

# Cleveland Clinic Laboratories

## Technical Update • December 2020

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

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

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

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

Test Update Page #	Summary of Changes by Test Name	Name Change Order Code	New Test	Test Discontinued	Special Information	Specimen Requirement	Component Change(s)	Methodology	Days Performed/Reported Reference Range	Stability	CPT	Fee
3	18 OH Corticosterone											
10	Adenovirus PCR, Quant											
9	Adenovirus Quantitative Real-time PCR											
3	AFP L3% & Total, Hepatocellular Carcinoma											
3	ANA											
3	Anti-Alpha Fodrin Ab, IgA											
3	Anti-Alpha Fodrin Ab, IgG											
3	Aquaporin-4 Receptor Antibody, IgG by IFA with Reflex to Titer, Serum											
3	BAL, Routine											
3	Beta HCG, Quantitative, Blood											
3	Beta hCG Quant Tumor Marker											
3	Carbamazepine											
4	Carbamazepine, Free											
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4	Cardiolipin Antibodies											
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4	Cell Count/Diff, Body Fluid											
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Summary of Changes  
by Test Name

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4	CSF, Cell Count and Diff													
5	Cyclic Citrullinated Peptide Ab, IgG													
5	DNA Autoantibodies, Double Stranded													
5	FISH for TFE3													
5	FISH for TFE3 and TFEB Panel													
5	FISH for TFEB													
5	Free Cortisol Stimulation Panel													
5	Hepatitis A Antibody, IgM													
5	Hepatitis Acute Panel													
5	Hepatitis B Core Antibody, IgM													
5	Hepatitis B Core Antibody Total													
5	Hepatitis B Surface Ab, Immunity													
5	Hepatitis B Surface Ab, Qual.													
6	Hepatitis B Surface Ab, Quant													
6	Hepatitis B Surface Antigen													
6	Hepatitis B Surface Antigen Conf													
6	Hepatitis B Virus (HBV) Drug Resistance, Genotype and BCP/Precore Mutations by Sequencing													
6	Hepatitis C Antibody IA													
6	Hepatitis C Antibody IA w/Confirm													
6	Hepatitis Remote Panel													
6	HIV-1/2 Ab Confirmatory													
6	IgE													
6	Metanephrines, Urine 24 hour													
6	Metanephrines, Urine Random													
7	Neopterin													
7	Norwalk-Like Virus Antigen													
7	Phenytoin													
7	Phenytoin, Free													
7	PSA													
8	PSA, Free													
8	PSA, Screening													
10	Routine Flu A/B & RSV													
10	Routine Flu A/B by PCR													
10	Routine RSV by PCR													
8	Synovial Fluid, Routine Analysis													
8	Theophylline													
8	Valproic Acid													
8	Valproic Acid, Free													
8	Valproic Acid, Total and Free													
8	Vancomycin													

# Test Changes

Test Name	Order Code	Change	Effective Date
18 OH Corticosterone	18OHC	<p><b>Reference Range:</b>            Premature (26–28 Weeks): Day 4: 10–670 ng/dL            Premature (31–35 Weeks): Day 4: 57–410 ng/dL  <b>Full-term Day 3: 31–546 ng/dL</b>            Full-Term (31 Days–11 Months): 5–220 ng/dL            12–23 Months: 18–155 ng/dL            24 Months to 9 Years: 6–85 ng/dL            10 to 14 Years: 10–72 ng/dL            Adults: 9–58 ng/dL            8 a.m. Supine: 4–21 ng/dL            8 a.m. Upright: 5–46 ng/dL</p>	Effective immediately
AFP L3% & Total, Hepatocellular Carcinoma	AFPL3	<p><b>Special Information: This test is New York DOH approved. Plasma specimens will be rejected.</b></p> <p><b>Clinical Information: The purpose of this test is surveillance and monitoring of hepatocellular carcinoma.</b> The <math>\mu</math>TASWako method is used and results cannot be used interchangeably with any other assay methods or kits. The AFP L3 Percent assay is intended as a risk assessment for the development of hepatocellular carcinoma in patients with chronic liver diseases. Patients with elevated serum AFP-L3 percent should be more intensely evaluated for evidence of hepatocellular carcinoma since elevated values have been shown to be associated with a seven-fold increase in the risk for developing hepatocellular carcinoma within 21 months. <b>Results cannot be interpreted as absolute evidence of the presence or absence of malignant disease.</b> For pregnant females, the result is not interpretable as a tumor marker.</p> <p><b>Specimen Requirement:</b> 1 mL serum from a serum separator (gold) tube; Minimum: 0.5 mL; Remove serum from cells within 2 hours of collection; Frozen</p> <p><b>Methodology: Quantitative Liquid Chromatography/Immunoassay</b></p> <p><b>Days Performed: Monday, Thursday</b></p> <p><b>Reported: 2–6 days</b></p>	Effective immediately
ANA	ANAS	<p><b>Stability:</b>            Ambient: 24 hours            Refrigerated: 7 days            Frozen: <b>1 year, up to 2 freeze/thaw cycles</b></p>	12/22/20
Anti-Alpha Fodrin Ab, IgA	FODIGA	<p><b>Days Performed: Monday–Friday</b>  <b>Reported: 13–15 days</b></p>	Effective immediately
Anti-Alpha Fodrin Ab, IgG	FODIGG	<p><b>Days Performed: Monday–Friday</b>  <b>Reported: 13–15 days</b></p>	Effective immediately
Aquaporin-4 Receptor Antibody, IgG by IFA with Reflex to Titer, Serum	NMOIFA	<p><b>Clinical Information:</b> Useful for initial evaluation of neuromyelitis optica (NMO) spectrum disorders.  <b>Days Performed: Monday, Wednesday, Friday</b>  <b>Reported: 2–7 days</b></p>	Effective immediately
BAL, Routine	BALAVI	<p><b>Reference Range:</b>            BAL, Routine: Refer to report  <b>BAL reference ranges: No reference ranges established</b>  <i>(Note: Test directory update only)</i></p>	Effective immediately
Beta HCG, Quantitative, Blood	HCGQT	<p><b>Special Information:</b> Patients taking a biotin dose of up to 5 mg/day should refrain from taking biotin for 4 hours prior to sample collection. Patients taking a biotin dose of 5 to 10 mg/day should refrain from taking biotin for 8 hours prior to sample collection. Patients taking a biotin dose &gt; 10 mg/day should consult with their physician or the laboratory prior to having a sample taken. Clinicians should consider biotin interference as a source of error, when clinically suspicious of the laboratory result. <b>Add-ons will only be accepted from the emergency department providing an unopened/unprocessed tube is available for testing.</b></p>	Effective immediately
Beta hCG Quant Tumor Marker	BHCG	<p><b>Special Information:</b> Allow specimen to clot completely at room temperature. Specimens left to clot at 2–8 °C or specimens subjected to repeated freeze/thaw cycles are not acceptable. Cerebrospinal fluid (CSF) is unacceptable. This test is New York DOH approved. <b>Add-ons will only be accepted from the emergency department providing an unopened/unprocessed tube is available for testing.</b></p>	Effective immediately
Carbamazepine	CARBAM	<p><b>Special Information:</b> Do not collect in a gel separator tube. <b>Draw immediately before next dose.</b></p>	Effective immediately

## Test Changes (Cont.)

Test Name	Order Code	Change	Effective Date
Carbamazepine, Free	CARBFR	<b>Special Information:</b> Do not collect in a gel separator tube. <b>Draw immediately before next dose.</b>	Effective immediately
Carbamazepine, Free and Total	CARBFT	<b>Special Information:</b> Do not collect in a gel separator tube. <b>Draw immediately before next dose.</b>	Effective immediately
Cardiolipin Antibodies	CARDIO	<b>Stability:</b> Ambient: 1 day Refrigerated: 7 days Frozen: <b>1 year, up to 2 freeze/thaw cycles</b>	Effective immediately
Cardiolipin IgA Antibodies	CARDIA	<b>Stability:</b> Ambient: 1 day Refrigerated: 7 days Frozen: <b>1 year, up to 2 freeze/thaw cycles</b>	Effective immediately
Cardiolipin IgG Antibodies	CARDIG	<b>Stability:</b> Ambient: 1 day Refrigerated: 7 days Frozen: <b>1 year, up to 2 freeze/thaw cycles</b>	Effective immediately
Cardiolipin IgM Antibodies	CARDIM	<b>Stability:</b> Ambient: 1 day Refrigerated: 7 days Frozen: <b>1 year, up to 2 freeze/thaw cycles</b>	Effective immediately
Cell Count/Diff, Body Fluid	CCBF	<b>Reference Range:</b> Body fluid RBC: < 2000 cells/ $\mu$ L Body fluid TNC: < 1000 cells/ $\mu$ L <b>Neutrophils: 0–1%</b> <b>Lymphocytes: 18–36%</b> <b>Macrophages: 64–80%</b> <b>Mesothelials: 0–2%</b> (Note: Test directory update only)	Effective immediately
Chlamydia Antibody Panel, IgM	CHLAMM	<b>Special Information:</b> Contaminated, hemolyzed, or lipemic serum will be rejected. Ideally, acute and convalescent samples should be tested simultaneously at the same facility. If the sample submitted was collected during the acute phase of illness, submit a marked convalescent sample within 25 days for paired testing. <b>Clinical Information:</b> Differentiate between Chlamydophila species ( <i>C. psittaci</i> , <i>C. pneumoniae</i> ). Differentiate early IgM response to infection from persistent low-level titer. Because of cross-reactivity, a <i>C. pneumoniae</i> -specific reaction will exhibit titers two-fold or greater than <i>C. trachomatis</i> or <i>C. psittaci</i> serology. Seroconversion, a fourfold or greater rise in antibody titer between acute and convalescent sera, is considered strong evidence of recent infection. <b>Specimen Requirement:</b> 1 mL serum from a serum separator (gold) tube; Minimum: <b>0.15 mL</b> ; Separate serum from cells within 2 hours of collection; <b>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;'</b> Refrigerated  *OR* 1 mL serum from a plain no additive (red) tube; Minimum: <b>0.15 mL</b> ; Separate serum from cells within 2 hours of collection; <b>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;'</b> Refrigerated <b>Stability:</b> Ambient: After separation from cells: <b>48 hours</b> Refrigerated: After separation from cells: 2 weeks Frozen: After separation from cells: 1 year ( <b>Avoid repeated freeze/thaw cycles</b> )	Effective immediately
CSF, Cell Count and Diff	CCCSF	<b>Reference Range:</b> RBC, CSF: 0–5 cells/ $\mu$ L Total Nucleated Cells, CSF: 0–5 cells/ $\mu$ L <b>Neutrophils: &lt; 3%</b> <b>Lymphocytes: 50–90%</b> <b>Monocytes: 10–50%</b> <b>Macrophages: 0%</b> (Note: Test directory update only)	Effective immediately

## Test Changes (Cont.)

Test Name	Order Code	Change	Effective Date
Cyclic Citrullinated Peptide Ab, IgG	CCP	<b>Stability:</b> Ambient: 1 day Refrigerated: 7 days Frozen: <b>1 year, up to 2 freeze/thaw cycles</b>	12/22/20
DNA Autoantibodies, Double Stranded	DSDNA	<b>Days Performed:</b> Monday–Friday <b>Reported:</b> 15–22 days	Effective immediately
<b>FISH for TFE3</b>	TFE3FH	<b>Test Name:</b> <i>Previously FISH for Renal Cell Carcinoma TFE3</i> <b>Note:</b> <i>Order code change (previously TFE3RC). Testing may be performed on renal tissue and other tissue types. FISH FOR TFE3 RENAL CELL CARCINOMA will be removed as an alias name.</i>	12/8/20
<b>FISH for TFE3 and TFEB Panel</b>	TFEFSH	<b>Test Name:</b> <i>Previously FISH for Renal Cell Carcinoma Panel</i> <b>Note:</b> <i>Order code change (previously TRFCCP). Testing may be performed on renal tissue and other tissue types.</i>	12/8/20
<b>FISH for TFEB</b>	TFEBFH	<b>Test Name:</b> <i>Previously FISH for Renal Cell Carcinoma TFEB</i> <b>Note:</b> <i>Order code change (previously TFE3RC). Testing may be performed on renal tissue and other tissue types. FISH FOR TFEB RENAL CELL CARCINOMA will be removed as an alias name.</i>	12/8/20
Free Cortisol Stimulation Panel	CRTSIM	<b>Special Information: Grossly hemolyzed specimens and serum separator tubes will be rejected. Specimens received ambient will be rejected.</b> Three separate specimen tubes MUST be drawn for this assay; one at baseline, one 30 minutes post, and one 60 minutes post. For each timed specimen submitted, each tube must be clearly marked with time drawn. Submit all tubes with one test request form. Draw morning baseline specimen. Administer 250 µg Cortrosyn. Draw additional specimens at 30 and 60 minutes. Cortrosyn is not provided by the performing lab. <b>Note:</b> <i>Clinical Information will be removed.</i> <b>Specimen Requirement:</b> 2 mL serum from a plain no additive (red) tube; Minimum: 0.7 mL; <b>Do not use gel separator tubes; Separate serum from cells ASAP and freeze; This assay requires 3 separate tubes; One drawn at baseline, one drawn 30 minutes post, and one drawn 60 minutes post;</b> Frozen *OR* 2 mL plasma from an EDTA (lavender) tube; Minimum: 0.7 mL; <b>Do not use gel separator tubes; Separate plasma from cells ASAP and freeze; This assay requires 3 separate tubes; One drawn at baseline, one drawn 30 minutes post, and one drawn 60 minutes post;</b> Frozen *OR* 2 mL plasma from an <b>EDTA (white) plasma preparation tube (PPT); Do not use gel separator tubes; Separate plasma from cells ASAP and freeze; This assay requires 3 separate tubes; One drawn at baseline, one drawn 30 minutes post, and one drawn 60 minutes post;</b> Frozen <b>Stability:</b> Ambient: <b>48 hours</b> Refrigerated: 1 week Frozen: 2 years <b>Days Performed:</b> Sunday–Thursday <b>Reported:</b> 4–8 days	Effective immediately
Hepatitis A Antibody, IgM	AHAVM	<b>Days Performed:</b> Sunday–Saturday <b>Reported:</b> 1–3 days	Effective immediately
Hepatitis Acute Panel	HACUTP	<b>Days Performed:</b> Sunday–Saturday <b>Reported:</b> 1–3 days	Effective immediately
Hepatitis B Core Antibody, IgM	AHBCM	<b>Days Performed:</b> Sunday–Saturday <b>Reported:</b> 1–3 days	Effective immediately
Hepatitis B Core Antibody Total	AHBCOT	<b>Days Performed:</b> Sunday–Saturday <b>Reported:</b> 1–3 days	Effective immediately
Hepatitis B Surface Ab, Immunity	AHBSI	<b>Days Performed:</b> Sunday–Saturday <b>Reported:</b> 1–3 days	Effective immediately
Hepatitis B Surface Ab, Qual.	AHBSAG	<b>Days Performed:</b> Sunday–Saturday <b>Reported:</b> 1–3 days	Effective immediately

## Test Changes (Cont.)

Test Name	Order Code	Change	Effective Date
Hepatitis B Surface Ab, Quant	AHBSQ	<b>Days Performed:</b> Sunday–Saturday <b>Reported:</b> 1–3 days	Effective immediately
Hepatitis B Surface Antigen	HBSAG	<b>Days Performed:</b> Sunday–Saturday <b>Reported:</b> 1–3 days	Effective immediately
Hepatitis B Surface Antigen Conf	HBSAGC	<b>Days Performed:</b> Sunday–Saturday <b>Reported:</b> 1–3 days	Effective immediately
Hepatitis B Virus (HBV) Drug Resistance, Genotype and BCP/Precore Mutations by Sequencing	HEPBDR	<b>Special Information:</b> Patient <b>must</b> have a viral load greater than 600 IU/mL. <b>This test is New York DOH approved. Thawed specimens will be rejected.</b>	Effective immediately
Hepatitis C Antibody IA	AHCV	<b>Days Performed:</b> Sunday–Saturday <b>Reported:</b> 1–3 days	Effective immediately
Hepatitis C Antibody IA w/Confirm	AHCV1B	<b>Days Performed:</b> Sunday–Saturday <b>Reported:</b> 1–3 days	Effective immediately
Hepatitis Remote Panel	HREMOP	<b>Days Performed:</b> Sunday–Saturday <b>Reported:</b> 1–3 days	Effective immediately
HIV-1/2 Ab Confirmatory	HIV12M	<b>Days Performed:</b> Monday–Friday <b>Reported:</b> 1–3 days	Effective immediately
IgE	IGE	<b>Clinical Information:</b> The test is used as an aid in assessment of patients with suspected allergic diseases, primary immunodeficiencies, parasitic infections, certain malignancies, and also to identify candidates for anti-IgE immunotherapy, among others. <b>Specimen Requirement:</b> 0.5 mL serum from a serum separator (gold) tube; Minimum: 0.3 mL; Refrigerated <b>*OR* 0.5 mL plasma from an EDTA (lavender) tube; Minimum: 0.3 mL; Refrigerated</b> <b>*OR* 0.5 mL plasma from a lithium heparin (light green) plasma separator tube (PST); Minimum: 0.3 mL; Refrigerated</b>	Effective immediately
Metanephrines, Urine 24 hour	UMETAN	<b>Stability:</b> Ambient: <b>3 days</b> Refrigerated: <b>2 weeks</b> Frozen: 1 month ( <b>one freeze/thaw cycle allowed</b> ) <b>Methodology:</b> High Performance Liquid Chromatography/Tandem Mass Spectrometry (LC/MS/MS)	1/5/21
Metanephrines, Urine Random	UMETRA	<b>Stability:</b> Ambient: <b>3 days</b> Refrigerated: <b>2 weeks</b> Frozen: 1 month <b>Methodology:</b> High Performance Liquid Chromatography/Tandem Mass Spectrometry (LC/MS/MS)	1/5/21

## Test Changes (Cont.)

Test Name	Order Code	Change	Effective Date
Neopterin	NEOPT	<p><b>Special Information:</b> CRITICAL: MUST protect from light. Specimens not protected from light will be rejected. If tube other than a gel-barrier tube is used, transfer separated serum or plasma to a plastic transport tube. <b>Grossly lipemic, hemolyzed or icteric specimens will be rejected.</b></p> <p><b>Specimen Requirement:</b> 0.8 mL serum from a serum separator (gold) tube; Minimum: 0.3 mL (Note: This volume does NOT allow for repeat testing); CRITICAL: MUST protect from light; Specimens that are not protected from light will be rejected; <b>Frozen</b></p> <p>*OR* 0.8 mL serum from a plain no additive (red) tube; Minimum: 0.3 mL (Note: This volume does NOT allow for repeat testing); Transfer separated serum to a plastic transport tube; CRITICAL: MUST protect from light; Specimens that are not protected from light will be rejected; <b>Frozen</b></p> <p>*OR* 0.8 mL plasma from an EDTA (lavender) tube; Minimum: 0.3 mL (Note: This volume does NOT allow for repeat testing); Transfer separated plasma to a plastic transport tube; CRITICAL: MUST protect from light; Specimens that are not protected from light will be rejected; <b>Frozen</b></p> <p><b>Stability:</b>                      Ambient: Unacceptable                      Refrigerated: <b>3 days</b>                      Frozen: 6 months</p> <p><b>Days Performed: Wednesday</b></p> <p><b>Reported: 6–9 days</b></p>	Effective immediately
Norwalk-Like Virus Antigen	NORWLK	<p><b>Includes:</b>  <b>Norovirus Antigen</b>                      (Note: Test directory update only, no changes to the test build)</p> <p><b>Special Information: Rectal swabs and stool in transport media containing preservatives will be rejected. Stool contaminated with metal ions or oxidizing agents or detergents will be rejected.</b></p> <p><b>Note:</b> Clinical Information will be removed.</p> <p><b>Specimen Requirement:</b> 2 g stool in a <b>clean</b> container; Minimum: 1 g; Frozen</p> <p><b>Stability:</b>                      Ambient: Unacceptable                      Refrigerated: <b>72 hours</b>                      Frozen: 1 year</p> <p><b>Days Performed: Monday, Wednesday, Friday</b></p> <p><b>Reported: 2–5 days</b></p>	Effective immediately
Phenytoin	PHT	<p><b>Special Information:</b> Do not collect in a gel separator tube. <b>Draw once steady state is achieved.</b></p>	Effective immediately
Phenytoin, Free	PHTFR	<p><b>Special Information:</b> Do not collect in a gel separator tube. <b>Draw once steady state is achieved.</b></p>	Effective immediately
PSA	PSA	<p><b>Special Information:</b> For an individual patient, the significance of a PSA level should be interpreted in a broad clinical context, including age, race, family history, digital rectal exam, prostate size, results of prior testing (prostate biopsy, free PSA, PCA3), and use of 5-alpha reductase inhibitors. Considering the high incidence of asymptomatic cancer in the general population that may not pose an ultimate risk to the patient, the decision to recommend urological evaluation or prostate biopsy should be individualized after considering all of these factors. Reference: Punglia S, Rinaa, M.D., M.P.H., D'Amico V, Anthony, M.D., Ph.D., Catalona J, William, M.D., Roehl A, Kimberly, M.P.H., Kuntz M., Karen, Sc.D. Effect of Verification Bias on Screening for Prostate Cancer Measurement of Prostate-Specific Antigen. N Engl J Med 2003;349:335-42. Patients taking a biotin dose of up to 5 mg/day should refrain from taking biotin for 4 hours prior to sample collection. Patients taking a biotin dose of 5 to 10 mg/day should refrain from taking biotin for 8 hours prior to sample collection. Patients taking a biotin dose &gt; 10 mg/day should consult with their physician or the laboratory prior to having a sample taken. Clinicians should consider biotin interference as a source of error, when clinically suspicious of the laboratory result. <b>Add-ons will only be accepted from the emergency department providing an unopened/unprocessed tube is available for testing.</b></p>	Effective immediately

## Test Changes (Cont.)

Test Name	Order Code	Change	Effective Date
PSA, Free	PSATF	<b>Special Information:</b> For an individual patient, the significance of a PSA level should be interpreted in a broad clinical context, including age, race, family history, digital rectal exam, prostate size, results of prior testing (prostate biopsy, free PSA, PCA3), and use of 5-alpha reductase inhibitors. Considering the high incidence of asymptomatic cancer in the general population that may not pose an ultimate risk to the patient, the decision to recommend urological evaluation or prostate biopsy should be individualized after considering all of these factors. Reference: Punglia S, Rinaa, M.D., M.P.H., D'Amico V, Anthony, M.D., Ph.D., Catalona J, William, M.D., Roehl A, Kimberly, M.P.H., Kuntz M., Karen, Sc.D. Effect of Verification Bias on Screening for Prostate Cancer Measurement of Prostate-Specific Antigen. N Engl J Med 2003;349:335-42. Patients taking a biotin dose of up to 5 mg/day should refrain from taking biotin for 4 hours prior to sample collection. Patients taking a biotin dose of 5 to 10 mg/day should refrain from taking biotin for 8 hours prior to sample collection. Patients taking a biotin dose > 10 mg/day should consult with their physician or the laboratory prior to having a sample taken. Clinicians should consider biotin interference as a source of error, when clinically suspicious of the laboratory result. <b>Add-ons will only be accepted from the emergency department providing an unopened/unprocessed tube is available for testing.</b>	Effective immediately
PSA, Screening	PSAS1	<b>Special Information:</b> For an individual patient, the significance of a PSA level should be interpreted in a broad clinical context, including age, race, family history, digital rectal exam, prostate size, results of prior testing (prostate biopsy, free PSA, PCA3), and use of 5-alpha reductase inhibitors. Considering the high incidence of asymptomatic cancer in the general population that may not pose an ultimate risk to the patient, the decision to recommend urological evaluation or prostate biopsy should be individualized after considering all of these factors. Reference: Punglia S, Rinaa, M.D., M.P.H., D'Amico V, Anthony, M.D., Ph.D., Catalona J, William, M.D., Roehl A, Kimberly, M.P.H., Kuntz M., Karen, Sc.D. Effect of Verification Bias on Screening for Prostate Cancer Measurement of Prostate-Specific Antigen. N Engl J Med 2003;349:335-42. Patients taking a biotin dose of up to 5 mg/day should refrain from taking biotin for 4 hours prior to sample collection. Patients taking a biotin dose of 5 to 10 mg/day should refrain from taking biotin for 8 hours prior to sample collection. Patients taking a biotin dose > 10 mg/day should consult with their physician or the laboratory prior to having a sample taken. Clinicians should consider biotin interference as a source of error, when clinically suspicious of the laboratory result. <b>Add-ons will only be accepted from the emergency department providing an unopened/unprocessed tube is available for testing.</b>	Effective immediately
Synovial Fluid, Routine Analysis	RTSYNF	<b>Reference Range:</b> Synovial Fluid, Routine Analysis: Refer to report Synovial fluid RBC: < 2000 cells/ $\mu$ L Synovial fluid TNC: 0–200 cells/ $\mu$ L <b>Neutrophils: &lt; 25%</b> <b>Crystals: None</b> (Note: Test directory update only)	Effective immediately
Theophylline	THEO	<b>Special Information:</b> Do not collect in a gel separator tube. <b>Sample should be obtained at the time of the expected peak serum concentration.</b>	Effective immediately
Valproic Acid	VPA	<b>Special Information:</b> Do not collect in a gel separator tube. <b>Draw immediately before next dose.</b>	Effective immediately
Valproic Acid, Free	VPAFR	<b>Special Information:</b> Do not collect in a gel separator tube. <b>Draw immediately before next dose.</b>	Effective immediately
Valproic Acid, Total and Free	VPAFT2	<b>Special Information:</b> Do not collect in a gel separator tube. <b>Draw immediately before next dose.</b>	Effective immediately
Vancomycin	VANCR	<b>Special Information:</b> Do not collect in a gel separator tube. <b>Usual sampling time varies dependent upon desired measurement of peak or trough values. For trough values, draw immediately before next dose.</b>	Effective immediately



# New Tests

Test Name	Order Code	Change	Effective Date
Adenovirus Quantitative Real-time PCR	ADVQNT	<p><b>Clinical Information:</b> Adenovirus is an important cause of morbidity and mortality in the transplant setting, causing pneumonia, hemorrhagic cystitis, hepatitis, encephalitis, pancreatitis, enteritis, and disseminated disease with the mortality rate reaching 60% in some especially high risk situations such as pediatric hematopoietic stem cell transplantation. Since proper management is dependent upon early diagnosis, quantitative adenovirus DNA PCR is useful for detecting the virus, tracking the course of infection, and monitoring response to treatment. Treatment of adenovirus in immunocompromised patients presents challenges, including drug toxicity, delayed onset of disease after discontinuing therapy, and emergence of mutations that may affect the ability of diagnostic assays to detect them efficiently.</p> <p><b>Specimen Requirement:</b> 2 mL plasma from an EDTA (lavender) tube; Minimum: 0.5 mL; Do not use gel separator tubes; Transfer plasma to standard aliquot tube; Frozen</p> <p>*OR* 2 mL serum from a plain no additive (red) tube; Minimum: 0.5 mL; Do not use gel separator tubes; Transfer serum to standard aliquot tube; Frozen</p> <p>*OR* 2 mL plasma from an ACD A (yellow) or ACD B (yellow) tube; Do not use gel separator tubes; Transfer plasma to standard aliquot tube; Frozen</p> <p><b>Stability:</b>            Ambient: 4 days            Refrigerated: 4 days            Frozen: 2 weeks</p> <p><b>Methodology:</b> Real-Time Polymerase Chain Reaction (RT-PCR)</p> <p><b>Days Performed:</b> Monday–Saturday</p> <p><b>Reported:</b> 2–3 days</p> <p><b>CPT:</b> 87799 x 1</p> <p><b>Price:</b> \$190.00 (non-discountable)</p>	Effective immediately
CNS Demyelinating Disease Evaluation, Serum	CDS1SE	<p><b>Includes:</b>            NMO/AQP4 FACS, S            MOG FACS, S            CNS Demyelinating Disease Interp, S</p> <p><b>Special Information:</b> When the results of this assay require further evaluation of myelin oligodendrocyte glycoprotein (MOG-IgG1), the MOG-IgG1 titer will be performed at an additional cost. When the results of this assay require further evaluation of neuromyelitis optica (NMO)/Aquaporin-4-IgG, the neuromyelitis optica (NMO)/aquaporin-4-IgG titer will be performed at an additional charge. New York State approved. Grossly hemolyzed, lipemic or icteric specimens will be rejected.</p> <p><b>Clinical Information:</b> Diagnosis of inflammatory demyelinating diseases (IDDs) with similar phenotype to neuromyelitis optica spectrum disorder (NMOSD), including optic neuritis (single or bilateral) and transverse myelitis. Diagnosis of autoimmune myelin oligodendrocyte glycoprotein (MOG)-opathy. Diagnosis of neuromyelitis optica (NMO). Distinguishing NMOSD, acute disseminated encephalomyelitis (ADEM), optic neuritis, and transverse myelitis from multiple sclerosis early in the course of disease. Diagnosis of ADEM. Prediction of a relapsing disease course. Aquaporin-4 (AQP4)-IgG and myelin oligodendrocyte glycoprotein (MOG)-IgG antibodies may drop below detectable levels in setting of therapies for acute attack (IV methylprednisolone or plasmapheresis) or attack prevention (immunosuppressants).</p> <p><b>Specimen Requirement:</b> 3 mL serum from a plain no additive (red) tube; Minimum: 2 mL; Refrigerated</p> <p>*OR* 3 mL serum from a serum separator (gold) tube; Minimum: 2 mL; Refrigerated</p> <p><b>Stability:</b>            Ambient: 72 hours            Refrigerated: 28 days            Frozen: 28 days</p> <p><b>Methodology:</b> Fluorescent Activated Cell Sorting Assay (FACS)</p> <p><b>Days Performed:</b> Monday, Tuesday, Thursday</p> <p><b>Reported:</b> 8–11 days</p> <p><b>CPT:</b> 86255 x 2</p> <p><b>Price:</b> \$664.00 (non-discountable)</p>	Effective immediately

## New Tests (Cont.)

Test Name	Order Code	Change	Effective Date
Routine Flu A/B & RSV	RTFRSV	<p><b>Specimen Requirement:</b> 3 mL nasopharyngeal swab in saline; Refrigerated                      *OR* 3 mL nasopharyngeal swab in Universal Transport Media (UTM); Refrigerated                      *OR* 3 mL nasopharyngeal swab in Viral Transport Media (VTM); Refrigerated</p> <p><b>Stability:</b>                      Ambient: 24 hours                      Refrigerated: 7 days                      Frozen: Unacceptable</p> <p><b>Methodology:</b> Polymerase Chain Reaction (PCR)</p> <p><b>Reference Range:</b>                      Influenza A PCR: Negative                      Influenza B PCR: Negative                      RSV PCR: Negative</p> <p><b>Days Performed:</b> 7 days per week  <b>CPT:</b> Varies  <b>Price:</b> \$368.00</p>	Effective immediately
Routine Flu A/B by PCR	RTFLU	<p><b>Specimen Requirement:</b> 3 mL nasopharyngeal swab in saline; Refrigerated                      *OR* 3 mL nasopharyngeal swab in Universal Transport Media (UTM); Refrigerated                      *OR* 3 mL nasopharyngeal swab in Viral Transport Media (VTM); Refrigerated</p> <p><b>Stability:</b>                      Ambient: 24 hours                      Refrigerated: 7 days                      Frozen: Unacceptable</p> <p><b>Methodology:</b> Polymerase Chain Reaction (PCR)</p> <p><b>Reference Range:</b>                      Influenza A PCR: Negative                      Influenza B PCR: Negative</p> <p><b>Days Performed:</b> 7 days per week  <b>CPT:</b> 87502 x 1  <b>Price:</b> \$215.00</p>	Effective immediately
Routine RSV by PCR	RTRSV	<p><b>Specimen Requirement:</b> 3 mL nasopharyngeal swab in saline; Refrigerated                      *OR* 3 mL nasopharyngeal swab in Universal Transport Media (UTM); Refrigerated                      *OR* 3 mL nasopharyngeal swab in Viral Transport Media (VTM); Refrigerated</p> <p><b>Stability:</b>                      Ambient: 24 hours                      Refrigerated: 7 days                      Frozen: Unacceptable</p> <p><b>Methodology:</b> Polymerase Chain Reaction (PCR)</p> <p><b>Reference Range:</b> Negative</p> <p><b>Days Performed:</b> 7 days per week  <b>CPT:</b> 87634 x 1  <b>Price:</b> \$153.00</p>	Effective immediately

## Discontinued Tests

Test Name	Order Code	Test Information	Effective Date
Adenovirus PCR, Quant	ADEQNT	This test will no longer be available. Suggest ordering Adenovirus Quantitative Real-time PCR (ADVQNT)	Effective immediately