To: SHC & LPCH Medical Staff

From: Stanford Health Care Clinical Laboratory

Subject: New 2-Step Testing Algorithm for *C. difficile*

Date: September 20, 2021

There is clear evidence that reliance on PCR assays that only detect the presence of the *C. difficile* organism without a test for fecal free toxin results in overdiagnosis and overtreatment of colonized patients[1]. Prior studies show that adults with PCR-positive/toxin-negative results have clinical outcomes similar to patients with PCR-negative results and that only toxin-positive patients benefit from *C. difficile* treatment.[2,3] Local data from Stanford Health Care and Lucile Packard Children's Hospital are consistent with these studies[4,5].

At SHC Clinical Laboratory, we have been offering a sensitive PCR assay with a revised cut-off to increase assay specificity while retaining high sensitivity[6]. Clinical practice guidelines for *C. difficile* infection in adults and children by the Infectious Diseases Society of America (IDSA) recommends a 2-step testing algorithm (PCR following by toxin testing in PCR-positives) to help reduce overtreatment in PCR-positive/toxin-negative patients[7]. **Starting September 20, 2021, the Clinical Laboratory will adopt a 2-step testing algorithm where *C. difficile* PCR-positive patients will be reflexed to toxin rapid immunoassay (EIA) and both results will be reported in EPIC to guide therapy.**

Current clinical and laboratory criteria for testing of patients will remain in place.

For questions, please contact the Medical Director of the Clinical Microbiology, Niaz Banaei, at nbanaei@stanfordhealthcare.org

References:

[1]DMID 2017 87:365-370 PMID: 28087170
[2]JAMA Intern Med 2015 175:1792-801 PMID: 26348734
[3]Lancet ID 2013 13:936-45 PMID: 24007915
[4]JPID 2018 PMID: 30476169
[5]JCM 2019 57:e01288-19 PMID: 31511334
[6]JCM. 2017 55:2651-2660. PMID: 28615471
[7]CID. 2018 66(7):e1-e48. PMID: 29462280

Niaz Banaei, MD
Professor of Pathology and Medicine (Infectious Diseases & Geographic Medicine)
Medical Director, Stanford Health Care Clinical Microbiology Laboratory
Director, Stanford Clinical Microbiology Fellowship
Associate Program Director, Stanford Clinical Pathology Residency Training
Stanford University School of Medicine
Rm. 1602, 3375 Hillview Ave
Palo Alto, Ca 94304
Phone 650-736-8052