Cleveland Clinic

Cleveland Clinic Laboratories

Technical Update • August 2024

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

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

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

For additional detail, contact Laboratory Customer Service at 216.444.5755 or 800.628.6816, or via email at clientservices@ccf.org.

Test Update Page #	Summary of Changes by Test Name	Order Code	Name Change	New Test	Test Discontinued	Special Information	Specimen Requirement	Component Change(s)	Methodology	Reference Range	Days Performed/Reported	Stability	CPT
3	5-Flucytosine, Antibiotic Assay, Serum		■			■	■		■	■	■	■	
3	AFP, Serum (Tumor Marker)							■					
3	Angelman Syndrome and Prader-Willi Syndrome by Methylation-Specific MLPA		■				■						
4	Anti-HMGCR Antibody, IgG		■			■	■						
20	Anti-sp100 and anti-gp210 Antibodies, IgG			■									
4	Antimicrobial Susceptibility – Not Otherwise Specified											■	
20	Aripiprazole and Metabolite			■									
4	Autoimmune Encephalopathy Evaluation, CSF										■		
4	Bacterial Vaginosis (BV), NAAT					■							
4	Benzene Quantitation, Whole Blood						■		■		■		
5	Beta-2 Transferrin					■	■					■	
5–6	BK Virus (BKV) DNA, Quantitative PCR, Plasma		■			■	■	■					
6–7	BK Virus (BKV) DNA, Quantitative PCR, Urine		■			■	■	■					
7	Candida & Trichomonas vaginalis, NAAT					■							
8	Chlamydia trachomatis and Neisseria gonorrhoeae by Transcription-Mediated Amplification (TMA), Ocular specimens		■			■		■				■	
8	Chlamydia trachomatis by Transcription-Mediated Amplification (TMA), Ocular specimens		■			■	■	■			■		
8	Cortisol by LC-MS/MS, Serum or Plasma		■				■						

Test Update Page #		Order Code	Name Change	New Test	Test Discontinued	Special Information	Specimen Requirement	Component Change(s)	Methodology	Reference Range	Days Performed/Reported	Stability	CPT
9	Cytomegalovirus (CMV) DNA, Qualitative PCR, Non-Plasma					■	■	■					
10	Cytomegalovirus (CMV) DNA, Quantitative PCR, Plasma					■	■	■					
11–12	Epstein-Barr Virus (EBV) DNA, Quantitative PCR, Plasma		■			■	■	■					
12	Fibrinogen Antigen					■			■		■		
12	Flow Cytometric Immunophenotyping for Leukemia/ Lymphoma											■	
12–13	Hepatitis B Virus (HBV) DNA, Quantitative PCR, Plasma/Serum		■			■	■	■					
13–15	Hepatitis C Virus (HCV) RNA, Quantitative PCR, Plasma/Serum		■			■	■	■					
22	Her-2-Neu Serum				■								
15	Histoplasma Galactomannan EIA, CSF						■					■	
22	HIV Phenotype				■								
15–16	Human Immunodeficiency Virus 1 (HIV-1) RNA, Quantitative PCR, Plasma		■			■	■	■					
16	Hypersensitivity Pneumonitis Evaluation						■						
22	Lactate, Precipitated				■								
16	Lactate/Pyruvate					■	■						
22	Mycobacterium tuberculosis Detection and Rifampin Resistance by PCR, Respiratory				■								
16	Neisseria gonorrhoeae by Transcription-Mediated Amplification (TMA), Ocular specimens		■			■	■	■			■		
16	Paraneoplastic Autoantibody Evaluation, CSF										■		
16	Prolactin									■			
17	Prothrombin Antibody, IgG		■			■	■						
17	Pseudocholinesterase, Total		■			■	■		■	■	■	■	■
17	Pyruvic Acid					■	■						
18	Pyruvic Acid, CSF					■	■					■	
18	RBC Band 3 Protein Reduction in Hereditary Spherocytosis					■	■						
18	Selenium Blood					■							
18	Telomere Length Measurement						■						
22	Testosterone, Free, Adult Males by ED/LC-MS/MS				■								
22	Testosterone, Free/Total, Males by ED/LC-MSMS				■								
18	Thyroglobulin Antibody					■							
18	Thyroglobulin, Serum with Reflex to IA or LC-MS/MS					■							
18	Torch Antibodies, IgM					■		■	■	■			■
19	Treponema pallidum Antibody, IgG by IFA (CSF)		■			■					■		
19	Trofile Co-receptor Tropism Assay					■	■	■			■		
21	TSH w/Reflex			■									

Test Update Page #		Order Code	Name Change	New Test	Test Discontinued	Special Information	Specimen Requirement	Component Change(s)	Methodology	Reference Range	Days Performed/Reported	Stability	CPT
21	Tuberculosis PCR and Culture, Respiratory			■									
19	UBA1 Mutation Testing for VEXAS Syndrome					■	■						
19	Vasoactive Intestinal Polypeptide (VIP), Plasma		■			■	■		■	■	■	■	

Test Changes

Test Name	Order Code	Change	Effective Date
5-Flucytosine, Antibiotic Assay, Serum	FLCYT	**Name:** Previously Antibiotic Assay Flucytosine **Special Information:** This test is New York state approved. **Clinical Information: This test is useful for monitoring serum concentration during therapy, evaluating potential toxicity, and evaluating patient compliance.** **Specimen Requirement: 0.5** mL serum from no additive (Red) tube; Minimum: **0.3** mL; **Refrigerated; Trough specimen should be collected immediately prior to next dose. Peak level should be collected 1 to 2 hours after oral dose, or 30 minutes after IV infusion. Separate serum from cells ASAP or within 2 hours of collection and transfer to standard aliquot tube.** **Stability:** Ambient: **28 days** Refrigerated: **28 days** Frozen: **28 days** **Methodology: Liquid Chromatography-Tandem Mass Spectrometry (LC-MS/MS)** **Reference Range:** Antibiotic Assay Flucytosine: **Therapeutic: Peak >25.0 mcg/mL (difficult infections may require higher concentrations)** **Toxic: Peak >100.0 mcg/mL** **Days Performed: Tue, Thu** **Reported: 4–9** days	8/19/24
AFP, Serum (Tumor Marker)	AFP	**For interface clients only–Test build may need to be modified** **Includes:** AFP, Tumor Marker DxI **Note:** *AFP, Tumor Marker Centaur XP will be removed* **Special Information:** The Alpha-Fetoprotein test was performed using the Beckman Unicel DxI immunoenzymatic assay. Results obtained with different assay methods or kits cannot be used interchangeably. **Methodology:** Immunoenzymatic Assay	9/10/24
Angelman Syndrome and Prader-Willi Syndrome by Methylation-Specific MLPA	PRADER	**Name:** Previously Prader-Willi/Angelman Methylation **Specimen Requirement:** 3 mL whole blood in EDTA (Lavender) tube; Refrigerated. Note: *ACD A or B (Yellow) tubes are no longer acceptable*	8/19/24

Test Changes (Cont.)

Test Name	Order Code	Change	Effective Date
Anti-HMGCR Antibody, IgG	HMGCR	**Name:** Previously Anti-HMGCR Autoantibodies **Special Information:** Contaminated, **or severely** hemolyzed, icteric, or lipemic specimens **will be rejected. This test is New York state approved.** **Clinical Information:** Useful for differential diagnosis of myositis in patients with or without statin exposure. IgG antibodies to 3-hydroxy-3-methylglutaryl-coenzyme A reductase (HMGCR) are mainly associated with necrotizing autoimmune myopathy (NAM) in a subset of statin-treated patients. Although infrequent, these antibodies may also be observed in statin-naive patients with NAM. Strong clinical correlation is recommended in the absence of muscle fiber necrosis, elevated serum creatine kinase, perimysial pathology, and/or statin exposure. **Specimen Requirement:** 0.5 mL serum from serum separator (Gold) tube; Minimum: **0.3** mL; Refrigerated; **Separate serum from cells ASAP or within 2 hours of collection and** transfer to standard aliquot tube.	8/19/24
Antimicrobial Susceptibility–Not Otherwise Specified	SUSNOS	**Stability:** Ambient: 1 week Refrigerated: **Unacceptable** Frozen: Unacceptable	8/19/24
Autoimmune Encephalopathy Evaluation, CSF	ENCCSF	**Reported: 9–13** days	effective immediately
Bacterial Vaginosis (BV), NAAT	BVAMP	**Special 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. **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%. 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. 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.	effective immediately
Benzene Quantitation, Whole Blood	BENZE	**Specimen Requirement: 5** mL whole blood in potassium oxalate/sodium fluoride (Gray) tube; Minimum: **2.2** mL; Refrigerated; Send whole blood in original collection tube**(s). Separate specimens must be submitted when multiple tests are ordered.** **Methodology: Gas Chromatography Mass Spectrometry (GCMS)** **Reported: 4–11** days	effective immediately

Test Changes (Cont.)

Test Name	Order Code	Change	Effective Date
Beta-2 Transferrin	B2TRAN	**Special Information: If direct collection is not feasible, specimen may be collected using a plain cotton swab or gauze and submitted in a sterile container (plain test tube, collection container, microtube, or syringe). Do not collect with a culture swab. Specimens collected with additives or grossly contaminated with blood will be rejected. This test is New York State approved.** **Clinical Limitation: Aural or nasal specimens may be contaminated with saliva, which can degrade transferrin protein. Specimens should be frozen immediately after collection.** **Clinical Information:** Detection of a beta-2 transferrin band by **immunofixation** is **indicative of** the presence of cerebrospinal fluid. **Specimen Requirement:** 2 mL aural or nasal fluid in sterile container; **Frozen** **Stability:** Ambient: **2 weeks** Refrigerated: **2 weeks** Frozen: **2 weeks**	8/19/24
BK Virus (BKV) DNA, Quantitative PCR, Plasma	BKQUAN	**For interface clients only–Test build may need to be modified** **Name:** Previously BK Virus DNA Quantification **Special Information: BKQUAN should only be utilized for EDTA plasma. For urine, utilize UBKQT.** **Clinical Limitation: For full limitations, refer to the assay instructions for use available on the manufacturer's website. The most important limitations are summarized as follows. Recommendations regarding monitoring BKV viral load post-transplant and medically relevant BKV DNA thresholds vary among transplant type and transplant institutions. As with any molecular test, mutations within the target regions of cobas BKV could affect primer and/or probe binding resulting in the under-quantitation of virus or failure to detect the presence of virus. Due to the potential for variability in BKV DNA measurements across different BKV assays, it is recommended that the same device be used for the serial quantitation of BKV DNA when managing individual patients.** **Clinical Information: BK virus (BKV) is a common viral pathogen that can cause polyoma virus nephropathy in kidney transplant patients. It is also associated with hemorrhagic cystitis in immunocompromised patients, especially in hematopoietic stem cell transplant recipients. cobas BKV is an FDA-approved in vitro nucleic acid amplification test for the quantitation of BK virus (BKV) DNA in human EDTA plasma and urine stabilized in cobas PCR Media. In EDTA plasma, cobas BKV is intended for use as an aid in the management of BKV in transplant patients. In patients undergoing monitoring of BKV in EDTA plasma, serial DNA measurements can be used to indicate the need for potential treatment changes and to assess viral response to treatment. In urine stabilized in cobas PCR Media, cobas BKV is intended for use as an aid in the management of BKV in transplant patients. The results from cobas BKV are intended to be read and analyzed by a qualified licensed healthcare professional in conjunction with clinical signs and symptoms and relevant laboratory findings. Test results must not be the sole basis for patient management decisions. The assay is a quantitative PCR assay that targets highly-conserved regions of the BKV located in the BKV small t-antigen region and the BKV VP2 region, and is reported out in international units (IU/mL). The linear range of the assay in EDTA plasma is 21.5 to 100,000,000 IU/mL (1.33–8.00 log IU/mL). The lower limit of detection of the assay in EDTA plasma is 21.5 IU/mL.** **Specimen Requirement:** 2 mL plasma from EDTA plasma preparation (White) tube; **Minimum volume for testing is 1.0 mL of plasma. Aliquots must be made from specimen prior to testing in any lab outside of Molecular Microbiology, and must be placed in a sterile aliquot tube. Centrifuge and** refrigerate. **Collect EDTA plasma according to standard protocol. Separate plasma by centrifugation (at 1,100 RCF for a minimum of 10 minutes)** within 24 hours of collection. **Plasma must be aliquoted first if sample is to be frozen.** Sample cannot be shared with a test performed outside of Molecular Microbiology. Sample can only be shared with CMVQNT, HCQPCR, HIVRNA, HBVDNU, EBVQNT, or BKQUAN. *OR* 2 mL plasma from EDTA (Lavender) tube; **Minimum volume for testing is 1.0 mL of plasma. Aliquots must be made from specimen prior to testing in any lab outside of Molecular Microbiology, and must be placed in a sterile aliquot tube. Centrifuge, aliquot and** refrigerate **ASAP. Collect EDTA plasma according to standard protocol. Centrifuge (at >1300 RCF for a minimum of 10 minutes) and aliquot into a sterile secondary tube** within 24 hours of collection. **Plasma must be aliquoted first if sample is to be frozen.** Sample cannot be shared with a test performed outside of Molecular Microbiology. Sample can only be shared with CMVQNT, HCQPCR, HIVRNA, HBVDNU, EBVQNT, or BKQUAN. *(continued on page 6)*	10/8/24

Test Changes (Cont.)

Test Name	Order Code	Change	Effective Date
BK Virus (BKV) DNA, Quantitative PCR, Plasma *(continued from page 5)*	BKQUAN	**Stability:** Ambient: 24 hours **for plasma or for whole blood unspun/unseparated** Refrigerated: 6 days **for plasma separated from whole blood within 24 hours; 24 hours for whole blood unspun/unseparated** Frozen: 6 months **for plasma if separated from whole blood and aliquoted into a secondary tube within 24 hours (plasma cannot be frozen in PPT tubes)** **Methodology: Polymerase Chain Reaction (PCR), Quant** **Reference Range:** BKV DNA: **Not detected** **Plasma BKV** DNA (IU/mL): *No reference range* **Plasma BKV** DNA (log IU/mL): *No reference range* **Days Performed: 7** days a week **Reported: 1–3** days	10/8/24
BK Virus (BKV) DNA, Quantitative PCR, Urine	UBKQT	**For interface clients only–Test build may need to be modified** **Name:** Previously BK Virus Quantitation, Urine **Special Information: UBKQT should only be utilized for urine. For EDTA plasma, utilize BKQUAN.** **Clinical Limitation: For full limitations, refer to the assay instructions for use available on the manufacturer's website. The most important limitations are summarized as follows. Recommendations regarding monitoring BKV viral load post-transplant and medically relevant BKV DNA thresholds vary among transplant type and transplant institutions. As with any molecular test, mutations within the target regions of cobas BKV could affect primer and/or probe binding resulting in the under-quantitation of virus or failure to detect the presence of virus. Due to the potential for variability in BKV DNA measurements across different BKV assays, it is recommended that the same device be used for the serial quantitation of BKV DNA when managing individual patients.** **Clinical Information: BK virus (BKV) is a common viral pathogen that can cause polyoma virus nephropathy in kidney transplant patients. It is also associated with hemorrhagic cystitis in immunocompromised patients, especially in hematopoietic stem cell transplant recipients. cobas BKV is an FDA-approved in vitro nucleic acid amplification test for the quantitation of BK virus (BKV) DNA in human EDTA plasma and urine stabilized in cobas PCR Media. In EDTA plasma, cobas BKV is intended for use as an aid in the management of BKV in transplant patients. In patients undergoing monitoring of BKV in EDTA plasma, serial DNA measurements can be used to indicate the need for potential treatment changes and to assess viral response to treatment. In urine stabilized in cobas PCR Media, cobas BKV is intended for use as an aid in the management of BKV in transplant patients. The results from cobas BKV are intended to be read and analyzed by a qualified licensed healthcare professional in conjunction with clinical signs and symptoms and relevant laboratory findings. Test results must not be the sole basis for patient management decisions. The assay is a quantitative PCR assay that targets highly-conserved regions of the BKV located in the BKV small t-antigen region and the BKV VP2 region, and is reported out in international units (IU/mL). The linear range of the assay in urine is 200 to 100,000,000 IU/mL (2.30–8.00 log IU/mL). The lower limit of detection of the assay in urine is 12.2 IU/mL.** **Specimen Requirement:** 5 mL random urine in sterile container; Refrigerated; **Collect or transfer 5 mL of urine into a sterile, plastic, preservative-free container.** Specimen must be transferred into cobas PCR Urine Sample Kit within 24 hours of collection. **The correct volume of urine has been added when the fluid level is between the two black lines on the tube label.** **Stability:** Ambient: 24 hours **for neat urine; 90 days for urine stabilized in cobas PCR media** Refrigerated: 24 hours **for neat urine; 90 days for urine stabilized in cobas PCR media** **Methodology: Polymerase Chain Reaction (PCR), Quant** **Reference Range:** **BKV DNA: Not detected** **Urine BKV DNA (IU/mL): *No reference range*** **Urine BKV DNA (log IU/mL): *No reference range*** **Days Performed: 7 days a week** **Reported: 1–3** days *(continued on page 7)*	10/8/24

Test Changes (Cont.)

Test Name	Order Code	Change	Effective Date
BK Virus (BKV) DNA, Quantitative PCR, Urine *(continued from page 6)*	UBKQT	**Specimen Requirement:** 5 mL random urine in sterile container; Refrigerated; **Collect or transfer 5 mL of urine into a sterile, plastic, preservative-free container.** Specimen must be transferred into cobas PCR Urine Sample Kit within 24 hours of collection. **The correct volume of urine has been added when the fluid level is between the two black lines on the tube label.** **Stability:** Ambient: 24 hours **for neat urine; 90 days for urine stabilized in cobas PCR media** Refrigerated: 24 hours **for neat urine; 90 days for urine stabilized in cobas PCR media** **Methodology: Polymerase Chain Reaction (PCR), Quant** **Reference Range:** **BKV DNA: Not detected** **Urine BKV DNA (IU/mL): *No reference range*** **Urine BKV DNA (log IU/mL): *No reference range*** **Days Performed: 7 days a week** **Reported: 1–3** days	10/8/24
Candida & Trichomonas vaginalis, NAAT	CVTV	**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. FUNGSC: in-house **Yeast Screen (culture).** Note that the Aptima Multitest Swab Specimen cannot be used to add-on FUNGSC. Please refer to FUNGSC test directory entry for specimen collection requirements and details. **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, and 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. Trichomonas only testing by NAAT is available as a stand-alone test (order code TRVAMP) when complicated vulvovaginal candidiasis is not on the differential. **Yeast screen** is available as a stand-alone test (order code FUNGSC) and is the test of choice when trying to recover a **yeast** isolate for potential susceptibility testing. FUNGSC cannot be added onto the Aptima Multitest Swab Specimen – please refer to FUNGSC test directory entry for specimen collection requirements and details.	effective immediately

Test Changes (Cont.)

Test Name	Order Code	Change	Effective Date
Chlamydia trachomatis and Neisseria gonorrhoeae by Transcription-Mediated Amplification (TMA), Ocular specimens	CTNGAO	**For interface clients only–Test build may need to be modified** **Name:** Previously Chlamydia trachomatis and Neisseria gonorrhoeae, NA Amplification, Ocular specimens **Includes:** **C. trachomatis by TMA** **N. gonorrhoeae by TMA** **APTIMA Media Type** **Specimen Source** **Special Information:** Specimens must be collected using an APTIMA Multitest or Unisex swab collection kit. Specimen source is required. This test is New York State approved. **Clinical Information:** This report is intended for use in clinical monitoring or management of patients; it is not intended for use in medico-legal applications. **Specimen Requirement:** One **eye** Aptima Multitest **Swab**; Refrigerated; Ocular (corneal/conjunctiva) sites only. Indicate specimen source. *OR* One **eye** Aptima Unisex Swab; Refrigerated; Ocular (corneal/conjunctiva) sites only. Indicate specimen source. **Stability:** Ambient: 60 days Refrigerated: 60 days Frozen: **1 year**	10/15/24
Chlamydia trachomatis by Transcription-Mediated Amplification (TMA), Ocular specimens	CTNAAO	**For interface clients only–Test build may need to be modified** **Name:** Previously Chlamydia trachomatis, NA Amplification, Ocular specimens **Includes:** **C. trachomatis by TMA** **APTIMA Media Type** Specimen Source **Special Information:** Specimens must be collected using an APTIMA **Multitest or Unisex** swab collection kit. Specimen source is required. This test is New York State approved. **Clinical Information:** This report is intended for use in clinical monitoring or management of patients; it is not intended for use in medico-legal applications. **Specimen Requirement: One eye Aptima Multitest Swab; Refrigerated; Ocular (corneal/conjunctiva) sites only. Indicate specimen source.** *OR* One **eye** Aptima Unisex Swab; Refrigerated; Ocular (corneal/conjunctiva) sites only. Indicate specimen source. **Days Performed: Sun**–Sat **Reported:** 2–**5** days	10/15/24
Cortisol by LC-MS/MS, Serum or Plasma	PCORT	**For interface clients only–Test build may need to be modified** **Name:** Previously Cortisol, Plasma **Includes:** Cortisol **by LC-MS/MS, Serum or** Plasma **Specimen Requirement:** 1 mL plasma from sodium or lithium heparin (Green) tube; Frozen; Specimen should be collected between 8-10 a.m. Separate plasma from cells ASAP or within 2 hours of collection and transfer into standard aliquot tube. *OR* 1 mL plasma from EDTA (Lavender) tube; Frozen; Specimen should be collected between 8-10 a.m. Separate plasma from cells ASAP or within 2 hours of collection and transfer into standard aliquot tube. *OR* **1 mL serum from serum separator (Gold) tube; Frozen; Specimen should be collected between 8-10 a.m. Separate serum from cells ASAP or within 2 hours of collection and transfer into standard aliquot tube.**	10/8/24

Test Changes (Cont.)

Test Name	Order Code	Change	Effective Date
Cytomegalovirus (CMV) DNA, Qualitative PCR, Non-Plasma	CMVQL	**For interface clients only–Test build may need to be modified** **Special Information: CMVQL should only be used for saliva and urine. For EDTA plasma, utilize CMVQNT. For amniotic fluid, utilize CMVAMF. For all other specimen types (CSF, BAL, fluids, tissue, bone marrow), utilize CMVCSF.** **Clinical Limitation: For full limitations, refer to the assay instructions for use available on the manufacturer's website. The most important limitations are summarized as follows. Mutations within the highly-conserved regions of the CMV DNA polymerase (UL54) gene covered by cobas CMV may affect primers and/or probe binding resulting in the failure to detect the presence of virus. The cobas CMV mitigates this risk through the use of redundant amplification primers. Detection of CMV in patients >21 days of age is not specific for congenital CMV (cCMV), and could be the result of postnatal infection. Detection of CMV in saliva could be due to contamination from human milk feeding or other sources. Confirmation with a second specimen (ideally urine) is recommended.** Samples containing mucin at concentrations >25 mg/mL may produce invalid results with the CMV assay. The results of **this assay** are not intended to be used as the sole basis for diagnosis, treatment, or other patient management decisions. Viral nucleic acid may persist in vivo, independent of viability, **and the** assay does not distinguish between viable and nonviable virus. **Clinical Information: Cytomegalovirus (CMV) is a common viral pathogen that can cause severe disease in immunocompromised patients, and lead to a range of presentations in congenitally-exposed infants. The cobas CMV assay is an FDA-approved test for human EDTA plasma, which has been modified and validated as a lab-develop test to accept alternative sample types of saliva swabs in viral transport media and urine for qualitative CMV detection. The assay is a real-time PCR assay that targets highly-conserved regions of the CMV DNA polymerase (UL54) gene.** The results of this test should be **interpreted within the context of all relevant clinical and laboratory findings.** **Specimen Requirement:** 3 mL saliva in Universal Transport Media (UTM); **The minimum volume of saliva swab transport media accepted is 1 mL.** Refrigerated; Saliva swab specimens are only accepted from infants less than 21 days of age. Obtain a regular-tip flocked swab and tube containing 3 mL Universal Transport Medium. Confirm that the **infant has not been fed with human milk within the** 1 hour before specimen collection. **Infant** can be held or remain in the bassinet for specimen collection. Wash hands and put gloves on. Remove the sterile flocked swab from its wrapping. Place the swab between the baby's cheek and gum on one side of the mouth. Keep the swab in place for 10-15 seconds. Move the swab to the other side of the mouth for another 10-15 seconds. Make sure the swab appears moist when removed. Remove the swab from the mouth and insert it into the UTM tube. Break off the swab tip. Close the cap. *OR* 5 mL random urine in sterile container; **The minimum volume of urine accepted is 1 mL**.Refrigerated; Collect or transfer **5 mL** of urine into a sterile, **plastic, preservative-free** container. Specimen must be transferred into cobas PCR Urine Sample Kit within 24 hours of collection. The correct volume of urine has been added when the fluid level is between the two black lines on the tube label. **Stability:** Ambient: 48 hours for saliva **swab** in UTM; 24 hours for neat urine; 90 days for urine stabilized in cobas PCR media Refrigerated: 7 days for saliva **swab** in UTM; 24 hours for neat urine; 90 days for urine stabilized in cobas PCR media Frozen: 14 days for saliva **swab in UTM**; Not acceptable for urine **Methodology: Real-Time Polymerase Chain Reaction (RT-PCR)** **Reference Range:** **CMV DNA: Not detected**	10/8/24

Test Changes (Cont.)

Test Name	Order Code	Change	Effective Date
Cytomegalovirus (CMV) DNA, Quantitative PCR, Plasma	CMVQNT	**For interface clients only–Test build may need to be modified** **Special Information: CMVQNT should only be utilized for EDTA plasma. For saliva and urine, utilize CMVQL. For amniotic fluid, utilize CMVAMF. For all other specimen types (CSF, BAL, fluids, tissue, bone marrow), utilize CMVCSF.** **Clinical Limitation: For full limitations, refer to the assay instructions for use available on the manufacturer's website. The most important limitations are summarized as follows. Mutations within the highly-conserved regions of the CMV DNA polymerase (UL54) gene covered by cobas CMV may affect primers and/or probe binding resulting in the under-quantitation of virus or failure to detect the presence of virus. The cobas CMV mitigates this risk through the use of redundant amplification primers. Negative test results do not preclude CMV infection or tissue-invasive CMV disease, and test results should therefore not be the sole basis for patient management decisions. Due to potential variability from measurements with different CMV assays, it is recommended that the same device (or assay) be used for the measurement of CMV viral load when managing CMV infection in individual patients. Current guidelines based on the precision of PCR tests suggest that the changes in serial viral load measurements should be at least 3-fold (0.5 log10) to represent biologically important changes.** **Clinical Information: Cytomegalovirus (CMV) is a common viral pathogen that can cause severe disease in immunocompromised patients, and lead to a range of presentations in congenitally-exposed infants. cobas CMV is an FDA-approved in vitro nucleic acid amplification test for the quantitation of cytomegalovirus (CMV) DNA in human EDTA plasma, and is intended for use as an aid in the management of CMV in solid organ transplant patients and in hematopoietic stem cell transplant patients. In patients receiving anti-CMV therapy, serial DNA measurements can be used to assess viral response to treatment. The results from cobas CMV must be interpreted within the context of all relevant clinical and laboratory findings. This test is not intended for use as a screening test for blood or blood products. The assay is a quantitative PCR assay that targets highly-conserved regions of the CMV DNA polymerase (UL54) gene, and is reported out in international units (IU/mL). The linear range of the assay is 34.5 to 10,000,000 IU/mL (1.54–7.00 log IU/mL). The lower limit of detection of the assay is 34.5 IU/mL.** **Specimen Requirement:** 2 mL plasma from EDTA plasma preparation (White) tube; **Minimum volume for testing is 1.0 mL of plasma. Aliquots must be made from specimen prior to testing in any lab outside of Molecular Microbiology, and must be placed in a sterile aliquot tube.** Centrifuge and refrigerate. **Collect EDTA plasma according to standard protocol.** Plasma must be separated from whole blood within 36 hours of collection by centrifugation **(at 1,100 RCF for a minimum of 10 minutes)** for samples stored at 2-25 degrees Celsius. **Specimen stability is increased to 6 days if plasma is separated from whole blood within 24 hours and stored at 2-8 degrees Celsius. Plasma must be aliquoted first if sample is to be frozen.** Sample cannot be shared with a test performed outside of Molecular Microbiology. Sample can only be shared with CMVQNT, HCQPCR, HIVRNA, HBVDNU, EBVQNT, or BKQUAN. *OR* 2 mL plasma from EDTA (Lavender) tube; **Minimum volume for testing is 1.0 mL of plasma. Aliquots must be made from specimen prior to testing in any lab outside of Molecular Microbiology, and must be placed in a sterile aliquot tube.** Centrifuge, aliquot and refrigerate ASAP. **Collect EDTA plasma according to standard protocol. Centrifuge (at >1300 RCF for a minimum of 10 minutes), aliquot into a sterile secondary tube, and test within 36 hours of collection. Specimen stability is increased to 6 days if plasma is separated from whole blood within 24 hours and stored at 2-8 degrees Celsius. Plasma must be aliquoted first if sample is to be frozen.** Sample cannot be shared with a test performed outside of Molecular Microbiology. Sample can only be shared with CMVQNT, HCQPCR, HIVRNA, HBVDNU, EBVQNT, or BKQUAN. **Stability:** Ambient: 36 hours **for plasma or for whole blood unspun/unseparated** Refrigerated: 6 days **for plasma separated from whole blood within 24 hours;** 36 hours **for whole blood unspun/unseparated** Frozen: 12 weeks **for plasma if separated from whole blood and aliquoted into a secondary tube within 24 hours (plasma cannot be frozen in PPT tubes)** **Reference Range:** **CMV DNA: Not detected** CMV DNA (IU/mL): ***No reference range*** CMV DNA (log IU/mL): ***No reference range*** **Days Performed: 7 days a week 24 hours** **Reported: 1–3** days	10/8/24

Test Changes (Cont.)

Test Name	Order Code	Change	Effective Date
Epstein-Barr Virus (EBV) DNA, Quantitative PCR, Plasma	EBVQNT	**For interface clients only–Test build may need to be modified** **Name:** Previously Epstein-Barr Virus DNA Quantification by PCR **Includes:** **EBV DNA** EBV DNA (IU/mL) EBV DNA (log IU/mL) **Clinical Limitation: For full limitations, refer to the assay instructions for use available on the manufacturer's website. The most important limitations are summarized as follows. Recommendations regarding monitoring EBV viral load post-transplant and medically relevant EBV DNA thresholds vary among transplant type and transplant institutions. While elevated EBV viral load may suggest post-transplant lymphoproliferative disorders (PTLD), the diagnosis of PTLD is made based on histological evaluation of tissue biopsy. PTLD may be present without detectable EBV viral load, and an increase in EBV viral load is not necessarily diagnostic of PTLD. As with any molecular test, mutations within the target regions of cobas EBV could affect primer and/or probe binding resulting in the under-quantitation of virus or failure to detect the presence of virus. Due to the potential for variability in EBV DNA measurements across different EBV assays, it is recommended that the same device be used for the serial quantitation of EBV DNA when managing individual patients.** **Clinical Information: Epstein-Barr virus (EBV) is a common viral pathogen that can cause disease in transplant recipients through reactivation of latent virus or through a new primary infection, especially in EBV-negative transplant recipients who receive grafts from EBV-positive donors. For these patients, the most severe form of EBV-related disease is post-transplant lymphoproliferative disorder (PTLD), which results from uncontrolled proliferation of lymphocytes, typically B cells. Early identification of primary EBV infections and DNA level monitoring can support prompt therapeutic intervention to prevent progression to EBV-related disease. cobas EBV is an FDA-approved in vitro nucleic acid amplification test for the quantitation of Epstein-Barr virus (EBV) DNA in human EDTA plasma. cobas EBV is intended for use as an aid in the management of EBV in transplant patients. In patients undergoing monitoring of EBV, serial DNA measurements can be used to indicate the need for potential treatment changes and to assess response to treatment. The results from cobas EBV are intended to be read and analyzed by a qualified licensed healthcare professional in conjunction with clinical signs and symptoms and relevant laboratory findings. Negative test results do not preclude EBV infection or EBV disease. Test results must not be the sole basis for patient management decisions. cobas EBV is not intended for use as a screening test for donors of blood or blood products or human cells, tissues, and cellular and tissue-based products (HCT/Ps). The assay is a quantitative PCR assay that targets highly-conserved regions of the EBV located in the EBV EBNA-1 gene and the EBV BMRF gene, and is reported out in international units (IU/mL). The linear range of the assay is 35.0 to 100,000,000 IU/mL (1.54–8.00 log IU/mL). The lower limit of detection of the assay is 18.8 IU/mL.** **Specimen Requirement:** 2 mL plasma from EDTA plasma preparation (White) tube; **Minimum volume for testing is 1.0 mL of plasma. Aliquots must be made from specimen prior to testing in any lab outside of Molecular Microbiology, and must be placed in a sterile aliquot tube. Centrifuge and** refrigerate.**Collect EDTA plasma according to standard protocol. Separate plasma by centrifugation (at 1,100 RCF for a minimum of 10 minutes) within 24 hours of collection. Plasma must be aliquoted first if sample is to be frozen.** Sample cannot be shared with a test performed outside of Molecular Microbiology. Sample can only be shared with CMVQNT, HCQPCR, HIVRNA, HBVDNU, EBVQNT, or BKQUAN. *OR* **2 mL plasma from EDTA (Lavender) tube; Minimum volume for testing is 1.0 mL of plasma. Aliquots must be made from specimen prior to testing in any lab outside of Molecular Microbiology, and must be placed in a sterile aliquot tube. Centrifuge, aliquot and refrigerate ASAP. Collect EDTA plasma according to standard protocol. Centrifuge (at >1300 RCF for a minimum of 10 minutes) and aliquot into a sterile secondary tube within 24 hours of collection. Plasma must be aliquoted first if sample is to be frozen. Sample cannot be shared with a test performed outside of Molecular Microbiology. Sample can only be shared with CMVQNT, HCQPCR, HIVRNA, HBVDNU, EBVQNT, or BKQUAN.** *(continued on page 12)*	10/8/24

Test Changes (Cont.)

Test Name	Order Code	Change	Effective Date
Epstein-Barr Virus (EBV) DNA, Quantitative PCR, Plasma *(continued from page 11)*	EBVQNT	**Stability:** Ambient: 24 hours **for plasma or for whole blood unspun/unseparated** Refrigerated: 6 days **for plasma separated from whole blood within 24 hours; 24 hours for whole blood unspun/unseparated** Frozen: 6 months for plasma **if separated from whole blood and aliquoted into a secondary tube within 24 hours (plasma cannot be frozen in PPT tubes)** **Methodology: Polymerase Chain Reaction (PCR), Quant** **Reference Range:** **EBV DNA: Not detected** **Days Performed: 7 days a week** **Reported: 1–3** days	10/8/24
Fibrinogen Antigen	FIBRAG	**Special Information:** 3.2% sodium citrate is the preferred anticoagulant recommended by NCCLS. Serum or hemolyzed specimens are unacceptable. **This test is New York State approved.** **Methodology: Quantitative Immunoturbidimetric** **Days Performed: Tue, Fri** **Reported:** 3–**5** days	8/19/24
Flow Cytometric Immunophenotyping for Leukemia/ Lymphoma	RLLLIP	**Specimen Requirement:** 4 mL bone marrow in sodium heparin (Green) tube; Ambient **or Refrigerated**; Include unstained bone marrow slide. Label bone marrow slide with patient ID number using solvent-resistant marker. **New York samples >8 hours old must be refrigerated.** *OR* **4** mL whole blood in EDTA (Lavender) tube; Ambient **or Refrigerated; New York samples >8 hours old must be refrigerated.** *OR* 8 mL body fluid in clean container; **Ambient or** Refrigerated; Include 1 unstained cytospin smear *OR* **4** mL whole blood in sodium heparin (Green) tube; Ambient **or Refrigerated; New York samples >8 hours old must be refrigerated.** *OR* **4 mL bone marrow in EDTA (Lavender) tube; Refrigerated; Include unstained bone marrow slide. Label bone marrow slide with patient ID number using solvent-resistant marker. New York samples >8 hours old must be refrigerated.** **Stability:** Ambient: **72 hours. Acceptability of samples >72 hours will be at the discretion of the pathologist.** Refrigerated: **72 hours. Acceptability of samples >72 hours will be at the discretion of the pathologist.** Frozen: Unacceptable	8/15/24
Hepatitis B Virus (HBV) DNA, Quantitative PCR, Plasma/Serum	HBVDNU	**For interface clients only–Test build may need to be modified** **Name:** Previously Hepatitis B Virus DNA Quantification **Includes:** **HBV DNA** **HBV DNA (IU/mL)** **HBV DNA (log IU/mL)** **Clinical Limitation: For full limitations, refer to the assay instructions for use available on the manufacturer's website. The most important limitations are summarized as follows. Though rare, mutations within the highly conserved regions of a viral genome covered by cobas HBV, may affect primers and/or probe binding resulting in the under-quantitation of virus or failure to detect the presence of virus.** **Clinical Information: Hepatitis B virus (HBV) is one of several viruses known to cause viral hepatitis. Patients with chronic HBV infection are at high risk of long-term complications of infection, including chronic hepatitis, cirrhosis, and hepatocellular carcinoma. cobas HBV is an FDA-approved in vitro nucleic acid amplification test for the quantitation of hepatitis B virus (HBV) DNA in human EDTA plasma or serum of HBV-infected individuals. This test is intended for use as an aid in the** management of **patients with** chronic HBV infection **undergoing** anti-viral therapy. **The test can be used to measure HBV DNA levels at baseline and during treatment to aid in assessing response to treatment. The results from cobas HBV must be interpreted within the context of all relevant clinical and laboratory findings. The cobas HBV is not intended for use as a screening test for the presence of HBV in blood or blood products or as a diagnostic test to confirm the presence of HBV infection. The assay is a quantitative PCR that targets highly conserved regions of HBV and is reported out in international units (IU/mL). The linear range of the assay is 10 to 1,000,000,000 IU/mL (1.00–9.00 log IU/mL). The lower limit of detection of the assay is 2.7 IU/mL in EDTA plasma and 2.4 IU/mL in serum.** *(continued on page 13)*	10/8/24

Test Changes (Cont.)

Test Name	Order Code	Change	Effective Date
Hepatitis B Virus (HBV) DNA, Quantitative PCR, Plasma/Serum *(continued from page 12)*	HBVDNU	**Specimen Requirement:** 2 mL plasma from EDTA plasma preparation (White) tube; **Minimum volume for testing is 1.0 mL of plasma/serum. Aliquots must be made from specimen prior to testing in any lab outside of Molecular Microbiology, and must be placed in a sterile aliquot tube. Centrifuge and** refrigerate**. Collect EDTA plasma according to standard protocol.** Separate plasma **by centrifugation (at 1,100 RCF for a minimum of 10 minutes)** within 24 hours of collection. **Plasma** must be aliquoted first if sample is to be frozen. Sample cannot be shared with a test performed outside of Molecular Microbiology. Sample can only be shared with CMVQNT, HCQPCR, HIVRNA, HBVDNU, EBVQNT, or BKQUAN. *OR* 2 mL plasma from EDTA (Lavender) tube; **Minimum volume for testing is 1.0 mL of plasma/serum. Aliquots must be made from specimen prior to testing in any lab outside of Molecular Microbiology, and must be placed in a sterile aliquot tube. Centrifuge, aliquot and** refrigerate **ASAP. Collect EDTA plasma according to standard protocol. Centrifuge (at >1300 RCF for a minimum of 10 minutes) and aliquot into a sterile secondary tube within 24 hours of collection. Plasma** must be aliquoted first if sample is to be frozen. Sample cannot be shared with a test performed outside of Molecular Microbiology. Sample can only be shared with CMVQNT, HCQPCR, HIVRNA, HBVDNU, EBVQNT, or BKQUAN. *OR* 2 mL serum from serum separator (Gold) tube; **Minimum volume for testing is 1.0 mL of plasma/serum. Aliquots must be made from specimen prior to testing in any lab outside of Molecular Microbiology, and must be placed in a sterile aliquot tube. Centrifuge and** refrigerate. **Collect serum according to standard protocol.** Separate serum **by centrifugation (at 1,100 RCF for a minimum of 10 minutes)** within 24 hours of collection. **Serum** must be aliquoted first if sample is to be frozen. Sample cannot be shared with a test performed outside of Molecular Microbiology. Sample can only be shared with HCQPCR. *OR* **2 mL serum from serum separator (Speckled or Tiger Top) tube; Minimum volume for testing is 1.0 mL of plasma/serum. Aliquots must be made from specimen prior to testing in any lab outside of Molecular Microbiology, and must be placed in a sterile aliquot tube. Centrifuge, aliquot and refrigerate ASAP. Collect serum according to standard protocol. Centrifuge (at 1,100 RCF for a minimum of 10 minutes) and aliquot into a sterile secondary tube within 24 hours of collection. Serum must be aliquoted first if sample is to be frozen. Sample cannot be shared with a test performed outside of Molecular Microbiology. Sample can only be shared with HCQPCR.** **Stability:** Ambient: 24 hours **for plasma/serum or for whole blood unspun/unseparated** Refrigerated: 6 days **for plasma/serum separated from whole blood within 24 hours; 24 hours for whole blood unspun/unseparated** Frozen: 12 weeks **for plasma/serum if separated from whole blood and aliquoted into a secondary tube within 24 hours (plasma/serum cannot be frozen in PPT/SST tubes)** **Methodology: Polymerase Chain Reaction (PCR), Quant** **Reference Range:** **HBV DNA: Not detected** **Days Performed: 7 days a week** **Reported: 1–3** days	10/8/24
Hepatitis C Virus (HCV) RNA, Quantitative PCR, Plasma/Serum	HCQPCR	**For interface clients only–Test build may need to be modified** **Name:** Previously Hepatitis C RNA Quantification by PCR **Includes:** **HCV RNA** **HCV RNA (IU/mL)** **HCV RNA (log IU/mL)** **Clinical Limitation: For full limitations, refer to the assay instructions for use available on the manufacturer's website. The most important limitations are summarized as follows. Though rare, mutations within the highly conserved regions of a viral genome covered by cobas HCV may affect primer and/or probe binding resulting in the under quantitation of virus or failure to detect the presence of virus. Our laboratory accepts remnant specimens previously tested for anti-HCV from select other laboratories, in accordance with reflex testing algorithms recommended by the Centers for Disease Control (https://www.cdc.gov/mmwr/volumes/72/wr/mm7228a2.htm). This is associated with a small risk of carryover contamination, which may lead to rare cases of false positive results. In this setting, if results are discordant with clinical history/presentation or other lab findings, it is recommended to submit a dedicated specimen for repeat HCV RNA testing.** *(continued on page 14)*	10/8/24

Test Changes (Cont.)

Test Name	Order Code	Change	Effective Date
Hepatitis C Virus (HCV) RNA, Quantitative PCR, Plasma/Serum *(continued from page 13)*	HCQPCR	**Clinical Information: HCV is a single stranded, positive sense RNA virus, which can be transmitted by blood and blood products. Detection of antibodies to HCV (anti-HCV) indicates prior exposure to hepatitis C but does not distinguish between cleared or active infection. Detection of HCV RNA with the detection of anti-HCV identifies an active hepatitis C infection. The results of HCV RNA testing together with other biochemical and clinical information, may be used to confirm an active HCV infection, measure the level of virus in the blood and assist in HCV prevention counseling medical care and treatment decision making. cobas HCV is an FDA-approved in vitro nucleic acid amplification test for both the detection and quantitation of hepatitis C virus (HCV) RNA, in human EDTA plasma or serum, of HCV antibody positive or HCV infected individuals. Specimens containing HCV genotypes 1 to 6 are validated for detection and quantitation in the assay. cobas HCV is intended for use as an aid in the diagnosis of HCV infection in the following populations: individuals with antibody evidence of HCV with evidence of liver disease, individuals suspected to be actively infected with HCV antibody evidence, and individuals at risk for HCV infection with antibodies to HCV. Detection of HCV RNA indicates that the virus is replicating and therefore is evidence of active infection. cobas HCV** is intended for use as an aid in the management of HCV infected patients undergoing anti viral therapy. **The assay can be used to measure HCV RNA levels at baseline during treatment, at the end of and at the end of follow up of treatment to determine sustained or non sustained viral response. The** results **must be** interpreted within the context of all relevant clinical and laboratory findings**. cobas HCV has not been approved for use as a screening test for the presence of HCV in blood or blood products. The assay is a quantitative PCR that targets highly-conserved regions of HCV and is reported out in international units (IU/mL). The linear range of the assay is 15 to 100,000,000 IU/mL (1.18–8.00 log IU/mL). The lower limit of detection of the assay is 15 IU/mL.** **Specimen Requirement: 2** mL plasma from EDTA plasma preparation (White) tube; **Minimum volume for testing is 1.0 mL of plasma/serum. Aliquots must be made from specimen prior to testing in any lab outside of Molecular Microbiology, and must be placed in a sterile aliquot tube. Centrifuge and** refrigerate. **Collect EDTA plasma according to standard protocol. Separate plasma by centrifugation (at 1,100 RCF for a minimum of 10 minutes)** within 24 hours of collection. **Plasma** must be aliquoted first if sample is to be frozen. Sample can only be shared with **AHCV1B,** CMVQNT, HCQPCR, HIVRNA, HBVDNU, EBVQNT, or BKQUAN. *OR* **2** mL plasma from EDTA (Lavender) tube; **Minimum volume for testing is 1.0 mL of plasma/serum. Aliquots must be made from specimen prior to testing in any lab outside of Molecular Microbiology, and must be placed in a sterile aliquot tube. Centrifuge, aliquot and** refrigerate **ASAP. Collect EDTA plasma according to standard protocol. Centrifuge (at >1300 RCF for a minimum of 10 minutes) and aliquot into a sterile secondary tube** within 24 hours **of collection. Plasma must be aliquoted first if sample is to be frozen.** Sample cannot be shared with a test performed outside of Molecular Microbiology. Sample can only be shared with **AHCV1B**, CMVQNT, HCQPCR, HIVRNA, HBVDNU, EBVQNT, or BKQUAN. *OR* **2** mL serum from serum separator (Gold) tube; **Minimum volume for testing is 1.0 mL of plasma/serum. Aliquots must be made from specimen prior to testing in any lab outside of Molecular Microbiology, and must be placed in a sterile aliquot tube. Centrifuge and** refrigerate. **Collect serum according to standard protocol. Separate serum by centrifugation (at 1,100 RCF for a minimum of 10 minutes)** within 24 hours of collection. **Serum** must be aliquoted first if sample is to be frozen. Sample cannot be shared with a test performed outside of Molecular Microbiology. Sample can only be shared with **AHCV1B** or HBVDNU. *OR* **2 mL serum from serum separator (Speckled or Tiger Top) tube; Minimum volume for testing is 1.0 mL of plasma/serum. Aliquots must be made from specimen prior to testing in any lab outside of Molecular Microbiology, and must be placed in a sterile aliquot tube. Centrifuge, aliquot and refrigerate ASAP. Collect serum according to standard protocol. Centrifuge (at 1,100 RCF for a minimum of 10 minutes) and aliquot into a sterile secondary tube within 24 hours of collection. Serum must be aliquoted first if sample is to be frozen. Sample cannot be shared with a test performed outside of Molecular Microbiology. Sample can only be shared with AHCV1B or HBVDNU.** *(continued on page 15)*	10/8/24

Test Changes (Cont.)

Test Name	Order Code	Change	Effective Date
Hepatitis C Virus (HCV) RNA, Quantitative PCR, Plasma/Serum *(continued from page 14)*	HCQPCR	**Stability:** Ambient: 24 hours **for plasma/serum or for whole blood unspun/unseparated** Refrigerated: 6 days **for plasma/serum separated from whole blood within 24 hours; 24 hours for whole blood unspun/unseparated** Frozen: 12 weeks **for plasma/serum if separated from whole blood and aliquoted into a secondary tube within 24 hours (plasma/serum cannot be frozen** in PPT/SST tubes) **Reference Range:** **HCV RNA: Not detected** **Days Performed: 7 days a week** **Reported: 1–3** days	10/8/24
Histoplasma Galactomannan EIA, CSF	HISCSF	**Specimen Requirement:** 2 mL cerebrospinal fluid (CSF) in sterile container; Frozen **Stability:** Ambient: **7 days** Refrigerated: **7 days** Frozen: **3 months (3x freeze/thaw cycles)**	effective immediately
Human Immunodeficiency Virus 1 (HIV-1) RNA, Quantitative PCR, Plasma	HIVRNA	**For interface clients only–Test build may need to be modified** **Name:** Previously HIV Quant RNA by PCR **Includes:** **HIV-1 RNA** **HIV-1 RNA (copies/mL)** **HIV-1 RNA (log copies/mL)** **Clinical Limitation: For full limitations, refer to the assay instructions for use available on the manufacturer's website. The most important limitations are summarized as follows. Though rare, mutations within the highly conserved regions of a viral genome covered by cobas HIV-1 may affect primers and/or probe binding resulting in the under-quantitation of virus or failure to detect the presence of virus. Samples from subjects under 19 years of age were not evaluated. False positive results have been reported in patients with history of chimeric antigen receptor (CAR) T cell immunotherapy using lentiviral vectors, which can cross react with assay targets (PMID: 31694968). This assay does not detect HIV-2.** **Clinical Information: Human immunodeficiency virus (HIV) is the etiologic agent of acquired immunodeficiency syndrome (AIDS). Quantitative measurements of HIV viremia in the plasma have shown that higher virus levels are correlated with more rapid clinical progression of HIV disease. Furthermore, nearly two decades of clinical research have established that reductions in plasma virus levels with the use of antiretroviral therapy (ART) significantly decrease the risk of clinical progression, including death, development of AIDS, opportunistic infections, and HIV-associated morbidity. HIV viral load is also predictive of the risk of transmission of HIV, and randomized controlled clinical trials have established that early initiation of ART with suppression of the viral load reduces HIV transmission by 96%. cobas HIV-1 is an in vitro nucleic acid amplification test for the quantitation of human immunodeficiency virus type 1 (HIV-1) in EDTA plasma of HIV-1-infected individuals.** This test is intended for use in conjunction with clinical presentation **and other laboratory markers for** the clinical management of HIV-1 infected patients. The test can be used to **assess patient prognosis by measuring the baseline HIV-1 level or to monitor the effects of** antiretroviral therapy **by measuring changes in HIV-1 RNA levels during the course of antiretroviral treatment. This assay is not intended for use as a screening test for the presence of HIV-1 in donated blood or plasma or as a diagnostic test to confirm the presence of HIV-1 infection. The assay is a quantitative PCR assay that targets highly-conserved regions of the HIV-1 genome including the HIV-1 gag gene and the HIV-1 LTR region, and is reported out in copies/mL.** The linear range of the assay is 20 to 10,000,000 copies/mL **(1.30–7.00 log copies/mL). The lower limit of detection of the assay is 13.2 copies/mL.** **Specimen Requirement: 2** mL plasma from EDTA plasma preparation (White) tube; **Minimum volume for testing is 1.0 mL of plasma. Aliquots must be made from specimen prior to testing in any lab outside of Molecular Microbiology, and must be placed in a sterile aliquot tube. Centrifuge and** refrigerate. **Collect EDTA plasma according to standard protocol. Separate plasma by centrifugation (at 1,100 RCF for a minimum of 10 minutes)** within 24 hours of collection. **Plasma** must be aliquoted first if sample is to be frozen. *(continued on page 16)*	10/8/24

Test Changes (Cont.)

Test Name	Order Code	Change	Effective Date
Human Immunodeficiency Virus 1 (HIV-1) RNA, Quantitative PCR, Plasma *(continued from page 15)*	HIVRNA	**Specimen Requirement (continued): Sample cannot be shared with a test performed outside of Molecular Microbiology.** Sample can only be shared with CMVQNT, HCQPCR, HIVRNA, HBVDNU, EBVQNT, or BKQUAN. *OR* **2** mL plasma from EDTA (Lavender) tube; **Minimum volume for testing is 1.0 mL of plasma. Aliquots must be made from specimen prior to testing in any lab outside of Molecular Microbiology, and must be placed in a sterile aliquot tube. Centrifuge, aliquot and** refrigerate **ASAP. Collect EDTA plasma according to standard protocol. Centrifuge (at >1300 RCF for a minimum of 10 minutes) and aliquot into a sterile secondary tube** within 24 hours of collection. **Plasma must be aliquoted first if sample is to be frozen. Sample cannot be shared with a test performed outside of Molecular Microbiology.** Sample can only be shared with CMVQNT, HCQPCR, HIVRNA, HBVDNU, EBVQNT, or BKQUAN. **Stability:** Ambient: 24 hours for plasma **or for whole blood unspun/unseparated** Refrigerated: 6 days for plasma **separated from whole blood within 24 hours; 24 hours for whole blood unspun/unseparated** Frozen: **12 weeks for plasma if separated from whole blood and aliquoted into a secondary tube within 24 hours (plasma cannot be frozen in PPT tubes)** **Methodology: Polymerase Chain Reaction (PCR), Quant** **Reference Range:** **HIV-1 RNA: Not detected** **Days Performed: 7 days a week** **Reported: 1–3** days	10/8/24
Hypersensitivity Pneumonitis Evaluation	HYPNE2	**Specimen Requirement:** 5 mL serum from serum separator (Gold) tube; Minimum: **1.6** mL (**0.8** mL per aliquot tube); Refrigerated; Separate serum from cells ASAP or within 2 hours of collection. Transfer 2.5 mL serum to two aliquot tubes.	8/19/24
Lactate/Pyruvate	LACPYR	**Special Information:** Place whole blood on ice immediately after collection. Deproteinize whole blood within 30 minutes of collection to stop additional evolution of lactate/pyruvate. Specimen processing/deproteinization instructions: Collect one 5 mL gray (sodium fluoride/potassium oxalate) tube. Within 30 minutes of draw, add 1 mL well mixed blood to 2 mL cold 12 % TCA. Repeat with separate 1 mL of oxalated whole blood into a second tube of cold 12 % TCA. (Note: 1:2 ratio of blood to 12 % TCA must be maintained for accurate quantitation). Vortex precipitation tubes vigorously and refrigerate or place on wet ice for 10 minutes. **Write the precipitation time on the precipitation tube.** After 10 minutes of cold incubation, centrifuge for 10 minutes at 1000G. Decant supernatant into a clean, well-sealed transport tube. Label tube as "TCA Precipitate". Precipitated sample can be transported at refrigerated temperature. *Stability Information is for precipitated sample. **Specimen Requirement:** 4 mL blood in potassium oxalate/sodium fluoride (Gray) tube; Refrigerated; Please refer to special information for processing instructions.	effective immediately
Neisseria gonorrhoeae by Transcription-Mediated Amplification (TMA), Ocular specimens	NGNAAO	**For interface clients only–Test build may need to be modified** **Name:** Previously Neisseria gonorrhoeae, NA Amplification, Ocular specimens **Includes:** **N. gonorrhoeae by TMA** **APTIMA Media Type** **Specimen Source** **Special Information:** Specimens must be collected using an APTIMA **Multitest or Unisex** swab collection kit. Specimen source is required. This test is New York State approved. **Clinical Information:** This report is intended for use in clinical monitoring or management of patients; it is not intended for use in medico-legal applications. **Specimen Requirement: One eye Aptima Multitest Swab; Refrigerated; Ocular (corneal/conjunctiva) sites only. Indicate specimen source**. *OR* One **eye** Aptima Unisex Swab; Refrigerated; Ocular (corneal/conjunctiva) sites only. Indicate specimen source. **Days Performed: Sun**–Sat **Reported:** 2–**5** days	10/15/24
Paraneoplastic Autoantibody Evaluation, CSF	PARCSF	**Reported: 11–18** days	effective immediately
Prolactin	PROL	**Reference Range:** Female: **4.4–33.8** ng/mL Male: **4.1-25.1** ng/mL	10/8/24

Test Changes (Cont.)

Test Name	Order Code	Change	Effective Date
Prothrombin Antibody, IgG	PTABGM	**Name:** Previously Prothrombin Antibody **Special Information:** Preferred second-line testing for strong suspicion of seronegative antiphospholipid syndrome (APS). Order incrementally or concurrently with other non-criteria antiphospholipid antibody tests. **Severely** hemolyzed or **icteric** specimens **will be rejected**. This test is New York **state** approved. **Clinical Information:** IgG antibodies to prothrombin may be a risk factor for either venous or arterial thrombosis in antiphospholipid syndrome (APS). Strong clinical correlation is recommended in the absence of lupus anticoagulant, IgG and/or IgM cardiolipin and/or beta2 glycoprotein antibodies. If results are positive, repeat testing with two or more specimens drawn at least 12 weeks apart to demonstrate persistence of antibodies. Results should not be used alone for diagnosis and must be interpreted in light of APS-specific clinical manifestations and/or other criteria phospholipid antibody tests. **Specimen Requirement:** 0.5 mL serum from serum separator (Gold) tube; Refrigerated; **Separate serum from cells ASAP or within 2 hours of collection and** transfer to standard aliquot tube. *OR* 0.5 mL plasma from sodium citrate (Light Blue) tube; Refrigerated; **Separate plasma from cells ASAP or within 2 hours of collection and** transfer to standard aliquot tube.	8/19/24
Pseudocholinesterase, Total	PCHE	**Name:** Previously Pseudocholinesterase, Total, Serum **Special Information: Specimen must be drawn prior to surgery or more than two days following surgery. Unspun or hemolyzed specimens will be rejected. This test is New York state approved.** **Clinical Information: This is an acceptable test for determining acute exposure to organophosphate insecticides.** **Specimen Requirement: 0.5** mL serum from serum separator (Gold) tube; Minimum: **0.1** mL; Refrigerated; **Specimen must be drawn prior to surgery or more than two days following surgery. Allow specimen to clot completely at room temperature. Separate serum from cells** within 2 hours of collection **and transfer to standard aliquot tube.** *OR* **0.5 mL plasma from EDTA (Lavender) tube; Minimum: 0.1 mL; Refrigerated; Specimen must be drawn prior to surgery or more than two days following surgery. Separate plasma from cells within 2 hours of collection and transfer to standard aliquot tube.** **Stability:** Ambient: **4** hours Refrigerated: **1 week** Frozen: **3 months** **Methodology: Quantitative Enzymatic** **Reference Range: Reference Interval: 2,900-7,100 U/L** **Reported:** 2–**5** days **CPT:** 82480	10/15/24
Pyruvic Acid	PYRUV	**Special Information:** Place whole blood on ice immediately after collection. Deproteinize whole blood within 30 minutes of collection to stop additional evolution of lactate/pyruvate. Specimen processing/deproteinization instructions: Collect one 5 mL gray (sodium fluoride/potassium oxalate) tube. Within 30 minutes of draw, add 1 mL well mixed blood to 2 mL cold 12 % TCA. Repeat with separate 1 mL of oxalated whole blood into a second tube of cold 12 % TCA. (Note: 1:2 ratio of blood to 12 % TCA must be maintained for accurate quantitation). Vortex precipitation tubes vigorously and refrigerate or place on wet ice for 10 minutes. **Write the precipitation time on the precipitation tube.** After 10 minutes of cold incubation, centrifuge for 10 minutes at 1000G. Decant supernatant into a clean, well-sealed transport tube. Label tube as “TCA Precipitate”. Precipitated sample can be transported at refrigerated temperature. *Stability Information is for precipitated sample. **Specimen Requirement:** 4 mL blood in potassium oxalate/sodium fluoride (Gray) tube; Refrigerated; Refer to special information for processing instructions.	effective immediately

Test Changes (Cont.)

Test Name	Order Code	Change	Effective Date
Pyruvic Acid, CSF	FPYRUV	**Special Information:** Specimen processing/deproteinization instructions: Collect 3 mL spinal fluid in clean tube. Add 1 mL well mixed CSF to 2 mL cold 12% TCA. Repeat with separate 1 mL of CSF into a second tube of cold 12% TCA. (Note: 1:2 ratio of CSF to 12% TCA must be maintained for accurate quantitation). Vortex precipitation tubes vigorously and refrigerate or place on wet ice for 10 minutes. **Write the precipitation date and time on the precipitation tube.** After 10 minutes of cold incubation, centrifuge for 10 minutes at 1000G. Decant supernatant into a clean, well-sealed transport tube. Label tube as " Spinal fluid TCA Precipitate". Precipitated sample can be transported at refrigerated temperature. **Specimen Requirement:** 1 mL cerebrospinal fluid (CSF) in clean container; Refrigerated; **Refer to special information for processing instructions.** **Stability:** Ambient: **3 days untreated;** 8 hours **once TCA treated (deproteinized)** Refrigerated: **21 days untreated; 30 days once TCA treated (deproteinized)** Frozen: **30 days once TCA-treated (deproteinized) * Frozen stability information is for TCA treated sample only *** **Reported: 1**–4 days	effective immediately
RBC Band 3 Protein Reduction in Hereditary Spherocytosis	RBCB3	**Special Information:** Specimens must be analyzed within 7 days of collection. **Clotted or hemolyzed specimens will be rejected. This test is New York state approved.** **Clinical Information:** Use to confirm diagnosis of hereditary spherocytosis when hemolytic anemia and spherocytes are present. **Specimen Requirement:** 4 mL whole blood in EDTA (Lavender) tube; Refrigerated *OR* 4 mL whole blood in sodium or lithium heparin (Green) tube; Refrigerated **Methodology: Flow Cytometry (FC)**	8/19/24
Selenium Blood	SELEN	**Special Information:** *Special information has been removed.*	effective immediately
Telomere Length Measurement	TELMSR	**Specimen Requirement:** 18 mL whole blood in acid citrate dextrose (ACD) A (Yellow) tube; Ambient; Complete required test requisition. Specimen must be delivered to Cleveland Clinic Laboratories by 3 p.m. **Collect Monday through Thursday only, and** do not collect the day before or the day of a major holiday. Separate specimens must be submitted when multiple tests are ordered.	effective immediately
Thyroglobulin Antibody	TGAB	**Special Information:** The Thyroglobulin Antibody test was performed using the Beckman Coulter UniCel DxI 800 Chemiluminescence Immunoassay method. Results obtained with different assay methods or kits cannot be used interchangeably. **Patients taking a biotin dose greater than 5 mg/day should refrain from taking biotin for at least 12 hours. Clinicians should consider biotin interference as a source of error, when clinically suspicious of the laboratory result.** **Days Performed:** Mon–Fri **7:30 am–4:00 pm**	effective immediately
Thyroglobulin, Serum with Reflex to IA or LC-MS/MS	THYRORF	**Special Information:** In this test, Thyroglobulin Antibody is analyzed by the Access Thyroglobulin Antibody assay (Beckman). If the result is negative (<4.0 IU/mL), the Thyroglobulin tests will be performed by immunoassay using the Access Thyroglobulin assay (Beckman). If the antibody result is positive (>=4.0 IU/mL), the Thyroglobulin tests will be performed by LC-MS/MS. Results obtained from different assay method or kits cannot be used interchangeably. **Patients taking a biotin dose greater than 5 mg/day should refrain from taking biotin for at least 12 hours. Clinicians should consider biotin interference as a source of error, when clinically suspicious of the laboratory result.** **Days Performed:** Mon–Fri **7:30 am–4:00 pm**	effective immediately
Torch Antibodies, IgM	TORCHM	**For interface clients only–Test build may need to be modified** **Clinical Information:** This test **should not be used for blood donor screening, associated reentry protocols, or for screening human cellular and tissue-based products (HCT/P).** **Stability:** Ambient: After separation from cells: **48 hours** Refrigerated: After separation from cells: 2 weeks Frozen: After separation from cells: 1 year (Avoid repeated freeze/thaw cycles) **Methodology:** Semi-Quantitative Chemiluminescent Immunoassay **Reference Range:** Toxoplasma IgM: Refer to report Rubella IgM**: Refer to report** CMV IgM: **Refer to report** **CPT:** 86762, 86778, 86645	8/19/24

Test Changes (Cont.)

Test Name	Order Code	Change	Effective Date
Treponema pallidum Antibody, IgG by IFA (CSF)	FTACSF	**Name:** Previously FTA Antibodies CSF **Special Information: Contaminated, heat-inactivated, or hemolyzed specimens will be rejected. This test is New York State approved.** **Clinical Information:** The significance of a reactive FTA-ABS CSF test is unknown. The CSF from persons treated in the secondary or latent stages of syphilis and without signs of neurosyphilis may be reactive. A nonreactive result in the FTA-ABS CSF test suggests the absence of neurosyphilis. **Stability:** Ambient: **48 hours** Refrigerated: 5 days Frozen: 1 year **Methodology: Semi-Quantitative Indirect Fluorescent Antibody** **Reported:** 2–**5** days	8/19/24
Trofile Co-receptor Tropism Assay	TROFLE	**For interface clients only–Test build may need to be modified** **Special Information:** Separate specimens must be submitted when multiple tests are ordered. Thawed specimens will be rejected. This test is New York DOH approved. **Clinical Information: This test is useful in patients with an undetectable viral load. HIV-1 phenotyping test to determine the tropism (ie, CCR5 or CXCR4) of the virus in patients being considered for CCR5 antagonist therapy.** **Specimen Requirement: 4** mL **whole blood** in EDTA (Lavender) tube; Minimum: **4** mL; **Critical** Frozen; **Transfer 4mL whole blood to standard aliquot tube and freeze immediately.** Separate specimens must be submitted when multiple tests are ordered. **Reference Range:** **EER Trofile (DNA) Co-Receptor Tropism: Refer to report** **Trofile DNA Co-Receptor Tropism: Refer to report** **Trofile DNA, Tropotype: Refer to report** **Trofile DNA, Interpretation: Refer to report** **Days Performed: Varies**	10/15/24
UBA1 Mutation Testing for VEXAS Syndrome	VEXAS	**Special Information:** Requisition and Pathology report MUST accompany **all** samples **except blood**. Ship FedEx priority overnight Monday through Friday (mark Saturday delivery when shipping on Friday). **Specimen Requirement:** 10 mL whole blood in EDTA (Lavender) tube; Refrigerated *OR* 10 mL bone marrow in EDTA (Lavender) tube; Refrigerated; Requisition and Pathology report MUST accompany sample. *OR* 10 mL whole blood in acid citrate dextrose (ACD) A or B (Yellow) tube; Refrigerated *OR* 10 mL bone marrow in acid citrate dextrose (ACD) A or B (Yellow) tube; Refrigerated; Requisition and Pathology report MUST accompany sample. *OR* One formalin fixed paraffin block; Refrigerated; Requisition and Pathology report MUST accompany sample. *OR* 10 unstained slide(s); Refrigerated; 4-5 microns. Requisition and Pathology report MUST accompany sample. *OR* unspecified fresh tissue in RPMI; Refrigerated; Requisition and Pathology report MUST accompany sample. *OR* unspecified fresh tissue in saline; Ambient; Requisition and Pathology report MUST accompany sample. *OR* unspecified frozen tissue; Frozen; Ship on dry ice. Requisition and Pathology report MUST accompany sample. *OR* 200 ng extracted DNA in sterile container; Minimum of 10 ng/μL. Requisition and Pathology report MUST accompany sample. Note: *Pathology report is not required for blood specimens.*	effective immediately
Vasoactive Intestinal Polypeptide (VIP), Plasma	VIP	**Name:** Previously VIP **Special Information: Critical Frozen. Fast for 10 to 12 hours and avoid antacid medications or medications that affect intestinal motility for at least 48 hours prior to collection. Separate specimens must be submitted when multiple tests are ordered. This test is New York DOH approved.** **Specimen Requirement:** 1 mL plasma from **EDTA (Lavender) tube; Critical** Frozen**; Fast for 10 to 12 hours and avoid antacid medications or medications that affect intestinal motility for at least 48 hours prior to collection.** Separate **plasma** from cells **immediately and** transfer to standard aliquot tube **and freeze.** Separate specimens must be submitted when multiple tests are ordered. **Stability:** Ambient: After separation from cells: Unacceptable Refrigerated: After separation from cells: **Unacceptable** Frozen: After separation from cells: **180 days** **Methodology: Enzyme-Linked Immunosorbent Assay (ELISA)** **Reference Range: Up to 36** pg/mL **(mean 14)** **Days Performed: Mon–Fri** **Reported: 6–10** days	effective immediately

New Tests

Test Name	Order Code	Change	Effective Date
Anti-sp100 and anti-gp210 Antibodies, IgG	ANSPGP	**Special Information:** Heat-inactivated, contaminated, grossly icteric, severely lipemic, or grossly hemolyzed specimens will be rejected. This test is New York state approved. **Clinical Information:** This test is useful for the evaluation of individuals with suspected primary biliary cholangitis (PBC) who test negative for anti-mitochondrial antibodies (AMA). **Specimen Requirement:** 1 mL serum from serum separator (Gold) tube; Minimum: 0.3 mL; Refrigerated; Separate serum from cells ASAP or within 2 hours of collection and transfer to standard aliquot tube. **Stability:** Ambient: After separation from cells: 48 hours Refrigerated: After separation from cells: 2 weeks Frozen: After separation from cells: 1 month (avoid repeated freeze/thaw cycles) **Methodology:** Semi Quantitative Enzyme Linked Immunosorbent Assay **Reference Range:** Anti-gp210 Ab, IgG: Negative: </=20.0 Units Equivocal: 20.1–24.9 Units Positive: >/= 25.0 Units Anti-sp100 Ab, IgG: Negative: </=20.0 Units Equivocal: 20.1–24.9 Units Positive: >/= 25.0 Units **Days Performed:** Wed **Reported:** 2–9 days **CPT:** 83516	10/17/24
Aripiprazole and Metabolite	ARPRZL	**Includes:** Aripiprazole Serum/Plasma Dehydroaripiprazole, Serum/Plasma Total Aripiprazole and Metabolite S/P **Special Information:** Gel separator tubes will be rejected. This test is New York state approved. **Clinical Information:** This test is useful to optimize drug therapy and monitor patient adherence. The therapeutic range is based on serum pre-dose (trough) draw at steady-state concentration. Adverse effects to aripiprazole therapy may include headache, nausea, somnolence and blurred vision. **Specimen Requirement:** 1 mL serum from no additive (Red) tube; Minimum: 0.5 mL; Refrigerated; Separate serum from cells ASAP or within 2 hours of collection and transfer to standard aliquot tube. *OR* 1 mL plasma from EDTA (Lavender) tube; Minimum 0.5 mL; Refrigerated; Separate plasma from cells ASAP or within 2 hours of collection and transfer to standard aliquot tube. **Stability:** Ambient: 2 weeks Refrigerated: 2 weeks Frozen: 2 weeks **Methodology:** Quantitative Liquid Chromatography–Tandem Mass Spectrometry **Reference Range:** Total Aripiprazole and Metabolite: Therapeutic: 150.0–500.0 ng/mL Toxic: >/= 1000.0 ng/mL **Days Performed:** Wed, Sat **Reported:** 2–9 days **CPT:** 80342/G0480	10/17/24

New Tests (Cont.)

Test Name	Order Code	Change	Effective Date
TSH w/Reflex	TSHRF	**Clinical Information:** Produced by the anterior pituitary gland, thyroid-stimulating hormone (TSH) stimulates the thyroid gland to convert iodine and the amino acid tyrosine into the thyroid hormones thyroxine (T4) and triiodothyronine (T3), which in turn regulate metabolism, growth, and development. These free thyroid hormones also work in a negative feedback loop to regulate the amount of TSH that is released from the pituitary gland. Testing for TSH is a highly sensitive indicator for hypothyroidism and an important tool in diagnosing thyroid dysfunction. An elevated TSH result usually indicates an underactive thyroid (hypothyroidism), and a decreased TSH result indicates an overactive thyroid (hyperthyroidism) or excessive amounts of thyroid medication in an individual being treated for hypothyroidism. The latest "third-generation" assays for TSH are sensitive enough to distinguish moderately low but still clinically normal levels of TSH from lower levels indicative of hyperthyroidism. If TSH is abnormal, Free T4 will be performed and billed. **Specimen Requirement:** 1 mL plasma from lithium heparin plasma separator (Light Green) tube; Ambient collection; Centrifuge and refrigerate. *OR* 1 mL serum from serum separator (Gold) tube; Ambient collection. **Stability:** Ambient: 5 days Refrigerated: 7 days Frozen: 30 days **Methodology:** Electro Chemiluminescence Immunoassay (ECLIA) **Reference Range:** 0 Days to 5 Days: 0.700–15.200 uU/mL 6 Days to 90 Days: 0.720–11.000 uU/mL 4 Months to 12 Months: 0.730–8.350 uU/mL 1 Year to 6 Years: 0.700–5.970 uU/mL 7 Years to 11 Years: 0.600–4.840 uU/mL 12 Years to 20 Years: 0.510–4.300 uU/mL 21 Years to 99 Years: 0.270–4.200 uU/mL Pregnancy first trimester (9-12 weeks): 0.180–2.990 uU/mL Pregnancy second trimester: 0.110–3.980 uU/mL Pregnancy third trimester: 0.480–4.710 uU/mL **Days Performed:** 7 days a week 24 hours **Reported:** 8 hours **CPT:** 84443	9/10/24
Tuberculosis PCR and Culture, Respiratory	TBPCRX	**Special Information:** Species and subspecies within the M. tuberculosis complex are not distinguished. If positive for M. tuberculosis complex a result for rifampin resistance is reported. Although 95% of mutations conferring rifampin resistance will be detected, other resistance mutations are possible. Similarly, false positive rifampin resistance may occur due to mutations that do not confer resistance. In vitro susceptibility testing is required. **Clinical Information:** The Xpert MTB/RIF assay should be performed on specimens from patients for whom there is clinical suspicion of tuberculosis and who have received less than 3 days of anti-tuberculosis therapy. PCR is recommended for rapid detection of M. tuberculosis in respiratory specimens. PCR is 98% sensitive for detection of smear positive/culture positive pulmonary infection. M. tuberculosis may also be detected in smear-negative sputum samples because of the greater sensitivity of the MTB/RIF assay compared to acid fast microscopy. A positive result may occur in the presence of non-viable M. tuberculosis. A negative result does not rule-out infection. Culture is always performed when PCR is requested because culture is more sensitive. The predictive value for the absence of smear positive/culture positive tuberculosis is 99.7% for one negative Xpert PCR assay and 100% for two negative Xpert PCR assays. Therefore, the Xpert assay can be used to help determine if continued isolation is warranted in patients with suspected pulmonary tuberculosis. (Steingart Cochran Rev 2013; Luetkemeyer CID 2016) **Specimen Requirement:** 5 mL sputum in clean, leakproof container; Sputum may be expectorated or induced. For patients suspected of having pulmonary tuberculosis, PCR testing of at least 1 high quality sputum sample and culture of 3 sputum specimens (collected at least 8 hours apart with at least one first morning specimen) are recommended. Refrigeration is preferred if transport is delayed longer than 2 hours. Volume: 5 mL (preferred); 1 mL minimum. *OR* 10 mL bronchoscopy specimen in clean, leakproof container; Larger volumes improve recovery. Collect BAL, wash, or aspirate into sputum trap or sterile cup. Volume: at least 10 mL (preferred). Place bronchial brush in sterile, leak-proof tube or cup with enough non-bacteriostatic sterile saline to cover the brush (1-10 ml). Transfer temperature is ambient. Refrigeration is preferred if transport is delayed longer than 2 hours. *(continued on page 23)*	10/8/24

New Tests (Cont.)

Test Name	Order Code	Change	Effective Date
Tuberculosis PCR and Culture, Respiratory		**Specimen Requirement:** 5 mL sputum in clean, leakproof container; Sputum may be expectorated or induced. For patients suspected of having pulmonary tuberculosis, PCR testing of at least 1 high quality sputum sample and culture of 3 sputum specimens (collected at least 8 hours apart with at least one first morning specimen) are recommended. Refrigeration is preferred if transport is delayed longer than 2 hours. Volume: 5 mL (preferred); 1 mL minimum. *OR* 10 mL bronchoscopy specimen in clean, leakproof container; Larger volumes improve recovery. Collect BAL, wash, or aspirate into sputum trap or sterile cup. Volume: at least 10 mL (preferred). Place bronchial brush in sterile, leak-proof tube or cup with enough non-bacteriostatic sterile saline to cover the brush (1-10 ml). Transfer temperature is ambient. Refrigeration is preferred if transport is delayed longer than 2 hours. **Stability:** Ambient: Respiratory specimens can be stored at a maximum of 35°C for up to three days. Refrigerated: Respiratory samples can be stored at 2-8°C for up to seven days. Sputum concentrates can be stored at 2-8°C for up to seven days. **Methodology:** Real-Time Polymerase Chain Reaction (RT-PCR) **Days Performed:** 7 days a week **Reported:** 1–2 days **CPT:** 87015, 87116, 87118, 87186, 87206, 87556, 87798	

Discontinued Tests

Test Name	Order Code	Test Information	Effective Date
Her-2-Neu Serum	HER2S	Test will no longer be orderable. There is no recommended replacement.	effective immediately
HIV Phenotype	HIVPHE	Test will no longer be orderable. Recommended replacement test is HIV 1 Drug Resistance by Next Generation Sequencing (HIVNGS).	8/29/24
Lactate, Precipitated	LACPRE	Test will no longer be orderable. Recommended replacement test is Lactate/Pyruvate (LACPYR).	10/10/24
Mycobacterium tuberculosis Detection and Rifampin Resistance by PCR, Respiratory	MTBRIF	Test will no longer be orderable. Recommended replacement test is Tuberculosis PCR and Culture, Respiratory (TBPCRX) when culture + amplification is needed.	10/8/24
Testosterone, Free, Adult Males by ED/ LC-MS/MS	FTESAM	Test will no longer be orderable. Recommended replacement test is Testosterone, Total and Free, Serum (TFTEST).	10/8/24
Testosterone, Free/ Total, Males by ED/ LC-MSMS	FTTESM	Test will no longer be orderable. Recommended replacement test is Testosterone, Total and Free, Serum (TFTEST).	10/8/24