Methods. Ten sites across the United States collected samples that were tested at 4 clinical sites comparing the BCID-FP to traditional culture, MALDI-TOF MS, microbiological and biochemical techniques. Discrepant results were analyzed by a bi-directional PCR/sequencing directly in residual blood culture samples. Sensitivity and specificity were determined for each fungal target.

Results. A total of 725 contrived samples along with 120 retrospective and 21 prospective collected (fresh/frozen) clinical samples were tested with the BCID-FP. Of the 11 *Candida* species on the panel (*C. albicans*, *C. auris*, *C. dubliniensis*, *C. famata*, *C. glabrata*, *C. guilliermondii*, *C. kefyr*, *C. krusei*, *C. lusitaniae*, *C. parapsilosis*, and *C. tropicalis*), sensitivity and specificity ranged from 97.1 to 100% and 99.8 to 100%, respectively. For the other organisms detected on the panel, sensitivity and specificity were 100% for both *Cryptococcus neoformans* and *C. gattii*. Sensitivity and specificity for *Fusarium* sp. and *Rhodotorula* sp. were 98.6% and 100% and 96.2% and 99.9%, respectively. In 4 of the 141 clinical samples, the ePlex BCID-FP panel correctly identified an additional *Candida* species that was undetected by traditional methods.

Conclusion. The ePlex BCID-FP panel offers a faster turnaround time than a standard of care methods for the detection of important fungal pathogens in positive blood cultures in a time frame that may allow for earlier antifungal interventions. The BCID-FP panel also is the only FDA-cleared panel available to date containing the highly anti-fungal drug-resistant *C. auris* target.

Disclosures. **All authors:** No reported disclosures.

640. Randomized Clinical Trial Evaluating Clinical Impact of RAPid IDentification and Antimicrobial Susceptibility Testing for Gram-Negative Bacteremia (RAPIDS-GN)

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Background. Rapid blood culture diagnostics increase cost and have unclear benefit for patients with Gram-negative bacilli (GNB) bloodstream infections (BSIs). We conducted a multicenter, prospective randomized controlled trial (RAPIDS-GN), comparing outcomes of patients with GNB BSI who had blood culture testing with standard of care (SOC) culture and antibiotic susceptibility testing (AST) vs. rapid organism identification (ID) and phenotypic AST using the Accelerate Pheno System (AXDX).

Methods. Subjects with blood culture Gram stain showing GNB were randomized to receive SOC testing with antimicrobial stewardship review (AS) or AXDX plus SOC testing with AS, at two academic medical centers between October 2017 and October 2018. SOC testing included rapid MALDI-TOF mass spectrometry ID and agar dilution or broth microdilution AST. In a modified intention to treat analysis, subjects were excluded if: Gram stain was erroneous, culture was positive during off-hours, blood culture in the prior week had GNB, they were deceased/on comfort care, or admitted to a nonparticipating hospital. The primary outcome was time to first antibiotic modification within 72 hours after randomization. Subjects without antibiotic modifications were assigned a time of 72 hours. No censoring was observed. T-tests and Wilcoxon rank-sum tests were used for statistical analyses.

Results. Of 500 randomized subjects, 448 were included (226 SOC, 222 AXDX). Groups did not differ in baseline characteristics (Table 1). Median (IQR) hours to first antibiotic modification was faster in the AXDX vs. SOC group [8.6 (2.6, 27.6) vs. 14.9 (3.3, 41.1)], $P = 0.02$ (Figure 1). Median (IQR) hours to first Gram-negative antibiotic modification (including escalation and de-escalation) was faster in the AXDX than SOC group [17.4 (4.9, 72) vs. 42.1 (10.1, 72)], $P < 0.001$ (Figure 2). Groups did not differ in clinical outcomes (Table 2). Mean (S.D.) time to results was faster for AXDX than SOC for organism ID [2.7 (1.2) h vs. 15.6 (20.3) h, $P < 0.001$] and AST [13 (55.7) h vs. 54.6 (45.5) h, $P < 0.001$].

Conclusion. In the largest trial to evaluate the clinical impact of a blood culture diagnostic for GNB BSI, we found that rapid organism ID and phenotypic AST led to faster changes in antibiotic therapy for Gram-negative bacteremia.

Table 1. Demographic and clinical characteristics by treatment arm

Characteristic	SOC (N=226)	AXDX (N=222)
Male	130 (58%)	122 (55%)
Mean (S.D.) age in years	66 (18.3)	62 (20.3)
Mean (S.D.) Pitt Bacteremia Score	2.0 (1.9)	1.9 (1.6)
ICU at randomization	64 (28%)	80 (36%)
Neutropenic at randomization	43 (19%)	30 (14%)
Escherichia coli in blood culture	103 (46%)	98 (44%)
Urinary source of bacteremia	88 (39%)	71 (32%)

Figure 1. Time to first antibiotic modification by treatment arm among all subjects

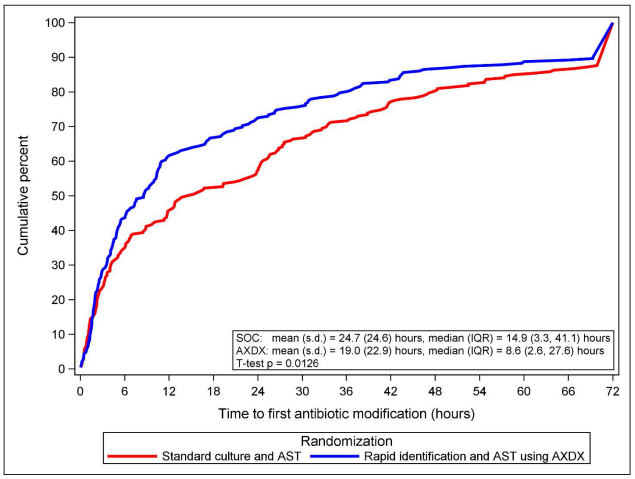

Figure 2. Time to gram-negative (GN) antibiotic modification by treatment arm among all subjects.

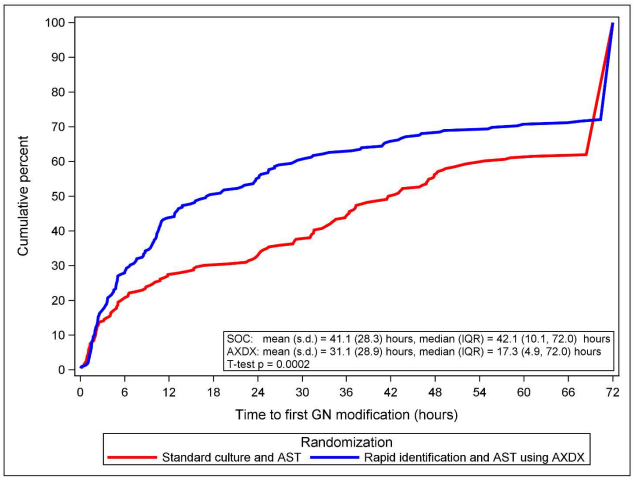

Table 2. Outcomes by treatment arm

Outcome	SOC (N=226)	AXDX (N=222)	p-value
30 day mortality	18 (8%)	25 (12%)	0.26
Mean (S.D.) Length of stay up to 30 days	7.1 (7.2)	8.1 (7.7)	0.17
In ICU within 72 hours after randomization	29 (13%)	43 (19%)	0.07
Hospital-onset *Clostridioides difficile* infection	5 (2%)	6 (3%)	0.77
Acquisition of multidrug-resistant organism[1,2]	23 (10%)	23 (10%)	1.0
MRSA	8 (4%)	7 (3%)	1.0
VRE	6 (3%)	11 (5%)	0.23
CRE	5 (2%)	0	0.06
MDR *Pseudomonas aeruginosa*	6 (3%)	10 (5%)	0.32

[1]MRSA, methicillin-resistant *Staphylococcus aureus*; VRE, vancomycin-resistant *Enterococcus* species; CRE, carbapenem-resistant *Enterobacteriaceae;* MDR, multidrug-resistant

[2]Some subjects had more than 1 organism

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