

# Cleveland Clinic Laboratories

## Technical Update • April 2024

Cleveland Clinic Laboratories is dedicated to keeping you updated and informed about recent testing changes. This Technical Update is provided on a monthly basis to notify you of any changes to the tests in our catalog.

Recently changed tests are bolded, and they could include revisions to methodology, reference range, days performed, or CPT code. Deleted tests and new tests are listed separately. For your convenience, tests are listed alphabetically and order codes are provided.

To compare the new information with previous test information, refer to the online Test Directory at [clevelandcliniclabs.com](http://clevelandcliniclabs.com). Test information is updated in the online Test Directory on the Effective Date stated in the Technical Update. Please update your database as necessary.

For additional detail, contact Laboratory Customer Service at 216.444.5755 or 800.628.6816, or via email at [clientservices@ccf.org](mailto:clientservices@ccf.org).

Test Update Page #	Summary of Changes by Test Name	Order Code	Name Change	New Test	Test Discontinued	Special Information	Specimen Requirement	Component Change(s)	Methodology	Reference Range	Days Performed/Reported	Stability	CPT
3	ACTH												
30	Acylcarnitines, Plasma w/ Consultation												
20	Allergen, Food, Nutmeg IgE												
20	Allergen, Fungi and Molds, Bipolaris spcifera (Curvularia) IgE												
21	Allergen, Fungi and Molds, Curvularia lunata IgE												
21	Allergen Lupine Seed IgE												
22	Allergen, Weed, Sagebrush/Wormwood IgE												
22	Apricot, IgE												
3	Arginine Vasopressin												
23	Asparagus, IgE allergen												
3	Autoimmune Encephalopathy Evaluation, CSF												
3	Autoimmune Encephalopathy Evaluation, Serum												
23-24	Autoimmune Pediatric CNS Disorders, CSF												
24	Autoimmune Pediatric CNS Disorders, Serum												
3	Basic Metabolic Panel												
3	Beta Globin (HBB) Sequencing												
3	Cadmium, Whole Blood												
25	Carnitine Free and Total, Plasma												
30	Carnitine Free & Total, Plasma												
25	Cheese Mozzarella IgE allergen												

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Order Code	Name Change	New Test	Test Discontinued	Special Information	Specimen Requirement	Component Change(s)	Methodology	Days Performed/Reported	Reference Range	Stability	CPT
26	Cheese Parmesan IgE allergen										
26	Cheese Swiss IgE allergen										
3	Chloride										
30	CK, Total and CKMB										
30	CKMB										
4	Comprehensive Metabolic Panel										
4	Cryofibrinogen										
4-5	Cryptococcal antigen detection										
5	Electrolyte Panel										
5-6	Enteric Bacterial Panel by PCR										
6	Ethosuximide										
6-7	Expanded Stool Gastrointestinal Panel by PCR										
7	F-Actin (Smooth Muscle) Antibody, IgG ELISA										
7	Filariasis Abs IgG4										
8	Fungal CSF culture and CAD										
8	Fungal culture and smear - Dermal (hair, skin and nail)										
10	Fungal Culture and Smear (Non Dermal)										
11	Fungal culture - Dermal (hair, skin and nail)										
12	Fungal Culture (Non Dermal)										
13	Fungal Susceptibility - yeast										
13	Gastric Parietal Cell IgG Serum										
13	Group B Streptococcus by PCR, Routine Prenatal Screening										
13	Growth Hormone										
30	H.pylori CLO Test										
13-15	High Risk Human Papilloma Virus (HPV), PCR for Detection and Genotyping										
26	Hops, IgE allergen										
15	Islet antigen-2 antibody										
15	Ketamine & Metabolite, Serum/Plasma										
15	Lipid Panel, Basic										
15	Lipid Panel, Nonfasting										
15	LPT to Beryllium, Blood										
15	Lysozyme										
15	Mitochondrial M2 IgG Serum										
26	Mosquito IgE Allergen										
30	MRSA Culture Screen										
15-16	Neutrophil Oxidative Burst, Blood										
16	Organism Identification, Mold										
16	Organism Identification, Yeast										
16	Osmolality, Stool										

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Order Code	Name Change	New Test	Test Discontinued	Special Information	Specimen Requirement	Component Change(s)	Methodology	Reference Range	Days Performed/Reported	Stability	CPT
27-28	Plasma Carnitine Free/Total and Acylcarnitines Panel										
16	Propafenone										
17	Renal Function Panel										
17	SARP4										
28-29	Spinach IgE allergen										
18	Staphylococcus aureus & MRSA Screen, Culture, Skin										
18	Staphylococcus aureus & MRSA Screen, PCR, Nasal										
29	Summer Squash, IgE										
29	Tea, IgE										
18	Tularemia Antibodies, IgG and IgM										
30	Turmeric IgE allergen										
18	UBA1 Mutation Testing for VEXAS Syndrome										
18	Venlafaxine & Metabolite										
19	Yeast Screen										

## Test Changes

Test Name	Order Code	Change	Effective Date
ACTH	ACTH	<b>Specimen Requirement:</b> 1 mL plasma from EDTA (Lavender) tube; Place specimen on ice after draw. Transport Frozen; Separate plasma from cells ASAP. <b>Transfer plasma to to CCL transport tube and freeze immediately.</b>	effective immediately
Arginine Vasopressin	ADH	<b>Order Code:</b> Previously AVAS	5/23/24
Autoimmune Encephalopathy Evaluation, CSF	ENCCSF	<b>Clinical Limitation:</b> Specimens from pediatric specimens are no longer accepted for the Autoimmune Encephalopathy Evaluation. The Autoimmune Pediatric CNS Disorders may be ordered as APCNSS for serum and APCNSC for CSF, or specific antibodies may be ordered directly: GAD65 Antibody, CSF (GADCSF); MOG IgG, Serum (MOGFAC).	6/6/24
Autoimmune Encephalopathy Evaluation, Serum	ENC SER	<b>Clinical Limitation:</b> Specimens from pediatric specimens are no longer accepted for the Autoimmune Encephalopathy Evaluation. The Autoimmune Pediatric CNS Disorders may be ordered as APCNSS for serum and APCNSC for CSF, or specific antibodies may be ordered directly: GAD65 Antibody, CSF (GADCSF); MOG IgG, Serum (MOGFAC).	6/6/24
Basic Metabolic Panel	BMP	<b>Reference Range:</b> Chloride: 0 Years to 99 Years: <b>98-107</b> mmol/L Anion Gap: 0 Years and above: <b>8-15</b> mmol/L <i>Note: No change to other Basic Metabolic Panel components</i>	6/4/24
Beta Globin (HBB) Sequencing	BGHBB	<b>Order Code:</b> Previously BGLSEQ	5/23/24
Cadmium, Whole Blood	CADM	<b>Order Code:</b> Previously CADMWB	5/23/24
Chloride	CL	<b>Reference Range:</b> 0 Years to 99 Years: <b>98-107</b> mmol/L	6/4/24

## Test Changes (Cont.)

Test Name	Order Code	Change	Effective Date
Comprehensive Metabolic Panel	CMP	<p><b>Reference Range:</b>            Chloride: 0 Years to 99 Years: <b>98–107</b> mmol/L            Anion Gap: 0 Years and above: <b>8–15</b> mmol/L  <i>Note: No change to other Comprehensive Metabolic Panel components</i></p>	6/4/24
Cryofibrinogen	CRYOFI	<p><b>Special Information: Fasting for at least 8 hours is required. Proper collection and transport of specimen is critical to the outcome of the assay. Quantities less than 3 mL may affect the sensitivity of the assay. Grossly hemolyzed or lipemic specimens will be rejected. This test is New York state approved.</b></p> <p><b>Clinical Information: This test is useful in evaluation of patients with vasculitis, macroglobulinemia, or multiple myeloma in whom symptoms occur with exposure to cold.</b></p> <p><b>Specimen Requirement:</b> 3 mL plasma from sodium citrate (Light Blue) tube; Ambient; Fasting for at least <b>8</b> hours is required. Collect in 2 pre-warmed (37C), 3.5 mL, sodium citrate light blue top tubes. <b>Immediately after collection, place tubes in heel warmer or 37°C (warm, not hot) water. Keep samples warm</b> at 37C from collection until plasma separation. If possible, spin in a 37C centrifuge. Combine plasma from two tubes into one screw capped transport tube.</p>	5/21/24
Cryptococcal antigen detection	CAD	<p><b>Name:</b> Previously Cryptococcus Ag Detection</p> <p><b>Special Information: The Cryptococcal antigen lateral flow assay is a dipstick immunochromatographic assay. The test utilizes specimen wicking up the membrane to interact with capture gold-conjugated anti-CrAG antibodies. The antibody-antigen complex continues to wick up the membrane and interact with test line which has the immobilized anti-CrAg monoclonal antibodies. The antibody-antigen complex forms a visible line at the "test line". In order to report a test positive, a visible line is also needed at the "control line" which ensures proper migration of the specimen through the membrane. Thus, positive test results will create two lines (test and control), negative test results will only form one line (control). Test may result as invalid if a control line does not develop. Semi-quantitative titration procedures are employed with an initial positive or if there is an extremely faint line to rule out false negative results from high titer specimens (hook effect/postzone)</b></p> <p>If Cryptococcal Antigen Detection is positive, a titer will be performed at an additional charge with CPT code 87899 applied.</p> <p>If Cryptococcal Antigen Detection is positive, fungal culture will be reflexed.</p> <p><b>Clinical Limitation: Testing is limited CSF and serum specimens only. CSF specimens submitted for initial diagnosis that test positive by the lateral flow assay, should also be submitted for routine fungal culture. Culture can aid in differentiating between the 2 common Cryptococcus species causing disease (Cryptococcus neoformans and Cryptococcus gattii) and can be used for antifungal susceptibility testing, if necessary. CAD test should not be used as a screening procedure for the general population. This test should not be used as a test of cure or to guide treatment decisions. Bloody lumbar puncture and/or contamination of the cerebrospinal fluid (CSF) specimen with serum, other yeast infections such as Trichosporon may lead to a positive Cryptococcus antigen result. CAD titers can be utilised to monitor therapy but titers acquired by different assays are not interchangeable; titers acquired by lateral flow assay may be higher than other antigen assays such as agglutination tests. Extremely high concentrations of cryptococcal antigen can result in negative CAD results. If high burden is suspected, sample may be diluted to resolve false negative. Please call the lab/ medical director in such instances.</b></p> <p><b>Clinical Information: Cryptococcus species are typically acquired by the pulmonary route and have a predilection for CNS infections. CSF is the specimen of choice for detection of cryptococcal meningitis in adults. Cryptococcus antigen test on serum and CSF specimens is a rapid and sensitive diagnostic method for detection of Cryptococcal infections. Declining titers may indicate regression of infection. However, monitoring titers to cryptococcal antigen should not be used as a test of cure or to guide treatment decisions. Low-level titers may persist for extended periods of time following appropriate therapy and resolution of infection</b></p> <p><i>(continued on page 5)</i></p>	5/21/24

## Test Changes (Cont.)

Test Name	Order Code	Change	Effective Date
Cryptococcal antigen detection <i>(continued from page 4)</i>	CAD	<p><b>Specimen Requirement:</b> 1 mL cerebrospinal fluid (CSF) in sterile container; Minimum: 0.1 mL; <b>Sterile technique should be used to collect specimen to decrease contamination issues. FUNCSF order is suggested in recovering Cryptococcus from clinical specimen with consistently low titers and in cases where susceptibility testing may be indicated.</b> *OR* 1 mL serum from serum separator (Gold) tube; Minimum 0.1 mL; Serum should be separated as soon as possible after collection by centrifuging. <b>Grossly hemolysed samples may cause false positive results and will be rejected.</b></p> <p><b>Stability:</b> Refrigerated: Serum separated from clot: 1 week; Serum not separated from clot: 72 hours; CSF: 72 hours Frozen: Serum: Indefinitely; CSF: Indefinitely</p> <p><b>Days Performed:</b> Sun–Sat 7:30 am–4:00 pm</p>	5/21/24
Electrolyte Panel	LYTE	<p><b>Reference Range:</b> Chloride: 0 Years to 99 Years: <b>98–107</b> mmol/L Anion Gap: 0 Years and above: <b>8–15</b> mmol/L <i>Note: No change to other Electrolyte Panel components</i></p>	6/4/24
Enteric Bacterial Panel by PCR	STLPCR	<p><b>For interface clients only–Test build may need to be modified</b></p> <p><b>Clinical Limitation:</b> The BD Max Enteric Bacterial Panel results are meant to be used in conjunction with clinical presentation, laboratory findings, and epidemiological information. Results of this test should not be used as the sole basis for diagnosis, treatment, or other patient management decisions. Positive results do not rule out co-infection with other organisms that are not detected by this test, and may not be the sole or definitive cause of patient illness. Some targets on this panel have potential for false positives due to non-specific cross reactivity. Negative results in the setting of clinical illness compatible with gastroenteritis may be due to infection by pathogens that are not detected by this test or non-infectious causes such as ulcerative colitis, irritable bowel syndrome, or Crohn’s disease.</p> <p><b>Clinical Information:</b> The BD Max Enteric Bacterial Panel is an FDA-cleared multiplex real-time PCR assay that qualitatively detects nucleic acids from the following targets: Campylobacter species (C. jejuni/C. coli), Salmonella species, Shiga-like toxin producing E.coli (STEC), and Shigella/Enteroinvasive E.coli (EIEC). Specimens positive for organisms of public health concern may be reflexed to culture and/or sendout testing at a public health lab as indicated in the result comments.</p> <p>The Infectious Diseases Society of America recommends stool pathogen testing in individuals with diarrhea accompanied by fever, bloody or mucoid stools, severe abdominal cramping or tenderness, or signs of sepsis; in an outbreak setting; and in immunocompromised hosts with diarrhea. Identification of the infectious etiology of diarrheal illness can help guide appropriate therapy, prevent unnecessary or harmful antibiotic exposure, and facilitate further workup. Repeat testing within 14 days of the same episode of diarrhea, or for test of cure, is not recommended.</p> <p>Immunocompromised individuals with persistent diarrhea may benefit from additional testing (ie. STLPCR: Expanded Stool Gastrointestinal Panel by PCR, OVAP: Stool Ova/Parasite Exam, CRYSP0: Cryptosporidium/Cyclospora/Cystoisospora Exam, MICSP0: Microsporidia Exam, and gastrointestinal biopsy, among others). Individuals with travel history outside the United States with persistent diarrhea lasting &gt;14 days may benefit from additional parasitic testing (ie. OVAP: Stool Ova/Parasite exam, CRYSP0: Cryptosporidium/Cyclospora/Cystoisospora exam). Individuals with onset of diarrhea after more than 3 days of hospital admission or with prior antibiotic exposure history may benefit from testing for C. difficile (CDPCR).</p> <p><b>Specimen Requirement:</b> One stool in Cary-Blair kit; <b>Refrigerated;</b> The stool must be passed into a clean, dry, wide mouthed container and not contaminated by urine or water. A bed pan is an ideal initial collection container provided it has been thoroughly cleaned and the patient is cautioned against contaminating the specimen with urine. A plastic bag placed over the toilet seat is also acceptable. Select bloody, slimy, or watery portions of the stool using the collection spoon provided in the cap of the container. Place enough stool (~1g) in the Cary-Blair transport vial (Oracle #1124361, or #1570140 as part of STUL kit) to bring the liquid level up to the “fill to here” line. Mash and mix the stool with the spoon along the sides of the container. Tighten the cap and shake the vial until the mixture appears homogeneous.</p> <p><i>(continued on page 6)</i></p>	5/21/24

## Test Changes (Cont.)

Test Name	Order Code	Change	Effective Date
Enteric Bacterial Panel by PCR <i>(continued from page 5)</i>	STLPCR	<p><b>Specimen Requirement (continued):</b> *OR* One stool in sterile container; Refrigerated; The stool must be passed into a clean, dry, wide mouthed container and not contaminated by urine or water. A bed pan is an ideal initial collection container provided it has been thoroughly cleaned and the patient is cautioned against contaminating the specimen with urine. A plastic bag placed over the toilet seat is also acceptable. Select bloody, slimy, or watery portions of the stool using the collection spoon provided in the cap of the container. Place enough stool (~1g) in the Cary-Blair transport vial (Oracle #1124361, or #1570140 as part of STUL kit) to bring the liquid level up to the "fill to here" line. Mash and mix the stool with the spoon along the sides of the container. Tighten the cap and shake the vial until the mixture appears homogeneous.</p> <p><b>Stability:</b> Refrigerated: 5 days in Cary-Blair transport media or as unpreserved stool in a sterile container Frozen: 24 hours in Cary-Blair transport media or as unpreserved stool in a sterile container</p> <p><b>Reference Range:</b> Campylobacter species (C. jejuni/C. coli) DNA: Not detected Salmonella species DNA: Not detected Shiga-like toxin producing E. coli (STEC) DNA: Not detected Shigella/Enteroinvasive E. coli (EIEC) DNA: Not detected</p>	5/21/24
Ethosuximide	ETHO	<b>Order Code:</b> Previously ETHOS	5/28/24
Expanded Stool Gastrointestinal Panel by PCR	STGIPI	<p><b>Name:</b> Previously Stool Gastrointestinal Panel (In-house) by PCR</p> <p><b>Clinical Limitation:</b> The Biofire FilmArray Gastrointestinal (GI) Panel is indicated as an aid in the diagnosis of specific agents of gastrointestinal illness and results are meant to be used in conjunction with other clinical, laboratory, and epidemiological data. Positive results do not rule out coinfection with organisms not included in the panel. The agent detected may not be the definite cause of the disease. Some targets on this panel have potential for false positives due to contaminated transport media, or non-specific cross reactivity. Some have been associated with asymptomatic colonization/infection. Negative results in the setting of clinical illness compatible with gastroenteritis may be due to infection by pathogens that are not detected by this test or non-infectious causes such as ulcerative colitis, irritable bowel syndrome, or Crohn's disease. Some patients may experience financial toxicity with this expanded multiplex panel, as it is variably reimbursed by insurance.</p> <p><b>Clinical Information:</b> The Biofire FilmArray Gastrointestinal (GI) Panel is an FDA-cleared multiplexed nucleic acid test that qualitatively detects and identifies nucleic acids from 21 bacterial, viral, and parasitic targets directly from stool samples in Cary-Blair transport media. This panel does not contain Clostridium difficile, which must be ordered separately (CDPCR) if clinically appropriate. <b>This panel contains the following targets:</b> Campylobacter species (C. jejuni/C. coli/C. upsaliensis), Plesiomonas shigelloides, Salmonella species, Vibrio species (V. parahaemolyticus/V. vulnificus/ V. cholerae), Vibrio cholerae, Yersinia enterocolitica, Enteroaggregative E.coli (EAEC), Enteropathogenic E.coli (EPEC), Enterotoxigenic E.coli (ETEC), Shiga-like toxin producing E.coli (STEC), <b>E.coli O157</b>, Shigella/Enteroinvasive E.coli (EIEC), Adenovirus F 40/41, Astrovirus, Norovirus <b>GI/GII</b>, Rotavirus <b>A</b>, Sapovirus (<b>Genogroups I, II, IV, V</b>), Cryptosporidium, Cyclospora cayetanensis, Entamoeba histolytica, and Giardia lamblia. <b>Specimens positive for organisms of public health concern may be reflexed to culture and/or sendout testing at a public health lab as indicated in the result comments.</b></p> <p><b>The Infectious Diseases Society of America recommends stool pathogen testing in individuals with diarrhea accompanied by fever, bloody or mucoid stools, severe abdominal cramping or tenderness, or signs of sepsis; in an outbreak setting; and in immunocompromised hosts with diarrhea. Identification of the infectious etiology of diarrheal illness can help guide appropriate therapy, prevent unnecessary or harmful antibiotic exposure, and facilitate further workup. Repeat testing within 14 days of the same episode of diarrhea, or for test of cure, is not recommended.</b></p> <p><b>Consider a more limited PCR panel for the most common enteric bacterial pathogens only (STLPCR) for patients who are not immunocompromised or severely-ill. Immunocompromised individuals with persistent diarrhea may benefit from additional testing (ie. OVAP: Stool Ova/Parasite Exam, CRYSP0: Cryptosporidium/Cyclospora/Cystoisospora Exam, MICSPO: Microsporidia Exam, and gastrointestinal biopsy, among others).</b></p> <p><i>(continued on page 7)</i></p>	5/21/24

## Test Changes (Cont.)

Test Name	Order Code	Change	Effective Date
Expanded Stool Gastrointestinal Panel by PCR <i>(continued from page 6)</i>	STGIPI	<p><b>Clinical Information (continued):</b></p> <p><b>Individuals with travel history outside the United States with persistent diarrhea lasting &gt;14 days may benefit from additional parasitic testing (ie. OVAP: Stool Ova/Parasite exam, CRYSP0: Cryptosporidium/Cyclospora/Cystoisospora exam). Individuals with onset of diarrhea after more than 3 days of hospital admission or with prior antibiotic exposure history may benefit from testing for C. difficile (CDPCR).</b></p> <p><b>Specimen Requirement:</b> One stool in Cary-Blair kit; <b>The stool must be passed into a clean, dry, wide mouthed container and not contaminated by urine or water. A bed pan is an ideal initial collection container provided it has been thoroughly cleaned and the patient is cautioned against contaminating the specimen with urine. A plastic bag placed over the toilet seat is also acceptable. Select bloody, slimy, or watery portions of the stool using the collection spoon provided in the cap of the container. Place enough stool (~1g) in the Cary-Blair transport vial (Oracle #1124361, or #1570140 as part of STUL kit) to bring the liquid level up to the “fill to here” line. Mash and mix the stool with the spoon along the sides of the container. Tighten the cap and shake the vial until the mixture appears homogeneous.</b></p> <p><b>Stability:</b> Ambient: 4 days in Cary-Blair transport media Refrigerated: 4 days in Cary-Blair transport media</p> <p><b>Reference Range:</b> <b>Campylobacter species</b> (C. jejuni/C. coli/C. upsaliensis) <b>DNA:</b> Not detected Plesiomonas shigelloides <b>DNA:</b> Not detected Salmonella species <b>DNA:</b> Not detected Vibrio species <b>DNA:</b> Not detected Vibrio cholerae <b>DNA:</b> Not detected Yersinia enterocolitica <b>DNA:</b> Not detected E. coli (EAEC) <b>DNA:</b> Not detected <b>Enteropathogenic E. coli (EPEC) DNA:</b> Not detected <b>Enterotoxigenic E. coli (ETEC) DNA:</b> Not detected <b>Shiga-like toxin producing E. coli (STEC) DNA:</b> Not detected E. coli O157 <b>DNA:</b> Not detected <b>Shigella/Enteroinvasive E. coli (EIEC) DNA:</b> Not detected Adenovirus F 40/41 <b>DNA:</b> Not detected Astrovirus <b>RNA:</b> Not detected Norovirus GI/GII <b>RNA:</b> Not detected Rotavirus A <b>RNA:</b> Not detected Sapovirus (<b>Genogroups I, II, IV, V) RNA:</b> Not detected Cryptosporidium <b>DNA:</b> Not detected Cyclospora <b>cayetanensis DNA:</b> Not detected <b>Entamoeba histolytica DNA:</b> Not detected Giardia lamblia <b>DNA:</b> Not detected</p> <p><b>Days Performed:</b> 7 days a week <b>Reported:</b> 24 hours</p>	5/21/24
F-Actin (Smooth Muscle) Antibody, IgG ELISA	SMTHS	<b>Days Performed:</b> Mon, Thu, Fri	4/2/24
Filariasis Abs IgG4	FILAR1	<p><b>Special Information: This test is New York state approved.</b></p> <p><b>Specimen Requirement:</b> 0.2 mL serum from serum separator (Gold) tube; Refrigerated; <b>Separate serum from cells and transfer to standard aliquot tube. *OR*</b> 0.2 mL serum from no additive (Red) tube; Refrigerated; <b>Separate serum from cells and transfer to standard aliquot tube.</b></p> <p><b>Stability:</b> Ambient: <b>1 week</b> Refrigerated: <b>2 weeks</b> Frozen: <b>1 month</b></p> <p><b>Methodology:</b> Semi Quantitative Enzyme Linked Immunosorbent Assay <b>Days Performed:</b> Varies <b>Reported:</b> 4–18 days</p>	6/18/24



## Test Changes (Cont.)

Test Name	Order Code	Change	Effective Date
Fungal CSF culture and CAD	FUNCSF	<p><b>Name:</b> Previously Fungus CSF Culture/CAD</p> <p><b>Includes:</b> Specimens may include some pre-processing steps such as concentration to aid in the recovery of fungal organisms and Cryptococcal antigen detection (CAD)</p> <p><b>Special Information:</b> Clinical specimens for fungal cultures are processed and plated on selective fungal media to optimize recovery of fungal organisms. Cultures are incubated for 28 days; negative results are auto-updated daily. Any fungal organisms recovered will be isolated and identified by various methods. Additional CPT codes may be applicable for recovery and identification of fungal organisms– 87015–concentration of specimen, 87102 Fungal culture, 87106–ID by MALDI-TOF Mass Spec for yeast, 87107–ID by MALDI-TOF Mass Spec for Mold, 87153–DNA sequencing, 87899–Antigen test. Fungal susceptibility testing for yeast <b>ONLY</b> will be performed (CPT 87186). Yeast susceptibility testing is determined by colorimetric microdilution broth. A standardized inoculation of test organism is incubated with appropriate dilutions of antifungal agents; minimum inhibitory concentration (MIC) are determined by inhibition of growth at the lowest antifungal concentration. MIC are determined and interpreted according to CLSI standards. Filamentous mold susceptibility testing is a send-out test and can be requested by contacting the lab.</p> <p><b>Clinical Limitation:</b> CSF specimens submitted for initial diagnosis that test positive by the lateral flow assay, should also be submitted for routine fungal culture. Culture can aid in differentiating between the 2 common Cryptococcus species causing disease (Cryptococcus neoformans and Cryptococcus gattii) and can be used for antifungal susceptibility testing, if necessary. CAD test should not be used as a screening procedure for the general population. Bloody lumbar puncture and/ or contamination of the cerebrospinal fluid (CSF) specimen with serum, other yeast infections such as Trichosporon may lead to a positive Cryptococcus antigen result. CAD titers can be utilised to monitor therapy but titers acquired by different assays are not interchangeable; titers acquired by lateral flow assay may be higher than other antigen assays such as agglutination tests. Extremely high concentrations of cryptococcal antigen can result in negative CAD results. If high burden is suspected, sample may be diluted to resolve false negative. Please call the lab/ medical director in such instances.</p> <p><b>Clinical Information:</b> Fungal cultures are not routinely performed on CSF due to the low probability of fungal infections except Cryptococcus species which have a predilection for CNS infections. CSF is the specimen of choice for detection of cryptococcal meningitis in adults and Candida meningitis in children. Cryptococcus antigen test will always be performed on CSF specimens as it is a rapid and sensitive diagnostic method for detection of Cryptococcal meningitis. Declining titers may indicate regression of infection. However, monitoring titers to cryptococcal antigen should not be used as a test of cure or to guide treatment decisions. Low-level titers may persist for extended periods of time following appropriate therapy and resolution of infection.</p> <p><b>Specimen Requirement:</b> 0.5 mL-10 mL cerebrospinal fluid (CSF) in sterile container; Minimum: 1 mL; Ambient; <b>Sterile technique should be used to collect specimen to decrease contamination issues. Larger volumes of specimen are preferred and concentrated to aid in recovery of fungal organisms. Grossly hemolysed sample may give a false positive result on CAD testing and as such will be rejected for the antigen test but fungal cultures will be set up.</b></p> <p><b>Stability:</b>            Ambient: &lt;6 hours is optimal; up to 48 hours acceptable. &gt;48 hours reach out to medical director            Refrigerated: 24 hours acceptable. &gt;24 hours reach out to medical director            Frozen: Unacceptable</p> <p><b>Methodology:</b> Culture</p> <p><b>Days Performed:</b> Sun–Sat Refer to individual components</p> <p><b>Reported:</b> 6 weeks</p>	5/21/24



## Test Changes (Cont.)

Test Name	Order Code	Change	Effective Date
Fungal culture and smear–Dermal (hair, skin and nail)	FHSNSM	<p><b>Name:</b> Previously Fungal Culture and Smear Hair, Skin, Nail</p> <p><b>Includes:</b> Specimens may include some pre-processing steps to aid in recovery of fungal organisms.</p> <p><b>Special Information:</b> Fungal smears are performed directly on specimen using a Calcofluor white stain that nonspecifically binds chitin in the cell wall of fungi. Fluorescent microscopy is utilised to detect and report as yeast and/or hyphae present. CPT code: 87206. Clinical specimens for dermal fungal cultures are processed and plated on selective fungal media to optimize recovery of fungal organisms. Cultures are incubated for 28 days; negative results are auto-updated daily. Any fungal organisms recovered will be isolated and identified by various methods. Additional CPT codes may be applicable for recovery and identification of fungal organisms 87106–ID by MALDI-TOF Mass Spec for yeast, 87107–ID by MALDI-TOF Mass Spec for Mold, 87153–DNA sequencing. Fungal susceptibility testing for yeast and filamentous mold recovered is <b>ONLY</b> performed by request when clinically relevant (CPT 87186). Yeast susceptibility testing is performed in-house by colorimetric microdilution broth. A standardized inoculation of test organism is incubated with appropriate dilutions of antifungal agents; minimum inhibitory concentration (MIC) are determined by inhibition of growth at the lowest antifungal concentration. MIC are determined and interpreted according to CLSI standards. Filamentous mold susceptibility testing is a send-out test and can be requested by contacting the lab.</p> <p><b>Clinical Limitation:</b> Not all fungal organisms recovered in cultures may be significant; clinical correlation needed to determine significance.</p> <p><b>Clinical Information:</b> Aseptic technique should be utilised to minimise contamination and for optimal recovery of organisms. Specimen should be transported immediately to the microbiology laboratory in dry conditions at ambient temperatures. Refrigeration may impact recovery of dermatophytes. Isolation and identification of fungi from keratinized tissue such as hair, skin and nails are commonly due to dermatophytic fungi. Opportunistic superficial infections caused by other fungal organisms and yeasts resembling dermatophytoses will also be identified and reported. However, normally saprophytic or environmental fungi are often recovered from these sites. Clinical correlation with patient symptoms is necessary to determine significance of recovered organism. If specific fungi are suspected the “rule out” feature in Epic can be utilised. If fungal smears are needed order FCULSM; for fungal blood cultures HISTCL; for CSF order FUNCSE; for dermal samples of hair, skin and nail order ACFSC or FHSNSM (with smear); for candidiasis on vaginal and oral samples order fungal screen FUNGSC.</p> <p>If culture only (without smear) is desired, order ACFSC–Fungal Culture Hair, Skin, Nail.</p> <p><b>Specimen Requirement:</b> entire collection of hair in sterile container; Ambient; Hair root is essential for the recovery of fungal organisms so plucking or pulling hair with intact hair shaft is ideal. Cutting hair is not recommended. In cases of alopecia (hair loss), hair can be collected from the region by using a soft bristle toothbrush and rubbing in circular motions over the margins or patches. Collected specimens should be sent in a sterile container or dry paper envelope. Ensure that the specimen is secured within the container to prevent loss of specimen. Specimen should be transported dry in ambient temperatures for optimal recovery. *OR* entire collection of skin in sterile container; Ambient; The affected area should be cleaned with 70% alcohol and allowed to dry. Skin should be scraped with a dull edged object or vigorously brushed in a circular motion with a toothbrush. Be careful not to draw blood. Leading edge of the skin lesion is the preferred sample for optimal recovery of fungal organisms. Ensure that the specimen is secured within the container to prevent loss of specimen. Specimen should be transported dry in ambient temperatures for optimal recovery. *OR* entire collection of nails in sterile container; Ambient; Nails should be cleaned with 70% alcohol and then clipped or scraped with a scalpel. Clip generous portion of the affected area and place in sterile container along with any material or debris from under the nail/nailbed. Ensure that the specimen is secured within the container to prevent loss of specimen. Specimen should be transported dry in ambient temperatures for optimal recovery.</p> <p><b>Stability:</b>            Ambient: 7 days            Refrigerated: 7 days            Frozen: Unacceptable</p> <p><b>Days Performed:</b> Sun–Sat 7:30 am–4:00 pm</p>	5/21/24

## Test Changes (Cont.)

Test Name	Order Code	Change	Effective Date
Fungal Culture and Smear (Non Dermal)	FCULSM	<p><b>Includes:</b> Specimens may include some pre-processing steps such as concentration and use of mucolytic agents to aid in the recovery of fungal organisms.</p> <p><b>Special Information:</b> Fungal smears are performed directly on specimen using a Calcofluor white stain that nonspecifically binds chitin in the cell wall of fungi. Fluorescent microscopy is utilised to detect and report as yeast and/or hyphae present. CPT code: 87206. Clinical specimens for fungal cultures are processed and plated on selective fungal media to optimize recovery of fungal organisms. Cultures are incubated for 28 days; negative results are auto-updated daily. Any fungal organisms recovered will be isolated and identified by various methods. Yeast from respiratory specimen will be ruled for <i>Cryptococcus</i> species and <i>Candida auris</i> and will be reported with minimal ID (Yeast not <i>Cryptococcus</i>); full genus and species ID will only be reported if clinically indicated and requested by clinicians. Additional CPT codes may be applicable for recovery and identification of fungal organisms—87176- Tissue processing, 87015—concentration of specimen, 87102 Fungal culture, 87106—ID by MALDI-TOF Mass Spec for yeast, 87107—ID by MALDI-TOF Mass Spec for Mold, 87153—DNA sequencing. Fungal susceptibility testing for yeast recovered <b>ONLY</b> from sterile sites will be performed automatically (CPT 87186). Yeast susceptibility testing is determined by colorimetric microdilution broth. A standardized inoculation of test organism is incubated with appropriate dilutions of antifungal agents; minimum inhibitory concentration (MIC) are determined by inhibition of growth at the lowest antifungal concentration. MIC are determined and interpreted according to CLSI standards. For yeasts recovered from non-sterile sites are performed in-house by request only—by contacting the lab. Filamentous mold susceptibility testing is a send-out test and can be requested by contacting the lab.</p> <p><b>Clinical Limitation:</b> Not all fungal organisms recovered in cultures may be significant; clinical correlation needed to determine significance.</p> <p><b>Clinical Information:</b> For optimal recovery of organisms—specimen should be collected using sterile technique, reduce contamination and transported immediately to the microbiology laboratory. Isolation and identification of fungi in the clinical laboratory can help guide patient care. However, fungi can be pathogens, colonizers and/or contaminants. Clinical correlation with patient symptoms is necessary to determine significance of recovered organism. If specific fungi are suspected the “rule out” feature in Epic can be utilised. If fungal smears are needed order FCULSM; for fungal blood cultures HISTCL; for CSF order FUNCSF; for dermal samples of hair, skin and nail order ACFSC or FHSNSM (with smear); for candidiasis on vaginal and oral samples order fungal screen FUNGSC.</p> <p><b>Specimen Requirement:</b> 1-5 g tissue in sterile container; <b>Refrigerated</b>; Biopsy specimens should be collected in a sterile screw-top container with a small amount of sterile saline to prevent specimen from drying out. Specimens from periphery of a cutaneous lesion for recovery of fungal organisms. Specimen for Histopathology should be collected and sent separately. *OR* 1-2 mL min (prefer 20-50 mL) body fluid in sterile container; <b>Refrigerated</b>; Specimen source is required for processing. Larger volumes are preferred to improve recovery of fungal organisms. Specimen should be collected using sterile technique in a leakproof sterile screw-top container. If specimen volumes are small especially from lesion aspirates- instilling a small volume of sterile saline may aid collection. Specimen may be submitted in a sterile syringe only after removing needle and capping. Swabs are not preferred for fungal cultures; E-swabs are <b>ONLY</b> acceptable for hard-to-collect specimen sources such as ear canal. Specimen for Histopathology should be collected and sent separately. *OR* eye specimen in sterile container; Corneal scrapings may be submitted in a sterile container but due to the scarcity of material, it is preferred that non-inhibitory fungal plates such as Potato Dextrose Agar (PDA) be inoculated at time of collection. Scrapings should be placed in two or three places on the plate, using an X or C shaped motion. Vitreous fluid may be submitted in a sterile container. If irrigation fluid used to aid in collection submit entire collection to aid in recovery of fungal organisms.</p> <p><b>Stability:</b>            Ambient: 72 hours            Refrigerated: <b>7 days</b>            Frozen: Unacceptable</p> <p><b>Days Performed:</b> Sun–Sat 7:30 am–4:00 pm</p>	5/21/24

## Test Changes (Cont.)

Test Name	Order Code	Change	Effective Date
Fungal culture–Dermal (hair, skin and nail)	ACFSC	<p><b>Name:</b> Previously Fungal Culture Hair,Skin,Nails</p> <p><b>Includes:</b> Specimens may include some pre-processing steps to aid in recovery of fungal organisms.</p> <p><b>Special Information:</b> Fungal smears–direct detection of fungi from clinical specimens will NOT be performed. Please order FHSNSM if fungal smears are needed. Clinical specimens for dermal fungal cultures are processed and plated on selective fungal media to optimize recovery of fungal organisms. Cultures are incubated for 28 days; negative results are auto-updated daily. Any fungal organisms recovered will be isolated and identified by various methods. Additional CPT codes may be applicable for recovery and identification of fungal organisms, 87106–ID by MALDI-TOF Mass Spec for yeast, 87107–ID by MALDI-TOF Mass Spec for Mold, 87153–DNA sequencing. Fungal susceptibility testing for yeast and filamentous mold recovered is ONLY performed by request when clinically relevant (CPT 87186). Yeast susceptibility testing is performed in-house by colorimetric microdilution broth. A standardized inoculation of test organism is incubated with appropriate dilutions of antifungal agents; minimum inhibitory concentration (MIC) are determined by inhibition of growth at the lowest antifungal concentration. MIC are determined and interpreted according to CLSI standards. Filamentous mold susceptibility testing is a send-out test and can be requested by contacting the lab.</p> <p><b>Clinical Limitation:</b> Not all fungal organisms recovered in cultures may be significant; clinical correlation needed to determine significance.</p> <p><b>Clinical Information:</b> Aseptic technique should be utilised to minimise contamination and for optimal recovery of organisms. Specimen should be transported immediately to the microbiology laboratory in dry conditions at ambient temperatures. Refrigeration may impact recovery of dermatophytes. Isolation and identification of fungi from keratinized tissue such as hair, skin and nails are commonly due to dermatophytic fungi. Opportunistic superficial infections caused by other fungal organisms and yeasts resembling dermatophytoses will also be identified and reported. However, normally saprophytic or environmental fungi are often recovered from these sites. Clinical correlation with patient symptoms is necessary to determine significance of recovered organism. If specific fungi are suspected the “rule out” feature in Epic can be utilised. If fungal smears are needed order FCULSM; for fungal blood cultures HISTCL; for CSF order FUNCSEF; for dermal samples of hair, skin and nail order ACFSC or FHSNSM (with smear); for candidiasis on vaginal and oral samples order fungal screen FUNGSC.</p> <p>Fungal smear is not included. If desired, order Fungal Culture and Smear–Dermal (hair, skin and nail) (FHSNSM).</p> <p><b>Specimen Requirement:</b> Entire collection of hair in sterile container; Ambient; Hair root is essential for the recovery of fungal organisms so plucking or pulling hair with intact hair shaft is ideal. Cutting hair is not recommended. In cases of alopecia (hair loss), hair can be collected from the region by using a soft bristle toothbrush and rubbing in circular motions over the margins or patches. Collected specimens should be sent in a sterile container or dry paper envelope. Ensure that the specimen is secured within the container to prevent loss of specimen. Specimen should be transported dry in ambient temperatures for optimal recovery. *OR* entire collection of skin in sterile container; Ambient; The affected area should be cleaned with 70% alcohol and allowed to dry. Skin should be scraped with a dull edged object or vigorously brushed in a circular motion with a toothbrush. Be careful to not draw blood. Leading edge of the skin lesion is the preferred sample for optimal recovery of fungal organisms. Ensure that the specimen is secured within the container to prevent loss of specimen.</p> <p>Specimen should be transported dry in ambient temperatures for optimal recovery. *OR* entire collection of nails in sterile container; Ambient; Nails should be cleaned with 70% alcohol and then clipped or scraped with a scalpel. Clip generous portion of the affected area and place in sterile container along with any material or debris from under the nail/nailbed. Ensure that the specimen is secured within the container to prevent loss of specimen. Specimen should be transported dry in ambient temperatures for optimal recovery.</p> <p><b>Stability:</b>            Ambient: 7 days            Refrigerated: 7 days            Frozen: Unacceptable</p> <p><b>Days Performed:</b> Sun–Sat 7:30 am–4:00 pm</p>	5/21/24

## Test Changes (Cont.)

Test Name	Order Code	Change	Effective Date
Fungal Culture (Non Dermal)	FCUL	<p><b>Name:</b> Previously Fungal Culture (Non Dermal Sites)</p> <p><b>Includes:</b> Specimens may include some pre-processing steps such as concentration and use of mucolytic agents to aid in the recovery of fungal organisms.</p> <p><b>Special Information:</b> Fungal smears–direct detection of fungi from clinical specimens will NOT be performed. Please order FCULSM if fungal smears are needed. Clinical specimens for fungal cultures are processed and plated on selective fungal media to optimize recovery of fungal organisms. Cultures are incubated for 28 days; negative results are auto-updated daily. Any fungal organisms recovered will be isolated and identified by various methods. Yeast from respiratory specimen will be ruled for <i>Cryptococcus</i> species and <i>Candida auris</i> and will be reported with minimal ID (Yeast not <i>Cryptococcus</i>); full genus and species ID will only be reported if clinically indicated and requested by clinicians. Additional CPT codes may be applicable for recovery and identification of fungal organisms–87176sub- Tissue processing, 87015–concentration of specimen, 87102 Fungal culture, 87106–ID by MALDI-TOF Mass Spec for yeast, 87107–ID by MALDI-TOF Mass Spec for Mold, 87153–DNA sequencing. Fungal susceptibility testing for yeast recovered ONLY from sterile sites will be performed automatically (CPT 87186). Yeast susceptibility testing is determined by colorimetric microdilution broth. A standardized inoculation of test organism is incubated with appropriate dilutions of antifungal agents; minimum inhibitory concentration (MIC) are determined by inhibition of growth at the lowest antifungal concentration. MIC are determined and interpreted according to CLSI standards. For yeasts recovered from non-sterile sites are performed in-house by request only–by contacting the lab. Filamentous mold susceptibility testing is a send-out test and can be requested by contacting the lab. Additional billing is applied for sequencing, identification, and susceptibility testing. CPT codes vary based on methodology.</p> <p><b>Clinical Limitation:</b> Not all fungal organisms recovered in cultures may be significant; clinical correlation needed to determine significance.</p> <p><b>Clinical Information:</b> For optimal recovery of organisms–specimen should be collected using sterile technique, reduce contamination and transported immediately to the microbiology laboratory. Isolation and identification of fungi in the clinical laboratory can help guide patient care. However, fungi can be pathogens, colonizers and/or contaminants. Clinical correlation with patient symptoms is necessary to determine significance of recovered organism. If specific fungi are suspected the “rule out” feature in Epic can be utilized. If fungal smears are needed order FCULSM; for fungal blood cultures HISTCL; for CSF order FUNCSF; for dermal samples of hair, skin and nail order ACFSC or FHSNSM (with smear); for candidiasis on vaginal and oral samples order fungal screen FUNGSC.</p> <p><b>Specimen Requirement:</b> 1-5 g tissue in sterile container; <b>Refrigerated;</b> Biopsy specimens should be collected in a sterile screw-top container with a small amount of sterile saline to prevent specimen from drying out. Specimens from periphery of a cutaneous lesion for recovery of fungal organisms. Specimen for Histopathology should be collected and sent separately. *OR* 1-2 mL min (prefer 20-50 mL) body fluid in sterile container; <b>Refrigerated;</b> Specimen source is required for processing. Larger volumes are preferred to improve recovery of fungal organisms. Specimen should be collected using sterile technique in a leakproof sterile screw-top container. If specimen volumes are small especially from lesion aspirates- instilling a small volume of sterile saline may aid collection. Specimen may be submitted in a sterile syringe only after removing needle and capping.</p> <p>Swabs are not preferred for fungal cultures; E-swabs are ONLY acceptable for hard-to-collect specimen sources such as ear canal. Specimen for Histopathology should be collected and sent separately. *OR* eye specimen in sterile container; Corneal scrapings may be submitted in a sterile container but due to the scarcity of material, it is preferred that non-inhibitory fungal plates such as Potato Dextrose Agar (PDA) be inoculated at time of collection. Scrapings should be placed in two or three places on the plate, using an X or C shaped motion. Vitreous fluid may be submitted in a sterile container. If irrigation fluid used to aid in collection submit entire collection to aid in recovery of fungal organisms.</p> <p><b>Stability:</b>            Ambient: 72 hours            Refrigerated: <b>7 days</b>            Frozen: Unacceptable</p> <p><b>Days Performed:</b> Sun–Sat 7:30 am–4:00 pm</p>	5/21/24

## Test Changes (Cont.)

Test Name	Order Code	Change	Effective Date
Fungal Susceptibility–yeast	FUNSUS	<p><b>Name:</b> Previously Fungal Susceptibility</p> <p><b>Special Information:</b> Yeast susceptibility testing is determined by colorimetric microdilution broth. A standardized inoculation of test organism is incubated with appropriate dilutions of antifungal agents; minimum inhibitory concentration (MIC) are determined by inhibition of growth at the lowest antifungal concentration. MIC are determined and interpreted according to CLSI standards. Mold susceptibility testing is not performed in-house but is available as a send out test. Indicate organism identification, original date of collection, and specimen site on the test order. Submit a pure culture of the test organism. Contraindications: lack of viability, culture mixed or contaminated <b>or wrong ID will incur extra charges or result in cancellation of the test.</b> Note specific drug requests on the requisition.</p> <p><b>Clinical Limitation:</b> CLSI guidelines are available only for the interpretation of <b>Candida species susceptibility test results. In vitro studies may not correlate with clinical outcome.</b></p> <p><b>Clinical Information:</b> Useful for determining in vitro minimal inhibitory concentrations of non-fastidious yeast. Susceptibility testing can aid in management due to recurrent infections, invasive infections and where certain antifungals are contraindicated.</p> <p><b>Specimen Requirement:</b> Isolate of organism on agar slant; Ambient; <b>Pure isolates of a single organism should be sent on an agar slant at ambient temperatures.</b></p> <p><b>Stability:</b>                      Ambient: 4 weeks                      Refrigerated: 4 weeks                      Frozen: Unacceptable</p> <p><b>Days Performed:</b> Sun–Sat 7:30 am–4:00 pm</p>	5/21/24
Gastric Parietal Cell IgG Serum	PARIES	Days Performed: Tue	4/2/24
Group B Streptococcus by PCR, Routine Prenatal Screening	GBPCR	<p><b>Name:</b> Previously Routine, Prenatal Group B Strep PCR</p> <p><b>Specimen Requirement:</b> One vaginal/rectal swab, culturette; <b>Collect specimen with Cepheid Collection Device, Oracle 1616432. *OR* one vaginal/rectal E-Swab</b></p> <p><b>Reference Range:</b>                      Group B Streptococcus <b>DNA:</b> Negative</p>	5/21/24
Growth Hormone	GH	<p><b>Reference Range:</b></p> <p><b>Male:</b>                      0 Months to 3 Months: 0.80-33.5 ng/mL                      3 Months to 2 Years: 0.14-6.27 ng/mL                      2 Years to 7 Years: 0.05-5.11 ng/mL                      7 Years to 12 Years: 0.02-4.76 ng/mL                      12 Years to 14 Years: 0.01-6.20 ng/mL                      14 Years to 19 Years: 0.02-3.81 ng/mL                      19 Years and up: &lt;1.00 ng/mL</p> <p><b>Female:</b>                      0 Months to 3 Months: 0.80-33.5 ng/mL                      3 Months to 2 Years: 0.14-6.27 ng/mL                      2 Years to 7 Years: 0.05-5.11 ng/mL                      7 Years to 12 Years: 0.02-4.76 ng/mL                      12 Years to 14 Years: 0.01-6.20 ng/mL                      14 Years to 19 Years: 0.02-5.22 ng/mL                      19 Years and up: &lt;3.61 ng/mL</p>	5/21/24
High Risk Human Papilloma Virus (HPV), PCR for Detection and Genotyping	HPVHRT	<p><b>For interface clients only–Test build may need to be modified</b></p> <p><b>Name:</b> Previously Human Papillomavirus (HPV) DNA Detection with Genotyping 16, 18, High-Risk Types by PCR, Thin Prep</p> <p><b>Special Information:</b> In order to facilitate accurate and complete interpretation of cervical screening results, hrHPV test results associated with a cytology report will be held until the cytology report is finalized.</p> <p><b>Clinical Limitation:</b> Detection of high-risk HPV is dependent on the number of copies present in the specimen and may be affected by specimen collection methods, patient factors, stage of infection and the presence of interfering substances. Though rare, mutations within the highly conserved regions of the genomic DNA of Human papillomavirus covered by the cobas HPV Test's primers and/or probes may result in failure to detect the presence of the viral DNA.</p> <p><i>(continued on page 14)</i></p>	5/21/24

## Test Changes (Cont.)

Test Name	Order Code	Change	Effective Date
High Risk Human Papilloma Virus (HPV), PCR for Detection and Genotyping <i>(continued from page 13)</i>	HPVHRT	<p>For FNA specimens from patients suspected of head and neck squamous cell carcinoma, hrHPV PCR results should be evaluated in the context of clinical history and cytology/pathology results (i.e. tumor type and location, p16 immunohistochemical stain, and hrHPV in-situ hybridization studies if available). Assay analytical sensitivity may be diminished with suboptimal collection or specimen pre-processing. Visibly bloody specimens and those contaminated with excessive ultrasound gel may cause assay inhibition leading to false-negative or indeterminate results. If results are incongruent with history, recommend submitting a dedicated specimen for re-testing or request an alternate method for hrHPV detection.</p> <p><b>Clinical Information:</b> Persistent infection with human papillomavirus (HPV) is the principal cause of cervical cancer and its precursor cervical intraepithelial neoplasia (CIN). The presence of HPV has been implicated in greater than 99% of cervical cancers worldwide. HPV is a small, non-enveloped, double-stranded DNA virus, with a genome of approximately 8000 nucleotides. There are more than 118 different types of HPV and approximately 40 different HPV types that can infect the human anogenital mucosa. However, only a subset of approximately 14 of these types are considered high-risk for the development of cervical cancer and its precursor lesions.</p> <p>The cobas HPV test performed on the Roche cobas 4800 platform is multiplexed qualitative real-time PCR assay that detects and differentiates between high-risk HPV (hrHPV) types 16, 18, and other (31, 33, 35, 39, 45, 51, 52, 56, 58, 59, 66, and 68). The assay targets a ~200 nucleotide portion of the polymorphic L1 region of the HPV genome, while type-specific probes labeled with different fluorophores differentiates between hrHPV types 16, 18, and other. The test does not detect low-risk HPV types. The assay is FDA-approved for cervical cancer screening in the following situations: reflex testing from ASCUS cervical cytology test results for patients 21 years and older, co-testing with cervical cytology for patients 30 years and older, and first-line primary cervical cancer screening for patients 25 years and older. This lab only accepts specimens collected in ThinPrep PreservCyt solution.</p> <p>This assay has been additionally modified and validated as a lab-developed test to accept fine-needle aspirate (FNA) specimens in ThinPrep PreservCyt solution from patient suspected to have or diagnosed with squamous cell carcinoma of the head and neck. Determination of tumor hrHPV-status in patients suspected to have oropharyngeal squamous cell carcinoma (OPSCC) is critical to staging, prognostication, and therapeutic decision-making. While p16 immunohistochemistry (IHC) is a surrogate marker that can be used to predict hrHPV status, it may be either impossible to perform or unreliable on FNA specimens with scant material. Additionally, p16 IHC can be nonspecifically positive in SCCs from other sites. Accurate classification and staging of a tumor is enhanced when more than one biomarker is utilized (i.e. p16 IHC alongside hrHPV-specific testing) to assess for hrHPV status.</p> <p><b>Specimen Requirement:</b> One cervical specimen in PreservCyt; Ambient; Cervical specimens <b>should be</b> collected in ThinPrep PreservCyt solution using an endocervical brush/spatula. Follow the manufacturer's instructions for collecting cervical specimens. <b>High Risk HPV testing can be performed on a sterile aliquot of the specimen made prior to Cytology processing. Residual specimen after Cytology processing is only acceptable if the ThinPrep processor used is a T2000 or T3000 instrument. Specimens treated with glacial acetic acid are not acceptable for hrHPV testing. *OR* one fine needle aspirate in PreservCyt; Ambient; High Risk HPV testing of fine needle aspirate (FNA) specimens is only indicated for patients suspected of HPV-positive Head and Neck Squamous Cell Carcinoma (HNSCC).</b></p> <p>Fine needle aspirate (FNA) specimens may be collected directly into ThinPrep PreservCyt solution for maximal analytic sensitivity. Residual FNA specimen resuspended in PreservCyt solution after Cytology processing (including after initial collection into intermediary media such as ThinPrep CytoLyt solution or Roswell Park Memorial Institute [RPMI] medium) is also acceptable if the ThinPrep processor used is a T2000 or T3000 instrument.</p> <p><b>Stability:</b>            Ambient: <b>6 months in PreservCyt</b>            Refrigerated: <b>6 months in PreservCyt</b></p> <p><b>Methodology: Qualitative Real-Time PCR</b></p> <p><i>(continued on page 15)</i></p>	5/21/24



## Test Changes (Cont.)

Test Name	Order Code	Change	Effective Date
High Risk Human Papilloma Virus (HPV), PCR for Detection and Genotyping <i>(continued from page 14)</i>		<b>Reference Range:</b> High Risk HPV Type 16 DNA: Not detected High Risk HPV Type 18 DNA: Not detected High Risk HPV Other Type (31, 33, 35, 39, 45, 51, 52, 56, 58, 59, 66, and 68) DNA: Not detected <b>Days Performed:</b> Mon–Sat	
Islet antigen-2 antibody	IA2AB	<b>Stability:</b> Ambient: <b>24 hours</b> Refrigerated: <b>14 days</b> Frozen: 14 days	effective immediately
Ketamine & Metabolite, Serum/Plasma	KETMIN	<b>Special Information:</b> Polymer gel separation tubes (SST or PST) will be rejected. This test is New York DOH approved. <b>Specimen Requirement:</b> 1 mL serum from no additive (Red) tube; Refrigerated; Do not use SST tube. <b>Separate serum from cells ASAP and transfer to standard aliquot tube.</b> *OR* 1 mL plasma from sodium or lithium heparin (Green) tube; Refrigerated; Do not use PST tube. <b>Separate plasma from cells ASAP and transfer to standard aliquot tube.</b> *OR* 1 mL plasma from EDTA (Lavender) tube; Refrigerated; <b>Separate plasma from cells ASAP and transfer to standard aliquot tube.</b> <b>Methodology:</b> Liquid Chromatography-Tandem Mass Spectrometry (LC-MS/MS) <b>Reference Range:</b> Norketamine, Serum/Plasma: <b>Refer to report</b> Ketamine, Serum/Plasma: <b>Refer to report</b> <b>Reported:</b> 5–7 days	effective immediately
Lipid Panel, Basic	LIPB	<b>Stability:</b> Ambient: 1 day Refrigerated: After separation from cells: 7 days Frozen: After separation from cells: <b>3 months</b>	effective immediately
Lipid Panel, Nonfasting	LIPNF	<b>Stability:</b> Ambient: 1 day Refrigerated: After separation from cells: 7 days Frozen: After separation from cells: <b>3 months</b>	effective immediately
LPT to Beryllium, Blood	BLDBE	<b>Special Information:</b> Contact testing laboratory at least 48 hours prior to collecting specimen at <a href="mailto:CellularImmunoPLMI@ccf.org">CellularImmunoPLMI@ccf.org</a> . Specimen should not be collected or delivered on weekends or holidays. <b>Specimen Requirement:</b> 80 mL whole blood in sodium heparin (Green) tube; Ambient; Collect Monday–Wednesday only. Specimens must be delivered to lab by <b>Thursday at 2pm each week; samples cannot be received on Fridays or Saturdays.</b> Do not aliquot. Specimen must remain at ambient temperature. Do not refrigerate or freeze. Collect sample in a sterile container using aseptic technique. Sample cannot be shared with other testing. This test cannot be added on to other testing.	4/2/24
Lysozyme	LYS02	<b>Reference Range:</b> < or = 4.50 ug/mL	effective immediately
Mitochondrial M2 IgG Serum	MITOS	<b>Days Performed:</b> Mon, Thu, Fri	4/2/24
Neutrophil Oxidative Burst, Blood	OXBRST	<b>Includes:</b> Neutrophil Oxidative Burst EER Neutrophil Oxidative Burst <b>Special Information:</b> CRITICAL AMBIENT. <b>THIS TEST REQUIRES MULTIPLE SPECIMENS. Collect one specimen from the patient and label with the patient Beaker label. Collect an additional specimen from an unrelated healthy person; label with the patient Beaker label and write that it is the "Control."</b> Deliver both tubes to the Send-Outs laboratory on the day of collection by 3 p.m. Patient and control specimens must be collected within 48 hours of test performance. Do NOT refrigerate or freeze as live neutrophils are required. Ambient stability is 24 hours for New York clients. This test is New York DOH approved. <i>(continued on page 16)</i>	effective immediately



## Test Changes (Cont.)

Test Name	Order Code	Change	Effective Date
Neutrophil Oxidative Burst, Blood <i>(continued from page 15)</i>		<b>Specimen Requirement:</b> 3 mL whole blood in sodium or lithium (Green) tube; Ambient; <b>CRITICAL AMBIENT. THIS TEST REQUIRES MULTIPLE SPECIMENS. Collect one specimen from the patient and label with the patient Beaker label. Collect an additional specimen from an unrelated healthy person; label with the patient Beaker label and write that it is the "Control." Deliver both tubes to the Send-Outs laboratory on the day of collection by 3 p.m. Patient and control specimens must be collected within 48 hours of test performance. Do NOT refrigerate or freeze as live neutrophils are required. AND 3 mL whole blood in sodium or lithium heparin (Green) tube; Ambient; Required control specimen- see instructions above. Minimum: 2 mL–1 mL per tube (patient and control).</b>	
Organism Identification, Mold	OIDMOL	<p><b>Special Information:</b> Indicate on test order: Original date of collection, specimen site, any pertinent preliminary identification information and telephone number including extension where report may be called if necessary. <b>When this test is ordered, the reflex tests may be performed and charged. All fungal organisms submitted will be identified and billed as appropriate. Additional CPT codes may be applicable for recovery and identification of fungal organisms–87107–ID by MALDI-TOF Mass Spec for mold, 87153–DNA sequencing.</b></p> <p>Antibiotic susceptibility testing must be requested and ordered separately. Contraindications: lack of viability, culture mixed or contaminated.</p> <p>Identification CPT code 87107 will apply. CPT code 87153 may be added if sequencing method is performed to complete the identification.</p> <p><b>Clinical Limitation: If the organism is received in mixed culture or contaminated, identification is not possible and would require additional orders.</b></p> <p><b>Clinical Information: Organism must be in pure culture, actively growing and limited to filamentous fungi. Do not submit mixed cultures. Use OID yeast for yeast identification.</b></p> <p><b>Specimen Requirement:</b> Isolate of organism on agar slant; Ambient; <b>Pure isolates of a single organism should be sent on an agar slant at ambient temperatures.</b></p> <p><b>Stability:</b> Ambient: 4 weeks Refrigerated: 4 weeks Frozen: Unacceptable</p> <p><b>Days Performed: Sun–Sat 7:30 am–4:00 pm</b></p>	5/21/24
Organism Identification, Yeast	OIDYEA	<p><b>Special Information: When this test is ordered, the reflex tests may be performed and charged. All fungal organisms submitted will be identified and billed as appropriate. Additional CPT codes may be applicable for recovery and identification of fungal organisms–87106–ID by MALDI-TOF Mass Spec for yeast, 87153–DNA sequencing.</b></p> <p><b>Clinical Limitation: If the organism is received in mixed culture or contaminated, identification is not possible and would require additional orders.</b></p> <p><b>Clinical Information: Organism must be in pure culture, actively growing. Do not submit mixed cultures.</b></p> <p><b>Specimen Requirement:</b> Isolate of organism on agar slant; Ambient; <b>Pure isolates of a single organism should be sent on an agar slant at ambient temperatures.</b></p> <p><b>Stability:</b> Ambient: 4 weeks Refrigerated: 4 weeks Frozen: Unacceptable</p> <p><b>Days Performed: Sun–Sat 7:30 am–4:00 pm</b></p>	5/21/24
Osmolality, Stool	SOSM	<p><b>Special Information:</b> Formed stool specimens will be rejected. <b>This test is New York state approved.</b></p> <p><b>Specimen Requirement:</b> 5 mL stool in clean container; <b>Frozen; Place liquid stool specimen on ice.</b> Do not add saline or water to liquefy specimen. Separate specimens must be submitted when multiple tests are ordered.</p> <p><b>Stability:</b> Ambient: Unacceptable Refrigerated: <b>1 week</b> Frozen: 1 month</p>	effective immediately
Propafenone	PROPAF	<b>Order Code:</b> Previously PROPA	5/23/24

## Test Changes (Cont.)

Test Name	Order Code	Change	Effective Date
Renal Function Panel	RFP	<b>Reference Range:</b> Chloride: 0 Years to 99 Years: <b>98–107</b> mmol/L Anion Gap: 0 Years and above: <b>8–15</b> mmol/L <i>Note: No change to other Renal Function Panel components</i>	6/4/24
SARP4	SARP4	<b>For interface clients only–Test build may need to be modified</b> <b>Reference Range:</b> Allergen, Dermatophagoides pteronyssinus IgE: < 0.35 kU/L Allergen, Dermatophagoides pteronyssinus Class: 0 Allergen, Dermatophagoides farinae IgE: < 0.35 kU/L Allergen, Dermatophagoides farinae Class: 0 Allergen, Cat Dander IgE: < 0.35 kU/L Allergen, Cat Dander Class: 0 Allergen, Dog Dander IgE: < 0.35 kU/L Allergen, Dog Dander Class: 0 Allergen, Cockroach IgE: < 0.35 kU/L Allergen, Cockroach Class: 0 Allergen, Alternaria tenuis (alternata) IgE: < 0.35 kU/L Allergen, Alternaria tenuis (alternata) Class: 0 Allergen, Cladosporium herbarum (Hormodendrum) IgE: < 0.35 kU/L Allergen, Cladosporium herbarum (Hormodendrum) Class: 0 Allergen, Aspergillus fumigatus IgE: < 0.35 kU/L Allergen, Aspergillus fumigatus Class: 0 Allergen, Timothy Grass IgE: < 0.35 kU/L Allergen, Timothy Grass Class: 0 Allergen, Short (Common) Ragweed IgE: < 0.35 kU/L Allergen, Short (Common) Ragweed Class: 0 Allergen, Cocklebur IgE: < 0.35 kU/L Allergen, Cocklebur Class: 0 Allergen, Lamb's Quarters (Goosefoot) IgE: < 0.35 kU/L Allergen, Lamb's Quarters (Goosefoot) Class: 0 Allergen, Pigweed IgE: < 0.35 kU/L Allergen, Pigweed Class: 0 Allergen, English Plantain (Ribwort) IgE: < 0.35 kU/L Allergen, English Plantain (Ribwort) Class: 0 Allergen, Russian Thistle IgE: < 0.35 kU/L Allergen, Russian Thistle Class: 0 Allergen, Oak Tree IgE: < 0.35 kU/L Allergen, Oak Tree Class: 0 Allergen, Elm Tree IgE: < 0.35 kU/L Allergen, Elm Tree Class: 0 Allergen, Box Elder (Maple) Tree IgE: < 0.35 kU/L Allergen, Box Elder (Maple) Tree Class: 0 Allergen, Willow Tree IgE: < 0.35 kU/L Allergen, Willow Tree Class: 0 Allergen, Beech IgE: < 0.35 kU/L Allergen, Beech Class: 0 Allergen, Birch Tree IgE: < 0.35 kU/L Allergen, Birch Tree Class: 0 Allergen, Walnut IgE: < 0.35 kU/L Allergen, Walnut Class: 0 <b>Mouse Urine IgE: &lt; 0.35 kU/L</b> <b>Mouse Urine Proteins Class: 0</b> IgE: 0 Weeks to 6 Weeks: not established 6 Weeks to 12 Weeks: <6.6 kU/L 3 Months to 6 Months: <10.2 kU/L 6 Months to 9 Months: <16.6 kU/L 9 Months to 12 Months: <22.6 kU/L 1 Years to 2 Years: <29.2 kU/L 2 Years to 3 Years: <51.7 kU/L 3 Years to 4 Years: <72 kU/L 4 Years to 5 Years: <90 kU/L 5 Years to 6 Years: <108 kU/L 6 Years to 7 Years: <126 kU/L 7 Years to 8 Years: <142 kU/L 8 Years to 9 Years: <160 kU/L 9 Years to 10 Years: <176 kU/L 10 Years to 11 Years: <192 kU/L 11 Years to 99 Years: <114 kU/L	5/21/24

## Test Changes (Cont.)

Test Name	Order Code	Change	Effective Date
Staphylococcus aureus & MRSA Screen, Culture, Skin	SANSAL	<p><b>Name:</b> Previously MRSA/Staph aureus Culture Screen</p> <p><b>Specimen Requirement:</b> One nasal E-swab; Ambient *OR* One rectal E-swab; Ambient *OR* One throat E-swab; Ambient *OR* One axillary E-swab; Ambient *OR* One groin E-swab; Ambient *OR* One skin/mucous membrane E-swab; Ambient</p> <p><b>Stability:</b>                      Ambient: 48 hours                      Refrigerated: <b>48 hours</b>                      Frozen: Unacceptable</p>	5/21/24
Staphylococcus aureus & MRSA Screen, PCR, Nasal	SAPCR	<p><b>Name:</b> Previously Staph aureus PCR</p> <p><b>Specimen Requirement:</b> One nasal swab in Amies or Stuart's media without charcoal; Refrigerated; <b>Collect specimen with Cepheid Collection Device, Oracle 1616432. Swabs in gel or other transport medium, dry swabs, and swabs with wooden shaft will be rejected.</b></p> <p><b>Reference Range:</b>                      MRSA PCR: Not Detected                      Staph aureus PCR: Not Detected</p>	5/21/24
Tularemia Antibodies, IgG and IgM	TULGMA	<p><b>Order Code:</b> Previously TULGM</p>	effective immediately
UBA1 Mutation Testing for VEXAS Syndrome	VEXAS	<p><b>Clinical Information:</b> UBA1 mutations are responsible for VEXAS (vacuoles, E1-enzyme, X-linked, autoinflammatory, somatic) syndrome. Testing should be considered in men aged &gt;50 years with refractory autoimmune disorders and cytopenias of unknown etiology. Testing of women and patients aged &lt;50 years may be considered after exclusion of more likely conditions.</p>	effective immediately
Venlafaxine & Metabolite	VENLA	<p><b>For interface clients only--Test build may need to be modified</b></p> <p><b>Includes:</b>                      Venlafaxine Serum/Plasma                      O-Desmethylvenlafaxine Serum/Plasma                      Total Venlafaxine and Metabolite S/P</p> <p><b>Special Information:</b> Pre-dose (trough) draw--At steady state concentration. Whole blood and gel separator tubes will be rejected. This test is New York DOH approved.</p> <p><b>Clinical Information:</b> This test is useful to optimize drug therapy and monitor patient adherence. The therapeutic range is based on serum pre-dose (trough) draw at steady-state concentration. Adverse effects to venlafaxine therapy may include nausea, vomiting, dizziness, tremor and blurred vision.</p> <p><b>Specimen Requirement:</b> 1 mL serum from no additive (Red) tube; Minimum: 0.5 mL; Refrigerated; Pre-dose (trough) draw--At steady state concentration. Do not use serum separator tubes. Separate serum from cells ASAP or within 2 hours of collection and transfer to standard aliquot tube. *OR* 1 mL plasma from EDTA (Lavender) tube; Minimum: 0.5 mL; Refrigerated; Pre-dose (trough) draw--At steady state concentration. Separate plasma from cells ASAP or within 2 hours of collection and transfer to standard aliquot tube.</p> <p><b>Stability:</b>                      Ambient: <b>2 weeks</b>                      Refrigerated: <b>2 weeks</b>                      Frozen: <b>2 weeks</b></p> <p><b>Methodology:</b> Quantitative Liquid Chromatography--Tandem Mass Spectrometry</p> <p><b>Reference Range:</b>                      Total Venlafaxine and Metabolite S/P:                      Therapeutic 195-400 ng/mL                      Toxic: Greater than or equal to 800 ng/mL</p> <p><b>Days Performed:</b> Wed, Sat</p> <p><b>Reported:</b> 2-9 days</p> <p><b>CPT:</b> 80338</p>	4/4/24

## Test Changes (Cont.)

Test Name	Order Code	Change	Effective Date
Yeast Screen	FUNGSC	<p><b>Name:</b> Previously Fungus Screen</p> <p><b>Includes:</b> Specimens may include some pre-processing steps to aid in recovery of yeast</p> <p><b>Special Information:</b> Specimens are plated on special fungal media for recovery, isolation and identification of yeast. Cultures are only held for 7 days. This is adequate time to culture yeast organisms but if fastidious yeast or filamentous mold infections are suspected fungal culture and smear (FCULSM) should be ordered by contacting the lab/medical director. Susceptibility testing on isolated recovered from vaginal and oral samples must be separately requested when clinically indicated. These requests can be made by calling lab client services or by calling the lab/medical director. Additional CPT codes may be applicable for recovery and identification of yeast–87102 Fungal culture, 87106–ID by MALDI-TOF Mass Spec for yeast, 87107–ID by MALDI-TOF Mass Spec for Mold, 87153–DNA sequencing, 87186–Fungal susceptibility testing for yeast by request only.</p> <p><b>Clinical Limitation:</b> Yeast especially Candida species are part of the normal vaginal and oral flora. Significance of recovery and identification of yeast from these sites requires clinical correlation.</p> <p><b>Clinical Information:</b> This test can be utilized to determining etiology of infectious vaginitis, monitoring therapeutic efficacy for vaginitis and/or management of chronic recurring disease. Diagnosis can be challenging as yeast are part of the normal vaginal and oral flora. Clinical factors such as clinical symptoms and signs consistent with disease should be considered. In cases of recurrent infections where development of resistance is suspected, susceptibility testing can be requested by contacting lab client services and/or the lab/medical director.</p> <p><b>Specimen Requirement:</b> vaginal E-swab; Wipe away excessive amount of secretion and discharge prior to collection. Secretions from the mucosal membrane of the vaginal vault should be collected with a moist E-swab. If fungal infections other than Candida species are suspected, fungal culture and smear should be ordered and required pre-approval for this specimen source by contacting the lab/medical director. *OR* other E-swab Mucosal surface of gums, oral lesions and oropharyngeal specimens can be screened when thrush is suspected. Lesions should be scraped gently and submitted for culture. If fungal infections other than Candida species are suspected, fungal culture and smear should be ordered and required pre-approval for this specimen source by contacting the lab/medical director.</p> <p><b>Stability:</b>            Ambient: <b>7 days</b>            Refrigerated: <b>7 days</b>            Frozen: Unacceptable</p> <p><b>Days Performed:</b> Sun–Sat 7:30 am–4:00 pm</p>	5/21/24

# New Tests

Test Name	Order Code	Change	Effective Date
Allergen, Food, Nutmeg IgE	NUTMEG	<p><b>Includes:</b> Allergen, Food, Nutmeg IgE</p> <p><b>Special Information:</b> Hemolyzed, icteric, or lipemic specimens will be rejected. This test is New York state approved.</p> <p><b>Clinical Information:</b> Allergen results of 0.10-0.34 kU/L are intended for specialist use as the clinical relevance is undetermined. Even though increasing ranges are reflective of increasing concentrations of allergen-specific IgE, these concentrations may not correlate with the degree of clinical response or skin testing results when challenged with a specific allergen. The correlation of allergy laboratory results with clinical history and in vivo reactivity to specific allergens is essential. A negative test may not rule out clinical allergy or even anaphylaxis.</p> <p><b>Specimen Requirement:</b> 0.5 mL serum from serum separator (Gold) tube; Minimum: 0.25 mL; Refrigerated; Separate serum from cells ASAP or within 2 hours of collection. Transfer serum to standard aliquot tube.</p> <p><b>Stability:</b>            Ambient: 48 hours            Refrigerated: 2 weeks            Frozen: 1 year</p> <p><b>Methodology:</b> Quantitative ImmunoCAP Fluorescent Enzyme Immunoassay</p> <p><b>Reference Range:</b>            Less than 0.10 kU/L: No significant level detected            0.10–0.34 kU/L: Clinical relevance undetermined            0.35–0.70 kU/L: Low            0.71–3.50 kU/L: Moderate            3.51–17.50 kU/L: High            17.51 kU/L or greater: Very High</p> <p><b>Days Performed:</b> Sun–Sat</p> <p><b>Reported:</b> 2–4 days</p> <p><b>CPT:</b> 86003</p>	6/11/24
Allergen, Fungi and Molds, Bipolaris spicifera (Curvularia) IgE	BPSPFR	<p><b>Includes:</b> Allergen, Fungi/Mold, B. spicifera IgE</p> <p><b>Special Information:</b> Hemolyzed, icteric, or lipemic specimens will be rejected. This test is New York state approved.</p> <p><b>Clinical Information:</b> Allergen results of 0.10-0.34 kU/L are intended for specialist use as the clinical relevance is undetermined. Even though increasing ranges are reflective of increasing concentrations of allergen-specific IgE, these concentrations may not correlate with the degree of clinical response or skin testing results when challenged with a specific allergen. The correlation of allergy laboratory results with clinical history and in vivo reactivity to specific allergens is essential. A negative test may not rule out clinical allergy or even anaphylaxis.</p> <p><b>Specimen Requirement:</b> 0.5 mL serum from serum separator (Gold) tube; Minimum: 0.25 mL; Refrigerated; Separate serum from cells ASAP or within 2 hours of collection. Transfer serum to standard aliquot tube.</p> <p><b>Stability:</b>            Ambient: 48 hours            Refrigerated: 2 weeks            Frozen: 1 year</p> <p><b>Methodology:</b> Quantitative ImmunoCAP Fluorescent Enzyme Immunoassay</p> <p><b>Reference Range:</b>            Less than 0.10 kU/L: No significant level detected            0.10–0.34 kU/L: Clinical relevance undetermined            0.35–0.70 kU/L: Low            0.71–3.50 kU/L: Moderate            3.51–17.50 kU/L: High            17.51 kU/L or greater: Very High</p> <p><b>Days Performed:</b> Sun–Sat</p> <p><b>Reported:</b> 2–4 days</p> <p><b>CPT:</b> 86003</p>	6/4/24

## New Tests (Cont.)

Test Name	Order Code	Change	Effective Date
Allergen, Fungi and Molds, Curvularia lunata IgE	CRVLRA	<p><b>Includes:</b> Allergen, Fungi/Mold, C. lunata IgE</p> <p><b>Special Information:</b> Hemolyzed, icteric, or lipemic specimens will be rejected. This test is New York state approved.</p> <p><b>Clinical Information:</b> Allergen results of 0.10-0.34 kU/L are intended for specialist use as the clinical relevance is undetermined. Even though increasing ranges are reflective of increasing concentrations of allergen-specific IgE, these concentrations may not correlate with the degree of clinical response or skin testing results when challenged with a specific allergen. The correlation of allergy laboratory results with clinical history and in vivo reactivity to specific allergens is essential. A negative test may not rule out clinical allergy or even anaphylaxis.</p> <p><b>Specimen Requirement:</b> 0.5 mL serum from serum separator (Gold) tube; Minimum: 0.25 mL; Refrigerated; Separate serum from cells ASAP or within 2 hours of collection. Transfer serum to standard aliquot tube.</p> <p><b>Stability:</b>                      Ambient: 48 hours                      Refrigerated: 2 weeks                      Frozen: 1 year</p> <p><b>Methodology:</b> Quantitative ImmunoCAP Fluorescent Enzyme Immunoassay</p> <p><b>Reference Range:</b>                      Less than 0.10 kU/L: No significant level detected                      0.10–0.34 kU/L: Clinical relevance undetermined                      0.35–0.70 kU/L: Low                      0.71–3.50 kU/L: Moderate                      3.51–17.50 kU/L: High                      17.51 kU/L or greater: Very High</p> <p><b>Days Performed:</b> Sun–Sat</p> <p><b>Reported:</b> 2–4 days</p> <p><b>CPT:</b> 86003</p>	6/4/24
Allergen Lupine Seed IgE	LUPNSD	<p><b>Includes:</b> Lupine Seed (Lupinus albus) IgE</p> <p><b>Special Information:</b> This test is New York state approved.</p> <p><b>Specimen Requirement:</b> 0.5 mL serum from no additive (Red) tube; Minimum: 0.34 mL; Ambient; Separate serum from cells ASAP and transfer to standard aliquot tube.</p> <p><b>Stability:</b>                      Ambient: 1 month                      Refrigerated: 1 month                      Frozen: 1 month</p> <p><b>Methodology:</b> Fluorescent Enzyme Immunoassay (FEIA) by ImmunoCAP</p> <p><b>Reference Range:</b>                      Less than 0.10 kU/L: Negative                      0.10–0.34 kU/L: Equivocal/Borderline                      0.35–0.69 kU/L: Low Positive                      0.70–3.49 kU/L: Moderate Positive                      3.50–17.49 kU/L: High Positive                      17.50 kU/L or greater: Very High Positive</p> <p><b>Days Performed:</b> Mon–Fri</p> <p><b>Reported:</b> 2–3 days</p> <p><b>CPT:</b> 86003</p>	5/28/24

## New Tests (Cont.)

Test Name	Order Code	Change	Effective Date
Allergen, Weed, Sagebrush/Wormwood IgE	SGBRSH	<p><b>Includes:</b> Allergen, Weed, Sagebrush/Wormwood IgE</p> <p><b>Special Information:</b> Hemolyzed, icteric, or lipemic specimens will be rejected. This test is New York state approved.</p> <p><b>Clinical Information:</b> Allergen results of 0.10-0.34 kU/L are intended for specialist use as the clinical relevance is undetermined. Even though increasing ranges are reflective of increasing concentrations of allergen-specific IgE, these concentrations may not correlate with the degree of clinical response or skin testing results when challenged with a specific allergen. The correlation of allergy laboratory results with clinical history and in vivo reactivity to specific allergens is essential. A negative test may not rule out clinical allergy or even anaphylaxis.</p> <p><b>Specimen Requirement:</b> 0.5 mL serum from serum separator (Gold) tube; Minimum: 0.25 mL; Refrigerated; Separate serum from cells ASAP or within 2 hours of collection. Transfer serum to standard aliquot tube.</p> <p><b>Stability:</b>                      Ambient: 48 hours                      Refrigerated: 2 weeks                      Frozen: 1 year</p> <p><b>Methodology:</b> Quantitative ImmunoCAP Fluorescent Enzyme Immunoassay</p> <p><b>Reference Range:</b>                      Less than 0.10 kU/L: No significant level detected                      0.10–0.34 kU/L: Clinical relevance undetermined                      0.35–0.70 kU/L: Low                      0.71–3.50 kU/L: Moderate                      3.51–17.50 kU/L: High                      17.51 kU/L or greater: Very High</p> <p><b>Days Performed:</b> Sun–Sat</p> <p><b>Reported:</b> 2–4 days</p> <p><b>CPT:</b> 86003</p>	6/13/24
Apricot, IgE	APRICT	<p><b>Includes:</b> Allergen, Food, Apricot IgE</p> <p><b>Special Information:</b> Hemolyzed, icteric, or lipemic specimens will be rejected. This test is New York state approved.</p> <p><b>Clinical Information:</b> Allergen results of 0.10-0.34 kU/L are intended for specialist use as the clinical relevance is undetermined. Even though increasing ranges are reflective of increasing concentrations of allergen-specific IgE, these concentrations may not correlate with the degree of clinical response or skin testing results when challenged with a specific allergen. The correlation of allergy laboratory results with clinical history and in vivo reactivity to specific allergens is essential. A negative test may not rule out clinical allergy or even anaphylaxis.</p> <p><b>Specimen Requirement:</b> 0.5 mL serum from serum separator (Gold) tube; Minimum: 0.25 mL; Refrigerated; Separate serum from cells ASAP or within 2 hours of collection. Transfer serum to standard aliquot tube.</p> <p><b>Stability:</b>                      Ambient: 48 hours                      Refrigerated: 2 weeks                      Frozen: 1 year</p> <p><b>Methodology:</b> Quantitative ImmunoCAP Fluorescent Enzyme Immunoassay</p> <p><b>Reference Range:</b>                      Less than 0.10 kU/L: No significant level detected                      0.10–0.34 kU/L: Clinical relevance undetermined                      0.35–0.70 kU/L: Low                      0.71–3.50 kU/L: Moderate                      3.51–17.50 kU/L: High                      17.51 kU/L or greater: Very High</p> <p><b>Days Performed:</b> Sun–Sat</p> <p><b>Reported:</b> 2–4 days</p> <p><b>CPT:</b> 86003</p>	6/11/24



## New Tests (Cont.)

Test Name	Order Code	Change	Effective Date
Asparagus, IgE allergen	ASPRGS	<p><b>Includes:</b> Allergen, Food, Asparagus IgE</p> <p><b>Special Information:</b> Hemolyzed, icteric, or lipemic specimens will be rejected. This test is New York state approved.</p> <p><b>Clinical Information:</b> Allergen results of 0.10-0.34 kU/L are intended for specialist use as the clinical relevance is undetermined. Even though increasing ranges are reflective of increasing concentrations of allergen-specific IgE, these concentrations may not correlate with the degree of clinical response or skin testing results when challenged with a specific allergen. The correlation of allergy laboratory results with clinical history and in vivo reactivity to specific allergens is essential. A negative test may not rule out clinical allergy or even anaphylaxis.</p> <p><b>Specimen Requirement:</b> 0.5 mL serum from serum separator (Gold) tube; Minimum: 0.25 mL; Refrigerated; Separate serum from cells ASAP or within 2 hours of collection. Transfer serum to standard aliquot tube.</p> <p><b>Stability:</b>                      Ambient: 48 hours                      Refrigerated: 2 weeks                      Frozen: 1 year</p> <p><b>Methodology:</b> Quantitative ImmunoCAP Fluorescent Enzyme Immunoassay</p> <p><b>Reference Range:</b>                      Less than 0.10 kU/L: No significant level detected                      0.10–0.34 kU/L: Clinical relevance undetermined                      0.35–0.70 kU/L: Low                      0.71–3.50 kU/L: Moderate                      3.51–17.50 kU/L: High                      17.51 kU/L or greater: Very High</p> <p><b>Days Performed:</b> Sun–Sat</p> <p><b>Reported:</b> 2–4 days</p> <p><b>CPT:</b> 86003</p>	6/4/24
Autoimmune Pediatric CNS Disorders, CSF	APCNSC	<p><b>Special Information:</b> Reflex Algorithm: Each reflex test performed incurs additional charge. If NMDA CSF antibody IgG is positive, then titer will be performed. PCCA/ANNA antibody IgG is screened by IFA. If the IFA screen is indeterminate, then a Neuronal Nuclear Antibodies (Hu and Tr/DNER) IgG by Immunoblot will be performed. If the IFA screen is positive at 1:10 or greater, then a PCCA/ANNA antibodies titer and Neuronal Nuclear Antibodies (Hu and Tr/DNER) IgG by Immunoblot will be performed. If LGI1 CSF antibody IgG is positive, then titer will be added.</p> <p>If CASPR2 CSF antibody IgG is positive, then titer will be added. If AQP4/NMO CSF antibody IgG by IFA is positive, then titer will be added. If GABA-BR CSF antibody IgG by IFA is positive, then titer will be added. If DPPX CSF antibody IgG by IFA is positive, then titer will be added.</p> <p>If mGluR1 CSF antibody IgG by IFA is positive, then titer will be added. If GABA-AR CSF antibody IgG by IFA is positive, then titer will be added. Grossly hemolyzed specimens will be rejected. This test is New York state approved.</p> <p><b>Clinical Information:</b> Use to evaluate subacute-onset encephalopathy, epilepsy, behavior changes, or movement disorders in individuals &lt;18 years of age.</p> <p><b>Specimen Requirement:</b> 3 mL cerebrospinal fluid (CSF) in sterile container; Minimum: 1.5 mL Frozen; Transfer 1.0 mL CSF in three aliquot tubes and freeze. Minimum: 0.5 mL per aliquot tube.</p> <p><b>Stability:</b>                      Ambient: 24 hours                      Refrigerated: 1 week                      Frozen: 30 days (avoid repeated freeze/thaw cycles)</p> <p><b>Methodology:</b>                      Enzyme-Linked Immunosorbent Assay (ELISA)                      Semi-Quantitative Cell-Based Indirect Fluorescent Antibody                      Semi-Quantitative Indirect Fluorescent Antibody</p> <p><i>(continued on page 24)</i></p>	6/6/24

## New Tests (Cont.)

Test Name	Order Code	Change	Effective Date
Autoimmune Pediatric CNS Disorders, CSF <i>(continued from page 23)</i>	APCNCS	<p><b>Reference Range:</b>            Paraneoplastic Abs (PCCA/ANNA) IgG, CSF: None detected            Glutamic Acid Decarboxylase Antibody CSF: 0.0–5.0 IU/mL            DPPX Ab IgG CBA-IFA Screen, CSF: Less than 1:1            mGluR1 Ab IgG CBA-IFA Screen, CSF: Less than 1:1            NMO/AQP4 Ab IgG CBA-IFA Screen, CSF: Less than 1:1            NMDA Receptor Ab IgG CBA-IFA, CSF: Less than 1:1            GABA-BR Ab IgG CBA-IFA Screen, CSF: Less than 1:1            CASPR2 Ab IgG CBA-IFA Screen, CSF: Less than 1:1            LGI1 Ab IgG CBA-IFA Screen, CSF: Less than 1:1            GABA-AR Ab IgG CBA-IFA Screen, CSF: Less than 1:1</p> <p><b>Days Performed:</b> Varies  <b>Reported:</b> 4–11 days  <b>CPT:</b> 86341x1; 86052x1; 86255x8</p>	6/6/24
Autoimmune Pediatric CNS Disorders, Serum	APCNSS	<p><b>Special Information:</b> Reflex Algorithm: Each reflex test performed incurs additional charge. If NMDA antibody IgG is positive, then titer will be performed. PCCA/ANNA antibody IgG is screened by IFA. If the IFA screen is indeterminate, then a Neuronal Nuclear Antibodies (Hu and Tr/DNER) IgG by Immunoblot will be performed. If the IFA screen is positive at 1:10 or greater, then a PCCA/ANNA antibodies titer and Neuronal Nuclear Antibodies (Hu and Tr/DNER) IgG by Immunoblot will be performed. If LGI1 antibody IgG is positive, then titer will be added. If CASPR2 antibody IgG is positive, then titer will be added. If AQP4/NMO antibody IgG by IFA is positive, then titer will be added. If GABA-BR antibody IgG by IFA is positive, then titer will be added. If MOG antibody IgG by IFA is positive, then titer will be added. If DPPX antibody IgG by IFA is positive, then titer will be added. If mGluR1 antibody IgG by IFA is positive, then titer will be added. If GABA-AR antibody IgG by IFA is positive, then titer will be added. Contaminated, hemolyzed, icteric, or lipemic specimens will be rejected. This test is New York state approved.</p> <p><b>Clinical Information:</b> Used to evaluate subacute-onset encephalopathy, epilepsy, behavior changes, or movement disorders in individuals &lt;18 years of age.</p> <p><b>Specimen Requirement:</b> 3 mL serum from serum separator (Gold) tube; Minimum: 1.5 mL; Frozen; Separate serum from cells ASAP or within 2 hours of collection. Transfer 1.0 mL serum in three aliquot tubes and freeze. Minimum: 0.5 mL per aliquot tube</p> <p><b>Stability:</b>            Ambient: After separation from cells: 24 hours            Refrigerated: After separation from cells: 1 week            Frozen: After separation from cells: 30 days (avoid repeated freeze/thaw cycles)</p> <p><b>Methodology:</b>            Enzyme-Linked Immunosorbent Assay (ELISA)            Semi-Quantitative Cell-Based Indirect Fluorescent Antibody            Semi-Quantitative Indirect Fluorescent Antibody</p> <p><b>Reference Range:</b>            Purkinje Cell/Neuronal Nuclear IgG Scrn: None detected            DPPX Ab IgG CBA-IFA Screen, Serum: Less than 1:10            Glutamic Acid Decarboxylase Antibody: 0.0–5.0 IU/mL            mGluR1 Ab IgG CBA-IFA Screen, Serum: Less than 1:10            NMDA Receptor Ab IgG CBA-IFA, Serum: Less than 1:10            CASPR2 Ab IgG CBA-IFA Screen, Serum: Less than 1:10            LGI1 Ab IgG CBA-IFA Screen, Serum: Less than 1:10            GABA-BR Ab IgG CBA-IFA Scrn, Ser: Less than 1:10            NMO/AQP4 Ab IgG CBA-IFA Screen, Serum: Less than 1:10            MOG Ab IgG CBA-IFA Screen, Serum: Less than 1:10            GABA-AR Ab IgG CBA-IFA Screen, Serum: Less than 1:10</p> <p><b>Days Performed:</b> Varies  <b>Reported:</b> 4–11 days  <b>CPT:</b> 86341x1; 86362x1; 86052x1; 86255x8</p>	6/6/24

## New Tests (Cont.)

Test Name	Order Code	Change	Effective Date
Carnitine Free and Total, Plasma	CARNFT	<p><b>Includes:</b>            Carnitine Total            Carnitine Free (FC)            Acylcarnitine (AC)            AC/FC Ratio            Interpretation</p> <p><b>Special Information:</b> This test is New York State approved.</p> <p><b>Clinical Information:</b> This test is useful for evaluation of patients with a clinical suspicion of a wide range of conditions including organic acidemias, fatty acid oxidation disorders, and primary carnitine deficiency using plasma specimens.</p> <p><b>Specimen Requirement:</b> 0.5 mL plasma from sodium heparin (Green) tube; Minimum 0.2 mL; Frozen; Patient age is required. Centrifuge and aliquot plasma into standard aliquot tube. *OR* 0.5 mL plasma from EDTA (Lavender) tube; Minimum 0.2 mL; Frozen; Patient age is required. Centrifuge and aliquot plasma into standard aliquot tube. *OR* 0.5 mL plasma from lithium heparin (Green) tube; Frozen; Minimum 0.2 mL; Patient age is required. Centrifuge and aliquot plasma into standard aliquot tube.</p> <p><b>Stability:</b>            Ambient: 7 days            Refrigerated: 21 days            Frozen: 60 days</p> <p><b>Methodology:</b> Flow Injection Analysis-Tandem Mass Spectrometry (FIA-MS/MS)</p> <p><b>Days Performed:</b> Mon-Fri</p> <p><b>Reported:</b> 4-6 days</p> <p><b>CPT:</b> 82379</p>	effective immediately
Cheese Mozzarella IgE allergen	MZRLLA	<p><b>Includes:</b> Cheese Mozzarella IgE</p> <p><b>Special Information:</b> This test is New York state approved.</p> <p><b>Specimen Requirement:</b> 0.5 mL serum from no additive (Red) tube; Minimum: 0.34 mL; Ambient; Separate serum from cells ASAP and transfer to standard aliquot tube.</p> <p><b>Stability:</b>            Ambient: 1 month            Refrigerated: 1 month            Frozen: 1 month</p> <p><b>Methodology:</b> Fluorescent Enzyme Immunoassay (FEIA) by ImmunoCAP</p> <p><b>Reference Range:</b>            Less than 0.35 kU/L: Below Detection            0.35-0.69 kU/L: Low Positive            0.70-3.49 kU/L: Moderate Positive            3.50-17.49 kU/L: Positive            17.50-49.99 kU/L: Strong Positive            50.00 kU/L or greater: Very Strong Positive</p> <p><b>Days Performed:</b> Mon-Fri</p> <p><b>Reported:</b> 2-7 days</p> <p><b>CPT:</b> 86003</p>	5/28/24

## New Tests (Cont.)

Test Name	Order Code	Change	Effective Date
Cheese Parmesan IgE allergen	PRMSAN	<p><b>Includes:</b> Cheese Parmesan IgE</p> <p><b>Special Information:</b> This test is New York state approved.</p> <p><b>Specimen Requirement:</b> 0.5 mL serum from no additive (Red) tube; Minimum: 0.34 mL; Ambient; Separate serum from cells ASAP and transfer to standard aliquot tube.</p> <p><b>Stability:</b>                      Ambient: 1 month                      Refrigerated: 1 month                      Frozen: 1 month</p> <p><b>Methodology:</b> Fluorescent Enzyme Immunoassay (FEIA) by ImmunoCAP</p> <p><b>Reference Range:</b>                      Less than 0.35 kU/L: Below Detection                      0.35–0.69 kU/L: Low Positive                      0.70–3.49 kU/L: Moderate Positive                      3.50–17.49 kU/L: Positive                      17.50–49.99 kU/L: Strong Positive                      50.00 kU/L or greater: Very Strong Positive</p> <p><b>Days Performed:</b> Mon–Fri</p> <p><b>Reported:</b> 2–7 days</p> <p><b>CPT:</b> 86003</p>	5/28/24
Cheese Swiss IgE allergen	SWISS	<p><b>Includes:</b> Cheese Swiss IgE</p> <p><b>Special Information:</b> This test is New York state approved.</p> <p><b>Specimen Requirement:</b> 0.5 mL serum from no additive (Red) tube; Minimum: 0.34 mL; Ambient; Separate serum from cells ASAP and transfer to standard aliquot tube.</p> <p><b>Stability:</b>                      Ambient: 1 month                      Refrigerated: 1 month                      Frozen: 1 month</p> <p><b>Methodology:</b> Fluorescent Enzyme Immunoassay (FEIA) by ImmunoCAP</p> <p><b>Reference Range:</b>                      Less than 0.35 kU/L: Below Detection                      0.35–0.69 kU/L: Low Positive                      0.70–3.49 kU/L: Moderate Positive                      3.50–17.49 kU/L: Positive                      17.50–49.99 kU/L: Strong Positive                      50.00 kU/L or greater: Very Strong Positive</p> <p><b>Days Performed:</b> Mon–Fri</p> <p><b>Reported:</b> 2–7 days</p> <p><b>CPT:</b> 86003</p>	5/28/24
Hops, IgE allergen	HPSIGE	<p><b>Includes:</b> F324-IgE Hop (Food)</p> <p><b>Specimen Requirement:</b> 0.2 mL serum from serum separator (Gold) tube; Ambient; Separate serum from cells ASAP or within 2 hours of collection. Transfer serum to standard aliquot tube.</p> <p><b>Stability:</b>                      Ambient: 14 days                      Refrigerated: 14 days                      Frozen: 3 months</p> <p><b>Methodology:</b> Immunocap</p> <p><b>Reference Range:</b>                      Less than 0.10 kU/L: Negative                      0.10–0.31 kU/L: Equivocal/Low                      0.32–0.55 kU/L: Low                      0.56–1.40 kU/L: Moderate                      1.41–3.90 kU/L: High                      3.91 kU/L or greater: Very High</p> <p><b>Days Performed:</b> Sun–Sat</p> <p><b>Reported:</b> 3–5 days</p> <p><b>CPT:</b> 86003</p>	5/28/24

## New Tests (Cont.)

Test Name	Order Code	Change	Effective Date
Mosquito IgE Allergen	MOSQTO	<p><b>Includes:</b> Allergen, Insect, Mosquito, IgE</p> <p><b>Special Information:</b> Hemolyzed, icteric, or lipemic specimens will be rejected. This test is New York state approved.</p> <p><b>Clinical Information:</b> Allergen results of 0.10-0.34 kU/L are intended for specialist use as the clinical relevance is undetermined. Even though increasing ranges are reflective of increasing concentrations of allergen-specific IgE, these concentrations may not correlate with the degree of clinical response or skin testing results when challenged with a specific allergen. The correlation of allergy laboratory results with clinical history and in vivo reactivity to specific allergens is essential. A negative test may not rule out clinical allergy or even anaphylaxis.</p> <p><b>Specimen Requirement:</b> 0.5 mL serum from serum separator (Gold) tube; Minimum: 0.25 mL; Refrigerated; Separate serum from cells ASAP or within 2 hours of collection. Transfer serum to standard aliquot tube.</p> <p><b>Stability:</b>            Ambient: 48 hours            Refrigerated: 2 weeks            Frozen: 1 year</p> <p><b>Methodology:</b> Quantitative ImmunoCAP Fluorescent Enzyme Immunoassay</p> <p><b>Reference Range:</b>            Less than 0.10 kU/L: No significant level detected            0.10–0.34 kU/L: Clinical relevance undetermined            0.35–0.70 kU/L: Low            0.71–3.50 kU/L: Moderate            3.51–17.50 kU/L: High            17.51 kU/L or greater: Very High</p> <p><b>Days Performed:</b> Sun–Sat</p> <p><b>Reported:</b> 2–4 days</p> <p><b>CPT:</b> 86003</p>	6/11/24
Plasma Carnitine Free/Total and Acylcarnitines Panel	PCAPNL	<p><b>Includes:</b>            Carnitine Total            Carnitine Free (FC)            Acylcarnitine (AC)            AC/FC Ratio            Interpretation            Acetylcarnitine, C2            Acrylylcarnitine, C3:1            Propionylcarnitine, C3            Formiminoglutamate, FIGLU            Iso-/Butyrylcarnitine, C4            Tiglylcarnitine, C5:1            Isovaleryl-/2-Methylbutyrylcarn C5            3-OH-iso-/butyrylcarnitine, C4-OH            Hexenoylcarnitine, C6:1            Hexanoylcarnitine, C6            3-OH-isovalerylcarnitine, C5-OH            Benzoylcarnitine            Heptanoylcarnitine, C7            3-OH-hexanoylcarnitine, C6-OH            Phenylacetylcarnitine            Salicylcarnitine            Octenoylcarnitine, C8:1            Octanoylcarnitine, C8            Malonylcarnitine, C3-DC            Decadienoylcarnitine, C10:2            Decenoylcarnitine, C10:1            Decanoylcarnitine, C10            Methylmalonyl-/succinylcarn, C4-DC            3-OH-decenoylcarnitine, C10:1-OH            Glutarylcarnitine, C5-DC            Dodecenoylcarnitine, C12:1            Dodecanoylcarnitine, C12            3-Methylglutarylcarnitine, C6-DC            3-OH-dodecenoylcarnitine, C12:1-OH</p> <p><i>(continued on page 28)</i></p>	effective immediately

## New Tests (Cont.)

Test Name	Order Code	Change	Effective Date
Plasma Carnitine Free/Total and Acylcarnitines Panel	PCAPNL	<p><b>Includes (continued):</b>            3-OH-dodecanoylcarnitine, C12-OH            Tetradecadienoylcarnitine, C14:2            Tetradecenoylcarnitine, C14:1            Tetradecanoylcarnitine, C14            Octanedioylcarnitine, C8-DC            3-OH-tetradecenoylcarnitine C14:1OH            3-OH-tetradecanoylcarnitine, C14-OH            Hexadecenoylcarnitine, C16:1            Hexadecanoylcarnitine, C16            3-OH-hexadecenoylcarnitine,C16:1-OH            3-OH-hexadecanoylcarnitine, C16-OH            Octadecadienoylcarnitine, C18:2            Octadecenoylcarnitine, C18:1            Octadecanoylcarnitine, C18            Dodecanedioylcarnitine, C12-DC            3-OH-octadecadienoylcarn, C18:2-OH            3-OH-octadecenoylcarnitine C18:1-OH            3-OH-octadecanoylcarnitine, C18-OH            Comment (ACRN)</p> <p><b>Special Information:</b> This test is New York State approved.</p> <p><b>Clinical Information:</b> This test is useful for evaluation of patients with a clinical suspicion of a wide range of conditions including organic acidemias, fatty acid oxidation disorders, and primary carnitine deficiency using plasma specimens. It is also useful for diagnosis of fatty acid oxidation disorders and several organic acidurias using plasma specimens. It is also useful in evaluating treatment during follow-up of patients with fatty acid beta-oxidation disorders and several organic acidurias.</p> <p><i>(continued on page 29)</i></p> <p><b>Specimen Requirement:</b> MULTIPLE SPECIMEN TUBES MUST BE COLLECTED FOR THIS PANEL. 0.5 mL plasma from sodium heparin (Green) tube; Minimum: 0.2 mL; Frozen; This tube is for test: Carnitine Free and Total, Plasma (CARNFT). Collect specimen just prior to a scheduled meal or feeding. Patient age is required. Centrifuge and aliquot plasma into standard aliquot tube. AND 0.1 mL plasma from sodium heparin (Green) tube; Minimum 0.04 mL; Frozen; This tube is for test: Acylcarnitines, Quantitative, Plasma (ACRNPL). Collect specimen just prior to a scheduled meal or feeding. Patient age is required. Centrifuge and aliquot plasma into standard aliquot tube.</p> <p><b>Stability:</b>            Ambient: 7 days            Refrigerated: 21 days            Frozen: 60 days</p> <p><b>Methodology:</b> Flow Injection Analysis-Tandem Mass Spectrometry (FIA-MS/MS)</p> <p><b>Days Performed:</b> Mon-Fri</p> <p><b>Reported:</b> 3-6 days</p> <p><b>CPT:</b> 82379x1; 82017x1</p>	effective immediately
Spinach IgE allergen	SPNACH	<p><b>Includes:</b> Allergen, Food, Spinach IgE</p> <p><b>Special Information:</b> Hemolyzed, icteric, or lipemic specimens will be rejected. This test is New York state approved.</p> <p><b>Clinical Information:</b> Allergen results of 0.10-0.34 kU/L are intended for specialist use as the clinical relevance is undetermined. Even though increasing ranges are reflective of increasing concentrations of allergen-specific IgE, these concentrations may not correlate with the degree of clinical response or skin testing results when challenged with a specific allergen. The correlation of allergy laboratory results with clinical history and in vivo reactivity to specific allergens is essential. A negative test may not rule out clinical allergy or even anaphylaxis.</p> <p><b>Specimen Requirement:</b> 0.5 mL serum from serum separator (Gold) tube; Minimum: 0.25 mL; Refrigerated; Separate serum from cells ASAP or within 2 hours of collection. Transfer serum to standard aliquot tube.</p> <p><i>(continued on page 29)</i></p>	6/13/24

## New Tests (Cont.)

Test Name	Order Code	Change	Effective Date
Spinach IgE allergen <i>(continued from page 28)</i>		<p><b>Stability:</b> Ambient: 48 hours Refrigerated: 2 weeks Frozen: 1 year</p> <p><b>Methodology:</b> Quantitative ImmunoCAP Fluorescent Enzyme Immunoassay</p> <p><b>Reference Range:</b> Less than 0.10 kU/L: No significant level detected 0.10–0.34 kU/L: Clinical relevance undetermined 0.35–0.70 kU/L: Low 0.71–3.50 kU/L: Moderate 3.51–17.50 kU/L: High 17.51 kU/L or greater: Very High</p> <p><b>Days Performed:</b> Sun–Sat</p> <p><b>Reported:</b> 2–4 days</p> <p><b>CPT:</b> 86003</p>	
Summer Squash, IgE	SMSQSH	<p><b>Includes:</b> Allergen, Food, Summer Squash IgE</p> <p><b>Special Information:</b> Hemolyzed, icteric, or lipemic specimens will be rejected. This test is New York state approved.</p> <p><b>Specimen Requirement:</b> 0.5 mL serum from serum separator (Gold) tube; Minimum: 0.34 mL; Refrigerated; Separate serum from cells ASAP or within 2 hours of collection. Transfer serum to standard aliquot tube. Separate specimens must be submitted when multiple tests are ordered.</p> <p><b>Stability:</b> Ambient: 1 month Refrigerated: 1 month Frozen: 1 year</p> <p><b>Methodology:</b> Enzyme Immunoassay (EIA)</p> <p><b>Reference Range:</b> Refer to report</p> <p><b>Days Performed:</b> Varies</p> <p><b>Reported:</b> 4–7 days</p> <p><b>CPT:</b> 86003</p>	6/13/24
Tea, IgE	TEAIGE	<p><b>Includes:</b> Allergen, Food, Tea IgE</p> <p><b>Special Information:</b> Hemolyzed, icteric, or lipemic specimens will be rejected. This test is New York state approved.</p> <p><b>Clinical Information:</b> Allergen results of 0.10-0.34 kU/L are intended for specialist use as the clinical relevance is undetermined. Even though increasing ranges are reflective of increasing concentrations of allergen-specific IgE, these concentrations may not correlate with the degree of clinical response or skin testing results when challenged with a specific allergen. The correlation of allergy laboratory results with clinical history and in vivo reactivity to specific allergens is essential. A negative test may not rule out clinical allergy or even anaphylaxis.</p> <p><b>Specimen Requirement:</b> 0.5 mL serum from serum separator (Gold) tube; Minimum: 0.25 mL; Refrigerated; Separate serum from cells ASAP or within 2 hours of collection. Transfer serum to standard aliquot tube.</p> <p><b>Stability:</b> Ambient: 48 hours Refrigerated: 2 weeks Frozen: 1 year</p> <p><b>Methodology:</b> Quantitative ImmunoCAP Fluorescent Enzyme Immunoassay</p> <p><b>Reference Range:</b> Less than 0.10 kU/L: No significant level detected 0.10–0.34 kU/L: Clinical relevance undetermined 0.35–0.70 kU/L: Low 0.71–3.50 kU/L: Moderate 3.51–17.50 kU/L: High 17.51 kU/L or greater: Very High</p> <p><b>Days Performed:</b> Sun–Sat</p> <p><b>Reported:</b> 2–4 days</p> <p><b>CPT:</b> 86003</p>	6/13/24



## New Tests (Cont.)

Test Name	Order Code	Change	Effective Date
Turmeric IgE allergen	TRMRIC	<p><b>Includes:</b> Allergen, Food, Turmeric IgE</p> <p><b>Special Information:</b> Hemolyzed, icteric, or lipemic specimens will be rejected. This test is New York state approved.</p> <p><b>Specimen Requirement:</b> 0.5 mL serum from serum separator (Gold) tube; Minimum: 0.34 mL; Refrigerated; Separate serum from cells ASAP or within 2 hours of collection. Transfer serum to standard aliquot tube. Separate specimens must be submitted when multiple tests are ordered.</p> <p><b>Stability:</b>                      Ambient: 1 month                      Refrigerated: 1 month                      Frozen: 1 year</p> <p><b>Methodology:</b> Enzyme Immunoassay (EIA)</p> <p><b>Reference Range:</b> Refer to report</p> <p><b>Days Performed:</b> Varies</p> <p><b>Reported:</b> 4–7 days</p> <p><b>CPT:</b> 86003</p>	6/13/24

## Discontinued Tests

Test Name	Order Code	Test Information	Effective Date
Acylcarnitines, Plasma w/ Consultation	ACYLBI	Test will no longer be orderable. Recommended replacement test is Plasma Carnitine Free/Total and Acylcarnitines Panel (PCAPNL).	4/2/24
Carnitine Free & Total, Plasma	CARNPL	Test will no longer be orderable. Recommended replacement test is Carnitine Free and Total, Plasma (CARNFT).	4/2/24
CK, Total and CKMB	CKCKMB	Test will no longer be orderable. Recommended replacement test is High Sensitivity Troponin T (HSTNT).	6/11/24
CKMB	MBE	Test will no longer be orderable. Recommended replacement test is High Sensitivity Troponin T (HSTNT).	6/11/24
H.pylori CLO Test	UREASC	Test will no longer be orderable. Recommended replacement tests are Helicobacter pylori Culture (HPYCUL), Helicobacter pylori Antigen by EIA, Stool (HPYLAG) or Helicobacter pylori Breath Test (HPYLBR).	5/21/24
MRSA Culture Screen	MRSASC	Test will no longer be orderable. Recommended replacement test is MRSA/Staph aureus Culture Screen (SANSAL).	5/21/24