IMPORTANT LAB UPDATE

To: HealthEast Medical Laboratory Providers: Inpatient and Clinic HML clients
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Date: February 6, 2017
Subject: Clostridium Difficile (CDI) testing platform and reporting information updates

HealthEast Laboratories is pleased to announce that Clostridium Difficile results will be reported using Cepheid Xpert® C. difficile/Epi platform starting 2/12/2018.

C. difficile’s primary virulence factor is cytotoxin B. In the last several years, there have been outbreaks of CDI attributed to a number of emerging “hypervirulent” strains that include fluoroquinoline resistant strains belonging to PCR ribotype 027, PFGE type NAP1 and REA type BI,8,12 Strains of 027/NAP1/BI exhibit increased toxin production. The identification of a presumptive positive or negative 027/NAP1/BI result may aid in the identification of possible sources of an 027/NAP1/BI outbreak.

The Cepheid Xpert® C. difficile/Epi Assay is a qualitative in vitro diagnostic test for rapid detection of toxin B gene sequences and for presumptive identification of 027/NAP1/BI strains of toxigenic Clostridium difficile from unformed stool specimens collected from patients suspected of having C. difficile infection (CDI). The Cepheid Xpert® C. difficile/Epi assay detects the toxin B gene (tcdB), the binary toxin gene (CDT), and the single-base-pair deletion at nucleotide 117 within the gene encoding a negative regulator of toxin production (tcdCΔ117).

The test is available on a stat or routine basis, 7 days a week 7am-10pm. Testing is performed at St. Joseph’s Hospital Microbiology Laboratory.

C. difficile will continue to be reported out as Positive or Negative.

C. Difficile ribotype 027/NAP1/BI will now be reported with every CDI test. C. Diff 027/NAP1/BI strain will be resulted out as presumptive positive or presumptive negative. A presumptive positive result will be called to the patient care area. There is no Ribotype 027/NAP1/BI confirmatory test. Detection of 027/NAP1/BI strains of C. difficile by the Xpert C. difficile/Epi is solely for epidemiological purposes and is not intended to guide or monitor treatment for C. difficile infections.

The microbiology lab will no longer accept specimens in preservative. Specimens should be collected in a clean container and stored at 2-8°C for up to 5 days.

The microbiology lab will no longer accept specimens from children <2 years of age. Performance characteristics were not established for patients < 2 years of age on the Cepheid Xpert® C. difficile/Epi Assay.
The following statement will be reported on all CDI tests:

**Intended use:**
The Cepheid Xpert® *C. difficile/Epi* Assay is a qualitative *in vitro* diagnostic test for rapid detection of toxin B gene sequences and for presumptive identification of 027/NAP1/BI strains of toxigenic *Clostridium difficile* from unformed (liquid or soft) stool specimens collected from patients suspected of having *C. difficile* infection (CDI). The Xpert *C. difficile/Epi* Assay is intended as an aid in the diagnosis of CDI. Detection of 027/NAP1/BI strains of *C. difficile* by the Xpert *C. difficile/Epi* Assay is presumptive and is solely for epidemiological purposes and is not intended to guide or monitor treatment for *C. difficile* infections. The Cepheid Xpert *C. difficile/Epi* Assay is intended for use in hospital, reference or state laboratory settings. The device is not intended for point-of-care use.

**Methodology:**
The GeneXpert Instrument Systems automate and integrate sample lysis, nucleic acid purification and amplification, and detection of the target sequence in complex samples using real-time polymerase chain reaction (PCR). The Cepheid Xpert® *C. difficile/Epi* assay detects the toxin B gene (*tcdB*), the binary toxin gene (CDT), and the single-base-pair deletion at nucleotide 117 within the gene encoding a negative regulator of toxin production (*tcdC*Δ117). Presumptive identification of 027/NAP1/BI strains of *C. difficile* is by detection of binary toxin (CDT) gene sequences and the single base pair deletion at nucleotide 117 in the *tcdC* gene. The *tcdC* gene encodes for a negative regulator in *C. difficile* toxin production. A fluorescent signal becomes detected and increases each time the specific DNA strand is amplified. The Real-time PCR generates a growth curve with number of cycles on the x-axis and fluorescence on the y-axis. If the organism’s DNA is not detected by the real-time PCR reaction the growth curve will be flat and will be resulted as negative.