Labstract – September 2016

Clostridium difficile diagnostic testing - update

To Health Care Providers:

As of September 18, 2016, stool specimens tested at the PHO regional laboratories for *Clostridium difficile* that are both screen test GDH antigen positive and Toxin A/B positive will not require confirmation and screen test results will be sent out as a final report.

A review of PHOL performance data for the regional laboratory screen test algorithm from February 2015 to June 2016 demonstrated the high specificity of this result combination and therefore confirmatory testing is not required. This will improve the final report turn-around time and patient care.

The PHO Laboratory (PHOL) conducts a two-step testing algorithm at all laboratory sites for the laboratory diagnosis of *Clostridium difficile* infection (CDI).

- **Step one:** PHOL will screen all stool specimens that meet the acceptance criteria for *C.difficile* testing. PHOL – regional sites will screen stool specimens for glutamate dehydrogenase (GDH) antigen and toxins A/B with a rapid enzyme immunoassay. PHOL – Toronto site will screen stool specimens for GDH antigen with an automated enzyme immunoassay method. The difference in test method for the screening test is based on the volume of specimens received at each laboratory site within PHO.
- **Step two:** All stool specimens that require confirmatory testing (refer to the Interpretation Guide for *C. difficile* on page 3) will be tested for *C. difficile* toxin gene using a molecular LAMP (loop-mediated isothermal DNA amplification) assay. This testing is performed at a number of PHOL locations in order to optimize the testing turn-around time.

The current testing schedule will continue with testing of stool specimens available six days per week (Monday to Saturday) and results available within 24 hours of receipt at the laboratory. Testing on weekends will be dependent upon the ability of clients to notify and ship the specimens to their nearest PHOL. STAT and after hour testing is not available and specimens should be stored in refrigeration and shipped the next business day. Confirmatory toxin testing, if required, will be routinely performed within 24- 48 hours of a positive screen test or the next business day on weekends and holidays. Positive screen and confirmatory test results will be phoned or faxed to clients.

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Specimen submission criteria:

Only loose or watery stool specimens will be tested. Formed stool specimens and other specimen types as indicated below will be rejected. Formed stool specimens are the number one rejection reason for *C.difficile* testing at PHOL and can be as high as 50% for some laboratories. The *Stool Consistency Chart with Acceptance Criteria for Clostridium difficile Testing* is available to ensure specimens submitted are not rejected. The English version is included in this Labstract. The English version is available at www.publichealthontario.ca/cdiffsampling and French version is available at www.publichealthontario.ca/fr/prelevementcdiff.

Acceptable:	• Specimens from patients with diarrhea or with evidence of pseudomembranous colitis. • Feces should be loose or watery and, if poured, will conform to the shape of the container.
Not Acceptable:	• Formed feces specimens • Rectal swabs • Specimens submitted in transport media or SAF fixative • Specimens from children less than 12 months old • Insufficient specimen submitted (10 – 15 ml of feces requested)

Test of cure for CDI is not recommended. Toxin may persist in stool despite resolution of illness for weeks to months. In the absence of recurrent symptoms, laboratory testing is not helpful in making clinical decisions about patient treatment or precautions.

Refer to the *Clostridium difficile* Test Information Sheet at www.publichealthontario.ca/test_directory and *Clostridium difficile* Kit Instructions at www.publichealthontario.ca/kit_instructions for the manufacturer's reported sensitivity and specificity and additional submission requirements.

For further information:

- Contact the PHOL Customer Service Centre at 416-235-6556 or 1-877-604-4567 (toll-free), or by email at CustomerServiceCentre@oahpp.ca
- For PHOL specimen collection information and previous Labstracts, refer to www.publichealthontario.ca/labs
- The current version of the PHOL General Test Requisition and other forms are available at www.publichealthontario.ca/requisitions
- To subscribe to future Labstracts, email labstracts@oahpp.ca
- To register for Autofax and receive laboratory reports by fax directly from our laboratory information system as soon as they are released, contact the PHOL Customer Service Centre.

Interpretation Guide for *C. difficile* Results:

Test	GDH Ag	Toxin A/B	Interpretation
Screen Test (PHOL – regional sites) *C. difficile* GDH Antigen by Rapid Enzyme Immunoassay AND *C. difficile* Toxins A and B by Rapid Enzyme Immunoassay	**Detected**	**Detected**	***C. difficile* GDH antigen and toxin detected** **Results must be interpreted based on clinical findings and are supportive for the diagnosis of *C. difficile* infection (CDI)**
	Detected	Not Detected	Specimen referred for confirmatory testing
	Not detected	Detected	Specimen referred for confirmatory testing
	Invalid	Invalid	Specimen referred for confirmatory testing
	Not detected	Not detected	*C. difficile* GDH antigen and toxin not detected Results are not supportive for the diagnosis of *C. difficile* infection (CDI)

Test	GDH Ag	Interpretation
Screen Test (PHOL – Toronto site) *C. difficile* GDH Antigen by Enzyme Immunoassay	Detected	*C. difficile* GDH antigen detected Specimen referred for confirmatory testing
	Not Detected	*C. difficile* GDH antigen not detected Results are not supportive for the diagnosis of *C. difficile* infection (CDI)
	Indeterminate	Specimen referred for confirmatory testing

Test	Toxin Gene	Interpretation
Confirmatory Test *C. difficile* Toxin Gene LAMP Assay	Detected	*C. difficile* toxin gene detected Results must be interpreted based on clinical findings and are supportive for the diagnosis of *C. difficile* infection (CDI)
	Not Detected	*C. difficile* toxin gene not detected Results are not supportive for the diagnosis of *C. difficile* infection (CDI)
	Invalid	*C. difficile* toxin gene testing is invalid for this specimen. Retesting recommended if clinically indicated.

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Stool Consistency Chart with Acceptance Criteria for Clostridium difficile Testing