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THERE ARE NO NORMAL VALUES IN MICROBIOLOGY!
AN IMPROPERLY COLLECTED SPECIMEN MEANS UNINTERPRETABLE RESULTS!

IMPLEMENTATION OF A NEW TEST METHOD FOR DETECTION OF GENITAL/URINE CHLAMYDIA TRACHOMATIS (CT) AND/OR NEISSERIA GONORRHOEAE (GC) INFECTIONS

As of October 3, 2005, the CLS Microbiology laboratory will implement a new highly sensitive, test method to detect *Chlamydia trachomatis* and/or *Neisseria gonorrhoeae* directly from endocervical, male urethral, and female/male urine specimens. The Gen-Probe APTIMA system utilizes nucleic acid amplification technology (NAAT) to simultaneously detect BOTH CT and/or GC from a single urine specimen or uni-sex swab. Effective October 3, 2005, both CT and GC results will be reported on swab and urine specimens.

1. Background:

The Calgary Laboratory Services (CLS) Microbiology Laboratory currently uses the Gen-Probe PACE2 nucleic acid hybridization technology to detect *Chlamydia trachomatis* (CT) and/or *Neisseria gonorrhoeae* (GC) directly from endocervical and male urethral specimens and only performs nucleic acid amplification testing (NAAT) for the detection of *Chlamydia trachomatis* directly from male and female urines.

Additional funds were recently provided by the Calgary Health Region to facilitate the implementation of a new and more sensitive NAAT for the detection of CT and GC from all types of genital and urine specimens.

2. Description of the Gen-Probe APTIMA Assay:

The Gen-Probe APTIMA assay is a second-generation nucleic acid amplification test (NAAT) that uses a target captures approach and transcription-mediated amplification for the *in vitro* qualitative detection and differentiation of ribosomal RNA from CT and GC.

Urine and urethral samples are highly sensitive for detecting CT infections in men and women, and GC infections in men. To exclude GC infections in women, an endocervical sample is required.

3. Test Request for CT and GC:

There is no change in requesting a CT/GC test on the CLS Microbiology requisition when using the new Gen-Probe APTIMA collection Kit. A properly completed CLS Microbiology requisition must accompany all specimens and provide accurate patient demographic information including; patient's name, personal health number and the location of the ordering physician. All specimens MUST also have a label that provides matching patient demographic information and site of collection matching that provided on the requisition.

4. Collection Procedure(s) for the new Gen-Probe APTIMA assay:

Comprehensive specimen collection information is found in our Guide to Services available at
www.calgarylabservices.com

Gen-Probe APTIMA is approved for testing adult (> 13 years) endocervical and male urethral swabs as well as female and male urine specimens. This testing method is not validated for any other sources. Results from other sources should be interpreted with caution. The Gen-Probe APTIMA assay is also not approved for the evaluation of suspected sexual abuse or for other medico-legal indications.

Detailed step-by-step instructions for the proper collection procedure(s) for endocervical and urethral swabs are provided on the back of the collection kit.

a. Endocervical: When collecting an endocervical specimen, use the provided large tipped cleaning swab (white shaft) to remove excess cervical mucous. The provided unisex specimen collection swab (blue shaft) is then inserted and rotated within the endocervical canal to ensure adequate sampling. **Remove the cap** from the specimen transport tube and place the specimen collection swab (blue shaft) into the tube breaking the swab shaft at the scoreline. **Recap the tube**.

b. Urethral: *Patient should not have urinated for at least 1 hour prior to specimen collection.* Collect the specimen using the provided unisex specimen collection swab (blue shaft). Then **remove the cap** from the specimen transport tube and place the specimen collection swab (blue shaft) into the tube breaking the swab shaft at the scoreline. **Recap the tube**.

c. Urine: *Patient should not have urinated for at least 1 hour prior to specimen collection. Female patients should not cleanse the labial area prior to providing the specimen.* Instruct the patient to provide a first-void urine sample of 20-30 ml. of initial urine stream into a sterile urine collection container. Collection of larger volumes of urine may result in specimen dilution that may reduce test sensitivity.

Note: Urine specimens submitted in Urine Culture Transport Tubes (grey stopper) are not acceptable for testing.

5. Ordering of the new collection uni-sex swab:

The revised ordering templates will be available on line for ordering on **September 19, 2005**. The Gen-Probe APTIMA Swab collection kit is unisex and should be ordered from CLS as per your normal CLS ordering protocol as of September 19. **For questions regarding ordering, contact Debbie O'Bray at 770-3768**.

CLS Item order information:

CLS #	Source Med. #	Item Description
GEN301041	GEN301041 **APTIMA** Combo	Chlamydia/GC APTIMA Collection Kit - Unisex - White - Bx/50

- As of October 3, 2005 the new Gen-Probe APTIMA unisex swab collection kit (white label) should be used for endocervical and urethral swabs. Please discard all old Gen-Probe collection kits (blue and pink labels) as of this date once you receive the new Gen-Probe APTIMA unisex swab (white label).
- **After November 7, 2005 the old Gen-Probe collection kits for male and female swabs (blue and pink labels) will no longer be accepted for testing**.
- Urines will continue to be submitted to the lab in sterile collection containers.

6. Specimen Transport:

After collection, store specimen at room temperature until transported to the lab. Urine specimens must be transported to the lab within 24 hours of collection. Place each specimen in a separate biohazard bag.

IF YOU HAVE ANY QUESTIONS CALL 770-3396 (Brenda Kirkham, Manager, Microbiology) or 770-3698 (Valerie Wood, Supervisor, Microbiology) or 770-3757 (Microbiologist On Call)