Billings Clinic℠

Laboratory Communiqué

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The *Laboratory Communiqué* is a quarterly publication released by Billings Clinic Laboratory Services as an informational tool for medical staff and laboratorians.

In This Issue

NEW TESTS

Xpert *C. difficile*, PCR Assay

Test Code: BC 5909
CPT: 87493

The Cepheid Xpert *C. difficile* Assay, performed on the Cepheid GeneXpert® Dx System, is a qualitative *in-vitro* diagnostic test for rapid detection of toxin B gene sequences from unformed (liquid or soft) stool specimens collected from patients suspected of having *Clostridium difficile* infection (CDI). The test utilizes automated real-time polymerase chain reaction (PCR) to detect the toxin gene sequences associated with toxin producing *C. difficile.* The Xpert *C. difficile* Assay is intended as an aid in the diagnosis of CDI.

The GeneXpert® Dx System automates and integrates sample purification, nucleic acid amplification and detection of the target sequence in simple or complex samples using real-time PCR and RT-PCR assays. The system requires the use of single-use disposable cartridges that hold the PCR reagents and host the PCR process. Because the cartridges are self-contained, cross-contamination between samples is eliminated.

Clostridium difficile is a Gram-positive, spore-forming anaerobic bacillus that was first linked to disease in 1978. *C. difficile* infection (CDI) ranges from diarrhea to severe life-threatening pseudomembranous colitis. Mature colonic bacteria flora in a healthy adult is generally resistant to *C. difficile* colonization. However, if the normal colonic flora is altered, resistance to colonization is lost. The most common risk factor is exposure to antibiotics. *C. difficile*'*s* primary virulence factor is cytotoxin B. The genes coding for toxin A (*tcdA;* the enterotoxin) and toxin B (*tcdB)* are parts of the pathogenicity locus (PaLoc). Most pathogenic strains are toxin A-positive, toxin B-positive (A+B+) strains although toxin A-negative, toxin B-positive (A-B+) variant isolates have been recognized as pathogenic.

Laboratory Services

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Specimen Collection and Transport

- Collect the unformed stool specimen in a clean container. Follow your institutions guidelines of collecting samples for *C. difficile* testing.
- Label with Sample ID and send to the laboratory
- Store specimen at 2-8°C.

Reporting of Results

Only one specimen is needed to determine if *C. difficile* Toxin is present of absent.

- Toxigenic *C. difficile* Positive
- Toxigenic *C. difficile* Negative
- Invalid Interpretation: Presence or absence of *C. difficile* cannot be determined. Inhibition of the Xpert *C. difficile* assay has been observed in the following substances: Zinc oxide pastes and Vagisil Cream. The patient will not be charged for this test.

Test Updates

The following reference range has been changed for the Sysmex XE 5000 and XT 1800 at the main laboratory for the age range 18 yrs to 150 yrs:

MCHC	Old Range	33.0 – 37.0 gm/dL
	New Range	31.0 – 36.2 gm/dL

The following reference range has been changed for the Sysmex Oncology XL80, Heights XL80 and West End XL80 only:

RDW	Old Range	11.0 – 15.1%
	New Range	10.6 – 13.7%

For more information about Billings Clinic Laboratory please call (406) 657-4060 or 1-866-232-2522. www.billingsclinic.com.

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