Cleveland Clinic

Cleveland Clinic Laboratories

Technical Update • September 2013

Cleveland Clinic Laboratories is dedicated to keeping you updated and informed about recent testing changes. That's why we are happy to provide this technical update on a monthly basis.

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

If you wish to compare the new information with previous test demographics, refer to the Test Directory, which can be accessed at clevelandcliniclabs.com.

Deleted tests and new tests are listed separately. 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	Billing Code	Name Change	New Test	Test Discontinued	Special Information	Specimen Requirement	Component Change	Methodology	Reference Range	Days Performed/Reported	CPT
3	5-Methyltetrahydrofolate							■					
10	Allergen, Shell Fish Panel, IgE				■								
3	Allergen, Tomato IgG										■		
3	Anti IgE											■	■
3	Arsenic, Fractionated Urine						■						
3	Chromosomal Microarray SNP, Constitutional						■						
3	Circulating Tumor Cells for Breast Cancer			■									
3	CMV by PCR - CSF, Fluid, and Tissue			■				■					
3	Complement Deficiency Assay							■					
10	Dabigatran				■								
3	Diphenhydramine									■	■		■
3	Diphenhydramine, Urine									■	■	■	
4	Fatty Acid Profile of Lipids												■
4	Fungal Culture & Smear (Non-Dermal Sites)			■				■					
11	Fungal Culture & Smear - Hair, Skin, and Nails				■								
11	Fungal Culture - Hair, Skin, and Nails				■								
4	Fungal Culture (Non-Dermal Sites)			■				■					
12	Galectin-3, Serum				■								
15	Haemophilus influenzae B Antibody IgG					■							
4	Hepatitis C Virus FibroSURE							■			■		
5	HIV Genotyping						■	■					
5	HIV P24 Antigen						■	■	■	■	■	■	

Test Update Page #	Summary of Changes by Test Name	Order Code	Billing Code	Name Change	New Test	Test Discontinued	Special Information	Specimen Requirement	Component Change	Methodology	Reference Range	Days Performed/Reported	CPT
5	Insulin Antibody										■		
5	Insulin, Free and Total										■		
5	JAK2 Exon 12-15 Sequencing			■				■		■	■	■	
5	Lead, Blood	■					■						
6	Neopterin, CSF							■					
15	Neuromyelitis Optica Autoantibody IgG, CSF					■							
15	Neuromyelitis Optica Evaluation					■							
6	Neurotransmitter Metabolites/Amines							■					
12	NMO/Aquaporin-4 IgG, Cell Binding Assay				■								
12	NMO/Aquaporin-4 IgG, Cell Binding Assay, CSF				■								
6	NMP22 bladder Tumor Marker						■	■					
12	Oligosaccharide and Glycan Screening				■								
6	OSHA Zinc Protoporphyrin	■					■						
6	Oxycodone Screen, Urine								■				
6	Pancreatitis Panel											■	■
7	Paraneoplastic Autoantibody Evaluation, CSF						■	■	■	■			
8	Paraneoplastic Autoantibody Evaluation, Serum						■		■	■	■		
8	PNH Panel by FCM						■	■				■	
13	Rivaroxiban				■								
8	Rufinamide									■			
13	SCA1 DNA Test				■								
13	SCA2 Expansion Analysis				■								
14	SCA3 DNA Test				■								
14	SCA6 DNA Test				■								
14	SCA7 Expansion Analysis				■								
9	Streptococcus pneumoniae Antigen, Urine			■			■						
14	Tapentadol & Metabolite, Confirmation/Quantitation, Urine				■								
9	Testosterone							■		■			
9	Tetrahydrobiopterin & Neopterin, CSF							■					
9	Toxic Shock Syndrome Antibodies								■	■		■	■
9	Universal PCR, Bacterial							■					
9	Universal PCR, Bacterial, Fungal & AFB PCR							■					
9	Universal PCR, Fungal							■					
9	Voltage-Gated Calcium Channel IgG Autoantibodies										■		

Test Changes

Test Name	Order Code	Billing Code	Change	Effective Date
5-Methyltetrahydrofolate	5MTH	83879	**Specimen Requirement:** 3.5 mL cerebrospinal fluid (CSF) in special collection vials consisting of 5 numbered vials per set; CSF should be collected from the first drop into the containers in the order indicated; Fill each tube to the marked line (0.5 mL in vials 1, 2, and 5 and 1 mL in vials 3 and 4); Vial 3 contains antioxidants to protect the sample from oxidation; One set of vials is required per patient; If specimens are NOT blood contaminated, place tubes on ice ASAP. If specimens are blood contaminated, they must be centrifuged and transferred into clean vials before freezing; **Call Client Services at 800.628.6816 or 216.444.5755 for specimen collection vials**; Frozen	9/26/2013
Allergen, Tomato IgG	TOMIGG	89472	Test build may need to be modified **Methodology: Immunoassay (IA)**	9/16/2013
Anti IgE	ANTIGE	88108	**Reference Range: Normal** **Days Performed: Wednesday** **Reported: 6** - 9 days	8/23/2013
Arsenic, Fractionated Urine	UASFR	88171	**Special Information:** The ACGIH Biological Exposure Index for the sum of inorganic and methylated forms (species) of arsenic is 35 µg/L. For specimens with a total arsenic concentration between 35 - 2,000 µg/L, fractionation is performed at an additional cost to determine the proportion of the inorganic, methylated, and organic forms. Inorganic forms of arsenic are most toxic. Methylated forms arise primarily from metabolism of inorganic forms but may also come from dietary sources and are of moderate toxic potential. **The organic forms of arsenic are considered nontoxic and arise primarily from food.** The sum of the inorganic, methylated, and organic forms of arsenic may be lower than the total arsenic level. If low-level chronic poisoning is suspected, the µg/gCRT ratio may be more sensitive than the total arsenic concentration. It may be appropriate to fractionate specimens with a µg/gCRT ratio > 30 despite a total arsenic concentration < 35 µg/L; the laboratory will perform upon request.	9/19/2013
Chromosomal Microarray SNP, Constitutional	CRMSNP	89612	**Special Information: FISH to confirm CRMSNP will be added by Cytogeneticist when required for the completion of the Chromosomal Microarray test. Days performed excludes Cleveland Clinic observed holidays. Specimens are processed as soon as appropriate FISH probe(s) are received from the vendor. Patient will be charged based on the number of confirmatory probes performed. Price is per probe and one probe is equivalent to $3,600.00 (non-discountable) with CPT 88368x2.**	9/12/2013
Circulating Tumor Cells for Breast Cancer	CTC	82886	**Test Name:** Previously Circulating Tumor Cells	9/26/2013
CMV by PCR - CSF, Fluid, and Tissue	CMVCSF	79779	**Test Name:** Previously CMV Detection CSF/Fluid by PCR **Specimen Requirement:** 1 mL cerebrospinal fluid (CSF) in a sterile container; Specimen source is required; Frozen *OR* 1 mL Bronchoalveolar Lavage (BAL) in sterile container; Specimen source is required; Frozen *OR* 1 mL random urine in a sterile container; Specimen source is required; Frozen *OR* **Tissue in a sterile container; Specimen source is required; Frozen**	8/15/2013
Complement Deficiency Assay	COMPDF	86162	**Specimen Requirement:** 1 mL serum from a red top tube; **Allow sample to clot for 1 hour at room temperature;** Centrifuge in refrigerated centrifuge, aliquot and freeze; Transport temperature Frozen	9/18/2013
Diphenhydramine	DIPHEN	87797	**Methodology:** **Liquid Chromatography - Tandem Mass Spectrometry (LC-MS/MS)** **Reference Range:** **Usual antihistaminic/hypnotic range:** 100 - 1,000 ng/mL **CPT: 83789**	11/4/2013
Diphenhydramine, Urine	UDIPHN	87818	**Methodology:** **Liquid Chromatography - Tandem Mass Spectrometry (LC-MS/MS)** **Reference Range: Concentrations of Diphenhydramine between 100 - 3,500 ng/mL were found in urine during the first 24 hours of ingestion of 100 mg of the drug.** **Days Performed:** Monday - Friday **Reported: 4 - 8** days	11/4/2013

Test Changes (cont.)

Test Name	Order Code	Billing Code	Change	Effective Date
Fatty Acid Profile of Lipids	CFA	76258	**CPT: 82725**	9/5/2013
Fungal Culture & Smear (Non-Dermal Sites)	FCULSM	77917	**Test Name:** Previously listed as Fungal Culture and Smear **Specimen Requirement:** 3 mL gastric aspirate in a sterile container; Ambient *OR* 3 mL sputum in a sterile container; Undiluted first morning sputum or induced sputum; Patient Preparation: remove dentures, rinse mouth with water; Ambient *OR* 50 mL body fluid in a sterile container; Aspiration site must be prepared under sterile conditions; Ambient *OR* Surgical aspirate in a sterile container; Site must be prepared under sterile conditions; Ambient *OR* Culturette swab of surgical area; Aspiration site must be prepared under sterile conditions; Ambient *OR* Surgical tissue in sterile container with 0.5 mL sterile saline or sterile water. The portion of the surgical specimen for fungal culture should be separated using sterile conditions from the portion sent to Surgical Pathology; Ambient **Skin, Hair and Nails are no longer acceptable specimen types**	10/1/2013
Fungal Culture (Non-Dermal Sites)	FCUL	75980	**Test Name:** Previously listed as Fungal Culture **Specimen Requirement:** 3 mL gastric aspirate in a sterile container; Ambient *OR* 3 mL sputum in a sterile container; Undiluted first morning sputum or induced sputum; Patient Preparation: remove dentures, rinse mouth with water; Ambient *OR* 50 mL body fluid in a sterile container; Aspiration site must be prepared under sterile conditions; Ambient *OR* 50 mL random urine in a sterile container; Collect from first morning void; 24 hour specimens are unacceptable; Ambient *OR* Surgical aspirate in a sterile container; Site must be prepared under sterile conditions; Ambient **Skin, Hair and Nails are no longer acceptable specimen types**	10/1/2013
Hepatitis C Virus FibroSURE	HCVSUR	84198	**Specimen Requirement:** 3 mL serum from a serum separator tube; Protect from light; Centrifuge and aliquot into **2 tubes, one containing 2.5 mL serum and the other 0.5 mL serum**; Freeze both tubes ASAP; Transport Frozen **Reference Range:** Alanine aminotransferase (ALT): male: 0 - 55 IU/L female: 0 - 40 IU/L α2-Macroglobulin: 110 - 276 mg/dL Apolipoprotein A-1: male: **110 - 180** mg/dL female: **110 - 205** mg/dL Bilirubin, total: 0.1-1.2 mg/dL γ-Glutamyl transferase (GT): male: 0 - 65 IU/L female: 0 - 60 IU/L Haptoglobin: 34 - 200 mg/dL Fibrosis stage (Fibro test): F0 – no fibrosis: **0.00 - 0.21** F0 - F1: 0.21 - 0.27 F1 – portal fibrosis: 0.27 - 0.31 F1 - F2: 0.31 - 0.48 F2 – bridging fibrosis with few septa: 0.48 - 0.58 F3 – bridging fibrosis with many septa: 0.58 - 0.72 F3 - F4: 0.72 - 0.74 F4 – cirrhosis: 0.74 - 1.00 Activity Grade (ActiTest): A0 – no activity: 0.00 - 0.17 A0 - A1: 0.17 - 0.29 A1 – minimal activity: 0.29 - 0.36 A1 - A2: 0.36 - 0.52 A2 – moderate activity: 0.52 - 0.60 A2 - A3: 0.60 - 0.63 A3 – severe activity: 0.63 - 1.00	10/3/2013

Test Changes (cont.)

Test Name	Order Code	Billing Code	Change	Effective Date
HIV Genotyping	HIVGEN	80797	**Special Information:** The HIV-1 viral load must be **> 1000 copies/mL** for this analysis to be successful. A HIV-1 RNA viral load must either be ordered at the same time as the genotyping, which will delay the genotyping result, **or have been performed within the past 4 weeks. If a recent viral load isn't available, the ordering clinician will be contacted to either change the genotyping order to a HIV-1 RNA viral load order or to cancel the order entirely. The specimen tube will be held 2 weeks pending this request, after which time the tube will be discarded and the order credited if no resolution is received. If the viral load order shows a HIV-1 load of > 1000 copies/mL, the clinician may then reorder the genotyping which will necessitate a new specimen tube.** **Specimen Requirement:** 5 mL plasma from an EDTA white top tube; Separate plasma from cells within 2 hours of collection, aliquot, and store at **-70°C; A viral load result > 1000 copies/mL, collected within 4 weeks of the genotyping order, MUST be provided**; Frozen	9/26/2013
HIV P24 Antigen	HIVAGT	50162	**Special Information: The measurement of HIV-1 p24 (core) antigen is performed by the Immune Complex Dissociation (ICD) modification of the standard p24 antigen assay. This modification results in a significant increase in the sensitivity of the p24 antigen assay.** Positive samples will be confirmed by Neutralization **at no additional cost**. **Includes:** HIV-1 p24 **(ICD)** Antigen Screen HIV-1 p24 **(ICD)** Confirmation **HIV-1 (ICD) Antigen Level (pg/mL)** Test build may need to be modified **Specimen Requirement: 1 mL** serum from a serum separator tube; Separate serum from cells, aliquot and **freeze ASAP; Frozen** **Methodology:** **Enzyme-Linked Immunosorbent Assay (ELISA)** Neutralization, if indicated **Reference Range:** **HIV-1 p24 (ICD) Antigen Screen: Negative** **HIV-1 p24 (ICD) Confirmation: Negative** **HIV-1 (ICD) Antigen Level: Not available** **Days Performed: Monday, Thursday** **Reported: 3 - 7** days	8/29/2013
Insulin Antibody	INSAB	41025	**Reference Range: < 0.4 U/mL**	9/18/2013
Insulin, Free and Total	INSFT	77990	**Reference Range:** Insulin, Total: 1.0 - 24.0 µU/mL Insulin, Free: 1.0 - 24.0 µU/mL Insulin Antibody: **< 0.4 U/mL**	9/18/2013
JAK2 Exon 12-15 Sequencing	JAKNON	87775	**Test Name:** Previously JAK2 Exon 12 & Non-V617F Mutation **Specimen Requirement: 8 mL** whole blood in an EDTA lavender top tube; **Place specimen on ice after draw;** Specimen MUST be sent to Cleveland Clinic Laboratories on the day of collection and **MUST be received in the performing laboratory by 2 p.m. EST on Friday; Do not collect or send specimens on weekends or holidays; Refrigerated** **Methodology:** Polymerase Chain Reaction (PCR) **Sequencing** **Reference Range: JAK2 exon 12 - 15 mutations not detected** **Days Performed: 1 day per week** **Reported: 7 - 10** days	9/26/2013
Lead, Blood	**LEAD2**	83655	**Order Code:** Previously LEAD **Special Information: Specimen type, capillary or venous, will be required to be entered at the time of order.** Test build may need to be modified	10/1/2013

Test Changes (cont.)

Test Name	Order Code	Billing Code	Change	Effective Date
Neopterin, CSF	NEOCSF	83920	**Specimen Requirement:** 3.5 mL cerebrospinal fluid (CSF) in special collection vials consisting of 5 numbered vials per set; CSF should be collected from the first drop into the containers in the order indicated; Fill each tube to the marked line (0.5 mL in vials 1, 2, and 5 and 1 mL in vials 3 and 4); Vial 3 contains antioxidants to protect the sample from oxidation; One set of vials is required per patient; If specimens are NOT blood contaminated, place tubes on ice ASAP. If specimens are blood contaminated, they must be centrifuged and transferred into clean vials before freezing; **Call Client Services at 800.628.6816 or 216.444.5755 for specimen collection vials;** Frozen	9/26/2013
Neurotransmitter Metabolites/Amines	NEUR	83783	**Specimen Requirement:** 3.5 mL cerebrospinal fluid (CSF) in special collection vials consisting of 5 numbered vials per set; CSF should be collected from the first drop into the containers in the order indicated; Fill each tube to the marked line (0.5 mL in vials 1, 2, and 5 and 1 mL in vials 3 and 4); Vial 3 contains antioxidants to protect the sample from oxidation; One set of vials is required per patient; If specimens are NOT blood contaminated, place tubes on ice ASAP. If specimens are blood contaminated, they must be centrifuged and transferred into clean vials before freezing; **Call Client Services at 800.628.6816 or 216.444.5755 for specimen collection vials;** Frozen	9/26/2013
NMP22 Bladder Tumor Marker	NMP22	79588	**Special information:** 1) Between midnight and noon, patient voids into a clean container. 2) Immediately after collection, medical personnel transfers a portion of the specimen into an **NMP22 Urine Stabilizer Vial** which may be obtained from Client Services. 3) Fill container to the Fill Line (approximately 10 mL). Stabilized urine should be blue/green in color. 4) Immediately store urine in refrigerator and transport specimen Frozen **Specimen Requirement:** 5 mL random urine in a **NMP22 Urine Stabilizer Vial;** Frozen	10/10/2013
OSHA Zinc Protoporphyrin	**OSHALZ**	88273	**Order Code:** Previously OSHAZP **Special Information: Specimen type will be required to be entered at the time of order.** Test build may need to be modified	10/1/2013
Oxycodone Screen, Urine	OXYCOD	82615	**Includes:** Codeine, Morphine 6-Acetylmorphine, Hydromorphone Oxycodone, **Noroxycodone** Oxymorphone, **Noroxymorphone** Hydrocodone, **Norhydrocodone** Test build will need to be modified	9/5/2013
Pancreatitis Panel	PANCPL	83724	**Days Performed:** Varies **Reported: 15 - 30 days** **CPT:** 81223, 81404**x2**, **81224**	10/3/2013

Test Changes (cont.)

Test Name	Order Code	Billing Code	Change	Effective Date
Paraneoplastic Autoantibody Evaluation, CSF	PARCSF	87937	**Special Information:** Reflex algorithm: If IFA patterns are indeterminate, Paraneoplastic Autoantibody Western Blot will be performed at an additional charge. If IFA pattern suggests presence of Neuromyelitis Optica, **NMO/Aquaporin-4 IgG will be performed** at an additional charge. If client requests, or if IFA patterns suggest CRMP-5 IgG, CRMP-5 IgG Western Blot will be performed at an additional charge. If IFA pattern suggests GAD65 Antibody, GAD65 Antibody radioimmunoprecipitation assay will be performed at an additional charge. If IFA pattern suggests presence of Amphiphysin Autoantibody, Amphiphysin Antibody Western Blot will be performed at an additional charge. **Neuron-restricted patterns of IgG staining that do not fulfill criteria for the listed autoantibodies may be reported as "unclassified antineuronal IgG." If detected, newly identified autoantibody specificities may be reported. Complex patterns that include non-neuronal elements may be reported as "non-interpretable"** **Includes:** Anti-Glial Nuclear Antibody Type 1 Anti-neuronal Nuclear Antibody, Types 1, 2, & 3 Purkinje Cell Cytoplasmic Antibody, Types 1, 2, & Tr Amphiphysin Antibody CRMP-5 IgG CRMP-5 IgG Western Blot, if indicated GAD65 Antibody, if indicated Paraneoplastic Autoantibody Western Blot, if indicated Amphiphysin Western Blot, if indicated **NMO/Aquaporin-4 IgG Cell Binding Assay, if indicated** Test build may need to be modified **Specimen Requirement:** 4 mL cerebrospinal fluid in a **sterile** container; Refrigerated **Methodology:** Indirect Fluorescent Antibody (IFA) Radioimmunoprecipitation (RIPA), if indicated Western Blot, if indicated **Cell Binding Assay (CBA), if indicated**	9/4/2013

Test Changes (cont.)

Test Name	Order Code	Billing Code	Change	Effective Date
Paraneoplastic Autoantibody Evaluation, Serum	PARNEO	82929	**Special Information:** Reflex algorithm: If IFA patterns are indeterminate, Paraneoplastic Autoantibody Western Blot will be performed at an additional charge. If client requests, or if IFA patterns suggest CRMP-5-IgG, CRMP-5-IgG Western Blot will be performed at an additional charge. If IFA pattern suggests GAD65 Antibody, GAD65 Antibody radioimmunoassay will be performed at an additional charge. If IFA suggests presence of Neuromyelitis Optica, **NMO/Aquaporin-4 IgG will be performed** at an additional charge. If IFA pattern suggests presence of Amphiphysin Autoantibody, Amphiphysin Antibody Western Blot will be performed at an additional charge. If ACh Receptor Binding Antibody is > 0.02 nmol/L or if Striational Antibodies are ≥ 1:60, ACh Receptor Modulating Antibodies and CRMP-5-IgG Western Blot will be performed at an additional charge. **Neuron-restricted patterns of IgG staining that do not fulfill criteria for Amphiphysin, ANNA-1, ANNA-2, ANNA-3, AGNA-1, PCA-1, PCA-2, PCA-Tr, or CRMP-5-IgG may be reported as "unclassified antineuronal IgG". Complex patterns that include non neuronal elements may be reported as "non-interpretable".** **Includes:** AChR Ganglionic Neuronal Antibody Anti-neuronal Nuclear Antibody, Type 1, 2, & 3 Purkinje Cell Cytoplasmic Antibody, Type 1, 2, & Tr Amphiphysin Antibody CRMP-5-IgG Striational (Striated muscle) Antibody Calcium Channel Bind Ab, P/Q Type and N-Type Anti-Glial Nuclear Ab, Type 1 ACh Receptor (Muscle) Binding Antibody Neuronal (V-G) K+ Channel Antibody Amphiphysin, Western Blot, if indicated CRMP-5, Western Blot, if indicated GAD65 Antibody, if indicated ACh Receptor Muscle Modulating Antibody, if indicated **NMO/Aquaporin-4 IgG Cell Binding Assay, if indicated** Paraneoplastic Ab, Western Blot, if indicated Test build may need to be modified **Methodology:** Indirect Immunofluorescence Assay (IFA) Enzyme Immunoassay (EIA) Radioimmunoassay (RIA) Western Blot (WB), if indicated **Cell Binding Assay (CBA), if indicated** **Reference Range:** AChR Ganglionic Neuronal Antibody: **≤ 0.02 nmol/L** **NMO/Aquaporin-4 IgG: Negative** All other ranges are unchanged	9/4/2013
PNH Panel by FCM	PNHPNL	81442	**Special Information: Specimens between 24 - 48 hours old may give inaccurate results. Specimens greater than 48 hours old will be rejected.** **Specimen Requirement:** 4 mL whole blood in an EDTA lavender top tube; Do not collect on **Fridays**, weekends, or holidays; **Send to Cleveland Clinic Laboratories on the day of collection;** Ambient **Days Performed:** Monday - **Friday** **Reported:** 1 - 3 days	10/1/2013
Rufinamide	RUFIN	88110	**Methodology: Liquid Chromatography - Tandem Mass Spectrometry (LC-MS/MS)**	11/4/2013

Test Changes (cont.)

Test Name	Order Code	Billing Code	Change	Effective Date
Streptococcus pneumoniae Antigen, Urine	SPNAG	89542	**Test Name:** Previously Streptococcus pneumoniae Antigen Detection **Special Information: A positive result is presumptive evidence of pneumococcal pneumonia. Correlation of test results with clinical finding is required. A negative result does not exclude infection by S. pneumoniae since the antigen present in the sample may be below the detection limit of the test. This test has not been evaluated on patients taking antibiotics for more than one day, or on patients who recently completed a course of antibiotic therapy. Cross-reactivity with closely related bacteria in the Streptococcus mitis group may occur. Streptococcus pneumoniae vaccine may cause false positive results within two days following vaccination and testing is not recommended within five days following pneumococcal vaccination. This test has only been validated for urine samples. Antigen testing is not recommended for the diagnosis of pneumococcal pneumonia in children.**	9/19/2013
Testosterone	TESTO	84403	**Specimen Requirement: 2 mL** serum from a serum separator tube; Refrigerated **Methodology: Electro Chemiluminescence Immunoassay (ECLIA)**	10/28/2013
Tetrahydrobiopterin & Neopterin, CSF	TBIOPT	83782	**Specimen Requirement:** 3.5 mL cerebrospinal fluid (CSF) in special collection vials consisting of 5 numbered vials per set; CSF should be collected from the first drop into the containers in the order indicated; Fill each tube to the marked line (0.5 mL in vials 1, 2, and 5 and 1 mL in vials 3 and 4); Vial 3 contains antioxidants to protect the sample from oxidation; One set of vials is required per patient; If specimens are NOT blood contaminated, place tubes on ice ASAP. If specimens are blood contaminated, they must be centrifuged and transferred into clean vials before freezing; **Call Client Services at 800.628.6816 or 216.444.5755 for specimen collection vials;** Frozen	9/26/2013
Toxic Shock Syndrome Antibodies	TSS	76679	**Includes:** Toxic Shock Syndrome Toxin (TSST-1) Antibody Staphylococcal enterotoxin B (SEB) Antibody **Staphylococcal enterotoxin C (SEC) Antibody** Test build may need to be modified **Methodology: Qualitative Immunoassay** **Days Performed:** Varies **Reported: 4 - 9** days **CPT:** 86609**x3**	8/26/2013
Universal PCR, Bacterial	BACPCR	87852	**Specimen Requirement:** Actively growing isolate of organism; Ambient *OR* Fresh tissue in a sterile container; Frozen *OR* Paraffin embedded tissue; Ambient *OR* 1 mL body fluid in a sterile container; **Sputum is NOT an acceptable specimen type;** Frozen	9/26/2013
Universal PCR, Bacterial, Fungal & AFB PCR	FABPCR	87871	**Specimen Requirement:** Actively growing isolate of organism; Ambient *OR* Fresh tissue in a sterile container; Frozen *OR* Paraffin embedded tissue; Ambient *OR* 1 mL body fluid in a sterile container; **Sputum is NOT an acceptable specimen type;** Frozen	9/26/2013
Universal PCR, Fungal	FUNPCR	87854	**Specimen Requirement:** Actively growing isolate of organism; Ambient *OR* Fresh tissue in a sterile container; Frozen *OR* Paraffin embedded tissue; Ambient *OR* 1 mL body fluid in a sterile container; **Sputum is NOT an acceptable specimen type;** Frozen	9/26/2013
Voltage-Gated Calcium Channel IgG Autoantibodies	VOLTCA	82925	**Reference Range: < 30 pmol/L**	9/9/2013

New Tests

Test Name	Order Code	Billing Code	Test Information	Effective Date
Allergen, Shell Fish Panel, IgE	SHLFSH	89625	**Includes:** Crab, Shrimp, Blue Mussel, Lobster, Clam, Scallop, Oyster **Specimen Requirement:** 1 mL serum from a serum separator tube; Refrigerated **Methodology:** Fluorescent Enzyme Immunoassay (FEIA) by ImmunoCAP **Reference Range:** Crab: < 0.35 kU/L, Class: 0 Shrimp: < 0.35 kU/L, Class: 0 Blue Mussel: < 0.35 kU/L, Class: 0 Lobster: < 0.35 kU/L, Class: 0 Clam: < 0.35 kU/L, Class: 0 Scallop: < 0.35 kU/L, Class: 0 Oyster: < 0.35 kU/L, Class: 0 **Days Performed:** Sunday - Saturday **Reported:** 1 - 2 days **CPT:** 86003x7 **Price:** $231.00	9/24/2013
Dabigatran	DBGTRN	89644	**Special Information:** Research Use Only. Dabigatran etexilate is a novel, orally administered direct thrombin inhibitor. It has proven effective for treating and preventing venous thromboembolism, preventing stroke in patients with atrial fibrillation, and treating myocardial infarct. It can be used to prevent hemorrhagic and thromboembolic complications associated with long term anticoagulation with Warfarin. As an active form, Dabigatran is a potent, competitive and reversible direct inhibitor of the active site of thrombin with a half life of approximately 12 hours. Dabigatran will be measured by chromogenic anti-IIa assay using specific Aniara Dabigatran calibrator performed on the STA-R Evolution Coagulometer **Specimen Requirement:** 2 mL plasma from a sodium citrate light blue top tube; Frozen **Methodology:** Chromogenic **Reference Range:** Expected plasma Dabigatran level (25th - 75th percentile range) after treatment Dose & Regimen: 220 mg od: Peak (2 hours post dose): 71 (35 - 162 ng/mL) Trough (12 hours post dose): 22 (13 - 36 ng/mL) 150 mg bid: Peak (2 hours post dose): 175 (117 - 275 ng/mL) Trough (12 hours post dose): 91 (61 - 143 ng/mL) **Days Performed:** Sunday - Saturday **Reported:** 4 hours **CPT:** 80299 **Price:** $304.00	9/26/2013

New Tests (cont.)

Test Name	Order Code	Billing Code	Test Information	Effective Date
Fungal Culture & Smear - Hair, Skin, and Nails	FHSNSM	89653	**Special Information:** Test includes culture for yeasts and molds plus microscopic examination using calcofluor stain. Full identification will be performed routinely on significant yeast isolates. Additional charges may apply. Limited identification is performed on nonsterile sites. In-house susceptibility testing on yeast isolates is performed only upon request and only when clinically indicated. Mold identification will be performed on significant isolates. Some dimorphic molds will require confirmation using DNA probes. Additional charges may apply. Mold susceptibilities are not performed in-house and will be sent to an outside reference lab upon request only. Note any special requests such as rule out Malassezia furfur on the requisition. All hair, skin, and nail specimens are screened for dermatophytes. **Includes:** Both fungal culture and calcofluor smear for dermal sources. Culture to various selective agar media selected for optimal growth and recovery of dermatophytes and other fungal pathogens is performed. Identification is routinely performed on potential fungal pathogens using a variety of methods including microscopic, biochemicals, temperature tolerance, probe and MALDI-TOF spectrometry. Additional charges may apply. Fungal smear is included. **Specimen Requirement:** 10 -12 hairs including the shaft in a sterile container. Thoroughly cleanse area with alcohol; Ambient *OR* Nails in a sterile container; Please cleanse area with alcohol and collect deep in the nail bed with the outermost edge discarded. A specimen from beneath the nail is preferred. Do not refrigerate; avoid moisture; Ambient **Methodology:** Culture, Microscopy (KOH with calcofluor) **Reference Range:** No fungal growth **Days Performed:** Sunday - Saturday **Reported:** Smear: 24 hours Cultures: 6 weeks Negative cultures are held for 4 weeks Positive results are released as available **CPT:** 87101 **Price:** $75.00	10/1/2013
Fungal Culture - Hair, Skin, and Nails	ACFSC	89652	**Special Information:** Hair, skin and nails are the only acceptable specimen types. For other sources, please order Fungal Culture (FCUL) or Fungal Culture and Smear (FCULSM). Always note specimen source on the requisition. Full identification will be performed routinely on significant yeast isolates. Additional charges may apply. DNA Probe testing is used to confirm suspect cases of some dimorphic molds. Additional charges may apply. Limited identification is performed on nonsterile sites. In-house susceptibility testing on yeast isolates is performed only upon request and only when clinically indicated. Mold susceptibilities are not performed in-house and will be sent to an outside reference lab upon request only. Note any special requests on the requisition including a request to rule out Malassezia furfur. **Includes:** Culture only, to various agar media selected for optimal growth and recovery, of dermatophytes and other fungal pathogens. Identification is routinely performed on potential fungal pathogens using a variety of methods including microscopic, biochemicals, temperature tolerance, probe and MALDI-TOF spectrometry. Additional charges may apply. Fungal smear is not included. **Specimen Requirement:** 10 -12 hairs including the shaft in a sterile container. Thoroughly cleanse area with alcohol; Ambient *OR* Nails in a sterile container; Please cleanse area with alcohol and collect deep in the nail bed with the outermost edge discarded. A specimen from beneath the nail is preferred. Do not refrigerate; avoid moisture; Ambient **Methodology:** Culture **Reference Range:** No fungal growth **Days Performed:** Sunday - Saturday **Reported:** 6 weeks Negative cultures are held for 4 weeks Positive results are released as available **CPT:** 87101 **Price:** $60.00	10/1/2013

New Tests (cont.)

Test Name	Order Code	Billing Code	Test Information	Effective Date
Galectin-3, Serum	GAL3	89623	**Special Information:** The Galectin-3 blood test is only indicated for use in patients with chronic heart failure and should not be used for diagnosis of heart failure or to monitor pharmacologic therapies used in the treatment of heart failure. Presence of human anti-mouse antibodies (HAMA) or rheumatoid factor (RF) greater than 50 IU/mL, or specimens with high levels of gamma globulins (≥2.5 g/dL), may cause falsely elevated results. Galectin-3 results should be interpreted with caution in patients with a history of therapeutic use of murine monoclonal antibodies (IgG) or their fragments, who have known autoimmune disorders, or who have diseases associated with hyperglobulinemia such as multiple myeloma. Levels of galectin-3 in the blood may be increased in patients with certain forms of advanced cancer and other conditions associated with organ fibrosis. **Specimen Requirement:** 1 mL serum from a serum separator tube; Allow specimen to clot for 30 minutes and then separate serum from cells ASAP; Refrigerated **Methodology:** Enzyme-Linked Immunosorbent Assay (ELISA) **Reference Range:** Low Risk: < 17.9 ng/mL Moderate Risk: 17.9 - 25.9 ng/mL High Risk: > 25.9 ng/mL **Days Performed:** 2 days per week **Reported:** 2 - 6 days **CPT:** 82777 **Price:** $81.00	9/5/2013
NMO/Aquaporin-4 IgG, Cell Binding Assay	NMOA4	89628	**Special Information:** For Research Use Only **Specimen Requirement:** 1 mL serum from a serum separator tube; Refrigerated **Methodology:** Indirect Immunofluorescence Assay (IFA) by Cell Binding Assay (CBA) **Reference Range:** Negative **Days Performed:** Monday - Friday **Reported:** 6 - 7 days **CPT:** 86255 **Price:** $212.00 (non-discountable)	9/4/2013
NMO/Aquaporin-4 IgG, Cell Binding Assay, CSF	FNMOA4	89630	**Special Information:** For Research Use Only **Specimen Requirement:** 1 mL cerebrospinal fluid (CSF) in a sterile container; Refrigerated **Methodology:** Indirect Immunofluorescence Assay (IFA) by Cell Binding Assay (CBA) **Reference Range:** Negative **Days Performed:** Monday - Friday **Reported:** 6 - 7 days **CPT:** 86255 **Price:** $452.00 (non-discountable)	9/4/2013
Oligosaccharide and Glycan Screening	OLIGLY	89627	**Special Information:** Interpretation of the urinary oligosaccharide and free glycan profiles are using pattern recognitions. **Specimen Requirement:** 10 mL urine in a clean container; First morning void preferred, but not required; Please include family history, clinical condition (asymptomatic or acute episode), diet and drug therapy information with the sample; Frozen **Methodology:** Matrix-Assisted Laser Desorption/Ionization-Time of flight/ Time of flight (MALDI-TOF/TOF) **Days Performed:** 1 day per week **Reported:** 9 - 12 days **CPT:** 82544, 82570, 84377 **Price:** $340.00 (non-discountable)	9/19/2013

New Tests (cont.)

Test Name	Order Code	Billing Code	Test Information	Effective Date
Rivaroxiban	RVXBAN	89645	**Special Information:** Research Use Only. Rivaroxiban (Bayer Pharma AG, Germany) is a highly selective direct factor Xa inhibitor with oral bioavailability. Rivaroxiban binds directly to the catalytic site of the serine protease factor Xa, independently of antithrombin, and inhibits both free and prothrombinase-bound factor Xa. It is indicated to prevent and treat thromboembolic disorders such as ischemic stroke, systemic embolism or nonvalvular atrial fibrillation. It also reduces the risk of recurrence of deep vein thrombosis or pulmonary embolism in patients receiving orthopedic surgery. Rivaroxiban can provide more consistent and predictable anticoagulation than other anticoagulants such as Warfarin. Routine laboratory monitoring for Rivaroxiban is not necessary. However, Rivaroxiban measurement will be necessary in patients suspicious of poor compliance or failure of therapy, patients who require potential dose adjustment or patients with hepatic/renal dysfunction. As a direct factor Xa inhibitor, clotting times of coagulation tests downstream from factor Xa including PT and APTT will be prolonged. Rivaroxiban will be measured by chromogenic anti-Xa assay using specific STA- Rivaroxiban in STA-R Evolution Coagulometer. **Specimen Requirement:** 2 mL plasma from a sodium citrate light blue top tube; Frozen **Methodology:** Chromogenic **Reference Range:** Dosage 20 mg qD: Peak (2 - 4 hours post dose): 215 (22 - 535 µg/L) Trough (24 hours post dose): 32 (6 - 329 µg/L) 15 mg qD: Peak (2 - 4 hours post dose): 215 (22 - 535 µg/L) Trough (24 hours post dose): 32 (6 - 329 µg/L) 10 mg qD: Peak (2 - 4 hours post dose): 101 (7 - 273 µg/L) Trough (24 hours post dose): 14 (4 - 51 µg/L) **Days Performed:** Sunday - Saturday **Reported:** 4 hours **CPT:** 80299 **Price:** $238.00	9/26/2013
SCA1 DNA Test	SCA1	89657	**Specimen Requirement:** 20 mL whole blood in EDTA lavender top tubes; Collect Monday - Wednesday only; Send to Cleveland Clinic Laboratories on the day of collection; Ambient **Methodology:** Polymerase Chain Reaction (PCR) Fragment Analysis by Capillary Electrophoresis **Reference Range:** ≤ 35 CAG trinucleotide repeats **Days Performed:** Monday - Friday **Reported:** 8 - 15 days **CPT:** 81479 **Price:** $470.00 (non-discountable)	10/10/2013
SCA2 Expansion Analysis	SCA2	89650	**Special Information:** Phase 1 testing is for SCA2 expansions with CAG repeat sizes that are determined using PCR and capillary electrophoresis fragment analysis. This method is accurate in detecting expansions < 80 repeats. Phase 2 testing is for patients under the age of 16 years who are homozygous for a normal repeat allele, an additional screen for expansions > 80 repeats will be done. This test is done using fluorescent short tandem repeat (STR)-primed PCR. **Specimen Requirement:** 10 mL whole blood in EDTA lavender top tubes; Collect Monday - Wednesday only; Send to Cleveland Clinic Laboratories on the day of collection; Ambient **Methodology:** Polymerase Chain Reaction (PCR) Fragment analysis by Capillary Electrophoresis Fluorescent Short Tandem Repeat (STR)-primed PCR, if indicated **Reference Range:** ≤ 31 CAG trinucleotide repeats **Days Performed:** Monday - Friday **Reported:** 22 - 23 days **CPT:** 81479 **Price:** $505.00 (non-discountable)	10/10/2013

New Tests (cont.)

Test Name	Order Code	Billing Code	Test Information	Effective Date
SCA3 DNA Test	SCA3	89654	**Specimen Requirement:** 20 mL whole blood in EDTA lavender top tubes; Collect Monday - Wednesday only; Send to Cleveland Clinic Laboratories on the day of collection; Ambient **Methodology:** Polymerase Chain Reaction (PCR) Fragment Analysis by Capillary Electrophoresis **Reference Range:** ≤ 40 CAG trinucleotide repeats **Days Performed:** Monday - Friday **Reported:** 8 - 15 days **CPT:** 81401 **Price:** $488.00 (non-discountable)	10/10/2013
SCA6 DNA Test	SCA6	89655	**Specimen Requirement:** 20 mL whole blood in EDTA lavender top tubes; Collect Monday - Wednesday only; Send to Cleveland Clinic Laboratories on the day of collection; Ambient **Methodology:** Polymerase Chain Reaction (PCR) Fragment Analysis by Capillary Electrophoresis **Reference Range:** ≤ 18 CAG trinucleotide repeats **Days Performed:** Monday - Friday **Reported:** 8 - 15 days **CPT:** 81479 **Price:** $495.00 (non-discountable)	10/10/2013
SCA7 Expansion Analysis	SCA7	89656	**Special Information:** Phase 1 testing is for SCA7 expansions with CAG repeat sizes that are determined using PCR and capillary electrophoresis fragment analysis. This method is accurate in detecting expansions < 80 repeats. Phase 2 testing is for patients under the age of 16 years who are homozygous for a normal repeat allele, an additional screen for expansions > 80 repeats will be done. This test is done using fluorescent short tandem repeat (STR)-primed PCR. **Specimen Requirement:** 10 mL whole blood in EDTA lavender top tubes; Collect Monday - Wednesday only; Send to Cleveland Clinic Laboratories on the day of collection; Ambient **Methodology:** Polymerase Chain Reaction (PCR) Fragment Analysis by Capillary Electrophoresis Fluorescent Short Tandem Repeat-primed PCR, if indicated **Reference Range:** ≤ 18 CAG trinucleotide repeats **Days Performed:** Monday - Friday **Reported:** 22 - 23 days **CPT:** 81479 **Price:** $495.00 (non-discountable)	10/10/2013
Tapentadol & Metabolite, Confirmation/Quantitation, Urine	TAPENU	89646	**Includes:** Tapentadol, Urine Tapentadol glucuronide, Urine Tapentadol-O-sulfate, Urine (qualitative only) N-desmethyltapentadol, Urine (qualitative only) **Specimen Requirement:** 2 mL random urine in a clean container; Ambient **Methodology:** Quantitative Liquid Chromatography-Tandem Mass Spectrometry (LC-MS/MS) **Reference Range:** (Positive Cutoff) Tapentadol, Urine: 50 ng/mL Tapentadol glucuronide, Urine: 100 ng/mL Tapentadol-O-sulfate, Urine: 100 ng/mL N-desmethyltapentadol, Urine: 100 ng/mL **Days Performed:** Tuesday **Reported:** 2 - 8 days **CPT:** 83925 **Price:** $99.00 (non-discountable)	9/19/2013

Discontinued Tests

Test Name	Order Code	Billing Code	Test Information	Effective Date
Haemophilus influenzae B Antibody IgG	HINFLU	50155	This test will no longer be available. Suggest ordering Influenza B Virus Antibody, IgG (INFLUB)	10/10/2013
Neuromyelitis Optica Autoantibody IgG, CSF	NMOCSF	87946	This test will no longer be available. Suggest ordering NMO/Aquaporin-4 IgG, Cell Binding Assay, CSF (FNMOA4)	9/4/2013
Neuromyelitis Optica Evaluation	NOEVAL	88071	This test will no longer be available. Suggest ordering NMO/Aquaporin-4 IgG, Cell Binding Assay (NMOA4)	9/4/2013