Legacy Laboratory Services

Chlamydia and Gonorrhoeae Conversion to New DNA Amplification Assay

June 2011

Introducing "Next Generation" Technology for CT/GC Assays

Legacy Laboratory Services is pleased to announce a new amplified DNA test for detection of Chlamydia trachomatis (CT) and Neisseria gonorrhoeae (GC) using the BD ProbeTec Qx assay. This assay offers improved specificity and sensitivity plus expanded specimen options.

Improved patient management

- Greater accuracy than other methods; test interpretation does not include an equivocal zone, meaning **less indeterminate results** for patients
- **Fewer rejected specimens** due to inhibition interference

Convenience

- **Pap Plus**—single vial testing for Pap, HPV and CT/GC provides **clinician ease and patient comfort**

Confidence in test results

- FDA clearance requires extremely rigorous manufacturer test development providing clinicians **greater assurance of accuracy**
- First FDA-cleared CT and GC nucleic acid amplified tests for use with both SurePath™ and ThinPrep® liquid Pap preparations
- FDA approval for **CT/GC testing on urine and swab** (endocervical, vaginal, and male urethral) specimens

The new BD ProbeTec™ Qx assay requires converting to different specimen collection devices for CT and GC testing. This conversion will take place during June and July 2011.

A representative from Legacy Laboratory Services will assist your clinic with updating your specimen collection supplies. They will work with you to set a date for you to convert to the new method and to assist with removing Aptima CT/GC collection devices. **Please note**: after August 1st, Legacy will refer specimens for CT/GC submitted in the Aptima collection devices which may increase turn around time.

Please note:

1. **Unpreserved Urine specimens must be refrigerated**.
2. **CT/GC tests from a Liquid Pap must be requested on the original order**; they cannot be aliquoted from a Pap that has already been processed.

For additional information, contact:

Mary Perkins, M.S. MT(ASCP), SH
Manager, Molecular Diagnostics Laboratory
503-413-2411

LEGACY HEALTH

Mitch Ryan, M.D.
Medical Director of Microbiology
503-413-7636

Assay performance characteristics[i] are shown below in Table 1, ordering details are provided in Table 2, and specimen type and stability are presented in Table 3.

Table 1. BD ProbeTec™ Q^x CT/GC Amplified DNA Assays Test Performance Characteristics [1]

Organism	n	Specimen Type	Sensitivity	95% Confidence Interval	Specificity	95% Confidence Interval
GC	6284	Swabs, Urine	99.3%	98.3%-99.8%	99.3%	99.1%-99.5%
	1715	SurePath™	100%	93.0%-100.0%	99.9%	99.6%-100.0%
	2074	ThinPrep®	95.3%	84.2%-99.4%	99.95%	99.7%-100.0%
CT	5388	Swabs, Urine	94.5%	92.6%-96.0%	98.9%	98.6%-99.2%
	1714	SurePath™	95.0%	90.0%-98.0%	99.7%	99.3%-99.9%
	2071	ThinPrep®	94.1%	88.7%-97.4%	99.8%	99.5%-100.0%

Table 2. Test Ordering

Mnemonic	Test Name
GC/CT BD	Neisseria gonorrhoeae (GC) & Chlamydia trachomatis (CT)
GC/BD	Neisseria gonorrhoeae (GC)
CT/BD	Chlamydia trachomatis (CT)

Table 3. Specimen type and stability

Specimen type	Temperature	Stability
Liquid Pap Preparation – SurePath™ or ThinPrep®	2 - 30° C	30 days
Swabs – Endocervical and Urethral	2 - 30° C	30 days
Urines – in UPT (Urine Preservative Transport)	2 - 30° C	30 days
Urines – Unpreserved	2 - 8° C (refrigerated)	24 hours

Supplies:
The following supplies for the BD ProbeTec™ Q^x CT/GC Amplified DNA Assay can be ordered by calling Client Services (503-413-1234) or marking our Supply Order Form appropriately and faxing to 503-413-5086:

- CT/GC BD Q^x Endocervical Swab (100/pkg.)
- CT/GC BD Q^x Urethral Swab (100/pkg.)
- CT/GC BD Q^x Urine Transport (100/pkg.)

Test performed: Sunday through Friday; **Turnaround**: 24 hrs.

CPT Codes: CT by Amplified DNA – 87491, GC by Amplified DNA – 87591

For any questions regarding this assay, please contact **Legacy Laboratory Client Services at 503-413-1234 or toll free 1-877-270-5566**.

---

[i] As determined by manufacturer, Becton Dickinson.

For additional information, contact:

Mary Perkins, M.S. MT(ASCP), SH
Manager, Molecular Diagnostics Laboratory
503-413-2411

Mitch Ryan, M.D.
Medical Director of Microbiology
503-413-7636