HNL Lab Medicine®

APRIL 2021

LAB-LINK

NEW AND UPDATED LABORATORY TESTING INFORMATION

HNL Lab Medicine®
794 Roble Road
Allentown, PA 18109
United States

TEST NAME / SUBJECT	EFFECTIVE DATE	PAGE

NEW TESTS

FOR THE MOST UP-TO-DATE TEST INFORMATION, VISIT OUR ONLINE HANDBOOK AT HNL.COM/TESTMENU

The American Medical Association (AMA) Current Procedural Terminology (CPT) codes published by HNL Lab Medicine are guidelines and are intended for informational purposes only. CPT coding is the exclusive responsibility of the billing entity. HNL Lab Medicine strongly recommends confirmation of CPT codes with third-party payors and/or the AMA. We assume no responsibility for billing errors due to reliance upon CPT codes provided by HNL Lab Medicine. 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 federal healthcare plan reimbursement is claimed may be subject to penalties. Individual components of profiles or panels may be ordered individually. 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.

NEW TEST

Carbapenemase Detection by PCR	
EFFECTIVE DATE:	**IMMEDIATELY**
NEW TEST CODE:	CARB5
INCLUDES:	This assay detects the most common variants of the following carbapenemase genes: • KPC • NDM • OXA-48-like • VIM • IMP
METHODOLOGY:	Real-time PCR
TESTING SCHEDULE:	Routine, daily
REPORT AVAILABILITY:	1-2 days following confirmation of carbapenem non-susceptibility
SPECIAL INSTRUCTIONS:	• Isolates belonging to the family Enterobacteriaceae (e.g. E. coli, Klebsiella spp.) identified as carbapenem non-susceptible on routine cultures will be reflexed to this assay to identify possible mechanisms of resistance. • Isolates from other laboratories may be submitted with identification and susceptibility report for testing if indicated. Organisms must be identified as Enterobacteriaceae, Pseudomonas aeruginosa, or Acinetobacter baumannii complex.
CLINICAL UTILITY:	Carbapenem resistant organisms present a challenge to healthcare providers and the institutions in which they work. Effective antibiotic treatment and infection control measures are needed for successful management of patients with carbapenemase producing organisms.

For questions, please call **877-402-4221**.

For technical questions related to this test, please ask for **Technical Support** between the hours of **8 a.m. and 4:30 p.m.** For general inquiries, Customer Care is available to assist at any time.

NEW TEST

NEW TEST

Urinalysis with Reflex to Culture	
EFFECTIVE DATE:	**4/5/21**
NEW TEST CODE:	UAWRC
INCLUDES:	Urinalysis with reflex to urine culture if indicated
METHODOLOGY:	Urinalysis – • Automated analyzer Urine culture – • Standard quantitative procedure for aerobic bacterial culture and identification
TESTING SCHEDULE:	Routine, daily
REPORT AVAILABILITY:	Urinalysis – • 1 day Urine culture – • Preliminary, 1 day • Final with no growth, 1-2 days • Cultures with pathogens, minimum of 1 day
SPECIMEN REQUIREMENTS:	MINIMUM VOLUME: • **Urinalysis** – 7ml random urine • **Urine culture** – minimum 3 ml in boric acid tube (fill to minimum fill line), < 3 ml submit in sterile container, refrigerated. CONTAINER: • **Urinalysis** – plastic urine container • **Urine culture** – boric acid tube contained in a midstream urine collection kit, < 3 ml submit in sterile container - Do not submit in blue capped cup with needle. COLLECTION: • First morning specimens yield highest bacterial counts from overnight incubation in the bladder. • Forcing fluids dilutes the urine and may cause reduced colony counts. • Hair from perineum will contaminate the specimen. • The urine stream from a male may be contaminated by bacteria from beneath the prepuce. • Bacteria from vaginal secretions, vulva or distal urethra may contaminate the specimen as may organisms from hands or clothing. • For clean catch urines, patients should cleanse themselves with towelettes as follows: MALES: 1. Wipe head of penis in a single motion with first towelette. Repeat with second towelette. If not circumcised, hold foreskin back before cleansing 2. Urinate a small amount into toilet or bedpan 3. Place urine collection container under stream and continue to urinate 4. Finish voiding into toilet or bedpan 5. Transfer urine from collection container to preservative tubes using transfer "straw" (located in lid of container) until it reaches the "fill line" on tube FEMALES: 1. Separate the labia 2. Wipe inner labial folds front to back in a single motion with first towelette. Wipe down through center of labial folds with second towelette keeping the labia separated 3. Urinate a small amount into toilet or bedpan 4. Place urine collection container under stream and continue to urinate. 5. Finish voiding into toilet or bedpan 6. Transfer urine from collection container to preservative tube using transfer "straw" (located in lid of container) until it reaches "fill line" on tube

SPECIAL INSTRUCTIONS:	Urinalysis – Transport to lab within 2 hours of collection, if delay in transport, refrigerate specimen for urine culture portion: • Boric acid - Preservative tube is preferred. • Non-preservative tube (sterile container). If delay in transport, refrigerate specimen.
REFERENCE RANGE:	The urine culture is done only if urinalysis has any of the following parameters: positive for blood, leukocyte esterase, nitrite, protein, or microscopic showing bacteria, blood or WBCs.
CLINICAL UTILITY:	Urinary tract infections are among the most common infections in humans. Cultures from females may contain a high degree of bacterial contamination from normal fecal, skin and urogenital flora, and any reported growth of bacteria needs to be evaluated by a physician for clinical significance.

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NEW TEST

BRAF Mutation, PCR	
EFFECTIVE DATE:	**4/5/21**
NEW TEST CODE:	BRAF
INCLUDES:	BRAF Mutations • V600E • V600K • V600D
METHODOLOGY:	Polymerase Chain Reaction (PCR)
TESTING SCHEDULE:	Routine, Monday - Friday
REPORT AVAILABILITY:	3-7 days; Report available in CoPath
SPECIMEN REQUIREMENTS:	MINIMUM VOLUME: • Formalin-fixed Paraffin-embedded tissue, FFPE COLLECTION: • Tumor selection area of FFPE is selected by board-certified Pathologist
REFERENCE RANGE:	No BRAF Mutation
CLINICAL UTILITY:	BRAF, a serine-threonine protein kinase, is a central mediator in signaling cascades leading to cell cycling and cell growth. Oncogenic BRAF mutations have been found in ~8-15% of colorectal cancers, ~1-4% of non-small cell lung carcinoma, and in ~50% of melanoma cases; the most frequently found activating BRAF mutations involves codon 600 in exon 15, primarily V600E. The result of these mutations is enhanced BRAF kinase activity and increased phosphorylation of downstream targets prompting cell proliferation. Results from BRAF Mutation analyses of patient carcinomas and melanomas can help in patient treatment decisions regarding the administration of anti-EGFR treatments as well as BRAF inhibitor therapy.

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NEW TEST

Fragile X, DNA Diagnostic	
EFFECTIVE DATE:	**4/5/21**
NEW TEST CODE:	FRGLX
INCLUDES:	The purpose of this assay is to amplify and detect the cytosine-guanine-guanin (CGG) repeats in the 5'-untranslated region of the fragile X mental retardtion-1 (FMR1) gene. Polymerase chain reaction of gDNA, followed by fragment sizing can convert product size to the number of CGG repeats. Number of CGG repeats is used to distinguish four types of alleles: normal, intermediate, premutation and full mutation.
METHODOLOGY:	Polymerase Chain Reaction (PCR) and Capillary Electrophoresis
TESTING SCHEDULE:	Routine, Monday - Friday
REPORT AVAILABILITY:	3-7 days; Results available in CoPath
SPECIMEN REQUIREMENTS:	MINIMUM VOLUME: • 3 mL EDTA blood CONTAINER: • EDTA blood COLLECTION: • Refrigerate, 2-8C
REFERENCE RANGE:	Normal alleles
CLINICAL UTILITY:	• Diagnostic testing of individuals with undiagnosed intellectual disability, developmental delay or autism • Diagnostic testing for women with infertility problems associated with elevated follicle stimulating hormone (FSH) levels before the age of 40 with no known cause • Diagnostic testing for individuals with late-onset intention tremor and/or cerebellar ataxia of unknown origin

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NEW TEST

Spinal Muscular Atrophy, Diagnostic	
EFFECTIVE DATE:	**4/5/21**
NEW TEST CODE:	SMN12
INCLUDES:	This SMA assay is a quantitates exon 7 copy numbers of SMN1 and SMN2 genes.
METHODOLOGY:	Polymerase Chain Reaction (PCR) and Capillary Electrophoresis
TESTING SCHEDULE:	Routine, Monday - Friday
REPORT AVAILABILITY:	3-7 days; Results available in CoPath
SPECIMEN REQUIREMENTS:	MINIMUM VOLUME: • 3 mL EDTA whole blood CONTAINER: • EDTA whole blood COLLECTION: • Refrigerate, 2-8C
REFERENCE RANGE:	2 copies SMN1 gene, and 2 copies SMN2 gene
CLINICAL UTILITY:	Diagnostic testing to confirm a suspected case of Spinal Muscular Atrophy

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NEW TEST

SC5b-9 Level terminal Complement Complex	
EFFECTIVE DATE:	**IMMEDIATLY**
NEW TEST CODE:	SC5B9
METHODOLOGY:	Enzyme Linked Immunosorbent Assay (ELISA)
TESTING SCHEDULE:	First Tuesday of each month
REPORT AVAILABILITY:	Up to 4 weeks
SPECIMEN REQUIREMENTS:	MINIMUM VOLUME: • 1 mL plasma from Lavender Top Tube (EDTA) CONTAINER: • Centrifuge specimen within 30 minutes of collection • Transfer the plasma to a plastic aliquot tube and immediately place on dry ice • Specimen must remain on dry ice until it arrives at the lab COLLECTION: • Specimen cannot be collected at an HNL Lab Medicine Patient Center without prior notification.
REFERENCE RANGE:	72-244 ng/mL
CLINICAL UTILITY:	SC5b-9 is a measurement of the complement system activation. It can be transiently elevated after a severe allergic reaction. Elevation can help characterize the severe allergic reaction.

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NEW TEST

Pregabalin, Quantitative, Urine	
EFFECTIVE DATE:	**4/6/21**
NEW TEST CODE:	UQ770
INCLUDES:	Identification and quantitation of pregabalin in urine
METHODOLOGY:	Liquid Chromatography-Tandem Mass Spectrometry (LC/MS/MS)
TESTING SCHEDULE:	Routine, 6 days per week
REPORT AVAILABILITY:	1-3 days
SPECIMEN REQUIREMENTS:	MINIMUM VOLUME: • 5 mL random urine CONTAINER: • Plastic urine container (preservative-free)
REFERENCE RANGE:	Negative
CLINICAL UTILITY:	Useful for the identification and quantitation of pregabalin in urine. If an interpretive report for prescribed medication compliance is required, please contact your sales representative for Pain Management test menus.

For questions, please call **877-402-4221**.

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