Cleveland Clinic

Cleveland Clinic Laboratories

Technical Update • September 2017

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

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

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

For additional detail, contact Client Services at 216.444.5755 or 800.628.6816, or via email at clientservices@ccf.org.

Test Update Page #	Summary of Changes by Test Name	Order Code	Name Change	New Test	Test Discontinued	Special Information	Specimen Requirement	Component Change(s)	Methodology	Reference Range	Days Performed/Reported	Stability	CPT	Fee
3	Alpha Galactosidase, Serum											■		
3	Aspergillus fumigatus Antibody, IgG by ELISA					■	■							
3	Bartonella PCR					■	■					■	■	
4	Beta Globin (HBB) Gene Sequencing					■	■		■		■	■		
4	Bone marrow Cancer Chromosome Microarray + SNP						■							
4	Campylobacter Culture					■								
5, 14	Carotene					■	■			■	■	■		■
5	Catheter Tip Culture					■								
5	Chromosomal Microarray SNP, Constitutional						■							
5	Chromosome Analysis, Blood						■					■		
5	Chromosome Analysis, Bone Marrow						■					■		
6	Chromosome Analysis, Leukemic Blood						■					■		
12	Complete Atopic Dermatitis Panel			■										
6	CSF Culture & Stain					■								
12	DNA and RNA Extraction (Buffy Coat)			■										
14	DNA Extraction				■									
6	Drug Analysis, Urine					■	■					■		
6	Drug Screen, Blood					■	■				■			
7	Ear Culture and Gram Stain					■								
13	Eye Culture			■										
7	FISH for Myelodysplasia						■					■		

Test Update Page #	Summary of Changes by Test Name	Order Code	Name Change	New Test	Test Discontinued	Special Information	Specimen Requirement	Component Change(s)	Methodology	Reference Range	Days Performed/Reported	Stability	CPT	Fee
13	FISH for WWTR1/CAMTA1			■										
7	Hemoglobin Electrophoresis							■						
7	Hemoglobin Evaluation Cascade							■						
7	Hepatitis A Antibody, Total											■		
7–8, 14	Hepatitis C Genotyping					■	■		■		■	■		■
8	Hepatitis C RNA by PCR						■							
8	Hepatitis Delta Antibody					■	■				■	■		
8	Human Papillomavirus (HPV) DNA Detection with Genotyping 16,18, High-Risk Types by PCR, Sure Path						■					■		
9	Human Papillomavirus (HPV) DNA Detection with Genotyping 16,18, High-Risk Types by PCR, Thin Prep					■	■							
14	Humoral Immunity Panel				■									
13	Humoral Immunity Panel I			■										
9	IgE											■		
9	Legionella pneumophila PCR											■		
9	MRSA/Staph aureus Culture Screen					■								
14	Myeloma Prognostic Risk Signature				■									
9	Neutrophil Cytoplasmic Antibody											■		
9	Osmolality, Urine						■					■		
9	Pancreatic Elastase, Fecal					■						■		
14	Reticulin Antibody, IgA with reflex to Titer				■									
10	Reticulin IgA and IgG Antibodies					■	■				■		■	
14	Spinal Muscular Atrophy Carrier Screening and Diagnostic			■										
14	Spinal Muscular Atrophy DNA Test				■									
14	Stool Chemistry Panel				■									
10	Sulfonylurea Hypoglycemia Panel, Quantitative, Urine					■	■		■				■	
11	Sulfonylurea Hypoglycemics		■			■	■						■	
11	Testosterone, Free and Total						■					■		
11	Trypsinogen					■								

Client ID/Mnemonic Code Needed to Place Orders

The CCL Logistics Department is making a change to the laboratory supply ordering process. **Starting on September 1, 2017, all clients will be required to enter a Client ID/Mnemonic code when placing an order on the Supply Storefront on clevelandcliniclabs.com**. This information will help us track supply usage, which keeps us compliant with laboratory standards.

If you do not know your Client ID/Mnemonic code, please contact Client Services at 800.628.6816 for assistance.

SMA Carrier Screening Available on October 25, 2017

In March 2017, the American College of Obstetricians and Gynecologists (ACOG) updated their genetic carrier screening recommendations to include screening for spinal muscular atrophy (SMA). ACOG now recommends that all women who are pregnant or considering pregnancy be offered both cystic fibrosis (CF) and SMA carrier screening.

Our lab currently offers cystic fibrosis carrier screening and beginning on October 25, 2017, genetic testing for spinal muscular atrophy will also be available in the Molecular Pathology lab at Cleveland Clinic Laboratories. This copy number analysis of SMN1 and SMN2 genes may be used for both carrier screening and diagnostic confirmation.

Test Changes

Test Name	Order Code	Change	Effective Date
Alpha Galactosidase, Serum	ALPGAL	**Stability:** Ambient: Unacceptable Refrigerated: **24 hours** Frozen: 2 weeks	Effective immediately
Aspergillus fumigatus Antibody, IgG by ELISA	ASPIGG	**Special Information: Contaminated, lipemic or turbid specimens are unacceptable.** Separate serum from cells ASAP or within 2 hours of collection. **This test is New York DOH approved.** **Specimen Requirement:** 1 mL serum from a red top tube with no additive; Minimum: **0.05 mL;** Remove serum from cells **ASAP or** within 2 hours of collection **and transfer to standard aliquot tube;** Refrigerated *OR* 1 mL serum from a serum separator (gold) tube; Minimum: **0.05 mL;** Remove serum from cells **ASAP or** within 2 hours of collection **and transfer to standard aliquot tube;** Refrigerated	Effective immediately
Bartonella PCR	BARPCR	**Special Information: Causes for rejection: Heparin tube collections, bone marrow** **Specimen Requirement: 1 mL** whole blood in an EDTA lavender top tube; Minimum: 0.5 mL; **Send specimen in original tube (preferred);** Refrigerated *OR* **1 mL** whole blood in an **EDTA royal blue top tube;** Minimum: 0.5 mL; **Send specimen in original tube (preferred); Refrigerated** **Stability:** Ambient: 7 days Refrigerated: 7 days Frozen: **7 days** **CPT: 87801 x 1**	Effective immediately

Test Changes (Cont.)

Test Name	Order Code	Change	Effective Date
Beta Globin (HBB) Gene Sequencing	BGHBBB	**Special Information: Include a recent CBC (within past 3 months) and a Patient History for Hemoglobinopathy/Thalassemia testing form with the order. This test is New York DOH approved.** **Clinical Limitation: Diagnostic errors can occur due to rare sequence variations. Large deletions, and mutations in distal regulatory elements are not detected.** **Clinical Information: Useful for molecular confirmation of a suspected structural hemoglobinopathy or beta thalassemia. Characteristics: Structural hemoglobinopathies or thalassemias (insufficient or absent beta-chain production). Incidence: Varies with ethnicity. Inheritance: Usually autosomal recessive, infrequently autosomal dominant. Cause: Pathogenic mutations in the HBB gene.** Mutations tested: The complete protein coding sequence with exon/intron boundaries, proximal promoter, 5' and 3' untranslated regions, and intronic mutations IVS-II-654, IVS-II-705 and IVS-II-745. Clinical Sensitivity: Up to 97%, depending on ethnicity. **Methodology: Bidirectional sequencing of the HBB coding regions, intron-exon boundaries, proximal promoter, 5' and 3' untranslated regions, and intronic mutations IVS-II-654, IVS-II-705 and IVS-II-745.** Analytical sensitivity: 99%. **Normal: This specimen has a normal sequence of the b-globin gene. No mutations were identified within the b-globin coding region, the intron/exon splice site boundaries or intronic positions IVS-II 654, IVS-II 705, and IVS-II 745. Gene deletions or mutations causing thalassemias or hemoglobinopathies outside of these regions will not be identified.** **Specimen Requirement:** 3 mL whole blood in an EDTA lavender top tube; Minimum: 1 mL; A completed ARUP 'Patient History for Hemoglobinopathy/Thalassemia Testing' form is required; The required form may be obtained by calling Client Services at 800.628.6816 or 216.444.5755; **Submit a recent CBC (within past 3 months);** Refrigerated *OR* 3 mL whole blood in an ACD A or B (yellow) tube; Minimum: 1 mL; A completed ARUP 'Patient History for Hemoglobinopathy/Thalassemia Testing' form is required; The required form may be obtained by calling Client Services at 800.628.6816 or 216.444.5755; **Submit a recent CBC (within past 3 months);** Refrigerated *OR* 100 µL extracted DNA at a concentration of 50 ng/µL in a sterile container; A completed ARUP 'Patient History for Hemoglobinopathy/Thalassemia Testing' form is required; The required form may be obtained by calling Client Services at 800.628.6816 or 216.444.5755; **Submit a recent CBC (within past 3 months);** Refrigerated **Stability:** Ambient: 72 hours Refrigerated: 1 week; **Note: Extracted DNA samples must be shipped refrigerated** Frozen: Unacceptable **Methodology:** **Bidirectional Sequence Analysis** Polymerase Chain Reaction (PCR) **Days Performed: Sunday–Saturday** **Reported:** 15–**22** days	Effective immediately
Bone marrow Cancer Chromosome Microarray + SNP	BMHSNP	**Specimen Requirement:** 4 mL bone marrow in an **EDTA lavender top tube;** Note: Collect specimen Monday–Friday only; If aliquoting is necessary, sterile aliquot tubes must be used; Ambient	10/16/17
Campylobacter Culture	CAMPY	**Clinical Information: Methods are for recovery of Campylobacter jejuni and Campylobacter coli, the species most commonly associated with gastroenteritis. Contact Cleveland Clinic Laboratories to request susceptibility testing (requires sending to specialty laboratory for agar dilution).**	9/14/17

Test Changes (Cont.)

Test Name	Order Code	Change	Effective Date
Carotene	CAROT	**Special Information:** Patient Preparation: 12 hour fast prior to collection is preferred, but not required. **Protect from light during collection, storage, and shipment, and use amber transport tubes. Separate serum from cells within one hour of collection. Separate specimens must be submitted when multiple tests are ordered. This test is New York DOH approved. Unacceptable conditions: Any specimen other than serum; refrigerated or room temperature specimens; hemolyzed or icteric specimens** **Clinical Information: Use to assess** fat malabsorption. **Specimen Requirement:** 2 mL serum from a serum separator (gold) tube; Minimum: **0.6 mL;** Protect specimen from light **during collection, storage and shipment; Separate serum from cells within one hour of collection; Use amber transport tubes; Separate specimens MUST be submitted when multiple tests are ordered;** Frozen *OR* 2 mL serum from a **red top tube with no additive;** Minimum: **0.6 mL;** Protect specimen from light **during collection, storage and shipment; Separate serum from cells within one hour of collection; Use amber transport tubes; Separate specimens MUST be submitted when multiple tests are ordered; Frozen** **Stability:** Ambient: **After separation from cells: Unacceptable** Refrigerated: **After separation from cells: 4 hours** Frozen: **After separation from cells: 1 month** **Reference Range: 60–200 µg/dL** **Days Performed:** Monday–**Saturday** **Reported: 2–4** days	10/25/17
Catheter Tip Culture	CTCUL	**Special Information: Culture performed on intravascular catheter tips (e.g., central, CVP, Hickman, Broviac, peripheral, arterial, umbilical, hyperalimentation, Swan-Ganz). Cleanse skin around catheter site with alcohol. Aseptically remove catheter and clip 5 cm of distal tip directly into a sterile container.** If culture is positive, identification will be performed on clinically significant organisms at an additional charge. Identification CPT codes that may apply include: 87077, 87106, 87107, 87153. Antimicrobial susceptibilities are performed when indicated, and the following CPT codes may apply: 87181, 87184, 87185, 87186. **Foley catheter tips, chest tube tips and abdominal drainage tips are not acceptable for culture.** **Clinical Information: Blood cultures are the essential test for diagnosing catheter-related bacteremia. The clinical relevance of catheter tip cultures is controversial. A positive culture may indicate contamination during removal.**	9/14/17
Chromosomal Microarray SNP, Constitutional	CRMSNP	**Specimen Requirement:** 4 mL whole blood in an **EDTA lavender top tube;** Minimum: 1 mL; If aliquoting is necessary, sterile aliquot tubes must be used; Ambient	10/16/17
Chromosome Analysis, Blood	CHRBLD	**Specimen Requirement:** 4 mL whole blood in a sodium heparin green top tube; Minimum: 2 mL; **May also be transported refrigerated;** Deliver specimen to Cleveland Clinic Laboratories immediately after collection; If aliquoting is necessary, sterile aliquot tubes must be used; Ambient **Stability:** Ambient: 48 hours Refrigerated: **Acceptable for transport** Frozen: Unacceptable	10/4/17
Chromosome Analysis, Bone Marrow	CHRBMH	**Specimen Requirement:** 2–3 mL bone marrow in a sodium heparin green top tube; Minimum: 1 mL; **May also be transported refrigerated;** If aliquoting is necessary, sterile aliquot tubes must be used; Ambient **Stability:** Ambient: 48 hours Refrigerated: **Acceptable for transport** Frozen: Unacceptable	10/4/17

Test Changes (Cont.)

Test Name	Order Code	Change	Effective Date
Chromosome Analysis, Leukemic Blood	CHRBLL	**Specimen Requirement:** 4 mL whole blood in a sodium heparin green top tube; Minimum: 2 mL; **May also be transported refrigerated;** Deliver to Cleveland Clinic Laboratories within 24 hours of collection; If aliquoting is necessary, sterile aliquot tubes must be used; Ambient **Stability:** Ambient: 48 hours Refrigerated: **Acceptable for transport** Frozen: Unacceptable	10/4/17
CSF Culture & Stain	CSFCUL	**Special Information: Aseptically collect cerebrospinal fluid (CSF) from a lumbar puncture into sterile tubes. Send second tube to the Microbiology laboratory. Include specimen description (e.g., LP, shunt) on requisition.** Do not refrigerate specimens. **CSF Gram stains are performed STAT (within one hour of receipt in laboratory).** If culture is positive, identification will be performed at an additional charge for clinically significant organisms. Identification CPT codes that may apply include: 87077, 87106, 87107, 87153, 87158. Antimicrobial susceptibilities are performed when indicated, and the following CPT codes may apply: 87181, 87184, 87185, 87186 **Clinical Information: If anaerobic infection is suspected, also order an anaerobic culture (ANACUL) in addition to the aerobic culture (CSFCUL). An order for CSFCUL on a shunt specimen includes a broth culture incubated for 14 days to optimize recovery of Cutibacterium (formerly Propionibacterium) acnes.**	9/14/17
Drug Analysis, Urine	UDRUGC	**Special Information: Cautions: Not intended for therapeutic compliance testing.** Not intended for use in employment-related testing. Test results are qualitative. **Submission of less than 30 mL urine compromises the ability to perform all necessary testing. This test is New York State approved.** **Clinical Information: Useful for the qualitative detection and identification of prescription or over-the-counter drugs frequently found in drug overdose or used with a suicidal intent.** Drugs of toxic significance that are not detected by this test are: Digoxin, lithium, many drugs of abuse/illicit drugs, some benzodiazepines, and some opiates. **Drugs detected are presumptive. Additional testing may be required to confirm the presence of any drugs detected.** **Specimen Requirement:** 30 mL random urine in a clean container **(No preservatives);** Minimum: **1.1 mL;** Refrigerated **Stability:** Ambient: 3 **hours** Refrigerated: 14 days Frozen: 14 days	Effective immediately
Drug Screen, Blood	BDRUG	**Special Information: Cautions: Not intended for therapeutic compliance testing. Not intended for use in employment-related testing. Plasma or serum gel tubes will be rejected. This test is New York State approved.** **Clinical Information: Useful for detection and identification of prescription or over-the-counter drugs frequently found in drug overdose or used with a suicidal intent.** This test is designed to qualitatively identify drugs present in the specimen; **quantification of identified drugs, when available, may be performed upon client request. Drugs of toxic significance that are not detected by this test are: Digoxin, lithium, many drugs of abuse or illicit drugs, some benzodiazepines, and some opioids. Drugs detected are presumptive. Additional testing may be required to confirm the presence of any drugs detected.** **Specimen Requirement: 2.75 mL** serum from a red top tube with no additive; Minimum: **1.1 mL; Do not draw serum separator tubes (SST);** Refrigerated **Days Performed: Monday**–Sunday **Reported: 4**–5 days	Effective immediately

Test Changes (Cont.)

Test Name	Order Code	Change	Effective Date
Ear Culture and Gram Stain	EARCSM	**Special Information: Inner ear: For intact eardrum, clean ear canal with soap solution and collect fluid via syringe aspiration. Submit in sterile container. For ruptured eardrum, collect fluid on flexible shaft swab via an auditory speculum. Outer ear: Use moistened swab to remove any debris or crust from ear canal. Obtain sample by firmly rotating swab in outer canal. For otitis externa, vigorous swabbing is required – surface swabbing may miss streptococcal cellulitis.** If culture is positive, identification will be performed on clinically significant organisms at an additional charge. Identification CPT codes that may apply include: 87077, 87106, 87107, 87153, 87158. Antimicrobial susceptibilities are performed when indicated, and the following CPT codes may apply: 87181, 87184, 87185, 87186 **Clinical Information: Otitis media can usually be diagnosed and treated without culture. Tympanocentesis should be reserved for complicated, recurrent, or chronic persistent otitis media. Respiratory viruses, Streptococcus pneumoniae, Haemophilus influenzae and Moraxella catarrhalis are the most common organisms causing acute otitis media. Chronic external otitis is often due to seborrhea. The primary etiology of necrotizing otitis externa infection is Pseudomonas aeruginosa.**	9/14/17
FISH for Myelodysplasia	FSHMDS	**Specimen Requirement: 2–3 mL** bone marrow in an **EDTA lavender top tube; If aliquoting is necessary, sterile aliquot tubes must be used; Refrigerated** *OR* **2–3 mL** bone marrow in a sodium heparin green top tube; **If aliquoting is necessary, sterile aliquot tubes must be used; Refrigerated** *OR* **5–7 mL** whole blood in an EDTA lavender top tube; **If aliquoting is necessary, sterile aliquot tubes must be used;** Refrigerated *OR* **5–7 mL** whole blood in a sodium heparin green top tube; **If aliquoting is necessary, sterile aliquot tubes must be used; Refrigerated** **Stability:** Ambient: **48 hours** Refrigerated: **Acceptable** Frozen: **Unacceptable**	10/24/17
Hemoglobin Electrophoresis	HBELEC	**For Interfaced Clients Only: Test build may need to be modified** **Includes:** Hemoglobin A2 Hemoglobin Fetal **Reviewed by**	9/12/17
Hemoglobin Evaluation Cascade	HBEVAL	**For Interfaced Clients Only: Test build may need to be modified** **Includes:** Hemoglobin Fetal Hemoglobin A2 Percent **Reviewed by**	9/12/17
Hepatitis A Antibody, Total	AHAVT	**Stability:** Ambient: **12 hours** Refrigerated: **7** days Frozen: 1 year	9/11/17
Hepatitis C Genotyping	HEPGEN	**Special Information:** A quantitative HCV PCR must be performed within four weeks prior to HCV Genotype order. The viral load of the HCV must be **greater than 500 IU/mL** for the genotype to be performed. Viral loads **below 500 IU/mL** will be rejected. Specimens collected in heparin will be rejected. **Test not performed on weekends or major holidays.** **Clinical Limitation:** Viral loads **below 500 IU/mL** are below the limit of detection of the assay. The HCV Genotype may not be determined. **Clinical Information:** This assay is designed for the genotyping of Hepatitis C virus in human serum and plasma. This test allows the genotyping of the **5** major HCV types and **subtyping of 1a and 1b.** Therapy based on the HCV viral genotype has proven to be cost effective when managing patients with chronic Hepatitis C. **Specimen Requirement:** 3 mL plasma from an EDTA white plasma preparation tube (PPT); Minimum: 1 mL; Centrifuge PPT tube; Do not aliquot; Refrigerated *OR* 3 mL serum from a serum separator (gold) tube; Minimum: 1 mL; Centrifuge serum separator tube (SST); Do not aliquot; **Refrigerated** *(continued on page 8)*	11/7/17

Test Changes (Cont.)

Test Name	Order Code	Change	Effective Date
Hepatitis C Genotyping *(continued from page 7)*		*OR* 3 mL plasma from an EDTA lavender top tube; Minimum: 1 mL; Separate plasma from whole blood within **6 hours** of collection by centrifugation; Transfer plasma to a sterile, polypropylene screw-cap tube; Refrigerated **Stability:** Ambient: **Plasma may be stored at 15–30 °C for up to 3 days; Whole blood may be stored at 15–30 °C for up to 6 hours prior to centrifugation** Refrigerated: **Plasma may be stored at 2–8 °C for up to 3 days; Whole blood may be stored at 2–8 °C for up to 6 hours prior to centrifugation** Frozen: **Plasma may be stored frozen up to 60 days** **Methodology:** Reverse Transcription/Polymerase Chain Reaction (RT/PCR) **Days Performed: Twice** per week **Reported: 5–7 weeks**	
Hepatitis C RNA by PCR	HCQPCR	**Specimen Requirement:** 3 mL plasma from an EDTA white plasma preparation tube (PPT); Minimum: 1.5 mL; Centrifuge within 24 hours of collection; Do not aliquot; Refrigerated *OR* 3 mL serum from a serum separator (gold) tube; Minimum: 1.5 mL; Centrifuge within 24 hours of collection; Do not aliquot; Refrigerated	10/16/17
Hepatitis Delta Antibody	AHD	**Special Information: Unacceptable conditions include room temperature specimens, specimens containing particulate material or obvious microbial contamination, and hemolyzed or lipemic specimens. This test is New York DOH approved.** **Clinical Information:** Order this assay only when patient has an acute or chronic hepatitis B infection. **This test detects total antibodies (IgG and IgM) to the hepatitis Delta agent. Consider ordering HBV IgM core antibody testing to determine whether HDV infection is a coinfection or a superinfection with HBV.** **Specimen Requirement:** 1 mL serum from a serum separator (gold) tube; Minimum: 0.5 mL; Separate serum from cells ASAP **or within 2 hours of collection and transfer to standard aliquot tube;** Frozen *OR* 1 mL plasma from an EDTA lavender top tube; Minimum: 0.5 mL; Separate plasma from cells ASAP **or within 2 hours of collection and transfer to standard aliquot tube;** Frozen *OR* 1 mL plasma from a sodium citrate (light blue) tube; Minimum: 0.5 mL; Separate plasma from cells ASAP **or within 2 hours of collection and transfer to standard aliquot tube;** Frozen *OR* 1 mL plasma from a sodium or lithium heparin green top tube; Minimum: 0.5 mL; **Separate plasma from cells ASAP or within 2 hours of collection and transfer to standard aliquot tube;** Frozen **Stability:** Ambient: **After separation from cells:** Unacceptable Refrigerated: After separation from cells: 5 days Frozen: After separation from cells: Indefinitely (Avoid repeated freeze/thaw cycles) **Days Performed:** Tuesday, Friday **Reported:** 2–**6** days	Effective immediately
Human Papillomavirus (HPV) DNA Detection with Genotyping 16,18, High-Risk Types by PCR, Sure Path	HPVHRS	**Specimen Requirement:** 3 mL cervical specimen in a SurePath collection device; Cervical brush in SurePath Pap Transport media; Transport each SurePath vial in an individually sealed bag; Ambient *OR* **One vaginal specimen in a SurePath collection device; Vaginal sample in SurePath Pap Transport media; Transport each SurePath vial in an individually sealed bag; Ambient** **Stability:** Ambient: **15–30 °C for up to 4 weeks** Refrigerated: **2–8 °C for up to 6 months** Frozen: **Not acceptable–will be rejected**	10/24/17

Test Changes (Cont.)

Test Name	Order Code	Change	Effective Date
Human Papillomavirus (HPV) DNA Detection with Genotyping 16,18, High-Risk Types by PCR, Thin Prep	HPVHRT	**Clinical Information: This is a qualitative test for the detection of Human Papillomavirus (HPV) in cervical or vaginal specimens. The test specifically identifies HPV type 16 and HPV type 18 while concurrently detecting the other HPV high-risk types (31,33,35,39,45,51,52,56,58,59,66 and 68). This test does not detect HPV low-risk types.** **Specimen Requirement:** One cervical specimen in Cytyc PreservCyt solution (ThinPrep); Cervical specimens collected in PreservCyt solution using an endocervical brush/spatula; Follow the manufacturer's instructions for collecting cervical specimens; Ambient *OR* **One vaginal specimen in Cytyc PreservCyt solution (ThinPrep); Vaginal specimens collected in PreservCyt solution using an endocervical brush/spatula; Follow the manufacturer's instructions for collecting cervical specimens; Ambient**	10/24/17
IgE	IGE	**Stability:** Ambient: **1 day** Refrigerated: **7 days** Frozen: **14 days**	9/11/17
Legionella pneumophila PCR	LEGPCR	**Stability:** Ambient: **24 hours** Refrigerated: **7 days** Frozen: **30 days**	Effective immediately
MRSA/Staph aureus Culture Screen	SANSAL	**Special Information: Insert a sterile swab into the nose until resistance is met at the level of the turbinates (approximately 1–2 cm into one nostril). Rotate the swab against the nasal mucosa for three seconds. Apply slight pressure with a finger on the outside of the nose to ensure good contact between swab and inside of nose. Using the same swab, repeat for the other nostril. Samples from other anatomic sites may be submitted.** **Clinical Information: This screening culture detects colonization with methicillin resistant Staphylococcus aureus (MRSA) and methicillin susceptible S. aureus (MSSA). An overnight broth enrichment step is included. This test should not be used to diagnose and treat infections. MRSA and MSSA screening is also available by PCR (SAPCR) for faster turnaround time but is limited to nares specimens.**	9/14/17
Neutrophil Cytoplasmic Antibody	ANCA	**Stability:** Ambient: **24** hours Refrigerated: 7 days Frozen: **14 days**	9/11/17
Osmolality, Urine	UOSM	**Specimen Requirement:** 3 mL random urine in a clean container; Minimum: 0.5 mL; **Submit in CCL aliquot tube;** Refrigerated *OR* 3 mL timed urine (well-mixed) in a clean container; Minimum: 0.5 mL; Refrigerated **Stability:** Ambient: **1 week** Refrigerated: 1 week Frozen: 1 week	9/19/17
Pancreatic Elastase, Fecal	PANCEF	**Special Information:** When ordering Pancreatic Elastase along with Fecal Fat, Qualitative (FFAT), please submit two separate specimens. Pancreatic Elastase needs to be sent frozen and Fecal Fat, Qualitative should be sent refrigerated. Unacceptable conditions: Stool in media or preservative; Swabs. This test is New York DOH approved. **Clinical Information:** Screen for exocrine pancreatic insufficiency. **Normal: Greater than 200 µg/g;** Moderate to mild exocrine pancreatic insufficiency: 100–200 µg/g; **Severe exocrine pancreatic insufficiency: Less than 100 µg/g. Reference range does not apply for infants less than one month old. Note: Enzyme substitution therapy does not influence the determination of pancreatic elastase 1.** **Stability:** Ambient: **1 week** Refrigerated: 1 week Frozen: 1 year	Effective immediately

Test Changes (Cont.)

Test Name	Order Code	Change	Effective Date
Reticulin IgA and IgG Antibodies	RETAB	**Special Information: If positive, results will be titered at no additional charge. Specimens that are grossly hemolyzed or grossly lipemic will be rejected. Specimens received at ambient temperature will be rejected. This test is New York DOH approved.** **Clinical Information: Celiac disease (CD) is a genetically inherited autoimmune digestive disease and tends to occur in families of European descent. Family members of people with CD or dermatitis herpetiformis are at increased risk of CD. CD is characterized by a permanent intolerance to gluten. When gluten is ingested, the immune system triggers an isolated inflammatory response in the small intestinal mucosa. A lifetime gluten-free diet can completely stop the immune response. Once the patient is on a gluten-free diet, the small intestine begins to repair itself and the antibody levels decline and eventually disappear. However, reintroduction of gluten-containing products stimulates the immune response again. A significant reduction in morbidity and mortality occurs when patients adhere to the gluten-free diet. Patients with CD produce various autoantibodies, including endomysial (EMA), tissue transglutaminase (tTG), gliadin, and reticulin antibodies, as part of the immune response. IgA antibodies usually predominate although patients may also produce IgG autoantibodies. The levels of these antibodies decline following institution of a gluten-free diet. tTG is the primary autoantigen recognized by EMA antibodies in patients with CD and is currently considered the most useful first level screening test for CD. Reticulin antibodies are no longer considered useful in the diagnosis of CD because they lack the sensitivity and specificity of the EMA and tTG tests. Serological screening offers a minimally invasive option for rapid identification of those likely to have CD and to select those who should be subjected to biopsy. Markedly positive (serologically) individuals are highly likely to have CD and should undergo biopsy to confirm the diagnosis. Clinical Reference: 1. Murray JA: The widening spectrum of celiac disease. *Am J Clin Nutr* 1999;69:354-365 2. Lazzari R, Volta U, Bianchi FB, et al: R1 reticulin antibodies: markers of celiac disease in children on a normal diet and on gluten challenge. *J Pediatr Gastroenterol Nutr* 1984;3:516-522** **Specimen Requirement:** 0.5 mL serum from a serum separator (gold) tube; Minimum: 0.2 mL; **Centrifuge and aliquot serum into standard transport tube;** Refrigerated *OR* 0.5 mL serum from a red top tube with no additive; Minimum: 0.2 mL; **Centrifuge and aliquot serum into standard transport tube; Refrigerated** **Days Performed:** Monday–**Sunday** **Reported:** 3–4 days **CPT:** 86255 x 1; **(86256–Titer, if appropriate, no additional charge)**	Effective immediately
Sulfonylurea Hypoglycemia Panel, Quantitative, Urine	USULFO	**Special Information: This test is New York DOH approved.** **Clinical Information: Test may be useful in evaluating if etiology of hypoglycemia is from exposure to sulfonylurea hypoglycemic drugs. However, serum or plasma is the preferred specimen.** **Specimen Requirement:** 5 mL random urine in a clean container; Minimum: 1.2 mL; **Transfer 5 mL urine to standard aliquot tube;** Refrigerated **Methodology: Liquid Chromatography-Tandem Mass Spectrometry (LC-MS/MS)** **CPT: 80377 x 1 (G0480, if appropriate)**	Effective immediately

Test Changes (Cont.)

Test Name	Order Code	Change	Effective Date
Sulfonylurea Hypoglycemics	SULFON	**Test Name:** Previously Sulfonylurea Hypoglycemics, Serum **Special Information: This test is New York DOH approved. Separator tubes are unacceptable.** **Clinical Information: Preferred test for evaluating if etiology of hypoglycemia is sulfonylurea ingestion.** **Specimen Requirement:** 1 mL serum from a red top tube with no additive; Minimum: 0.4 mL; Do not use serum separator tubes; Separate serum from cells ASAP or within 2 hours of collection; Frozen *OR* 1 mL plasma from an EDTA lavender top tube; Minimum: 0.4 mL; **Do not use plasma separator tubes;** Separate plasma from cells ASAP or within 2 hours of collection; Frozen *OR* 1 mL plasma from a **potassium oxalate/sodium fluoride (gray)** tube; Minimum: 0.4 mL; **Do not use plasma separator tubes; Separate plasma from cells ASAP or within 2 hours of collection; Frozen** *OR* 1 mL plasma from a sodium heparin green top tube; Minimum: 0.4 mL; **Do not use plasma separator tubes;** Separate plasma from cells ASAP or within 2 hours of collection; Frozen **CPT: 80377 x 1 (G0480, if appropriate)**	Effective immediately
Testosterone, Free and Total	FTESTO	**Specimen Requirement:** 2 mL serum from a serum separator (gold) tube; Minimum: 1 mL; **Separate serum from cells prior to freezing; Frozen** **Stability:** Refrigerated: 3 days Frozen: **30 days**	9/11/17
Trypsinogen	TRYPSI	**Special Information:** Grossly lipemic specimens will be rejected.	Effective immediately

New Tests

Test Name	Order Code	Change	Effective Date
Complete Atopic Dermatitis Panel	ATOPIC	**Includes:** Total IgE Staphylococcal Enterotoxin A IgE Staphylococcal Enterotoxin B IgE Anti–IgE Codfish/Scrod IgE Egg White IgE Milk Cow IgE Peanut IgE Soybean IgE Wheat IgE Candida albicans IgE Malassezia mix IgE Manganese Superoxide Dismutase Specific IgE **Special Information:** Lipemic samples may lead to rejection. **Clinical Information:** To assist in the evaluation of triggers in atopic dermatitis (AD). Although the diagnosis of AD is primarily on clinical criteria, the immunologic findings are useful in assessing causative agents and monitoring treatment and can direct specific therapeutic options for the patients with this disease. **Specimen Requirement:** 5 mL serum from a red top tube with no additive; Minimum: 4.5 mL; Centrifuge and transfer serum into standard aliquot tube; Ambient *OR* 5 mL serum from a serum separator (gold) tube; Minimum: 4.5 mL; Centrifuge and transfer serum into standard aliquot tube; Ambient **Stability:** Ambient: 4 weeks Refrigerated: 4 weeks Frozen: 1 year **Methodology:** Fluorescent Enzyme Immunoassay (FEIA) by ImmunoCAP Enzyme-Linked Immunosorbent Assay (ELISA) **Reference Range:** Refer to report **Days Performed:** Varies **Reported:** 6–8 days **CPT:** 83520 x 1, 86003 x 11, 82785 x 1 **Price:** $305.00 (non-discountable)	9/20/17
DNA and RNA Extraction (Buffy Coat)	NUCBUF	**Specimen Requirement:** 3 mL peripheral blood in an EDTA lavender top tube *OR* 3 mL bone marrow in an EDTA lavender top tube **Stability:** Ambient: Transport within 48 hours Refrigerated: Refrigerated specimens are acceptable Frozen: Will be rejected **Methodology:** Extraction (EXT) **Days Performed:** 5 days per week **CPT:** 81479 x 1	9/27/17

New Tests (Con't)

Test Name	Order Code	Change	Effective Date
Eye Culture	EYEC	**Special Information:** Media and incubation conditions are employed for the recovery of aerobic bacteria. For conjunctival specimens, sample each eye with separate swabs (premoistened with sterile saline) by rolling over conjunctiva. When only one eye is infected, sampling both can help distinguish indigenous microflora from true pathogens. For corneal scrapings, scrape ulcers and lesions with sterile spatula and inoculate scraping directly onto media. Prepare smears by rubbing material onto 1–2 cm area of slide. For vitreous fluid, prepare eye for needle aspiration of fluid and transfer fluid to sterile tube. If culture is positive, identification will be performed on clinically significant organisms at an additional charge. Identification CPT codes that may apply include: 87077, 87106, 87107, 87153, 87158. Antimicrobial susceptibilities are performed when indicated, and the following CPT codes may apply: 87181, 87184, 87185, 87186 **Clinical Information:** Conjunctivitis is usually caused by bacteria or viruses associated with upper respiratory tract infections. Organisms comprising skin and mucous membrane flora (e.g., coagulase negative staphylococci, diphtheroids, viridans group streptococci) are generally considered nonpathogenic when recovered from the conjunctival mucosa, but pathogenic if recovered from the surface or interior of the eye (especially in patients who have had cataract or LASIK surgery). Corneal infections (e.g., keratitis) are usually associated with ocular trauma, complications of cataract surgery, or improper care/use of contact lens. Endophthalmitis, diagnosed by aspiration of vitreous or aqueous fluid or biopsy, may result from exogenous introduction of pathogens into the eye during trauma or post-surgery, as well as endogenous spread from the bloodstream. Anaerobic cultures require a separate order. **Specimen Requirement:** Fluid (unspecified) in a sterile container; Ambient *OR* Drainage (unspecified) in a sterile container; Ambient *OR* Scrapings (unspecified); Place directly on culture media plates; Media is available through Client Services at 800.628.6816 or 216.444.5755 for direct inoculation, particularly for corneal scrapings **Stability:** Ambient: 24 hours Refrigerated: Unacceptable Frozen: Unacceptable **Methodology:** Culture, Identification **Reference Range:** No growth **Days Performed:** Sunday–Saturday **Reported:** 7 days **CPT:** 87070 x 1 **Price:** $46.00	Effective immediately
FISH for WWTR1/CAMTA1		**Note:** *This test was previously announced in the July 2017 Technical Update.* **Price:** $631.00 (non-discountable)	Effective immediately
Humoral Immunity Panel I	HUMOR1	**Special Information:** Plasma is unacceptable for this assay. This test is New York DOH approved. **Specimen Requirement:** 4 mL serum from a serum separator (gold) tube; Minimum: 1 mL total; Draw 2 serum separator (SST) tubes; Separate serum from cells ASAP or within 2 hours of collection; Transfer four 1 mL aliquots of serum to individual standard transport tubes; Refrigerated **Stability:** Ambient: After separation from cells: 2 hours Refrigerated: After separation from cells: 8 days Frozen: After separation from cells: 1 year (Avoid repeated freeze/thaw cycles) **Methodology:** Quantitative Nephelometry Semi-Quantitative Multiplex Bead Assay **Reference Range:** Refer to report **Days Performed:** Monday–Saturday **Reported:** 2–5 days **CPT:** 82784 x 3, 82787 x 4, 86317 x 16 **Price:** $458.00 (non-discountable)	10/26/17

New Tests (Con't)

Test Name	Order Code	Change	Effective Date
Spinal Muscular Atrophy Carrier Screening and Diagnostic	SMA12	**Recommended Usage:** Intended for Spinal Muscular Atrophy (SMA) carrier screening and diagnostic purposes. **Specimen Requirement:** 4 mL peripheral blood in an EDTA lavender top tube; Minimum: 0.5 mL; Newborn and infant draws are especially arduous, but a minimum of 0.5 mL is imposed; Blood specimens are transported and stored at room temperature no longer than 24 hours **Stability:** Ambient: Blood may be transported ambient temperature within 24 hours Refrigerated: Blood may be transported ambient temperature within 24 hours; After 24 hours blood must be stored at 2–8 °C for up to 7 days Frozen: Frozen samples will be rejected **Methodology:** Multiplex-Ligation Probe Amplification (MLPA) **Days Performed:** 2 days per week **Reported:** 5 days **CPT:** 81401 x 1, G0452 x 1 **Price:** $247.00	10/25/17

Fee Increases

Test Name	Order Code	List Fee	CPT Code	Effective Date
Carotene	CAROT	$36.00 (non-discountable)	82380	10/25/17

Fee Reductions

Test Name	Order Code	List Fee	CPT Code	Effective Date
Hepatitis C Genotyping	HEPGEN	$398.00	87902	11/7/17

Discontinued Tests

Test Name	Order Code	Test Information	Effective Date
DNA Extraction	DNAEXT	This test will no longer be available. Suggest ordering DNA and RNA Extraction (Buffy Coat) (NUCBUF).	9/27/17
Humoral Immunity Panel	HUMORZ	This test will no longer be available. Suggest ordering Humoral Immunity Panel I (HUMOR1).	10/26/17
Myeloma Prognostic Risk Signature	MYPRS	This test will no longer be available.	Effective immediately
Reticulin Antibody, IgA with reflex to Titer	RTICAB	Note: *This test was previously announced in the August 2017 Technical Update with a suggested replacement of Reticulin Antibodies, Serum (RTIABS). Instead of RTIABS, we suggest ordering Reticulin IgA and IgG Antibodies (RETAB). We apologize for any inconvenience this may have caused.*	Effective immediately
Spinal Muscular Atrophy DNA Test	SMADNA	This test will no longer be available. Suggest ordering Spinal Muscular Atrophy Carrier Screening and Diagnostic (SMA12).	10/25/17
Stool Chemistry Panel	SCHEM	This test will no longer be available.	11/14/17