LifeLabs Medical Laboratory Services

Vancouver Island Physicians' Newsletter

July 2009

CHANGES in CHLAMYDIA / GONORRHEA TESTING at LIFELABS

Background

LifeLabs has been providing Chlamydia and gonorrhea testing by nucleic acid amplification using the BD ProbeTec system for nearly five years. **Effective August 17, 2009, LifeLabs will be changing to a new, state-of-the-art nucleic acid amplification testing method called Gen-Probe APTIMA.** The new system offers the following advantages: liquid swab transport, outstanding accuracy, no false positive results due to cross reactions with normal flora organisms, and improved sensitivity for urine testing in females. It can be used for testing both swab and urine specimens on males and females.

Performance of the APTIMA assay

The accuracy of the Gen-Probe APTIMA system in published studies is in the range of 98–100%, but we performed our own validation of the APTIMA system to insure good performance for testing of BC patients. Cooperating clinics collected dual Gen-Probe APTIMA and BD ProbeTec swabs that were tested in parallel on the two systems. We also tested urine specimens on the two systems. Discrepancies were resolved by repeat testing on both systems and by testing using alternative DNA amplification methods. 1534 specimens were tested by both methods for Chlamydia and gonorrhea. A total of 269 specimens were positive for one or both organisms, and the APTIMA system demonstrated >99% sensitivity and specificity overall for both swab and urine specimens compared to the BD ProbeTec system. The results by specimen type are shown above. Based on this excellent performance, the Gen-Probe APTIMA system was chosen for implementation.

Specimen type	Sensitivity (%)		Specificity (%)	
	CT	GC	CT	GC
Swab	100	100	99.6	100
Urine	100	98.1	100	100

Ordering the new APTIMA test

There will be no change in how Chlamydia and gonorrhea (CT / GC) testing is ordered. The standard outpatient requisition will continue to be used. As per MSP guidelines, both tests will be done when either or both are ordered.

Collection procedures

The most important change in the collection procedures is that the new APTIMA swabs (see below) must be used.

1. **Ordering new swabs:**

   You may have already received a supply of the new swabs, but if not, they can be ordered by calling: **1-800-304-4011 local 2124 or 250-881-3111 local 2124.**

2. **Swab collection:**

   Due to the liquid transport of swab specimens, there are some changes in the procedures for swab specimen collection as outlined on the next page.

Editor-in-Chief: Dr. Colette Pienaar • **Associate Editor:** Dr. Jan Palaty

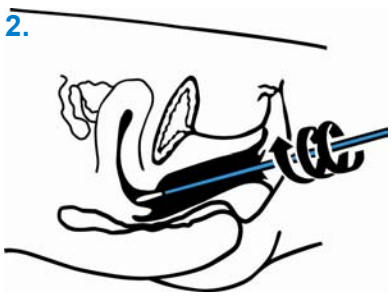
a) Endocervical swabs:

You will note that the kit contains two swabs.

1.

- Use **white shaft swab** first to remove excess cervical mucous
- Discard after cleaning

2.



Insert the **blue shaft swab** into the cervical canal and rotate to collect the sample for testing

3.

- Remove cap from tube
- Place swab into tube
- Break shaft at scored line

4.

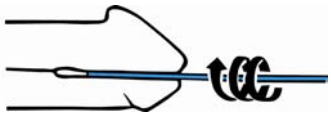
Replace cap on tube

If a Pap test is being collected at the same time, it is best to collect the CT / GC sample before the Pap sample.

b) Urethral swabs:

The patient should not have urinated for at least one hour before specimen collection. The same unisex collection kit used for cervical specimens is also used for urethral specimens. Discard the large cleaning swab with the white shaft.

1.



Insert the **blue shaft swab** 2–4 cm into the urethra to collect the specimen

2.

- Remove cap from tube
- Place swab into tube
- Break shaft at scored line

3.

Replace cap on tube

3. Urine collection:

Urine is an acceptable alternative specimen to either cervical or urethral swabs. The collection of urine specimens will remain unchanged. Remember that, unlike a urine collection for bacterial culture, the first void specimen (20–30 ml) is required for CT / GC testing.

Reporting of results

Results will be reported as positive, negative, or inconclusive for *Chlamydia trachomatis*, *Neisseria gonorrhoeae* or both. Negative results will generally be reported within 24 hours after receipt of the specimen in the laboratory. Most positive results will be reported within 48 hours. Inconclusive results and occasional positive results may require 72 hours before reporting due to the need for confirmatory testing.

Interpretation of results

Positive or negative results are generally very reliable and indicate the presence or absence of infection. However, in low prevalence populations, such as in British Columbia, false positive or false negative results are rare but possible. Inconclusive results indicate low activity in the assay that is neither low enough to be negative nor high enough to be positive. Repeat testing may be indicated when inconclusive results are obtained. Inconclusive results can also occur in previously treated patients due to residual nucleic acid in the sample.

Additional information

Further information about our new Chlamydia / gonorrhea test can be obtained by contacting a LifeLabs Medical Microbiologist at:
1-800-304-4011 or 250-881-3100.

Dr. Michael T. Kelly, Head of Medical Microbiology

Artwork and photograph on this page provided by Gen-Probe APTIMA