On-Demand Molecular Testing for the Physician Office Laboratory

GeneXpert® System

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

1. Patient arrives for appointment
2. Physician consults with patient and collects sample
3. On-demand testing enable the lab to process samples in under 1 minute – less time than it takes to process a send-out
4. Ease of use makes in-house molecular testing feasible for the physician office lab without specialized training
5. 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”**

![Pathway Diagram]

**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

**CPT Code 2016 Medicare National Limit Amount**

<table>
<thead>
<tr>
<th>Test</th>
<th>CPT Code</th>
<th>Amount</th>
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<tbody>
<tr>
<td>CT</td>
<td>87491</td>
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**TV**

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## 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

<table>
<thead>
<tr>
<th>Specimen Swab &amp; LB</th>
<th>18 hrs</th>
<th>Incubate Blood Agar Plate (BAP)</th>
<th>48hrs</th>
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</thead>
<tbody>
<tr>
<td>Specimen Prep</td>
<td>19hrs</td>
<td>Confirm with Hemolysis or Latex Agglutination Test (LAT)</td>
<td>24hrs</td>
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<tr>
<td>Test &amp; Results</td>
<td>20hrs</td>
<td>Re-incubate BAP Confirm with Hemolysis or LAT</td>
<td>72hrs</td>
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</table>

#### Other NAAT

| Specimen Swab & LB | 18 hrs | Specimen Prep | 20 mins | Specimen Prep | 30 mins | Test & Results | 60+ mins |

#### Xpert GBS LB

| Specimen Swab & LB | 18 hrs | Specimen Prep | 1 min | Test & Results | 35-55 mins |

<table>
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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 America¹
- Rapid Flu Test (immunoassay-based) manufacturers recommend results be confirmed by RT-PCR²,³

WORKFLOWS

Xpress Workflow

<table>
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Confirmatory Workflow

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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

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:

For In Vitro Diagnostic Use.