



On-Demand Molecular Testing for the Physician Office Laboratory

Xpert[®] CT/NG *for Chlamydia/Gonorrhea Testing*



Xpert[®] GBS LB *for Group B Streptococcus Screening*

Xpert[®] Flu *for Influenza Testing*

Simple, Fast, and Accurate

 **Cepheid[®]**
A better way.

Today, physicians are seeking approaches to improve efficiencies and better serve their patients. Expanding lab testing capabilities with 'on-site molecular diagnostics' empowers Non-Waived Physician Office Laboratories to more effectively support physicians with value added services that will attract new patients and increase satisfaction amongst existing ones.



THE CHALLENGE

- Current systems and test protocols are highly complex
- Lengthy test procedures — up to 6-8 hours
- Batch size test requirements inappropriate for POL services
- Limited menu and system functionality



THE SOLUTION

- GeneXpert® System enables on-demand STAT testing
- Self contained cartridge & test controls ensures results integrity
- "Moderate complexity" rating extends test capabilities to many POL facilities
- Broad test menu, including Chlamydia/Gonorrhea, Group B Strep, and Flu

GENEXPERT SYSTEM

- Available in a compact one, two, four, or sixteen module cabinet with LIS connectivity
- Each independent module runs the same Xpert test cartridge
- Testing can begin as soon as the order is received, no need to batch samples

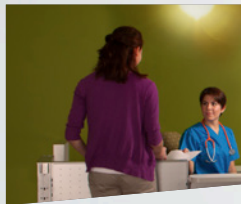


— GX-IV Processing Unit: 11" W x 12" H x 11.7" D

— GX-XVI Processing Unit: 22.75" W x 25.8" H x 13.25" D



ON-DEMAND WORKFLOW



Patient arrives for appointment



Patient consults with physician



Test is run in Office Lab



Test results available same visit



XPert CT/NG: *Chlamydia trachomatis* (CT) and *Neisseria gonorrhoeae* (NG)

Xpert CT/NG test introduces the Sample Adequacy Control that ensures patient sample is genuine by detecting for human DNA.

Targets	2 independent NG targets and CT target selected for superior inclusivity
Time to results	90 minutes for positive samples
Hands on time	~1min/sample

Specimen type/Performance

Specimen	CT Performance	NG Performance
Patient collected vaginal swabs	Sensitivity 99.5% Specificity 99.1%	Sensitivity 100% Specificity 99.9%
Endocervical swabs	Sensitivity 96% Specificity 99.6%	Sensitivity 100% Specificity >99.9%
Urine (Male)	Sensitivity 98.5% Specificity 99.8%	Sensitivity 98.3% Specificity 99.9%
Urine (Female)	Sensitivity 98.1% Specificity 99.8%	Sensitivity 94.4% Specificity >99.9%



XPert GBS LB: *Group B Streptococcus*

Cepheid's GeneXpert System, with Xpert GBS LB and Xpert GBS is the only solution to fully meet CDC criteria for both antenatal and intrapartum testing.

Xpert GBS LB

Time to Results	35 minutes for positive samples, 55 minutes for all
Hands on time	~1min/sample
Specimen type	Swab incubated in LIM Broth
Performance	Sensitivity: 99% Specificity: 92.4% PPV: 79.7% NPV: 99.7%



XPert FLU: Influenza

Rapid determination of Flu A and Flu B infection and identification of 2009 H1N1 strain type maximizes medical decision making – enabling testing to take place in real time during a patient presentation.

Time to Results	75 minutes
Hands on time	~2 min/sample
Specimen type	Nasal Aspirate/ Wash; Nasopharyngeal Swab
Performance	
<i>Nasal Aspirate/Wash</i>	Flu A: 99.4% Sensitivity 100% Specificity
<i>Nasopharyngeal Swab</i>	Flu B: 100% Sensitivity 100% Specificity
<i>Nasopharyngeal Swab</i>	H1N1: 100% Sensitivity 99.3% Specificity



WORKFLOW:

3 EASY STEPS TAKES JUST MINUTES

1

Collect Sample*

**Sample container varies with test.*



2

Transfer sample to cartridge



3

Insert cartridge into GeneXpert System and start test



➤ 2013 Medicare National Limitation Amount*

Test	CPT Code	Medicare National Limitation Amount
CT/NG	CT 87491	\$48.24
	NG 87591	\$48.24
GBS LB (Antepartum)	87150	\$48.24
Flu	Flu A and B 87502	\$116.96
	H1N1 87503	\$28.55

* See [http://www.cms.gov/Medicare/Fee-for-Service-Payment/ClinicalLabFeeSched/clinlab.html] for state specific rates. Effective April 1, 2013 and while sequestration is in effect, all CMS payments for services will be reduced by 2%. The rates above do not reflect this reduction (see: http://www.cms.gov/Outreach-and-Education/Outreach/FFSPovPartProg/Downloads/2013-03-08-standalone.pdf).

DISCLAIMER: The reimbursement information that we provide is to help laboratory personnel understand and comply with billing and reimbursement requirements that may apply to Cepheid products. It is your responsibility to check with your billing office and/or payers in your area to verify correct coding. It is the ordering provider's responsibility to determine medical necessity and the proper site for delivery of any services. Use of the codes presented here does not guarantee coverage or payment for specific targets or at any specific level, as reimbursement policies are subject to changing laws, regulations, rules and policies. Policies may vary widely from insurer to insurer, and often reflect different patient conditions.

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