

Accelerate PhenoTest[®] BC kit

March 17, 2020

ICD-10 Coordination and Maintenance Committee Meeting

Centers for Medicare & Medicaid Services

Baltimore, MD

Coding Need

Adding unique ICD-10-PCS code(s) would:

- Allow for tracking of Accelerate PhenoTest use in the inpatient setting
- Facilitate clinical outcomes studies on its use

Sepsis Mortality Twice Prior Estimates¹

48.9 million cases per year globally

11.0 million deaths annually

Nearly 1 in 5 deaths worldwide due to sepsis

Antimicrobial resistance is an important driver of sepsis

¹ Rudd. (2020). Global, regional, and national sepsis incidence and mortality, 1990–2017: analysis for the Global Burden of Disease Study. *Lancet*, 395, 200–211.

Optimizing Antibiotics

within the first 24 hours is critical

80% of sepsis deaths could be prevented with rapid diagnosis and treatment¹

7.6% decrease in chance of survival per hour of delay of effective therapy¹

¹Kumar A, et al. (2006). Duration of hypotension before initiation of effective antimicrobial therapy is the critical determinant of survival in human septic shock. *Crit Care Med* 2006; 34(6):1589-96.

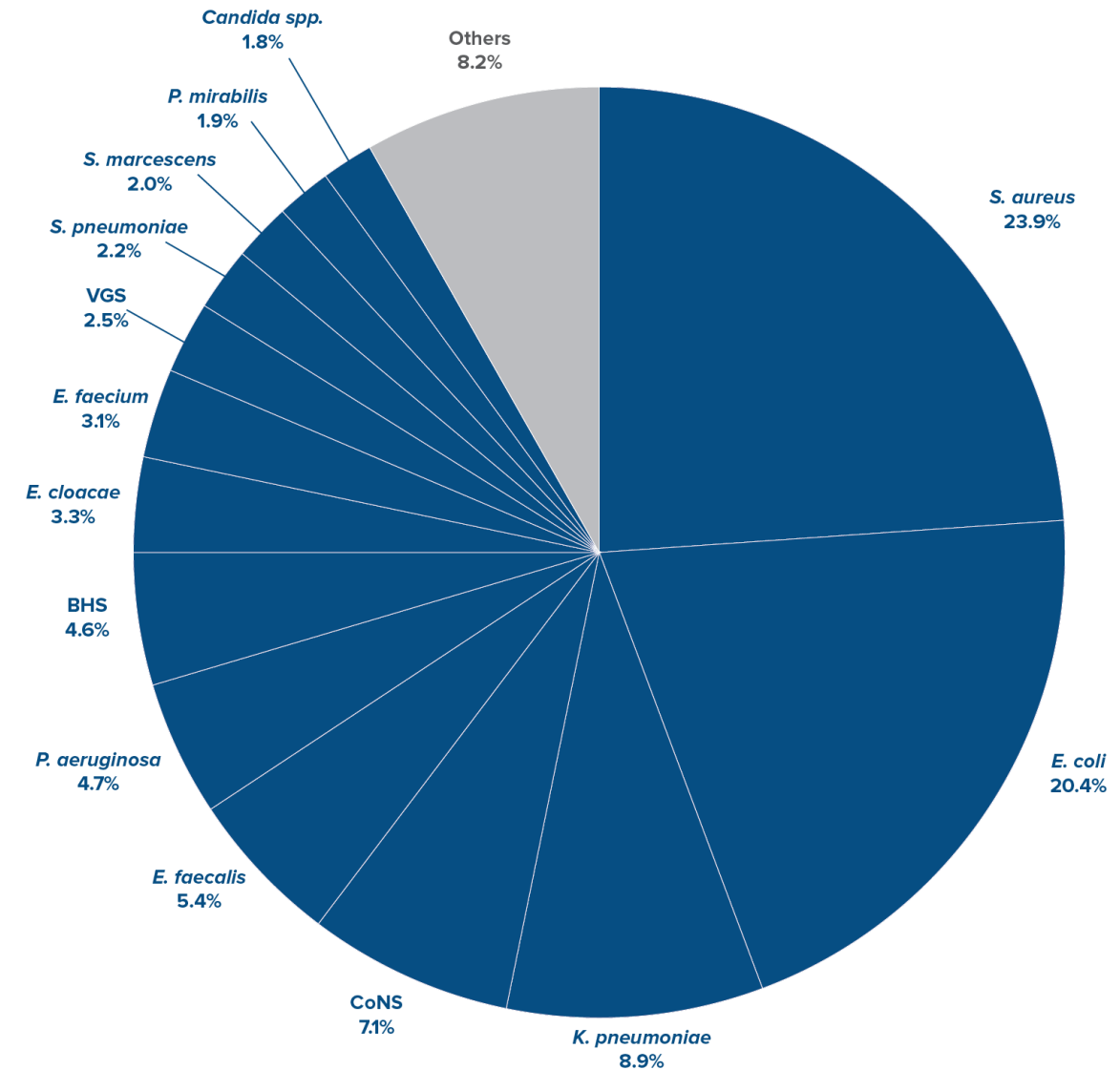
Coverage by Prevalence

Panel coverage is ~91% of organisms identified in positive blood cultures according to the most recent national survey data.

Additional targets represented in “Others” category are most commonly blood culture contaminants.

Frequency of organisms isolated from patients with bloodstream infections from US medical centers (INFORM program, 2015-2017). Abbreviations: CoNS = coagulase-negative staphylococci; BHS = β -hemolytic streptococci; VGS = viridans group streptococci.

Adapted from Sader et al.¹

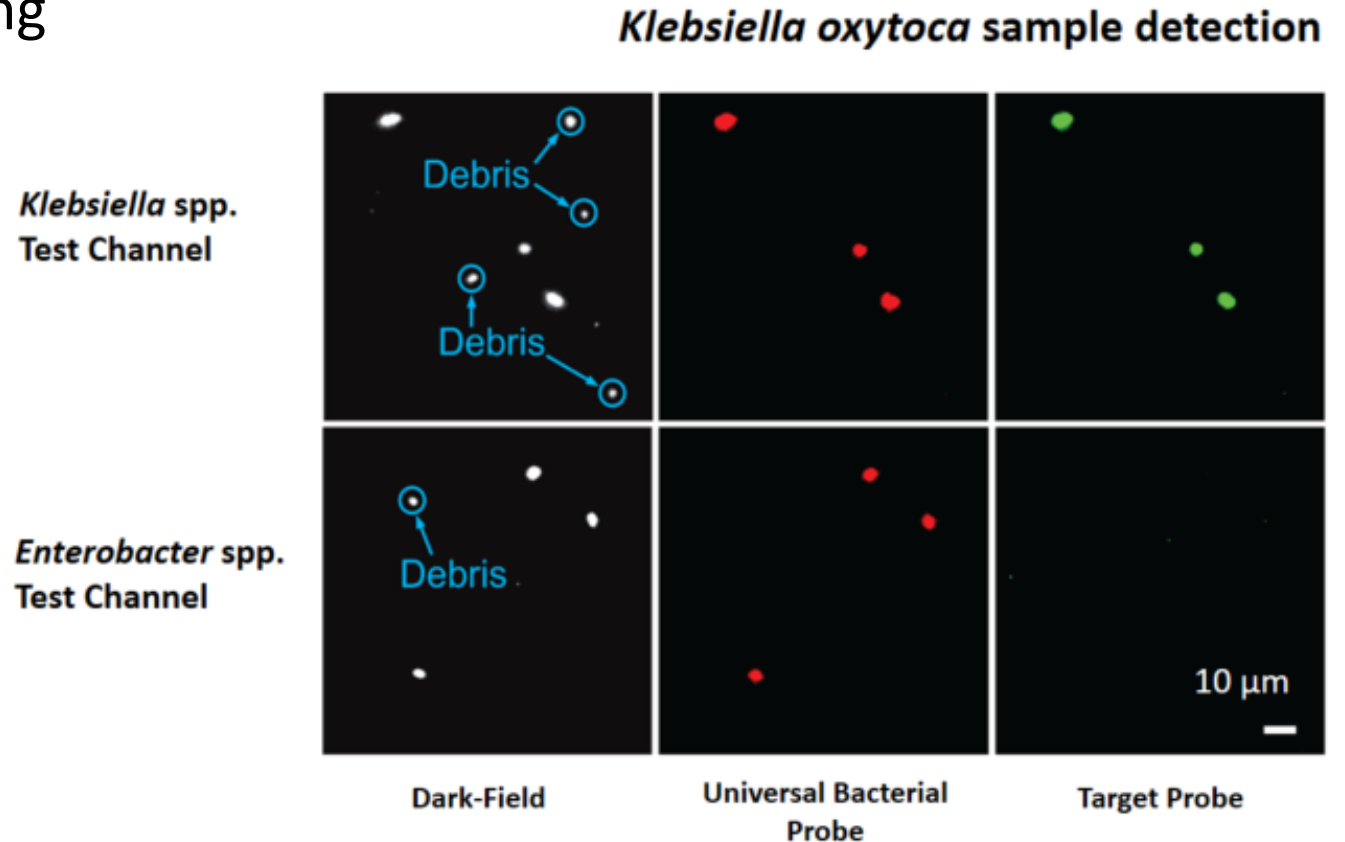


¹ Sader HS, et al. Frequency of occurrence and antimicrobial susceptibility of bacteria isolated from patients hospitalized with bloodstream infections in United States medical centers (2015-2017). *Diagn Microbiol Infect Dis* 2019; June 11:114850. doi: 10.1016/j.diagmicrobio.2019.06.002. [Epub ahead of print]

Organism Identification:

Fluorescence *in situ* hybridization (FISH)

Colocalization of target and universal probe signal confirms presence and identity of target while differentiating from non-specific staining

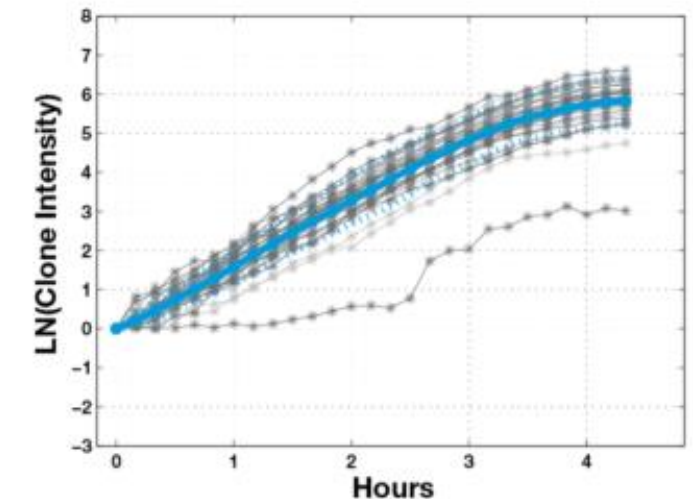
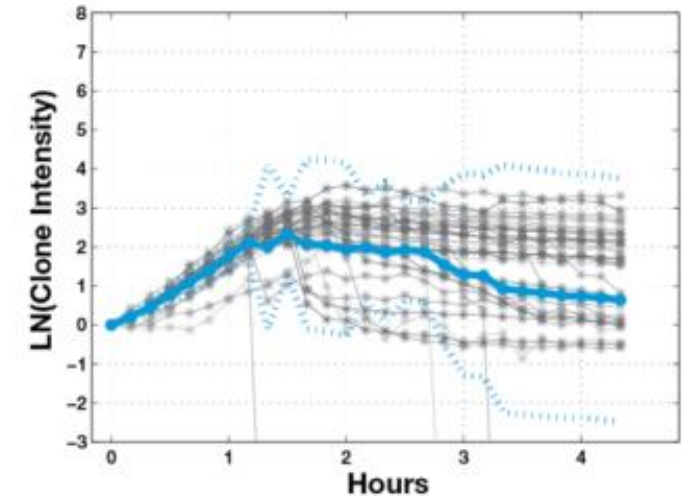
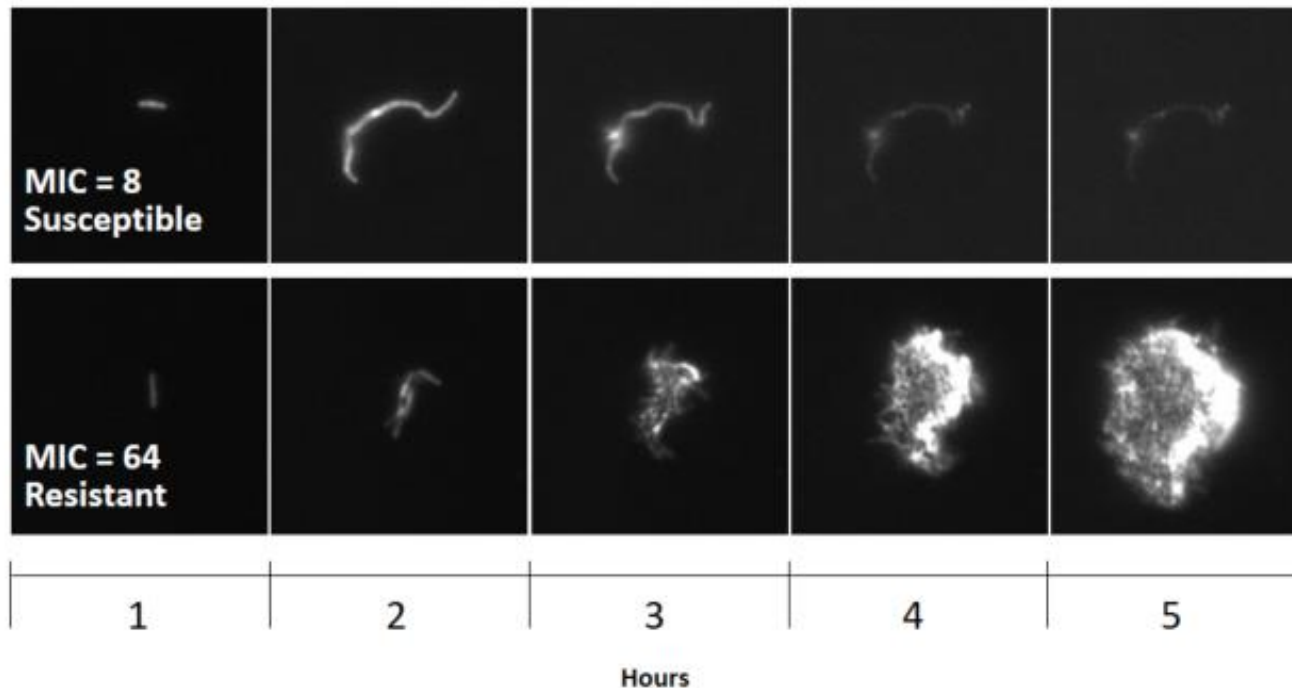


Antimicrobial Susceptibility

Morphokinetic Cellular Analysis (MCA)

Measures morphological and kinetic changes over time of organisms exposed to antibiotics

E. coli samples vs. piperacillin-tazobactam

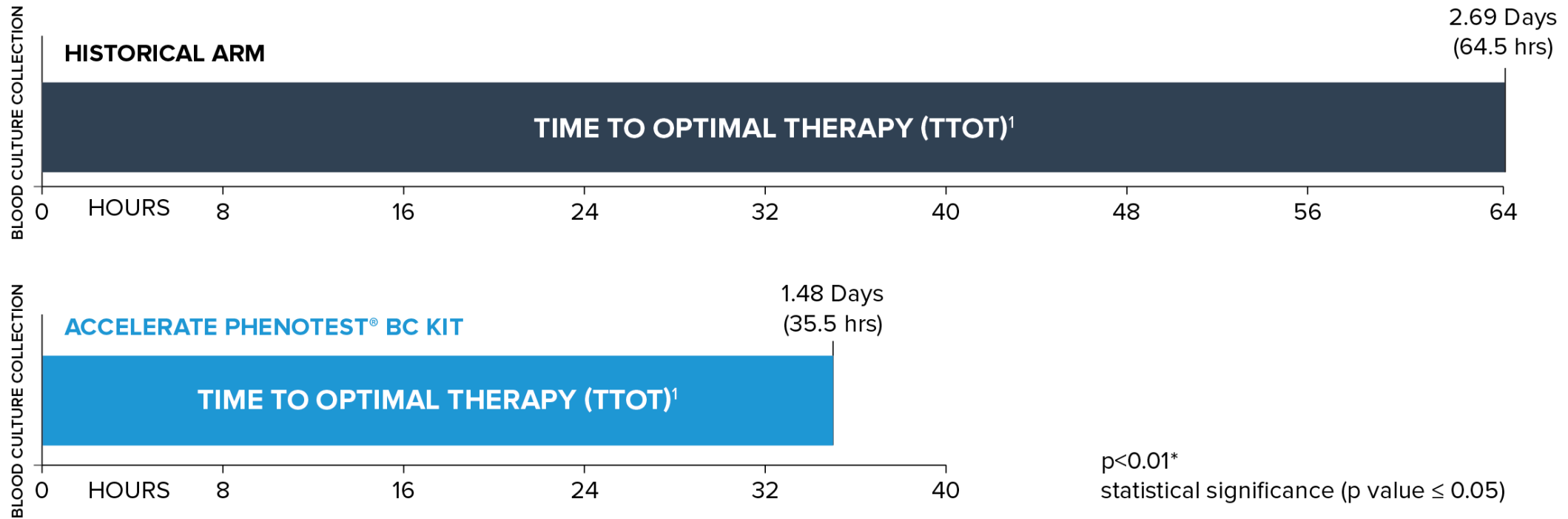


Today's standard of care can take days to optimize antibiotic therapy¹



¹ Pearson, et al. (2019). Impact of Accelerate Pheno™ Rapid Blood Culture Detection System with Real-time Notification vs. Standard Antibiotic Stewardship on Clinical Outcomes in Bacteremic Patients. *Open Forum Infect Dis.* 2019 Oct; 6(Suppl 2): S724.

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Clinical Outcomes Benefits

OUTCOMES DATA FROM 2019



Length of Stay

–2.4 days¹

–2.2 days²

–2.0 days³



Days on Therapy (DOT)

–4.6 days²

–2.0 days³

–1.6 days¹



Readmission Rates

–34.4%²



Time to Optimal Therapy

–24.8 hours⁴

–29.0 hours¹

¹ Pearson et al. (2019). Impact of Accelerate Pheno™ Rapid Blood Culture Detection System...*Open Forum Infect Dis.* 2019 Oct; 6(Suppl 2): S724.

² Walsh T. (2019). Impact of Accelerate Pheno™ System on Management of Gram Negative Bacteremia at an Academic Medical Center. Presented at SCACM West Virginia

³ Sheth et al. (2019). Identification (ID) and Antimicrobial Susceptibility Testing (AST) on Antibiotic Therapy. Presented at ECCMID 2019.

⁴ Banerjee et al. (2019). Randomized clinical trial evaluating clinical impact of RAPid Identification and antimicrobial Susceptibility testing for Gram-Negative bacteremia (RAPIDS-GN). Presented at IDWeek 2019.

Summary

Adding a unique ICD-10-PCS code would:

- Improve coding precision for this new unique test
- Allow for tracking of Accelerate PhenoTest use in the inpatient setting
- Facilitate additional clinical outcomes studies across the 400+ contracted and live instruments