Health Network LABORATORIES®

LAB-LINK

VOLUME 3 • December 2016

For the most up-to-date test information, visit our online handbook at HealthNetworkLabs.com

As your laboratory partner,

Health Network Laboratories is

pleased to keep you

connected to new and updated

laboratory testing information.

In This Issue

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.

Health Network Laboratories
794 Roble Road
Allentown, PA 18109-9110

Health Network LABORATORIES®
794 Roble Road • Allentown, PA • 18109-9110
Toll Free 1-877-402-4221
HealthNetworkLabs.com

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

HCV NS5A Resistance Assay (NS5A)	
Effective Date:	10/26/2016
Alternate Name:	• Hepatitis C Virus (HCV) NS5A Drug Resistance Assay • NS5A Drug Resistance Assay
Suggested CPT Code:	87900, 87902
Methodology:	Polymerase Chain Reaction (PCR) amplification and DNA next generation sequencing
Testing Schedule:	Routine, daily
Report Available:	9-12 days
Specimen Requirements:	Minimum Volume: 2 mL EDTA plasma Container: 2 White top tubes, EDTA PPT
Special Instructions and/or Comments:	• Centrifuge specimens within 6 hours of collection and freeze. • Once frozen, transport specimens submerged in dry ice.
Reference Range:	Accompanies report
Clinical Utility:	Useful for assessment of drug susceptibility by nucleic acid sequencing of a patient's hepatitis C virus (HCV) to the NS5A inhibitors. Assay should be used for patients with documented HCV genotype 1a or 1b. This assay may be unsuccessful when the HCV viral load is <500 IU/mL

For more information, please contact Gayle McCarthy at 877-402-4221.

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NEW TEST:
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HCV NS5B Drug Resistance Assay (NS5B)	
Effective Date:	10/26/2016
Alternate Name:	• Hepatitis C Virus (HCV) NS5B Drug Resistance Assay • NS5B Drug Resistance Assay
Suggested CPT Code:	87900, 87902
Methodology:	Polymerase Chain Reaction (PCR) amplification and DNA next generation sequencing.
Testing Schedule:	Routine, daily
Report Available:	9-12 days
Specimen Requirements:	Minimum Volume: 2 mL EDTA plasma Container: 2 White top tubes, EDTA PPT
Special Instructions and/or Comments:	• Centrifuge specimens within 6 hours of collection and freeze. • Once frozen, transport specimens submerged in dry ice.
Reference Range:	Accompanies report
Clinical Utility:	Useful for assessment of drug susceptibility by nucleic acid sequencing of a patient's hepatitis C virus (HCV) to the NS5B inhibitors. Assay should be used for patients with documented HCV genotype 1a or 1b. This assay may be unsuccessful when the HCV viral load is <1000 IU/mL

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

BRAF Mutation Detection	
Effective Date:	12/01/2016
Includes:	BRAF Mutations Tested: • Codon 600 • V600E • V600D • V600K
Suggested CPT Code:	81210
Methodology:	Real Time Polymerase Chain Reaction, RT-PCR
Testing Schedule:	Routine, Monday-Friday
Report Available:	5-10 days
Specimen Requirements:	Container: Formalin-fixed paraffin embedded tissue, FFPE Collection: FFPE Tumor Tissue
Special Instructions and/or Comments:	Protect FFPE Block from excessive heat.
Reference Range:	Mutation Not Detected.
Clinical Utility:	The BRAF gene encodes a serine/threonine protein kinase which plays a key role in regulating the MAPK/ERK signaling pathway, affecting cell growth, differentiation and proliferation. Codon 600 in exon 15 of the gene is frequently mutated in various cancers. The mutations result in a constitutively active form of the protein that may lead to cancer progression. Studies have shown that patients with advanced melanoma that harbor BRAF codon 600 mutations are likely to experience clinical benefit from kinase inhibitor drugs that target the mutant variants of the protein. BRAF mutations also may occur in patients with colorectal cancer that lack other driver mutations, such as KRAS and EGFR. The intended use of this assay is to aid the treating physician in the selection of the appropriate therapy for the patient.

For more information, please contact Nancy Holihan at 877-402-4221

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NEW TEST:
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EGFR Mutation Test	
Effective Date:	12/01/2016
Includes:	EGFR Mutations Tested: • Exon 18 : G719A, G719C, G719S • Exon 19 : deletions and complex mutations • Exon 20 : S768I, T790M and insertions • Exon 21 : L858R, L861Q
Suggested CPT Code:	81235
Methodology:	Microdissection of the tumor area of patient FFPE block, followed by cell lysis and DNA extraction. Real-time PCR for the qualitative detection of defined mutations of the epidermal growth factor receptor (EGFR) gene from non-small cell lung cancer (NSCLC) patients.
Testing Schedule:	Routine, Monday - Friday
Report Available:	5 - 10 Days
Specimen Requirements:	Container: Formalin fixed Paraffin Embedded Tissue, FFPE Tissue Block Collection: FFPE Tumor Tissue
Special Instructions and/or Comments:	Protect FFPE Block from extreme heat.
Reference Range:	Mutation Not Detected.
Clinical Utility:	The test is intended to aid in identifying patients with NSCLC whose tumors have defined EGFR mutations and for whom safety and efficacy of a drug have been established.

For more information, please contact Nancy Holihan at 877-402-4221.

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NEW TEST:
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NRAS Mutation Detection	
Effective Date:	04/02/2013
Includes:	NRAS Mutations Tested: • Exon 2 (codons 12 and 13) • Exon 3 (codon 59 and 61) • Exon 4 (codon 117 and 146)
Suggested CPT Code:	81311
Methodology:	Real Time Polymerase Chain Reaction, RT-PCR
Testing Schedule:	Routine, Monday - Friday
Report Available:	5-10 days
Specimen Requirements:	Container: Formalin fixed paraffin embedded tissue, FFPE tissue block Collection: FFPE Tumor Tissue
Special Instructions and/or Comments:	Protect FFPE block from excessive heat.
Reference Range:	Mutation Not Detected.
Clinical Utility:	NRAS is a member of the RAS family of small GTPases that are central components of growth factor receptor signaling. Mutations that render these GTPases constitutively active have been implicated in various cancers. Tumors harboring an NRAS mutation show relative insensitivity to anti-tyrosine kinase receptor therapies that signal through the RAS/RAF pathway. Clinical studies have shown that tumors carrying activating mutant variants of the RAS genes are less responsive to epidermal growth factor receptor (EGFR) inhibition. The intended use of this assay is to aid the treating physician in the selection of the appropriate therapy for the patient. The results of this study are to be interpreted in context with other clinical and histological findings of the patient.

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NEW TEST:
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KRAS Mutation Detection	
Effective Date:	12/01/2016
Includes:	KRAS Mutations Tested: • Exon 2 (codons 12 and 13) • Exon 3 (codon 59 and 61) • Exon 4 (codon 117 and 146)
Suggested CPT Code:	81275, 81276
Methodology:	Real Time Polymerase Chain Reaction, RT-PCR
Testing Schedule:	Routine, Monday - Friday
Report Available:	5 - 10 Days
Specimen Requirements:	Container: Formalin-fixed paraffin embedded tissue, FFPE Collection: FFPE Tumor Tissue
Special Instructions and/or Comments:	Protect FFPE block from excessive heat.
Reference Range:	Mutation Not Detected.
Clinical Utility:	The intended use of this assay is to aid the treating physician in the selection of the appropriate therapy for the patient. Tumors harboring a KRAS mutation show relative insensitivity to anti-tyrosine kinase receptor therapies that signal through the RAS/RAF pathway. The results of this study are to be interpreted in context with other clinical and histological findings of the patient.

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NEW TEST:
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HCV Genotype with NS5A Reflex (HCV1A)	
Effective Date:	11/15/2016
Includes:	Hepatitis C Virus Genotyping. HCV 1a genotypes will reflex to NS5A resistance testing.
Suggested CPT Code:	87902
Methodology:	Reverse Transcription Polymerase Chain Reaction (RT-PCR) followed by solid phase electrochemical methodology .
Testing Schedule:	Routine, Monday - Friday
Report Available:	4-6 Days
Specimen Requirements:	Minimum Volume: 3 mL EDTA plasma Container: 3 White Top Tubes, EDTA OR 3 Lavender Top Tubes, EDTA
Special Instructions and/or Comments:	• Freshly drawn specimens may be stored at 2 - 8°C for up to 24 hours prior to centrifugation. • For **WHITE TOP EDTA TUBES**: Centrifuge specimen for 20 minutes at 800-1600xg (3000rpm) within 24 hours of collection. Do not aliquot. Freeze one tube. Refrigerate remaining tubes. • For **LAVENDER TOP EDTA TUBES**: Centrifuge specimen for 20 minutes at 800-1600xg (3000rpm) within 24 hours of collection. Transfer plasma to plastic aliquot tube. Freeze plasma from one tube. Refrigerate remaining plasma.
Reference Range:	HCV Genotype: 1a, 1b, 2a/c, 2b, 3, 4, 5, 6
Clinical Utility:	NS5A polymorphisms are associated with resistance to NS5A inhibitor therapy in patients with Hepatitis C virus (HCV) Genotype 1a. Patients shown to be infected with HCV Genotype 1a should be tested for NS5A Drug Resistance.

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NEW TEST:
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H Pylori Stool Antigen (HPSAG)	
Effective Date:	8/01/2016
Includes:	Stool assay for H pylori antigen
Alternate Name:	• HPSA • Helicobacter pylori stool antigen
Suggested CPT Code:	87338
Methodology:	Lateral Flow Immunoassay
Testing Schedule:	Monday - Friday
Report Available:	1 to 3 days
Specimen Requirements:	Minimum Volume: 0.5 mL or 0.5 grams of semi-solid or liquid stool or 20 mm diameter solid stool. Container: Plastic, leak-proof container. **Do not place stool in preservative, transport media or swab.**
Special Instructions and/or Comments:	• Specimen should be transported in an airtight container and stored at 2-8 C until tested. • Specimen may be held refrigerated for up to 72 hours. • If testing will not occur within 72 hours specimen can be frozen for up to 30 days.
Reference Range:	Not detected
Clinical Utility:	Colonization with H. pylori is associated with increased risk of patients developing gastritis, peptic ulcer disease, and gastric adenocarcinoma. Stool antigen testing provides a sensitive measure of infection including during and after treatment. The AGA and ACG guidelines do not recommend the use of serology-based tests for the diagnosis of H. pylori infection. The guidelines recommend test, treat and retest to confirm eradication with an Active Infection Test prior to prescribing a Proton Pump Inhibitor (PPI) and for patients under the age of 55, with no alarm symptoms. The HPSAG assay used by Health Network Laboratories is a noninvasive stool test that will detect active infections, is one of the tests recommended by the guidelines and is adopted by Health Plans nationwide. Patients of all ages can be tested for active infection using the HPSAG with no risk of side effects. References: Guidelines from the American Gastroenterological Association (AGA) and the American College of Gastroenterology (ACG)

For more information, please contact Georgia Colasante at 877-402-4221.

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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.

Protein Electrophoresis, Urine (UPRE)	
Description of Change	A total protein will be added to any 24 hour urine sample with a monoclonal protein present
Effective Date:	12/01/2016
Includes:	• ***Pathologist's Interpretive Report*** • ***Reflexed when appropriate:*** ***Urine immunoelectrophoresis*** ***Total protein***
Suggested CPT Code:	84166, 84166-26, reflex 84155
Methodology:	Agarose Electrophoresis Gel
Testing Schedule:	Routine, 3-5 times per week
Report Available:	4-7 days
Specimen Requirements:	Minimum Volume: 20-40 mL random urine OR Entire 24-Hour urine collection Container: Plastic urine container OR 24 hour urine container, no preservatives
Reference Range:	No suggestion of monoclonal protein.
Clinical Utility:	Useful for monitoring patients with monoclonal gammopathies.

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

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TEST CHANGE:
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Monoclonal Gammopathy Screening Profile (MGSP)	
Description of Change	Reflex algorithm and test methodology are being updated. Please refer to the algorithm section of the handbook.
Effective Date:	12/01/2016
Includes:	• Serum Protein Electrophoresis • Serum Free Light Chain Profile • Reflexed when appropriate: Immunoglobulin G, A, M Serum Protein Immunofixation
Suggested CPT Code:	84155, 84165, 84165-26, 83520(x2) reflex 82784 x3, 86334, 86334-26
Methodology:	***Electrophoresis Turbidometry***
Testing Schedule:	See individual test listings
Report Available:	4-7 days
Specimen Requirements:	Minimum Volume: 4 mL serum Container: 2 Gold top tubes, serum separator
Reference Range:	See individual test listings
Clinical Utility:	Screening for monoclonal gammopathies. * See algorithm in separate Algorithm section of Handbook.

SEE next page for Monoclonal Gammopathy Algorithm.

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

Testing Algorithm

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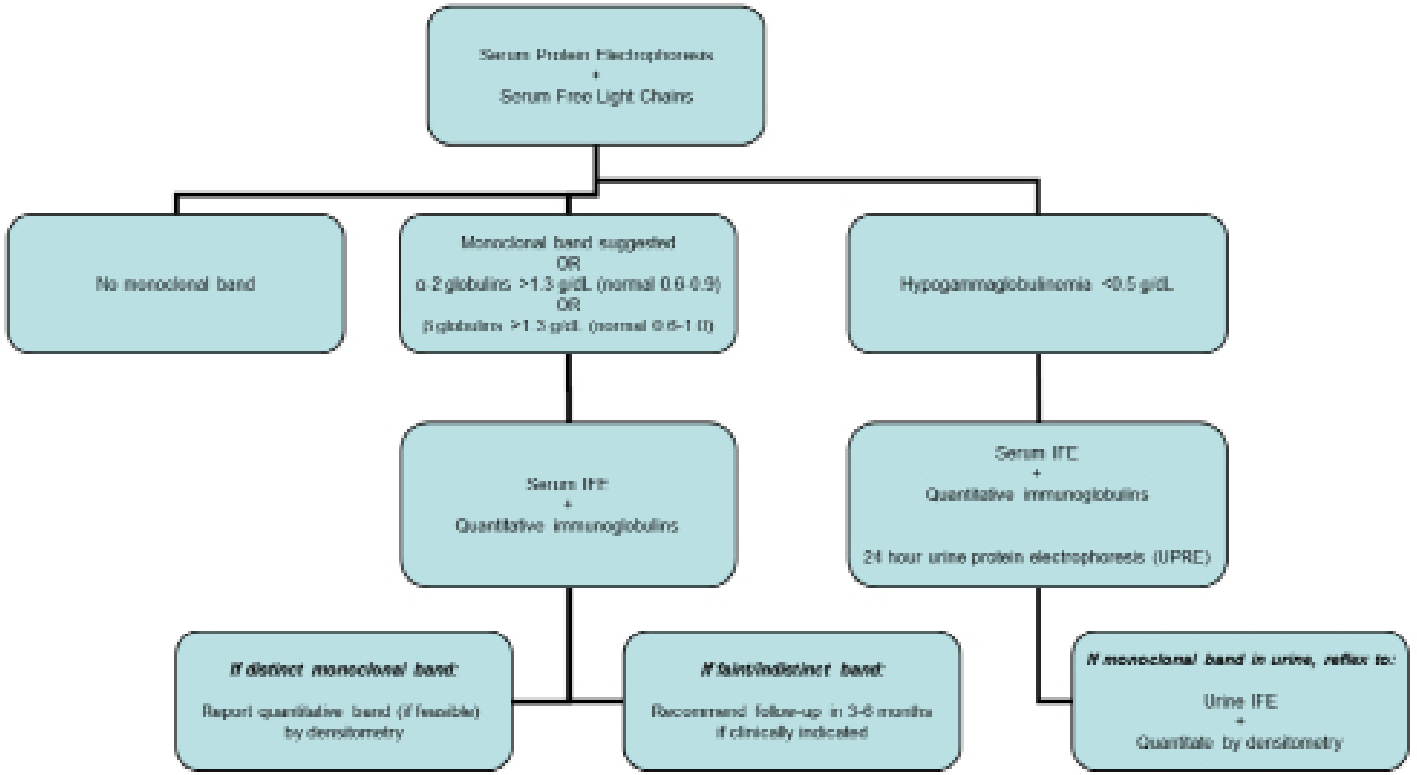
Monoclonal Gammopathy Screening Algorithm



Screening Panels for Detection of Monoclonal Gammopathies
Katzmann et al. Clin Chem 2009; 55(8):1517-1522

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