



351 Rolling Oaks Drive, #100  
Thousand Oaks, CA 91361  
Tel.: 805-373-8582  
Fax 805-373-0023

Wayne M. Schultheis, M.D., Director  
Edward I. Blackman, M.D.  
Richard H. Kelty, M.D.  
Regina P. C. Singson, M.D.  
James J. Yin, M.D.  
Danielle E. Westfall, M.D.

### **Lab Update: C. difficile GDH/Toxin testing**

We are pleased to announce the availability of an expanded menu of C. difficile testing options at TOPA Diagnostics. Effective 6/19/17, TOPA will be offering C. difficile GDH and Toxin testing by Enzyme Immunoassay (EIA).

The PCR assays in use at TOPA are highly sensitive and specific for the presence of C. difficile organisms, but do not distinguish between colonization and active infection. The addition of GDH/Toxin testing, as a supplement to PCR testing, is intended to aid in the distinction between colonization and active infection, and to assist in optimum patient management and the avoidance of inappropriate treatment of colonized patients.

If C. difficile is detected on the multiplex GI pathogen panel or by stand-alone PCR testing, GDH/Toxin testing by EIA will be automatically performed as a reflex test. GDH/Toxin EIA may also be ordered as a stand-alone test.

Interpretation is based on the combination of results, as follows:

For patients with a positive PCR test for C. difficile:

- A positive toxin result (regardless of GDH result) indicates that C. difficile toxin is detected; results are consistent with active C. difficile infection.
- A negative toxin result (regardless of GDH result) indicates that C. difficile toxin is not detected. These results would not exclude active infection, but are most suggestive of asymptomatic colonization.

If PCR testing is not performed:

- Positive results for both GDH and Toxin indicate that C. difficile toxin is detected; results are consistent with active C. difficile infection.
- Positive results for GDH alone indicate that C. difficile toxin is not detected. These results would not exclude active infection, but are most suggestive of asymptomatic colonization.
- Negative results for both GDH and Toxin indicate that C. difficile is not detected.
- Positive results for Toxin alone are considered indeterminate; repeat testing of a new sample is recommended.

The following testing options are now available at TOPA Diagnostics:

- Multiplex GI Pathogen panel for 22 pathogens (with reflex to GDH/Toxin EIA if PCR is positive for C. difficile)
- PCR for C. difficile and NAP1 variant (with reflex to GDH/Toxin EIA if PCR is positive for C. difficile)
- C difficile GDH/Toxin EIA

**For additional information call Edward Blackman MD at TOPA Diagnostics.**