



LAB - LINK

VOLUME 5 • April 2011

Health Network Laboratories
2024 Lehigh Street
Allentown, PA 18103
877-402-4221 • www.healthnetworklabs.com

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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NEW TEST

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NEW TEST:

HNL is pleased to expand our testing menu to include the following test.

HunterHeart Panel	
Effective Date:	02/25/2011
Test Code:	HHP
Includes:	Cholesterol, Total; DL, Cholesterol; LDL, Cholesterol; VLDL, Calculation; Non – HDL, Cholesterol; Cholesterol/HDL Ratio; Triglycerides; Lp – PLA2; Lipoprotein a; Apolipoprotein ; sd – LDL; HDL2B; Apo E Genotype; CRP, High Sensitivity; Homocysteine; Vitamin D3, 25 – OH; Vitamin D2, 25 – OH; Vitamin D, Total 25 – OH; Factor V Mutation; TSH; Insulin; Glucose; Alkaline Phosphatase; AST; Bilirubin, Total; BUN; Creatinine; GFR, Calculated; Fibrinogen
CPT Code:	80061, 82172, 82248, 82306, 82565, 82664, 82947, 83090, 83525, 83695, 83698, 83701, 83890, 83891, 83896(x10), 83898(x3), 83908(x2), 83912(x2), 84075, 84443, 84450, 84520, 85384, 86141
Methodology:	See individual test listings.
Testing Schedule:	Daily
Report Available:	14 days (maximum)
Specimen Requirements:	Container: 4 Gold top tubes, serum separator 1 Blue top tube, sodium citrate 2 Lavender tubes, EDTA 1 Lavender tube, EDTA, placed immediately on wet ice until processing is performed.
Special Instructions and/or Comments	Patient should be fasting for 12 – 14 hours. <u>Gold top tubes, serum separator:</u> <ul style="list-style-type: none"> ▪ Centrifuge tubes. ▪ Refrigerate 3 of the 4 tubes. ▪ From the 4th tube, transfer a minimum of 2 mL's of serum into a properly labeled aliquot tube. ▪ The aliquot tube must indicate the sample is serum. ▪ Refrigerate the aliquot tube with the other refrigerated samples from this patient. <u>Blue top tube, sodium citrate:</u> <ul style="list-style-type: none"> ▪ Centrifuge sample. ▪ Remove plasma and transfer plasma into a properly labeled aliquot tube. ▪ The aliquot tube must indicate the sample is citrated plasma. ▪ Freeze the aliquot tube. ▪ Sample should remain frozen till testing can be performed. <u>2 Lavender tubes, EDTA: DO NOT process. Refrigerate samples</u> <u>1 Lavender tube, EDTA, placed immediately on wet ice. Keep sample cold prior to centrifugation.</u> <ul style="list-style-type: none"> ▪ Centrifuge sample. ▪ Immediately remove the plasma and transfer plasma into a properly labeled aliquot tube. ▪ The aliquot tube must indicate the sample is EDTA plasma. ▪ Freeze the aliquot tube immediately. ▪ Sample should remain frozen till testing can be performed.
Reference Range:	See individual test listings.
Critical Values:	See individual test listings.
Clinical Utility:	Provide a patient's risk assessment for cardiovascular disease, secondary dyslipidemias and metabolic syndrome.

For more information, please contact Melanie Ritter at 877-402-4221.

NEW TEST:

HNL is pleased to expand our testing menu to include the following test.

HunterHeart Metabolic Panel	
Effective Date:	02/25/2011
Test Code:	HHMP
Includes:	Cholesterol, Total; HDL, Cholesterol; LDL, Cholesterol; Non – HDL, Cholesterol; VLDL, Calculation; Cholesterol/HDL Ratio; Triglycerides; Lp – PLA2 ; Lipoprotein a; Apolipoprotein B; sd – LDL; HDL2B; CRP, High Sensitivity; Homocysteine ; Vitamin D3, 25 – OH ; Vitamin D2, 25 – OH ; Vitamin D, Total 25 – OH; TSH; Insulin; Glucose; Alkaline Phosphatase; AST; Bilirubin, Total; BUN; Creatinine; GFR, Calculated; Fibrinogen
CPT Code:	80061, 82172, 82248, 82306, 82565, 82664, 82947, 83090, 83525, 83695, 83698, 83701, 84075, 84443, 84450, 84520, 85384, 86141
Methodology:	See individual test listings.
Testing Schedule:	Daily
Report Available:	14 days (maximum)
Specimen Requirements:	Container: 4 Gold top tubes, serum separator 1 Blue top tube, sodium citrate 1 Lavender tube, EDTA, placed immediately on wet ice until processing is performed.
Special Instructions and/or Comments	<p>Patient should be fasting for 12 – 14 hours.</p> <p><u>Gold top tubes, serum separator:</u></p> <ul style="list-style-type: none"> ▪ Centrifuge tubes. ▪ Refrigerate 3 of the 4 tubes. ▪ From the 4th tube, transfer a minimum of 2 mL's of serum into a properly labeled aliquot tube. ▪ The aliquot tube must indicate the sample is serum. ▪ Refrigerate the aliquot tube with the other refrigerated samples from this patient. <p><u>Blue top tube, sodium citrate:</u></p> <ul style="list-style-type: none"> ▪ Centrifuge sample. ▪ Remove plasma and transfer plasma into a properly labeled aliquot tube. ▪ The aliquot tube must indicate the sample is citrated plasma. ▪ Freeze the aliquot tube. ▪ Sample should remain frozen till testing can be performed. <p><u>1 Lavender tube, EDTA, placed immediately on wet ice. Keep sample cold prior to centrifugation.</u></p> <ul style="list-style-type: none"> ▪ Centrifuge sample. ▪ Immediately remove the plasma and transfer plasma into a properly labeled aliquot tube. ▪ The aliquot tube must indicate the sample is EDTA plasma. ▪ Freeze the aliquot tube immediately. ▪ Sample should remain frozen till testing can be performed.
Reference Range:	See individual test listings.
Critical Values:	See individual test listings.
Clinical Utility:	Provide a patient's risk assessment for cardiovascular disease, secondary dyslipidemias and metabolic syndrome.

For more information, please contact Melanie Ritter at 877-402-4221.

NEW TEST:

HNL is pleased to expand our testing menu to include the following test.

HunterHeart Follow-Up Panel	
Effective Date:	02/25/2011
Test Code:	HHFP
Includes:	Cholesterol, Total; HDL, Cholesterol; LDL, Cholesterol; Non – HDL, Cholesterol ; VLDL, Calculation; Cholesterol/HDL Ratio; Triglycerides ; Lp – PLA2 ; Lipoprotein a ; Apolipoprotein B; sd – LDL ; HDL2B ; CRP, High Sensitivity ; Homocysteine ; Vitamin D3, 25 – OH ; Vitamin D2, 25 – OH ; Vitamin D, Total 25 – OH
CPT Code:	80061, 82172, 82306, 82664, 83090, 83695, 83698, 83701, 86141
Methodology:	See individual test listings.
Testing Schedule:	Daily
Report Available:	14 days (maximum)
Specimen Requirements:	Container: 4 Gold top tubes, serum separator 1 Lavender tube, EDTA, placed immediately on wet ice until processing is performed.
Special Instructions and/or Comments	<p>Patient should be fasting for 12 – 14 hours.</p> <p><u>Gold top tubes, serum separator:</u></p> <ul style="list-style-type: none"> ▪ Centrifuge tubes. ▪ Refrigerate 3 of the 4 tubes. ▪ From the 4th tube, transfer a minimum of 2 mL's of serum into a properly labeled aliquot tube. ▪ The aliquot tube must indicate the sample is serum. ▪ Refrigerate the aliquot tube with the other refrigerated samples from this patient. <p><u>Blue top tube, sodium citrate:</u></p> <ul style="list-style-type: none"> ▪ Centrifuge sample. ▪ Remove plasma and transfer plasma into a properly labeled aliquot tube. ▪ The aliquot tube must indicate the sample is citrated plasma. ▪ Freeze the aliquot tube. ▪ Sample should remain frozen till testing can be performed. <p><u>1 Lavender tube, EDTA, placed immediately on wet ice. Keep sample cold prior to centrifugation.</u></p> <ul style="list-style-type: none"> ▪ Centrifuge sample. ▪ Immediately remove the plasma and transfer plasma into a properly labeled aliquot tube. ▪ The aliquot tube must indicate the sample is EDTA plasma. ▪ Freeze the aliquot tube immediately. ▪ Sample should remain frozen till testing can be performed.
Reference Range:	See individual test listings.
Critical Values:	See individual test listings.
Clinical Utility:	Provide a patient's risk assessment for cardiovascular disease, secondary dyslipidemias and metabolic syndrome.

For more information, please contact Melanie Ritter at 877-402-4221.

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.

Lead, Whole Blood	
Description of Change:	New CDC guidelines for pediatric levels caused change in reference range
Effective Date:	03/ 02/2011
Test Code:	LEAD
CPT Code:	83655
Alternate Name:	Pb, Blood
Methodology:	Anodic stripping voltametry (ASV)
Testing Schedule:	Routine, 2 times per week
Report Available:	1-3 days
Specimen Requirements:	<p><u>Minimum Volume:</u> 1 full lavender top, EDTA BD Microtainer™ tube 3 mL whole blood, 1 full Royal Blue top, trace metal tube, lavender label OR lavender top, EDTA OR half-full lavender top, EDTA BD Microtainer™ tube</p> <p><u>Container:</u> NOTE: If unable to collect a full Royal Blue top, trace metal tube, please collect in Microtainer™ tube.</p> <p><u>Collection:</u></p> <ul style="list-style-type: none"> • Wash venipuncture site thoroughly with soap and water. • Dry thoroughly with clean disposable towel.
Reference Range:	<p><i><u>Blood Lead Reference Ranges:</u></i> <i>Birth to 6 years: <5 ug/dL</i> <i>> 6 years: <10 ug/dL</i> <i>Blood lead levels in the range of 5-9 ug/dL have been associated with adverse health effects in children aged 6 years and younger. Refer to current CDC guidelines for recommended interventions.</i> <i>For OSHA occupational monitoring, workers with whole blood lead levels at or above 40 ug/dL should be referred to a physician for medical evaluation and follow-up.</i></p>
Clinical Utility:	Detecting lead toxicity.

For more information, please contact Joann Sell at 877-402-4221.

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.

Hepatitis C Antibody Profile	
Description of Change:	The HCV confirmatory test is changing from RIBA to RNA quantitation by PCR.
Effective Date:	03/02/2011
Test Code:	HCP
Includes:	<ul style="list-style-type: none">• <i>Hepatitis C (HCV) Antibody Screen</i>• <i>Reflexed when appropriate:HCV RNA Quantitation by PCR</i>
CPT Code:	<i>86803, Reflexed when appropriate: 87522</i>
Alternate Name:	<ul style="list-style-type: none">• Anti-HCV• HCV Antibodies• HCV Serology
Methodology:	<ul style="list-style-type: none">• <i>HCV Antibody Screen: Chemiluminescent Microparticle Enzyme Immunoassay (CMIA)</i>• <i>Reflex Confirmation: HCV RNA quantitation by PCR</i>
Testing Schedule:	Routine, 5 times per week
Report Available:	<i>2-4 days (may be extended if reflex required)</i>
Specimen Requirements:	Minimum Volume: 2 mL serum Container: Gold top tube, serum separator
Special Instructions and/or Comments	The Department of Health requires mandatory reporting of any confirmed positive result.
Reference Range:	<i>Negative: no antibody detected.</i> <i>NOTE: Repeatedly reactive screens S/Co < 3.9 will automatically be confirmed</i>
Clinical Utility:	<i>Assess exposure to hepatitis C virus infection. HCV antibodies are typically not detected until approximately 14 weeks after exposure (or 5 weeks after appearance of the first biochemical marker of illness); absence of these antibodies after this period is strong evidence against HCV infection. Confirmatory testing is recommended for all 'weakly reactive' EIA samples (i.e. S/Co < 3.9).</i>

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

ADDITIONAL INFORMATION

Lab Link Going Green

Health Network Laboratories believes in working in concert with the environment. We have a robust recycling program for paper, plastic and other materials, and are adding hybrid cars to our courier fleet. To further support our conservation efforts, we are offering the opportunity of receiving *Lab Links* electronically instead of paper.

If you would like to begin receiving these bi-monthly updates electronically, please send an e-mail to info@healthnetworklabs.com providing the names and e-mail addresses of those in your office or practice that would like to take advantage of this distribution alternative.

Also as a reminder, all of our *Lab Links* are accessible on the “Quick Links” section of our web site at www.healthnetworklabs.com.

If you have any questions, please contact Customer Care at (610) 402-8150.

ADDITIONAL INFORMATION

Her-2/neu Test Change

On April 4, 2011, Health Network Laboratories began performing chromogenic in situ hybridization (CISH) for Her-2/neu detection on cases with equivocal (2+) staining by immunohistochemical analysis (IHC). The CISH methodology replaced fluorescence in situ hybridization (FISH).

CISH is a process in which a labeled complementary DNA or RNA strand is used to localize a specific DNA or RNA sequence in a tissue specimen and is a favored alternative to FISH. CISH has several advantages over FISH including the use of an ordinary microscope; the method is less cumbersome and more economical; the signal intensity is permanent; and pathologists are able to correlate findings with the underlying tumor histomorphology. CISH allows observers to select fields of invasive ductal carcinoma, avoiding foci of intraductal carcinoma for which Her-2/neu has a different clinical significance.

The reporting of CISH results is slightly different from FISH reporting. Namely, a test for chromosome 17 aneuploidy (CEP17) is not performed with CISH so there is no ratio reported. Rather, cases will be reported based upon the number of Her-2/neu signals present within neoplastic cells as follows:

Negative	<4 signals
Equivocal	4-6 signals
Positive	> 6 signals

Recent studies have shown that complete chromosome 17 polysomy is rare, and that an increase in CEP17 copy number in FISH analysis is most often due to aneusomy of 17q or amplification of the centromeric region of chromosome 17. Further, it has been shown that in Her-2/neu non-amplified tumors showing an increased number of CEP17 signals/nucleus, the Her-2/neu gene copy number usually falls in the equivocal range of 4-6. As with FISH, any case that has an equivocal result on the initial count (30 nuclei) will have an additional 30 nuclei counted and the reported result will be based upon the average for the total 60 nuclei count. HNL will be using the "SPOT-Light® HER2 CISH Kit", which is FDA approved as an aid in the assessment of patients for whom Herceptin® (trastuzumab) treatment is being considered.

If you have any questions, please contact Kathy Lezzeni at 877-402-4221.

REFERENCES:

1. Gong Y, et.al. Performance of Chromogenic in-situ hybridization on testing HER2 status in breast carcinomas with chromosome 17 polysomy and equivocal (2+) HercepTest results. Am J Clin Pathol 2009; 132: 228-236.
2. Hanna WM and Kwok K. Chromogenic in-situ hybridization: a viable alternative to fluorescence in-situ hybridization in the HER2 testing algorithm. Modern Pathology 2006; 19: 481-487.
3. Interpretation guide from SPOT-Light Her2 CISH Kit (Invitrogen)
4. Wolff A, et. al. ASCO/CAP Guideline Recommendations for HER2 Testing in Breast Cancer, J. Clin. Oncol. 25(1), 2007.

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ADDITIONAL INFORMATION

Critical Value Changes

Please note revisions to several critical laboratory value ranges. These changes will go into effect on **April 19, 2011**. The revised critical values can also be viewed on-line in the General Information section of the Laboratory Handbook using the Quick Links feature on Health Network Laboratories' home page, www.healthnetworklabs.com.

Revised Laboratory Critical Value Ranges

Analyte	Low Limit	High Limit
Calcium	< 6.0 mg/dL	> 13.0 mg/dL
Calcium, Ionized	< 3.0 mg/dL	
CO2 content		no limit
Creatinine		no limit
Hematocrit	no limit	no limit
Hemoglobin		>60 Days: > 21.0 g/dL
Phosphorus		> 8.0 mg/dL
Platelets	< 30 thousand/ μ L (10^9 /L)	> 1000 thousand/ μ L (10^9 /L)
PT		no limit
WBC		> 30.0 thousand/ μ L (10^9 /L)

If you have any questions, please contact Customer Care at 877- 402-4221.

ADDITIONAL INFORMATION

CDC Recommended Best Practices for Health Care Professionals on the Use of Polymerase Chain Reaction (PCR) for Diagnosing B. pertussis

Due to its continued resurgence, health care professionals will likely see more patients with suspected B. pertussis. The following CDC defined 'best practices' will help health care professionals optimize the use of PCR testing for pertussis by avoiding inhibiting factors leading to inaccurate results.

Recommendations for Testing:

- Only patients with signs and symptoms consistent with pertussis should be tested by PCR to confirm the diagnosis.
- Whenever possible, patients should be tested during the first three weeks of cough when bacterial DNA is still present in the nasopharynx to decrease the risk of a false negative result.
- Obtain specimens for PCR testing by aspiration or swabbing the posterior nasopharynx, not the throat or anterior nares.
- Acceptable specimen types for pertussis PCR testing include nasopharyngeal swabs (flocked swab) in Universal Transport Media (UTM) or nasopharyngeal aspirates. The UTM with Flocked swab is the same collection kit that is used for collecting Influenza/viral specimens and can be obtained from HNL.
- The swab shaft should be handled with care and only above the indentation on the shaft which marks where the swab is snapped off after the insertion into the UTM.
- Certain pertussis vaccines have been found to contain PCR-detectable B. pertussis DNA, as evidenced by environmental sampling in health care clinics. Accidental transfer of the DNA from environmental surfaces to the clinical specimen can result in specimen contamination and a false-positive result.

Best Practices for Preparing and Administering Vaccines

Take care to avoid contamination of surfaces when preparing and administering vaccines, which should be done in areas separate from specimen collection areas. This may reduce the possibility of cross contamination of clinical specimens.

Adhere to Basic Infection-control Measures

- Wear clean gloves for each specimen collection or vaccine preparation and administration. Immediately dispose of the gloves after each procedure.
- Clean the used surfaces with a 10% bleach solution to reduce the amount of nucleic acid in the environment.

For the entire guidance on PCR best practices in diagnosing B. pertussis, please use the following link:

<http://www.cdc.gov/pertussis/clinical/diagnostic-testing/diagnosis-pcr-bestpractices.html>.

For additional information regarding B. pertussis PCR testing at HNL please contact: Carol Beckwith, Manager Molecular Diagnostics @ 610-402-8170.