

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

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

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Subject: Group B Streptococcus (GBS) testing platform and reporting information updates

HealthEast Laboratories is pleased to announce that Group B Streptococcus results will be reported using Cepheid Xpert® GBS LB Assay starting **2/12/2018**.

GBS bacterial infection is associated with serious illness in newborns born to women who are colonized with the microorganism. Transmission of GBS occurs from GBS-colonized women to their newborn before birth (antepartum) or during birth (intrapartum). In the United States, GBS infection is the major cause of death in newborns who develop sepsis, pneumonia, or meningitis. Current standard of care for preventing neonatal GBS disease is screening pregnant woman at 35-37 weeks of gestation to determine their GBS colonization status.

The Cepheid Xpert® *GBS LB Assay* is a qualitative *in vitro* diagnostic test designed to detect Group B Streptococcus (GBS) DNA from enriched vaginal/rectal swab specimens, using fully automated real-time polymerase chain reaction (PCR) with fluorogenic detection of the amplified DNA.

Testing is performed at St. Joseph's Hospital Microbiology Laboratory. The test is available 7 days a week **7am-330pm**.

GBS will continue to be reported out as Positive or Negative. Penicillin allergic women with positive GBS will have susceptibilities performed.

The following statement will be reported on all GBS tests:

Intended use:

The Cepheid Xpert GBS LB Assay, performed on the GeneXpert® Instrument Systems, is a qualitative *in vitro* diagnostic test designed to detect Group B *Streptococcus* (GBS) DNA from enriched vaginal/rectal swab specimens, using fully automated realtime polymerase chain reaction (PCR) with fluorogenic detection of the amplified DNA. Xpert GBS LB Assay testing is indicated as an aid in determining GBS colonization status in antepartum women. This assay does not diagnose or monitor treatment for GBS infections. The Cepheid Xpert GBS LB 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 simple or complex samples using real-time polymerase chain reaction (PCR). The GBS primers and probe detect a target within a 3' DNA region adjacent to the *cfb* gene of *S. agalactiae*. 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.

