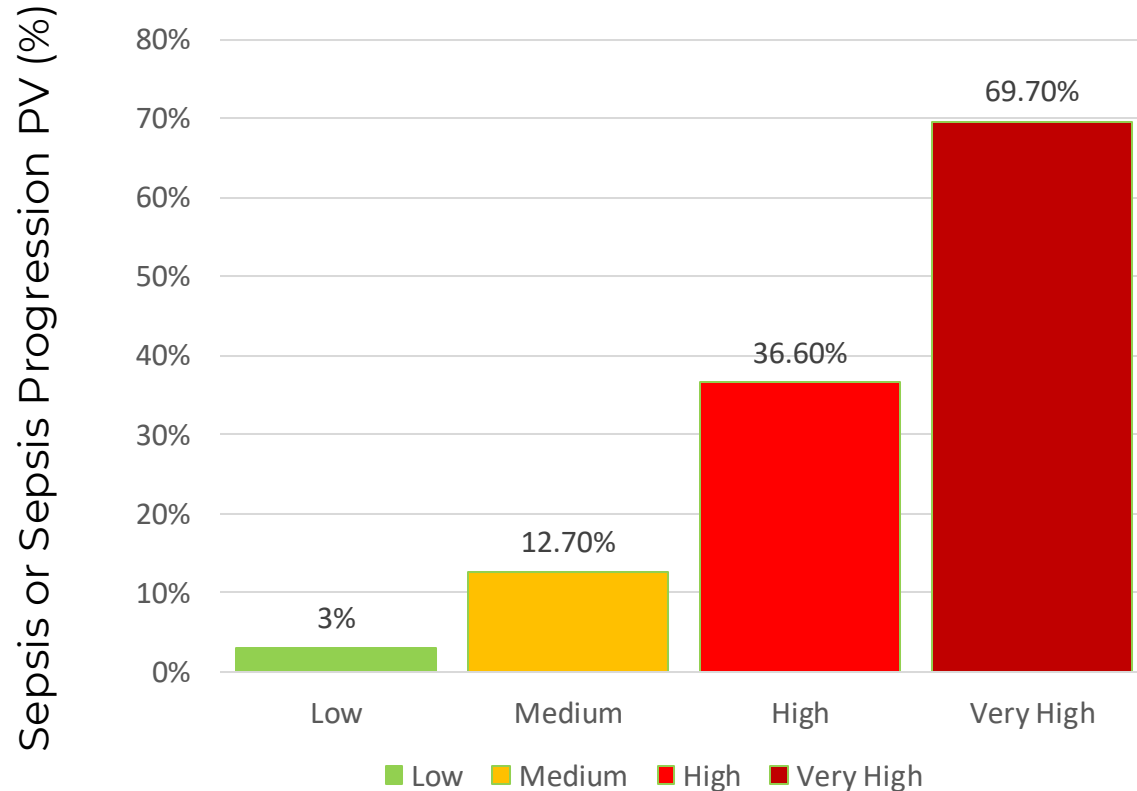
# Final result user interface provides visibility into the model, increasing trust between the provider and the AI.

- Results integrate within the EHR
- EHR agnostic
- Sepsis ImmunoScore™ result will also be posted in the Laboratory Information System





# Diagnosis of sepsis or progression to sepsis in the next 24 hours



Sepsis ImmunoScore Risk Category

Risk Category	Predictive Value	Likelihood Ratio
Low	3.0%	0.1
Medium	12.7%	0.5
High	36.6%	2.0
Very High	69.7%	8.3



# Sepsis ImmunoScore™ Clinical Utility

- Aid in clinical decision making of sepsis diagnosis
- Determine appropriate patient disposition
- Deliver appropriate utilization of antimicrobial therapy for patients at medium – very high risk
- Prevent inappropriate utilization of antimicrobial therapy for patients at low risk
- No adverse events associated with Sepsis ImmunoScore™



Compressed screenshot of user interface. Data for demonstration purposes only.



# Sepsis ImmunoScore™ FDA Validated AI Sepsis Tool

Special Communication | AI in Medicine



FREE

October 15, 2024

## FDA Perspective on the Regulation of Artificial Intelligence in Health Care and Biomedicine

Haider J. Warraich, MD<sup>1</sup>; Troy Tazbaz, BS<sup>1</sup>; Robert M. Califf, MD<sup>1</sup>

✂ Author Affiliations | Article Information

<sup>1</sup>US Food and Drug Administration, Silver Spring, Maryland

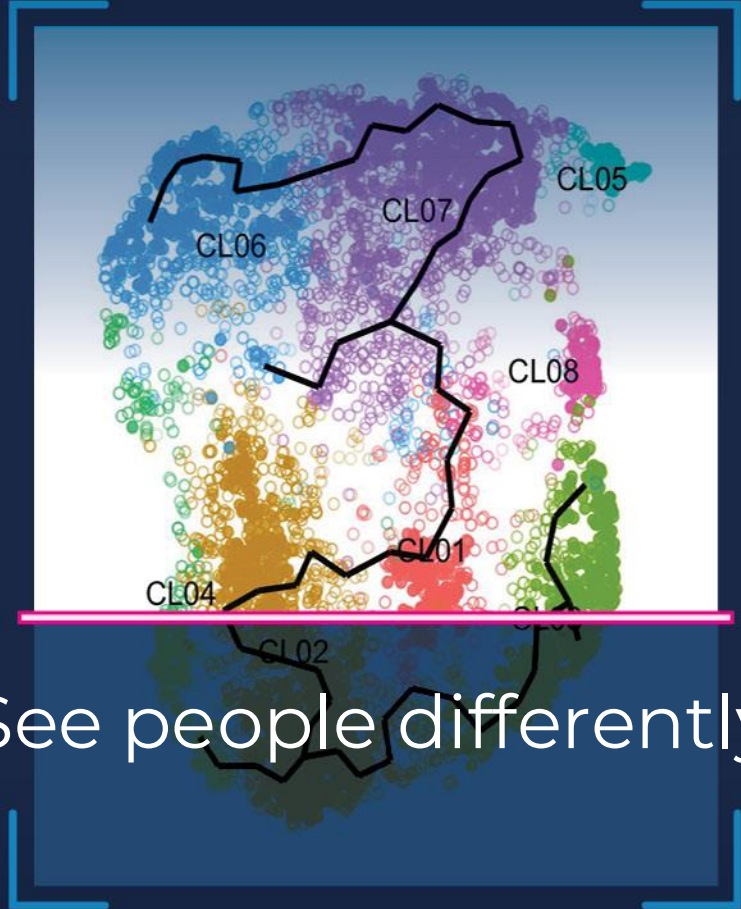
A practical application of this schema involves the marketing authorization granted to Sepsis ImmunoScore (Prenosis, Inc), an AI algorithm granted de novo classification as a Class II device.<sup>14</sup> The software identifies patients at risk for having or developing sepsis using 22 predetermined inputs from EHRs to generate a risk score, although it should not be used as the sole basis to determine the presence or risk of sepsis. Given potential risks, including algorithm failure, model bias, clinician overreliance, incorrect interpretation, or poor input, special controls were established to provide reasonable assurance of its safety and effectiveness. These mitigation measures included clinical and nonclinical performance testing, software verification, validation and hazard analysis, labeling, human factors assessment, technological characteristics, and postmarket management, including ongoing performance evaluation.

FDA cited the Sepsis ImmunoScore as an example of the proper way to develop and validate AI algorithms as a regulated medical device. Prenosis was the **only company mentioned** in the article across many fields in healthcare!





Precision Therapeutics for Acute Care



See people differently

symptoms

age

notes

gender

See beyond diagnosis

weight

protocols

race