

# Cleveland Clinic Laboratories

## Technical Update • November 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	Special Information	Specimen Requirement	Component Change(s)	Methodology	Days Performed/Reported	Reference Range	Stability	CPT
30	6-Monoacetylmorphine (6-MAM) Confirmation, Urine											
4	AFB Culture & Stain											
5	AFB Culture, Blood and Bone Marrow											
30	AFB Stain Only											
5	Allergen, Food Adult/Child											
5	Allergen, Food Panel Adult ACA											
5	Allergen, Food Panel RL											
5	Allergen, Foods Group											
6	Allergen, Nut Panel Group											
6	Allergen, Ohio Head and Neck Environmental and Food Panel											
6	Allergen, Ohio Head and Neck Food Panel Group C											
6	Allergen, Peanut IgE											
6	Allergen, Peanut IgE with Reflex to Peanut Components, IgE											
7	Allergen, Pediatric Profile											
7	Allergen, Pediatric RL											
7	Allergen, Screen											
7-8	Amphetamines Confirmation, Urine											
8	Anti-Nuclear Antibodies by IFA, Synovial Fluid											

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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
8	Bacterial Culture and Gram Stain, Abscess and Wound (Aerobic Culture)										
8	Bacterial Culture and Gram Stain, Cerebrospinal Fluid (CSF)										
8-9	Bacterial Culture and Gram Stain, External Ear										
9	Bacterial Culture and Gram Stain, Eye										
9	Bacterial Culture and Gram Stain, Respiratory, Bronchoscopy (BAL)										
9	Bacterial Culture and Gram Stain, Respiratory, Sputum and Tracheal Aspirate										
9	Bacterial Culture and Gram Stain, Sterile Body Fluid										
10	Bacterial Culture and Gram Stain, Tissue										
10	Bacterial Culture, Eye										
10	Bacterial Culture, Intravascular Catheter Tip										
10	Bacterial Culture, Respiratory, Cystic Fibrosis										
10	Bacterial Culture, Stool, Aeromonas										
11	Bacterial Culture, Throat										
11	Bacterial Culture, Tissue and Wound, ANAEROBIC										
11	Bacterial Culture, Urine										
11	Bacteriology Culture and Gram Stain, Sinus										
11-12	Benzodiazepines Confirmation, Urine										
12	Bilirubin, Direct										
12	Bilirubin, Fractionated										
12	BK Virus (BKV) DNA, Quantitative PCR, Plasma										
30	Blood Parasite Microscopy Only										
24	Blood Parasite Microscopy smear, including % parasitemia										
30	Blood Parasites										
12-13	Bordetella pertussis and parapertussis DNA, NAAT, Nasopharyngeal Swab										
13-14	Buprenorphine Quantitation, Urine										
14	Clostridium difficile Toxin by PCR										
14	Cocaine Metabolite Confirmation, Urine										
14	COVID & Influenza A/B & RSV PCR, Routine										
15	Coxsackie A, 6 Antibodies										
15	Cryptococcal antigen screen and titer by LFA										
15	Expanded Respiratory Pathogen Panel by PCR, Expedited										
15	Fentanyl and Metabolite Confirmation, Urine										
15	Filariasis Abs IgG4										
15	Fungal CSF culture and CAD										
16	Fungal culture – Dermal (hair, skin and nail)										
16	Fungal Culture (Non Dermal)										

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		Order Code	Name Change	New Test	Special Information	Specimen Requirement	Component Change(s)	Methodology	Days Performed/Reported	Reference Range	Stability	CPT
16	Fungal culture and smear – Dermal (hair, skin and nail)											
16	Glutathione Total											
16	Group B Streptococcus by PCR, Routine Prenatal Screening											
16	Hepatitis C Virus (HCV) Genotyping by RT-PCR, Plasma/Serum											
30	Herpes Simplex IgM, Abs											
30	Herpes Simplex IgM, Abs, with IgG Reflex											
17	Herpes Simplex Virus (HSV-1 & HSV-2) and Varicella Zoster Virus (VZV), NAAT, Lesion Swab											
17	Herpesvirus 6 IgG Ab											
17	HTLV I/II DNA PCR											
30	Hu Antibody with Reflex to Titer and Western Blot											
18	Insulin Like Growth Factor 1 with Calculated Z-Score											
18	Listeria Antibody											
18	Listeria Antibody, CSF											
25	Ma2/Ta Antibody, IgG CSF											
18	Ma2/Ta Antibody, IgG Serum											
19	Magnesium, Urine 24 Hour											
30	Magnesium, Urine Random											
25	Magnesium/Creatinine Ratio, Urine											
26	Malaria Binax Antigen, screen											
19	Melatonin											
19	Methadone Quantitation, Urine											
26-28	Myelopathy, Autoimmune/Paraneoplastic Evaluation, Serum											
20	Opiate Confirmation, Urine											
20	Oxycodone Confirmation, Urine											
21	Phencyclidine Confirmation, Urine											
28-29	Quantitative Pain Panel, Urine											
30	Quantitative Toxicology Panel, Urine											
21	Staphylococcus aureus & MRSA Screen, Culture, Skin											
21	Staphylococcus aureus & MRSA Screen, PCR, Nasal											
29-30	Stiff-Person Spectrum Disorders Evaluation, including Progressive Encephalomyelitis with Rigidity and Myoclonus, Serum											
21	STRATIFY JCV DxSelect Antibody and Index with Reflex to Inhibition Assay											
21	Syphilis Treponemal with reflex											
22	THC Metabolite Confirmation, Urine											
22	Tramadol and Metabolite Quantitation, Urine											
22	Trichinella IgG Antibody											
22	Varicella-Zoster IgG Ab											

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Test Update Page #	Order Code	Name Change	New Test	Test Discontinued	Special Information	Specimen Requirement	Component Change(s)	Methodology	Reference Range	Days Performed/Reported	Stability	CPT
23	Varicella Zoster IgG Ab, CSF											
23	Vitamin B5 (Pantothenic Acid) Bioassay											
23	Vitamin D, 1,25-Dihydroxy											
30	VRE Culture Screen											

## Test Changes

Test Name	Order Code	Change	Effective Date
AFB Culture & Stain	AFC	<p><b>Clinical Information:</b> Culture is performed to identify infection due to mycobacteria. Negative cultures do not rule-out infection. Multiple cultures (three) are generally performed to optimize sensitivity and to help determine the clinical significance of pulmonary infection with non-tuberculous mycobacteria. Clinical presentation, radiographic findings and histopathology should be evaluated in conjunction with culture data. (PMID: 32797222). For patients in whom a diagnosis of pulmonary M. tuberculosis is in the differential, PCR is recommended on at least one respiratory specimen, and may be ordered on up to two specimens collected at least eight hours apart, including one first-morning sputum. Sensitivity of PCR for smear positive, culture positive TB is 97%; sensitivity for smear-negative, culture positive TB is 67%. (PMID 31173647).</p> <p><b>Specimen Requirement:</b> 10 mL bronchoscopy specimen in sterile container; <b>Refrigerated;</b> Larger volumes improve recovery. Collect BAL, wash, or aspirate into sputum trap or sterile cup. Volume: at least 10 mL (preferred). Place bronchial brush in sterile, leak-proof tube or cup with enough non-bacteriostatic sterile saline to cover the brush (1-10 ml). *OR* 10 mL tracheal aspirate in sterile container; <b>Refrigerated;</b> Larger volumes improve recovery. Volume 5-10 mL (preferred). *OR* 1-5 g tissue in sterile container; <b>Refrigerated;</b> Biopsy material from the periphery of a cutaneous lesion. Tissue may be kept moist with a small amount (1-3 ml) of sterile saline. Send a separate portion for histopathology using sterile technique. Tissue in formalin is unacceptable for culture. *OR* 5 mL sputum in sterile container; Refrigerated; Sputum may be expectorated or induced. Collection of 3 sputum specimens at least 8 hours apart with at least one first morning specimen is recommended. Volume: 5 mL (preferred); 1 mL minimum. *OR* 10 mL body fluid in sterile container; <b>Refrigerated;</b> Aspirate pleural, pericardial, peritoneal, or synovial fluid using sterile technique after skin disinfection or during surgical procedure. Transfer fluid to sterile tube or cup. Volume: 10-15 mL (preferred); 1 mL minimum. *OR* unspecified aspirate(s) in sterile container; <b>Refrigerated;</b> Larger volumes improve recovery. Aspirate from closed abscess to surface using sterile technique after skin disinfection. Aspirate from both the center and wall of the abscess. For open wounds remove exudate by rinsing with sterile saline. Collect specimen from margin of lesion or abscess using a syringe. If specimen volume is small, instilling a small volume of sterile, non-bacteriostatic saline into the lesion may aid collection. Transfer specimen to sterile tube or submit in syringe after removing needle and capping. Swabs are unacceptable. *OR* 5 mL gastric aspirate in sterile container; Refrigerated; Patient must be fasting. Transport to Laboratory for receipt within 4 hours of collection. If specimen not received in lab within 4 hours, neutralize with (100 mg) sodium bicarbonate (pH 7). For increased sensitivity, collect specimens on 3 consecutive days. Volume: 5-10 mL (preferred). *OR* 40 mL random urine in sterile container; <b>Refrigerated;</b> Submit entire first morning void in sterile container without preservative. 40 mL preferred. For increased sensitivity, collect specimens on 3 consecutive days. Twenty-four hour collections are unacceptable. Patient Preparation: Usual preparation for clean-catch mid-void urine collection. *OR* 5 mL cerebrospinal fluid (CSF) in sterile container; <b>Refrigerated;</b> Culture yield is increased with larger specimen volumes. Specimen volumes between 0.5 and 2 mL will be processed with a disclaimer. *OR* 1 g stool in sterile container; <b>Refrigerated;</b> Pass stool and collect as for bacterial culture. Submit in sterile, leak-proof container, without preservatives.</p>	1/7/25

## Test Changes (Cont.)

Test Name	Order Code	Change	Effective Date
AFB Culture, Blood and Bone Marrow	AFCO	<p><b>Name:</b> Previously AFB Culture Only</p> <p><b>Clinical Information:</b> An AFB Culture only test should be performed to identify an infection due to mycobacteria in blood or bone marrow specimens. Broth medium will be utilized for culturing blood or bone marrow sites. Identification of positive cultures will be performed utilizing current methodologies. Susceptibility testing will be performed on significant isolates. A single negative culture does not rule out the presence of a mycobacterial infection.</p> <p><b>CPT:</b> 87116</p>	1/7/25
Allergen, Food Adult/ Child	FOODAD	<p><b>Clinical Information:</b> These key food and inhalant allergens have been selected to reflect common sensitivities in children and adults. This panel is recommended for children 3 years and older.</p> <p><b>For peanut specific allergen, IgE (kU/L) interpretation:</b> &lt;0.10, Class 0–Below Detection; 0.10–0.34, Class 0/1–Clinical relevance undetermined, for Specialist use only.; 0.35–0.69, Class 1–Low; 0.70–3.49, Class 2–Moderate; 3.50–17.49, Class 3–High; 17.50–49.99, Class 4–Very High; 50.00–99.99, Class 5–Very High; &gt;=100, Class 6–Very High</p> <p>Specific evaluation of <b>other</b> allergic reactions. IgE (kU/L) Interpretation: &lt;0.35, Class 0–Below Detection; 0.35–0.69, Class 1–Low; 0.70–3.49, Class 2–Moderate; 3.50–17.49, Class 3–High; 17.50–49.99, Class 4–Very High; 50.00–99.99, Class 5–Very High; &gt;=100, Class 6–Very High</p> <p><b>Reference Range:</b> Allergen, Peanut IgE: &lt; 0.10 kU/L Allergen, Peanut Class: 0</p> <p><b>Note:</b> other component reference ranges have no change</p>	12/19/24
Allergen, Food Panel Adult ACA	FODACA	<p><b>Clinical Information:</b> For peanut specific allergen, IgE (kU/L) interpretation: &lt;0.10, Class 0–Below Detection; 0.10–0.34, Class 0/1–Clinical relevance undetermined, for Specialist use only.; 0.35–0.69, Class 1–Low; 0.70–3.49, Class 2–Moderate; 3.50–17.49, Class 3–High; 17.50–49.99, Class 4–Very High; 50.00–99.99, Class 5–Very High; &gt;=100, Class 6–Very High</p> <p>Specific evaluation of <b>other</b> allergic reactions. IgE (kU/L) Interpretation: &lt;0.35, Class 0–Below Detection; 0.35–0.69, Class 1–Low; 0.70–3.49, Class 2–Moderate; 3.50–17.49, Class 3–High; 17.50–49.99, Class 4–Very High; 50.00–99.99, Class 5–Very High; &gt;=100, Class 6–Very High</p> <p><b>Reference Range:</b> Allergen, Peanut IgE: &lt; 0.10 kU/L Allergen, Peanut Class: 0</p> <p><b>Note:</b> other component reference ranges have no change</p>	12/19/24
Allergen, Food Panel RL	FOODRL	<p><b>Clinical Information:</b> For peanut specific allergen, IgE (kU/L) interpretation: &lt;0.10, Class 0–Below Detection; 0.10–0.34, Class 0/1–Clinical relevance undetermined, for Specialist use only.; 0.35–0.69, Class 1–Low; 0.70–3.49, Class 2–Moderate; 3.50–17.49, Class 3–High; 17.50–49.99, Class 4–Very High; 50.00–99.99, Class 5–Very High; &gt;=100, Class 6–Very High</p> <p>Specific evaluation of <b>other</b> allergic reactions. IgE (kU/L) Interpretation: &lt;0.35, Class 0–Below Detection; 0.35–0.69, Class 1–Low; 0.70–3.49, Class 2–Moderate; 3.50–17.49, Class 3–High; 17.50–49.99, Class 4–Very High; 50.00–99.99, Class 5–Very High; &gt;=100, Class 6–Very High</p> <p><b>Reference Range:</b> Allergen, Peanut IgE: &lt; 0.10 kU/L Allergen, Peanut Class: 0</p> <p><b>Note:</b> other component reference ranges have no change</p>	12/19/24
Allergen, Foods Group	FOODS	<p><b>Clinical Information:</b> For peanut specific allergen, IgE (kU/L) interpretation: &lt;0.10, Class 0–Below Detection; 0.10–0.34, Class 0/1–Clinical relevance undetermined, for Specialist use only.; 0.35–0.69, Class 1–Low; 0.70–3.49, Class 2–Moderate; 3.50–17.49, Class 3–High; 17.50–49.99, Class 4–Very High; 50.00–99.99, Class 5–Very High; &gt;=100, Class 6–Very High</p> <p>Specific evaluation of <b>other</b> allergic reactions. IgE (kU/L) Interpretation: &lt;0.35, Class 0–Below Detection; 0.35–0.69, Class 1–Low; 0.70–3.49, Class 2–Moderate; 3.50–17.49, Class 3–High; 17.50–49.99, Class 4–Very High; 50.00–99.99, Class 5–Very High; &gt;=100, Class 6–Very High</p> <p><b>Reference Range:</b> Allergen, Peanut IgE: &lt; 0.10 kU/L Allergen, Peanut Class: 0</p> <p><b>Note:</b> other component reference ranges have no change</p>	12/19/24

## Test Changes (Cont.)

Test Name	Order Code	Change	Effective Date
Allergen, Nut Panel Group	NUTPNL	<p><b>Clinical Information:</b> For peanut specific allergen, IgE (kU/L) interpretation: &lt;0.10, Class 0–Below Detection; 0.10–0.34, Class 0/1–Clinical relevance undetermined, for Specialist use only; 0.35–0.69, Class 1–Low; 0.70–3.49, Class 2–Moderate; 3.50–17.49, Class 3–High; 17.50–49.99, Class 4–Very High; 50.00–99.99, Class 5–Very High; &gt;=100, Class 6–Very High</p> <p>Specific evaluation of <b>other</b> allergic reactions. IgE (kU/L) Interpretation: &lt;0.35, Class 0–Below Detection; 0.35–0.69, Class 1–Low; 0.70–3.49, Class 2–Moderate; 3.50–17.49, Class 3–High; 17.50–49.99, Class 4–Very High; 50.00–99.99, Class 5–Very High; &gt;=100, Class 6–Very High</p> <p><b>Reference Range:</b> Allergen, Peanut IgE: &lt; 0.10 kU/L Allergen, Peanut Class: 0</p> <p><b>Note:</b> other component reference ranges have no change</p>	12/19/24
Allergen, Ohio Head and Neck Environmental and Food Panel	OHNSEF	<p><b>Clinical Information:</b> As an aid in diagnosing sensitivity to common allergens. Clinical correlation is required.</p> <p><b>For peanut specific allergen, IgE (kU/L) interpretation:</b> &lt;0.10, Class 0–Below Detection; 0.10–0.34, Class 0/1–Clinical relevance undetermined, for Specialist use only; 0.35–0.69, Class 1–Low; 0.70–3.49, Class 2–Moderate; 3.50–17.49, Class 3–High; 17.50–49.99, Class 4–Very High; 50.00–99.99, Class 5–Very High; &gt;=100, Class 6–Very High</p> <p>Specific evaluation of <b>other</b> allergic reactions. IgE (kU/L) Interpretation: &lt;0.35, Class 0–Below Detection; 0.35–0.69, Class 1–Low; 0.70–3.49, Class 2–Moderate; 3.50–17.49, Class 3–High; 17.50–49.99, Class 4–Very High; 50.00–99.99, Class 5–Very High; &gt;=100, Class 6–Very High</p> <p><b>Reference Range:</b> Allergen, Peanut IgE: &lt; 0.10 kU/L Allergen, Peanut Class: 0</p> <p><b>Note:</b> other component reference ranges have no change</p>	12/19/24
Allergen, Ohio Head and Neck Food Panel Group C	OHNSFC	<p><b>Clinical Information:</b> As an aid in diagnosing sensitivity to common allergens. Clinical correlation is required.</p> <p><b>For peanut specific allergen, IgE (kU/L) interpretation:</b> &lt;0.10, Class 0–Below Detection; 0.10–0.34, Class 0/1–Clinical relevance undetermined, for Specialist use only; 0.35–0.69, Class 1–Low; 0.70–3.49, Class 2–Moderate; 3.50–17.49, Class 3–High; 17.50–49.99, Class 4–Very High; 50.00–99.99, Class 5–Very High; &gt;=100, Class 6–Very High</p> <p>Specific evaluation of <b>other</b> allergic reactions. IgE (kU/L) Interpretation: &lt;0.35, Class 0–Below Detection; 0.35–0.69, Class 1–Low; 0.70–3.49, Class 2–Moderate; 3.50–17.49, Class 3–High; 17.50–49.99, Class 4–Very High; 50.00–99.99, Class 5–Very High; &gt;=100, Class 6–Very High</p> <p><b>Reference Range:</b> Allergen, Peanut IgE: &lt; 0.10 kU/L Allergen, Peanut Class: 0</p> <p><b>Note:</b> other component reference ranges have no change</p>	12/19/24
Allergen, Peanut IgE	PEANUT	<p><b>Clinical Information:</b> Specific evaluation of allergic reactions. IgE (kU/L) Interpretation: &lt;0.10, Class 0–Below Detection; 0.10–0.34, Class 0/1–Clinical relevance undetermined, for Specialist use only; 0.35–0.69, Class 1–Low; 0.70–3.49, Class 2–Moderate; 3.50–17.49, Class 3–High; 17.50–49.99, Class 4–Very High; 50.00–99.99, Class 5–Very High; &gt;=100, Class 6–Very High</p> <p><b>Reference Range:</b> Allergen, Peanut IgE: &lt; 0.10 kU/L Allergen, Peanut Class: 0</p>	12/19/24
Allergen, Peanut IgE with Reflex to Peanut Components, IgE	PNTRFX	<p><b>Clinical Information:</b> Values &gt;=0.10 kU/L will reflex to the Allergen Peanut Component IgE panel, and will be billed accordingly. Specific evaluation of allergic reactions. IgE (kU/L) Interpretation: &lt;0.10, Class 0–Below Detection; 0.10–0.34, Class 0/1–Clinical relevance undetermined, for Specialist use only; 0.35–0.69, Class 1–Low; 0.70–3.49, Class 2–Moderate; 3.50–17.49, Class 3–High; 17.50–49.99, Class 4–Very High; 50.00–99.99, Class 5–Very High; &gt;=100, Class 6–Very High</p> <p><b>Reference Range:</b> Allergen, Peanut IgE: &lt; 0.10 kU/L Allergen, Peanut Class: 0</p>	12/19/24

## Test Changes (Cont.)

Test Name	Order Code	Change	Effective Date
Allergen, Pediatric Profile	SCRPED	<p><b>Clinical Information:</b> These allergens have been selected to reflect common sensitivities in children. This panel is recommended for children from the ages of 3 months to 3 years.</p> <p><b>For peanut specific allergen, IgE (kU/L) interpretation:</b> &lt;0.10, Class 0–Below Detection; 0.10–0.34, Class 0/1–Clinical relevance undetermined, for Specialist use only; 0.35–0.69, Class 1–Low; 0.70–3.49, Class 2–Moderate; 3.50–17.49, Class 3–High; 17.50–49.99, Class 4–Very High; 50.00–99.99, Class 5–Very High; &gt;=100, Class 6–Very High</p> <p>Specific evaluation of <b>other</b> allergic reactions. IgE (kU/L) Interpretation: &lt;0.35, Class 0–Below Detection; 0.35–0.69, Class 1–Low; 0.70–3.49, Class 2–Moderate; 3.50–17.49, Class 3–High; 17.50–49.99, Class 4–Very High; 50.00–99.99, Class 5–Very High; &gt;=100, Class 6–Very High</p> <p><b>Reference Range:</b> Allergen, Peanut IgE: &lt; 0.10 kU/L Allergen, Peanut Class: 0</p> <p><b>Note:</b> other component reference ranges have no change</p>	12/19/24
Allergen, Pediatric RL	PEDMH	<p><b>Clinical Information:</b> For peanut specific allergen, IgE (kU/L) interpretation: &lt;0.10, Class 0–Below Detection; 0.10–0.34, Class 0/1–Clinical relevance undetermined, for Specialist use only; 0.35–0.69, Class 1–Low; 0.70–3.49, Class 2–Moderate; 3.50–17.49, Class 3–High; 17.50–49.99, Class 4–Very High; 50.00–99.99, Class 5–Very High; &gt;=100, Class 6–Very High</p> <p>Specific evaluation of <b>other</b> allergic reactions. IgE (kU/L) Interpretation: &lt;0.35, Class 0–Below Detection; 0.35–0.69, Class 1–Low; 0.70–3.49, Class 2–Moderate; 3.50–17.49, Class 3–High; 17.50–49.99, Class 4–Very High; 50.00–99.99, Class 5–Very High; &gt;=100, Class 6–Very High</p> <p><b>Reference Range:</b> Allergen, Peanut IgE: &lt; 0.10 kU/L Allergen, Peanut Class: 0</p> <p><b>Note:</b> other component reference ranges have no change</p>	12/19/24
Allergen, Screen	SCR	<p><b>Clinical Information:</b> For peanut specific allergen, IgE (kU/L) interpretation: &lt;0.10, Class 0–Below Detection; 0.10–0.34, Class 0/1–Clinical relevance undetermined, for Specialist use only; 0.35–0.69, Class 1–Low; 0.70–3.49, Class 2–Moderate; 3.50–17.49, Class 3–High; 17.50–49.99, Class 4–Very High; 50.00–99.99, Class 5–Very High; &gt;=100, Class 6–Very High</p> <p>Specific evaluation of <b>other</b> allergic reactions. IgE (kU/L) Interpretation: &lt;0.35, Class 0–Below Detection; 0.35–0.69, Class 1–Low; 0.70–3.49, Class 2–Moderate; 3.50–17.49, Class 3–High; 17.50–49.99, Class 4–Very High; 50.00–99.99, Class 5–Very High; &gt;=100, Class 6–Very High</p> <p><b>Reference Range:</b> Allergen, Peanut IgE: &lt; 0.10 kU/L Allergen, Peanut Class: 0</p> <p><b>Note:</b> other component reference ranges have no change</p>	12/19/24
Amphetamines Confirmation, Urine	UAMPC	<p><b>For interface clients only–Test build may need to be modified</b></p> <p><b>Special Information:</b> For medical purposes only; not valid for legal or forensic purposes.</p> <p><b>Clinical Information:</b> For specimen validity interpretations, the following rules are applied: Diluted: Creatinine is greater than or equal to 2mg/dL but less than 20mg/dL and Specific Gravity is less than 1.003. Substituted: Creatinine is less than 2mg/dL and the Specific gravity is less than 1.003 or greater than or equal to 1.020. Adulterated: pH is less than 4 or greater than or equal to 11; Nitrite is greater than or equal to 500mg/L; Oxidant is greater than or equal to 200mg/L.</p> <p><b>Specimen Requirement:</b> 5 mL random urine; <b>Minimum:</b> 1 mL; Refrigerated; <b>No preservatives.</b></p> <p><b>Stability:</b> Ambient: 3 days Refrigerated: <b>7 days</b> Frozen: <b>7 days</b></p> <p><b>Methodology:</b> Liquid Chromatography-Tandem Mass Spectrometry (LC-MS/MS) (continued on page 8)</p>	1/7/25



## Test Changes (Cont.)

Test Name	Order Code	Change	Effective Date
Amphetamines Confirmation, Urine (continued from page 7)		<p><b>Reference Range:</b>            Amphetamine: &lt; 25 ng/mL            Methamphetamine: &lt; 25 ng/mL            Phentermine: &lt; 25 ng/mL            Methylenedioxyamphetamine (MDA): &lt; 25 ng/mL            Methylenedioxyethylamphetamine (MDEA): &lt; 25 ng/mL            Methylenedioxymethamphetamine (MDMA): &lt; 25 ng/mL            Specimen Validity pH, Urine: 4.5–8.0            Specimen Validity Specific Gravity, Urine: 1.003–1.035            Specimen Validity Creatinine, Urine: 20.0–300.0 mg/dL            Specimen Validity Nitrites, Urine: &lt;500 mg/L            Specimen Validity Oxidants, Urine: &lt;200 mg/L</p> <p><b>Days Performed:</b> 6 days per week 8:00 am  <b>Reported:</b> 2–4 days</p>	
Anti-Nuclear Antibodies by IFA, Synovial Fluid	BFANA	<p><b>Special Information:</b> This test reflexes to <b>Synovial Fluid ANA Titer</b> and Pattern if ANA by IFA is positive in order to rule out false positive ANA by IFA. Bacterial contamination, gross hemolysis, lipemic or icteric specimens, and specimens other than synovial fluid are unacceptable.</p> <p><b>Stability:</b>            Ambient: 7 days            Refrigerated: 14 days            Frozen: 60 days (1 freeze/thaw cycle)</p> <p><b>Reference Range:</b> Negative</p>	effective immediately
Bacterial Culture and Gram Stain, Abscess and Wound (Aerobic Culture)	WCUL	<p><b>Name:</b> Previously Abscess and Wound Culture with Gram Stain</p> <p><b>Special Information:</b> Media and incubation conditions are employed for the recovery of aerobic bacteria from an abscess, lesion or wound. Aspirates of purulent material are superior to swab specimens. Prior to specimen collection, remove surface exudate by cleansing with sterile saline or 70% alcohol and then aspirate with needle and syringe. Transfer aspirate fluid to a sterile container (or Port-A-Cul vial if anaerobic culture is also ordered). If a swab specimen must be used, a flocced swab (e.g., Eswab) is preferred because it collects more material than standard swabs. If culture is positive, identification will be performed on clinically significant organisms at an additional charge. Antimicrobial susceptibilities are performed when indicated.</p> <p><b>Specimen Requirement:</b> aspirate(s) in sterile container; Collection Ambient; <b>Transport Refrigerated</b> *OR* purulent material should be transferred to a sterile container. Collection Ambient; <b>Transport Refrigerated</b> *OR* swab(s) in E-Swab; Collection Ambient; <b>Transport Refrigerated</b></p> <p><b>Stability:</b>            Ambient: 24 hours. <b>48 hours if E Swab</b>            Refrigerated: <b>24 hours. 48 hours if E Swab</b>            Frozen: Unacceptable</p>	1/7/25
Bacterial Culture and Gram Stain, Cerebrospinal Fluid (CSF)	CSFCUL	<p><b>Name:</b> Previously CSF Culture &amp; Stain</p> <p><b>Special Information:</b> Aseptically collect CSF from a lumbar puncture into sterile tubes. Send second tube to the Microbiology laboratory. Include specimen description (eg, LP, shunt) on requisition. Do not refrigerate specimens. CSF collected by means other than lumbar puncture (e.g. shunt, EVD, reservoir, etc.) should be placed into a sterile cup for transport. CSF Gram stains are performed STAT (within 1 h of receipt in laboratory).</p> <p><b>Clinical Information:</b> If anaerobic infection associated with an indwelling device is suspected, also order an anaerobic culture (ANACUL) in addition to the aerobic culture (CSFCUL).</p> <p><b>CPT:</b> 87205; 87070</p>	1/7/25
Bacterial Culture and Gram Stain, External Ear	EARCSM	<p><b>Name:</b> Previously Ear Culture and Gram Stain</p> <p><b>Special Information:</b> For ruptured eardrum, collect fluid on flexible shaft swab via an auditory speculum. Outer ear: Obtain sample by firmly rotating swab in outer canal. For otitis externa, vigorous swabbing is required</p> <p><b>Clinical Information:</b> Otitis media can usually be diagnosed and treated without culture. Respiratory viruses, Streptococcus pneumoniae, Haemophilus influenzae, and Moraxella catarrhalis are the most common organisms causing acute otitis media. Chronic external otitis is often due to seborrhea. The primary etiology of necrotizing otitis externa infection is Pseudomonas aeruginosa.</p> <p>(continued on page 9)</p>	1/7/25



## Test Changes (Cont.)

Test Name	Order Code	Change	Effective Date
Bacterial Culture and Gram Stain, External Ear <i>(continued from page 8)</i>		<b>Specimen Requirement:</b> skin in E-Swab; Collection Ambient; Transport Ambient <b>Stability:</b> Ambient: <b>48 hours</b> Refrigerated: <b>48 hours</b> Frozen: Unacceptable	
Bacterial Culture and Gram Stain, Eye	EYECSM	<b>Name:</b> Previously Eye Culture and Gram Stain <b>Special Information:</b> Media and incubation conditions are employed for the recovery of aerobic bacteria. For conjunctival specimens, sample each eye with separate swabs (premoistened with sterile saline) by rolling over conjunctiva. When only one eye is infected, sampling both can help distinguish indigenous microflora from true pathogens. For corneal scrapings, scrape ulcers and lesions with sterile spatula and inoculate scraping directly onto media. Prepare smears by rubbing material onto 1-2 cm area of slide. For vitreous fluid, prepare eye for needle aspiration of fluid and transfer fluid to sterile tube. If culture is positive, identification will be performed on clinically significant organisms at an additional charge. Antimicrobial susceptibilities are performed when indicated. <b>Specimen Requirement:</b> drainage in sterile container; Ambient *OR* fluid in sterile container; Ambient *OR* scrapings in sterile container; Ambient; Place directly on culture media plates. Media is available through the Microbiology laboratory for direct inoculation, particularly for corneal scrapings. *OR* <b>one eye E-Swab</b> <b>Stability:</b> Ambient: 24 hours. <b>48 hours if E Swab.</b> Refrigerated: <b>24 hours. 48 hours if E Swab.</b> Frozen: Unacceptable	1/7/25
Bacterial Culture and Gram Stain, Respiratory, Bronchoscopy (BAL)	BALCSM	<b>Name:</b> Previously Bronchoscopy Culture and Gram Stain <b>Special Information:</b> Quantitative culture for the recovery of aerobic bacteria is performed on respiratory specimens collected during bronchoscopy. Separate test orders are required to rule out the presence of mycobacteria, fungi, viruses, and atypical bacterial pathogens in respiratory specimens. <b>Clinical Information:</b> Distinguishing colonizing organisms from pathogens can be difficult. Susceptibility testing is performed on potential pathogens <b>found in significant quantity</b> . Correlation of culture results with clinical findings is essential.	1/7/25
Bacterial Culture and Gram Stain, Respiratory, Sputum and Tracheal Aspirate	RCULST	<b>Name:</b> Previously Respiratory Culture and Stain	1/7/25
Bacterial Culture and Gram Stain, Sterile Body Fluid	BFCUL	<b>Name:</b> Previously Body Fluid Culture and Stain <b>Special Information:</b> <b>INVASIVELY COLLECTED synovial, peritoneal, pericardial, pleural, and amniotic fluids are acceptable for bacterial sterile body fluid culture. Specimens from indwelling DRAINS should be tested as "abscess and wound" culture and not as "sterile body fluid" culture. To collect the sterile body fluid, disinfect overlying skin with iodine or chlorhexidine preparation and obtain specimen with needle and syringe. Submit the fluid in a sterile specimen container or a capped syringe WITHOUT a needle. Swabs will be rejected. Fluid may be inoculated into a set of blood culture bottles (up to 10 ml per bottle) to maximize test sensitivity. If using bottles, also provide a separate aliquot of at least 1 ml for preparation of Gram stain and inoculation of solid media.</b> <b>Clinical Information:</b> If adequate volume of specimen is received, then normally sterile body fluids are cultured for aerobic and anaerobic bacteria using both solid and liquid nutrient media to provide opportunity for high specificity (solid media) and high sensitivity (broth media) culture. <b>Specimen Requirement:</b> 5 mL peritoneal fluid in sterile container; Collect Ambient; Transport Refrigerated *OR* 5 mL pericardial fluid in sterile container; Collect Ambient; Transport Refrigerated *OR* 5 mL amniotic fluid in sterile container; Collect Ambient; Transport Refrigerated *OR* 5 mL pleural fluid in sterile container; Collect Ambient; Transport Refrigerated *OR* 5 mL synovial fluid in sterile container; Collect Ambient; Transport Refrigerated <b>Stability:</b> Ambient: 24 hours Refrigerated: <b>48 hours</b> Frozen: Unacceptable	1/7/25

## Test Changes (Cont.)

Test Name	Order Code	Change	Effective Date
Bacterial Culture and Gram Stain, Tissue	TISCUL	<p><b>Name:</b> Previously Tissue Culture &amp; Stain</p> <p><b>Special Information:</b> Add drops of sterile saline to keep small pieces of tissue moist. If culture is positive, identification will be performed on clinically significant organisms at an additional charge. Antimicrobial susceptibilities are performed when indicated.</p> <p><b>Clinical Information:</b> Media and incubation conditions are employed for the recovery of aerobic and anaerobic bacteria. All tissue cultures are incubated for a minimum of 3 days. Brain, bone and heart valve specimens are incubated for 5 days. Shoulder, hip or knee tissue submitted to diagnose a prosthetic joint infection includes a thioglycollate broth culture with 14 day incubation; broth culture with extended incubation also occurs if "Cutibacterium acnes" is <b>selected in the Rule Out field when ordering.</b></p> <p><b>Specimen Requirement: Variable tissue in sterile container</b></p> <p><b>CPT:</b> 87070; 87176; 87205</p>	1/7/25
Bacterial Culture, Eye	EYEC	<p><b>Name:</b> Previously Eye Culture</p> <p><b>Special Information:</b> Media and incubation conditions are employed for the recovery of aerobic bacteria. For conjunctival specimens, sample each eye with separate swabs (premoistened with sterile saline) by rolling over conjunctiva. When only one eye is infected, sampling both can help distinguish indigenous microflora from true pathogens. For corneal scrapings, scrape ulcers and lesions with sterile spatula and inoculate scraping directly onto media. Prepare smears by rubbing material onto 1-2 cm area of slide. For vitreous fluid, prepare eye for needle aspiration of fluid and transfer fluid to sterile tube. If culture is positive, identification will be performed on clinically significant organisms at an additional charge. Antimicrobial susceptibilities are performed when indicated.</p> <p><b>Specimen Requirement:</b> drainage in sterile container; Ambient *OR* fluid in sterile container; Ambient *OR* scrapings in sterile container; Ambient; Place directly on culture media plates. Media is available through the Microbiology laboratory for direct inoculation, particularly for corneal scrapings. *OR* <b>one eye E-Swab</b></p> <p><b>Stability:</b>            Ambient: 24 hours. <b>48 hours if E Swab.</b>            Refrigerated: <b>24 hours. 48 hours if E Swab.</b>            Frozen: Unacceptable</p>	1/7/25
Bacterial Culture, Intravascular Catheter Tip	CTCUL	<p><b>Name:</b> Previously Catheter Tip Culture</p> <p><b>Special Information:</b> Culture performed on intravascular catheter tips (eg, central, CVP, Hickman, Broviac, Peripheral, arterial, umbilical, hyperalimentation, Swan-Ganz). Cleanse skin around catheter site with alcohol. Aseptically remove catheter and clip 5 cm of distal tip directly into a sterile container. If culture is positive, identification will be performed on clinically significant organisms. Antimicrobial susceptibilities are performed when indicated.</p> <p><b>Stability:</b>            Ambient: 24 hours            Refrigerated: <b>24 hours</b>            Frozen: Unacceptable</p>	1/7/25
Bacterial Culture, Respiratory, Cystic Fibrosis	CFRCUL	<p><b>Name:</b> Previously Cystic Fibrosis Respiratory Culture</p> <p><b>Special Information:</b> Selective media are <b>used</b> to optimize recovery of aerobic bacteria associated with infection in cystic fibrosis <b>lungs</b> including Staphylococcus aureus, Pseudomonas aeruginosa, Burkholderia cepacia complex, Stenotrophomonas maltophilia, Haemophilus influenzae, and other gram-negative bacilli. Identification of B. cepacia complex species is <b>characterized</b> by molecular testing performed at the B. cepacia Research Laboratory and Repository. Separate test orders are required to rule out the presence of mycobacteria, fungi, viruses, and atypical bacterial pathogens.</p> <p><b>Clinical Information:</b> Susceptibility testing is performed on potential pathogens in significant amounts (typically defined as moderate growth in sputum or tracheal aspirate specimens that is greater than normal background respiratory <b>microbiota</b>).</p>	1/7/25
Bacterial Culture, Stool, Aeromonas	AERPLE	<p><b>Name:</b> Previously Aeromonas</p> <p><b>Special Information:</b> Transfer stool into Cary-Blair transport media immediately after collection and prior to transport. Alternatively, stool may be transported in a sterile container if received within 2 h of collection.</p> <p><b>Specimen Requirement:</b> 5 mL stool in <b>C/S/Cary Blair</b>; Refrigerated; To optimize recovery, transfer stool into Cary-Blair transport media (<b>available within STUL kit</b>) immediately after collection and prior to transport. *OR* <b>5 mL stool in sterile container; Refrigerated; Stool may be transported in a sterile container if received within 2 h of collection.</b></p>	1/7/25

## Test Changes (Cont.)

Test Name	Order Code	Change	Effective Date
Bacterial Culture, Throat	THRCUL	<p><b>Name:</b> Previously Throat Culture, Routine</p> <p><b>Special Information:</b> Use swab to sample inflamed areas and exudate from the posterior pharynx. Place swab in transport medium. Routine throat cultures will be processed only for growth of <b>Streptococcus pyogenes (Group A streptococcus)</b>. If culture is positive, identification will be performed on clinically significant organisms at an additional charge. Identification CPT code that may apply is 87077. Antimicrobial susceptibilities are performed when requested, and the following CPT codes may apply: 87181, 87184, 87186.</p> <p><b>Specimen Requirement:</b> one E-Swab; Ambient *OR* <b>one swab in Amies or Stuart's media without charcoal; Ambient</b></p> <p><b>Stability:</b>            Ambient: <b>48 hours</b>            Refrigerated: <b>48 hours</b>            Frozen: Unacceptable</p>	1/7/25
Bacterial Culture, Tissue and Wound, ANAEROBIC	ANACUL	<p><b>Name:</b> Previously Anaerobe Culture</p> <p><b>Special Information:</b> Aerobic culture and gram stain requires a separate order (e.g. WCUL, TISCUL, CSFCUL). Submit tissue or aspirates. Swabs are suboptimal and will be rejected, unless collected using the eSwab collection and transport system. A sterile container may be used for tissue if transported to the microbiology lab immediately (add <b>5</b> drops of sterile saline to keep small pieces of tissue moist). Fluid collections should be aspirated through disinfected tissue or skin. Anaerobic cultures are routinely held 5 days. If culture is positive, identification will be performed on clinically significant organisms at an additional charge. Antimicrobial susceptibilities are performed on pure culture isolates <b>in significant quantity</b> or upon request.</p> <p><b>Clinical Information:</b> Specimens from mucosal surfaces which have anaerobic bacteria as normal flora should not be submitted for anaerobic culture. These specimens will routinely be rejected: throat or nasopharyngeal swabs, oral surface swabs, sputum, tracheal aspirates, bronchial washings, voided or catheterized urine, gastric and small bowel contents, feces, rectal swabs, cervical or vaginal swabs. <b>Tissue specimens are preferred, and the only swab collection device that is acceptable for anaerobic culture is the eSwab collection and transport system.</b></p> <p><b>Specimen Requirement:</b> tissue in sterile container; <b>Refrigerated *OR* wound in E-Swab; Refrigerated</b></p> <p><b>Stability:</b>            Ambient: 24 hours. <b>48 hours if E Swab</b>            Refrigerated: <b>24 hours. 48 hours if E Swab</b>            Frozen: Unacceptable</p>	1/7/25
Bacterial Culture, Urine	URCUL	<p><b>Name:</b> Previously Urine Culture</p>	1/7/25
Bacteriology Culture and Gram Stain, Sinus	SINUSC	<p><b>Name:</b> Previously Sinus Culture and Gram Stain</p> <p><b>Special Information:</b> If culture is positive, identification will be performed on clinically significant organisms at an additional charge. Antimicrobial susceptibilities are performed when indicated.</p> <p><b>Specimen Requirement:</b> sinus aspirate in sterile container; Collection Ambient; Transport Refrigerated *OR* <b>one swab; Collection Ambient; Transport Refrigerated; BD Culturette with Aluminum Shaft</b></p>	1/7/25
Benzodiazepines Confirmation, Urine	UBENZC	<p><b>For interface clients only–Test build may need to be modified</b></p> <p><b>Special Information: For medical purposes only; not valid for legal or forensic purposes.</b></p> <p><b>Clinical Information:</b> For specimen validity interpretations, the following rules are applied: Diluted: Creatinine is greater than or equal to 2mg/dL but less than 20mg/dL and Specific Gravity is less than 1.003. Substituted: Creatinine is less than 2mg/dL and the Specific gravity is less than <b>1.003</b> or greater than or equal to 1.020. Adulterated: pH is less than 4 or greater than or equal to 11; Nitrite is greater than or equal to 500mg/L; Oxidant is greater than or equal to 200mg/L.</p> <p><b>Specimen Requirement: 5 mL random urine; Minimum: 1 mL; Frozen, Critical; No preservatives.</b> Sample must be frozen immediately after collection.</p> <p><b>Stability:</b>            Ambient: <b>Unacceptable</b>            Refrigerated: <b>Unacceptable</b>            Frozen: 7 days</p> <p><i>(continued on page 12)</i></p>	1/7/25

## Test Changes (Cont.)

Test Name	Order Code	Change	Effective Date
Benzodiazepines Confirmation, Urine <i>(continued from page 11)</i>		<p><b>Methodology:</b> Liquid Chromatography-Tandem Mass Spectrometry (LC-MS/MS)</p> <p><b>Reference Range:</b>            7-aminoclonazepam: &lt; 25 ng/mL            Alpha-hydroxyalprazolam: &lt; 25 ng/mL            Alpha-hydroxytriazolam: &lt; 25 ng/mL            Oxazepam: &lt; 25 ng/mL            Lorazepam: &lt; 25 ng/mL            Nordiazepam: &lt; 25 ng/mL            Temazepam: &lt; 25 ng/mL            Specimen Validity pH, Urine: 4.5–8.0            Specimen Validity Specific Gravity, Urine: 1.003–1.035            Specimen Validity Creatinine, Urine: 20.0–300.0 mg/dL            Specimen Validity Nitrites, Urine: &lt;500 mg/L            Specimen Validity Oxidants, Urine: &lt;200 mg/L</p> <p><b>Days Performed:</b> 6 days per week 8:00 am  <b>Reported:</b> 2–4 days</p>	
Bilirubin, Direct	DBIL	<b>Reference Range:</b> <0.3 mg/dL	1/7/25
Bilirubin, Fractionated	BILIFR	<p><b>Reference Range:</b>            Bilirubin, Total:            0 Days to 30 Days: Results are flagged as abnormal due to the age-related nature of reference intervals in this patient population. Clinician review of acceptable bilirubin levels and risk categories is recommended using age-related or other pertinent reference information (e.g. Bhutani nomograms).            31 Days to 99 Years: 0.2–1.3 mg/dL            0 Days to 30 Days (Urgent): &gt; 15.0 mg/dL            Bilirubin, Indirect:            0 Days to 30 Days: Results are flagged as abnormal due to the age-related nature of reference intervals in this patient population. Clinician review of acceptable bilirubin levels and risk categories is recommended using age-related or other pertinent reference information (e.g. Bhutani nomograms).            31 Days to 99 Years: &lt;1.4 mg/dL            Bilirubin, Direct: &lt;0.3 mg/dL</p>	1/7/25
BK Virus (BKV) DNA, Quantitative PCR, Plasma	BKQUAN	<p><b>Specimen Requirement:</b> 2 mL plasma from EDTA plasma preparation (White) tube; Centrifuge and refrigerate. Collect EDTA plasma according to standard protocol. Separate plasma by centrifugation (at 1,100 RCF for a minimum of 10 minutes) within 24 hours of collection. Plasma must be aliquoted first if sample is to be frozen. Sample cannot be shared with a test performed outside of Molecular Microbiology. Sample can only be shared with CMVQNT, HCQPCR, HIVRNA, HBVDNU, EBVQNT, or BKQUAN. *OR* 2 mL plasma from EDTA (Lavender) tube; Centrifuge, aliquot and refrigerate ASAP. Collect EDTA plasma according to standard protocol. Centrifuge (at &gt;1300 RCF for a minimum of 10 minutes) and aliquot into a sterile secondary tube within 24 hours of collection. Plasma must be aliquoted first if sample is to be frozen. Sample cannot be shared with a test performed outside of Molecular Microbiology. Sample can only be shared with CMVQNT, HCQPCR, HIVRNA, HBVDNU, EBVQNT, or BKQUAN. *OR* 2 mL plasma from Pink KEDTA tube; Centrifuge and refrigerate. Collect EDTA plasma according to standard protocol. Centrifuge (at &gt;1300 RCF for a minimum of 10 minutes) and aliquot into a sterile secondary tube within 24 hours of collection. Plasma must be aliquoted first if sample is to be frozen. Sample cannot be shared with a test performed outside of Molecular Microbiology. Sample can only be shared with CMVQNT, HCQPCR, HIVRNA, HBVDNU, EBVQNT, or BKQUAN.</p>	effective immediately
Bordetella pertussis and parapertussis DNA, NAAT, Nasopharyngeal Swab	BORAMP	<p><b>Name:</b> Previously Bordetella pertussis and parapertussis DNA, Nucleic Acid Amplification, Nasopharyngeal Swab</p> <p><b>Clinical Limitation:</b> The IS481 sequence used in the Solana Bordetella Complete Assay can also be found in strains of other organisms (i.e., <i>B. holmesii</i> and <i>B. bronchiseptica</i>). The IS1001 sequence may also be found in strains of other organisms (i.e., <i>B. bronchiseptica</i>). <i>B. holmesii</i> infection may cause clinical illness similar to <i>B. pertussis</i>, and mixed outbreaks involving both <i>B. pertussis</i> and <i>B. holmesii</i> infection have been reported. Additional testing should be performed if necessary to differentiate <i>B. holmesii</i> and <i>B. pertussis</i>. <i>B. bronchiseptica</i> is a rare cause of infection in humans. When clinical factors suggest that <i>B. pertussis</i> may not be the cause of respiratory infection, other clinically appropriate investigation(s) should be carried out in accordance with published guidelines.</p> <p><i>(continued on page 13)</i></p>	12/17/24

## Test Changes (Cont.)

Test Name	Order Code	Change	Effective Date
Bordetella pertussis and parapertussis DNA, NAAT, Nasopharyngeal Swab <i>(continued from page 12)</i>		<p><b>Clinical Limitation (continued):</b> Environmental contamination of an exam room from a prior patient or a recent pertussis vaccination administration may result in false-positive test results. As with any nucleic acid amplification test, positive results do not rule out coinfection with other organisms, detected organisms may not be the definite cause of disease, and negative results do not rule out infection.</p> <p><b>Clinical Information:</b> Bordetella pertussis (BP), a gram-negative bacterium, is the predominant causative agent of whooping cough or pertussis, a vaccine-preventable, highly infectious disease that is reportable to public health organizations. Pertussis occurs most commonly in children but also occurs in adolescents and adults and outbreaks have been documented in fully vaccinated populations due to waning immunity (immunity has been shown to decrease 5-10 years after vaccination). Early (catarrhal) pertussis disease is non-specific, and classic signs of pertussis (paroxysmal coughing, inspiratory 'whoop', post-tussive emesis, as well as apnea or cyanosis in infants) do not arise until approximately two weeks after the initial onset of symptoms. Bordetella parapertussis (BPP) is known to cause a milder pertussis-like disease. For diagnosis of pertussis, NAAT performed on a nasopharyngeal swab collected within 2-3 weeks of symptom onset is the most sensitive method. The Solana Bordetella Complete Assay is an in vitro diagnostic test for the qualitative detection of BP and BPP nucleic acids isolated from nasopharyngeal swab specimens obtained from patients suspected of having respiratory tract infection attributable to Bordetella pertussis and Bordetella parapertussis. The assay uses isothermal helicase-dependent amplification to target the IS481 and IS1001 sequence of BP and BPP genomes, respectively. Both targets can exhibit cross reactivity with other members of the Bordetella genus.</p> <p><b>Specimen Requirement:</b> 3 mL nasopharyngeal swab in Universal Transport Media (UTM); Refrigerated; 1. Tilt patient's head back 70 degrees. 2. Gently and slowly insert a mini-tipped flocked swab with a flexible shaft through the nostril parallel to the palate (not upwards) until resistance is encountered or the distance is equivalent to that from the ear to the nostril of the patient, indicating contact with the nasopharynx. 3. Gently rub and roll the swab. 4. Leave swab in place for several seconds to absorb secretions. 5. Slowly remove swab while rotating it. Specimens can be collected from both sides using the same swab, but it is not necessary to collect specimens from both sides if the swab is saturated with fluid from the first collection. If a deviated septum or blockage create difficulty in obtaining the specimen from one nostril, use the same swab to obtain the specimen from the other nostril. 6. Place swab, tip first, into the transport tube provided. Break the swab shaft at the score line, discard the top portion of the stem, and close the cap. *OR* 3 mL nasopharyngeal swab in saline; Refrigerated; Sterile saline may be used if UTM cannot be sourced. *OR* 3 mL nasopharyngeal swab in Viral Transport Media; Refrigerated; Viral transport media (including VTM, M4RT, M5, or M6) may be used if UTM cannot be sourced.</p> <p><b>Stability:</b>            Ambient: 49 hours            Refrigerated: 97 hours            Frozen: 5 months at or below -70C</p> <p><b>Methodology:</b> Target amplification nucleic acid probe, qualitative</p>	
Buprenorphine Quantitation, Urine	UQNTBU	<p><b>For interface clients only–Test build may need to be modified</b></p> <p><b>Name:</b> Previously Buprenorphine Quant, Urine</p> <p><b>Special Information:</b> For medical purposes only; not valid for <b>legal</b> or forensic purposes.</p> <p><b>Clinical Information:</b> For specimen validity interpretations, the following rules are applied: Diluted: Creatinine is greater than or equal to 2mg/dL but less than 20mg/dL and Specific Gravity is less than 1.003. Substituted: Creatinine is less than 2mg/dL and the Specific gravity is less than 1.003 or greater than or equal to 1.020. Adulterated: pH is less than 4 or greater than or equal to 11; Nitrite is greater than or equal to 500mg/L; Oxidant is greater than or equal to 200mg/L.</p> <p><b>Specimen Requirement:</b> 5 mL random urine; <b>Minimum:</b> 1 mL; Refrigerated; <b>No preservatives.</b></p> <p><b>Stability:</b>            Ambient: 3 days            Refrigerated: <b>7 days</b>            Frozen: <b>7 days</b></p> <p><i>(continued on page 14)</i></p>	1/7/25

## Test Changes (Cont.)

Test Name	Order Code	Change	Effective Date
Buprenorphine Quantitation, Urine <i>(continued from page 13)</i>		<p><b>Reference Range:</b>            Buprenorphine: &lt; <b>5 ng/mL</b>            Norbuprenorphine: &lt; <b>10 ng/mL</b>            Specimen Validity pH, Urine: 4.5–8.0            Specimen Validity Specific Gravity, Urine: 1.003–1.035            Specimen Validity Creatinine, Urine: 20.0–300.0 mg/dL            Specimen Validity Nitrites, Urine: &lt;500 mg/L            Specimen Validity Oxidants, Urine: &lt;200 mg/L</p> <p><b>Days Performed:</b> 6 days per week <b>8:00 am</b></p> <p><b>Reported:</b> 2–4 days</p>	
Clostridium difficile Toxin by PCR	CDPCR	<p><b>Stability:</b>            Ambient: 24 hours            Refrigerated: <b>72 hours</b>            Frozen: Frozen stools have not been validated and will be rejected.</p>	1/7/25
Cocaine Metabolite Confirmation, Urine	UCOCC	<p><b>For interface clients only–Test build may need to be modified</b></p> <p><b>Name:</b> Previously Cocaine Confirmation, Urine</p> <p><b>Special Information:</b> For medical purposes only; not valid for <b>legal or</b> forensic purposes.</p> <p><b>Clinical Information:</b> For specimen validity interpretations, the following rules are applied: Diluted: Creatinine is greater than or equal to 2mg/dL but less than 20mg/dL and Specific Gravity is less than 1.003. Substituted: Creatinine is less than 2mg/dL and the Specific gravity is less than <b>1.003</b> or greater than or equal to 1.020. Adulterated: pH is less than 4 or greater than or equal to 11; Nitrite is greater than or equal to 500mg/L; Oxidant is greater than or equal to 200mg/L.</p> <p><b>Specimen Requirement:</b> 5 mL random urine; <b>Minimum:</b> 1 mL; Refrigerated; <b>No preservatives.</b></p> <p><b>Stability:</b>            Ambient: 3 days            Refrigerated: <b>7 days</b>            Frozen: <b>7 days</b></p> <p><b>Methodology:</b> Liquid Chromatography-Tandem Mass Spectrometry (LC-MS/MS)</p> <p><b>Reference Range:</b>            Benzoylcegonine: &lt; <b>25 ng/mL</b>            Specimen Validity pH, Urine: 4.5–8.0            Specimen Validity Specific Gravity, Urine: 1.003–1.035            Specimen Validity Creatinine, Urine: 20.0–300.0 mg/dL            Specimen Validity Nitrites, Urine: &lt;500 mg/L            Specimen Validity Oxidants, Urine: &lt;200 mg/L</p> <p><b>Days Performed:</b> 6 days per week <b>8:00 am</b></p> <p><b>Reported:</b> 2–4 days</p>	1/7/25
COVID & Influenza A/B & RSV PCR, Routine	CVFLRS	<p><b>Clinical Information:</b> Clinical signs and symptoms of respiratory viral infection due to SARS-CoV-2 (agent of COVID-19), influenza A (Flu A), influenza B (Flu B), and respiratory syncytial virus (RSV) can be similar. These viruses are responsible for significant morbidity and mortality, especially in young, immunocompromised, and elderly patients. Accurate and timely diagnosis and differentiation between these viruses can help guide appropriate antiviral therapy, decrease inappropriate use of antibiotics, and assist in infection prevention/control efforts. The FDA-cleared Panther Fusion SARS-CoV-2/Flu A/B/RSV assay is a fully automated multiplexed reverse-transcription real-time polymerase chain reaction (RT-PCR) test intended to aid in the differential diagnosis of SARS-CoV-2, Flu A, Flu B, and RSV infections in humans. It is not intended to detect influenza C virus infections. SARS-CoV-2, Flu A, Flu B, and RSV are generally detectable in nasopharyngeal (NP) <b>and nasal</b> swabs during the acute phase of infection. The assay has been modified and validated to additionally accept lower respiratory specimens (bronchoalveolar lavage, tracheal aspirate, sputum), and swabs in alternative transport media such as liquid Amies (eSwab) and saline. Nasal swabs demonstrate modestly decreased analytical sensitivity compared to NP swabs in some studies, but can be useful in cases where a patient is unable or unwilling to have an NP swab collected. Some individuals can have disease isolated to the lower respiratory tract; consider submitting these specimen types in patients with evidence of lower respiratory disease.</p>	effective immediately



## Test Changes (Cont.)

Test Name	Order Code	Change	Effective Date
Coxsackie A, 6 Antibodies	COXSA6	<b>Specimen Requirement:</b> 2 mL serum from no additive (Red) tube; Ambient; Centrifuge and transfer serum to standard aliquot tube. <b>Separate specimens must be submitted when multiple tests are ordered.</b> *OR* 2 mL serum from serum separator (Gold) tube; Ambient; Centrifuge and transfer serum to standard aliquot tube. <b>Separate specimens must be submitted when multiple tests are ordered.</b> <b>Reported:</b> 7–12 days	effective immediately
Cryptococcal antigen screen and titer by LFA	CAD	<b>Stability:</b> Ambient: <b>24 hours</b> Refrigerated: <b>7 days (72 hours preferred for Cryptococcus Antigen test)</b> Frozen: <b>Indefinitely</b>	1/7/25
Expanded Respiratory Pathogen Panel by PCR, Expedited	RPRACV	<b>Specimen Requirement:</b> 3 mL nasopharyngeal swab in Universal Transport Media (UTM); Refrigerated; 1. Tilt patient's head back 70 degrees. 2. Gently and slowly insert a mini-tipped flocked swab with a flexible shaft through the nostril parallel to the palate (not upwards) until resistance is encountered or the distance is equivalent to that from the ear to the nostril of the patient, indicating contact with the nasopharynx. 3. Gently rub and roll the swab. 4. Leave swab in place for several seconds to absorb secretions. 5. Slowly remove swab while rotating it. Specimens can be collected from both sides using the same swab, but it is not necessary to collect specimens from both sides if the swab is saturated with fluid from the first collection. If a deviated septum or blockage create difficulty in obtaining the specimen from one nostril, use the same swab to obtain the specimen from the other nostril. 6. Place swab, tip first, into the transport tube provided. Break the swab shaft at the score line, discard the top portion of the stem, and close the cap. *OR* 3 mL <b>nasopharyngeal swab</b> in Viral Transport Media; Refrigerated; Viral transport media (including VTM, M4RT, M5, or M6) may be used to collect swabs if UTM cannot be sourced.	12/19/24
Fentanyl and Metabolite Confirmation, Urine	UFENT	<b>For interface clients only–Test build may need to be modified</b> <b>Special Information:</b> For medical purposes only; not valid for <b>legal or</b> forensic purposes. <b>Clinical Information:</b> For specimen validity interpretations, the following rules are applied: Diluted: Creatinine is greater than or equal to 2mg/dL but less than 20mg/dL and Specific Gravity is less than 1.003. Substituted: Creatinine is less than 2mg/dL and the Specific gravity is less than <b>1.003</b> or greater than or equal to 1.020. Adulterated: pH is less than 4 or greater than or equal to 11; Nitrite is greater than or equal to 500mg/L; Oxidant is greater than or equal to 200mg/L. <b>Specimen Requirement:</b> 5 mL random urine; <b>Minimum:</b> 1 mL; Refrigerated; <b>No preservatives.</b> <b>Stability:</b> Ambient: 3 days Refrigerated: <b>7 days</b> Frozen: <b>7 days</b> <b>Methodology:</b> Liquid Chromatography-Tandem Mass Spectrometry (LC-MS/MS) <b>Reference Range:</b> Fentanyl: < <b>1 ng/mL</b> Norfentanyl: < <b>1 ng/mL</b> Specimen Validity pH, Urine: 4.5–8.0 Specimen Validity Specific Gravity, Urine: 1.003–1.035 Specimen Validity Creatinine, Urine: 20.0–300.0 mg/dL Specimen Validity Nitrites, Urine: <500 mg/L Specimen Validity Oxidants, Urine: <200 mg/L <b>Days Performed:</b> 6 days per week <b>8:00 am</b> <b>Reported:</b> 2–4 days	1/7/25
Filariasis Abs IgG4	FILAR1	<b>Specimen Requirement:</b> 0.2 mL serum from serum separator (Gold) tube; Refrigerated; Separate serum from cells and transfer to standard aliquot tube. <b>Separate specimens must be submitted when multiple tests are ordered.</b> *OR* 0.2 mL serum from no additive (Red) tube; Refrigerated; Separate serum from cells and transfer to standard aliquot tube. <b>Separate specimens must be submitted when multiple tests are ordered.</b> <b>Reported:</b> 7–12 days	effective immediately
Fungal CSF culture and CAD	FUNCSF	<b>Stability:</b> Ambient: <b>24 hours</b> Refrigerated: <b>7 days (72 hours preferred for Cryptococcus Antigen test)</b> Frozen: <b>Indefinitely</b>	1/7/25



## Test Changes (Cont.)

Test Name	Order Code	Change	Effective Date
Fungal culture–Dermal (hair, skin and nail)	ACFSC	<b>Days Performed:</b> Sun–Sat 7:00 am–3:30 pm <b>CPT:</b> 87101	1/7/25
Fungal Culture (Non Dermal)	FCUL	<b>Days Performed:</b> Sun–Sat 7:00 am–3:30 pm <b>CPT:</b> 87102	1/7/25
Fungal culture and smear–Dermal (hair, skin and nail)	FHSNSM	<b>Days Performed:</b> Sun–Sat 7:00 am–3:30 pm <b>CPT:</b> 87101; 87206	1/7/25
Glutathione Total	GLUTAT	<b>Reported:</b> 6–10 days	effective immediately
Group B Streptococcus by PCR, Routine Prenatal Screening	GBPCR	<b>Clinical Information:</b> Many <b>healthy people</b> harbor Streptococcus agalactiae (Group B streptococcus <b>[GBS]</b> ) in the vaginal and/or rectal area, but this bacterium can rarely cause neonatal infections if a baby is exposed to the bacterium during childbirth. This test is intended for screening of pregnant women for vaginal and rectal GBS colonization between <b>36</b> and <b>38</b> weeks gestation. <b>The specimen is enriched with a broth culture before PCR is performed to attempt to detect GBS.</b> If the patient is β-lactam allergic, susceptibility testing should also be requested. <b>Do not use this test to diagnosis of GBS infection.</b>	1/7/25
Hepatitis C Virus (HCV) Genotyping by RT-PCR, Plasma/Serum	HEPGEN	<b>For interface clients only–Test build may need to be modified</b> <b>Name:</b> Previously Hepatitis C Virus (HCV) Genotyping, Reverse Transcription PCR <b>Clinical Limitation:</b> 1. Multiple genotype assay results may be caused by a mixed genotype infection, recombination of HCV genotypes, or assay probe cross-reactivity. 2. The Abbott RealTime HCV Genotype II assay is capable of detecting both genotypes in a genotype mixture when the concentrations of both genotypes are near equal; however, the assay may not detect the lower concentration genotype. 3. Performance has not been established with the Abbott RealTime HCV Genotype II assay for HCV genotype 6 specimens. HCV genotype 6 specimens may generate a HCV genotype 1 result with the Abbott RealTime HCV Genotype II assay based on probe cross-reactivity of the HCV genotype 1 probe. 4. A specimen with a result of “Unable to Genotype” cannot be presumed to be negative for HCV RNA. <b>Specimen Requirement:</b> 2 mL plasma from EDTA plasma preparation (White) tube; Minimum: 1 mL; Refrigerated; <b>Collect EDTA plasma according to standard protocol.</b> Separate plasma by centrifugation (at 1,100 RCF for a minimum of 10 minutes) within 6 hours of collection. <b>Plasma must be aliquoted first if sample is to be frozen. Sample can only be shared with AHCV1B, CMVQNT, HCQPCR, HIVRNA, HBVDNU, EBVQNT, or BKQUAN.</b> *OR* 2 mL plasma from EDTA (Lavender) tube; Minimum: 1 mL; Refrigerated; <b>Collect EDTA plasma according to standard protocol.</b> Centrifuge (at >1300 RCF for a minimum of 10 minutes) and aliquot into a sterile secondary tube within 6 hours of collection. <b>Plasma must be aliquoted first if sample is to be frozen. Sample cannot be shared with a test performed outside of Molecular Microbiology. Sample can only be shared with AHCV1B, CMVQNT, HCQPCR, HIVRNA, HBVDNU, EBVQNT, or BKQUAN.</b> *OR* 2 mL serum from serum separator (Gold) tube; Minimum: 1 mL; Refrigerated; <b>Collect serum according to standard protocol.</b> Separate serum by centrifugation (at 1,100 RCF for a minimum of 10 minutes) within 6 hours of collection. <b>Serum must be aliquoted first if sample is to be frozen. Sample cannot be shared with a test performed outside of Molecular Microbiology. Sample can only be shared with AHCV1B or HBVDNU.</b> *OR* 2 mL serum from no additive (Red) tube; Minimum: 1 mL; Refrigerated; <b>Collect serum according to standard protocol.</b> Centrifuge (at 1,100 RCF for a minimum of 10 minutes) and aliquot into a sterile secondary tube within 6 hours of collection. <b>Serum must be aliquoted first if sample is to be frozen. Sample cannot be shared with a test performed outside of Molecular Microbiology. Sample can only be shared with AHCV1B or HBVDNU.</b> <b>Reference Range:</b> <b>HCV Genotype:</b> Refer to report	12/17/24

## Test Changes (Cont.)

Test Name	Order Code	Change	Effective Date
Herpes Simplex Virus (HSV-1 & HSV-2) and Varicella Zoster Virus (VZV), NAAT, Lesion Swab	HSVZV	<p><b>For interface clients only–Test build may need to be modified</b></p> <p><b>Name:</b> Previously Herpes Simplex Virus (HSV) 1 &amp; 2 and Varicella-Zoster Virus (VZV) DNA, Nucleic Acid Amplification, Lesion Swab</p> <p><b>Special Information:</b> Use order code HSPCRC for HSV testing on CSF specimens. Use order code HSVNEO for HSV testing on neonatal surface swabs. Use order code PCRHSV for send-out HSV testing on other non-lesional specimen types including plasma, serum, amniotic fluid, BAL, and tissue.</p> <p><b>Clinical Limitation:</b> As with any nucleic acid amplification test, positive results do not rule out coinfection with other organisms, detected organisms may not be the definite cause of disease, and negative results do not rule out infection.</p> <p><b>Clinical Information:</b> Herpes simplex virus types 1 and 2 (HSV-1 and HSV-2), and varicella-zoster virus (VZV), are DNA viruses of the family Herpesviridae. HSV infections in humans can cause lesions at a variety of cutaneous and mucocutaneous sites. These lesions can be a result of the primary infection by the virus or they can result from a reactivation of the latent virus, causing recurrent episodes of the disease. Primary VZV infection results in chickenpox (varicella), which may rarely result in complications including encephalitis or pneumonia. Even when clinical symptoms of chickenpox have resolved, VZV remains dormant in the nervous system of the infected person (virus latency). In approximately 10 to 20% of cases, VZV reactivates later in life producing shingles.</p> <p>The Solana HSV 1+2/VZV Assay is an in vitro diagnostic test that uses isothermal amplification technology (helicase-dependent amplification, HDA) for the qualitative detection and differentiation of HSV-1, HSV-2, and VZV DNA from cutaneous or mucocutaneous lesion samples obtained from symptomatic patients suspected of infection by one of these viruses. The assay has targets for HSV-1 US7 (glycoprotein 1), HSV-2 noncoding region between UL47 (VP13/14) and UL48 (VP16), and VZV ORF6 (DNA-helicase primase), as well as a competitive process internal control.</p> <p><b>Specimen Requirement:</b> 3 mL swab(s) in Universal Transport Media (UTM); <b>Refrigerated;</b> Acceptable specimen types include flocced swabs from active cutaneous or mucocutaneous lesions submitted in universal transport medium (UTM) or an equivalent viral transport medium. 1. Obtain a collection kit which includes a sterile flocced swab and a container including universal transport media (UTM). Vigorously swab the base of the unroofed lesion, applying enough pressure to collect vesicular fluid and/or epithelial cells. 3. Place the swab in the tube containing UTM and break off the tip. Close the cap. *OR* 3 mL swab(s) in Viral Transport Media; <b>Refrigerated</b></p> <p><b>Stability:</b>            Ambient: 48 hours            Refrigerated: 7 days            Frozen: 7 days</p> <p><b>Methodology:</b> Target amplification nucleic acid probe, qualitative</p> <p><b>Reference Range:</b>            Herpes Simplex Virus 1 (HSV-1) DNA: <b>Not Detected</b>            Herpes Simplex Virus 2 (HSV-2) DNA: <b>Not Detected</b>            Varicella Zoster Virus (VZV) DNA: <b>Not Detected</b></p>	12/17/24
Herpesvirus 6 IgG Ab	HHV6	<p><b>Special Information:</b> This test is New York state approved.</p> <p><b>Specimen Requirement:</b> 0.5 mL serum from serum separator (Gold) tube; Refrigerated; <b>Centrifuge and transfer serum to standard aliquot tube. Separate specimens must be submitted when multiple tests are ordered.</b> *OR* 0.5 mL serum from no additive (Red) tube; Refrigerated; <b>Centrifuge and transfer serum to standard aliquot tube. Separate specimens must be submitted when multiple tests are ordered.</b></p> <p><b>Reported:</b> 6–10 days</p>	effective immediately
HTLV I/II DNA PCR	HTLV12	<p><b>Special Information:</b> Hemolyzed specimens will be rejected. <b>This test is New York DOH approved.</b></p> <p><b>Specimen Requirement:</b> 1 mL whole blood in EDTA (Lavender) tube; Frozen; <b>Separate specimens must be submitted when multiple tests are ordered.</b> *OR* 1 mL whole blood in acid citrate dextrose (ACD) A or B (Yellow) tube; Frozen; <b>Separate specimens must be submitted when multiple tests are ordered.</b></p> <p><b>Methodology:</b> Qualitative Real-Time PCR</p> <p><b>Reported:</b> 5–8 days</p>	effective immediately

## Test Changes (Cont.)

Test Name	Order Code	Change	Effective Date
Insulin Like Growth Factor 1 with Calculated Z-Score	ILGF1	<p><b>For interface clients only–Test build may need to be modified</b></p> <p><b>Name:</b> Previously Insulin Like Growth Factor 1</p> <p><b>Includes:</b>                      Insulin Like Growth Factor 1  <b>Insulin-Like Growth Factor 1 z-score Calculation</b></p>	12/17/24
Listeria Antibody	LISTRI	<p><b>Special Information: This test is New York state approved.</b></p> <p><b>Specimen Requirement:</b> 1 mL serum from no additive (Red) tube; Refrigerated; <b>Separate specimens must be submitted when multiple tests are ordered. *OR* 1 mL serum from serum separator (Gold) tube; Refrigerated; Separate specimens must be submitted when multiple tests are ordered.</b></p> <p><b>Stability:</b>                      Ambient: <b>1 week</b>                      Refrigerated: 2 weeks                      Frozen: 1 month</p> <p><b>Methodology:</b> Semi-Quantitative Complement Fixation</p> <p><b>Reported:</b> 6–10 days</p> <p><b>CPT:</b> 86609</p>	effective immediately
Listeria Antibody, CSF	LISCSF	<p><b>Specimen Requirement:</b> 1 mL cerebrospinal fluid (CSF) in clean container; Refrigerated; <b>Separate specimens must be submitted when multiple tests are ordered.</b></p> <p><b>Stability:</b>                      Ambient: <b>1 week</b>                      Refrigerated: 2 weeks                      Frozen: 1 month</p> <p><b>Reported:</b> 6–10 days</p>	effective immediately
Ma2/Ta Antibody, IgG Serum	MATA	<p><b>For interface clients only–Test build may need to be modified</b></p> <p><b>Name:</b> Previously Recombx MaTa Autoantibody Test</p> <p><b>Special Information:</b> Contaminated, heat-inactivated, hemolyzed, or lipemic specimens will be rejected. This test is New York state approved.</p> <p><b>Clinical Information:</b> This test is useful in the diagnosis of autoimmune cerebellar ataxia and encephalitis. The presence of Ma2/Ta antibodies may be associated with cerebellar ataxia, encephalitis, dementia, and brainstem encephalitis. Ma2/Ta antibody disease may be paraneoplastic and is primarily associated with testicular cancer and adenocarcinoma.</p> <p><b>IgG antibodies to Ma2/Ta are associated with paraneoplastic neurologic syndromes with phenotypes most often including a combination of limbic encephalitis, diencephalic encephalitis, and brainstem encephalitis. Patients with anti-Ma2/Ta paraneoplastic neurologic syndromes should be thoroughly evaluated for cancer, including testicular cancer and adenocarcinoma, as neurologic symptoms often precede cancer diagnosis. Use of immune checkpoint inhibitors has also been associated with an increased risk of anti-Ma2 paraneoplastic neurologic disease. Consider sending testing in CSF as well as serum to improve diagnostic yield. Results (positive or negative) should be interpreted in the context of the patient's complete clinical picture, as false positives may occur, and a negative result does not exclude the diagnosis of paraneoplastic neurologic disease.</b></p> <p><b>Specimen Requirement:</b> 1 mL serum from serum separator (Gold) tube; <b>Minimum: 0.3 mL;</b> Refrigerated; <b>Separate serum from cells ASAP or within 2 hours of collection and transfer to standard aliquot tube.</b></p> <p><b>Stability:</b>                      Ambient: <b>After separation from cells: 48 hours</b>                      Refrigerated: <b>After separation from cells: 2 weeks</b>                      Frozen: <b>After separation from cells: 1 month</b></p> <p><b>Methodology:</b> Immunoblot (IB), Qualitative</p> <p><b>Reference Range:</b> Negative</p> <p><b>Days Performed:</b> Mon, Thu, Sat</p> <p><b>Reported:</b> 2–5 days</p> <p><b>CPT:</b> 84182</p>	12/17/24

## Test Changes (Cont.)

Test Name	Order Code	Change	Effective Date
Magnesium, Urine 24 Hour	UMAGD	<p><b>Specimen Requirement:</b> 10 mL 24 hour (well-mixed) urine; <b>Collection Ambient or Refrigerated</b>; Transport Refrigerated</p> <p><b>Stability:</b>                      Ambient: <b>7 days</b>                      Refrigerated: <b>7 days</b>                      Frozen: <b>2 weeks</b></p> <p><b>Methodology:</b> Colorimetric Endpoint</p> <p><b>Reference Range:</b>                      0 Days to 17 Years: See comment                      18 Years to 999 Years: 12–291 mg/24 hrs</p> <p><b>Days Performed:</b> Sun–Sat 24 hours</p> <p><b>Reported:</b> 1–2 days</p>	1/14/25
Melatonin	MELAT	<p><b>Special Information:</b> Gel separator tubes will be rejected. Separate specimens must be submitted when multiple tests are ordered. This test is New York state approved.</p> <p><b>Clinical Information:</b> Primarily of use in research studies.</p> <p><b>Specimen Requirement:</b> 1 mL serum from no additive (Red) tube; <b>Minimum: 0.4 mL</b>; Refrigerated; Separate serum from cells ASAP or within 2 hours of collection and transfer to standard aliquot tube. Separate specimens must be submitted when multiple tests are ordered. *OR* 1 mL plasma from EDTA (Lavender) tube; <b>Minimum: 0.4 mL</b>; Refrigerated; Separate plasma from cells ASAP or within 2 hours of collection and transfer to standard aliquot tube. Separate specimens must be submitted when multiple tests are ordered.</p> <p><b>Stability:</b>                      Ambient: <b>2 weeks</b>                      Refrigerated: <b>1 month</b>                      Frozen: <b>1 year</b></p> <p><b>Methodology:</b> High Performance Liquid Chromatography/Tandem Mass Spectrometry (LC/MS/MS)</p> <p><b>Reference Range:</b> Refer to report</p> <p><b>Days Performed:</b> Varies</p> <p><b>Reported:</b> 9–12 days</p> <p><b>CPT:</b> 80375</p>	12/5/24
Methadone Quantitation, Urine	UQMET	<p><b>For interface clients only–Test build may need to be modified</b></p> <p><b>Special Information:</b> For medical purposes only; not valid for <b>legal or forensic</b> purposes.</p> <p><b>Clinical Information:</b> For specimen validity interpretations, the following rules are applied: Diluted: Creatinine is greater than or equal to 2mg/dL but less than 20mg/dL and Specific Gravity is less than 1.003. Substituted: Creatinine is less than 2mg/dL and the Specific gravity is less than <b>1.003</b> or greater than or equal to 1.020. Adulterated: pH is less than 4 or greater than or equal to 11; Nitrite is greater than or equal to 500mg/L; Oxidant is greater than or equal to 200mg/L.</p> <p><b>Specimen Requirement:</b> 5 mL random urine; <b>Minimum: 1 mL</b>; Refrigerated; <b>No preservatives.</b></p> <p><b>Stability:</b>                      Ambient: 3 days                      Refrigerated: <b>7 days</b>                      Frozen: <b>7 days</b></p> <p><b>Methodology:</b> Liquid Chromatography-Tandem Mass Spectrometry (LC-MS/MS)</p> <p><b>Reference Range:</b>                      Methadone: &lt; <b>25 ng/mL</b>                      EDDP: &lt; <b>25 ng/mL</b>                      Specimen Validity pH, Urine: 4.5–8.0                      Specimen Validity Specific Gravity, Urine: 1.003–1.035                      Specimen Validity Creatinine, Urine: 20.0–300.0 mg/dL                      Specimen Validity Nitrites, Urine: &lt;500 mg/L                      Specimen Validity Oxidants, Urine: &lt;200 mg/L</p> <p><b>Days Performed:</b> 6 days per week <b>8:00 am</b></p> <p><b>Reported:</b> 2–4 days</p>	1/7/25

## Test Changes (Cont.)

Test Name	Order Code	Change	Effective Date
Opiate Confirmation, Urine	OPICON	<p><b>For interface clients only–Test build may need to be modified</b></p> <p><b>Special Information:</b> For medical purposes only; not valid for <b>legal or</b> forensic purposes.</p> <p><b>Clinical Information:</b> For specimen validity interpretations, the following rules are applied: Diluted: Creatinine is greater than or equal to 2mg/dL but less than 20mg/dL and Specific Gravity is less than 1.003. Substituted: Creatinine is less than 2mg/dL and the Specific gravity is less than <b>1.003</b> or greater than or equal to 1.020. Adulterated: pH is less than 4 or greater than or equal to 11; Nitrite is greater than or equal to 500mg/L; Oxidant is greater than or equal to 200mg/L.</p> <p><b>Specimen Requirement: 5 mL random urine; Minimum: 1 mL; Refrigerated; No preservatives.</b></p> <p><b>Stability:</b> Ambient: 3 days Refrigerated: <b>7 days</b> Frozen: <b>7 days</b></p> <p><b>Methodology: Liquid Chromatography-Tandem Mass Spectrometry (LC-MS/MS)</b></p> <p><b>Reference Range:</b> <b>6-Monoacetylmorphine (6-MAM): &lt; 5 ng/mL</b> Codeine: &lt; <b>25 ng/mL</b> Morphine: &lt; <b>25 ng/mL</b> Hydrocodone: &lt; <b>25 ng/mL</b> <b>Norhydrocodone: &lt; 25 ng/mL</b> Oxycodone: &lt; <b>25 ng/mL</b> Hydromorphone: &lt; <b>25 ng/mL</b> Oxymorphone: &lt; <b>25 ng/mL</b> <b>Noroxycodone: &lt; 25 ng/mL</b> <b>Noroxymorphone: &lt; 25 ng/mL</b> Specimen Validity pH, Urine: 4.5–8.0 Specimen Validity Specific Gravity, Urine: 1.003–1.035 Specimen Validity Creatinine, Urine: 20.0–300.0 mg/dL Specimen Validity Nitrites, Urine: &lt;500 mg/L Specimen Validity Oxidants, Urine: &lt;200 mg/L</p> <p><b>Days Performed: 6 days per week 8:00 am</b></p> <p><b>Reported: 2–4 days</b></p>	1/7/25
Oxycodone Confirmation, Urine	UOXYCC	<p><b>For interface clients only–Test build may need to be modified</b></p> <p><b>Special Information:</b> For medical purposes only; not valid for <b>legal or</b> forensic purposes.</p> <p><b>Clinical Information:</b> For specimen validity interpretations, the following rules are applied: Diluted: Creatinine is greater than or equal to 2mg/dL but less than 20mg/dL and Specific Gravity is less than 1.003. Substituted: Creatinine is less than 2mg/dL and the Specific gravity is less than <b>1.003</b> or greater than or equal to 1.020. Adulterated: pH is less than 4 or greater than or equal to 11; Nitrite is greater than or equal to 500mg/L; Oxidant is greater than or equal to 200mg/L.</p> <p><b>Specimen Requirement: 5 mL random urine; Minimum: 1 mL; Refrigerated; No preservatives.</b></p> <p><b>Stability:</b> Ambient: 3 days Refrigerated: <b>7 days</b> Frozen: <b>7 days</b></p> <p><b>Methodology: Liquid Chromatography-Tandem Mass Spectrometry (LC-MS/MS)</b></p> <p><b>Reference Range:</b> Oxycodone: &lt; <b>25 ng/mL</b> Oxymorphone: &lt; <b>25 ng/mL</b> Specimen Validity pH, Urine: 4.5–8.0 Specimen Validity Specific Gravity, Urine: 1.003–1.035 Specimen Validity Creatinine, Urine: 20.0–300.0 mg/dL Specimen Validity Nitrites, Urine: &lt;500 mg/L Specimen Validity Oxidants, Urine: &lt;200 mg/L</p> <p><b>Days Performed: 6 days per week</b></p> <p><b>Reported: 2–4 days</b></p>	1/7/25

## Test Changes (Cont.)

Test Name	Order Code	Change	Effective Date
Phencyclidine Confirmation, Urine	UPCPC	<p><b>For interface clients only–Test build may need to be modified</b></p> <p><b>Special Information:</b> For medical purposes only; not valid for legal or forensic purposes.</p> <p><b>Clinical Information:</b> For specimen validity interpretations, the following rules are applied: Diluted: Creatinine is greater than or equal to 2mg/dL but less than 20mg/dL and Specific Gravity is less than 1.003. Substituted: Creatinine is less than 2mg/dL and the Specific gravity is less than 1.003 or greater than or equal to 1.020. Adulterated: pH is less than 4 or greater than or equal to 11; Nitrite is greater than or equal to 500mg/L; Oxidant is greater than or equal to 200mg/L.</p> <p><b>Specimen Requirement:</b> 5 mL random urine; <b>Minimum:</b> 1 mL; Refrigerated; <b>No preservatives.</b></p> <p><b>Stability:</b>            Ambient: 3 days            Refrigerated: <b>7 days</b>            Frozen: <b>7 days</b></p> <p><b>Methodology:</b> Liquid Chromatography-Tandem Mass Spectrometry (LC-MS/MS)</p> <p><b>Reference Range:</b>            Phencyclidine (PCP): &lt; <b>10 ng/mL</b>            Specimen Validity pH, Urine: 4.5–8.0            Specimen Validity Specific Gravity, Urine: 1.003–1.035            Specimen Validity Creatinine, Urine: 20.0–300.0 mg/dL            Specimen Validity Nitrites, Urine: &lt;500 mg/L            Specimen Validity Oxidants, Urine: &lt;200 mg/L</p> <p><b>Days Performed:</b> 6 days per week <b>8:00 am</b></p> <p><b>Reported:</b> 2–4 days</p>	1/7/25
Staphylococcus aureus & MRSA Screen, Culture, Skin	SANSAL	<p><b>Special Information: Additional billing is applied for identification and susceptibility testing. CPT codes vary based on methodology</b></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/mucus membrane swab in <b>Amies or Stuart's media without charcoal</b>; Ambient</p>	1/7/25
Staphylococcus aureus & MRSA Screen, PCR, Nasal	SAPCR	<p><b>Clinical Limitation:</b> The <b>Staphylococcus aureus</b> PCR test is a <b>screening test for nasal carriage. A negative result does not preclude MRSA/SA colonization.</b></p> <p><b>Clinical Information:</b> This test detects Staphylococcus aureus (SA) and methicillin-resistant Staphylococcus aureus (MRSA) from nasal swabs to determine <b>if the patient carries S. aureus in their normal microbiome. This test is only for nares specimens.</b> Specimens other than nares require culture (SANSAL).</p>	1/7/25
STRATIFY JCV DxSelect Antibody and Index with Reflex to Inhibition Assay	JCVIDX	<p><b>Name:</b> Previously STRATIFY JCV Antibody and Index with Reflex to Inhibition Assay</p> <p><b>Special Information:</b> <b>This assay will be performed at no charge. If the Index Value is between 0.20-0.40 (inclusive), then Stratify JCV™ Antibody Inhibition Assay will be performed. If reflexed, turnaround time may be extended.</b> Grossly hemolyzed, lipemic, or icteric specimens will be rejected.</p> <p><b>Clinical Information:</b> JC Virus (JCV) is associated with progressive multifocal leukoencephalopathy (PML). Detection of antibodies to JCV in serum or plasma is a reliable indicator of exposure to JCV. The analytical performance characteristics were determined for multiple sclerosis patients. <b>Interpretive criteria: Negative: &lt; 0.20; Indeterminate: 0.20–0.40; Positive: &gt; 0.40.</b></p>	12/16/24
Syphilis Treponemal with reflex	SYPHTX	<p><b>Reference Range:</b>            Syphilis <b>Treponemal</b> Screen: Non-reactive</p>	effective immediately

## Test Changes (Cont.)

Test Name	Order Code	Change	Effective Date
THC Metabolite Confirmation, Urine	UTHCC	<p><b>For interface clients only–Test build may need to be modified</b></p> <p><b>Name:</b> Previously Cannabinoid Confirmation, Ur</p> <p><b>Special Information:</b> For medical purposes only; not valid for <b>legal or</b> forensic purposes.</p> <p><b>Clinical Information:</b> For specimen validity interpretations, the following rules are applied: Diluted: Creatinine is greater than or equal to 2mg/dL but less than 20mg/dL and Specific Gravity is less than 1.003. Substituted: Creatinine is less than 2mg/dL and the Specific gravity is less than <b>1.003</b> or greater than or equal to 1.020. Adulterated: pH is less than 4 or greater than or equal to 11; Nitrite is greater than or equal to 500mg/L; Oxidant is greater than or equal to 200mg/L.</p> <p><b>Specimen Requirement: 5 mL</b> random urine; <b>Minimum: 1 mL</b>; Refrigerated; <b>No preservatives.</b></p> <p><b>Stability:</b>            Ambient: 3 days            Refrigerated: <b>7 days</b>            Frozen: <b>7 days</b></p> <p><b>Methodology: Liquid Chromatography-Tandem Mass Spectrometry (LC-MS/MS)</b></p> <p><b>Reference Range:</b>  <b>Delta-9-carboxy-THC: &lt; 10 ng/mL</b>            Specimen Validity pH, Urine: 4.5–8.0            Specimen Validity Specific Gravity, Urine: 1.003–1.035            Specimen Validity Creatinine, Urine: 20.0–300.0 mg/dL            Specimen Validity Nitrites, Urine: &lt;500 mg/L            Specimen Validity Oxidants, Urine: &lt;200 mg/L</p> <p><b>Days Performed: 6 days per week 8:00 am</b></p> <p><b>Reported: 2–4 days</b></p>	1/7/25
Tramadol and Metabolite Quantitation, Urine	TRAQNT	<p><b>For interface clients only–Test build may need to be modified</b></p> <p><b>Name:</b> Previously Tramadol and Metabolite, Quantitation</p> <p><b>Special Information:</b> For medical purposes only; not valid for <b>legal or</b> forensic purposes.</p> <p><b>Clinical Information:</b> For specimen validity interpretations, the following rules are applied: Diluted: Creatinine is greater than or equal to 2mg/dL but less than 20mg/dL and Specific Gravity is less than 1.003. Substituted: Creatinine is less than 2mg/dL and the Specific gravity is less than <b>1.003</b> or greater than or equal to 1.020. Adulterated: pH is less than 4 or greater than or equal to 11; Nitrite is greater than or equal to 500mg/L; Oxidant is greater than or equal to 200mg/L.</p> <p><b>Specimen Requirement: 5 mL</b> random urine; <b>Minimum: 1 mL</b>; Refrigerated; <b>No preservatives.</b></p> <p><b>Stability:</b>            Ambient: 3 days            Refrigerated: <b>7 days</b>            Frozen: <b>7 days</b></p> <p><b>Reference Range:</b>            Tramadol: &lt; <b>25 ng/mL</b>  <b>O-Desmethyltramadol: &lt; 25 ng/mL</b>            Specimen Validity pH, Urine: 4.5–8.0            Specimen Validity Specific Gravity, Urine: 1.003–1.035            Specimen Validity Creatinine, Urine: 20.0–300.0 mg/dL            Specimen Validity Nitrites, Urine: &lt;500 mg/L            Specimen Validity Oxidants, Urine: &lt;200 mg/L</p> <p><b>Days Performed: 6 days per week 8:00 am</b></p> <p><b>Reported: 2–4 days</b></p>	1/7/25
Trichinella IgG Antibody	TRICH	<p><b>Specimen Requirement:</b> 1 mL serum from no additive (Red) tube; Refrigerated; <b>Centrifuge and transfer serum to standard aliquot tube. Separate specimens must be submitted when multiple tests are ordered.</b> *OR* 1 mL serum from serum separator (Gold) tube; Refrigerated; <b>Centrifuge and transfer serum to standard aliquot tube. Separate specimens must be submitted when multiple tests are ordered.</b></p> <p><b>Reported: 7–12 days</b></p>	effective immediately
Varicella-Zoster IgG Ab	VZVG2	<p><b>Reference Range: Positive</b></p>	effective immediately



## Test Changes (Cont.)

Test Name	Order Code	Change	Effective Date
Varicella Zoster IgG Ab, CSF	CVZVG	<b>Reference Range:</b> <b>0.9 S/Co or less: Negative—No significant level of IgG antibody to varicella-zoster virus detected</b> <b>1.0 S/Co or greater: Positive—IgG antibody to varicella-zoster virus detected, which may indicate a current or past varicella-zoster infection</b>	effective immediately
Vitamin B5 (Pantothenic Acid) Bioassay	VITB5	<b>Specimen Requirement:</b> 1 mL serum from serum separator (Gold) tube; Frozen; MUST protect specimen from light. <b>Allow specimen to clot for 30 minutes then centrifuge and transfer serum to amber transport tube. Separate specimens must be submitted when multiple tests are ordered.</b> <b>Methodology:</b> Bioassay <b>Reported:</b> 7–14 days <b>CPT:</b> 84591	effective immediately
Vitamin D, 1,25-Dihydroxy	125VTD	<b>Reference Range:</b> <b>0 Days to 364 Days: 32.1-196.0 pg/mL</b> <b>1 Years to 2 Years: 47.1-151.0 pg/mL</b> <b>3 Years to 18 Years: 45.0-102.0 pg/mL</b> <b>19 Years and above: 19.9-79.3 pg/mL</b>	12/19/24

# New Tests

Test Name	Order Code	Change	Effective Date
Blood Parasite Microscopy smear, including % parasitemia	BPMSM	<p><b>Special Information:</b> Malaria is a potentially life-threatening condition, and testing for this infection should be conducted as quickly as possible. Consequently, this test is not recommended as the primary screening method when specimens can be delivered within a few hours of collection. Laboratories that cannot ensure prompt specimen delivery should first conduct an initial screening for malaria and other blood parasites, such as a malaria antigen test, before sending the specimen for further analysis. This test is used to confirm a presumptive malaria diagnosis, identify the infecting Plasmodium and Babesia species, and determine the percent parasitemia. A percent parasitemia calculated more than 8 hours after blood collection may not accurately reflect the patient's current state of parasitemia. Additionally, if malaria parasites have degraded or their morphology has altered due to specimen age or suboptimal transportation conditions, the calculation of percent parasitemia may be either impossible or inaccurate.</p> <p><b>Clinical Limitation:</b> A single negative result does not exclude the possibility of parasitic infection. If there is strong suspicion testing should be conducted at least three times using samples collected at different times throughout the fever cycle. Delay in sample processing or transport can impact quality of smears thus the sensitivity and specificity of blood parasite detection.</p> <p>Testing can not be performed on grossly hemolysed, or clotted blood specimens.</p> <p><b>Clinical Information:</b> Malaria is a mosquito-borne disease caused by Plasmodium parasites, which are a major cause of illness and death globally. Malaria can also affect travelers from non-endemic areas. The primary Plasmodium species responsible for malaria are P. falciparum, P. vivax, P. malariae, and P. ovale. P. knowlesi, a simian parasite, has also been known to infect humans in parts of Southeast Asia and is significant due to its potential to cause severe illness. P. falciparum is particularly concerning due to its resistance to many antimalarial drugs. In the U.S., Babesia microti is the main cause of human cases, with notable outbreaks in the Northeast and Midwest. Other species like Babesia duncani and Babesia divergens have also been reported in certain areas. Babesia microti is nationally notifiable.</p> <p>Babesia microti shares its tick vector with Borrelia burgdorferi (Lyme disease) and Anaplasma phagocytophilum (human granulocytic anaplasmosis), making concurrent testing for these diseases advisable in endemic regions. Additionally, babesiosis can be transmitted via blood transfusion, prompting the FDA to mandate donor screening for this parasite in 2018. While most cases of babesiosis are mild or asymptomatic, severe cases can occur, particularly in asplenic individuals. Thick film microscopy, is used for screening, while thin films help determine percent parasitemia, which indicates the severity and helps monitor treatment response. Percent parasitemia is calculated from microscopic fields on the thin blood film. Percent parasitemia exclude malarial gametocytes as they are not infectious and are not targeted by most antimalarial treatments and will be reported out within the comments. Microfilaria, Trypanosomes if seen will be reported but alternate molecular or serological testing is recommended.</p> <p><b>Specimen Requirement:</b> 2-3 mL whole blood in EDTA (Lavender) tube; Minimum: 0.5 mL; Collection Ambient; Transport Refrigerated; Prompt delivery of specimens to the laboratory is crucial for accurate and reliable results. Laboratories that are unable to deliver specimens within a few hours of collection should conduct an initial screening for malaria, such as a Malaria Binax antigen test, before sending the specimen. This preliminary testing helps ensure timely diagnosis and effective patient management. *OR* 4 unstained whole blood slides; Collection Ambient; Transport Ambient; Minimum of 4 unstained slides—2 thick and 2 thin slides should be prepared and submitted in addition to EDTA blood. Slides should be prepared per routine hematology processes and as described by the CDC protocol <a href="https://www.cdc.gov/dpdx/diagnosticProcedures/blood/specimenproc.html">https://www.cdc.gov/dpdx/diagnosticProcedures/blood/specimenproc.html</a></p> <p><b>Stability:</b>            Ambient: 24 hrs            Refrigerated: 24 hrs            Frozen: Unacceptable</p> <p><b>Methodology:</b> Stain</p> <p><b>Days Performed:</b> 7 days a week 7:00 am–3:30 pm</p> <p><b>Reported:</b> 1–2 days</p> <p><b>CPT:</b> 87207</p>	1/7/25

## New Tests (Cont.)

Test Name	Order Code	Change	Effective Date
Ma2/Ta Antibody, IgG CSF	MA2CSF	<p><b>Special Information:</b> This test is New York state approved.</p> <p><b>Clinical Information:</b> This test is useful in the diagnosis of autoimmune cerebellar ataxia and encephalitis. The presence of Ma2/Ta antibodies may be associated with cerebellar ataxia, encephalitis, dementia, and brainstem encephalitis. Ma2/Ta antibody disease may be paraneoplastic and is primarily associated with testicular cancer and adenocarcinoma.</p> <p>IgG antibodies to Ma2/Ta are associated with paraneoplastic neurologic syndromes with phenotypes most often including a combination of limbic encephalitis, diencephalic encephalitis, and brainstem encephalitis. Patients with anti-Ma2/Ta paraneoplastic neurologic syndromes should be thoroughly evaluated for cancer, including testicular cancer and adenocarcinoma, as neurologic symptoms often precede cancer diagnosis. Use of immune checkpoint inhibitors has also been associated with an increased risk of anti-Ma2 paraneoplastic neurologic disease. Consider sending testing in serum as well as CSF to improve diagnostic yield. Results (positive or negative) should be interpreted in the context of the patient's complete clinical picture, as false positives may occur, and a negative result does not exclude the diagnosis of paraneoplastic neurologic disease.</p> <p><b>Specimen Requirement:</b> 1 mL cerebrospinal fluid (CSF) in clean container; Minimum: 0.6 mL; Refrigerated</p> <p><b>Stability:</b>            Ambient: 48 hours            Refrigerated: 2 weeks            Frozen: 1 month</p> <p><b>Methodology:</b> Immunoblot (IB), Qualitative</p> <p><b>Reference Range:</b> Negative</p> <p><b>Days Performed:</b> Mon, Thu, Sat</p> <p><b>Reported:</b> 2–5 days</p> <p><b>CPT:</b> 84182</p>	12/17/24
Magnesium/Creatinine Ratio, Urine	UMGCRR	<p><b>Includes:</b>            Magnesium Random, Urine            Creatinine Random, Urine</p> <p><b>Specimen Requirement:</b> 10 mL random urine; Collection Ambient or Refrigerated</p> <p><b>Stability:</b>            Ambient: 7 days            Refrigerated: 7 days            Frozen: 2 weeks</p> <p><b>Methodology:</b>            Colorimetric Endpoint            Enzymatic</p> <p><b>Reference Range:</b>            Urine Creatine:            18 Years and older: 20-300 mg/dL            Magnesium/Creatinine Ratio, Urine:            30 days to 365 days: 0.10-0.48 mg/mg            12 Months up to 24 Months: 0.09-0.37 mg/mg            24 months up to 36 months: 0.07-0.34 mg/mg            3 Years to 4 Years: 0.07-0.29 mg/mg            5 Years to 6 Years: 0.06-0.21 mg/mg            7 Years to 9 Years: 0.05-0.18 mg/mg            10 Years to 13 Years: 0.05-0.15 mg/mg            14 Years to 17 Years: 0.05-0.13 mg/mg            18 Years and older: 0.02-0.10 mg/mg</p> <p><b>Days Performed:</b> Sun–Sat 24 hours</p> <p><b>Reported:</b> 1–2 days</p>	1/14/25

## New Tests (Cont.)

Test Name	Order Code	Change	Effective Date
Malaria Binax Antigen, screen	MALAGS	<p><b>Includes:</b> Blood Parasite Microscopy smear, including % parasitemia (BPMSM)</p> <p><b>Special Information:</b> The malaria antigen test should be treated as a STAT test and processed immediately upon receipt in the lab. It is crucial to use this test for patients who have an appropriate travel history and a strong suspicion of malaria. Blood samples must also be delivered to the lab promptly after collection to ensure the accuracy, reliability and appropriate utilization of the test results. All malaria antigen screen tests will be reflexed to Blood parasite microscopy smear, regardless of a positive or negative result.</p> <p><b>Clinical Limitation:</b> A negative test result does not exclude infection with malaria, particularly at low levels of parasitemia. Test performance depends on antigen load in the specimen and may not directly correlate with microscopy performed on the same specimen. Binax antigen test can cross react with rheumatoid factor, chronic viral infections such as hepatitis C and other parasitic infections. The Binax malaria test can be affected by the prozone effect, and both antigens may test positive due to dual infection or high levels of parasitemia. The antigen test may also remain positive for days after clearance of malarial parasitic infection. False negatives are also possible for HRP-2 negative Plasmodium falciparum species.</p> <p><b>Clinical Information:</b> Malaria is a major parasitic disease, which is endemic in many countries in various areas of the world. Each year it causes up to 3 million deaths and close to 5 billion cases of clinical illness worldwide. The rapid malaria antigen screen has better sensitivity of detection for Plasmodium falciparum as compared to the other Plasmodium species. It provides rapid results and is designed to be used as a screening tests but all test results are paired with a blood parasite microscopy smear. The antigen test is not designed to be used for assessment of treatment efficacy or as a test-of-cure as residual plasmodium antigen may be detected several days following clearance as determined by microscopy.</p> <p><b>Specimen Requirement:</b> 2–3 mL whole blood in EDTA (Lavender) tube; Minimum: 0.5 mL; Collection Ambient; Transport Refrigerated; Prompt delivery of specimens to the laboratory is crucial for accurate and reliable results. Laboratories that are unable to deliver specimens within a few hours of collection should conduct an initial screening for malaria, such as a Malaria Binax antigen test, before sending the specimen. This preliminary testing helps ensure timely diagnosis and effective patient management. Refer to Blood Parasite Microscopy smear, including % parasitemia for additional specimens (slides) needed to complete reflex testing.</p> <p><b>Stability:</b>            Ambient: 24 hrs            Refrigerated: 24 hrs            Frozen: Unacceptable</p> <p><b>Methodology:</b> Immunochromatography</p> <p><b>Days Performed:</b> 7 days a week 24 hours</p> <p><b>Reported:</b> 1–8 hours</p> <p><b>CPT:</b> 87899x2</p>	1/7/25
Myelopathy, Autoimmune/Paraneoplastic Evaluation, Serum	MLPTHY	<p><b>Special Information:</b> Reflex Algorithm: Each reflex test performed incurs additional charge. If the indirect immunofluorescence assay (IFA) patterns suggest anti-glial nuclear antibody (AGNA)-1, then the AGNA-1 immunoblot and AGNA-1 IFA titer will be performed. If the IFA patterns suggest amphiphysin antibody, then the amphiphysin immunoblot and amphiphysin IFA titer will be performed. If the IFA pattern suggests antineuronal nuclear antibody type 1 (ANNA-1), then the ANNA-1 IFA titer, ANNA-1 immunoblot, and ANNA-2 immunoblot will be performed. If the IFA pattern suggests ANNA-2 antibodies, then the ANNA-2 IFA titer, ANNA-2 immunoblot, and ANNA-1 immunoblot will be performed. If the client requests or the IFA pattern suggests ANNA-3 antibodies, then the ANNA-3 IFA titer will be performed. If the IFA pattern suggests adaptor protein 3 beta 2 (AP3B2) antibodies, then the AP3B2 cell-binding assay (CBA) and AP3B2 IFA titer will be performed. If the CRMP-5-IgG Western blot is positive, then the CRMP-5-IgG IFA titer will be performed. If the IFA pattern suggests Purkinje cytoplasmic antibody type 1 (PCA-1), then the PCA-1 immunoblot and PCA-1 IFA titer will be performed. If the IFA pattern suggests PCA-2 antibody, then the PCA-2 IFA titer will be performed. If gamma-aminobutyric acid B (GABA-B) receptor antibody CBA result is positive, then the GABA-B-receptor antibody IFA titer will be performed. If the dipeptidyl-peptidase-like protein-6 (DPPX) antibody CBA result is positive, then the DPPX antibody IFA titer will be performed.</p> <p><i>(continued on page 27)</i></p>	12/10/24

## New Tests (Cont.)

Test Name	Order Code	Change	Effective Date
Myelopathy, Autoimmune/Paraneoplastic Evaluation, Serum <i>(continued from page 26)</i>	MLPTHY	<p><b>Special Information (continued):</b> If the IFA pattern suggests metabotropic glutamate receptor 1 (mGluR1) antibody, then the mGluR1 antibody CBA and mGluR1 antibody IFA titer will be performed. If the IFA pattern suggests glial fibrillary acidic protein (GFAP) antibody, then the GFAP antibody CBA and GFAP antibody IFA titer will be performed. If the neuromyelitis optica/aquaporin-4-IgG (NMO/AQP4-IgG) fluorescence-activated cell sorting (FACS) screen assay requires further investigation, then the NMO/AQP4-IgG FACS titration assay will be performed. If the myelin oligodendrocyte glycoprotein (MOG) FACS screen assay requires further investigation, then the MOG FACS titration assay will be performed. If the IFA pattern suggests neuronal intermediate filament (NIF) antibody, then the alpha internexin CBA, NIF heavy chain CBA, NIF light chain CBA, and NIF antibody IFA titer will be performed. If the IFA pattern suggests neurochondrin antibody, then the neurochondrin antibody CBA and neurochondrin IFA titer will be performed. If the IFA pattern suggests septin-7 antibody, then the septin-7 CBA and septin-7 IFA titer will be performed. If the IFA pattern suggests tripartite motif-containing protein 46 (TRIM46) antibody, then the TRIM46 antibody CBA and TRIM46 IFA titer will be performed. This test should not be requested for patients who have recently received radioisotopes, therapeutically or diagnostically, because of potential assay interference. The specific waiting period before specimen collection will depend on the isotope administered, the dose given, and the clearance rate in the individual patient. Specimens will be screened for radioactivity prior to analysis. Radioactive specimens received in the laboratory will be held 1 week and assayed if sufficiently decayed or canceled if radioactivity remains. Grossly hemolyzed, lipemic or icteric specimens will be rejected. This test is New York state approved.</p> <p><b>Clinical Information:</b> This test is useful for evaluating patients with suspected autoimmune myelopathy, myelitis, and paraneoplastic myelopathy. Patients with autoimmune myelopathy present with subacute onset and rapid progression of spinal cord symptoms with one or more of the following: weakness, gait difficulties, loss of sensation, neuropathic pain, and bowel and bladder dysfunction. Clinical history and examination, spinal cord magnetic resonance imaging, and cerebrospinal fluid (CSF) testing may provide clues to an autoimmune diagnosis. Autoimmune myelopathy evaluation of both serum and CSF can assist in the diagnosis (paraneoplastic or idiopathic autoimmune) and aid distinction from other causes of myelopathy (multiple sclerosis, sarcoidosis, vascular disease). Early testing may assist in early diagnosis of occult cancer, prompt initiation of immune therapies, or both.</p> <p><b>Specimen Requirement:</b> 4 mL serum from no additive (Red) tube; Minimum: 2 mL; Refrigerated; Draw 2 tubes to ensure adequate serum volume. Specimen collection is recommended before initiation of immunosuppressant medication. This test should not be requested in patients who have recently received radioisotopes (refer to Special Information). Centrifuge and transfer serum to standard aliquot tube. *OR* 4 mL serum from serum separator (Gold) tube; Minimum: 2 mL; Refrigerated; Draw 2 tubes to ensure adequate serum volume. Specimen collection is recommended before initiation of immunosuppressant medication. This test should not be requested in patients who have recently received radioisotopes (refer to Special Information). Centrifuge and transfer serum to standard aliquot tube.</p> <p><b>Stability:</b> Ambient: 72 hours Refrigerated: 28 days Frozen: 28 days</p> <p><b>Methodology:</b> Cell Binding Assay (CBA) Flow Cytometry (FC) Immunoblot (IB) Indirect Immunofluorescence Assay (IFA) Radioimmunoassay (RIA) Western Blot (WB)</p> <p><i>(continued on page 28)</i></p>	12/10/24

## New Tests (Cont.)

Test Name	Order Code	Change	Effective Date
Myelopathy, Autoimmune/Paraneoplastic Evaluation, Serum <i>(continued from page 27)</i>	MLPTHY	<p><b>Reference Range:</b>                      Amphiphysin Ab: Negative                      Anti-Glial Nuclear Ab, Type 1: Negative                      Antineuronal Nuclear Ab-Type 1 (ANNA-1): Negative                      Antineuronal Nuclear Ab-Type 2 (ANNA-2): Negative                      Antineuronal Nuclear Ab-Type 3 (ANNA-3): Negative                      AP3B2 IFA, S: Negative                      CRMP-5 Western Blot: Negative                      DPPX Ab CBA, Serum: Negative                      GABA-B-Receptor Ab CBA: Negative                      GAD65 Antibody: &lt; or = 0.02 nmol/L                      GFAP IFA S: Negative                      mGluR1 Ab IFA, S: Negative                      MOG FACS, S: Negative                      Neurochondrin IFA, S: Negative                      NIF IFA S: Negative                      NMO Aquaporin 4 IgG: Negative                      Purkinje Cell Cytoplasmic Ab-Type 1 (PCA-1): Negative                      Purkinje Cell Cytoplasmic Ab-Type 2 (PCA-2): Negative                      Septin-7 IFA, S: Negative                      TRIM46 Ab IFA, S: Negative                      Autoimmune Myelopathy Interp, S: Refer to report</p> <p><b>Days Performed:</b> Sun–Sat  <b>Reported:</b> 9–13 days</p>	12/10/24
Quantitative Toxicology Panel, Urine	UQNTOX	<p><b>Special Information:</b> For medical purposes only; not valid for legal or forensic purposes.</p> <p><b>Clinical Limitation:</b> Assay does not differentiate between delta-8 or delta-9 carboxy-THC.</p> <p><b>Clinical Information:</b> For specimen validity interpretations, the following rules are applied: Diluted: Creatinine is greater than or equal to 2mg/dL but less than 20mg/dL and Specific Gravity is less than 1.003. Substituted: Creatinine is less than 2mg/dL and the Specific Gravity is less than 1.003 or greater than or equal to 1.020. Adulterated: pH is less than 4 or greater than or equal to 11; Nitrite is greater than or equal to 500mg/L; Oxidant is greater than or equal to 200mg/L.</p> <p><b>Specimen Requirement:</b> 5 mL random urine; Minimum: 1 mL; Refrigerated; No preservatives</p> <p><b>Stability:</b>                      Ambient: 3 days                      Refrigerated: 7 days                      Frozen: 7 days</p> <p><b>Methodology:</b> Liquid Chromatography-Tandem Mass Spectrometry (LC-MS/MS)</p> <p><b>Reference Range:</b>                      6-Monoacetylmorphine: &lt; 5 ng/mL                      Amphetamine: &lt; 25 ng/mL                      Buprenorphine: &lt; 5 ng/mL                      Benzoylcegonine: &lt; 25 ng/mL                      Codeine: &lt; 25 ng/mL                      EDDP: &lt; 25 ng/mL                      Fentanyl: &lt; 1 ng/mL                      Hydrocodone: &lt; 25 ng/mL                      Hydromorphone: &lt; 25 ng/mL                      MDA: &lt; 25 ng/mL                      MDEA: &lt; 25 ng/mL                      MDMA: &lt; 25 ng/mL                      Methadone: &lt; 25 ng/mL                      Methamphetamine: &lt; 25 ng/mL                      Morphine: &lt; 25 ng/mL                      Norbuprenorphine: &lt; 10 ng/mL                      Norfentanyl: &lt; 1 ng/mL                      Norhydrocodone: &lt; 25 ng/mL                      Noroxycodone: &lt; 25 ng/mL</p> <p><i>(continued on page 29)</i></p>	1/7/25

## New Tests (Cont.)

Test Name	Order Code	Change	Effective Date
Quantitative Toxicology Panel, Urine <i>(continued from page 28)</i>	UQNTOX	<p><b>Reference Range (continued):</b>            Noroxymorphone: &lt; 25 ng/mL            O-Desmethyltramadol: &lt; 25 ng/mL            Oxycodone: &lt; 25 ng/mL            Oxymorphone: &lt; 25 ng/mL            Phencyclidine: &lt; 10 ng/mL            Phentermine: &lt; 25 ng/mL            Delta-9-carboxy-THC: &lt; 10 ng/mL            Tramadol: &lt; 25 ng/mL            Specimen Validity pH, Urine: 4.5–8.0            Specimen Validity Specific Gravity, Urine: 1.003–1.035            Specimen Validity Creatinine, Urine: 20.0–300.0 mg/dL            Specimen Validity Oxidants, Urine: &lt;200 mg/L            Specimen Validity Nitrites, Urine: &lt;500 mg/L</p> <p><b>Days Performed:</b> 6 days per week 8:00 am  <b>Reported:</b> 2–4 weeks</p>	1/7/25
Stiff-Person Spectrum Disorders Evaluation, including Progressive Encephalomyelitis with Rigidity and Myoclonus, Serum	SPSDEV	<p><b>Includes:</b>            Amphiphysin Ab            GAD65 Ab Assay            DPPX Ab CBA            Glycine Alpha1 LCBA            Stiff-Person/PERM Interp            IFA Notes</p> <p><b>Special Information:</b> Reflex Algorithm: Each reflex test performed incurs additional charge. If client requests or if the indirect immunofluorescence assay (IFA) pattern suggests amphiphysin antibody, then amphiphysin immunoblot and amphiphysin IFA titer will be performed. If the dipeptidyl-peptidase-like protein-6 (DPPX) cell bound assay is positive, then DPPX antibody IFA titer will be performed. This test should not be requested for patients who have recently received radioisotopes, therapeutically or diagnostically, because of potential assay interference. The specific waiting period before specimen collection will depend on the isotope administered, the dose given, and the clearance rate in the individual patient. Specimens will be screened for radioactivity prior to analysis. Radioactive specimens received in the laboratory will be held 1 week and assayed if sufficiently decayed or canceled if radioactivity remains. Grossly hemolyzed, lipemic or icteric specimens will be rejected. This test is New York state approved.</p> <p><b>Clinical Information:</b> This test is useful for evaluating patients with suspected stiff-person syndrome (classical or focal forms, such as stiff-limb or stiff-trunk) and progressive encephalomyelitis with rigidity and myoclonus. Seropositivity supports the clinical diagnosis of stiff-person spectrum disorder (classical stiff-person, stiff-limb, stiff-trunk, or progressive encephalomyelitis with rigidity and myoclonus). A paraneoplastic basis should be considered. Negative results do not exclude the diagnosis of stiff-person spectrum disorder or progressive encephalomyelitis with rigidity and myoclonus (PERM). Glutamic acid decarboxylase 65 (GAD65) antibody positive values below 20 nmol/L should be interpreted with caution. Lower values are encountered in 8% of the general population. However, GAD65 autoimmunity (any antibody value) is associated with other autoimmune diseases that can cause neurological symptoms, including type 1 diabetes, pernicious anemia, hypothyroidism, and adrenal insufficiency.</p> <p><b>Specimen Requirement:</b> 2 mL serum from no additive (Red) tube; Minimum: 1 mL; Refrigerated; This test should not be requested in patients who have recently received radioisotopes (refer to Special Information). Centrifuge and transfer serum to standard aliquot tube. *OR* 2 mL serum from serum separator (Gold) tube; Minimum: 1 mL; Refrigerated; This test should not be requested in patients who have recently received radioisotopes (refer to Special Information). Centrifuge and transfer serum to standard aliquot tube.</p> <p><b>Stability:</b>            Ambient: 72 hours            Refrigerated: 28 days            Frozen: 28 days</p> <p><i>(continued on page 30)</i></p>	12/3/24



## New Tests (Cont.)

Test Name	Order Code	Change	Effective Date
Stiff-Person Spectrum Disorders Evaluation, including Progressive Encephalomyelitis with Rigidity and Myoclonus, Serum <i>(continued from page 29)</i>	SPSDEV	<p><b>Methodology:</b> Cell Binding Assay (CBA) Indirect Immunofluorescence Assay (IFA) Live Cell-Binding Assay (LCBA) Radioimmunoassay (RIA)</p> <p><b>Reference Range:</b> Amphiphysin Ab: Negative DPPX Ab CBA, Serum: Negative GAD65 Antibody: &lt; or = 0.02 nmol/L Glycine Alpha1 LCBA, S: Negative</p> <p><b>Days Performed:</b> Sun–Sat</p> <p><b>Reported:</b> 6–11 days</p> <p><b>CPT:</b> 86341x1; 86255x2; 0431Ux1</p>	12/3/24

## Discontinued Tests

Test Name	Order Code	Test Information	Effective Date
6-Monoacetylmorphine (6-MAM) Confirmation, Urine	U6AMCO	Test will no longer be orderable. Recommended replacement test is Opiate Confirmation, Urine (OPICON).	1/7/25
AFB Stain Only	AFS	Test will no longer be orderable. Recommended replacement tests are AFB Culture & Stain (AFC) or Tuberculosis PCR and Culture, Respiratory (TBPCR).	1/7/25
Blood Parasite Microscopy Only	BABESI	Test will no longer be orderable. Recommended replacement tests are Blood Parasite Microscopy smear, including % parasitemia (BPMSM) and Malaria Binax Antigen, screen (MALAGS).	1/7/25
Blood Parasites	BLDPAR	Test will no longer be orderable. Recommended replacement tests are Blood Parasite Microscopy smear, including % parasitemia (BPMSM) and Malaria Binax Antigen, screen (MALAGS).	1/7/25
Herpes Simplex IgM, Abs	HSVM	Test will no longer be orderable. Recommended replacement tests are Herpes Simplex Virus (HSV-1 & HSV-2) and Varicella Zoster Virus (VZV), NAAT, Lesion Swab [HSVZV], Herpes Simplex Virus (HSV-1 & HSV-2), Qualitative PCR, CSF [HSPCRC] or HSV PCR - Miscellaneous Specimen Types [PCRHSV] depending on specimen type.	12/19/24
Herpes Simplex IgM, Abs, with IgG Reflex	HSVGM	Test will no longer be orderable. Recommended replacement tests are Herpes Simplex Virus (HSV-1 & HSV-2) and Varicella Zoster Virus (VZV), NAAT, Lesion Swab [HSVZV], Herpes Simplex Virus (HSV-1 & HSV-2), Qualitative PCR, CSF [HSPCRC] or HSV PCR - Miscellaneous Specimen Types [PCRHSV] depending on specimen type.	12/19/24
Hu Antibody with Reflex to Titer and Western Blot	HUANT	Test will no longer be orderable. Recommended replacement tests are Neuronal Nuclear Antibodies (Hu, Ri, Yo, Tr/DNER) IgG by Immunoblot, Serum (HURIYO) or Hu Autoantibody (ANTIHU).	12/19/24
Magnesium, Urine Random	UMAGR	Test will no longer be orderable. Recommended replacement test is Magnesium/Creatinine Ratio, Urine (UMGCRR).	1/14/25
Quantitative Pain Panel, Urine	UQNTPP	Test will no longer be orderable. Recommended replacement test is Quantitative Toxicology Panel, Urine (UQNTOX).	1/7/25
VRE Culture Screen	VRESC	Test will no longer be orderable. Recommended replacement test is Bacterial Culture and Gram Stain, Abscess and Wound (Aerobic Culture) [WCUL].	1/7/25