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## TOPA Update (May 2015) C. difficile: BI/NAP1/027 variant

Recent publications have emphasized the clinical significance of a hypervirulent strain of C. difficile, referred to as the BI/NAP1/027 strain. The nomenclature is based on the three standard techniques used to characterize this strain, which is designated "BI" by restriction endonuclease analysis, "NAP1" by North American pulse field gel electrophoresis, and "027" by PCR ribotyping.

In published studies, the BI/NAP1/027 strain is associated with a lower cure rate and a higher relapse rate, in comparison to non-BI/NAP1/027 strains. Also, identification of the BI/NAP1/027 strain may influence antibiotic selection.

Standard therapy for mild-to-moderate C. difficile infection (CDI) consists of Vancomycin or metronidazole, with Vancomycin generally preferred for severe or complicated disease. A newer agent, Fidaxomicin, may be considered for recurrent CDI or where risk of recurrence is high, but the utility of this medication varies based on the C. difficile strain.

For <u>non-BI/NAP1/027</u> strains, treatment with fidaxomicin is associated with a lower rate of recurrence; but for BI/NAP1/027 strains, the risk of recurrence is not decreased by treatment with fidaxomicin versus other antimicrobial agents.

TOPA currently performs two assays for C. difficile. First, C. difficile is included in the GI Pathogen panel, which detects both the BI/NAP1/027 and <u>non-BI/NAP1/027</u> strains, but does not distinguish between the two. Second, TOPA performs a stand-alone test (Cepheid geneXpert), which detects C. difficile and determines the presence or absence of the BI/NAP1/027 strain.

The Cepheid assay detects the BI/NAP1/027 strain by identifying three genotypic features: presence of the toxin B gene (tcdB), binary toxin gene (CDT), and tcdC gene deletion at nucleotide 117 (tcdC $\Delta$ 117). Discordances may occur between genotypic and standard methods, and therefore the Cepheid results are considered "presumptive". In published reports, the agreement between the Cepheid assay for the BI/NAP1/027 strain and standard techniques was 93-98%.

For additional information, please call Edward Blackman MD at TOPA Diagnostics.

References: N Engl J Med 2015; 372: 1539-48 N Engl J Med 2011; 364: 422-31 CID 2012; 55: 351-357 J Clin Microbiol 2011; 49: 1831-1837 J Clin Microbiol 2010; 48: 4519-4524 JAMA 2015; 313: 398-408