HealthEast Medical Laboratory

**********IMPORTANT LAB UPDATE**********

To: HealthEast Medical Laboratory Providers: Inpatient and Clinic HML clients

From: Dr. Kristi Werdin, M.D., Medical Director 326-7127
Camilla Fischer, Microbiology Manager 232-3328

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Subject: Clostridium Difficile (CDI) testing platform and reporting information updates

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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 (*tcdC* 117).

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*□117). 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.