Technical Alert

Sexually Transmitted Infection Testing in Young Patients

TO: Medical Staff and Clients

FROM: Dr. A. Christian Whelen, PhD, M.S., D(ABMM)
V.P. - Technical Director (Microbiology)

Terrie Koyamatsu, M(ASCP)
Manager, DLS Microbiology

Dr. Wesley Kim, MD
Medical Director DLS and QMC West

Dr. Ana Ortega-Lopez, MD
Medical Director QMC Punchbowl, North Hawaii and Molokai

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SUBJECT: **Testing for Chlamydia and gonorrhea will be performed at a reference laboratory for patients under the age of 14 years - New order code effective November 19, 2018**

Although detection of *Chlamydia trachomatis* (CT) and *Neisseria gonorrhoeae* (GC) in urogenital specimens by nucleic acid amplification test (NAAT) is available at DLS, the FDA-labeling of this product is age-restricted to patients who are at least 14 years old. Neither is it labeled for the evaluation of suspected abuse cases. The test of choice in these circumstances is culture because of specificity, although this approach lacks sensitivity and collection methods are more invasive. The Centers for Disease Control and Prevention is also very cautious in its recommendations for tesing young patients (https://www.cdc.gov/mmwr/preview/mmwrhtml/rr6302a1.htm).

DLS has also secured a commitment from a reference laboratory to perform this off-label NAAT testing for our customers. Alternatively, there is the availability of CT/GC cuture capability (order codes 4183 and 625, respectively). The new order code (5127) and specimen collection devices (Aptima®) are different from the in-house order code (183) and our Cobas collection products.

These tests are made available for the expressed purpose of medical management of the patient, and are not intended or appropriate for law enforcement or investigation purposes.

Order code:	5127
Test name:	CT/GC RNA, TMA, Urogenital
Preferred specimen type:	Urine
Preferred container:	Sterile Container, minimum volume 2 mL
Special instructions:	Patient should not have urinated within one hour prior to collection, with optimal specimen being a first morning urine collection. Female patients should not cleanse the labial area prior to providing the specimen. Direct patient to provide a first-catch urine (a maximum of 20-30 mL of the initial urine stream) into a urine collection cup free of any preservatives.
Other acceptable types:	0.5mL of SurePath ™ preservative fluid collected in APTIMA ® specimen transfer Tube (Green label) or APTIMA ® Vaginal collection or Multitest collection kit (Orange label), or 2mL urine using the APTIMA ® urine specimen collection kit.
Special handling:	Urine specimen must be received in the lab on the same day of collection to ensure that urine is transferred into the required collection kit. International: Urine must be transferred into the APTIMA ® urine specimen collection kit within 24 hours of collection prior to sending specimen to the laboratory.
Specimen stability:	Refrigerated: 24 hours (urine); 30 days or more if received in APTIMA ®