Legacy Laboratory Services

Introducing "Pap Plus"—Single Vial Testing for Cervical Cancer, Chlamydia and Gonorrhoeae

June 2011

Chlamydia trachomatis (CT) and Neisseria gonorrhoeae (GC) testing from liquid based Cytology specimens collected during routine Cervical Cancer screening is now available from Legacy Laboratory Services.

Our addition of **FDA** approved Chlamydia and N. gonorrhoeae Amplified DNA Assays (BD ProbeTec $^{\text{TM}}$ Q $^{\text{X}}$) by Strand Displacement Amplification expands your "out of vial" testing options to include: **Cytology (either SurePath or ThinPrep), High Risk HPV, CT and GC testing**. The pairing of highly sensitive and specific nucleic acid amplification tests for CT and GC with <u>both</u> major liquid prep Pap tests is a welcome development, especially in women's health, as it can enhance disease detection capability from a single specimen.

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
- Only assays FDA-cleared for CT and GC testing of SurePath™ Pap specimens
- Additional FDA approval for CT/GC testing on urine and swab (endocervical, vaginal, and male urethral) specimens

Improved patient management

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

Please note

- 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.
- 2. Although there is minimal inhibition interference caused by blood, common gynecological products or spermicides, it is best to collect specimens for "out of the vial" testing during mid-cycle and with limited use of lubricants.
- 3. Unpreserved Urine specimens must be refrigerated.

For additional information, contact:

Expanded

Options from

Liquid Based

Testing

Cytology

Specimens



Assay performance characteristicsⁱ 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%
	5388	Swabs, Urine	94.5%	92.6%-96.0%	98.9%	98.6%-99.2%
СТ	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.

For additional information, contact:

ⁱ As determined by manufacturer, Becton Dickinson.