The Clinical Impact of BioFire BCID2 Compared to BCID in a U.S. Pediatric Hospital

Kelly E. Graff, MD[1], Claire Palmer, MS[1], Toraj Anarestani, MT(ASCP)[2], Darcy Velasquez, MS,MB(ASCP)[2], Stacey Hamilton, MT(ASCP)[2], Kristin Pretty, BS,M(ASCP),MB[2], Samuel R. Dominguez, MD,PhD[1,2]

University of Colorado Anschutz Medical Campus

[1]University of Colorado School of Medicine, Department of Pediatrics
[2]Children's Hospital Colorado, Department of Laboratory and Pathology Medicine

Children's Hospital Colorado

BACKGROUND

- BioFire FilmArray Blood Culture Identification (BCID) has been shown to decrease time to pathogen identification and time to effective and optimal antimicrobial therapy.
- BioFire Blood Culture Identification 2 (BCID2) has an additional 17 targets and resistance genes compared to BCID.
- There is limited data on the impact of these expanded targets in pediatrics.

METHODS

- From January - August 2020, we ran BCID2 simultaneously on 191 patient samples as a research use only prototype with the current standard of care on all blood culture specimens at Children's Hospital Colorado.
- We performed a head-to-head comparison between BioFire BCID2 with BCID when compared to standard culture.
- We hypothesized that BCID2 and BCID would be equivalent in their percent agreement with standard culture.
- Time to optimal therapy was compared to time to BCID2 result (as a proxy for time to theoretical optimal therapy). Sub-analyses were performed on *Enterococcus species* and CTX-M gene.

RESULTS

- The proportion of BCID2 results that matched standard culture was not significantly different from the proportion of BCID results that matched standard culture, difference 1.6% (95% CI: -0.4, 3.5%); p<0.0001

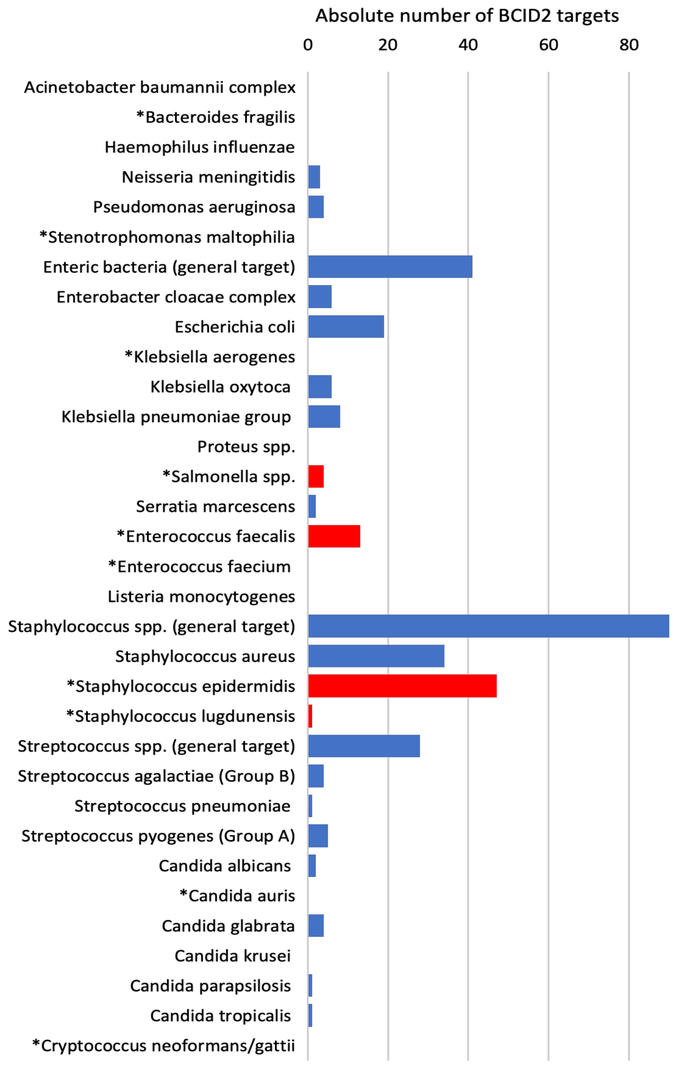

Figure 1: Absolute number of positive BCID2 targets. *indicates new target on BCID2 not previously on BCID. Red bars indicate new targets hit on BCID2.

Table 1. BCID2, BCID and standard blood culture agreement

Variable	Proportion with 95% CI	P-value
BCID matches standard blood culture[a]	89% (84, 93%)	*p<0.0001
BCID2 matches standard blood culture[b]	87% (82, 92%)	
BCID2 matches BCID (genus and species)[c]	68% (61, 75%)	

[a]19/24 (79%) of non-matching BCID2/culture due to the isolated organism not on the panel. Additional 3 false positives and 2 false negatives on the BCID2.
[b]18/21 (86%) of non-matching BCID/culture due to the isolated organism not on the panel. Additional 3 were false negatives on the BCID.
[c]56/61 (92%) discrepancies between BCID and BCID2 were due to additional BCID2 detection at the species level. Additional 5 were due to detection of *Salmonella species.* 1 false negative on BCID.
*Percent agreement between BCID and BCID2 was tested using two one-sided tests considering an equivalence margin of 10%. Significant p-value indicates equivalence.

Table 2. Time-to-event outcomes (hours)

All (n=191)	Median (95% CI)	P-value
Effective antimicrobial regimen[a]	4 (3, 12)	
Positive gram stain	17 (16, 19)	
Optimal antimicrobial regimen*[b]	29 (23, 39)	*p<0.0001
BCID2 result*	19 (17, 21)	
Enterococcus positive (n=13)	**Median (IQR)**	
BCID2 result*	17 (13, 21)	*p=0.0046
Optimal antimicrobial regimen*	51 (35, 66)	
CTX-M resistance detected (n=5)	**Median (IQR)**	
BCID2 result	16 (13, 18)	
Optimal antimicrobial regimen[c]	20 (11, 77)	

[a]n=176, number of events=130
[b]n=188, number of events=142
[c]n=3 (two patients never received optimal therapy)
*significant difference comparing time-to-event outcomes using Wilcoxon signed rank test

- 13 *Enterococcus faecalis* detected on BCID2. Theoretical reduction in time to optimal therapy of 34 hours (p=0.0046)
- 5 CTX-M genes were detected. No genes were detected identifying Carbapenem-resistant Enterobacteriaceae (CRE)

CONCLUSIONS

- BCID2 is an accurate diagnostic tool for rapid identification of blood culture results with detection of just under 90% of all organisms.
- BCID2 is equivalent to BCID in its percent agreement with standard culture in a pediatric population at a U.S. institution.
- The largest impact of BCID2 above BCID in our population was its ability to identify *Enterococcus* at the species level, Salmonella identification, and resistance gene detection.

IMPLICATIONS

- BCID2 has the potential to reduce time to optimal antimicrobial therapy overall, with the greatest impact for *Enterococcus* species.
- BCID2 panel additionally provides theoretical benefit of identifying CRE genes, which would be impactful in populations with high rates of resistance

DISCLOSURES

- This is an investigator-initiated industry-funded study funded by BioFire Diagnostics, LLC.