

New Molecular Test for Diagnosis of *C. difficile* Infection

What's New?

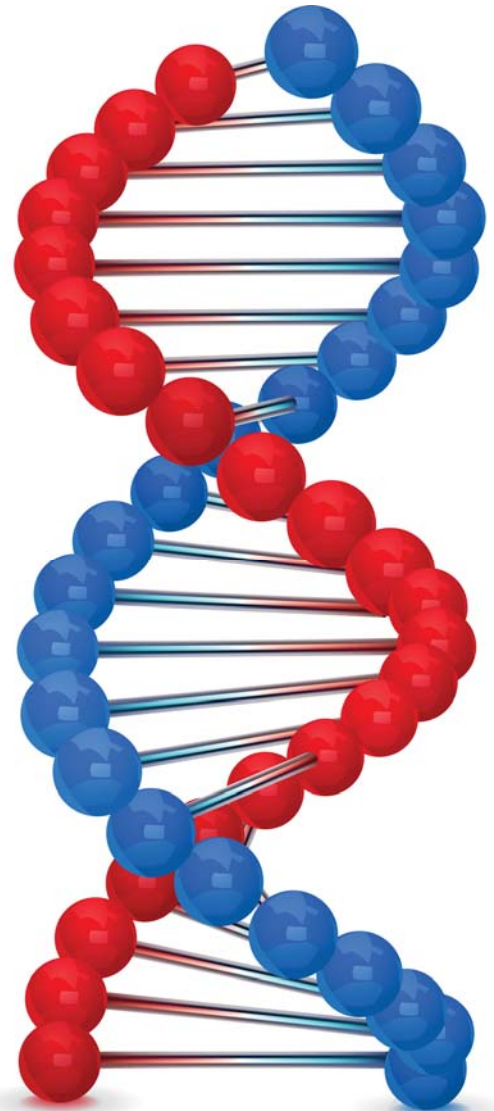
Effective June 3, 2013, LifeLabs will change to a direct nucleic acid amplification test for detection of toxigenic *C. difficile* in stool specimens. This test will replace direct toxin detection in stool specimens by enzyme immunoassay (EIA) backed up by toxigenic culture for *C. difficile* by PCR for EIA negative specimens. The new test offers improved diagnostic accuracy compared to EIA testing and more rapid result reporting than toxigenic culture.

Background

C. difficile is a major cause of diarrheal disease in both adults and children. It is the most common enteric pathogen detected at LifeLabs in British Columbia outpatients. Until recently, *C. difficile* was considered to be primarily a healthcare-associated infection that occurred mainly in hospitalized patients. However, recent publications have indicated that one third or more of patients with *C. difficile* infections (CDI) have no recent history of exposure to a healthcare facility, and it is now recognized that CDI is a significant problem in outpatients as well as in hospitalized patients. CDI cannot be diagnosed accurately on the basis of clinical features alone, and demonstration of toxigenic *C. difficile* in stool specimens is required.

New Molecular Testing

Nucleic acid amplification testing (NAAT) methods directly applicable to stool specimens have recently become available, and these tests offer improved accuracy and turn-around-time compared to older methods. The new NAAT to be offered at LifeLabs has published sensitivity and specificity of 92-95% and 99%, respectively. Studies of the new NAAT method at LifeLabs demonstrated greater than 95% accuracy overall compared to the gold standard toxigenic culture by PCR. Results of testing with the new method will generally be available within 48 hours and often within 24 hours of specimen receipt.



How to Order Testing

C. difficile testing is not included in routine stool cultures and must be specifically ordered. In many cases both a stool culture and *C. difficile* testing will be needed to accurately diagnose infectious diarrhea. When ordering *C. difficile* testing, please consider the following:

- Only order testing for patients with diarrhea. A useful definition of diarrhea is three or more soft or liquid stools in a 24 hour period.
- Only unformed stools (e.g. take the shape of the container) are acceptable for testing.
- Testing should only be ordered once per diarrheal episode, and follow-up testing is generally not required except for assessment of treatment failures.
- A history of antibiotic exposure is no longer required for *C. difficile* testing; up to 30% of patients with CDI have no history of antibiotic exposure.

Questions

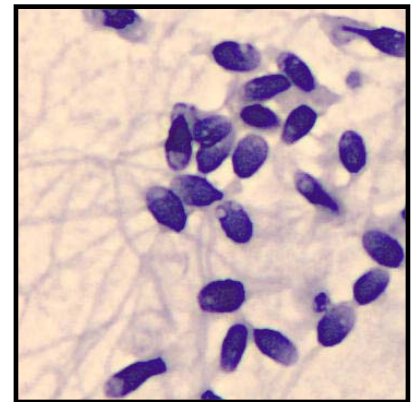
Questions about *C. difficile* testing or requests for consultations on CDI may be directed to a LifeLabs Medical Microbiologist by calling LifeLabs at 604-431-7206 or 1-800-431-7206.

Dr. Michael T. Kelly, Head of Medical Microbiology

Sperm Analysis Reporting

We would like to inform our physician clients that we have now finalized implementation of the World Health Organization (WHO) procedure for sperm analysis to include the three parts of the sperm motility grading system. It is recommended by the WHO (5th edition) that spermatozoa should be categorized as progressively motile (PR), non-progressively motile (NP) and immotile (IM). The total motility (%) is the combination of PR and NP.

Sperm motility should be assessed within one hour of specimen collection. However, in cases where the specimen age is greater than one hour and the total motility is less than 40%, the following comment will be added to reports: "WHO 5th edition (2010) states that sperm motility should be assessed within one hour of specimen collection. Motility may be compromised due to age of specimen."



Sperms on hematoxylin stain

Finally, there is a minor name change from sperm viability to sperm vitality with no changes to the procedure.

A. Zareh, Technologist and Dr. Zohra Daw, Hematopathologist

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