

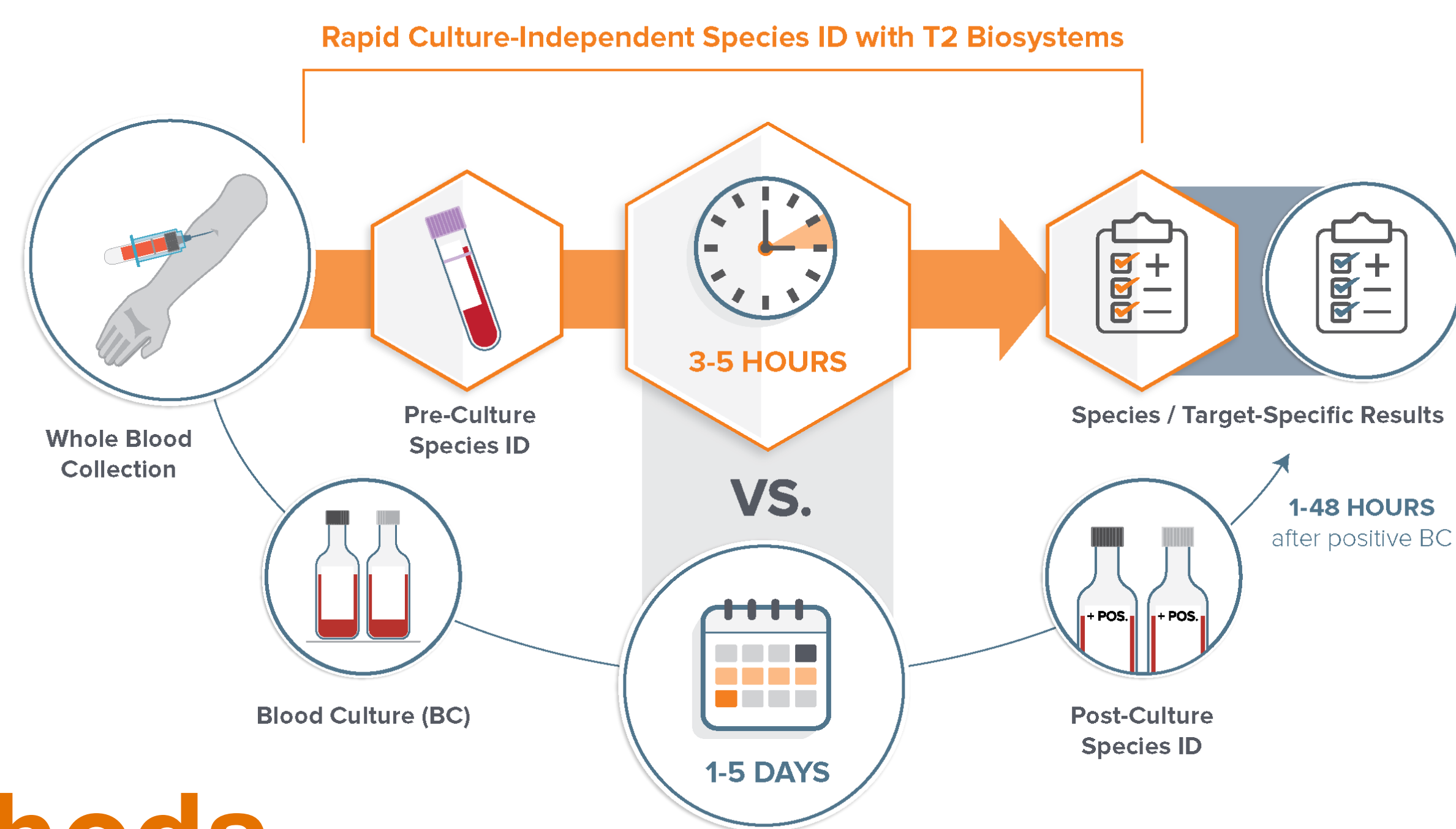
The T2Bacteria Panel Identifies 3 Times More On-Panel Bacterial Pathogens Compared to Conventional Blood Culture

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Background

- The T2Bacteria® Panel is an FDA cleared and CE marked culture independent *in vitro* diagnostic test that identifies common species that cause bacterial sepsis utilizing T2 magnetic resonance technology.
- This FDA cleared panel detects *Enterococcus faecium*, *Staphylococcus aureus*, *Klebsiella pneumoniae*, *Pseudomonas aeruginosa*, and *Escherichia coli* directly from whole blood within 3-5 hours.
- The CE-marked panel also has *Acinetobacter baumannii* as a sixth target.
- The T2Bacteria Panel has been demonstrated to be highly sensitive with a sensitivity of 90% and a limit of detection (LoD) of 2-11 CFU/mL.¹³
- The purpose of this study is to quantify the rate at which the T2Bacteria Panel detects on-panel species compared to blood culture in studies evaluating the T2Bacteria Panel.



Methods

INCLUSION:

Publications, presentations, and abstracts evaluating the T2Bacteria Panel were systematically screened and included if the study reported organism level detection data for both the T2Bacteria panel and conventional blood cultures.

EXCLUSION:

Studies were excluded if organism level data were not available for both on and off-panel organisms. Data relating to *Candida* species and the T2Candida Panel were excluded from analyses.

OUTCOMES:

The primary outcome is the ratio of on-panel organisms identified overall by the T2Bacteria Panel compared to conventional blood cultures.

Results

Table 1: Included Studies

Author	BC Method	Year	Location	Population
Bonura C ¹	Bactec FX	2023	Italy	ICU
Cruz H ²	Bactec FX	2023	Portugal	ICU
Parajo Pazos N ³	Bactec FX	2023	Spain	ICU
Giacobbe DR ⁴	Bactec FX	2022	Italy	ICU
Lucignano B ⁵	Bactec 9240, Bactec 70FX	2022	Italy	Pediatrics Sepsis
Seitz T ⁶	BacT/ALERT FN Plus	2022	Austria	ICU
Krifors A ⁷	BacT/ALERT VIRTUO	2022	Sweden	SICU
Quirino A ⁸	BacT/ALERT VIRTUO	2022	Italy	Suspected BSI
Paggi R ⁹	Bactec FX	2021	Italy	ICU
Drevinek P ¹⁰	Bactec FX	2021	Czech	ICU
Douka E ¹¹	Bactec 9240	2020	Greece	ICU
Walsh TJ ¹²	Bactec FX	2019	USA	HemOnc
Nguyen MH ¹³	BacT/ALERT, Bactec FX, VersaTREK	2019	USA	Suspected BSI
DeAngelis G ¹⁴	BacT/ALERT VIRTUO	2018	Italy	ED

Results

Table 2: Time to Pathogen Detection and Ratio of T2Bacteria Panel vs Blood Culture Pathogen Detection

Author	T2B Positive	Time to Species ID T2B (h)	Blood Culture Positive	Time to Species ID Blood Culture (h)	Δ (h)	T2B+/ BC+ Ratio
Bonura C ¹	48	4.91	21	93.64	88.73	2.29
Cruz H ²	51	6.1	29	42.6	36.5	1.76
Parajo Pazos N ³	20	NR	6	NR	36.9	3.33
Giacobbe DR ⁴	11	NR	3	NR	NR	3.67
Lucignano B ⁵	131	4.4	39	65.7	61.3	3.36
Seitz T ⁶	9	4.3	3	41.5	37.2	3.00
Krifors A ⁷	28	NR	8	NR	NR	3.50
Quirino A ⁸	18	4.5	8	NR	NR	2.25
Paggi R ⁹	28	3.7	11	37.6	33.9	2.55
Drevinek P ¹⁰	16	6.1	9	62	55.9	1.78
Douka E ¹¹	13	3.5	4	84	80.5	3.25
Walsh TJ ¹²	11	3.7	4	12.5	8.8	2.75
Nguyen MH ¹³	190	3.61	41	71.7	68.1	4.63
DeAngelis G ¹⁴	30	5.5	12	25.2	25.2	2.50
Total	n = 604		n = 198			3.05
Time (mean)		4.6 h		53.6 h		48.5 h

NR = not reported

Figure 1: Additional BSI Causing Pathogen Detection with the T2Bacteria Panel

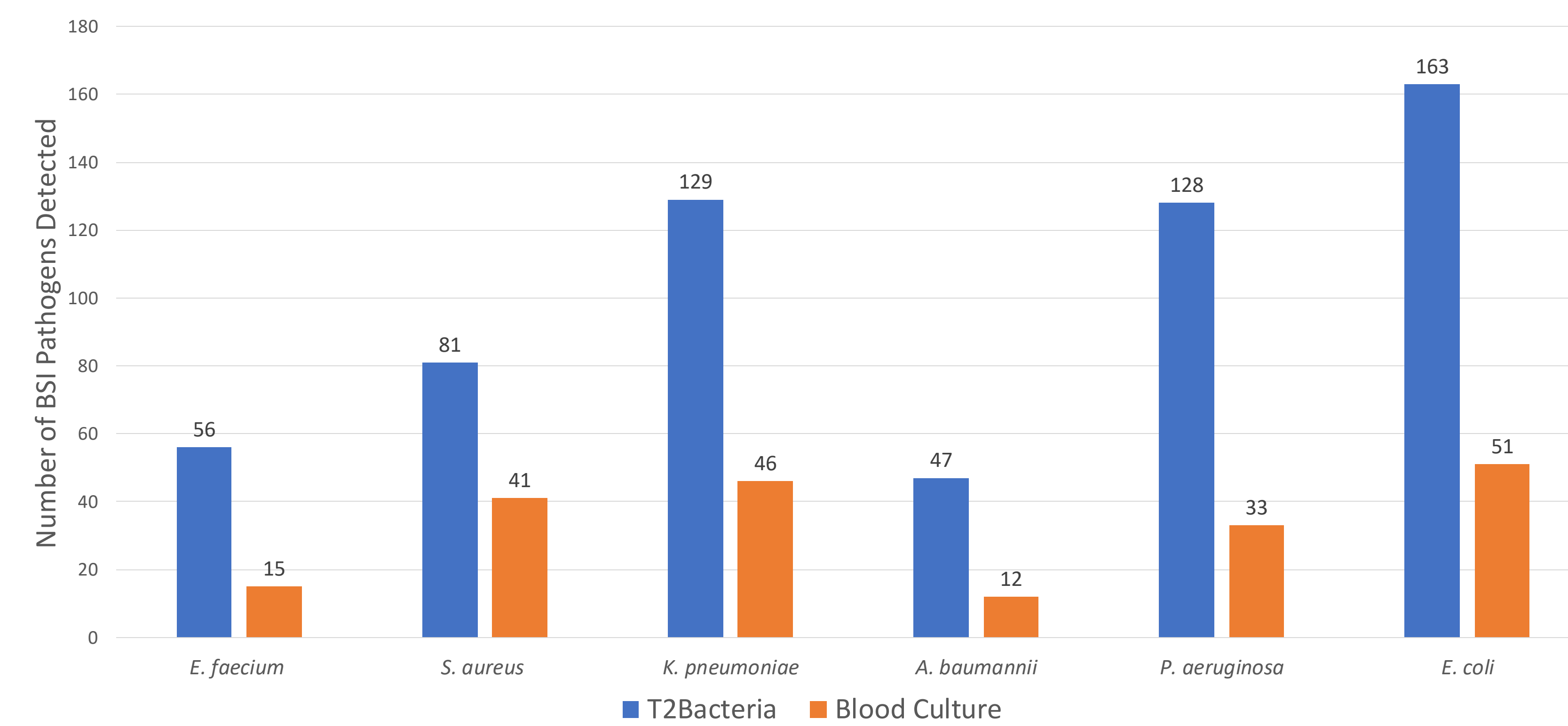


Table 3: T2Bacteria Panel Analytic Performance

Specific Bacteria Detected	Compared to Gold Standard (Blood Cultures)	
	Sensitivity (95%CI)	Specificity (95%CI)
<i>E. faecium</i> (n=56)	80% (51.91% to 95.67%)	98.47% (97.95% to 98.89%)
<i>S. aureus</i> (n=81)	87.8% (73.80% to 95.92%)	98.45% (97.93% to 98.87%)
<i>K. pneumoniae</i> (n=129)	93.48% (82.10% to 98.63%)	97.01% (96.32% to 97.60%)
<i>A. baumannii</i> (n=47)	83.33% (51.59% to 97.91%)	97.49% (96.56% to 98.23%)
<i>P. aeruginosa</i> (n=128)	100% (89.42% to 100%)	96.74% (96.03% to 97.35%)
<i>E. coli</i> (n=163)	86.27% (73.74% to 94.30%)	95.96% (95.19% to 96.65%)
T2Bacteria Panel	89.9% (84.83% to 93.72%)	97.34% (97.08% to 97.59%)

Results

- Across 14 studies, a total of 2998 T2Bacteria Panels were tested.
- A total of n=1511 were tested in the USA and n=1487 were tested outside of the US.
- The primary blood culture test methods included the Bactec (FX, 70FX or 9240) system (n=1227), and BacT/ALERT (FN Plus or VIRTUO) system (n=344), Bactec or BacT/ALERT or VersaTEK (n= 1427).
- The T2Bacteria Panel identified 604 on-panel organisms compared to 198 identifications from conventional blood cultures.
- The T2Bacteria Panel identified 3.05 times more on-panel organisms (n=406) than conventional blood cultures.
- The T2Bacteria Panel identified the following additional pathogens compared to conventional blood culture
 - E. faecium* (n=41), T2B+/BC+ Ratio = 3.73
 - S. aureus* (n=40), T2B+/BC+ Ratio = 1.97
 - K. pneumoniae* (n=83), T2B+/BC+ Ratio = 2.8
 - A. baumannii* (n=35), T2B+/BC+ Ratio = 3.91
 - P. aeruginosa* (n=95), T2B+/BC+ Ratio = 3.87
 - E. coli* (n=112), T2B+/BC+ Ratio = 3.19
- For studies (n=8) describing complete or partial clinical adjudication of T2B+/BC- cases, 430/503(85.5%) were deemed true infections.
- The sensitivity and specificity of the T2Bacteria Panel among these 14 studies was 89.9% and 97.34%.

Conclusion

- The highly sensitive T2Bacteria Panel identified 3.05 more on-panel organisms, directly from whole blood within 4.6 hours compared to conventional blood cultures at 48.h across 14 clinical studies.
- T2Bacteria Panel has the potential to improve care by allowing clinicians to optimize antibiotic therapy through added identification of BSI causing pathogens that otherwise were missed by conventional blood culture.
- Future studies are needed to evaluate the impact of these added detections compared to conventional blood cultures.

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