DIAGNOSTIC SERVICES OF MANITOBA | SERVICES DE DIAGNOSTIC DU MANITOBA

Physician Alert

Clinical Practice Change: Clinical Microbiology

Date: May 9, 2013

To: All healthcare providers who are currently using Diagnostic Services Manitoba Microbiology Laboratories

From: Dr. Michelle Alfa, Medical Director and Shirley Hoban, Technical Director, Clinical Microbiology, Diagnostic Services of Manitoba

Re: **New *C. difficile* Toxin Testing Algorithm**

TAKE HOME MESSAGE: <u>Effective May 13, 2013,</u> the testing algorithm for *C. difficile* will include a Nucleic Acid Amplification Test (NAAT). All *C. difficile* test results will be reported on the day the stool is tested (i.e. faster turn-around-time for complete testing).

Current *C. difficile* toxin testing algorithm:
When stool is submitted for *C. difficile* toxin testing, the Glutamate Dehydrogenase antigen (GD antigen) and *C. difficile* Toxin A/B antigen tests are used. For discordant results (i.e., GD antigen positive but *C. difficile* toxin A & B antigen test negative), the stool is further tested using the cytopathic effect (CPE) assay which takes 24–48 hours to report (Westman Lab currently resolves discordant results using culture which may take up to 5 days to report). The lab will test up to 2 stools/patient/week and if these are negative, the third stool received will be cultured. Subsequent stools are rejected.

Revised *C. difficile* testing algorithm:
NAAT tests have been shown to improve the sensitivity and speed of testing for *C. difficile* toxin. A one year prospective study at DSM evaluated NAAT testing compared to culture, CPE and antigen (enzyme immunoassay) testing. Based on our published data analysis (Walkty A et al., J. Clin. Microbiol. 2013), the GD antigen will be used to screen all stools and any GD (+) stools will be tested and resulted on the same day using the NAAT test. This provides the same sensitivity and specificity as the currently used algorithm but improves result turn-around-time.

The lab will test up to two stools on the same patient within a 7-day period. Testing more than two stools within a week does not increase the detection of true *C. difficile* disease (CJIDMM 2011:e12-e15) so additional stools will be rejected. If a patient (or cluster of patients) has persistent clinically significant diarrhea, elevated WBC and two stools are negative but clinically is still suspected to have toxigenic *C. difficile* disease; contact the Microbiologist on call to discuss if culture may be of value.

Stools <3 mL will be tested directly by the NAAT test and a disclaimer will be added to negative reports stating: "insufficient volume may affect test results; please submit another specimen if clinically warranted".

Changes to Reporting:
The patient report will be one of the following:

- *Positive for C. difficile toxin*
- *Negative for C. difficile toxin*
- *Invalid test result; submit another stool sample if clinically warranted.*

All test results using NAAT will have the following comment added to the patient report: *"This test was performed using a Health Canada cleared nucleic acid amplification assay for the detection of a segment of Clostridium difficile DNA known to be present in all known toxigenic strains of C. difficile, including A-B+ toxinotypes."*

If you have any questions or require further information, please contact Dr. Michelle Alfa or Shirley Hoban at 204-237-2484.