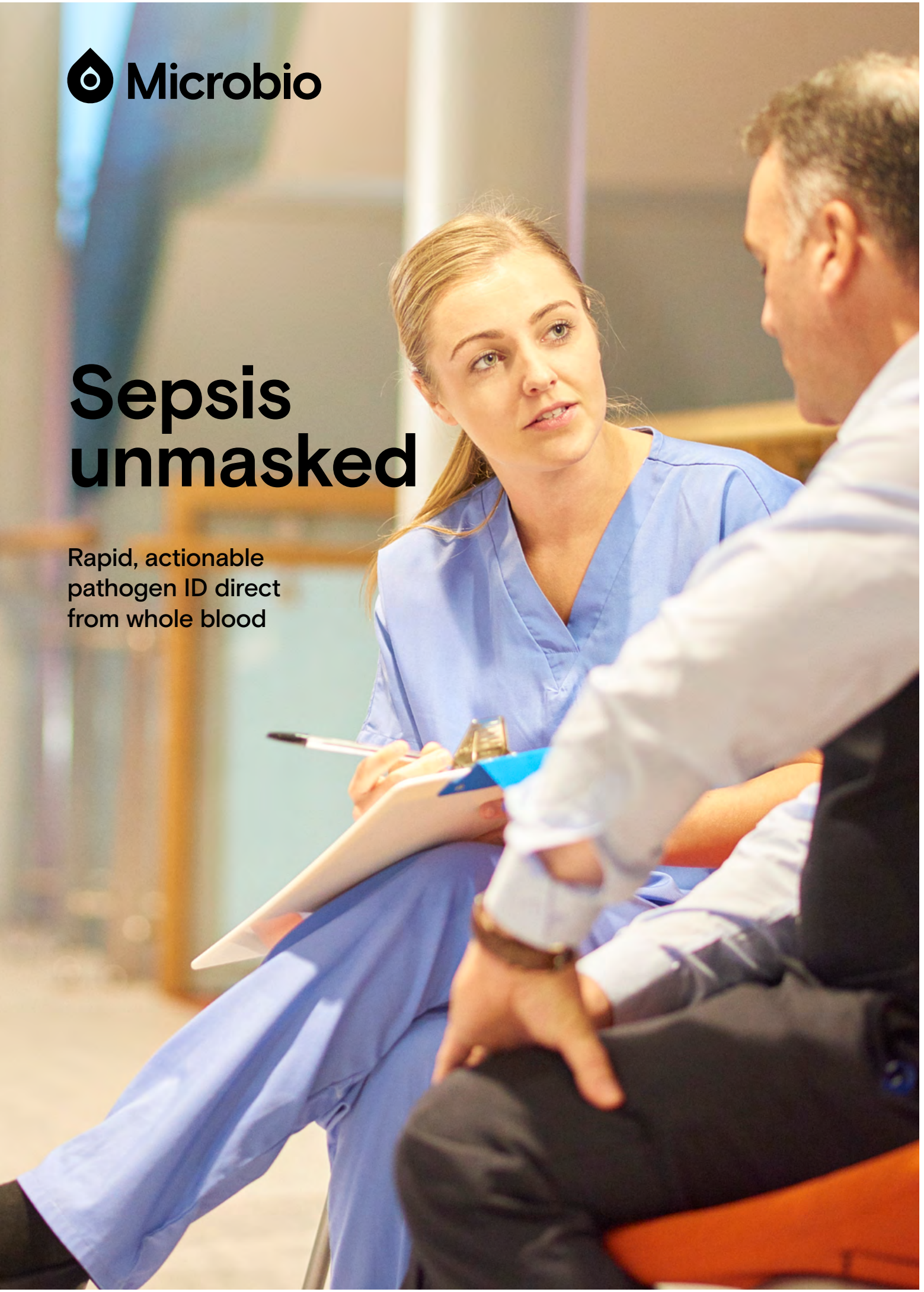

Microbio
Sepsis unmasked
Rapid, actionable pathogen ID direct from whole blood

The fight against sepsis

A CHALLENGE FOR CLINICIANS AND MOLECULAR LABORATORIES GLOBALLY

49
million victims a year

11
million deaths

20%
of all deaths worldwide

7.6%
drop in sepsis survival rates for every hour effective treatment is delayed[1]

Infectious disease experts agree: identifying the causative pathogens in bloodstream infections is crucial to the fight against sepsis.

Performance is paramount. A pathogen identification assay must be fast, delivering actionable intelligence in under 3 hours. It must identify the bacteria and fungi behind almost all sepsis cases, including ESKAPE pathogens. And it must be accurate.

Superior performance alone is not enough. If a new assay is to add real value to a laboratory's existing services, it must complement the tools already in use, especially blood culture. It must excel where those tools do not. That means it must identify fastidious pathogens and mixed infections.

Sepsis patients are critically ill, so any new assay must operate on minimally invasive sample sizes.

Additionally, laboratory budgets are tight and skilled staff are at a premium. Big-ticket proprietary hardware must compete for funds—and for space. Diverting skilled staff time to extensive training on new equipment and workflows is a significant additional overhead.

Microbio sees the challenges faced by clinical laboratories and clinicians trying to improve bloodstream infection management.

Introducing Microbio's InfectID-Bloodstream Infection. A novel qPCR pathogen identification assay which delivers performance, cost-effectiveness and easy implementation.

Without compromise.

1 Kumar, Anand, Daniel Roberts, Kenneth E. Wood, Bruce Light, Joseph E. Parrillo, Satendra Sharma, Robert Suppes, et al. "Duration of Hypotension before Initiation of Effective Antimicrobial Therapy Is the Critical Determinant of Survival in Human Septic Shock*:" Critical Care Medicine 34, no. 6 (June 2006): 1589–96. https://doi.org/10.1097/01.CCM.0000217961.75225.E9.

Taking up the fight

A NOVEL TOOL EMERGES

InfectID-BSI is a breakthrough diagnostic tool to identify the causative pathogens in bloodstream infections, giving clinicians the edge over sepsis.

A bioinformatics approach underpins this highly discriminatory SNP fingerprint assay. Paired with innovative, software-managed melt curve analysis InfectID-BSI detects and identifies the 26 most prevalent sepsis-causing bacteria and yeast directly from blood in under 3 hours. The target pathogens for InfectID-BSI were selected based on research published in a multi-centre study by Opota[2] et al in 2015, which identified the 20 pathogens responsible for 94% of sepsis cases.

By cleverly exploiting off-the-shelf hardware and existing skillsets, it minimises disruption and training, slipping seamlessly into existing workflows. It also eliminates the need to squander precious capital and laboratory space on single-purpose hardware.

With InfectID-BSI, clinical laboratories can now give clinicians the most valuable weapon in the fight against sepsis:

The intel they need. When they need it.

26 pathogens unambiguously identified

GRAM NEGATIVE

Escherichia coli
Pseudomonas aeruginosa
Klebsiella spp.
Enterobacter cloacae
Proteus mirabilis
Citrobacter freundii
Morganella morganii
Serratia marcescens
Stenotrophomonas maltophilia
Acinetobacter baumannii

GRAM POSITIVE

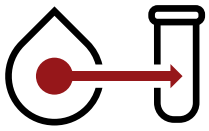
Staphylococcus aureus
Staphylococcus epidermidis
Enterococcus faecalis
Enterococcus faecium
Streptococcus anginosis
Streptococcus agalactiae
Streptococcus pyogenes
Streptococcus bovis
Streptococcus pneumoniae and
Streptococcus mitis group
Aerococcus viridans

YEAST

Candida albicans
Candida auris
Candida dubliniensis
Candida parapsilosis
Candida tropicalis
Candida glabrata

2 Opota, O., A. Croxatto, G. Prod'hom, and G. Greub. "Blood Culture-Based Diagnosis of Bacteraemia: State of the Art." Clinical Microbiology and Infection 21, no. 4 (April 2015): 313–22. https://doi.org/10.1016/j.cmi.2015.01.003

Informed clinical decision-making



DIRECT FROM WHOLE BLOOD

Rapid results—no need to wait for enrichment or culturing

<3 HR TIME TO RESULT

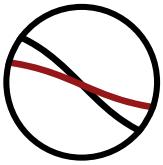
Allows for early targeted antimicrobial use

MINIMALLY INVASIVE SAMPLE SIZES

Ideal for difficult-to-bleed patients (validated using blood samples of <0.5mL)

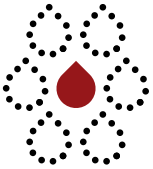
IDENTIFIES 26 PATHOGENS

Identifies >94% of sepsis-causing pathogens. More information than any other test on the market



USES THE MELT CURVE FEATURE OF qPCR

Assays are multiplexed without compromising accuracy (83.7% sensitivity; >99% specificity)

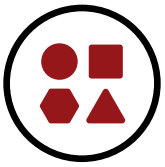


PROCESS 1-7 SAMPLES PER RUN

Two options for delivering results—run a single urgent sample or batch for less urgent samples

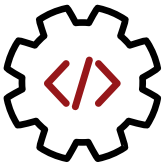
OUTPERFORMS BLOOD CULTURE

For every 100 patients that have positive blood cultures, InfectID-BSI detects pathogens in an additional 105 patients



INSTRUMENT AGNOSTIC

Runs on existing lab instruments using familiar workflows—no need for investment in new hardware or retraining of staff



AUTOMATED RESULT REPORTING

Software analysis of qPCR output removes manual interpretation of results to improve usability

qPCR MOLECULAR DETECTION TECHNOLOGY

Detects the genetic fingerprint of pathogens to avoid some limitations of culture-based methods

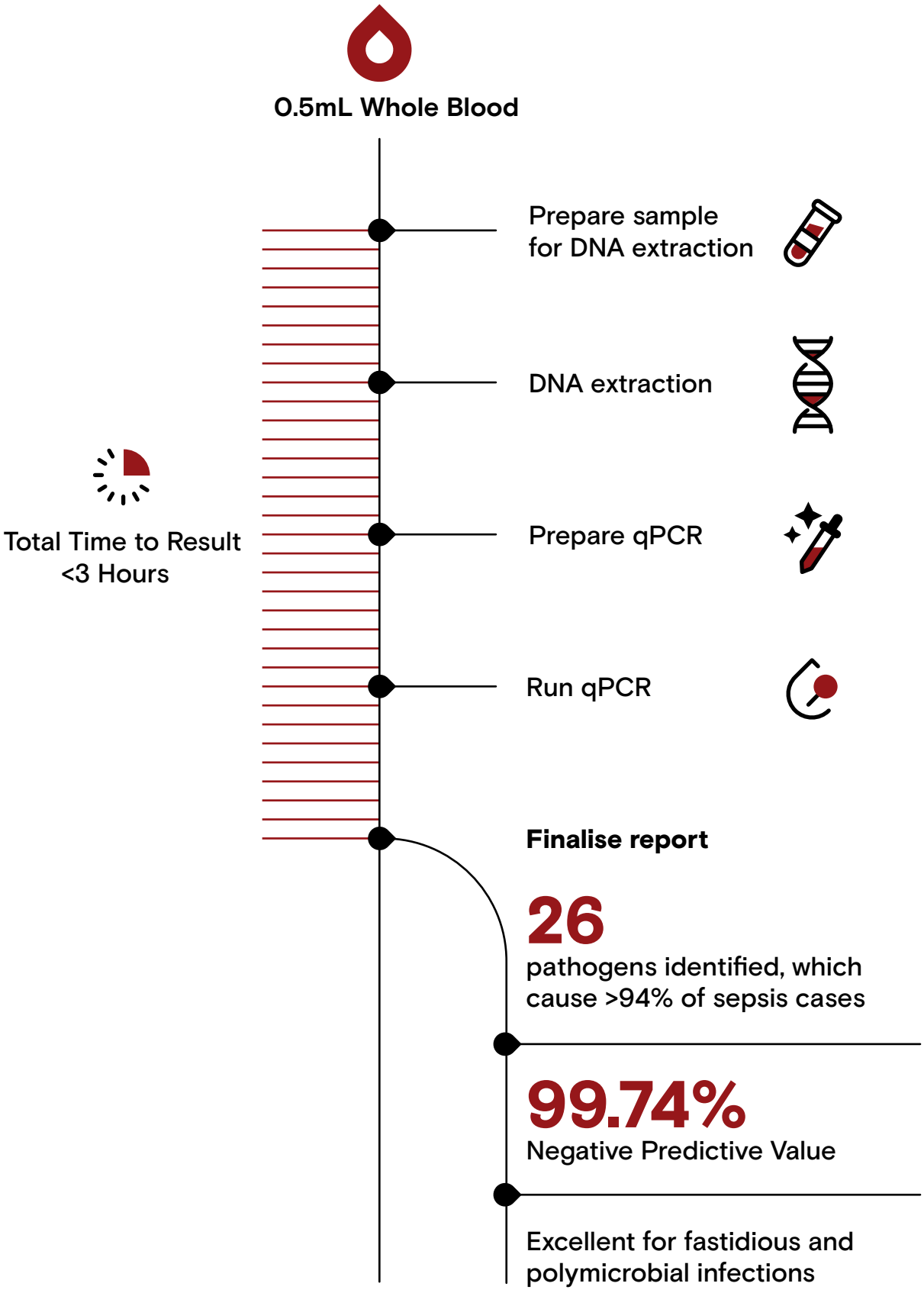
POWERFUL RULE-OUT TEST

Negative predictive value of 99.74% demonstrated in patient sample study

CE MARKED

Available now in the UK and Europe.

Maximise efficiency, minimise cost



Revealing the truth hidden in blood

PATIENT STUDY: INFECTID-BSI VERSUS BLOOD CULTURE

MIXED INFECTIONS

6.4%

Number of polymicrobial infections identified by InfectID-BSI[3]

0.5%

Number of polymicrobial infections identified by blood culture

FASTIDIOUS BACTERIA

6.9%

Number of *S. pneumoniae* and *A. viridans* infections identified by InfectID-BSI[3]

0%

Number of *S. pneumoniae* and *A. viridans* infections identified by blood culture[3]

POSITIVITY RATE

36.6%

InfectID-BSI positivity rate

18%

Blood culture positivity rate

An Australian study of 205 consented patients from the Emergency Departments at two public hospitals illustrated the benefits of InfectID-BSI when compared directly to blood culture.

These patients were triaged using sepsis risk-assessment guidelines. Clinical and laboratory data fields were collected as per the study protocol. Two patients were excluded due to not meeting protocol requirements.

At the time that blood was drawn for routine blood culture, an additional 4mL EDTA tube was taken for InfectID-BSI testing. The blood culture was processed by the public hospital pathology laboratories using standard procedures. The InfectID-BSI samples were sent to Microbio's laboratory where DNA was extracted prior to real-time qPCR analysis. All positive results from InfectID-BSI were independently confirmed by Sanger sequencing.

InfectID-BSI results were collated and compared to blood culture and clinical metadata. This data was subjected to statistical analysis to determine the performance of InfectID-BSI compared to blood culture.

Based on individual samples, InfectID-BSI had sensitivity of 83.7%, compared to 56.7% for blood culture[4,5]. Statistical analysis determined that for every 100 patients found positive by blood culture, InfectID-BSI detects pathogens in an additional 105 patients.

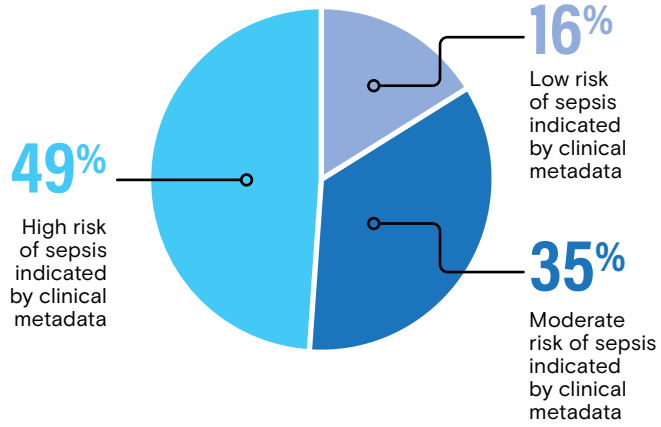
3 Simms, Lisa, Corey Davies, Nadeesha Jayasundara, Sumeet Sandhu, Alexander Pintara, Amorette Pretorius, Graeme R. Nimmo, et al. "Performance Evaluation of InfectID-BSI: A Rapid Quantitative PCR Assay for Detecting Sepsis-Associated Organisms Directly from Whole Blood." Pathology and Laboratory Medicine *Under review.*

4 Farlow, David, Lisa Simms, Corey Davies, Nadeesha Jayasundara, Sumeet Sandhu, Alexander Pintara, Raffaella Giardino, Anton Lord, and Flavia Huygens. "A Commercial Assay versus Traditional Blood Culture: Correlation with Clinical Metadata and Sepsis Criteria." In 32nd European Congress of Clinical Microbiology and Infectious Diseases. Lisbon, Portugal, 2022.

5 Simms, Lisa, Corey Davies, Nadeesha Jayasundara, Sumeet Sandhu, Alexander Pintara, Raffaella Giardino, Anton Lord, and Flavia Huygens. "A Commercial Innovative Diagnostic Assay for Sepsis Diagnosis Directly from Blood." In 32nd European Congress of Clinical Microbiology and Infectious Diseases. Lisbon, Portugal, 2022.

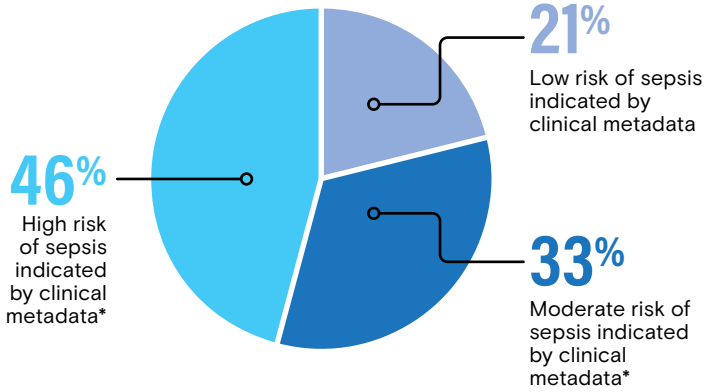
InfectID-BSI results supported by clinical metadata

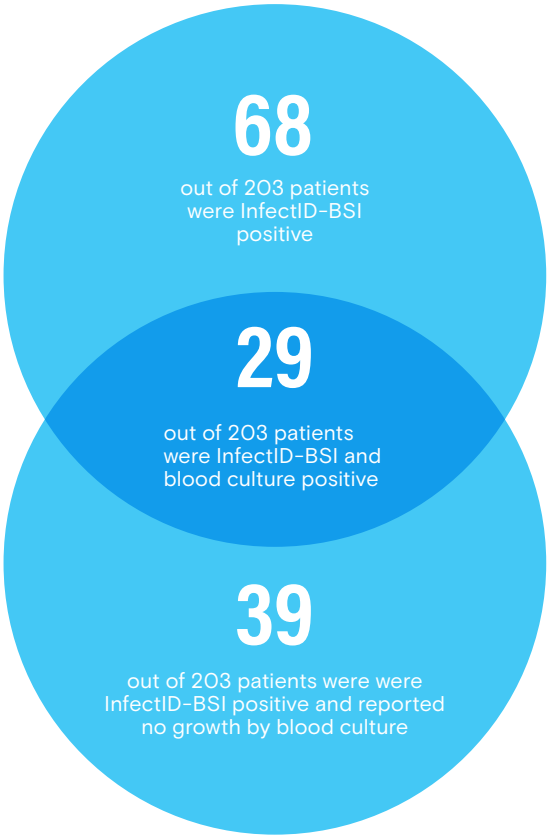
N=68 PATIENTS



N=39 PATIENTS

InfectID-BSI: positive. Blood culture: no growth





***InfectID-BSI detected fastidious bacteria in half (18/31) of patients with clinical metadata that indicated they have sepsis or may have sepsis**

Evaluate InfectID-BSI in your laboratory today

MRB400 InfectID-BSI Bacterial and Yeast Combined Detection Assay Kit for qPCR; 800 reactions

Microbio Ltd Bloodstream Infection (BSI) qPCR kit (InfectID-BSI-B1-B6/Y1 and InfectID-BSI-Y2) are in vitro nucleic acid amplification tests for the qualitative detection of sepsis-associated bacteria and yeast DNA directly from whole blood samples using real-time quantitative PCR (qPCR).

Microbio's InfectID-BSI products are for professional use only and are intended to be used by trained laboratory technicians with knowledge of molecular diagnostic methods working in routine diagnostic laboratories.

Results from Microbio's InfectID-BSI qPCR kit should be interpreted in conjunction with other clinical and laboratory findings. Cleared for sale under In Vitro Diagnostic Directive 98/79/EC.

Your local supplier of Microbio products is:

ADVISAINS

Ruko Pesona View Blok B No. 4, Jln. Ir. H. Juanda, Depok, Jawa Barat 16411.

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Microbio

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