

DIAGNOSE SEPSIS WITH MORE CERTAINTY  
IN JUST ONE HOUR



SeptiCyte® RAPID

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**IVD** For *in vitro* diagnostic use **CE** CE Marked

# INTRODUCING SEPTICYTE® RAPID A REVOLUTIONARY WAY TO DIAGNOSE SEPSIS



## Rule in/out sepsis

- Measures host response to systemic infection by PCR
- mRNA signature from blood
- High NPV and high PPV to differentiate sepsis vs. SIRS\*



## Actionable results in 1 hour

- 1 step sample to result
- Rapid assay turnaround time



## Ease of use

- Fully automated sample to result process
- All reagents integrated in single-use cartridges
- Compatible with EDTA sample collection
- 2-minute hands-on time



## Result as probability risk score (SeptiScore®)

- Result interpretation via 4 probability bands
- The SeptiScore® correlates with sepsis risk



## Increased laboratory service level

- Minimize need for additional diagnostic tests
- Early sepsis rule out to obviate pathogen ID tests



Patient's immune system unlocks rapid and accurate sepsis diagnosis to target treatment.

Sample  
Input

Homogenization  
+ Sample Lysis

RNA  
Extraction

RT-PCR  
Amplification + Detection

Result

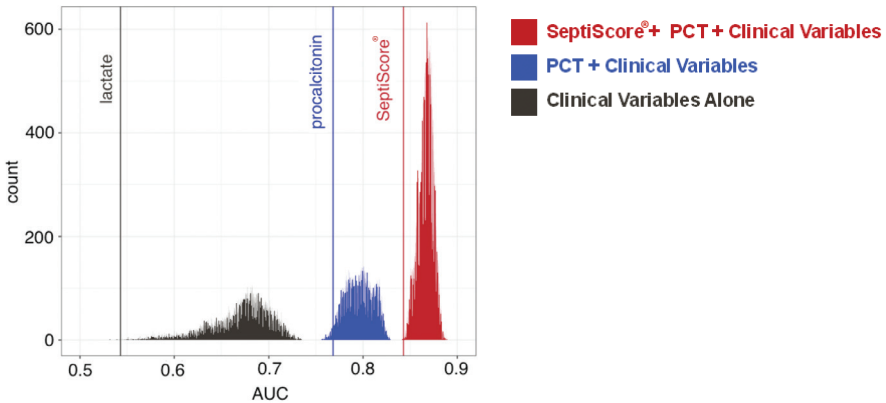
0 —————> 60 mins

\*SIRS (Systemic Inflammatory Response Syndrome) also referred to as Infection Negative Systemic Inflammation, (INSI)

# A RAPID, SENSITIVE, RELIABLE DIAGNOSTIC TEST

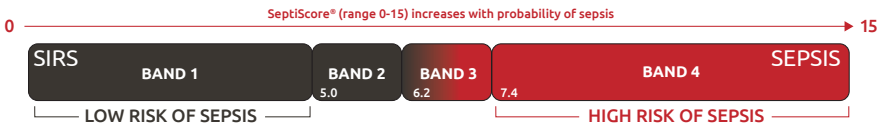
SeptiCyt<sup>®</sup> RAPID addresses the unmet and urgent need for a rapid, sensitive, and reliable diagnostic test to provide physicians with actionable results to rule out sepsis with high confidence, or to expedite preventative action with prompt therapeutic interventions.

## 1. SeptiScore<sup>®</sup> Outperforms Other Clinical Variables Including Lactate and Procalcitonin (PCT)



## 2. Clinically Validated and FDA Cleared For *In Vitro* Diagnostic Use

SeptiCyt<sup>®</sup> technology has been clinically validated and published independently in peer reviewed medical journals.<sup>(1-6)</sup> Below is a summary of SeptiCyt<sup>®</sup> RAPID performance data from 378 samples of suspected sepsis patients, which supported the FDA 510(k) market clearance. SeptiCyt<sup>®</sup> RAPID was shown to strongly discriminate sepsis vs. SIRS (AUC 0.84)?



BAND 1	PERFORMANCE
Sensitivity	0.94
Sepsis probability	≤ 9.4%
SIRS probability	≥ 90.6%
Likelihood Ratio	0.15

BAND 4	PERFORMANCE
Specificity	0.90
Sepsis probability	≥ 80.47%
SIRS probability	≤ 19.3%
Likelihood Ratio	6.05

### 3. Alignment with Surviving Sepsis Campaign (SSC) Guidelines for Clinical Management of Sepsis and Septic Shock.<sup>8</sup>

SSC Recommendations	SeptiCyt <sup>®</sup> RAPID Alignment
Rapid assessment of infectious vs non-infectious causes, (page 17) & unconfirmed infection (page 16)	1 hr. TAT with SeptiCyt <sup>®</sup> RAPID can differentiate infectious vs. non-infectious systemic inflammation
Against use of qSOFA vs SIRS, MEWS, NEWS as single screening tools (page 12)	SeptiScore <sup>®</sup> provides sepsis probability with high accuracy for use in conjunction with SIRS for early identification
Time to Antibiotics Recommendations (pages 16- 18)	1 hr. TAT can help to guide antibiotic administration

### References

1. Miller R et al. Crit Care Med 2015; 43:252. <https://doi.org/10.1097/01.ccm.0000474833.48035.b5>.
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4. Koster-Brouwer ME et al. Crit Care Med 2018; 46(3):368–74.
5. Montero MM et al. Sci Rep 2023; 13:944. <https://doi.org/10.1038/s41598-023-28178-y>.
6. Gravrand V et al. Viruses 2023; 15(2):419. <https://doi.org/10.3390/v15020419>.
7. Balk et al. 2022 medRxiv pre-print server: <https://doi.org/10.1101/2022.07.20.22277648>.
8. Surviving Sepsis Campaign: International Guidelines 2021. Critical Care Medicine 2021; 49:e1063-e1143.



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