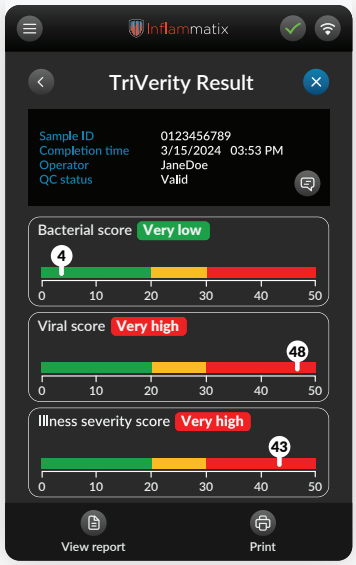
Inflammatix™
Advanced host-response diagnostics

TriVerity™ Acute Infection & Sepsis Test

A NOVEL TEST FOR HARD TO DIAGNOSE EMERGENCY DEPARTMENT PATIENTS SUSPECTED OF ACUTE INFECTION AND SEPSIS

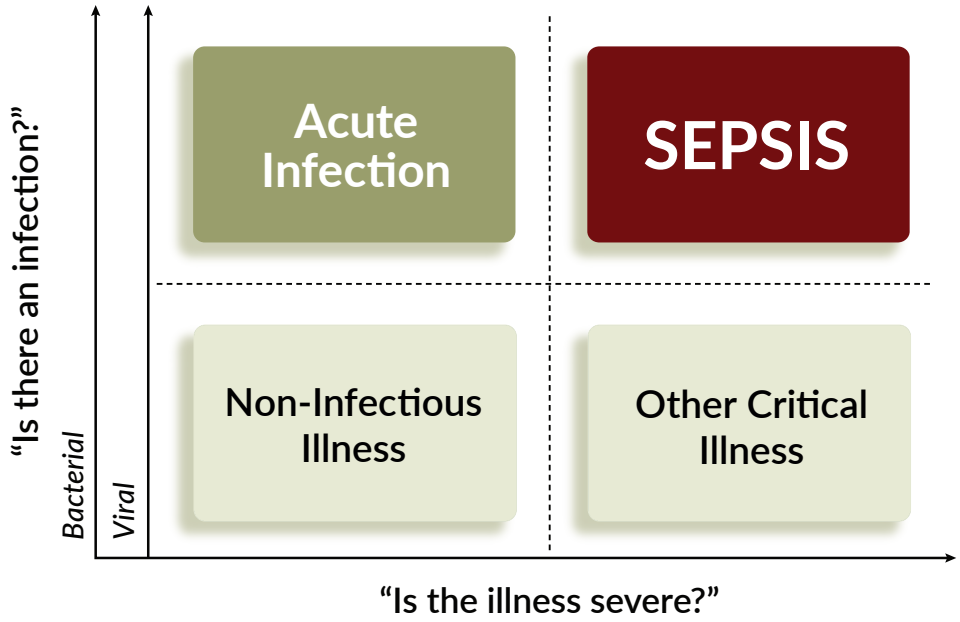
We are developing a rapid (~30 minutes) test to measure the immune response using proprietary machine-learning algorithms to generate clinically actionable results in a way that physicians routinely evaluate emergency department patients.

Our novel and actionable approach is a smarter approach since predicting sepsis is not enough, and just saying "not sepsis" is not a diagnosis.



Example TriVerity™ result

TriVerity results inform on infection status & disease severity



FDA BREAKTHROUGH DEVICE DESIGNATION
TriVerity
November 2023[1]

TriVerity test results provide actionable information by placing patients into diagnostic quadrants based on their risk of bacterial infection, viral infection, and illness severity.

The TriVerity Acute Infection and Sepsis Test System is not for sale, and does not have marketing approval or clearance from regulatory authorities in any jurisdiction. The features described may change during the development process.

The TriVerity test fits routine clinical workflows

1. Collect blood sample via routine draw
2. Insert tube directly into TriVerity Cartridge
3. Insert TriVerity cartridge into Myrna™ Instrument at or near point-of-care
4. Perform test which measures 29 host-response genes and applies machine-learning derived algorithms
5. Receive results in approx. 30 minutes

The TriVerty Acute Infection and Sepsis Test System includes the Myrna Instrument and TriVerity Cartridge

Advancing towards FDA submission, the TriVerity Classifiers performance continue to excel[1-7]

TriVerity Classifier development, which started on the NanoString nCounter® system, ported over to the Myrna Instrument with TriVerity Cartridges, with similar stellar performance. These initial on-Myrna results led to FDA Breakthrough Device Designation.[1,2] The SEPSIS-SHIELD FDA registrational study[3] in patients suspected of acute infection with one vital sign change or sepsis and two vital sign changes (with limited exclusion criteria) is in process.

	Studies on NanoString nCounter[4-7]		FDA Breakthrough Data on Myrna[2]		FDA Clearance Study on Myrna[3]	
Study	**Sensitivity[a]**	**Specificity[b]**	**Sensitivity[a]**	**Specificity[b]**	**Sensitivity[a]**	**Specificity[b]**
Patient samples	N=312[4,5] / 397[6,7]	N=312[4,5] / 397[6,7]	N=679 / 262[c]	N=679 / 262[c]	N~1,200	N~1,200
Bacterial Score	95% / 98%[4]	96% / 98%[6]	98%	95%	TBD	TBD
Viral Score	88% / 96%[5]	93% / 94%[6]	97%	92%	TBD	TBD
Severity score[d]	79% / 86%[5]	97% / 97%[7]	94%	97%	TBD	TBD

a) Sensitivity based on threshold between the "Very Low" band and other bands. b) Specificity based on threshold between the "Very High" band and all other bands. c) 679 patient samples tested to establish Bacterial and Viral Scores' performance. A subset of 262 samples run to establish Severity Score performance. d) Need for 7-day ICU level care (mechanical ventilation, vasopressors or renal replacement therapy).

1. Boyle A. Inflammatix sepsis test scores FDA breakthrough device designation. *BioWorld, 2023.*

2. Whitfield NN, et. al., Accuracy of a 29-gene host response test for diagnosis of bacterial and viral infections and prediction of illness severity, Poster presented at ESCMID Global, April 27, 2024, Barcelona, Spain.

3 https://clinicaltrials.gov/study/NCT04094818

4. Bauer W. et al., A novel 29-messenger RNA host-response assay from whole blood accurately identifies bacterial and viral infections in patients presenting to the emergency department with suspected infections: A prospective observational study. *Critical Care Medicine*, 2021.

5. Galtung et al., Prospective validation of a transcriptomic severity classifier among patients with suspected acute infection and sepsis in the emergency department. *European Journal of Emergency Medicine*, 2022.

6. Safarika et al., A 29-mRNA host response test from blood accurately distinguishes bacterial and viral infections among emergency department patients. *Intensive Care Medicine Experimental*, 2021.

7. Kostaki et al, A 29-mRNA host response whole-blood signature improves prediction of 28-day mortality and 7-day ICU-care in adults presenting to the emergency department with suspected acute infection and/or sepsis. *Shock*, 2022.

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See a list of our publications and find out more at **www.inflammatix.com**

Contact us to collaborate at **info@inflammatix.com**