



LAB - LINK

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As your laboratory partner,

Health Network Laboratories is

pleased to keep you

connected to new and updated

laboratory testing information.

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CPT (Current & Procedural Terminology) is a trademark of the AMA. Codes listed are guidelines and are for informational purposes only. Coding questions should be directed to the third party payor and/or the AMA. OIG guidelines recommend tests ordered should be reasonable and necessary for the patient, given their clinical condition. Physicians who order medically unnecessary tests for which Medicare reimbursement is claimed may be subject to penalties. Individual components of profiles or panels may be ordered individually at an additional charge. Physicians who consider Reflex testing unnecessary may order an initial test without the Reflexed test. Reflex or confirmation tests are performed at an additional charge.

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TEST CHANGE:

The following test change will be effective on the date indicated below. Please note that the changes are listed in Bold, italicized type. Additional information regarding the change will be provided where applicable.

Chlamydia trachomatis, Amplified DNA Probe	
Description of Change	New order code for Chlamydia trachomatis, Amplified DNA Probe (CTTMA)
Effective Date:	9/20/2011
Test Code:	CTTMA
CPT Code:	87491
Methodology:	GEN-PROBE® APTIMA® Amplified Deoxyribonucleic Acid (DNA) Probe, TIGRIS platform.
Testing Schedule:	Routine daily, Monday-Friday
Report Available:	1-4 days
Specimen Requirements:	<p>Minimum Volume: 1 swab from urethra OR 1 swab from endocervical canal OR 20-30 mL initial urine stream OR ThinPrep® Liquid Pap specimen. ThinPrep® Liquid Pap specimens go directly to Cytology Registration.</p> <p>Container:</p> <ul style="list-style-type: none"> • APTIMA™ transport swab OR GEN-PROBE® • APTIMA™ urine collection container <p>Collection:</p> <ul style="list-style-type: none"> • Follow instructions on collection kit package using ONLY the enclosed swab. • Endocervical sampling for N. gonorrhoeae and/or C. trachomatis: Remove excess mucus from cervix and surrounding mucosa using the white swab provided. Discard this swab. Insert the blue swab from collection kit 1-1.5 cm into endocervical canal. Gently rotate swab clockwise for 10-30 seconds in endocervical canal to ensure adequate sampling. Withdraw swab carefully; avoid any contact with vaginal mucosa. Remove the cap from the swab specimen transport tube and immediately place the specimen collection swab into the transport tube. Carefully break the swab shaft at the score line; use care to avoid splashing of contents. Re-cap the swab specimen transport tube tightly. • Urethral sampling for C. trachomatis and/or N. gonorrhoeae: Patient should not have urinated for a least 1 hour prior to sampling. Insert the blue swab 2-4 cm into urethra, gently rotate clockwise for 2-3 seconds to ensure contact with all urethral surfaces. Withdraw swab. Remove the cap from the swab specimen transport tube and immediately place the specimen collection swab into the transport tube. Carefully break the swab shaft at the score line; use care to avoid splashing of contents. Recap the swab specimen transport tube tightly. • Urine: Patient should not have urinated for at least 1 hour prior to specimen collection.

Specimen Requirements: (con't)	<ul style="list-style-type: none"> • Direct patient to provide first-catch urine (approximately 20 to 30 mL of initial urine stream) into a clean, dry container free of any preservative. Collection of larger volumes of urine may result in specimen dilution and may reduce test sensitivity. Female patients should not cleanse labial area prior to providing specimen. • Transport tube and transfer 2 mL of urine into specimen transport tube using disposable pipette provided. The correct volume of urine has been added when the fluid level is between black fill lines on the urine specimen transport tube label. • Tightly re-cap the urine specimen transport tube. • Urine specimens must be maintained at 2 C to 30 C in urine transport tube. • ThinPrep® Liquid Pap Specimens should be collected in the routine manner. Specimens must be run within 14 days of collection.
Special Instructions and/or Comments:	<ul style="list-style-type: none"> • DO NOT use for legal specimens, rectal, conjunctival or nasopharyngeal specimens. For these specimens, submit Chlamydia culture. • Conjunctival Specimens can also be ordered as Chlamydia trachomatis by DNA probe non-amplified (CTDNA). • Use only for urethral, endocervical, and urine specimens. • Transport at room temperature or refrigerated.
Reference Range:	Negative for Chlamydia trachomatis by Amplified DNA Probe.
Clinical Utility:	Useful in assessing presence of sexually transmitted diseases.
Additional Information:	<i>Chlamydia trachomatis, Amplified DNA Probe (CTMA) and Neisseria gonorrhoeae, Amplified DNA Probe (GCTMA) can be ordered on the same Accession Number.</i>

For more information, please contact Carol Beckwith at 877-402-4221



The information contained herein is based on a template provided to Molecular Diagnostics Alliance members by Roche Diagnostics for use in educating customers. Each member of the Molecular Diagnostics Alliance may modify the templates and information provided by Roche Diagnostics to meet its needs. Because this information was subject to modification over which Roche Diagnostics had no control, Roche Diagnostics disclaims any representations or warranties as to its accuracy or completeness. Questions about any of the materials provided herein should be directed to the Molecular Diagnostics Alliance member.

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TEST CHANGE:

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Neisseria gonorrhoeae, Amplified DNA Probe	
Description of Change	New order code for Neisseria gonorrhoeae, Amplified DNA Probe (GCTMA)
Effective Date:	9/20/2011
Test Code:	<i>GCTMA</i>
CPT Code:	87591
Alternate Name:	GC Amplified DNA;
Methodology:	<i>GEN-PROBE® APTIMA™ Amplified DNA Probe, TIGRIS platform</i>
Testing Schedule:	Routine Daily, Monday- Friday
Report Available:	1-4 days
Specimen Requirements:	<p><u>Minimum Volume:</u> 1 swab from urethra OR 1 swab from endocervical canal OR 20-30 mL initial urine stream OR ThinPrep® Liquid Pap specimen. ThinPrep® Liquid Pap specimens go directly to Cytology Registration.</p> <p><u>Container:</u> APTIMA™ transport swab OR GEN-PROBE® APTIMA™ urine collection container</p> <p><u>Collection:</u></p> <ul style="list-style-type: none"> • Follow instructions on collection kit package using ONLY the enclosed swab. • Endocervical sampling for N. gonorrhoeae and/or C. trachomatis: Remove excess mucus from cervix and surrounding mucosa using the white swab provided. Discard this swab. Insert the blue swab from collection kit 1-1.5 cm into endocervical canal. Gently rotate swab clockwise for 10-30 seconds in endocervical canal to ensure adequate sampling. Withdraw swab carefully; avoid any contact with vaginal mucosa. Remove the cap from the swab specimen transport tube and immediately place the specimen collection swab into the transport tube. Carefully break the swab shaft at the score line; use care to avoid splashing of contents. Re-cap the swab specimen transport tube tightly. • Urethral sampling for C. trachomatis and/or N. gonorrhoeae: Patient should not have urinated for at least 1 hour prior to sampling. Insert the blue swab 2-4 cm into urethra, gently rotate clockwise for 2-3 seconds to ensure contact with all urethral surfaces. Withdraw swab. Remove the cap from the swab specimen transport tube and immediately place the specimen collection swab into the transport tube. Carefully break the swab shaft at the score line; use care to avoid splashing of contents. Recap the swab specimen transport tube tightly. • Urine: Patient should not have urinated for at least 1 hour prior to specimen collection.

<p>Specimen Requirements: (con't)</p>	<ul style="list-style-type: none"> • Direct patient to provide first-catch urine (approximately 20 to 30 mL of initial urine stream) into a clean, dry container free of any preservative. Collection of larger volumes of urine may result in specimen dilution and may reduce test sensitivity. Female patients should not cleanse labial area prior to providing specimen. Transfer 2 mL of urine into specimen transport tube using disposable pipette provided. The correct volume of urine has been added when the fluid level is between black fill lines on the urine specimen transport tube label. Tightly re-cap the urine specimen transport tube. • Urine specimens must be maintained at 2 C to 30 C in urine transport tube. ThinPrep® Liquid Pap Specimens should be collected in the routine manner. Specimens must be run within 14 days of collection.
<p>Special Instructions and/or Comments:</p>	<ul style="list-style-type: none"> • DO NOT use for legal specimens, rectal, conjunctival or nasopharyngeal specimens. For these specimens, submit GC Culture. • Use only for urethral, endocervical and urine specimens. • Transport at room temperature or refrigerated.
<p>Reference Range:</p>	<p>Negative for <i>Neisseria gonorrhoeae</i> by Amplified DNA Probe.</p>
<p>Clinical Utility:</p>	<p>To aid in the assessment of sexually transmitted infections.</p>
<p>Additional Information:</p>	<p><i>Neisseria gonorrhoeae, Amplified DNA Probe (GCTMA) and Chlamydia trachomatis, Amplified DNA Probe (CTTMA) can be ordered on the same Accession Number.</i></p>

For more information, please contact Carol Beckwith at 877-402-4221



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TEST CHANGE:

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Hepatitis C Viral Load, RT-PCR	
Description of Change	Effective monitoring of Hepatitis C Virus (genotype 1) viral load during VICTRELIS™ (boceprevir) and INCIVEK™ (telaprevir) therapy.
Effective Date:	8/19/2011
Test Code:	HCVLD
CPT Code:	87522
Alternate Name:	<ul style="list-style-type: none"> • HCV Viral Load, • RT-PCR Hepatitis C Viral Load • Real Time RT-PCR
Methodology:	Real Time RT-PCR, COBAS®, Ampli Prep/COBAS® TaqMan® 48, FDA Approved
Testing Schedule:	Routine, 2 times per week
Report Available:	4-6 days
Specimen Requirements:	<p>Minimum Volume: 4 mL EDTA plasma</p> <p>Container: 2 White EDTA OR 2 Lavender top tubes, EDTA</p>
Special Instructions and/or Comments:	<ul style="list-style-type: none"> • DO NOT submit heparinized specimens. • Must be processed within 6 hours of collection. • Centrifuge white EDTA and refrigerate. • Centrifuge lavender EDTA, aseptically transfer plasma to plastic aliquot tube, freeze.
Reference Range:	<p>HCV RNA Not Detected: <7 IU/mL</p> <p>HCV RNA Not Detected: <0.85 log IU/mL</p>
Clinical Utility:	<p>Quantitates Hepatitis C Virus genotype 1 to LLoQ of 25 IU/mL and LOD of 7 IU/mL to monitor viral load in established Hepatitis C infected individuals during VICTRELIS™ and INCIVEK™ therapy.</p> <p>Quantitates Hepatitis C Virus genotypes 2 thru 6 to LLoQ 43 IU/mL and LOD of 18 IU/mL to monitor viral load in established Hepatitis C infected individuals.</p>
Additional Information	<p>Given the recent FDA approval of VITRELIS™ (boceprevir) and INCIVEK™ (telaprevir) indicated in combination with peg-interferon alpha and ribavirin for treatment of chronic Hepatitis C genotype 1 infections, viral load monitoring will play a significant role in the management of patients during these therapies. The clinical trials for both drugs involved HCV RNA testing with a lower limit of quantification (LLoQ) of 25 IU/mL and limit of selection (LOD) of 10 IU/mL. Laboratory testing recommendations for both drugs indicate a clinical assay used for patient management should have similar performance characteristics. HNL performs HCV RNA viral loads on the COBAS AmpliPrep/COBAS TaqMan HCV Test. This FDA approved assay has demonstrated in its own clinical trial a LLoQ of 43 IU/mL and a LOD of 7 IU/mL for HCV genotype 1.</p>

For more information, please contact Carol Beckwith at 877-402-4221

ADDITIONAL INFORMATION

LYME DISEASE TESTING

The CDC, ASTPHL, FDA, NIH, CSTE and NCCLS currently recommend a two-step process for diagnosis of Lyme disease. The first step uses an enzyme immunoassay (EIA). If the EIA is negative, no further testing of the specimen is recommended. If the EIA is positive or equivocal, a second test should be performed. The second step uses a Western immunoblot. Results are only considered positive if both the EIA and immunoblot are positive.

Lyme disease testing measures a person's antibody (or immune) response to the bacteria that causes Lyme disease, *Borrelia burgdorferi*. EIA tests are designed to be very "sensitive", meaning that when they are used properly, almost everyone with Lyme disease will test positive. It is also possible, however, to test positive with an EIA test even when you do not have Lyme disease. This can occur because of other medical conditions, including, but not limited to:

- Tick-borne relapsing fever
- Syphilis
- Anaplasmosis (formerly known as granulocytic ehrlichiosis)
- Leptospirosis
- Autoimmune disorders (some examples are: systemic lupus erythematosus, rheumatoid arthritis, patients with anti-nuclear antibodies)
- Bacterial endocarditis
- Infection with *Helicobacter pylori*, Epstein Barr virus, cytomegalovirus, Rocky Mountain Spotted Fever, tularemia or other viruses or bacteria can cause antibodies that will cross react
- Periodontal disease, or infection with *Treponema denticola*, a bacteria found in the mouth that can cause gum disease and/or infection after dental procedures
- Yaws
- Pinta
- Multiple sclerosis
- Amyotrophic lateral sclerosis

For this reason, any positive or equivocal EIA result must be confirmed by performing a western blot test.

The western blot also looks for antibodies, but western blots are specific for antibodies that the body makes against antigens that are part of the *Borrelia burgdorferi* bacteria. The test produces bands on a blot which represent the presence of antibodies to different components of the bacteria. The presence of one or two bands is not clinically relevant, but the combination of multiple, specific bands identify *Borrelia burgdorferi* infection.

Western blot tests for Lyme disease can detect two different classes of antibodies: IgM and IgG. IgM antibodies can be helpful for identifying patients during the first few weeks of infection. The downside of testing for IgM antibodies is that they are more likely to give false positive results especially in some patients such as those with the conditions listed above. Tests for IgG antibodies are more reliable, but

can take 4-6 weeks for the body to produce in large enough quantities for either the EIA or WB test to detect them.

WB results are interpreted in accordance with the criteria recommended by the CDC. For IgM blots at least 2 of the 3 following bands must be present: 24kDa, 39kDa and 41kDa. For IgG blots, at least 5 of the 10 following bands must be present: 18kDa, 21kDa, 28kDa, 30kDa, 39kDa, 41kDa, 45kDa, 58kDa, 66kDa and 93kDa.

A few notes to remember:

1. The immunoblot should not be run without first performing an EIA.
2. The immunoblot should not be run if the EIA is negative.
3. A positive IgM immunoblot is only meaningful during the first 4 weeks of illness.
4. For illnesses of longer than 4-6 week duration, if the IgG immunoblot is negative, it is unlikely to be Lyme disease, even if the IgM immunoblot is positive.

For more information, please contact Kim Pacella at 877-402-4221



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ADDITIONAL INFORMATION

MRSA SCREENING SPECIMEN COLLECTION

Health Network Laboratories is pleased to provide a new service for its clients.

Starting October 3, 2011, HNL's Patient Service Centers (PSC's) will be able to collect Methicillin Resistant Staph aureus (MRSA) screening specimens. Clients will now be able to send their patients to an HNL PSC to have the nasal swab specimen collected.

The MRSA screening test is used to actively look for MRSA colonization in patients in order to reduce the risk of potential transmission and infection. An MRSA screen looks solely for the presence of MRSA and no other pathogens. Colonization is the presence or growth of bacteria on or in the body; those who are colonized may or may not develop an infection and/or may spread the bacteria to others, in whom the bacteria may cause disease. An MRSA screening test may be ordered when a doctor or hospital wants to evaluate potential MRSA colonization in an individual, their family members, and/or a group of people in the community as the source of a MRSA infection. MRSA screening may also be a part of routine preoperative screening and decolonization of orthopedic and open heart surgery patients.

The MRSA screen specimen is tested using a real-time polymerase chain reaction (PCR) assay (nucleic acid amplified probe). The test code is MRSAS.

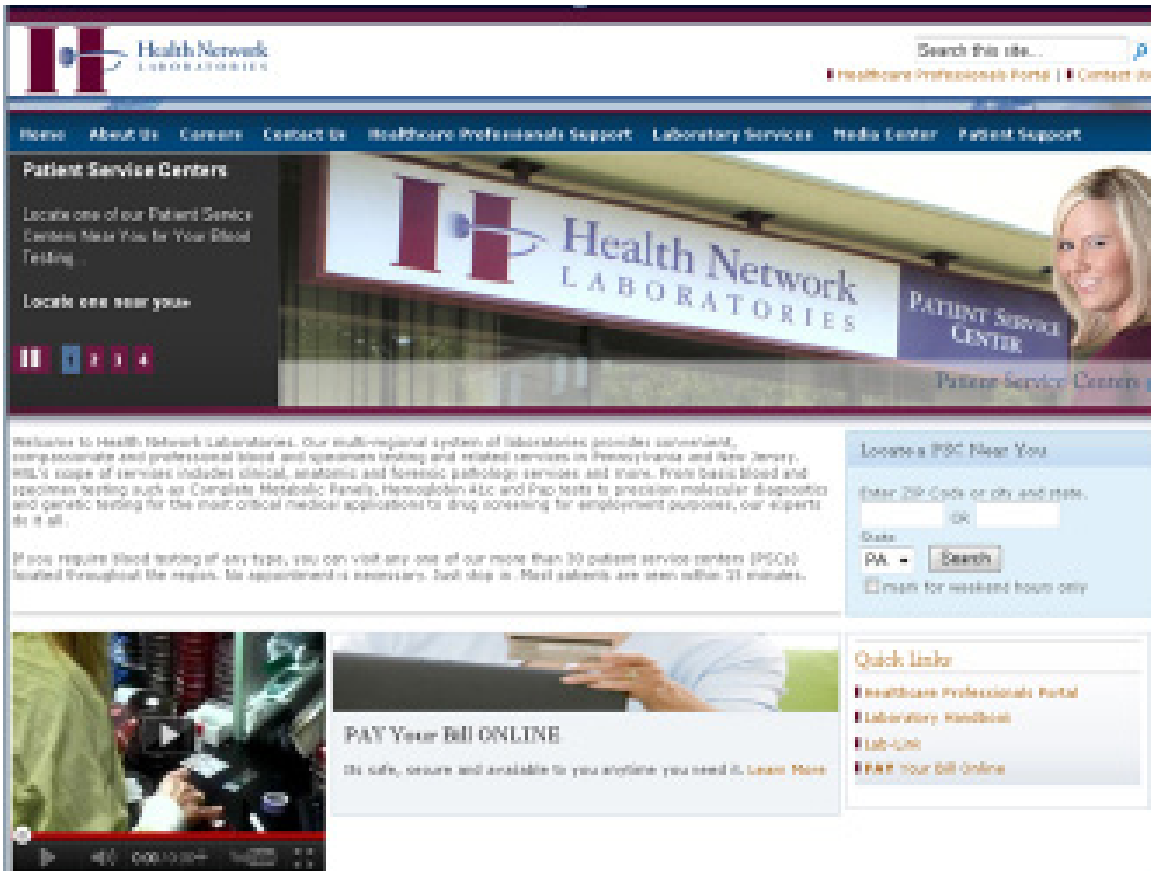
The specimen is collected by taking a swab of the anterior nares with a CultureSwab (red capped swab). The specimen will be collected as follows:

1. After opening the CultureSwab package, one of the swabs is discarded.
2. The remaining swab is carefully inserted into the patient's nostril (the swab tip must be inserted up to 1 inch from the edge of the nares).
3. The swab is rolled along the mucosa inside the nostril 5 times.
4. The same swab is inserted into the second nostril and sampling repeated as in steps 2 and 3.
5. The swab is replaced into its transport tube and sent to the clinical lab for testing.
6. The results will be available the next day.

For more information, please contact Customer Care at 877-402-4221

ADDITIONAL INFORMATION

On October 10th, HNL will be updating its web site:



In addition to a new home page with better graphics and easier navigation, there are two new features in particular we want to bring to your attention. The first is for patients who have a balance due because of an out-of-pocket deductible or a “patient balance bill” directive from the patient’s insurance provider will now be able to pay HNL on-line.

The other new feature is the Client Portal. The portal is a secure area where you will be able to maintain your client profile, communicate with us changes to your profile; order supplies and monitor your supply ordering history; and place test orders and/or access lab results through HNL’s internet based services such as Rapid Labs™ Reports, Web E/R, or Fast Orders. The portal will add an additional layer of security for patient information and laboratory results.

We are excited about the new layout and additional functionalities and welcome your comments.