

Title:	Multi-centre evaluation of Verigene® BC-GN test for rapid detection of Gram-negative bacteria from positive blood cultures from paediatric inpatients
Speaker:	Joel Mortensen
Author(s):	Mortensen J.; DeBurger B.; Turner N.; Roundtree S.; Ventrola C.; Blecker-Shelly D.; Sullivan K.
Affiliation(s):	Pathology and Laboratory Medicine, Cincinnati Children's Hospital (Cincinnati (Ohio), USA); Pathology and Laboratory Medicine, Children's Hospital of Philadelphia (Philadelphia (Pennsylvania), USA)
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<p>Objectives:</p> <p>Treatment of pediatric Gram-negative bacteremia has become challenging due to the rising incidence of third-generation cephalosporin and carbapenem resistance in Enterobacteriaceae and glucose non-fermenting Gram-negative organisms. This multi-center study evaluated the performance of the rapid Verigene Gram-negative Blood Culture Test (BC-GN) (Nanosphere, Northbrook, IL, USA), a microarray system that detects 9 bacterial targets (<i>Acinetobacter</i> spp., <i>Proteus</i> spp., <i>Citrobacter</i> spp., <i>Enterobacter</i> spp., <i>Escherichia coli</i>, <i>Klebsiella pneumoniae</i>, <i>Klebsiella oxytoca</i>, <i>Pseudomonas aeruginosa</i>, and <i>Serratia marcescens</i>); and 6 antimicrobial resistance determinants (CTX-M, KPC, NDM, VIM, IMP, and OXA) from positive blood culture bottles with Gram-negative organisms seen on Gram stain. The BC-GN is an Investigational Use Only assay at this time.</p> <p>Methods:</p> <p>BC-GN was performed on 82 blood cultures at two pediatric medical centers in the United States. These samples included 60 clinical blood cultures and 22 seeded blood cultures. Both clinical and seeded samples were in Bactec Peds Plus bottles. Samples were processed within 30 minutes of the signal of a positive blood culture or were stored at -70°C prior to testing. Standard identification (Vitek MS and Vitek 2) and antimicrobial susceptibility testing results (Vitek 2) were used as the reference standard.</p> <p>Results:</p> <p>BC-GN correctly detected: 8 blood cultures with <i>Acinetobacter</i> spp., 4 with <i>Citrobacter</i> spp., 14 with <i>Enterobacter</i> spp., 16 with <i>E. coli</i>, 3 with <i>K. oxytoca</i>, 2 with <i>Proteus</i> spp., 12 with <i>P. aeruginosa</i>, and one with <i>S. marcescens</i>. BC-GN correctly reported 12 of 13 blood cultures with <i>K. pneumoniae</i> but miscalled one, reporting <i>Enterobacter</i> spp. BC-GN also detected <i>K. pneumoniae</i> and <i>Citrobacter</i> spp. in a blood culture that grew <i>K. pneumoniae</i> only. BC-GN correctly reported "Not Detected" in 9 blood cultures that grew organisms that were not represented on the microarray. There were 4 "No Call" system error results. One resolved when repeated and a "Motor Stall" error also resolved when repeated. BC-GN detected seven patient isolates with phenotypic antimicrobial resistance markers. These isolates will be further studied using molecular methods. Six isolates with well-characterized resistance markers were correctly detected in seeded bottles.</p> <p>Conclusions:</p> <p>The Verigene BC-GN test has the potential for having a significant impact on the care of pediatric patients with Gram-negative sepsis due to the rapid detection of the major Gram-negative bacilli seen in the blood cultures of pediatric patients as well as major antimicrobial resistance markers.</p>	

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