DIAGNOSE SEPSIS WITH MORE CERTAINTY
IN JUST ONE HOUR

SeptiCyte® RAPID | Immunexpress

IVD For *in vitro* diagnostic use

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 cartridge
- 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

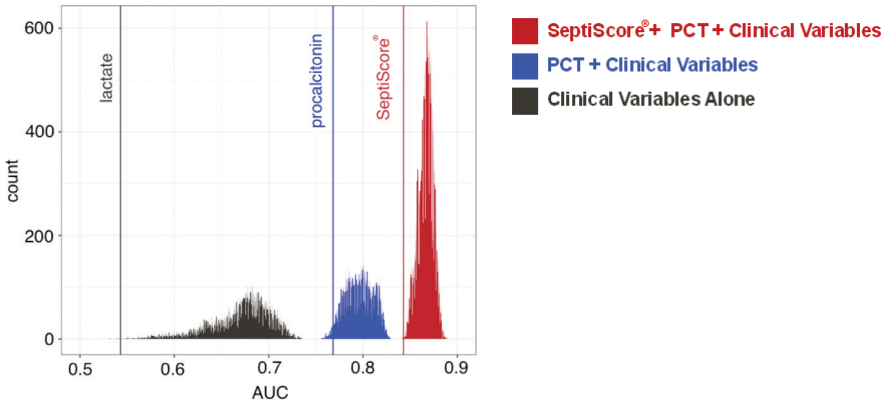
Patient's immune system unlocks rapid and accurate sepsis diagnosis to target treatment.

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

A RAPID, SENSITIVE, RELIABLE DIAGNOSTIC TEST

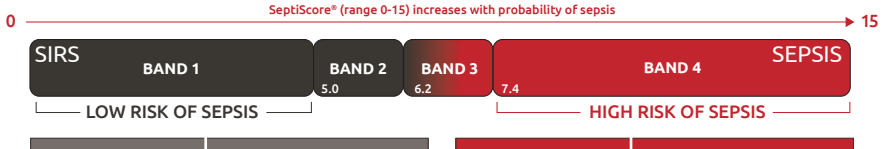
SeptiCyte® RAPID addresses the unmet and urgent need for a rapid, sensitive and reliable diagnostic test to provide physicians with actionable results to rule out sepsis with high confidence, or to expedite preventative action with prompt therapeutic interventions.

1. SeptiScore® Outperforms Other Clinical Variables Including Lactate and Procalcitonin (PCT)



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

SeptiCyte® technology has been clinically validated and published independently in peer reviewed medical journals.[1-6] Below is a summary of SeptiCyte® RAPID performance data from 378 samples of suspected sepsis patients, which supported the FDA 510(k) market clearance. SeptiCyte® RAPID was shown to strongly discriminate sepsis vs. SIRS (AUC 0.84)[7]



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.[8]

SSC Recommendations	SeptiCyte® RAPID Alignment
Rapid assessment of infectious vs non-infectious causes, (page 17) & unconfirmed infection (page 16)	1 hr. TAT with SeptiCyte® RAPID can differentiate infectious vs. non-infectious systemic inflammation
Against use of qSOFA vs SIRS, MEWS, NEWS as single screening tools (page 12)	SeptiScore® 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 and meet 3 hr. CMS* quality metric SEP-1 & SSC care management guidelines

*Centers for Medicare & Medicaid Services

References

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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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