



What is AcuSept?

AcuSept, a next-generation sepsis diagnostic test, invented and developed by Acumen Research Laboratories Pte Ltd, is a blood-based, host response gene expression test. AcuSept can help doctors quickly and accurately assess whether or not an infection condition in a patient has a risk of complication and developing into sepsis. Early and accurate diagnosis result of AcuSept can also help doctors determine the appropriate next steps for patient management. AcuSept:

- Provides a comprehensive assessment of a patient's current disease state rapidly and accurately, without risks associated with imaging radiation, imaging agents, or highly invasive procedures
- Integrates the expression levels of a panel of biomarker genes involved in the host response to systemic infection into a single score, which have been validated clinically to early and accurately identify patients with high risk of sepsis
- Has high sensitivity and negative predictive value (NPV), and improves the classification of patient disease status
- Superior over currently used tests such as Procalcitonin (PCT)
- High expected costs benefits and reduced hospital length of stay

What unmet clinical need is fulfilled by AcuSept?

Sepsis is defined as life-threatening organ dysfunction caused by a dysregulated host response to infection and is a leading cause of death worldwide, with 20-30 million cases each year and mortality rate of 30-60% in different countries. In the US, each year there are approximately 1 million sepsis patients and nearly 250,000 deaths, and total hospitalization costs in the US due to sepsis exceeds \$23 billion.

The signs and symptoms of the early stages of sepsis are non-specific, making early identification challenging. Delaying diagnosis by as short as one hour can decrease patients' rate of survival. Therefore, assessment tools that are able to better assist clinicians in early detection, empirical therapy and overall improved management of sepsis are needed.

AcuSept fulfills the urgent need of a targeted, robust method for rapid identification of patients' infection status, as well as risk or severity of sepsis to aid doctors in patient treatment and management.

Why gene expression?

AcuSept is a gene expression test, not a genetic test. Whereas genetic testing (usually gene mutations) may inform on lifetime disease risk, the AcuSept gene expression test provides a

current-state assessment of sepsis by assessing the AcuSept sepsis-specific gene expression signature in the immune system's activities associated with and regulated by sepsis.

Gene expression levels change depending on a person's disease status resulting from both genetic and environmental factors. Combining AcuSept with other clinical assessments provides a complete and current picture of the patients' disease status through its clinical utility in identifying patients likely to have sepsis, independent of identity or source of infectious agents which takes several days as microbiological culture of the blood is the method used.

How does AcuSept work?

As a blood test that can be easily integrated into any practice setting, AcuSept:

- Is performed through a quick, routine blood draw conveniently administered right at the Emergency Department (ED), General Wards or Intensive Care Unit (ICU)
- Provides objective, reproducible results within 4 hours (sample-to-answer)
- Complements current clinical and laboratory assessment of sepsis, while improving diagnostic accuracy
- Standard molecular diagnostics workflow, user-friendly with pre-dispensed and lyophilized reagents.

The AcuSept kit is in the format of PCR mini-array. All necessary reagents are pre-dispensed and lyophilized into breakable PCR strips. With suitable adaptors, AcuSept could be performed in majority of real-time PCR systems, including Roche LightCycler 480, ABI 7500/7900/ViiA7 and Bio-Rad CFX96 etc. Besides the specific biomarker genes, the PCR mini-array also contains several built-in quality control markers to ensure validity and accuracy of results.

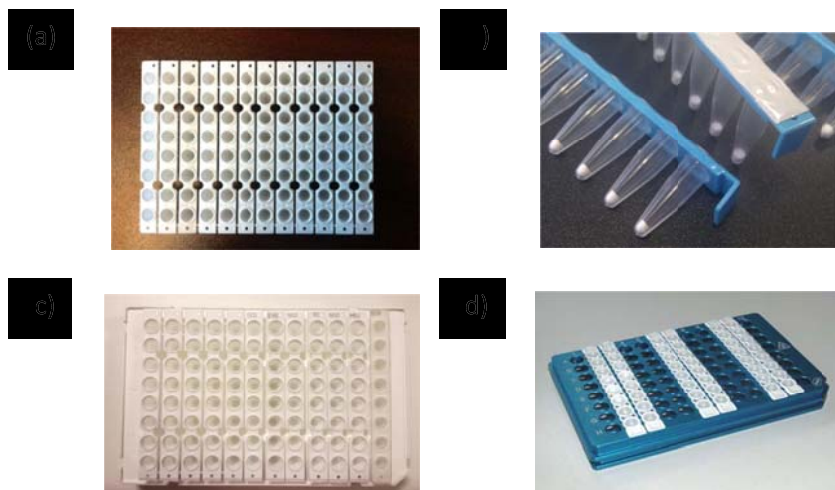


Figure 1. Breakable strips AcuSept PCR mini-array (a,b), disposable adaptor for the PCR run (c), and aluminum adaptor for the PCR run (d).

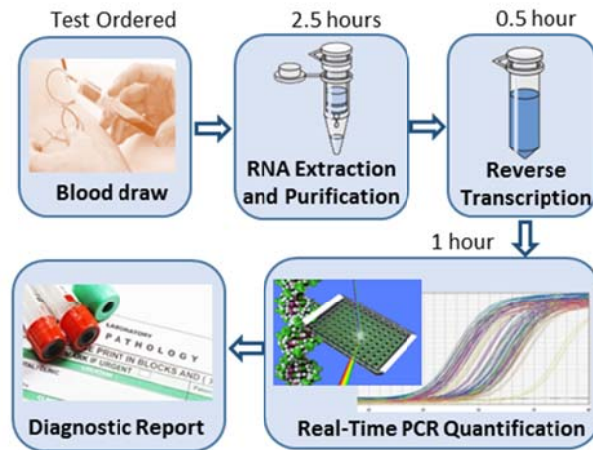


Figure 2. AcuSept workflow

How big is the market for AcuSept?

AcuSept is expected to exceed US\$1 billion sales to hospitals per year world-wide at steady state. Key markets include the US, Europe, Japan and China. The expected cost-benefit ratio presents an attractive value proposition to healthcare payers in both the public and private sectors.

What is Acumen's strategy for commercial success?

Acumen will take a 2-pronged strategy: firstly, through achieving regulatory approval in 2017 for launch of AcuSept in the Singapore and ASEAN markets, followed by CE and FDA approval for sales in the EU and US markets in 2018. Secondly, Acumen will non-exclusively license the core technology to suitable diagnostic companies; the first deal has been signed with Curetis AG in Oct 2015.

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