# What Is **FA-BCID?**

Using multiplex polymerase chain reaction (PCR)-based techniques (which amplify and detect multiple genetic sequences of interest in a single experiment), the FA-BCID panel can detect 24 sepsis-related pathogens (bacteria and yeast) and three antimicrobial resistance genes in patients with suspected sepsis.

The FA-BCID panel can identify specific pathogens from blood cultures that have tested positive (indicating initial microbial growth) with a turnaround time of approximately one hour. This is significantly faster than the time required to grow a full blood culture to identify pathogens.

The sensitivity and specificity of the FA-BCID panel are well-established for organisms (and antimicrobial resistance genes) included in the panel; however, its primary limitation from a diagnostic standpoint is an inability to detect other pathogens (and antimicrobial resistance mechanisms) not included in its panel.

Used along with antimicrobial stewardship programs (that actively correlate test results to changes in patient management), the FA-BCID panel may improve patient outcomes by, for example, reducing the time it takes to receive appropriate antimicrobial therapy and shortening hospital stays.



## Questions or comments about CADTH or this tool?

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CADTH Evidence Driven.

CADTH is an independent, not-for-profit organization responsible for providing Canada's health care decision-makers with objective evidence to help make informed decisions about the optimal use of drugs and medical devices in our health care system.

CADTH receives funding from Canada's federal, provincial, and territorial governments, with the exception of Quebec.

**March 2019 | cadth.ca**

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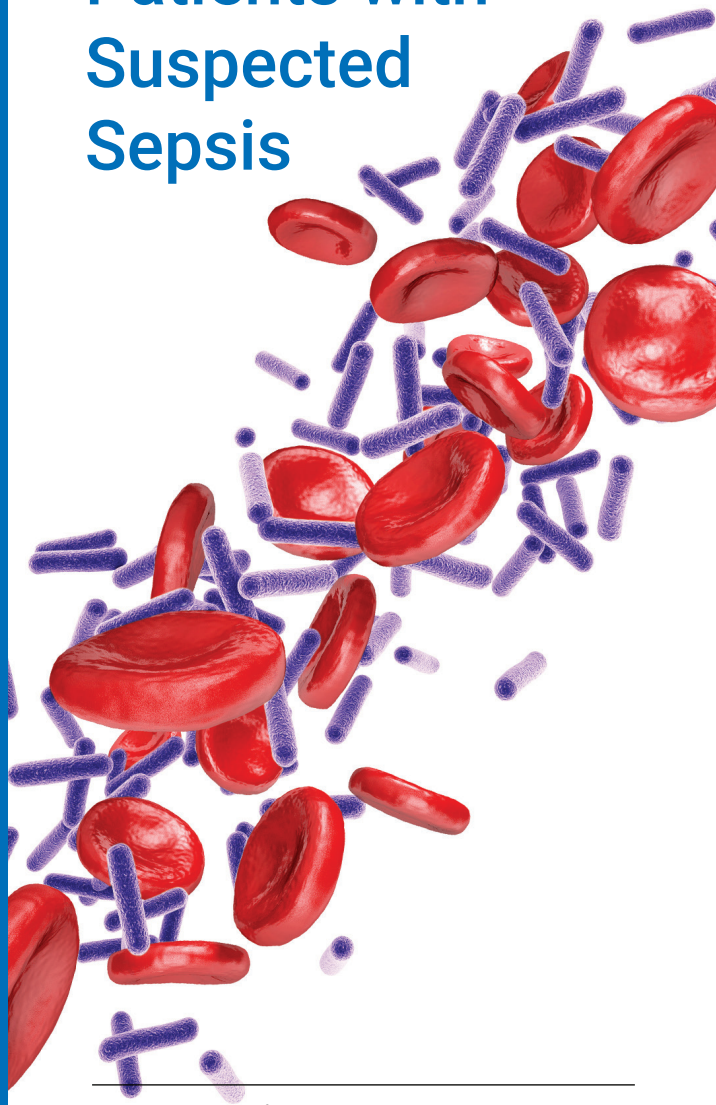
# Rapid Diagnostic Tests for Patients with Suspected Sepsis



Rapid Diagnostic Tests for Patients with Suspected Sepsis

## What Does the FA-BCID Panel Cost?

The FA-BCID technology consists of:

- An analyzer (a one-time purchase and is re-used for all tests).
- FA-BCID panels/tests (which contain the reagents to which the positive blood culture sample is added; a new panel is needed each time the test is run).
- A desktop computer with pre-loaded software to interpret the results by matching genes to a database.

The costs total about C$50,000 upfront, followed by C$180 per panel/test.

No comprehensive economic evaluations were identified.

## FA-BCID Panel and Blood Culture

To note, the FA-BCID panel is intended as an adjunct to blood culture (and not for independent use). This is because not all sepsis-related pathogens can be detected by the FA-BCID panel, and similarly, not all antimicrobial resistance mechanisms can be detected by the panel. As a result, while the FA-BCID panel provides preliminary results that can help to guide therapy, these results need to be subsequently confirmed via blood culture.



# Advantages and Limitations of Rapid Diagnostics Tests

A faster time to pathogen identification compared with blood culture alone.

A faster time to appropriate antimicrobial therapy and more judicious use of antimicrobial drugs.

Possible improvements in sepsis-related mortality and other patient-important outcomes.

Absence of pathogen detection altogether does not exclude the possibility of sepsis.

The absence of detection of antimicrobial resistance genes does not necessarily equate to antimicrobial susceptibility.

Identification of one (or more) pathogen(s) does not exclude the possibility of additional organism(s) that may be present.

## Implementation Status

The FA-BCID panel is commercially available and, as of July 2017, four Canadian hospitals were using FilmArray analyzers.

## FA-BCID Evidence

CADTH identified 22 studies of the FA-BCID panel. In most studies, the FA-BCID panel was compared with the diagnostic gold standard (blood culture alone).

The sensitivity and specificity of the FA-BCID panel have been well-established for the organisms and antimicrobial resistance genes included in the panel. However, there is limited direct evidence on the ability of the FA-BCID panel to improve clinical outcomes (such as mortality and other patient-important outcomes) or to reduce health care costs.

Very few studies have compared the FA-BCID panel with other rapid diagnostic tests. As a result, it is difficult to place the FA-BCID panel within the spectrum of available rapid diagnostic tests.

## Patient-Important Outcomes

CADTH identified two systematic reviews and meta-analyses that compared rapid diagnostic tests for sepsis (as a class of interventions) with blood culture. These included a variety of rapid diagnostic tests including PCR-based methods, matrix assisted laser desorption ionization-time of flight mass spectrometry (MALDI-TOF MS), and peptide nucleic acid fluorescent in situ hybridization-based methods.

Both reviews found that the rapid tests had a positive impact on clinical outcomes for patients with sepsis, including reduced mortality, improved time to appropriate antimicrobial therapy, and decreased length of stay in hospital.

## Other Commercially Available Rapid Diagnostic Tests for Patients With Suspected Sepsis

| | |
|---|---|
| MALDI-TOF MS | Magiplex sepsis real-time |
| Verigene | SepsiTest |
| Prove-it Sepsis | iCubate System |
| VYOO | Xpert MRSA/SA BC assay |
| LightCycler SeptiFast | T2 Candida Panel |