Cleveland Clinic

Cleveland Clinic Laboratories

Technical Update • May 2023

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. 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 Client Services at 216.444.5755 or 800.628.6816, or via email at clientservices@ccf.org.

Test Update Page #	Summary of Changes by Test Name	Order Code	Name Change	New Test	Test Discontinued	Special Information	Specimen Requirement	Component Change(s)	Methodology	Reference Range	Days Performed/Reported	Stability	CPT	Fee
25	1,5 Anhydroglucitol			■										
4–5	16s rDNA Bacterial Identification, Sanger Sequencing, Fresh Tissue	■	■			■					■	■		
5	AFB Culture & Stain												■	
5–6	Allergen, Expanded Respiratory Disease Profile Region 5					■		■					■	
6	Amino Acids, Plasma w/ Consultation							■						
6	Amino Acids, Urine w/ Consultation							■						
6	ANA by IFA Screen					■		■		■				
6	ANA by IFA with Reflex					■		■						
6	Anaplasma phagocytophilum (HGA) Antibodies, IgG and IgM						■							
6	Babesia Microti IgG & IgM Abs						■							
7–8	Bacterial Vaginosis (BV), NAAT		■			■	■	■		■	■			
8	Bartonella Antibody Panel (IFA)						■							
8	Bartonella henselae Abs						■							
8	Bartonella quintana Antibodies, IgG & IgM						■							
8	Blood Parasites											■		
8	Borrelia burgdorferi Antibodies, IgG and IgM by Immunoblot (CSF)										■			
8	Borrelia burgdorferi Antibodies, Total by ELISA, CSF										■			

Test Update Page #	Summary of Changes by Test Name	Order Code	Name Change	New Test	Test Discontinued	Special Information	Specimen Requirement	Component Change(s)	Methodology	Reference Range	Days Performed/Reported	Stability	CPT	Fee
8	Bronchoscopy Culture and Gram Stain												■	
9–10	Candida & Trichomonas vaginalis, NAAT		■				■	■		■				
10	Celiac Comprehensive Panel					■		■		■		■		
10	Celiac Gluten Free Panel					■		■		■		■		
10–11	Celiac Screen with Reflex					■		■		■		■		
11	Chlamydia Antibodies Evaluation						■							
11	Chlamydia Antibody Panel, IgG						■							
11	Chlamydia Antibody Panel, IgM						■							
26	Circulating Tumor Cell Count				■									
11	Citrate, Urine 24 Hour						■		■	■		■		
25	Clozapine			■										
26	Clozapine and Metabolites, Serum or Plasma, Quantitative				■									
12	Coxiella Burnetii IgG Abs						■							
12	Coxiella burnetii (Q-Fever) Antibodies, IgG and IgM, Phase I and II with Reflex to Titer						■							
26	Cross-Linked N-telopeptide, Serum				■									
12	Cryoglobulin, Qual, Reflex to IFE Typing & Quant IgA, IgG, & IgM						■							
12	Cryptococcus Ag Detection												■	
12	Cytomegalovirus Antiviral Drug Resistance by Sequencing					■	■		■		■	■	■	
12	DNA Content/Cell Cycle Analysis, Hydatidiform Mole					■					■			
12	Ehrlichia chaffeensis IgG & IgM Abs by IFA						■							
26	Epi ProColon				■									
13	Fungal Antibodies						■							
13	Fungal Antibodies with Reflex to Blastomyces dermatitidis Antibodies by Immunodiffusion, CSF						■							
13, 26	Fungus CSF Culture/CAD												■	■
13	Fungus Screen												■	
26	GC/Chlamydia Amplification, Urine				■									
26	GlycoMark				■									
13	Helicobacter pylori Breath Test		■			■				■		■		
26	Helicobacter pylori Breath Test, Pediatric				■									
26	HIV-2 Antibody Confirmation, Serum				■									
14	Inhibin B					■				■				
26	LH, Pediatric													■
14	LPT to Beryllium, BAL					■								
14	LPT to Beryllium, Blood					■	■							
14	Lupus Anticoagulant Diagnostic Interpretive Panel					■	■					■		

Test Update Page #	Summary of Changes by Test Name	Order Code	Name Change	New Test	Test Discontinued	Special Information	Specimen Requirement	Component Change(s)	Methodology	Reference Range	Days Performed/Reported	Stability	CPT	Fee
14	Lyme Reflex Panel, CSF										■			
26	Measles Virus Culture (Rubeola)				■									
14	Monoclonal Protein, Urine					■								
26	Mumps Virus Culture				■									
15–16	Mycoplasma genitalium, NAAT	■	■				■	■		■				
17–19	Neisseria gonorrhoeae (GC) & Chlamydia trachomatis (CT), NAAT		■			■	■	■						
26	Nocardia Culture and Stain				■									
26	Nocardia Culture Only				■									
26	Nocardia Stain Only				■									
19	Organism Identification, Yeast												■	
19	Phosphatidylethanol (PEth)					■		■				■		
26	Platelet Aggregation												■	■
19	Prader-Willi/Angelman Methylation					■	■		■		■	■		
26	Prothrombin Time and PTT Elevation Diagnostic Panel				■									
26	Prothrombin Time Elevation Diagnostic Panel				■									
20	Prothrombin Time Mixing Study					■	■					■		
26	PTT Elevation Diagnostic Panel				■									
20	PTT Incubated Mixing Study					■	■					■		
20	Respiratory Culture and Stain												■	
20	Rickettsia rickettsii IgG & IgM Abs						■							
21	Rickettsia Typhi IgG & IgM Abs						■							
21	THC Metabolite, Serum/Plasma, Qt					■	■					■		
21	Transglutaminase IgA Abs							■		■		■		
21	Transglutaminase IgG Abs							■		■		■		
21	Transglutaminase IgG and IgA						■	■		■		■		
22–23	Trichomonas vaginalis, NAAT		■			■	■	■						
24	Universal PCR, Acid Fast Bacilli					■	■					■		
24	Universal PCR, Fungal					■	■					■		
24	von Willebrand Diagnostic Interpretive Panel (Limited)					■	■					■		

Test Changes

Test Name	Order Code	Change	Effective Date
16s rDNA Bacterial Identification, Sanger Sequencing, Fresh Tissue	BCTSEQ	**Name:** Previously Bacterial PCR, Direct Specimen (BCTPCR) **Special Information: All specimens will be reviewed by the molecular microbiology lab for appropriateness of sequencing orders. The medical director may approve or reject specimens on a case-by-case basis. In general, the following criteria must be met for sequencing to be approved:** **1. Specimen must be a fresh tissue specimen from a sterile source/site.** **2. There is clinical or laboratory evidence for infection, or patient is immunocompromised.** **3. Cultures or other routine diagnostic methods did not reveal an etiologic pathogen*.** **Common reasons for rejection:** **1. Unacceptable sample type (ie. swab).** **2. Non-sterile specimen type/source (ie. colonic mucosal tissue, non-marginal amputation specimen) or specimen received in non-sterile container.** **3. Patient does not have clinical or laboratory evidence for infection and is not immunocompromised .** **4. Etiologic agent already identified in culture or infection is polymicrobial*.** **5. More than 3 specimens sent from a single procedure. In this case the highest yield specimens will be selected by the laboratory in consultation with the ordering provider if necessary.** **All tissues on which bacterial sequencing is ordered should at minimum also have tissue culture ordered. If tissue culture has not been concurrently ordered, the ordering provider will be contacted to place the correct order.** ***An exception to this criteria is infective endocarditis, where bacterial sequencing has been demonstrated to have improved sensitivity and specificity compared to culture.** **This test is not validated for fluids, tissues where polymicrobial infection is suspected and needs resolution, and formalin-fixed paraffin embedded tissue blocks. These samples will be sent to a reference laboratory for testing. If bacterial sequencing (BCTSEQ) is ordered alongside fungal and/or acid fast bacilli sequencing (FUNPCR, AFBPCR) on the same specimen, the sample will be sent to the University of Washington for testing even if it is a tissue specimen.** **Clinical Limitation: The sensitivity of detecting bacterial DNA from direct specimen is dependent on the organism load in the sample received or any process that may introduce exogenous microorganisms or bacterial DNA into the sample submitted. Some bacterial species with high divergence in areas targeted by primers may not be amplified. This test uses Sanger sequencing, which may not be able to identify organisms in a polymicrobial population.** **Clinical Information: This lab-developed test uses amplification and Sanger sequencing of the 16s ribosomal rRNA gene (16s rDNA) to detect and identify bacteria from sterile fresh tissue specimens. It targets the initial 500 bases of bacterial 16s rDNA (variable regions V1-V3). Genomic sequence variation existing in this region is generally sufficient to differentiate bacteria at the genus and sometimes species or species complex level. It is relatively expensive and labor-intensive, and recommended to be used only in cases where bacterial infection is high on the differential, but organisms cannot be recovered in routine cultures due to pre-administration of antimicrobials or fastidious growth requirements.** **This test can also be used internally by the microbiology lab to make or confirm bacterial identifications of cultured isolates and positive blood culture bottles, when routine phenotypic identification methods have been unsuccessful.** **Clinical Reference: Church DL, Cerutti L, Gürtler A, Griener T, Zelazny A, Emler S. Performance and Application of 16S rRNA Gene Cycle Sequencing for Routine Identification of Bacteria in the Clinical Microbiology Laboratory. Clin Microbiol Rev. 2020 Sep 9;33(4):e00053-19. doi: 10.1128/CMR.00053-19. PMID: 32907806; PMCID: PMC7484979.** **Specimen Requirement:** One frozen tissue in sterile container; Frozen; **Using sterile technique, transfer fresh tissue to a sterile container, and hand-deliver to the laboratory. Swabs are not acceptable specimen types. Transport frozen at -20C or colder.** *(continued on page 5)*	6/22/23

Test Changes (Cont.)

Test Name	Order Code	Change	Effective Date
16s rDNA Bacterial Identification, Sanger Sequencing, Fresh Tissue *(continued from page 4)*	BCTSEQ	**Stability:** Ambient: Unacceptable Refrigerated: Stable up to **7 days** at 2-8C Frozen: Stable up to 2 weeks at -20C **or colder** **Methodology:** Polymerase Chain Reaction (PCR) **Sanger** Sequencing **Days Performed: Twice** a week	6/22/23
AFB Culture & Stain	AFC	**Special Information:** Specimen collection methods should minimize contamination with respiratory, skin or urogenital flora. To prevent overgrowth of flora organisms, if specimen transport is delayed by more than 2 hours, specimens should be refrigerated. Frozen specimens are unacceptable. When sputum, stool or urine is collected in the outpatient setting, patients should be sent home with pre-labeled containers and instructed to record the collection time and date on the container and refrigerate until submission. Avoid use of tap water during specimen collection or transport as environmental mycobacteria present in water will cause false positive results. Tissue or fluid material is preferred to specimen collected with a swab. The hydrophobic mycobacterial cell wall may became trapped in swab fibers, preventing release into culture medium. Swabs provide a suboptimal volume of material and are only accepted with medical director approval. **If infection with Nocardia spp. is suspected, order culture for mycobacteria (AFC).** **Clinical Information:** Culture is performed to identify an infection due to a mycobacterium. A single negative culture does not rule out the presence of a mycobacterial infection. Mycobacterial culture includes an acid fast stain and culture in liquid and on solid media. Stain results are reported within 24 hours of specimen receipt. Providers are notified of initial positive smear or culture results and any identification of M. tuberculosis. For AFB stain-positive sputum samples, PCR for detection of M. tuberculosis and rifampin resistance (rpoB) will be performed automatically. Rifampin resistant and indeterminate results require confirmatory sequencing; additional charges may apply. PCR for M. tuberculosis vs. non-tuberculous mycobacteria may be performed if AFB stain is positive when indicated from BAL, fresh tissue and other sample types. Cultures for mycobacteria are incubated for 6 weeks and updated, if negative, on a weekly basis. Extended incubation or other special requests must be approved in consultation with a medical director. Specimens from all skin sites and wounds, fluid, and tissues of the extremities are cultured at both 35°C and 30°C to optimize recovery of M. marinum, M. chelonae, M. haemophilum and M. ulcerans. If these species are otherwise suspected, please notify the laboratory. Mycobacteria grown in culture are identified to species. Susceptibility testing is performed automatically for M. tuberculosis and by request for other species. Multiple identification procedures may be required, with the following CPT codes billed as applicable: Cepheid PCR 87556 87798, **Additional stain testing 87206,** MALDI-TOF 87118, DNA Probe 87149, Sequencing 87153, and Susceptibility Testing 87186. **CPT:** 87116; 87206; 87015	6/20/23
Allergen, Expanded Respiratory Disease Profile Region 5	RESPR5	**Includes:** Alternaria tenuis Aspergillus fumigatus Bermuda grass Birch Tree Cat dander Cladosporium herbarum (Hormodendrum) Cocklebur Cockroach Cottonwood Tree Dermatophagoides farinae Dermatophagoides pteronyssinus Dog dander Elm tree English Plantain (Ribwort) Hickory/Pecan tree *(continued on page 6)*	6/22/23

Test Changes (Cont.)

Test Name	Order Code	Change	Effective Date
Allergen, Expanded Respiratory Disease Profile Region 5 *(continued from page 5)*		Johnson grass Lamb's quarters (Goosefoot) Maple (Box Elder) Tree Mouse Urine Mulberry Oak tree Pigweed Rough Marshelder Sheep sorrel Short (common) ragweed Sycamore Tree Timothy Grass White Ash Tree **Clinical Information: As an aid in diagnosing sensitivity to common aeroallergens in Northern Ohio. Clinical correlation is required.** These allergens in this profile were selected based on regional pollen data and disease prevalence, as well as for their cross-reactivity with other comparable allergens. This profile is for the following areas: Indiana, Kentucky, Ohio, Tennesee, and West Virginia. Specific evaluation of allergic reactions. IgE (kU/L) Interpretation: <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; 50–99.99, Class 5–Very High; >=100, Class 6–Very High **CPT:** 86003x**28**	
Amino Acids, Plasma w/ Consultation	PAABI	**Reference Range:** *Amino acid components that currently report units in um/g Cr will be modified to report umol/g Cr*	6/22/23
Amino Acids, Urine w/ Consultation	UAABI	**Reference Range:** *Amino acid components that currently report units in um/g Cr will be modified to report umol/g Cr*	6/22/23
ANA by IFA Screen	ANAIFS	**For interface clients only–Test build may need to be modified** **Clinical Information:** Screening test of choice for **systemic** autoimmune disease. **Reference Range:** ANA (ANASC): Negative ANA Titer (ANAT): Negative <1:80 ANA Pattern (ANAP): No Pattern **ANA Titer 2 (ANAT2): Negative <1:80** **ANA Pattern 2 (ANAP2): No Pattern** **ANA Titer 3 (ANAT3): Negative <1:80** **ANA Pattern 3 (ANAP3): No Pattern**	6/22/23
ANA by IFA with Reflex	ANAIFR	**For interface clients only–Test build may need to be modified** **Clinical Information:** Screening test of choice for **systemic** autoimmune disease. **Reference Range:** ANA (ANASC): Negative ANA Titer (ANAT): Negative <1:80 ANA Pattern (ANAP): No Pattern **ANA Titer 2 (ANAT2): Negative <1:80** **ANA Pattern 2 (ANAP2): No Pattern** **ANA Titer 3 (ANAT3): Negative <1:80** **ANA Pattern 3 (ANAP3): No Pattern**	6/22/23
Anaplasma phagocytophilum (HGA) Antibodies, IgG and IgM	ANIGM	**Specimen Requirement: 1 mL** serum from serum separator (Gold) tube; **Minimum 0.4 mL;** Refrigerated; **Separate serum from cells ASAP or within 2 hours of collection and** transfer into standard aliquot tube. **For parallel testing, convalescent specimens must be received within 30 days from receipt of the acute specimens. Label specimens plainly as 'acute' and 'convalescent.'**	5/15/23
Babesia Microti IgG & IgM Abs	BMICGM	**Specimen Requirement:** 1 mL serum from serum separator (Gold) tube; **Minimum 0.4 mL**; Refrigerated; Remove serum from cells ASAP or within 2 hours of collection. Parallel testing is preferred and convalescent specimens MUST be received within 30 days from receipt of the acute specimens. Please mark specimens plainly as ACUTE or CONVALESCENT.	5/15/23

Test Changes (Cont.)

Test Name	Order Code	Change	Effective Date
Bacterial Vaginosis (BV), NAAT	BVAMP	**Name:** Previously Bacterial Vaginosis Amplification **Special Information: Microbiology Preanalytic Guidance: http://portals.ccf.org/plmi/Laboratory-Medicine/Microbiology-Specimen-Collection-Transport-Information.** **The specimen must be a vaginal swab** collected and transported using the Aptima Multitest Swab Specimen Collection Kit. **Up to two tests can be run on a single Aptima Multitest Swab specimen (ie. TRVAMP+BVAMP or CVTV+BVAMP)–if specimen sources have been correctly selected, the shared tests will print on the same label. Do not place more than one label on a single collection tube.** **Specimens collected from a non-vaginal source, with an inappropriate or expired collection device, or containing >1 swab may be rejected.** **Related alternative orders:** **1. BVSTN: in-house vaginal smear gram stain for bacterial vaginosis diagnosis by Nugent score (recommended over NAAT when ordered alone due to lower patient cost).** **2. BVCNSM: in-house vaginal smear gram stain for bacterial vaginosis diagnosis by Nugent score and microscopic exam for yeast (use when both BV and uncomplicated vulvovaginal candidiasis are on the differential).** **Clinical Limitation:** **1. The performance of the assay has not been evaluated in patients <14 years of age.** **2. Therapeutic failure or success cannot be determined with the assay since nucleic acid may persist following appropriate antimicrobial therapy.** **3. A negative result does not preclude a possible infection because results are dependent on adequate specimen collection. Test results may be affected by improper specimen collection, technical error, specimen mix-up, or other factors.** **4. The effects of tampon use and other specimen collection variables have not been assessed for their impact on assay detection.** **5. Interference with the Aptima BV assay was observed in the presence of the following substances: Mucus (1.5% V/V), Vaginal Moisturizing Gel (0.5% W/V) and Tioconazole (5% W/V).** **6. Additional microorganisms not detected by the Aptima BV assay such as Prevotella species and Mobiluncus species, Ureaplasma, Mycoplasma, and numerous fastidious or uncultivated anaerobes have also been found in women with BV, but are less associated with BV due to their relatively low prevalence, sensitivity, and/or specificity.** **7. Cross-reactivity was observed with the Aptima BV assay in the presence of Lactobacillus acidophilus.** **Clinical Information: Vaginitis syndrome is characterized by a spectrum of conditions including vaginal and vulvar irritation, odor, discharge and pruritus. Causes of vaginitis include mechanical and chemical factors (feminine hygiene products, contraceptive materials, etc.) as well as infectious agents. Up to 90% of infectious vaginitis cases are caused by bacterial vaginosis (BV), vulvovaginal candidiasis (candida vaginitis, CV) and trichomoniasis (Trichomonas vaginalis, TV). BV has been diagnosed in 22-50% of symptomatic patients, CV in 17-39%, and TV in 4-35%.** **Vaginitis syndrome is characterized by a spectrum of conditions including vaginal and vulvar irritation, odor, discharge and pruritus. Causes of vaginitis include mechanical and chemical factors (feminine hygiene products, contraceptive materials, etc.) as well as infectious agents. Up to 90% of infectious vaginitis cases are caused by bacterial vaginosis (BV), vulvovaginal candidiasis (candida vaginitis, CV) and trichomoniasis (Trichomonas vaginalis, TV). BV has been diagnosed in 22-50% of symptomatic patients, CV in 17-39%, and TV in 4-35%.** **BV is characterized by a change in the vaginal microbiota dominated by Lactobacillus species to a polymicrobial anaerobe-dominated microbiota that includes Gardnerella vaginalis, Atopobium vaginae, Prevotella, Bacteroides, Peptostreptococcus, Mobiluncus, Sneathia (Leptotrichia), Mycoplasma, and BV associated bacteria. BV can be diagnosed using clinical criteria (i.e., Amsel's diagnostic criteria), by determining the Nugent score from a vaginal Gram stain (order code BVSTN), or by nucleic acid amplification tests (NAAT). The latter can be associated with higher patient costs, but can be more convenient if microscopy is locally unavailable, or the same swab is already being collected for gonorrhea, chlamydia, and/or trichomonas testing.** *(continued on page 8)*	6/20/23

Test Changes (Cont.)

Test Name	Order Code	Change	Effective Date
Bacterial Vaginosis (BV), NAAT *(continued from page 7)*	BVAMP	The Aptima BV assay is an **FDA-cleared** in vitro NAAT that utilizes real time transcription-mediated amplification (TMA) for detection and quantitation of ribosomal RNA from bacteria associated with bacterial vaginosis (BV), including Lactobacillus (L. gasseri, L. crispatus, and L. jensenii), Gardnerella vaginalis, and Atopobium vaginae. **The assay uses an algorithm to report a qualitative result for BV based on detection of target organisms, and does not report results for individual organisms.** The assay is intended to aid in the diagnosis of BV on the automated Panther system using clinician-collected and patient-collected vaginal swab specimens from **patients** with a clinical presentation consistent with vaginitis and/or vaginosis. **Clinical Reference: Workowski KA, Bachmann LH, Chan PA, Johnston CM, Muzny CA, Park I, Reno H, Zenilman JM, Bolan GA. Sexually Transmitted Infections Treatment Guidelines, 2021. MMWR Recomm Rep. 2021 Jul 23;70(4):1-187. doi: 10.15585/mmwr.rr7004a1. PMID: 34292926; PMCID: PMC8344968.** **Specimen Requirement: One vaginal Aptima Multitest Collection Kit**; Ambient; **Vaginal Multitest (orange tube pink swab): A vaginal swab is the only acceptable specimen. Carefully insert the swab into the vagina about 2 inches past the introitus and gently rotate the swab for 10-30 seconds. Make sure the swab touches the vaginal walls so that moisture is absorbed by the swab. Vaginal swab specimens may be patient-collected in a clinical setting when a pelvic exam is not otherwise indicated (https://www.hologic.com/package-inserts/swab-collection-instructions-vaginal-main-english#4257225834-454981651). Place swab into Aptima transport tube. Snap off swab at the score line, and close the tube tightly.** **Reference Range: Not detected** **Days Performed:** Mon–**Sun** **Reported: 1–4** days	6/20/23
Bartonella Antibody Panel (IFA)	BARTAB	**Specimen Requirement:** 1 mL serum from serum separator (Gold) tube; **Minimum 0.4 mL**; Refrigerated; Parallel testing is preferred, and convalescent specimens must be received within 30 days from receipt of acute specimens. Label specimens plainly as 'acute' or 'convalescent.' Separate serum from cells ASAP or within 2 hours of collection and transfer into a standard aliquot tube.	5/15/23
Bartonella henselae Abs	CATSC	**Specimen Requirement:** 1 mL serum from serum separator (Gold) tube; **Minimum 0.4 mL;** Refrigerated; Parallel testing is preferred, and convalescent specimens must be received within 30 days from receipt of the acute specimens. Label specimens plainly as 'acute' or 'convalescent.' Separate serum from cells ASAP or within 2 hours of collection and transfer into a standard aliquot tube.	5/15/23
Bartonella quintana Antibodies, IgG & IgM	BARQAB	**Specimen Requirement:** 1 mL serum from serum separator (Gold) tube; **Minimum 0.4 mL**; Refrigerated; Separate serum from cells ASAP or within 2 hours of collection and transfer into a standard aliquot tube. Parallel testing is preferred, and convalescent specimens must be received within 30 days from receipt of the acute specimens. Label specimens plainly as 'acute' or 'convalescent.'	5/15/23
Blood Parasites	BLDPAR	**Stability:** Ambient: 24 hours Refrigerated: **24 hours** Frozen: Unacceptable	effective immediately
Borrelia burgdorferi Antibodies, IgG and IgM by Immunoblot (CSF)	LYIBCS	**Reported:** 2–**5** days	5/15/23
Borrelia burgdorferi Antibodies, Total by ELISA, CSF	BBURGM	**Reported:** 2–**5** days	5/15/23
Bronchoscopy Culture and Gram Stain	BALCSM	**Special Information:** 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. Blood cultures are recommended for patients being evaluated for pneumonia. If culture is positive, identification will be performed on clinically significant organisms at an additional charge. Identification CPT codes that may apply include: **87206**, 87077, 87106, 87107, 87153, 87158. Antimicrobial susceptibilities are performed when indicated, and the following CPT codes may apply: 87181, 87184, 87185, 87186. **CPT:** 87071; 87205; **87206**	6/20/23

Test Changes (Cont.)

Test Name	Order Code	Change	Effective Date
Candida & Trichomonas vaginalis, NAAT	CVTV	**For interface clients only–Test build may need to be modified** **Name:** Previously Candida / Trichomonas Amplification **Special Information: Microbiology Preanalytic Guidance: http://portals.ccf.org/plmi/Laboratory-Medicine/Microbiology-Specimen-Collection-Transport-Information. The specimen must be a vaginal swab** collected and transported using the Aptima Multitest Swab Specimen Collection Kit. **Up to two tests can be run on a single Aptima Multitest Swab specimen (ie. GCCT+CVTV or CVTV+BVAMP)–if specimen sources have been correctly selected, the shared tests will print on the same label. Do not place more than one label on a single collection tube. Specimens collected from a non-vaginal source, with an inappropriate or expired collection device, or containing >1 swab may be rejected. Related alternative orders: 1. TRVAMP: in-house Trichomonas vaginalis standalone NAAT (use when complicated vulvovaginal candidiasis is not on the differential). 2. CANSTN: in-house vaginal smear for yeast (use when diagnosing uncomplicated vulvovaginal candidiasis). 3. BVCNSM: in-house vaginal smear gram stain for bacterial vaginosis diagnosis by Nugent score and microscopic exam for yeast (use when both BV and uncomplicated vulvovaginal candidiasis are on the differential). 4. FUNGSC: in-house fungal culture for yeast (use for diagnosis of candida vaginitis in cases where wet mount is negative but disease is still suspected, and/or complicated vulvovaginal candidiasis is suspected).** **Clinical Limitation: 1. The performance of the assay has not been evaluated in patients <14 years of age. 2. Therapeutic failure or success cannot be determined with the assay since nucleic acid may persist following appropriate antimicrobial therapy. 3. A negative result does not preclude a possible infection because results are dependent on adequate specimen collection. Test results may be affected by improper specimen collection, technical error, specimen mix-up, or target levels below the assay limit of detection. 4. The effects of tampon use, douching, and specimen collection variables have not been assessed for their impact on assay detection. 5. Interference with the Aptima CV/TV assay was observed in the presence of the following substances: Tioconazole 6.5% Ointment (3% W/V, all analytes), Vaginal Moisturizing Gel (1% W/V, C spp; 5% W/V, C. glabrata; 3% W/V, TV), and Glacial Acetic Acid (5% V/V, C spp only). 6. Competitive interference may preclude detection of C. glabrata in low quantities if T. vaginalis is present in high quantities.** **Clinical Information: Vaginitis syndrome is characterized by a spectrum of conditions including vaginal and vulvar irritation, odor, discharge and pruritus. Causes of vaginitis include mechanical and chemical factors (feminine hygiene products, contraceptive materials, etc.) as well as infectious agents. Up to 90% of infectious vaginitis cases are caused by bacterial vaginosis (BV), vulvovaginal candidiasis (candida vaginitis, CV) and trichomoniasis (Trichomonas vaginalis, TV). BV has been diagnosed in 22-50% of symptomatic patients, CV in 17-39%, and TV in 4-35%. The Aptima CV/TV assay is an FDA-cleared in vitro nucleic acid amplification test (NAAT) for the detection of RNA from microorganisms associated with vulvovaginal candidiasis and trichomoniasis.** The assay utilizes real time transcription-mediated amplification (TMA) to detect and qualitatively report results for the following organisms: • Candida species group (C. albicans, C. tropicalis, C. parapsilosis, C. dubliniensis) • Candida glabrata • Trichomonas vaginalis. The assay differentiates between Candida glabrata and the Candida species group (C spp) by targeting the RNA component of RNAse P ribonucleoprotein; the assay does not differentiate among C spp. For Trichomonas vaginalis, the assay targets ribosomal RNA (rRNA) and differentiates the result from results for Candida glabrata and C spp. The assay is intended to aid in the diagnosis of vulvovaginal candidiasis and trichomoniasis on the automated Panther system using clinician-collected and patient-collected vaginal swab specimens from patients with a clinical presentation consistent with vaginitis or vulvovaginitis. **CV and TV may be detected by microscopy, culture, and nucleic acid using specimens collected with vaginal swabs. Use of this NAAT should be reserved diagnosis of complicated vulvovaginal candidiasis where identification of Candida glabrata (not easily recognized on microscopy due to lack of pseudohyphae/hyphae, increased azole resistance) may be important. Trichomonas only testing by NAAT is available as a stand-alone test (order code TRVAMP) when complicated vulvovaginal candidiasis is not on the differential.** **Clinical Reference: Workowski KA, Bachmann LH, Chan PA, Johnston CM, Muzny CA, Park I, Reno H, Zenilman JM, Bolan GA. Sexually Transmitted Infections Treatment Guidelines, 2021. MMWR Recomm Rep. 2021 Jul 23;70(4):1-187. doi: 10.15585/mmwr.rr7004a1. PMID: 34292926; PMCID: PMC8344968.** *(continued on page 10)*	6/20/23

Test Changes (Cont.)

Test Name	Order Code	Change	Effective Date
Candida & Trichomonas vaginalis, NAAT *(continued from page 9)*	CVTV	**Specimen Requirement: vaginal** swab in Aptima Multitest Collection Kit; Ambient; **Vaginal Multitest (orange tube pink swab): A vaginal swab is the only acceptable specimen. Carefully insert the swab into the vagina about 2 inches past the introitus and gently rotate the swab for 10-30 seconds. Make sure the swab touches the vaginal walls so that moisture is absorbed by the swab. Vaginal swab specimens may be patient-collected in a clinical setting when a pelvic exam is not otherwise indicated (https://www.hologic.com/package-inserts/swab-collection-instructions-vaginal-main-english#4257225834-454981651). Place swab into Aptima transport tube. Snap off swab at the score line, and close the tube tightly.** **Reference Range: Not detected** **Days Performed:** Mon–**Sun** **Reported: 1–4** days	6/20/23
Celiac Comprehensive Panel	CELCMP	**For interface clients only–Test build may need to be modified** **Special Information:** ***special information has been removed*** **Stability:** Ambient: 1 day; Whole Blood: 1 week Refrigerated: 7 days; Whole Blood: 1 week Frozen: **14 days, up to 2 freeze/thaw cycles** **Reference Range:** HLA-DQ2 (CELIA01): Refer to report HLA-DQ8 (CELIA02): Refer to report IgA (IGA): 0–11 Months: less than 83 mg/dL 1–3 Years: 20–100 mg/dL 4–6 Years: 27–195 mg/dL 7–9 Years: 34–305 mg/dL 10–11 Years: 53–204 mg/dL 12–13 Years: 58–358 mg/dL 14–15 Years: 47–249 mg/dL 16–19 Years: 61–348 mg/dL 20–99 Years: 70–400 mg/dL **Transglutaminase IgA Abs (TTGIGA): <4.0 U/mL** **Transglutaminase IgA Ab Interpretation (TGIGAQ): Negative** Gliadin IgA Ab (GLIADA): <20 Units Gliad Deamidated IgA Qual: Negative **Transglutaminase IgG Abs (TTGIGG): <6 U/mL** **Transglutaminase IgG Abs Interpretation (TGIGGQ): Negative**	6/22/23
Celiac Gluten Free Panel	CELGLU	**For interface clients only–Test build may need to be modified** **Special Information:** Multiple freeze thaw cycles from serum are not recommended. **Stability:** Ambient: 24 hours; Whole Blood: 1 week Refrigerated: 7 days; Whole Blood: 1 week Frozen: **14 days, up to 2 freeze/thaw cycles** **Reference Range:** HLA-DQ2 (CELIA01): Refer to report HLA-DQ8 (CELIA02): Refer to report	6/22/23
Celiac Screen with Reflex	CELSCR	**For interface clients only–Test build may need to be modified** **Special Information:** ***special information has been removed*** **Stability:** Ambient: 1 day Refrigerated: 7 days Frozen: **14 days, up to 2 freeze/thaw cycles** *(continued on page 11)*	6/22/23

Test Changes (Cont.)

Test Name	Order Code	Change	Effective Date
Celiac Screen with Reflex *(continued from page 10)*		**Reference Range:** IgA (IGA): 0–11 Months: less than 83 mg/dL 1–3 Years: 20–100 mg/dL 4–6 Years: 27–195 mg/dL 7–9 Years: 34–305 mg/dL 10–11 Years: 53–204 mg/dL 12–13 Years: 58–358 mg/dL 14–15 Years: 47–249 mg/dL 16–19 Years: 61–348 mg/dL 20–99 Years: 70–400 mg/dL **Transglutaminase IgA Abs (TTGIGA): <4.0 U/mL** **Transglutaminase IgA Ab Interpretation (TGIGAQ): Negative** Gliadin IgA Ab (GLIADA): <20 Units Gliad Deamidated IgA Qual: Negative **Transglutaminase IgG Abs (TTGIGG): <6 U/mL** **Transglutaminase IgG Abs Interpretation (TGIGGQ): Negative**	
Chlamydia Antibodies Evaluation	CIGIM	**Specimen Requirement:** 1 mL serum from serum separator (Gold) tube; **Minimum 0.4 mL**; Refrigerated**;** Parallel testing is preferred and convalescent specimens must be received within 30 days from receipt of acute specimens. Label specimens plainly as 'acute' or 'convalescent.' Separate serum from cells ASAP or within 2 hours of collection and transfer into standard aliquot tube. *OR* 1 mL serum from no additive (Red) tube; **Minimum 0.4 mL**; Refrigerated; Parallel testing is preferred and convalescent specimens must be received within 30 days from receipt of acute specimens. Label specimens plainly as 'acute' or 'convalescent.' Separate serum from cells ASAP or within 2 hours of collection and transfer into standard aliquot tube.	5/15/23
Chlamydia Antibody Panel, IgG	CHLAMG	**Specimen Requirement:** 1 mL serum from serum separator (Gold) tube; **Minimum 0.4 mL**; Refrigerated**;** Separate serum from cells within 2 hours of collection and transfer into a standard aliquot tube. Parallel testing is preferred and convalescent specimens must be received within 30 days from receipt of the acute specimens. Label specimens plainly as acute or convalescent. *OR* 1 mL serum from no additive (Red) tube; **Minimum 0.4 mL**; Refrigerated; Separate serum from cells within 2 hours of collection and transfer into a standard aliquot tube. Parallel testing is preferred and convalescent specimens must be received within 30 days from receipt of the acute specimens. Label specimens plainly as acute or convalescent.	5/15/23
Chlamydia Antibody Panel, IgM	CHLAMM	**Specimen Requirement:** 1 mL serum from serum separator (Gold) tube; **Minimum 0.4 mL**; Refrigerated**;** Separate serum from cells within 2 hours of collection. Parallel testing is preferred and convalescent specimens must be received within 30 days from receipt of the acute specimens. Please mark specimens plainly as 'acute' or 'convalescent. *OR* 1 mL serum from no additive (Red) tube; **Minimum 0.4 mL**; Refrigerated; Separate serum from cells within 2 hours of collection. Parallel testing is preferred and convalescent specimens must be received within 30 days from receipt of the acute specimens. Please mark specimens plainly as 'acute' or 'convalescent.	5/15/23
Citrate, Urine 24 Hour	UCITD	**Special Information:** Indicate total volume on requisition. **When possible, acidify urine with hydrochloric acid to obtain a pH <4 prior to transporting sample to testing laboratory.** **Specimen Requirement:** 5 mL 24-hour (well-mixed) urine from clean container; Minimum 1 mL; Refrigerate during collection; **Transfer aliquot to clean transport tube. Acidify to pH < 4 with hydrochloric acid, when possible. Indicate total urine volume on requisition.** **Stability:** Ambient: **None if not acidified.** 48 hours **if acidified (pH < 4)** Refrigerated: **7 days if not acidified. 14 days if acidified (pH < 4)** Frozen: **30 days if not acidified. 30 days if acidified (pH < 4)** **Methodology: Enzymatic** **Reference Range:** **Male 18 Years and up: 120–930 mg/24 hrs** **Female 18 Years and up: 250–1160 mg/24 hrs**	5/16/23

Test Changes (Cont.)

Test Name	Order Code	Change	Effective Date
Coxiella Burnetii IgG Abs	COXIGG	**Specimen Requirement:** 1 mL serum from serum separator (Gold) tube; **Minimum 0.4 mL**; Refrigerated**;** Separate serum from cells ASAP or within 2 hours of collection and transfer to standard aliquot tube. Parallel testing is preferred and convalescent specimens must be received within 30 days from receipt of the acute specimens. Label specimens plainly as 'acute' and 'convalescent.'	5/15/23
Coxiella burnetii (Q-Fever) Antibodies, IgG and IgM, Phase I and II with Reflex to Titer	COXGMR	**Specimen Requirement:** 1 mL serum from serum separator (Gold) tube; **Minimum 0.4 mL**; Refrigerated**;** Separate serum from cells ASAP or within 2 hours of collection and transfer to standard aliquot tube. Parallel testing is preferred and convalescent specimens must be received within 30 days from receipt of the acute specimens. Label specimens plainly as 'acute' and 'convalescent.'	5/15/23
Cryoglobulin, Qual, Reflex to IFE Typing & Quant IgA, IgG, & IgM	CRYAGM	**Special Information:** Collect in **2** pre-warmed 6 mL red top **tubes** and fill completely. Do not use serum separator tubes. Immediately after collection, place tubes in heel warmer or 37°C (warm, not hot) water. Keep samples warm, and allow to clot at 37°C for 90 minutes. Centrifuge at 37°C, if possible (do not use refrigerated centrifuge), and separate serum from cells. Refrigerate and transport serum after removal from cells. Proper collection and transport of specimen is critical to the outcome of the test. Quantities less than 3 mL may affect the sensitivity of the test. If Cryoglobulin Qualitative is positive, then Immunofixation Electrophoresis Typing and Quantitative IgA, IgG and IgM will be added. Additional charges apply. **Specimen Requirement:** 3 mL serum from no additive (Red) tube; Refrigerated; Collect in **2** pre-warmed 6 mL red top **tubes** and fill completely. Do not use serum separator tubes. Immediately after collection, place tubes in heel warmer or 37°C (warm, not hot) water. Keep samples warm, and allow to clot at 37°C for 90 minutes. Centrifuge at 37°C, if possible (do not use refrigerated centrifuge), and separate serum from cells. Refrigerate and transport serum after removal from cells.	6/20/23
Cryptococcus Ag Detection	CAD	**Special Information:** Testing can be performed only on CSF or serum. Test cannot be performed if specimen is hemolyzed or grossly contaminated. If Cryptococcal Antigen Detection is positive, a titer will be performed at an additional charge with CPT code **87899** applied. **If Cryptococcal Antigen Detection is positive, culture will be reflexed.** **CPT: 87899**	effective immediately
Cytomegalovirus Antiviral Drug Resistance by Sequencing	CYTSEQ	**Special Information:** Please submit most recent viral load and test date, if available. Heparinized specimens and serum are unacceptable. **Clinical Limitation:** This test may be unsuccessful if the plasma CMV DNA viral load is **less than 2.6 log IU/mL.** **Clinical Information: Provides antiviral susceptibility information for ganciclovir, foscarnet, cidofovir, maribavir, and letermovir. Intended for patients with viral load >2.6 log IU/mL.** **Specimen Requirement: 3** mL plasma from EDTA (Lavender) tube; **Minimum 2.5 mL;** Frozen; Draw 2 tubes to ensure adequate volume. Separate plasma from cells within 8 hours of collection. Transfer **3** mL plasma into a standard aliquot tube. Submit most recent viral load and test date, if available. *OR* **3** mL plasma from EDTA plasma preparation (White) tube; **Minimum 2.5 mL**; Frozen; Draw 2 tubes to ensure adequate volume. Separate plasma from cells within 8 hours of collection. Transfer **3** mL plasma into a standard aliquot tube. Submit most recent viral load and test date, if available. **Stability:** Ambient: **After separation from cells**: 8 hours Refrigerated: **After separation from cells:** 72 hours Frozen: **After separation from cells:** 1 month **Methodology: Massive Parallel Sequencing** **Reported: 4–10** days **CPT: 87900**; 87910	5/15/23
DNA Content/Cell Cycle Analysis, Hydatidiform Mole	DNAHYD	**Special Information:** ***special information has been removed*** **Days Performed: Tue, Thu**	5/15/23
Ehrlichia chaffeensis IgG & IgM Abs by IFA	ECHAFF	**Specimen Requirement:** 1 mL serum from serum separator (Gold) tube; **Minimum 0.4 mL**; Refrigerated; Separate serum from cells ASAP or within 2 hours of collection and transfer into standard aliquot tube. Parallel testing is preferred and convalescent specimens must be received within 30 days from receipt of the acute specimens. Label specimens plainly as 'acute' or 'convalescent.'	5/15/23

Test Changes (Cont.)

Test Name	Order Code	Change	Effective Date
Fungal Antibodies	FUNCF	**Specimen Requirement: 2** mL serum from serum separator (Gold) tube; **Minimum 1.2 mL**; Refrigerated; Separate serum from cells ASAP or within 2 hours of collection and transfer to standard aliquot tube. Parallel testing is preferred and convalescent specimens must be received within 30 days from receipt of the acute specimens. Label specimens plainly as 'acute' and 'convalescent.'	5/15/23
Fungal Antibodies with Reflex to Blastomyces dermatitidis Antibodies by Immunodiffusion, CSF	FANCSF	**Specimen Requirement: 2** mL Cerebrospinal fluid (CSF) in clean container; **Minimum 1 mL**; Refrigerated; Transfer 1 mL CSF into standard aliquot tube.	5/15/23
Fungus CSF Culture/ CAD	FUNCSF	**Special Information:** Test includes both culture for fungus plus a Cryptococcal Antigen test utilizing latex agglutination methodology. CAD results are available within 1 day. If culture is positive, identification will be performed at an additional charge. Identification CPT codes that may apply include: 87106, 87107, **87153, and 87186.** Antimicrobial susceptibilities are performed upon request and only when clinically indicated, with CPT code 87186 applied. Yeast susceptibilities are performed in-house. Mold susceptibilities are sent to an outside reference lab. If Cryptococcal Antigen Detection is positive, a titer will be performed at an additional charge with CPT code **87899** applied. **CPT:** 87102; **87899** **Price: $81.00**	effective immediately
Fungus Screen	FUNGSC	**Special Information:** The Fungal Screen is designed to detect rapidly growing yeast. For slower growing yeasts and molds, order a Fungal Culture (order code FCUL). If culture is positive, limited identification is performed from nonsterile sites. Full identification is performed from sterile sites with an additional charge. Identification CPT codes that may apply include: 87106, 87107, **87153**. Antimicrobial susceptibilities are performed on sterile sites, and CPT code 87186 would apply.	effective immediately
Helicobacter pylori Breath Test	HPYLBR	**Name:** Previously Helicobacter pylori Breath Test, Adult **Special Information:** Collection of breath samples should be performed by trained healthcare personnel only. Per instructions in collection kit. Phenylketonurics: Contains Phenylalanine Hypersensitivity: Patients who are hypersensitive to mannitol, citric acid, or Aspartame should avoid taking the drug solution as the drug solution contains these ingredients. Risk of Aspiration: Use with caution in patients with difficulty in swallowing or who may be at high risk for aspiration due to medical or physical conditions. Pregnancy/Lactation: The safety of the BreathTek UBT kit during pregnancy and lactation is not established. If particulate matter is visible in the reconstituted Pranactin-Citric solution after thorough mixing, the solution should not be used. Fast at least 1 hour prior to administering the BreathTek UBT. Patient should not have taken antibiotics, proton pump inhibitors or bismuth preparations within 2 weeks prior to administrating the BreathTek UBT. The effect of histamine 2-receptor antagonists may reduce urease activity on urea breath tests. They may be discontinued for 24-48 hours before the BreathTek UBT. Do not use any straw other than the straw provided in the kit. If repeat testing is needed, BreathTek UBT can be administered the following day. **The UBT kits must be stored per package insert. Do not use past the stated expiration date.** Additional kits can be obtained by contacting the Immunopathology lab at 216.444.9033. **Clinical Limitation: This test is only for patients age 3 years and older.** **Clinical Information:** A negative result does not rule out the possibility of H. pylori infection. If clinical signs are suggestive of H. pylori infection, retest with a new sample or an alternate method. **Despite very high specificity, false positive results may occur due to other gastric organisms such as H. heilmanni as well as in patients with hypo- or achlorhydria. Despite very high sensitivity, false negative results may occur in patients who have received antibiotics, proton pump inhibitors, or bismuth preparations. Clinical correlation is required.** **Specimen Requirement:** Submit one baseline (blue) and one post dose (gray) breath sample bag. Ambient **Stability:** Ambient: **14** days Refrigerated: Unacceptable Frozen: Unacceptable **Reference Range:** H pylori **Qualitative** Test **Result** (HPYTST): **Negative**	5/2/23

Test Changes (Cont.)

Test Name	Order Code	Change	Effective Date
Inhibin B	INHIBB	**Clinical Information:** Use to differentiate ovarian tumor with normal CA 125 as stromal or mucinous epithelial tumor. May be used for monitoring recurrence of stromal ovarian tumors. This test is performed using the **ANSH ultra-sensitive** Inhibin B ELISA kit. Values obtained with different methodologies or kits cannot be used interchangeably. **Reference Range:** Female: 1 day–12 years: <=182 pg/mL Female: 13–41 years (regular cycle, follicular phase): 8–223 pg/mL Female: 42–51 **years (regular cycle, follicular phase):** <=107 pg/mL **Female: 51–76 years (postmenopausal):** <=11 pg/mL Male: < 15 days: 68–373 pg/mL Male: 15 days–6 months: 42–516 pg/mL Male: 7 months–7 years: 24–300 pg/mL Male: 8–30 years: 47–383 pg/mL Male: 31–72 years: 10–357 pg/mL	5/15/23
LPT to Beryllium, BAL	BALBE	**Special Information:** Contact testing laboratory **at least one week** prior to collecting specimen at (216) 444-2502. Specimen should not be collected or delivered on weekends or holidays. **Clinical Information:** Lymphocyte proliferation test to Beryllium is a cellular assay used as an aid in diagnosis of prior sensitization to Beryllium in the environment. Beryllium-sensitized individuals may remain asymptomatic for extended periods and never develop chronic berylliosis. Clinical, epidemiological, and radiological correlation is required. Bronchoalveolar lavage testing may offer higher sensitivity than whole blood testing **where pulmonary disease is present.**	6/15/23
LPT to Beryllium, Blood	BLDBE	**Special Information:** Contact testing laboratory **at least 48 hours** prior to collecting specimen at (216) 444-2502. Specimen should not be collected or delivered on weekends or holidays. **Specimen Requirement: 80** mL whole blood in sodium heparin (Green) tube; **Minimum 80 mL;** Ambient; Collect Monday–**Wednesday** only. Deliver the specimen to the lab within 48 hours post collection. Do not aliquot. Specimen must remain at ambient temperature. Do not refrigerate. Do not freeze. Collect sample in a sterile container using aseptic technique. Sample cannot be shared with other testing. This test cannot be added on to other testing.	6/15/23
Lupus Anticoagulant Diagnostic Interpretive Panel	LUPUSP	**Special Information:** 3.2% sodium citrate is the preferred anticoagulant recommended by NCCLS. Patient preparation: Discontinue heparin therapy for 2 days prior to collection. If tests are abnormal, the following tests may be ordered and billed: PTT Mixing Study (85730), Factor II (85210), Factor V (85220), **Factor VII (85230)**, Factor X (85260), Factor VIII (85247), Von Willebrand Factor Antigen (85246), Ristocetin Co-factor (85245), Factor IX Assay (85250), Factor XI Assay (85270), Factor XII Assay (85280), Reptilase Time (85635), D-Dimer (85379), Fibrinogen Ag (85385), Fibrinogen (85384), Bethesda Assay (85335) and Factor VIII Chromogenic (85240). Sample must be accompanied by the completed Clinical History Form for Hemostasis and Thrombosis Evaluation. **Specimen Requirement:** 1 mL serum from serum separator (Gold) tube; Frozen AND 5 mL plasma from sodium citrate (Light Blue) tube; **Centrifuge, aliquot and freeze ASAP. Collection tubes must be filled to total fill volume. Inadequately filled tubes will be rejected. Non-testing sites: Centrifuge samples; Aliquot plasma into a separate tube and label with Epic Beaker labels. Specimens should be frozen (-20° C or colder). Indicate on each tube as plasma.** **Stability:** Ambient: 4 hours–**Main campus: ACCEPTABLE for Whole Blood. (Must be delivered ambient to testing lab less than 4 hours post collection.) Non-Testing Sites: UNACCEPTABLE.** Refrigerated: Unacceptable Frozen: **For Non-Testing sites, Frozen Plasma is ACCEPTABLE. (Centrifuge samples, then aliquot plasma into a separate tube and label with Epic Beaker labels. Specimens should be frozen at -20° C and they are stable for 2 weeks. Specimens frozen at -70° C are stable for up to 6 months.**	6/20/23
Lyme Reflex Panel, CSF	LYMCSF	**Reported:** 2–**5** days	5/15/23
Monoclonal Protein, Urine	URMPA	Clinical Information: As an aid in diagnosing monoclonal gammopathy. The test should usually be ordered with SPEP and serum free light chain analysis.	6/20/23

Test Changes (Cont.)

Test Name	Order Code	Change	Effective Date
Mycoplasma genitalium, NAAT	MYGAMP	**For interface clients only–Test build may need to be modified** **Name:** Previously Mycoplasma genitalium (MYGPCR) **Special Information: Microbiology Preanalytic Guidance: http://portals.ccf.org/plmi/Laboratory-Medicine/Microbiology-Specimen-Collection-Transport-Information.** **Up to two tests can be run on a single Aptima Multitest Swab specimen (ie. GCCT+MYGAMP)–if specimen sources have been correctly selected, the shared tests will print on the same label. Do not place more than one label on a single collection tube.** **Common reasons for specimen rejection:** **1. Inappropriate collection device for source selected.** **2. Transport tubes containing a cleaning swab or more than 1 swab.** **3. Overfilled or underfilled urine transport tubes.** **4. Collection device expired prior to specimen collection.** **Related alternative orders:** **1. URMPCR: sendout PCR test for Ureaplasma parvum, Ureaplasma urealyticum, Mycoplasma hominis, and Mycoplasma genitalium from urogenital sites. Not recommended due to inconsistent data and unclear role for urogenital Ureaplasma and M. hominis testing. The majority of Ureaplasma infections are not associated with overt urethritis or cervicitis symptoms.** **2. MYPLAS: in-house culture for Ureaplasma urealyticum and Mycoplasma hominis from urogenital sites. Not recommended due to inconsistent data and unclear role for urogenital Ureaplasma and M. hominis testing. Will not recover M. genitalium.** **3. All other available mycoplasma and ureaplasma orders are for testing from non-urogenital sites.** **Clinical Limitation:** **1. The performance of the assay has not been evaluated in individuals <15 years of age.** **2. Therapeutic failure or success cannot be determined with the assay since nucleic acid may persist following appropriate antimicrobial therapy.** **3. A negative result does not preclude a possible infection. Test results may be affected by improper specimen collection, technical error, specimen mix-up, or target levels below the assay limit of detection (LoD).** **4. The effects of tampon use, douching, and specimen collection variables have not been evaluated for their impact on assay detection.** **5. For females patients, a vaginal swab is the preferred specimen type due to higher clinical sensitivity for detecting M. genitalium than other specimen types; however, female urine or clinician collected endocervical swabs may be used as alternative specimens when vaginal swab specimens are not available. If female urine or clinician-collected endocervical swab specimens test negative, testing with a vaginal swab may be indicated.** **6. Assay interference may occur at high concentrations of mucus in the specimen. Competitive interference may preclude detection of M. genitalium in low quantities if M. pneumoniae is present in high quantities.** **Clinical Information:** Mycoplasma genitalium **is a sexually-transmitted gram-negative bacterium that lives on and in the epithelial cells of the urinary and genital tracts. M. genitalium can cause acute and chronic nongonoccal urethritis (NGU), cervicitis, and pelvic inflammatory disease. In lower risk populations, M. genitalium prevalence of approximately 1-3% has been reported in both men and women. In higher risk populations, prevalence of 10- 41% in men and 7.3-14% in women has been reported. The prevalence of M. genitalium in higher risk populations often exceeds that of Neisseria gonorrhoeae and is similar to the prevalence of Chlamydia trachomatis. M. genitalium infections largely go unrecognized, and infected individuals are either asymptomatic or have symptoms similar to those associated with other bacterial infections of the urogenital tract.** **Because M. genitalium is fastidious and difficult to culture, nucleic acid amplification testing (NAAT) is the diagnostic test of choice. The CDC recommends male patients with recurrent NGU should be tested for M. genitalium using an FDA-cleared NAAT. Female patients with recurrent cervicitis should be tested for M. genitalium, and testing should be considered for those with pelvic inflammatory disease. Screening of asymptomatic M. genitalium infection or extragenital testing for M. genitalium is not recommended.** *(continued on page 16)*	6/20/23

Test Changes (Cont.)

Test Name	Order Code	Change	Effective Date
Mycoplasma genitalium, NAAT *(continued from page 15)*		**The Aptima Mycoplasma genitalium assay is an FDA-approved in vitro NAAT that utilizes target capture, transcription-mediated amplification (TMA), and hybridization protection assay (HPA) technologies to detect 16s rRNA of M. genitalium. It is intended for use as an aid in the diagnosis of M. genitalium urogenital infections from clinician-collected and self-collected vaginal swabs (in a clinical setting), clinician-collected endocervical swabs, female and male urine, clinician-collected male urethral swabs, and self-collected penile meatal swabs (in a clinical setting).** **Clinical Reference: Workowski KA, Bachmann LH, Chan PA, Johnston CM, Muzny CA, Park I, Reno H, Zenilman JM, Bolan GA. Sexually Transmitted Infections Treatment Guidelines, 2021. MMWR Recomm Rep. 2021 Jul 23;70(4):1-187. doi: 10.15585/mmwr.rr7004a1. PMID: 34292926; PMCID: PMC8344968.** **Specimen Requirement:** One urethral APTIMA Collection Unisex swab; Ambient; **Male Urethral Unisex (white tube blue swab): The patient should not have urinated for at least 1 hr prior to sample collection. Insert the blue swab 2-4 cm into the urethra. Gently rotate the swab clockwise for 2-3 seconds in the urethra. Place swab into Aptima transport tube. Snap off swab at the score line, and close the tube tightly.** *OR* One endocervical APTIMA Collection Unisex swab; Ambient; **Endocervical Unisex (white tube blue swab): Remove excess mucus from cervical os and surrounding mucosa using the white cleaning swab, then DISCARD. Insert blue swab into the endocervical canal and gently rotate clockwise for 10-30 seconds. Place swab into Aptima transport tube. Snap off swab at the score line, and close the tube tightly.** *OR* 2 mL first-catch urine in APTIMA Urine specimen collection kit; Ambient; **For female patients, vaginal specimens are preferred due to superior test performance characteristics. The patient should not have urinated for at least 1 hour prior to specimen collection. The patient should collect first portion of random voided urine (first part of stream) into a sterile, plastic, preservative-free container. Transfer 2 mL of urine into the Aptima urine specimen transport tube using the disposable pipette provided within 24 hours of collection. Close the tube tightly. Work with one specimen at a time. The correct volume of urine has been added when the fluid level is between the black fill lines (window) on the urine transport tube. Do not overfill or underfill the APTIMA Urine transport tube** **Specimen Requirement (continued):** *OR* **One vaginal Aptima Multitest Collection Kit; Ambient; Vaginal Multitest (orange tube pink swab): A vaginal swab is the recommended specimen for female patients due to superior test performance characteristics. Carefully insert the swab into the vagina about 2 inches past the introitus and gently rotate the swab for 10-30 seconds. Make sure the swab touches the vaginal walls so that moisture is absorbed by the swab. Place swab into Aptima transport tube. Snap off swab at the score line, and close the tube tightly.** *OR* **One other specimen in Aptima Multitest Collection Kit; Ambient; Penile Meatal (orange tube pink swab): Roll the swab on the tip of the penis, outside the opening of the penis (hole through which urine is passed). It is not necessary to put the swab inside the opening of the penis. Make sure to roll the swab all the way around the opening of the penis to get the best sample. Ensure the swab does not touch any other area of the skin. Place swab into Aptima transport tube. Snap off swab at the score line, and close the tube tightly.***OR* **2 mL first-catch urine in sterile container; Ambient; For female patients, vaginal specimens are preferred due to superior test performance characteristics. The patient should not have urinated for at least 1 hour prior to specimen collection. The patient should collect first portion of random voided urine (first part of stream) into a sterile, plastic, preservative-free container.** **Stability:** Ambient: 2˚C to 8˚C. Swab in Aptima transport media: 60 days; Urine in Aptima transport media: 30 days; Urine unprocessed: 24 hours; ThinPrep PreservCyt solution in Aptima transport media: 60 days; ThinPrep PreservCyt unprocessed: 30 days Refrigerated: 15˚C to 30˚C. Swab in Aptima transport media: 60 days; Urine in Aptima transport media: 30 days; Urine unprocessed: 24 hours; ThinPrep PreservCyt solution in Aptima transport media: 60 days; ThinPrep PreservCyt unprocessed: 30 days Frozen: -20˚C to -70˚C Swab in Aptima transport media: 4 months; Urine in Aptima transport media: 4 months; Urine unprocessed: unacceptable; ThinPrep PreservCyt solution in Aptima transport media: 3 months; ThinPrep PreservCyt unprocessed: unacceptable **Reference Range: Not detected** **Reported: 1–4** days	

Test Changes (Cont.)

Test Name	Order Code	Change	Effective Date
Neisseria gonorrhoeae (GC) & Chlamydia trachomatis (CT), NAAT	GCCT	**Name:** Previously GC/Chlamydia Amplification, Genital, Rectal and Oral Specimens **Special Information: Microbiology Preanalytic Guidance: http://portals.ccf.org/plmi/Laboratory-Medicine/Microbiology-Specimen-Collection-Transport-Information.** **Up to two tests can be run on a single Aptima Multitest Swab specimen (ie. GCCT+TRVAMP)–if specimen sources have been correctly selected, the shared tests will print on the same label. Do not place more than one label on a single collection tube.** **Common reasons for specimen rejection:** **1. Inappropriate collection device for source selected.** **2. Transport tubes containing a cleaning swab or more than 1 swab.** **3. Overfilled or underfilled urine transport tubes.** **4. Collection device expired prior to specimen collection.** **Related alternative orders:** **1. MISCGC: in-house culture to recover GC for susceptibility testing (only suggested following positive NAAT if treatment failure is suspected).** **2. NGNAAO, CTNAAO, or CTNGAO: sendout GC, CT, or GC+CT NAAT for non-FDA approved sources including ocular, nasopharyngeal, and peritoneal.** **3. CTRACH: sendout CT culture for non-FDA approved sources including ocular, nasopharyngeal, and peritoneal.** **Clinical Limitation:** **1. The performance of the assay has not been evaluated in patients <14 years of age.** **2. The assay is not intended for the evaluation of suspected sexual abuse or for other medico-legal indications. For those patients for whom a false positive result may have adverse psycho-social impact, the CDC recommends retesting.** **3. Therapeutic failure or success cannot be determined with the assay since nucleic acid may persist following appropriate antimicrobial therapy.** **4. A negative result does not preclude a possible infection because results are dependent on adequate specimen collection. Test results may be affected by improper specimen collection, technical error, specimen mix-up, or target levels below the assay limit of detection.** **5. First catch female urine specimens are acceptable but may detect up to 10% fewer CT/GC infections when compared with vaginal and endocervical swab specimens.** **6. The effects of tampon use, douching, and specimen collection variables have not been assessed for their impact on assay detection.** **Clinical Information:** Chlamydia trachomatis (CT) and Neisseria gonorrhoeae (GC) **infections are two of the most common sexually transmitted infections (STI) worldwide. CDC STI Treatment Guidelines include testing and screening recommendations for CT and GC and provide guidance on testing methodology and frequency, as well as specimen types for specific patient populations. The CDC recommends the use of nucleic acid amplification tests (NAATs) for the detection of CT and GC in patients with and without symptoms.** **The Aptima Combo 2 assay is an FDA-cleared second generation NAAT that utilizes target capture, Transcription-Mediated Amplification (TMA), and Dual Kinetic Assay (DKA) technologies. The Aptima Combo 2 assay on the Panther system qualitatively detects CT and/or GC rRNA in clinician-collected endocervical, PreservCyt Solution liquid Pap specimens, vaginal, throat, rectal, and male urethral swab specimens; patient-collected vaginal swab specimens, and female and male urine specimens from symptomatic and asymptomatic individuals.** **In 2019, novel C. trachomatis variants were discovered which contain point mutations affecting detection by the original version of the Aptima Combo 2 assay. Variant strains of chlamydia with mutations affecting diagnostic test performance have been reported previously and are a natural product of microbial evolution. The updated version of the Aptima Combo 2 assay provides detection coverage for the variant strains of C. trachomatis that emerged in 2019.** *(continued on page 18)*	6/20/23

Test Changes (Cont.)

Test Name	Order Code	Change	Effective Date
Neisseria gonorrhoeae (GC) & Chlamydia trachomatis (CT), NAAT *(continued from page 17)*	GCCT	**Clinical Reference: Workowski KA, Bachmann LH, Chan PA, Johnston CM, Muzny CA, Park I, Reno H, Zenilman JM, Bolan GA. Sexually Transmitted Infections Treatment Guidelines, 2021. MMWR Recomm Rep. 2021 Jul 23;70(4):1-187. doi: 10.15585/mmwr.rr7004a1. PMID: 34292926; PMCID: PMC8344968.** **Specimen Requirement:** One endocervical APTIMA Collection unisex swab; Ambient; **Endocervical Unisex (white tube blue swab): Remove excess mucus from cervical os and surrounding mucosa using the white cleaning swab, then DISCARD. Insert blue swab into the endocervical canal and gently rotate clockwise for 10-30 seconds. Place swab into Aptima transport tube. Snap off swab at the score line, and close the tube tightly.** *OR* One urethral APTIMA collection unisex swab; Ambient; **Male Urethral Unisex (white tube blue swab): The patient should not have urinated for at least 1 hr prior to sample collection. Insert the blue swab 2-4 cm into the urethra. Gently rotate the swab clockwise for 2-3 seconds in the urethra. Place swab into Aptima transport tube. Snap off swab at the score line, and close the tube tightly.** *OR* One vaginal Aptima Multitest Collection Kit; Ambient; **Vaginal Multitest (orange tube pink swab): A vaginal swab is the recommended specimen for female patients who are clinically suspected of having a chlamydial or gonococcal infection. Carefully insert the swab into the vagina about 2 inches past the introitus and gently rotate the swab for 10-30 seconds. Make sure the swab touches the vaginal walls so that moisture is absorbed by the swab. Vaginal swab specimens may be patient-collected in a clinical setting when a pelvic exam is not otherwise indicated (https://www.hologic.com/package-inserts/swab-collection-instructions-vaginal-main-english#4257225834-454981651). Place swab into Aptima transport tube. Snap off swab at the score line, and close the tube tightly.** *OR* One rectal Aptima Multitest Collection Kit: Ambient; **Rectal Multitest (orange tube pink swab): Carefully insert the swab into the rectum about 1-2 inches past the anal margin and gently rotate the swab for about 5-10 seconds. Place swab into Aptima transport tube. Snap off swab at the score line, and close the tube tightly.** *OR* One throat Aptima Multitest Collection Kit; Ambient; **Throat Multitest (orange tube pink swab): Carefully insert swab into the throat ensuring contact with bilateral tonsils (if present) and the posterior pharyngeal wall, then withdraw the swab without touching the inside of the cheeks or tongue. Place swab into Aptima transport tube. Snap off swab at the score line, and close the tube tightly.** *OR* **2 mL first-catch urine in APTIMA Urine specimen collection kit; Ambient; First-catch urine is the optimal specimen for screening asymptomatic male patients. Urine may also be used for testing any symptomatic patient, but vaginal specimens are preferred when available due to greater test sensitivity. The patient should not have urinated for at least 1 hour prior to specimen collection. The patient should collect first portion of random voided urine (first part of stream) into a sterile, plastic, preservative-free container. Transfer 2 mL of urine into the Aptima urine specimen transport tube using the disposable pipette provided within 24 hours of collection. Close the tube tightly. Work with one specimen at a time. The correct volume of urine has been added when the fluid level is between the black fill lines (window) on the urine transport tube. Do not overfill or underfill the APTIMA Urine transport tube.** *OR* **2 mL first-catch urine in sterile container; Ambient; First-catch urine is the optimal specimen for screening asymptomatic male patients. Urine may also be used for testing any symptomatic patient, but vaginal specimens are preferred when available due to greater test sensitivity. The patient should not have urinated for at least 1 hour prior to specimen collection. The patient should collect first portion of random voided urine (first part of stream) into a sterile, plastic, preservative-free container.** *OR* Unspecified cervical Cytyc PreservCyt solution (Thin Prep); Ambient; PreservCyt Solution (ThinPrep) **is an acceptable specimen when added onto a ThinPrep Pap Test and no dedicated vaginal or endocervical swab specimens are available. It is not a recommended due to lower test sensitivity compared to other specimen types. For this reason, it is not available as a selectable specimen source/type during order entry, only as a laboratory add-on. In order to place an order on this specimen type, you must place a call to lab client services. If consulted prior to specimen collection, lab client services should advise the provider to collect a separate dedicated Vaginal Multitest Swab for optimal test performance characteristics. If consulted after specimen collection, lab client services should assist the provider in placing an add on order with "Fluid, Cervix"** *(continued on page 19)*	6/20/23

Test Changes (Cont.)

Test Name	Order Code	Change	Effective Date
Neisseria gonorrhoeae (GC) & Chlamydia trachomatis (CT), NAAT *(continued from page 18)*	GCCT	**as the specimen source, and have cytology perform the aliquot as below prior to cytology testing.** Prior to cytology testing and within 30 days of collection, cytology will transfer a 1 mL aliquot into an APTIMA Specimen Transfer Tube. The specimen must have been stored at 2-30C. **Stability:** Ambient: **15˚C to 30˚C.** Swab in APTIMA transport media: 60 days; **Urine in APTIMA transport media: 30 days; Urine unprocessed: 24 hours;** ThinPrep PreservCyt solution in APTIMA transport media: 14 days; ThinPrep PreservCyt unprocessed: 30 days Refrigerated: **2˚C to 8˚C** Swab in APTIMA transport media: 60 days; **Urine in APTIMA transport media: 30 days; Urine unprocessed: 24 hours;** ThinPrep PreservCyt solution in APTIMA transport media: 30 days; ThinPrep PreservCyt unprocessed: 30 days Frozen: **-20˚C to -70˚C** Swab in APTIMA transport media: 12 months; **Urine in APTIMA transport media: 12 months; Urine unprocessed: Unacceptable;** ThinPrep PreservCyt solution in APTIMA transport media: 12 months; ThinPrep PreservCyt unprocessed: Unacceptable **Methodology: Transcription-Mediated Amplification** **Reference Range:** **Neisseria gonorrhoeae (GC) (GCAMP): Not detected** **Chlamydia trachomatis (CT) (CLAMP): Not detected** **Days Performed:** Mon–**Sun**	6/20/23
Organism Identification, Yeast	OIDYEA	**Special Information:** Indicate on test order: Original date of collection, specimen site, any pertinent preliminary identification information and telephone number including extension where report may be called if necessary. Antibiotic susceptibility testing must be requested and ordered separately. Contraindications: lack of viability, culture mixed or contaminated. **CPT code 87153 may be added if sequencing method is performed to complete the identification.**	effective immediately
Phosphatidylethanol (PEth)	PETH	**For interface clients only–Test build may need to be modified** **Includes:** PEth 16:0/18.1 (POPEth) PEth 16:0/18.2 (PLPEth) **EER Peth** **Special Information:** Gel separator tubes will be rejected. Also unacceptable are plain (no additive) red tubes, citrate (light blue) tubes, or SPS or ACD solution (yellow) tubes. **This test is New York DOH approved.** **Stability:** Ambient: **2 hours** Refrigerated: 2 weeks Frozen: 1 month	5/15/23
Prader-Willi/Angelman Methylation	PRADER	**Special Information:** Counseling and informed consent are recommended for genetic testing. Plasma and serum will be rejected. **Clinical Limitation:** *removed* **Clinical Information:** *removed* **Specimen Requirement:** 3 mL whole blood in Acid Citrate Dextrose (ACD) A or B (Yellow) tube; **Minimum 1 mL**; Refrigerated *OR* 3 mL whole blood in EDTA (Lavender) tube; **Minimum 1 mL**; Refrigerated **Stability:** Ambient: **1 week** Refrigerated: **1 month** Frozen: **Unacceptable** **Methodology: Methylation-Specific Multiplex Ligation-Dependent Probe Amplification (MS-MLPA)** **Days Performed: Varies** **Reported: 13–15** days	5/15/23

Test Changes (Cont.)

Test Name	Order Code	Change	Effective Date
Prothrombin Time Mixing Study	PTMIX	**Special Information:** If tests are abnormal in the panel, the following tests may be ordered and billed: Factor II **(85210) ,** Factor V **(85220),** Factor VII **(85230),** Factor X **(85260),** Factor VIII **(85247),** Factor VIII Chromogenic **(85240),** Factor IX Assay **(85250),** Factor XI Assay **(85270),** Factor XII Assay **(85280),** Reptilase Time **(85635),** D-Dimer **(85379),** Thrombin Time **(85670),** Fibrinogen **(85384),** Bethesda Inhibitor **(85335),** Factor XIII Antigen **(85290),** Lupus Panel, DRVVT **(85613 x2),** STACLOT **(85730 & 85732),** Platelet Neutralization **(85597),** Anti-Xa **(85520) &** Fibrinogen Ag **(85385).** **Specimen Requirement: 6** mL plasma from sodium citrate (Light Blue) tube; **Minimum 2 mL; Centrifuge, aliquot and freeze ASAP. Non-Testing Sites: Centrifuge samples; Aliquot plasma into a separate tube and label with Epic Beaker labels. Specimens should be frozen (-20° C or colder).** **Stability:** Ambient: **Main campus: ACCEPTABLE for Whole Blood. (Must be delivered ambient to testing lab less than** 4 hours **post collection.) Non-Testing Sites: UNACCEPTABLE.** Refrigerated: Unacceptable Frozen: **For Non-Testing sites, Frozen Plasma is ACCEPTABLE. (Centrifuge samples, then aliquot plasma into a separate tube and label with Epic Beaker labels. Specimens should be frozen (-20° C or colder) and they are stable for 2 months.**	6/20/23
PTT Incubated Mixing Study	PTTIM	**Special Information:** If tests are abnormal in the panel, the following tests may be ordered and billed: PTT Immediate and 1 Hour Incubated Mix (85732 x2), Factor II (85210), Factor V (85220), Factor VII (85230), Factor X (85260), Factor VIII (85247), **Factor VIII Chromogenic (85240)**, Factor IX Assay (85250), Factor XI Assay (85270), Factor XII Assay (85280), Reptilase Time (85635), D-Dimer (85379), **von Willebrand Factor Antigen (85246), Platelet Neutralization (85597), Ristocetin Co-Factor (85245), Bethesda Inhibitor (85335), Dilute Russell Viper Venom Time (85613 x2), Hexagonal Phase Phospholipid Neutralization (85730 & 85732), Fibrinogen (85384)** & Fibrinogen Ag (85385). **Specimen Requirement: 6** mL plasma from sodium citrate (Light Blue) tube; **Minimum 2 mL; Centrifuge, aliquot and freeze ASAP. Collection tubes must be filled to total fill volume. Inadequately filled tubes will be rejected. Non-testing sites: Centrifuge samples; Aliquot plasma into a separate tube and label with Epic Beaker labels. Specimens should be frozen (-20C or colder).** **Stability:** Ambient: **Main campus: ACCEPTABLE for Whole Blood. (Must be delivered ambient to testing lab less than** 4 hours **post collection.) Non-Testing Sites: UNACCEPTABLE.** Refrigerated: Unacceptable Frozen: **For Non-Testing sites, Frozen Plasma is ACCEPTABLE. (Centrifuge samples, then aliquot plasma into a separate tube and label with Epic Beaker labels. Specimens should be frozen (-20° C or colder) and they are stable for 2 weeks. (**6 months at -70˚C**)**	6/20/23
Respiratory Culture and Stain	RCULST	**Special Information:** Gram stain and semi-quantitative culture for the recovery of aerobic bacteria is performed on sputum, tracheal aspirates and bronchial wash specimens. Prior to sputum collection, instruct patient to rinse mouth with water. Scoring of sputum and endotracheal aspirate gram stains is used to screen out improperly collected specimens that are contaminated with oral flora. Bronchoalveolar lavage and protected brush specimens should be ordered as bronchoscopy culture (BALCSM). Separate test orders are required to rule out the presence of mycobacteria, fungi, viruses, and atypical bacterial pathogens in respiratory specimens. Blood cultures are recommended for patients being evaluated for pneumonia. If culture is positive, identification will be performed on clinically significant, fast-growing, nonfastidious aerobic organisms at an additional charge. Identification CPT codes that may apply include: **87206**, 87077, 87106, 87107, 87153, 87158. Antimicrobial susceptibilities are performed when indicated, and the following CPT codes may apply: 87181, 87184, 87185, 87186. **CPT:** 87205; 87070; **87206**	6/20/23
Rickettsia rickettsii IgG & IgM Abs	ROCKY	**Specimen Requirement:** 1 mL serum from serum separator (Gold) tube; **Minimum 0.4 mL**; Refrigerated; Separate serum from cells ASAP or within 2 hours of collection and transfer to standard aliquot tube. Parallel testing is preferred and convalescent specimens MUST be received within 30 days from receipt of the acute specimens. Label specimens plainly as 'acute' or 'convalescent.'	5/15/23

Test Changes (Cont.)

Test Name	Order Code	Change	Effective Date
Rickettsia Typhi IgG & IgM Abs	TYPHUS	**Specimen Requirement:** 1 mL serum from serum separator (Gold) tube; **Minimum 0.4 mL**; Refrigerated; Separate serum from cells ASAP or within 2 hours of collection and transfer into standard aliquot tube. Parallel testing is preferred and convalescent specimens must be received within 30 days from receipt of the acute specimens. Label specimens plainly as 'acute' or 'convalescent.'	5/15/23
THC Metabolite, Serum/Plasma, Qt	THCMET	**Special Information: This test is a reflex from Drug Screen 9 Panel, Serum or Plasma (DRGSC9). This test is New York DOH approved.** **Clinical Limitation: For medical purposes only, not valid for forensic use.** **Clinical Information: Positive cutoff: 5 ng/mL** **Specimen Requirement:** 1 mL serum from no additive (Red) tube; Refrigerated; Do not use serum separator tubes. Separate serum from cells ASAP or within 2 hours of collection *OR* 1 mL plasma from EDTA (Lavender) tube; Refrigerated; Do not use plasma separator tubes. Separate plasma from cells ASAP or within 2 hours of collection *OR* 1 mL plasma from sodium heparin (Green) tube; Refrigerated; Do not use plasma separator tubes. Separate plasma from cells ASAP or within 2 hours of collection *OR* **1 mL plasma from potassium oxalate/sodium fluoride (Gray) tube; Refrigerated; Do not use plasma separator tubes. Separate plasma from cells ASAP or within 2 hours of collection** **Stability:** Ambient: After separation from cells: 1 week Refrigerated: After separation from cells: 2 weeks Frozen: After separation from cells: 3 years **(Avoid repeated freeze/thaw cycles)**	6/22/23
Transglutaminase IgA Abs	TGIGA	**For interface clients only–Test build may need to be modified** **Clinical Information: This is used as an aid in diagnosis of celiac disease. Clinical correlation is required.** **Stability:** Ambient: 24 hours Refrigerated: 7 days Frozen: **14 days**, up to 2 freeze thaw cycles **Reference Range:** Transglutaminase IgA Abs (**TTGIGA**): **<4.0 U/mL** **Transglutaminase IgA Ab Interpretation (TGIGAQ): Negative**	6/22/23
Transglutaminase IgG Abs	TGIGG	**For interface clients only–Test build may need to be modified** **Clinical Information: This test is used as an aid in diagnosis of celiac disease in IgA-deficient individuals only. Clinical correlation is required.** **Stability:** Ambient: 24 hours Refrigerated: 7 days Frozen: **14 days**, up to 2 freeze thaw cycles **Reference Range:** Transglutaminase IgG Abs (**TTGIGG**): **<6 U/mL** **Transglutaminase IgG Abs Interpretation (TGIGGQ): Negative**	6/22/23
Transglutaminase IgG and IgA	TGLGMA	**For interface clients only–Test build may need to be modified** **Clinical Information: See individual components.** **Stability:** Ambient: 24 hours Refrigerated: 7 days Frozen: **14 days**, up to 2 freeze thaw cycles **Reference Range:** **Transglutaminase IgA Abs (TTGIGA): <4.0 U/mL** **Transglutaminase IgA Ab Interpretation (TGIGAQ): Negative** **Transglutaminase IgG Abs (TTGIGG): <6 U/mL** **Transglutaminase IgG Abs Interpretation (TGIGGQ): Negative**	6/22/23

Test Changes (Cont.)

Test Name	Order Code	Change	Effective Date
Trichomonas vaginalis, NAAT	TRVAMP	**Name:** Previously Trichomonas vaginalis Amplification **Special Information: Microbiology Preanalytic Guidance: http://portals.ccf.org/plmi/Laboratory-Medicine/Microbiology-Specimen-Collection-Transport-Information.** **Up to two tests can be run on a single Aptima Multitest Swab specimen (ie. GCCT+TRVAMP)–if specimen sources have been correctly selected, the shared tests will print on the same label. Do not place more than one label on a single collection tube.** **Common reasons for specimen rejection:** **1. Inappropriate collection device for source selected.** **2. Transport tubes containing a cleaning swab or more than 1 swab.** **3. Overfilled or underfilled urine transport tubes.** **4. Collection device expired prior to specimen collection.** **Related alternative orders:** **1. TRICHO: in-house trichomonas vaginalis rapid antigen test (lower patient cost than NAAT, but with lower sensitivity; should not be used for asymptomatic screening).** **Clinical Limitation:** **1. The performance of the assay has not been evaluated in patients <14 years of age.** **2. Therapeutic failure or success cannot be determined with the assay since nucleic acid may persist following appropriate antimicrobial therapy.** **3. A negative result does not preclude a possible infection because results are dependent on adequate specimen collection. Test results may be affected by improper specimen collection, technical error, specimen mix-up, or target levels below the assay limit of detection.** **4. The effects of tampon use, douching, and specimen collection variables have not been assessed for their impact on assay detection.** **5. Competitive interference may preclude detection of T. vaginalis in low quantities if Trichomonas tenax or Pentatrichomonas hominis are present in high quantities (commensals of the oral cavity and large intestine respectively).** **Clinical Information:** Trichomonas vaginalis is a protozoan parasite that is a common cause of vaginitis and the most common nonviral sexually transmitted infection worldwide. **The majority of persons who have trichomoniasis (70%–85%) either have minimal or no genital symptoms, and untreated infections might last from months to years, and have been associated with reproductive morbidity. Symptomatic patients can present with vaginitis, vaginal discharge, cervicitis, urethritis, and/or other genitourinary symptoms. The CDC recommends diagnostic testing for T. vaginalis in patients seeking care for vaginal discharge, as well as considering asymptomatic screening in certain high risk groups. T. vaginalis can be diagnosed via wet mount, culture, rapid antigen testing, and nucleic acid amplification testing (NAAT), with the latter having the highest sensitivity.** **The Aptima Trichomonas vaginalis Assay is an in vitro FDA-cleared qualitative nucleic acid amplification test (NAAT) for the detection of ribosomal RNA (rRNA) from Trichomonas vaginalis to aid in the diagnosis of trichomoniasis using the Panther System. The assay uses target capture, transcription-mediated amplification (TMA), and hybridization protection assay (HPA) technologies. The assay may be used to test the following specimens from symptomatic or asymptomatic women: clinician-collected endocervical swabs, clinician-collected vaginal swabs, and specimens collected in PreservCyt Solution. The assay has been modified and validated as a laboratory-developed test for non-FDA approved specimen types of male urethral swabs and first-catch urine.** **Clinical Reference: Workowski KA, Bachmann LH, Chan PA, Johnston CM, Muzny CA, Park I, Reno H, Zenilman JM, Bolan GA. Sexually Transmitted Infections Treatment Guidelines, 2021. MMWR Recomm Rep. 2021 Jul 23;70(4):1-187. doi: 10.15585/mmwr.rr7004a1. PMID: 34292926; PMCID: PMC8344968.** *(continued on page 23)*	6/20/23

Test Changes (Cont.)

Test Name	Order Code	Change	Effective Date
Trichomonas vaginalis, NAAT *(continued from page 22)*	TRVAMP	**Specimen Requirement:** 2 mL first-catch urine in APTIMA Urine specimen collection kit; Ambient; **Vaginal specimens are preferred when available due to this being an FDA-approved specimen type. The patient should not have urinated for at least 1 hour prior to specimen collection. The patient should collect first portion of random voided urine (first part of stream) into a sterile, plastic, preservative-free container.** Transfer 2 mL of urine into the Aptima urine specimen transport tube using the disposable pipette **provided within 24 hours of collection. Close the tube tightly. Work with one specimen at a time.** The correct volume of urine has been added when the fluid level is between the black fill lines **(window)** on the urine transport tube. Do not overfill or underfill the APTIMA Urine transport tube. *OR* one endocervical APTIMA Collection Unisex swab; Ambient; **Endocervical Unisex (white tube blue swab): Remove excess mucus from cervical os and surrounding mucosa using the white cleaning swab, then DISCARD. Insert blue swab into the endocervical canal and gently rotate clockwise for 10-30 seconds. Place swab into Aptima transport tube. Snap off swab at the score line, and close the tube tightly.** *OR* one vaginal Aptima **Multitest Collection Kit**; Ambient; **Vaginal Multitest (orange tube pink swab): A vaginal swab is the recommended specimen for female patients due to this being an FDA-approved specimen type. Carefully insert the swab into the vagina about 2 inches past the introitus and gently rotate the swab for 10-30 seconds. Make sure the swab touches the vaginal walls so that moisture is absorbed by the swab. Place swab into Aptima transport tube. Snap off swab at the score line, and close the tube tightly.** *OR* one urethral APTIMA Collection Unisex swab; Ambient; **Male Urethral Unisex (white tube blue swab): The patient should not have urinated for at least 1 hr prior to sample collection. Insert the blue swab 2-4 cm into the urethra. Gently rotate the swab clockwise for 2-3 seconds in the urethra. Place swab into Aptima transport tube. Snap off swab at the score line, and close the tube tightly.** *OR* **2 mL first-catch urine in sterile container; Ambient; Vaginal specimens are preferred when available due to this being an FDA-approved specimen type. The patient should not have urinated for at least 1 hour prior to specimen collection. The patient should collect first portion of random voided urine (first part of stream) into a sterile, plastic, preservative-free container.** *OR* one cervical Cytyc PreservCyt solution (Thin Prep); Ambient; **PreservCyt Solution (ThinPrep) is an acceptable specimen when added onto a ThinPrep Pap Test and no dedicated vaginal or endocervical swab specimens are available. It is not a recommended due to lower test sensitivity for gonorrhea and chlamydia detection (often ordered on the same swab) compared to other specimen types. Due to this reason, it is not available as a selectable specimen source/type during order entry, only as a laboratory add-on. In order to place an order on this specimen type, you must place a call to lab client services. If consulted prior to specimen collection, lab client services should advise the provider to collect a separate dedicated Vaginal Multitest Swab for optimal test performance characteristics. If consulted after specimen collection, lab client services should assist the provider in placing an add on order with "Fluid, Cervix" as the specimen source, and have cytology perform the aliquot as below prior to cytology testing.** Prior to cytology testing and within 30 days of collection, **cytology will** transfer a 1 mL aliquot into an APTIMA Specimen Transfer Tube. The specimen must have been stored at 2-30C. **Stability:** Ambient: **15˚C to 30˚C. Swab in Aptima transport media: 60 days; Urine in Aptima transport media: 30 days; Urine unprocessed: 24 hours; ThinPrep PreservCyt solution in Aptima transport media: 14 days; ThinPrep PreservCyt unprocessed: 30 days** Refrigerated: **2˚C to 8˚C. Swab in Aptima transport media: 60 days; Urine in Aptima transport media: 30 days; Urine unprocessed: 24 hours; ThinPrep PreservCyt solution in Aptima transport media: 30 days; ThinPrep PreservCyt unprocessed: 30 days** Frozen: **-20˚C to -70˚C. Swab in Aptima transport media: 24 months; Urine in Aptima transport media: 12 months; Urine unprocessed: unacceptable; ThinPrep PreservCyt solution in Aptima transport media: 12 months; ThinPrep PreservCyt unprocessed: unacceptable** **Methodology:** **Transcription-Mediated Amplification** **Reference Range: Not detected** **Days Performed:** Mon–**Sun** **Reported: 1–4** days	6/20/23

Test Changes (Cont.)

Test Name	Order Code	Change	Effective Date
Universal PCR, Acid Fast Bacilli	AFBPCR	**Special Information:** ICD9/Diagnosis codes preferred, but not required. **If tissue specimen is held at any condition other than frozen as described in the stability section, add a note to the test order so that the appropriate disclaimer can be added.** **Specimen Requirement:** 1 mL body fluid in sterile container; Minimum 0.2 mL; Frozen; *OR* **fresh or frozen tissue in sterile container; Frozen; Place 1 cubic cm or less of tissue in a sterile, DNA-free container and ship on dry ice.** **Stability:** Ambient: Paraffin block: Indefinitely; **Tissue: 6 hours** Refrigerated: Unacceptable **(Tissue: 7 days with disclaimer)** Frozen: 30 days	6/22/23
Universal PCR, Fungal	FUNPCR	**Special Information:** ICD9/Diagnosis codes preferred, but not required. **If tissue specimen is held at any condition other than frozen as described in the stability section, add a note to the test order so that the appropriate disclaimer can be added.** **Specimen Requirement:** 1 mL body fluid in sterile container; Minimum 0.2 mL; Frozen; Sputum is NOT an acceptable specimen type. *OR* **fresh or frozen tissue in sterile container; Frozen; Place 1 cubic cm or less of tissue in a sterile, DNA-free container and ship on dry ice.** **Stability:** Ambient: Paraffin block: Indefinitely; **Tissue: 6 hours** Refrigerated: Unacceptable **(Tissue: 7 days with disclaimer)** Frozen: 30 days	6/22/23
von Willebrand Diagnostic Interpretive Panel (Limited)	VWFPR	**Special Information:** Sample must be accompanied by the completed Clinical History Form for Hemostasis and Thrombosis Evaluation. If test results in panel are abnormal, additional testing may be ordered and billed. **These tests include FIX (85250), FXI (85270), FXII (85280), FXIII Antigen (85290), Bethesda Inhibitor (85335), FVIII Chromogenic (85240), DRVVT (85613), Staclot (85730, 85732), PTT MIX (85730), and PNP (85597).** **Specimen Requirement:** 6 mL plasma from sodium citrate (Light Blue) tube; Minimum 3 mL; **Centrifuge, aliquot and freeze ASAP. Centrifuge samples; Aliquot plasma into a separate tube and label with Epic Beaker labels. Specimens should be frozen (-20C or colder).** **Stability:** Ambient: Unacceptable Refrigerated: Unacceptable Frozen: **-20° C stable for 2 weeks or -70° C stable for 6 months**	6/20/23

New Tests

Test Name	Order Code	Change	Effective Date
1,5 Anhydroglucitol	15AGTL	**Special Information:** Hemolyzed specimens will be rejected. **Clinical Information:** This test is useful for the quantitative determination of 1,5-anhydroglucitol (1,5-AG) in serum or plasma for the intermediate term (preceding 1–2 weeks) monitoring of glycemic control in people with diabetes. **Specimen Requirement:** 1 mL serum from serum separator (Gold) tube; Minimum 0.5 mL; Ambient *OR* 1 mL plasma from EDTA (Lavender) tube; Minimum 0.5 mL; Ambient; Separate plasma from cells and transfer to standard aliquot tube. **Stability:** Ambient: 7 days Refrigerated: 7 days Frozen: 28 days **Methodology:** Enzymatic **Reference Range:** Male/Female <= 1 Year: Not established Male 2–17 Years: 15.0–38.0 mcg/mL Male >= 18 Years: 7.3–36.6 mcg/mL Female 2–17 Years: 11.2–35.7 mcg/mL Female >= 18 Years 7.5–28.4 mcg/mL **Days Performed:** Sun, Tues, Thur, Sat **Reported:** 2–6 days	6/20/23
Clozapine	CLOZA	**Special Information:** Timing of specimen collection: Pre-dose (trough) draw – At steady state concentration. Do not collect in a gel separator tube. Centrifuge and transfer serum to a CCL tube and refrigerate within 2 hours of collection. **Clinical Limitation:** The clinical context should be taken into consideration when interpreting Clozapine results. Assess dose-related side effects and clinical evidence of toxicity if a Clozapine concentration is higher than expected. Poor adherence, drug interactions, or changes in smoking status may be relevant when Clozapine concentrations are lower than expected. **Clinical Information:** Normal reference range is based on therapeutic range. **Specimen Requirement:** 1 mL serum from plain red tube; Minimum 0.5 mL; Refrigerated; Centrifuge and aliquot within 2 hours of collection. Refrigerate serum aliquot. **Stability:** Ambient: 7 days Refrigerated: 21 days Frozen: 21 days **Methodology:** Turbidimetric Immunoassay (TUI) **Reference Range:** 350–600 ng/mL; Critical > 1000 ng/mL **Days Performed:** 6 days per week **Reported:** 1–4 days **CPT:** 80159 **Price:** $50.00	5/23/23

Fee Increases

Test Name	Order Code	List Fee	CPT Code	Effective Date
LH, Pediatric	LHPED	$255.00	83002	5/11/23
Platelet Aggregation	AGGPLP	$976.00	**82397x8; 85576x11; 85390x1**	5/9/23

Fee Reductions

Test Name	Order Code	List Fee	CPT Code	Effective Date
Fungus CSF Culture/CAD	FUNCSF	$81.00	87102; **87899**	effective immediately

Discontinued Tests

Test Name	Order Code	Test Information	Effective Date
Circulating Tumor Cell Count	CTCBPC	Test will no longer be orderable. There is no recommended replacement.	5/15/23
Clozapine and Metabolites, Serum or Plasma, Quantitative	CLOZSP	Test will no longer be orderable. Recommended replacement test is Clozapine (CLOZA).	6/20/23
Cross-Linked N-telopeptide, Serum	NTX	Test will no longer be orderable. Recommended replacement test is C Telopeptide, Beta Cross Linked (CTELO).	effective immediately
Epi ProColon	EPCOL	Test will no longer be orderable. There is no recommended replacement.	effective immediately
GC/Chlamydia Amplification, Urine	UGCCT	Test will no longer be orderable. Recommended replacement test is Neisseria gonorrhoeae (GC) & Chlamydia trachomatis (CT), NAAT (GCCT).	6/20/23
GlycoMark	GLYMRK	Test will no longer be orderable. Recommended replacement test is 1,5 Anhydroglucitol (15AGTL).	6/20/23
Helicobacter pylori Breath Test, Pediatric	HPYBRP	Test will no longer be orderable. Recommended replacement test is Helicobacter pylori Breath Test (HPYLBR).	5/2/23
HIV-2 Antibody Confirmation, Serum	HIV2CN	Test will no longer be orderable. Recommended replacement test is HIV-2 DNA/RNA PCR (HIV2PC)	5/9/23
Measles Virus Culture (Rubeola)	MEASLE	Test will no longer be orderable. There is no recommended replacement.	5/15/23
Mumps Virus Culture	MUMP	Test will no longer be orderable. Recommended replacement test is Mumps Virus RNA, Qualitative Real-Time PCR (MUMPCR).	5/15/23
Nocardia Culture and Stain	NOCARD	Test will no longer be orderable. Recommended replacement test is AFB Culture & Stain (AFC) if looking for Nocardia.	6/20/23
Nocardia Culture Only	NOCARC	Test will no longer be orderable. Recommended replacement test is AFB Culture & Stain (AFC) if looking for Nocardia.	6/20/23
Nocardia Stain Only	NOCARS	Test will no longer be orderable. Recommended replacement test is AFB Culture & Stain (AFC) if looking for Nocardia.	6/20/23
Prothrombin Time and PTT Elevation Diagnostic Panel	PTPTTE	Test will no longer be orderable. Recommended replacement tests are PTT Incubated Mixing Study (PTTIM) and/or Prothrombin Time Mixing Study (PTMIX).	6/20/23
Prothrombin Time Elevation Diagnostic Panel	PTEPNL	Test will no longer be orderable. Recommended replacement test is Prothrombin Time Mixing Study (PTMIX).	6/20/23
PTT Elevation Diagnostic Panel	PTTEPL	Test will no longer be orderable. Recommended replacement test is PTT Incubated Mixing Study (PTTIM).	6/20/23