On-Demand Molecular Testing for the Physician Office Laboratory

GeneXpert® System

How can on-site testing positively impact patient care and clinic operations?

Cepheid®
A better way.

On-site molecular diagnostics empowers Physician Office Laboratories (POLs) to more effectively support clinicians with value added services that will better guide clinical care, increase patient satisfaction, and improve efficiencies.

YOUR CHALLENGE

- Evolving guidelines places pressure on clinicians to provide same day results and treatment
- Slow time to results impacts treatment decisions and creates patient anxiety
- The complexity of current molecular systems poses barriers to running testing on-site
- Send out testing represents a potential missed opportunity to capture reimbursable testing in the POL

OUR SOLUTION

Patient arrives for appointment

Physician consults with patient and collects sample

On-demand testing enable the lab to process samples in under 1 minute – less time than it takes to process a send-out

Ease of use makes in-house molecular testing feasible for the physician office lab without specialized training

Fast, accurate results improve treatment decisions and patient satisfaction

Single platform with a growing test menu including CT/NG, Trichomonas, GBS, Flu/RSV, and more.

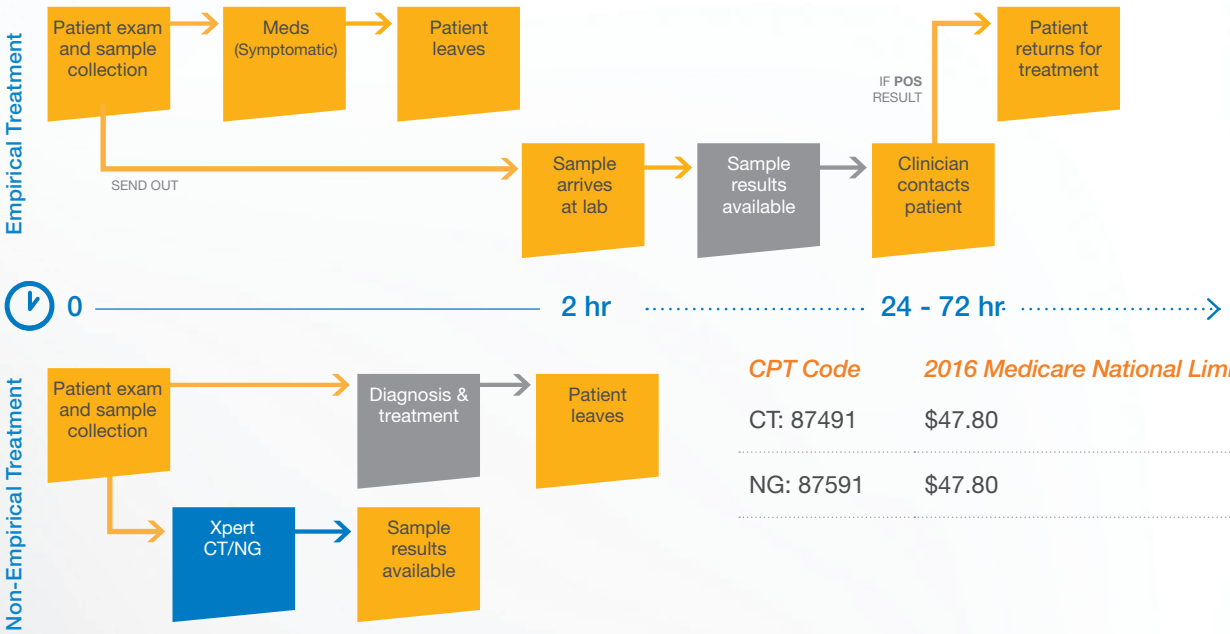
SEXUAL HEALTH TESTING

Cepheid's Xpert Sexually Transmitted Infections (STI) portfolio provides the only on-demand, Nucleic Acid Amplification Test (NAAT) testing that enables same day consultation and treatment of Chlamydia, Gonorrhea, and Trichomonas.

XPERT® CT/NG for Chlamydia and Gonorrhea testing*

- Independently detects 2 Gonorrhea targets eliminating the need for confirmatory testing
- Results within 90 minutes
- Sample adequacy control confirms patient DNA is present for analysis
- Flexible sample types: patient-collected vaginal swabs, clinician-collected endocervical swabs, and male/female urine

IMPACT ON PATIENT PATHWAY: "TEST AND TREAT"



CPT Code	*2016 Medicare National Limit Amount^*
CT: 87491	$47.80
NG: 87591	$47.80

XPERT® TV for *Trichomonas vaginalis* (TV) testing in women*

- Enables alignment with CDC guidelines to conduct highly sensitive and specific NAAT testing for the detection of TV
- Early Assay Termination supports positive results reporting within 40 minutes for rapid information with which to manage patients
- Intended for both symptomatic and asymptomatic patients so clinicians can screen individuals at higher risk of infection

TV CPT Code 87661 $47.80 2016 Medicare National Limit Amount^

REPRODUCTIVE HEALTH

XPERT® GBS LB for Antepartum Group B Strep testing*

- Supports antepartum screening at 35-37 weeks gestation
- Simple workflow — users perform one easy step (prepare a Lim Broth) and the GeneXpert® System does the rest
- Delivers fast and accurate NAAT results in as soon as 35 minutes (with Early Assay Termination for positives)
- Reduces the lab's pre-analytical steps for antenatal screening

IMPACT ON PATIENT PATHWAY

Antepartum

Elapsed (hours)	18 hrs	19hrs	20hrs	48hrs	72hrs
Culture Workflow	Specimen Swab & LB 18hrs			Incubate Blood Agar Plate (BAP) Confirm with Hemolysis or Latex Agglutination Test (LAT) 24hrs	Re-incubate BAP Confirm with Hemolysis or LAT 24hrs
Other NAAT	Specimen Swab & LB 18hrs	Reagent Prep 20mins	Specimen Prep 30mins	Test & Results 60+mins	
Xpert GBS LB	Specimen Swab & LB 18hrs	Specimen Prep 1min	Test & Results 35-55mins		

CPT Code	*2016 Medicare National Limit Amount^*
87150	$47.80

RESPIRATORY TESTING

XPERT® FLU/RSV XC for Flu A, Flu B, and/or RSV testing*

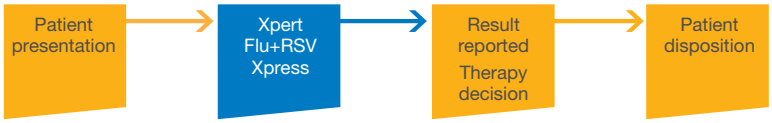
- Extended coverage ensures wide and complete coverage for Flu A (including avian and swine), Flu B, and RSV
- Built in redundancies to accommodate for strain mutations and unprecedented avian strain coverage
- Reimbursable test with added cost savings through platform consolidation for Flu and RSV testing

XPERT® FLU+RSV XPRESS for CLIA-waived Flu and RSV testing

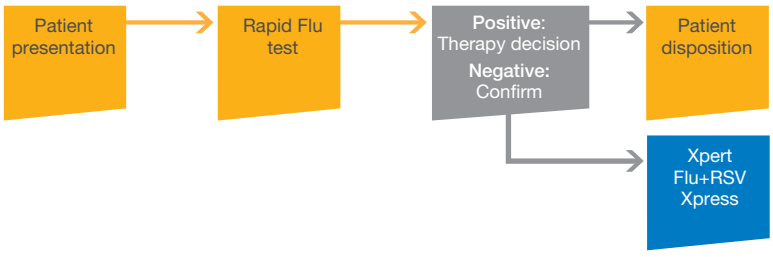
- CLIA-waived multiplex molecular Flu and RSV test
- Enables healthcare provider to quickly deliver targeted therapies
- Molecular (RT-PCR) is recommended as front line test or influenza diagnostics by the Infectious Disease Society of America[1]
- Rapid Flu Test (immunoassay-based) manufacturers recommend results be confirmed by RT-PCR[2,3]

WORKFLOWS

Xpress Workflow



Confirmatory Workflow



CPT Code	*2016 Medicare National Limit Amount^*
Molecular	
87631QW	$174.76
Rapid Immunoassay with Reflex to Molecular	
87804QW^	$16.33
87804QW-59#	$16.33
87631QW-59#	$174.76

WORKFLOW:

3 EASY STEPS TAKE LESS THAN A MINUTE

1. Collect Sample*

   **Sample container varies with test.*

2. Transfer sample to cartridge

3. Insert cartridge into GeneXpert System and start test

Ordering Information

CATALOG INFORMATION

TEST KITS:

Xpert CT/NG* (10 tests)	GXCT/NG-10
Xpert TV* (10 tests)	GXTV-10
Xpert GBS LB* (10 tests)	GXGBSLB-10
Xpert Flu/RSV XC* (10 tests)	GXFLU/RSV-10
Xpert Flu+RSV Xpress (10 tests)	GXFLU+RSV-XP-10

* Designed for use in POLs able to perform moderately complex non-waived tests.

^ 2016 Medicare National Limit Amount. Refer to http://www.cms.gov/Medicare/Medicare-Fee-for-Service-Payment/ClinicalLabFeeSched/clinlab.html for state-specific payment 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/FFSProvPartProg/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.

References:

1. Harper, et al. Seasonal Influenza in Adults and Children—Diagnosis, Treatment, Chemoprophylaxis, and Institutional Outbreak Management: Clinical Practice Guidelines of the Infectious Diseases Society of America. Clin Infect Dis. 2009 Apr 15;48(8):1003-32.
2. BD Veritor™ System – For Rapid Detection of Flu A+B [package insert]. DB. Dublin, Ireland. 2014.
3. Sofia Influenza A+B FIA [package insert]. Quidel. San Diego, CA. 2014.

For In Vitro Diagnostic Use.

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