

DIAGNOSE SEPSIS WITH MORE CERTAINTY  
IN JUST ONE HOUR



# INTRODUCING SEPTICYTE® RAPID A REVOLUTIONARY WAY TO DIAGNOSE SEPSIS



## Rule in/out sepsis

- Measures host response to systemic infection
- 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 3 probability bands
- The SeptiScore® correlates with sepsis risk

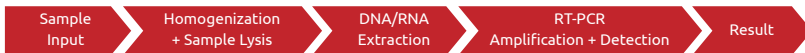


## Increased laboratory service level

- 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.



0 —————> 60 mins

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

## A RAPID, SENSITIVE, RELIABLE DIAGNOSTIC TEST

Sepsis, defined as life-threatening organ dysfunction caused by a dysregulated host response to infection, is one of the main causes of morbidity and mortality in critically ill patients. There remains a high unmet need for a rapid, sensitive, reliable diagnostic test to provide physicians with actionable results to rule out sepsis with high confidence or expedite preventative action with prompt therapeutic intervention for a potential life-threatening situation. SeptiCyte® RAPID seeks to address this unmet clinical challenge.



### Clinical validation

Clinical research results published in peer reviewed medical journals have demonstrated the accuracy of SeptiCyte® technology in both adults and children suspected of sepsis<sup>1-5</sup>. Clinical observations and *in silico* analyses have shown SeptiCyte® RAPID can discriminate sepsis from SIRS across a heterogeneous patient population, including those with immunosuppression.



### Actionable results in 1 hour

SeptiCyte® RAPID performance is independent of illness severity, superior to other clinical variables in discriminating SIRS/sepsis<sup>1</sup>. SeptiCyte® RAPID can recognize the host immune response to bacterial, viral or fungal pathogens causing sepsis and provide the physician with highly accurate and actionable results in 1 hour.



### Improve outcome, lower costs

Studies have revealed higher costs and mortality are associated with a delayed sepsis diagnosis<sup>6</sup>. So an early accurate sepsis rule in/rule out using SeptiCyte® RAPID can efficiently improve patient outcomes. Furthermore, it can relieve financial burdens. An economic study<sup>7</sup> indicated an average ICU in the US could save ~ \$5M/year adopting SeptiCyte® LAB.



### Expedite and optimize clinical workflow

With high accuracy, SeptiCyte® RAPID can strengthen clinical decision making either enabling early sepsis protocol implementation, if there is a high SeptiScore® (high PPV) or re-evaluating etiology of symptoms if there is a low SeptiScore® (high NPV), both of which improve patient management and antibiotic stewardship.

---

## References

1. Miller R, Lopansri B, McHugh L, Rapisarda A, Seldon T, Burke J. 2015. Validation of a novel host response assay to distinguish SIRS and sepsis in critically ill patients. *Am. J Respir Crit Care Med* . 2018 Oct 1; 198(7):903-913.
2. D.M. Verboom, M.E. Koster-Brouwer, J.P. Ruurda, et al., A high-risk gastro-intestinal surgery, *Journal of Critical Care*, <https://doi.org/10.1016/j.jccrc.2019.07.020>.
3. Zimmerman JJ, Sullivan E, Yager TD, et al: Diagnostic accuracy of a host gene expression signature that discriminates clinical severe sepsis syndrome and infection-negative systemic inflammation among critically ill children. *Crit Care Med* 2017; 45:e418–e425.
4. Koster-Brouwer ME, Verboom DM, Scicluna BP, Van De Groep K, Frencken JF, Janssen D, et al. Validation of a novel molecular host response assay to diagnose infection in hospitalized patients admitted to the ICU with acute respiratory failure. *Crit Care Med* 2018;46(3):368–74.
5. R Brandon, J Kirk, T Yager, S Cermelli, R Davis, D Sampson, P Sillekens, I Keuleers, T Vanhoey. Clinical performance of a rapid sepsis test on a near-patient molecular testing platform. # P481 ISICEM 2020, Brussels
6. Paoli CJ et al., Epidemiology and Costs of Sepsis in the United States-An Analysis Based on Timing of Diagnosis and Severity Level. *Crit Care Med* 2018:1889-1897.
7. McHugh L. Modeling improved patient management and hospital savings with SeptiCyte® LAB in the diagnosis of sepsis at ICU admission. *Open Forum Infectious Disease* 2018;5 (suppl 1):s589, #2022.

SeptiCyte® RAPID

· · · · · BIOCARTIS

SeptiCyte® RAPID is a CE marked IVD within the EU. Immunexpress is using the Idylla trademark under license from Biocartis. The SeptiCyte® RAPID Test uses SuperScript™ III. The SuperScript III trademark is owned by Life Technologies Corporation.

<sup>1</sup>Market availability varies and should be checked via [immunexpress.com](http://immunexpress.com).