



We cordially invite you to our
SCACM Exhibitor Workshop

Integration of the Simplexa[®] Direct *C. difficile* Assay in a two-step algorithm for the laboratory diagnosis of *C. difficile*

Presented by:

James W. Snyder, Ph.D. (ABMM), F(AAM)

University of Louisville School of Medicine
Division of Laboratory Medicine

WHEN:

Thursday
March 23, 2017
3:30 PM - 4:30 PM

WHERE:

Marriott East
7202 East 21st St
Indianapolis, IN

Clostridium difficile is a major pathogen responsible for infectious diarrhea in healthcare settings. The organism produces two primary virulence factors, Toxin A (tcdA, enterotoxin) and toxin B (tcdB, cytotoxin) which are responsible for considerable morbidity and risk of mortality. Most countries, including the United States, have experienced a marked increase in both community and hospital-acquired *Clostridium difficile* infection (CDI) with an estimated cost ranging from \$500 million to \$1.5 billion per year. In an effort to reduce healthcare costs including reduced length of hospital stays related to CDI, the clinical microbiology laboratories are challenged and pressured to provide rapid, accurate, and cost-effective test results.

Several conventional commercial tests including enzyme immunoassays (EIA) that detect the antigen glutamate dehydrogenase (GDH) and toxin, and PCR-based assays that target the genes that code for tcdA and tcdB or the combination of tcdB/027 (BI/NAP) are available for the laboratory diagnosis of CDI. Of the available PCR assays, the most recent is the Simplexa[®] *C. difficile* Direct assay. The assay targets a sequence which is in a well conserved region of *C. difficile* toxin B gene (tcdB). The purpose of our study was to compare this assay with our in-house two-step algorithm and two additional PCR-based assays (Great Basin, GeneXpert Infinity) in which PCR is used as a confirmatory rather than a direct assay. We demonstrated that the Simplexa[®] assay compared favorably to the Xpert Infinity which supports its utility for laboratories using a two-step method as a routine diagnostic platform, thereby, facilitating prompt patient management and infection control.