

Cleveland Clinic Laboratories

Technical Update • May 2015

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 information, 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	Special Information	Specimen Requirement	Component Change	Reference Range	Methodology	Days Performed	Stability	Reported	CPT	Fee
32	Adenosine Deaminase														
26	Adenosine Deaminase, Pleural Fluid														
26	Adenosine Deaminase, RBC														
26	Adenosine Deaminase, Serum														
26	Admark Alzheimer's Evaluation														
4	Admark ApoE Genotype (Symptomatic)														
4	Admark Phospho-Tau CSF														
5	Admark PS-1 Analysis														
30	Alpha-1-Antitrypsin Clearance														
5, 31	Aminolevulinic Acid Dehydratase (ALAD), Whole Blood														
5, 31	Anti Mullerian Hormone														
5	Arsenic, Urine 24 Hour														
31	Aspergillus galactomannan BAL														
31	Aspergillus galactomannan Serum														
32	Autosomal Dominant Ataxia Evaluation														
6	Barbiturates Confirmation, Urine														
6, 31	Benzoylcegonine Confirmation/Quantitation														
6, 31	Beta-2 Transferrin														
6	Bethesda Inhibitor														
32	Blau Syndrome NOD2/CARD15 Complete Gene Analysis														
32	Blood Culture														

Test Update Page #	Summary of Changes by Test Name	Order Code	Billing Code	Name Change	New Test	Special Information	Specimen Requirement	Component Change	Reference Methodology	Days Performed	Stability	Reported	CPT	Fee
32	Blood Culture, Special													
30	Bromide, Blood													
6	Bronchoscopy Culture and Gram Stain													
6	Burkholderia pseudomallei Antibody Panel													
6	Cadasil DNA Test													
6	CAR Autoantibody													
7, 31	Clomipramine													
32	CMV Detection, Blood													
7	Complete HNPP Evaluation													
7	Connexin 26													
8, 31	Cryptococcus Antibody													
27	Cytomegalovirus DNA Detection and Quantitation by PCR													
30	Cystinuria Profile, Quantitative 24 Hour Urine													
8	Digoxin, Free													
8	DM1 DNA Test													
8	DM2 DNA Test													
8	DNase-B Antibody													
8, 9, 30	Drug Analysis, Comprehensive													
9	Dystonia DNA Test													
9	Dystrophin													
27	Enterovirus PCR, Plasma													
10	EPM1 DNA Test													
10	FALS Disease DNA Test													
10	Familial Hypocalciuric Hypercalcemia Evaluation													
10	Fatty Acid Oxidation Probe Assay, Fibroblast Culture													
31	Fatty Acid Profile, Comprehensive													
30	FISH Neuroblastoma 2p24 MYCN Amplification													
11	Friedreich's Ataxia DNA Test													
11	FSHD DNA Test													
11	Galop Autoantibody Test													
11	Ganglionic nAChR Antibody Test													
11, 12	GCK (NDM) DNA Sequencing Test													
12	Giardia Antigen, Stool, EIA													
12	GQ1b Autoantibody													
32	Gram Stain, Respiratory													
12	Heavy Metals, Urine													
13	Heavy Metals with Cadmium, Urine													
13	Helicobacter pylori Breath Test, Adult													
28	Helicobacter pylori Breath Test, Pediatric													
13	Hemiplegic Migraine Evaluation													
28	HER2 FISH with D17S122 Reference Probe													
30	Histoplasma Abs, CF+ID, CSF													

Test Update Page #	Summary of Changes by Test Name	Order Code	Billing Code	Name Change	New Test	Test Discontinued	Specimen Information	Component Requirement	Reference Change	Methodology	Days Performed	Range Stability	Reported	CPT	Fee
30	HIV-2 Antibody Confirmation, Serum														
30	HLA-A, B, and C														
30	HLA B*1502 Typing														
30	HLA B5701														
13	HPV Genotypes 16, 18/45														
13	Hu Autoantibody														
14, 31	Human Epididymis Protein 4														
14	Hypercoagulation Diagnostic Interpretive Panel														
30	Hyperoxaluria, Urine														
14, 31	Insulin Like Growth Factor I														
14	IPF1 (NDM) DNA Sequencing Test														
15	KCNJ11 (NDM) DNA Sequencing Test														
31	KIT (D816V) Mutation by PCR														
15	LHON mtDNA Mutation														
15	Lupus Anticoagulant Diagnostic Interpretive Panel														
15, 30	Lysozyme														
16	Melanocyte Stimulation Hormone, Alpha (α-MSH)														
16	MELAS mtDNA Profile														
16	MERRF mtDNA Evaluation														
16	MFN2 DNA Sequencing Test														
30	MLH1 Hypermethylation and BRAF Mutation Analysis														
17	Monogenic Diabetes (MODY) Evaluation														
17	MuSK Antibody Test														
17	MYD88 L265P Mutation Analysis														
17, 18	Myelin Protein Zero DNA Sequencing Test														
18	Neoenkephalitis Paraneoplastic Profile with Recombx														
18	Neosensory Neuropathy Paraneoplastic Profile														
18	Neurofibromatosis Type 2 DNA														
28	NOD2 Genotyping														
19	OPMD DNA Test														
19	Phencyclidine Confirmation, Urine														
30	Plasminogen Activator Inhibitor Antigen														
19	Platelet Antibody Screen														
19	PMP22 DNA Sequencing Test														
19	PMP22 Duplication/Deletion DNA														
19	Porphyrins, Urine Fractionated														
20	Recombx CV2 Autoantibody Test														
20	Recombx MaTa Autoantibody Test														
20	Respiratory Culture and Stain														
20	RI Autoantibody														
20	ROS1 gene rearrangement by FISH														
20, 21	SCA1 DNA Test														
21	SCA2 Expansion Analysis														

Test Update Page #	Summary of Changes by Test Name	Order Code	Billing Code	Name Change	New Test	Test Discontinued	Specimen Information	Component Requirement	Reference Change	Methodology	Days Performed	Range Stability	Reported	CPT	Fee
21	SCA3 DNA Test														
21	SCA6 DNA Test														
22	SCA7 DNA Test														
22	SCA14 DNA Test														
22	SCA17 DNA Test														
23	SensoriMotor Neuropathy Profile Complete														
23	Sensory Neuropathy Profile xp														
29	SERPINA1 Genotyping														
32	SETX DNA Sequencing														
32	Staff Review														
23	Streptococcus pneumoniae Antigen, CSF														
23	Sulfatide Autoantibody														
31	Testosterone, Free														
23	Torch Antibodies, IgG & IgM														
24	Urine Culture														
24	VAP														
24	Vitamin B2														
24	Voltage-Gated Calcium Channel IgG Autoantibodies														
25	von Willebrand Disease Type 2N Sequence Analysis														
25	Warfarin Sensitivity Genotyping														
25, 31	Whole Mitochondrial Genome with Haplotyping														
25	Yo Autoantibody														

Test Changes

Test Name	Order Code	Billing Code	Change	Effective Date
Admark ApoE Genotype (Symptomatic)	APOALZ	82397	Special Information: Higher blood volumes ensure adequate DNA quantity, which varies with WBC, specimen condition, and need for confirmatory testing. Patients, 0–3 years have higher WBC, yielding more DNA per mL of blood. DNA yields and quality are better in fresh specimens. However, when necessary, most genetic tests are successful from DNA purified from whole blood that is several days old. Specimen Requirement: 8 mL whole blood in an EDTA lavender top tube; Minimum: 6 mL; Send to Cleveland Clinic Laboratories ASAP after collection; Ambient Stability: Ambient: 10 days Refrigerated: 10 days Frozen: Call Client Services Days Performed: Monday, Friday Reported: 15–23 days	5/5/2015
Admark Phospho-Tau CSF	PHOTAU	90106	Stability: Ambient: 3 days Refrigerated: 21 days Frozen: 4 months	6/4/2015

Test Changes (Cont.)

Test Name	Order Code	Billing Code	Change	Effective Date
Admark PS-1 Analysis	PS1SY	83019	Specimen Requirement: 8 mL whole blood in an EDTA lavender top tube; Minimum: 6 mL; Send to Cleveland Clinic Laboratories ASAP after collection; Ambient Methodology: Sanger Sequencing Stability: Ambient: 10 days Refrigerated: 10 days Frozen: Call Client Services Days Performed: Wednesday Reported: 29–43 days	5/5/2015
Aminolevulinic Acid Dehydratase (ALAD), Whole Blood	ALADWB	90109	Specimen Requirement: Full whole blood sodium heparin green top tube; Place specimen on ice after draw; Minimum: 3 mL; Patient should abstain from alcohol for 24 hours. Include a list of medications the patient is currently taking; Refrigerated *OR* Full whole blood lithium heparin green top tube; Place specimen on ice after draw; Minimum: 3 mL; Patient should abstain from alcohol for 24 hours. Include a list of medications the patient is currently taking; Refrigerated *OR* Full whole blood EDTA lavender top tube; Place specimen on ice after draw; Minimum: 3 mL; Patient should abstain from alcohol for 24 hours. Include a list of medications the patient is currently taking; Refrigerated Methodology: Enzymatic End Point Spectrofluorometric Reference Range: Normal: Patients ≥ 16 years: ≥ 4.0 nmol/L/sec Indeterminate: Patients ≥ 16 years: 3.5–3.9 nmol/L/sec Diminished: Patients ≥ 16 years: < 3.5 nmol/L/sec	6/1/2015
Anti Mullerian Hormone	MULLER	84474	Reference Range: (ng/mL) Male: 6–11 months: 56.677–495.299 1–6 years: 33.442–342.450 7–12 years: 2.903–189.781 13–99 years: 2.079–30.656 Female: 6 months–14 years: 0.256–6.345 15–17 years: 0.861–10.451 18–29 years: 0.401–16.015 30–39 years: 0.176–11.705 40–45 years: ≤ 6.282 46–50 years: ≤ 0.064 Post-menopausal: ≤ 0.004 Days Performed: Monday, Thursday Reported: 2–4 days	8/4/2015
Arsenic, Urine 24 Hour	UARSND	30120	Special Information: Indicate total volume. Provide all required demographics to meet State Health Department requirements. Patient preparation: Diet, medication, and nutritional supplements may introduce interfering substances. Patients should be encouraged to discontinue nutritional supplements, vitamins, minerals, nonessential over-the-counter medications (upon the advice of their physician), and avoid shellfish and seafood for 48–72 hours. High concentrations of iodine may interfere with elemental testing. Abstinence from iodine-containing medications or contrast agents for at least 1 month prior to collecting specimens for elemental testing is recommended. Urine specimens collected within 48 hours after administration of gadolinium (Gd) contrast media are unacceptable. Reference Range: Arsenic (µg/L): 0–35 µg/L Arsenic (µg/day): 0–50 µg/day Arsenic (µg/g CRT): < 30 µg/g CRT	5/18/2015

Test Changes (Cont.)

Test Name	Order Code	Billing Code	Change	Effective Date
Barbiturates Confirmation, Urine	UBARBC	90310	Includes: Pentobarbital, Secobarbital, Phenobarbital, Butalbital Specimen Requirement: 3.5 mL random urine in a clean container; Minimum: 1.5 mL; Ambient Stability: Ambient: 1 week Refrigerated: 1 month Frozen: 3 years Days Performed: Tuesday, Thursday, Saturday Reported: 2–5 days	7/9/2015
Benzoylcegonine Confirmation/ Quantitation	BECGO	87675	For Interfaced Clients Only: Test build will need to be modified Specimen Requirement: 10 mL random urine in a clean container with no preservative ; Minimum: 2.5 mL ; Refrigerated Stability: Ambient: 3 days Refrigerated: 2 weeks Frozen: 2 weeks Methodology: High Performance Liquid Chromatography – Tandem Mass Spectrometry (LC-MS/MS) Days Performed: 4 days per week Reported: 2–5 days	7/6/2015
Beta-2 Transferrin	B2TRAN	82885	For Interfaced Clients Only: Test build may need to be changed Specimen Requirement: 2 mL aural or nasal fluid in a sterile container; Refrigerate ASAP; Minimum; 1 mL; Send to Cleveland Clinic Laboratories on the day of collection ; Transport Refrigerated Stability: Ambient: 4 hours Refrigerated: 72 hours Frozen: Unacceptable Methodology: Qualitative Immunofixation Electrophoresis Reference Range: None detected Days Performed: Sunday–Saturday Reported: 2–5 days	7/9/2015
Bethesda Inhibitor	BETHDA	26110	Reference Range: 0–99 years: ≤ 0.4 Inhib Unit	5/4/2015
Bronchoscopy Culture and Gram Stain	BALCSM	90204	Specimen Requirement: Bronchial protected brush specimen in a sterile container; Refrigerated *OR* Bronchioalveolar lavage (BAL) in a sterile container; Refrigerated	4/28/2015
Burkholderia pseudomallei Antibody Panel	BPSEUD	82908	Specimen Requirement: 1 mL serum from a serum separator tube; Minimum: 0.3 mL ; Refrigerated *OR* 1 mL serum from a red top tube; Minimum: 0.3 mL; Refrigerated Days Performed: Tuesday, Friday Reported: 2–6 days	5/11/2015
Cadasil DNA Test	CADASL	82122	Specimen Requirement: 8 mL whole blood in an EDTA lavender top tube; Minimum: 6 mL; Send to Cleveland Clinic Laboratories ASAP after collection ; Ambient Methodology: Next Gen Sequencing Reference Range: No sequence variation detected Stability: Ambient: 10 days Refrigerated: 10 days Frozen: Unacceptable Days Performed: Sunday, Monday Reported: 29–43 days	5/5/2015
CAR Autoantibody	CARAB	81575	Specimen Requirement: 2 mL serum from a serum separator tube; Minimum: 0.5 mL ; Refrigerated *OR* 2 mL serum from a red top tube; Minimum: 0.5 mL ; Refrigerated Stability: Ambient: 3 days Refrigerated: 3 weeks Frozen: 4 months	5/5/2015

Test Changes (Cont.)

Test Name	Order Code	Billing Code	Change	Effective Date
Clomipramine	CLOM	79966	<p>For Interfaced Clients only: Test build will need to be modified Includes: Clomipramine/Norclomipramine Total Specimen Requirement: 1 mL serum from a red top tube; Minimum: 0.5 mL; Separate serum from cells within 2 hours of collection; Refrigerated *OR* 1 mL plasma from an EDTA lavender top tube; Minimum: 0.5 mL; Separate plasma from cells within 2 hours of collection; Refrigerated Stability: Ambient: 5 days Refrigerated: 2 weeks Frozen: 6 months Methodology: Quantitative Liquid Chromatography-Tandem Mass Spectrometry (LC-MS/MS) Reference Range: 220–500 ng/mL Days Performed: Monday, Wednesday, Friday Reported: 2–6 days</p>	7/2/2015
Complete HNPP Evaluation	HNPP	82120	<p>Special Information: Higher blood volumes ensure adequate DNA quantity, which varies with WBC, specimen condition, and need for confirmatory testing. Patients, 0–3 years have higher WBC, yielding more DNA per mL of blood. DNA yields and quality are better in fresh specimens. However, when necessary, most genetic tests are successful from DNA purified from whole blood that is several days old. Specimen Requirement: 8 mL whole blood in an EDTA lavender top tube; Minimum: 6 mL; Send to Cleveland Clinic Laboratories ASAP after collection; Ambient Methodology: Next Generation Sequencing Multiplex Ligation-dependent Probe Amplification (MLPA) Stability: Ambient: 10 days Refrigerated: 10 days Frozen: Unacceptable Days Performed: Monday, Wednesday, Thursday Reported: 29–43 days</p>	5/5/2015
Connexin 26	CON26	81933	<p>Special Information: DFNB1 or DFNA3 is suspected in patients who have congenital (DFNB1) or childhood-onset (DFNA3) nonsyndromic sensorineural hearing impairment, with no related systemic findings identified by thorough medical history and physical examination; and a family history of hearing loss consistent with either autosomal recessive or dominant inheritance. Higher blood volumes ensure adequate DNA quantity, which varies with WBC, specimen condition, and need for confirmatory testing. Patients, 0–3 years have higher WBC, yielding more DNA per mL of blood. DNA yields and quality are better in fresh specimens. However, when necessary, most genetic tests are successful from DNA purified from whole blood that is several days old. Specimen Requirement: Adult Requirement: 8 mL whole blood in an EDTA lavender top tube; Minimum: 6 mL; Send to Cleveland Clinic Laboratories ASAP after collection to optimize DNA quantity and quality; Ambient *OR* Pediatric Requirement: 2 mL whole blood in an EDTA lavender top tube; Minimum: 1 mL; Send to Cleveland Clinic Laboratories ASAP after collection to optimize DNA quantity and quality; Ambient Methodology: Sanger Sequencing Stability: Ambient: 10 days Refrigerated: 10 days Frozen: Unacceptable Days Performed: Friday Reported: 15–22 days</p>	5/12/2015

Test Changes (Cont.)

Test Name	Order Code	Billing Code	Change	Effective Date
Cryptococcus Antibody	CRYPAB	89349	Days Performed: Tuesday, Thursday, Saturday Reported: 2–5 days	5/1/2015
Digoxin, Free	DIGFR	90205	Days Performed: Sunday–Saturday Reported: 2–3 days	6/1/2015
DM1 DNA Test	DM1DNA	82403	<p>Special Information: Order this test only if a family member has been confirmed by prior testing. Higher blood volumes ensure adequate DNA quantity, which varies with WBC, specimen condition, and need for confirmatory testing. Patients, 0–3 years have higher WBC, yielding more DNA per mL of blood. DNA yields and quality are better in fresh specimens. However, when necessary, most genetic tests are successful from DNA purified from whole blood that is several days old.</p> <p>Specimen Requirement: 8 mL whole blood in an EDTA lavender top tube; Minimum: 6 mL; Send to Cleveland Clinic Laboratories ASAP after collection to optimize DNA quantity and quality;</p> <p>Ambient</p> <p>Methodology: Repeat Expansion Detection by PCR</p> <p>Stability: Ambient: 10 days Refrigerated: 10 days Frozen: Unacceptable</p> <p>Days Performed: Monday, Thursday Reported: 29–43 days</p>	5/5/2015
DM2 DNA Test	DM2DNA	82402	<p>Special Information: Order this test only if a family member has been confirmed by prior testing. Higher blood volumes ensure adequate DNA quantity, which varies with WBC, specimen condition, and need for confirmatory testing. Patients, 0 - 3 years have higher WBC, yielding more DNA per mL of blood. DNA yields and quality are better in fresh specimens. However, when necessary, most genetic tests are successful from DNA purified from whole blood that is several days old.</p> <p>Specimen Requirement: 8 mL whole blood in an EDTA lavender top tube; Minimum: 6 mL; Send to Cleveland Clinic Laboratories ASAP after collection to optimize DNA quantity and quality;</p> <p>Ambient</p> <p>Methodology: Repeat Expansion Detection by PCR</p> <p>Stability: Ambient: 10 days Refrigerated: 10 days Frozen: Unacceptable</p> <p>Days Performed: Wednesday Reported: 29–43 days</p>	5/5/2015
DNase-B Antibody	DASEAB	89459	Days Performed: Sunday, Wednesday, Friday Reported: 2–5 days	5/18/2015
Drug Analysis, Comprehensive	DRANCO	82053	<p>Includes: Creatinine, Urine Ethanol, Tapentadol 6-Acetylmorphine, Atenolol Benztropine, Caffeine Clonidine, Dextromethorphan Dextrorphan/Levorphanol Diltiazem, Guaifenesin Metoprolol, Milnacipran Propranolol, Theophylline Verapamil <i>continued on page 9</i></p>	4/14/2015

Test Changes (Cont.)

Test Name	Order Code	Billing Code	Change	Effective Date
Drug Analysis, Comprehensive (continued from page 8)			<p>Classes/Groups (see test directory for drugs tested within each class or group)</p> <p>Amphetamines, Benzodiazepines Cocaine & Metabolites, Fentanyl & Analogues Buprenorphine & Metabolites, Cannabinoids Methadone and Metabolite, Opiates Oxycodone, Sympathomimetics Barbiturates, Opioids Hallucinogens, Anticonvulsants Muscle Relaxants, Sedatives/Hypnotics Antidepressants, Antipsychotics Analgesics & NSAIDS, Antihistamines Local Anesthetics</p> <p>Specimen Requirement: 30 mL random urine in a clean container; Minimum: 3 mL; Refrigerated</p> <p>*AND* 10 mL whole blood in a potassium oxalate/sodium fluoride gray top tube; Minimum: 1.2 mL; Refrigerated</p> <p>Stability: Ambient: 3 days Refrigerated: 2 weeks Frozen: 6 months</p> <p>Methodology: Gas Chromatography Mass Spectrometry (GCMS) Immunoassay (IA) Liquid Chromatography-Tandem Mass Spectrometry (LC-MS/MS)</p> <p>Days Performed: Sunday-Saturday Reported: 6-11 days CPT: 80302, 80326, 80301, 80331, 80334, 80337, 80338, 80341, 80344, 80346, 80348, 80353, 80354, 80355, 80357, 80358, 80359, 80360, 80361, 80364, 80365, 80366, 80367, 80368, 80370, 80371, 80372, 80373, 80377, 82570, 83992 Price: \$599.00</p>	
Dystonia DNA Test	DYSTON	83018	<p>Special Information: Higher blood volumes ensure adequate DNA quantity, which varies with WBC, specimen condition, and need for confirmatory testing. Patients, 0 - 3 years have higher WBC, yielding more DNA per mL of blood. DNA yields and quality are better in fresh specimens. However, when necessary, most genetic tests are successful from DNA purified from whole blood that is several days old.</p> <p>Specimen Requirement: 8 mL whole blood in an EDTA lavender top tube; Minimum: 6 mL; Send to Cleveland Clinic Laboratories ASAP after collection to optimize DNA quantity and quality;</p> <p>Ambient</p> <p>Stability: Ambient: 10 days Refrigerated: 10 days Frozen: Unacceptable</p> <p>Days Performed: Alternate Thursday Reported: 29-43 days</p>	5/5/2015
Dystrophin	DYSTRO	76163	<p>Specimen Requirement: 10 mg muscle tissue; Minimum: 5 mg; Sample should be obtained by needle or open biopsy. Place sample in labeled cryovial and freeze immediately in liquid nitrogen or on dry ice. Do not treat with fixatives or saline; Frozen</p> <p>Stability: Ambient: Unacceptable Refrigerated: Unacceptable Frozen: 6 months</p> <p>Days Performed: Monday Reported: 29-43 days</p>	5/21/2015

Test Changes (Cont.)

Test Name	Order Code	Billing Code	Change	Effective Date
EPM1 DNA Test	EPMDNA	82118	<p>Special Information: Higher blood volumes ensure adequate DNA quantity, which varies with WBC, specimen condition, and need for confirmatory testing. Patients, 0 - 3 years have higher WBC, yielding more DNA per mL of blood. DNA yields and quality are better in fresh specimens. However, when necessary, most genetic tests are successful from DNA purified from whole blood that is several days old.</p> <p>Specimen Requirement: 10 mL whole blood in an EDTA lavender top tube; Minimum: 8 mL; Send to Cleveland Clinic Laboratories ASAP after collection to optimize DNA quantity and quality;</p> <p>Ambient</p> <p>Stability:</p> <p>Ambient: 10 days Refrigerated: 10 days Frozen: Unacceptable</p> <p>Days Performed: Upon receipt</p> <p>Reported: 29–43 days</p> <p>CPT: 81404</p>	6/2/2015
FALS Disease DNA Test	FALS	82343	<p>Special Information: Testing is not available to patients residing in New York state. Higher blood volumes ensure adequate DNA quantity, which varies with WBC, specimen condition, and need for confirmatory testing. Patients, 0–3 years have higher WBC, yielding more DNA per mL of blood. DNA yields and quality are better in fresh specimens. However, when necessary, most genetic tests are successful from DNA purified from whole blood that is several days old.</p> <p>Specimen Requirement: 8 mL whole blood in an EDTA lavender top tube; Minimum: 6 mL; Send to Cleveland Clinic Laboratories ASAP after collection to optimize DNA quantity and quality;</p> <p>Ambient</p> <p>Stability:</p> <p>Ambient: 10 days Refrigerated: 10 days Frozen: Unacceptable</p> <p>Methodology: Next Gen Sequencing</p> <p>Days Performed: Varies</p> <p>Reported: 29–43 days</p> <p>CPT: 81404</p>	6/1/2015
Familial Hypocalciuric Hypercalcemia Evaluation	FHHE	83294	<p>Special Information: Higher blood volumes ensure adequate DNA quantity, which varies with WBC, specimen condition, and need for confirmatory testing. Patients, 0 - 3 years, have higher WBC, yielding more DNA per mL of blood. DNA yields and quality are better in fresh specimens. However, when necessary, most genetic tests are successful from DNA purified from whole blood that is several days old.</p> <p>Specimen Requirement: 8 mL whole blood in an EDTA lavender top tube; Minimum: 6 mL; Send to Cleveland Clinic Laboratories ASAP after collection to optimize DNA quantity and quality;</p> <p>Ambient</p> <p>Stability:</p> <p>Ambient: 10 days Refrigerated: 10 days Frozen: Unacceptable</p> <p>Methodology: Sanger Sequencing</p> <p>Days Performed: Monday–Friday</p> <p>Reported: 29–43 days</p>	5/12/2015
Fatty Acid Oxidation Probe Assay, Fibroblast Culture	FAO	82923	<p>Special Information: Specimens received in formalin or fixative preservative are not acceptable. Patients residing in New York state require informed consent.</p> <p>Days Performed: Varies</p> <p>Reported: 16–72 days</p>	4/23/2015

Test Changes (Cont.)

Test Name	Order Code	Billing Code	Change	Effective Date
Friedreich's Ataxia DNA Test	FRIED	82524	<p>Special Information: Higher blood volumes ensure adequate DNA quantity, which varies with WBC, specimen condition, and need for confirmatory testing. Patients, 0–3 years, have higher WBC, yielding more DNA per mL of blood. DNA yields and quality are better in fresh specimens. However, when necessary, most genetic tests are successful from DNA purified from whole blood that is several days old.</p> <p>Specimen Requirement: 8 mL whole blood in an EDTA lavender top tube; Minimum: 6 mL; Send to Cleveland Clinic Laboratories ASAP after collection to optimize DNA quantity and quality; Ambient</p> <p>Stability: Ambient: 10 days Refrigerated: 10 days Frozen: Unacceptable</p> <p>Methodology: Repeat Expansion Detection by PCR Southern Blot</p> <p>Days Performed: Monday Reported: 29–43 days</p>	5/5/2015
FSHD DNA Test	FSHDNA	82117	<p>Special Information: Extracted DNA is not an acceptable specimen type for this assay</p> <p>Specimen Requirement: 15 mL whole blood in an EDTA lavender top tube; Minimum: 10 mL; Collect Monday - Wednesday only. Send to Cleveland Clinic Laboratories on the day of collection; Ambient</p> <p>Stability: Ambient: 72 hours Refrigerated: 72 hours Frozen: Unacceptable</p> <p>Reference Range: Restriction fragment length ≥ 42 kb</p> <p>Days Performed: Wednesday Reported: 15–29 days</p>	5/12/2015
Galop Autoantibody Test	GALOP	82116	<p>Specimen Requirement: 2 mL serum from a serum separator tube; Minimum: 0.5 mL; Refrigerated *OR* 2 mL serum from a red top tube; Minimum: 0.5 mL; Refrigerated</p> <p>Stability: Ambient: 3 days Refrigerated: 3 weeks Frozen: 4 months</p> <p>Days Performed: Tuesday, Thursday, Saturday Reported: 8–15 days</p>	5/5/2015
Ganglionic nAChR Antibody Test	GNGLAB	89616	<p>Specimen Requirement: 2 mL serum from a red top tube; Minimum: 0.5 mL; Refrigerated *OR* 2 mL serum from a serum separator tube; Minimum: 0.5 mL; Refrigerated</p> <p>Stability: Ambient: 3 days Refrigerated: 3 weeks Frozen: 4 months</p> <p>Reference Range: < 55 pMol/L</p> <p>Days Performed: Monday–Friday Reported: 8–15 days</p>	5/5/2015
GCK (NDM) DNA Sequencing Test	GCKNDM	83328	<p>Special Information: Higher blood volumes ensure adequate DNA quantity, which varies with WBC, specimen condition, and need for confirmatory testing. Patients, 0–3 years, have higher WBC, yielding more DNA per mL of blood. DNA yields and quality are better in fresh specimens. However, when necessary, most genetic tests are successful from DNA purified from whole blood that is several days old.</p> <p><i>continued on page 12</i></p>	5/21/2015

Test Changes (Cont.)

Test Name	Order Code	Billing Code	Change	Effective Date
GCK (NDM) DNA Sequencing Test (continued from page 11)			Specimen Requirement: Adult Requirement: 8 mL whole blood in an EDTA lavender top tube; Minimum: 6 mL; Send to Cleveland Clinic Laboratories ASAP after collection to optimize DNA quantity and quality; Ambient *OR* Pediatric Requirement: 2 mL whole blood in an EDTA lavender top tube; Minimum: 1 mL; Send to Cleveland Clinic Laboratories ASAP after collection to optimize DNA quantity and quality; Ambient Stability: Ambient: 10 days Refrigerated: 10 days Frozen: Unacceptable Methodology: Sanger Sequencing Days Performed: Tuesday Reported: 29–43 days	
Giardia Antigen, Stool, EIA	GIAEIA	89735	Stability: Ambient: Preserved with 10% formalin: 9 months Unpreserved: 2 hours Refrigerated: Preserved with 10% formalin: 9 months Unpreserved: 1 day Frozen: Preserved: Unacceptable Unpreserved: 1 week	5/18/2015
GQ1b Autoantibody	GQ1BAB	82181	Specimen Requirement: 2 mL serum from a serum separator tube; Minimum: 0.5 mL; Refrigerated *OR* 2 mL serum from a red top tube; Minimum: 0.5 mL; Refrigerated Stability: Ambient: 3 days Refrigerated: 3 weeks Frozen: 4 months Reference Range: < 1:100 titer Days Performed: Monday, Wednesday Reported: 8–15 days	5/5/2015
Heavy Metals, Urine	UTXM3	88693	Special Information: Specimens with a total arsenic concentration between 35 - 2000 ug/L, will be fractionated at an additional cost to determine the proportion of organic, inorganic, and methylated forms of arsenic present. PATIENT PREP: Diet, medication, and nutritional supplements may introduce interfering substances. Patients should be encouraged to discontinue nutritional supplements, vitamins, minerals, non-essential over-the-counter medications (upon the advice of their physician), and avoid shellfish and seafood for 48–72 hours. High concentrations of iodine may interfere with elemental testing. Abstinence from iodine-containing medications or contrast agents for at least 1 month prior to collecting specimens for elemental testing is recommended. Urine collected within 48 hours after administration of gadolinium (Gd) containing contrast media are not acceptable. Reference Range: Arsenic: 0 - 35 µg/L Arsenic: 0 - 50 µg/24 hours Arsenic: < 30 µg/g crt Lead: 0 - 23 µg/L Lead: 0 - 31 µg/day Lead: < 5 µg/g crt Creatinine, Mercury, & Fractionated Arsenic ranges are unchanged	5/18/2015

Test Changes (Cont.)

Test Name	Order Code	Billing Code	Change	Effective Date
Heavy Metals with Cadmium, Urine	UTXM4	88694	<p>Special Information: Specimens with a total arsenic concentration between 35–2000 ug/L, will be fractionated at an additional cost to determine the proportion of organic, inorganic, and methylated forms of arsenic present. PATIENT PREP: Diet, medication, and nutritional supplements may introduce interfering substances. Patients should be encouraged to discontinue nutritional supplements, vitamins, minerals, non-essential over-the-counter medications (upon the advice of their physician), and avoid shellfish and seafood for 48–72 hours. High concentrations of iodine may interfere with elemental testing. Abstinence from iodine-containing medications or contrast agents for at least 1 month prior to collecting specimens for elemental testing is recommended. Urine collected within 48 hours after administration of gadolinium (Gd) containing contrast media are not acceptable.</p> <p>Reference Range: Arsenic: 0 - 35 µg/L Arsenic: 0 - 50 µg/24 hours Arsenic: < 30 µg/g crt Cadmium: Refer to report (µg/L) Cadmium: Refer to report (µg/day) Cadmium: Refer to report (µg/g crt) Lead: 0 - 31 µg/day Lead: 0 - 23 µg/L Lead: < 5 µg/g crt Creatinine, Mercury, & Fractionated Arsenic ranges are unchanged</p>	5/18/2015
Helicobacter pylori Breath Test, Adult	HPYLBR	82747	<p>Specimen Requirement: Submit one baseline (blue) and one post dose (pink) breath sample bag; Ambient</p>	5/11/2015
Hemiplegic Migraine Evaluation	HEMMIG	87713	<p>Special Information: Higher blood volumes ensure adequate DNA quantity, which varies with WBC, specimen condition, and need for confirmatory testing. Patients, 0 - 3 years, have higher WBC, yielding more DNA per mL of blood. DNA yields and quality are better in fresh specimens. However, when necessary, most genetic tests are successful from DNA purified from whole blood that is several days old.</p> <p>Specimen Requirement: 8 mL whole blood in an EDTA lavender top tube; Minimum: 6 mL; Send to Cleveland Clinic Laboratories ASAP after collection to optimize DNA quantity and quality; Ambient</p> <p>Stability: Ambient: 10 days Refrigerated: 10 days Frozen: Unacceptable</p> <p>Methodology: Next Gen Sequencing Days Performed: Monday–Friday Reported: 29–43 days CPT: 81479, 81406, 81407</p>	6/1/2015
HPV Genotypes 16, 18/45	HPVGNO	89544	<p>Methodology: Transcription-Mediated Amplification Days Performed: Wednesday, Friday Reported: 2–6 days</p>	5/5/2015
Hu Autoantibody	ANTIHU	81952	<p>Specimen Requirement: 2 mL serum from a red top tube; Minimum: 0.5 mL; Refrigerated *OR* 2 mL serum from a serum separator tube; Minimum: 0.5 mL; Refrigerated</p> <p>Stability: Ambient: 3 days Refrigerated: 3 weeks Frozen: 4 months</p> <p>Days Performed: Monday, Wednesday Reported: 8–15 days</p>	5/5/2015

Test Changes (Cont.)

Test Name	Order Code	Billing Code	Change	Effective Date
Human Epididymis Protein 4	HEP4	88459	Special Information: Specimens from patients who have received preparations of mouse monoclonal antibodies for diagnosis or therapy may contain human anti-mouse antibodies (HAMA) Specimens containing HAMA may produce anomalous values when tested by this assay. HE4 elevations can be seen in approximately 30% of patients with congestive heart failure, and in a variety of non-ovarian cancers such as lung, bladder, and gastrointestinal. Stability: Ambient: 24 hours Refrigerated: 4 days Frozen: 90 days Methodology: Chemiluminescent Microparticle Immunoassay (CMIA) Days Performed: Monday, Wednesday, Friday Reported: 2–4 days	7/7/2015
Hypercoagulation Diagnostic Interpretive Panel	HYPER	173	Special Information: Patient Preparation: Discontinue Coumadin therapy for 7 days, heparin therapy for 2 days and thrombolytic therapy for 7 days prior to test, if possible. Submit a Coagulation Consultation Patient History Sheet. 3.2% sodium citrate is the preferred anticoagulant recommended by NCCLS. If tests are abnormal in the panel, the following tests may be ordered and billed: PTT Incubated Mixing Add On (85730, 85732 x2), Dilute Russell Viper Venom (85613), Platelet Neutralization (85597), Factor V Leiden (81241), MTHFR by PCR (81291), Thrombin Time (85670), Reptilase (85635), Fibrinogen Antigen (85385), Prot C Immunologic (85302), Prot S Immunologic (85306), Heparin fXa Inhibition (85520), and/or Anti-Xa Inhibitor Assay . Sample MUST be accompanied by a completed Clinical History Form for Hemostasis and Thrombosis Evaluation. This form is available on the Cleveland Clinic Laboratories Test Directory website or through Client Services at 800-628-6816 or 216-444-5755.	6/2/2015
Insulin Like Growth Factor I	ILGF1	75072	Reference Range: Male: 26–30 years: 88– 257 ng/mL All other ranges are unchanged	7/2/2015
IPF1 (NDM) DNA Sequencing Test	IPFNDM	83325	Special Information: Higher blood volumes ensure adequate DNA quantity, which varies with WBC, specimen condition, and need for confirmatory testing. Patients, 0–3 years, have higher WBC, yielding more DNA per mL of blood. DNA yields and quality are better in fresh specimens. However, when necessary, most genetic tests are successful from DNA purified from whole blood that is several days old. Specimen Requirement: Adult Requirement: 8 mL whole blood in an EDTA lavender top tube; Minimum: 6 mL; Send to Cleveland Clinic Laboratories ASAP after collection to optimize DNA quantity and quality; Ambient *OR* Pediatric Requirement: 2 mL whole blood in an EDTA lavender top tube; Minimum: 1 mL; Send to Cleveland Clinic Laboratories ASAP after collection to optimize DNA quantity and quality; Ambient Stability: Ambient: 10 days Refrigerated: 10 days Frozen: Unacceptable Methodology: Sanger Sequencing Days Performed: Monday–Friday Reported: 29–43 days CPT: 81404	6/2/2015

Test Changes (Cont.)

Test Name	Order Code	Billing Code	Change	Effective Date
KCNJ11 (NDM) DNA Sequencing Test	KCNJ	83327	<p>Special Information: Higher blood volumes ensure adequate DNA quantity, which varies with WBC, specimen condition, and need for confirmatory testing. Patients, 0–3 years, have higher WBC, yielding more DNA per mL of blood. DNA yields and quality are better in fresh specimens. However, when necessary, most genetic tests are successful from DNA purified from whole blood that is several days old.</p> <p>Specimen Requirement: Adult Requirement: 8 mL whole blood in an EDTA lavender top tube; Minimum: 6 mL; Send to Cleveland Clinic Laboratories ASAP after collection to optimize DNA quantity and quality; Ambient *OR* Pediatric Requirement: 2 mL whole blood in an EDTA lavender top tube; Minimum: 1 mL; Send to Cleveland Clinic Laboratories ASAP after collection to optimize DNA quantity and quality; Ambient</p> <p>Stability: Ambient: 10 days Refrigerated: 10 days Frozen: Unacceptable</p> <p>Methodology: Sanger Sequencing Days Performed: Monday–Friday Reported: 29–43 days CPT: 81404</p>	5/5/2015
LHON mtDNA Mutation	LHON	81739	<p>Special Information: Higher blood volumes ensure adequate DNA quantity, which varies with WBC, specimen condition, and need for confirmatory testing. Patients, 0–3 years, have higher WBC, yielding more DNA per mL of blood. DNA yields and quality are better in fresh specimens. However, when necessary, most genetic tests are successful from DNA purified from whole blood that is several days old.</p> <p>Specimen Requirement: 8 mL whole blood in an EDTA lavender top tube; Minimum: 6 mL; Send to Cleveland Clinic Laboratories ASAP after collection to optimize DNA quantity and quality; Ambient</p> <p>Stability: Ambient: 10 days Refrigerated: 10 days Frozen: Unacceptable</p> <p>Days Performed: Upon receipt Reported: 29–43 days</p>	5/5/2015
Lupus Anticoagulant Diagnostic Interpretive Panel	LUPUSP	24	<p>Special Information: 3.2% sodium citrate is the preferred anticoagulant recommended by NCCLS. Patient preparation: Discontinue heparin therapy for 2 days prior to collection. If tests are abnormal, the following tests may be ordered and billed: Factor II (85210), Factor V (85220), Factor X (85260), Factor VIII (85247), Von Willebrand Factor Antigen (85246), Ristocetin Co-factor (85245), Factor IX Assay (85250), Factor XI Assay (85270), Factor XII Assay (85280), Heparin fXa inhibition (85520), Fibrinogen, Anti-Xa Inhibitor Assay and/or Bethesda Assay. Sample MUST be accompanied by a completed Clinical History Form for Hemostasis and Thrombosis Evaluation. This form is available on the Cleveland Clinic Laboratories Test Directory website or through Client Services at 800-628-6816 or 216-444-5755.</p>	6/2/2015
Lysozyme	LYSO2	79801	<p>For Interfaced Clients only: Test build will need to be modified</p> <p>Specimen Requirement: 1 mL serum from a serum separator tube; Separate serum from cells within 2 hours of collection; Minimum: 0.4 mL; Refrigerated</p> <p>Methodology: Quantitative Enzyme-Linked Immunosorbent Assay Reference Range: 0.00–2.75 µg/mL Days Performed: Sunday, Tuesday, Thursday Reported: 2–6 days</p>	5/18/2015

Test Changes (Cont.)

Test Name	Order Code	Billing Code	Change	Effective Date
Melanocyte Stimulation Hormone, Alpha (α-MSH)	MSHA	90387	Stability: Ambient: Unacceptable Refrigerated: 24 hours Frozen: 1 month	5/18/2015
MELAS mtDNA Profile	MELAS	82401	Special Information: Higher blood volumes ensure adequate DNA quantity, which varies with WBC, specimen condition, and need for confirmatory testing. Patients, 0–3 years, have higher WBC, yielding more DNA per mL of blood. DNA yields and quality are better in fresh specimens. However, when necessary, most genetic tests are successful from DNA purified from whole blood that is several days old. Specimen Requirement: 8 mL whole blood in an EDTA lavender top tube; Minimum: 6 mL; Send to Cleveland Clinic Laboratories ASAP after collection; Ambient *OR* 100 mg muscle in a clean container; Frozen Stability: Ambient: Whole Blood: 10 days Muscle: Unacceptable Refrigerated: Whole Blood: 10 days Muscle: Unacceptable Frozen: Whole Blood: Unacceptable Muscle: Indefinitely at -70° C Days Performed: Varies Reported: 29–43 days	5/15/2015
MERRF mtDNA Evaluation	MERRF	82400	Special Information: Higher blood volumes ensure adequate DNA quantity, which varies with WBC, specimen condition, and need for confirmatory testing. Patients, 0–3 years, have higher WBC, yielding more DNA per mL of blood. DNA yields and quality are better in fresh specimens. However, when necessary, most genetic tests are successful from DNA purified from whole blood that is several days old. Specimen Requirement: 8 mL whole blood in an EDTA lavender top tube; Minimum: 6 mL; Send to Cleveland Clinic Laboratories ASAP after collection; Ambient *OR* 100 mg muscle in a clean container; Freeze immediately and store at -70° C or lower; Transport Frozen Stability: Ambient: Whole Blood: 10 days Muscle: Unacceptable Refrigerated: Whole Blood: 10 days Muscle: Unacceptable Frozen: Whole Blood: Unacceptable Muscle: Indefinitely at -70° C Days Performed: Monday Reported: 29–43 days	5/5/2015
MFN2 DNA Sequencing Test	MFN2	83400	Special Information: Higher blood volumes ensure adequate DNA quantity, which varies with WBC, specimen condition, and need for confirmatory testing. Patients, 0–3 years, have higher WBC, yielding more DNA per mL of blood. DNA yields and quality are better in fresh specimens. However, when necessary, most genetic tests are successful from DNA purified from whole blood that is several days old. Specimen Requirement: 8 mL whole blood in an EDTA lavender top tube; Minimum: 6 mL; Send to Cleveland Clinic Laboratories ASAP after collection; Ambient Stability: Ambient: 10 days Refrigerated: 10 days Frozen: Unacceptable Days Performed: Wednesday Reported: 29–43 days	5/5/2015

Test Changes (Cont.)

Test Name	Order Code	Billing Code	Change	Effective Date
Monogenic Diabetes (MODY) Evaluation	MODY	83309	<p>Special Information: Higher blood volumes ensure adequate DNA quantity, which varies with WBC, specimen condition, and need for confirmatory testing. Patients, 0–3 years, have higher WBC, yielding more DNA per mL of blood. DNA yields and quality are better in fresh specimens. However, when necessary, most genetic tests are successful from DNA purified from whole blood that is several days old.</p> <p>Specimen Requirement: 8 mL whole blood in an EDTA lavender top tube; Minimum: 6 mL; Send to Cleveland Clinic Laboratories ASAP after collection; Ambient</p> <p>Stability: Ambient: 10 days Refrigerated: 10 days Frozen: Unacceptable</p> <p>Methodology: Sanger Sequencing Multiplex Ligation-dependent Probe Amplification</p> <p>Days Performed: Monday–Friday Reported: 29–43 days CPT: 81404x2, 81405x2, 81406x2, 81479</p>	6/2/2015
MuSK Antibody Test	MUSK	82592	<p>Specimen Requirement: 2 mL serum from a red top tube; Minimum: 0.5 mL; Refrigerated *OR* 2 mL serum from a serum separator tube; Minimum: 0.5 mL; Refrigerated</p> <p>Stability: Ambient: 3 days Refrigerated: 3 weeks Frozen: 4 months</p> <p>Reference Range: < 1:10</p>	5/5/2015
MYD88 L265P Mutation Analysis	MYD88	89733	<p>For Interfaced Clients Only: Test build may need to be modified</p> <p>Specimen Requirement: One formalin fixed paraffin block; Ambient *OR* One bone marrow clot, formalin fixed, paraffin-embedded block; Ambient *OR* 4 mL whole blood in an EDTA lavender top tube; Minimum: 2 mL; Refrigerated *OR* 2 mL bone marrow in an EDTA lavender top tube; Minimum: 1 mL; Refrigerated</p> <p>Stability: Ambient: Blood/Bone marrow: 24 hours Paraffin block/bone marrow clot: Indefinitely Refrigerated: Blood/Bone marrow: 5 days Paraffin block/bone marrow clot: Indefinitely Frozen: Blood/Bone marrow: Unacceptable Paraffin block/bone marrow clot: Indefinitely</p> <p>Methodology: Allele-specific Polymerase Chain Reaction Real-Time Polymerase Chain Reaction (rtPCR) IHC Stain/process PCR cut</p> <p>Days Performed: 1 day per week Reported: 7–14 days</p>	7/9/2015
Myelin Protein Zero DNA Sequencing Test	MPZERO	82186	<p>Special Information: Higher blood volumes ensure adequate DNA quantity, which varies with WBC, specimen condition, and need for confirmatory testing. Patients, 0–3 years, have higher WBC, yielding more DNA per mL of blood. DNA yields and quality are better in fresh specimens. However, when necessary, most genetic tests are successful from DNA purified from whole blood that is several days old.</p> <p>Specimen Requirement: 8 mL whole blood in an EDTA lavender top tube; Minimum: 6 mL; Send to Cleveland Clinic Laboratories ASAP after collection; Ambient</p> <p><i>(continued on page 18)</i></p>	5/5/2015

Test Changes (Cont.)

Test Name	Order Code	Billing Code	Change	Effective Date
Myelin Protein Zero DNA Sequencing Test (continued from page 17)			Stability: Ambient: 10 days Refrigerated: 10 days Frozen: Unacceptable Methodology: Next Gen Sequencing Days Performed: Monday, Wednesday Reported: 29–43 days	
Neoencephalitis Paraneoplastic Profile with Recombx	CEPHAL	82188	Specimen Requirement: 2 mL serum from a red top tube; Minimum: 0.5 mL ; Refrigerated Stability: Ambient: 3 days Refrigerated: 3 weeks Frozen: 4 months Methodology: Enzyme-Linked Immunosorbent Assay (ELISA) Indirect Immunofluorescence Assay (IFA) Radioimmunoassay (RIA) Western Blot (WB) Immunoblot (IB) Days Performed: Monday–Friday Reported: 8–15 days	5/5/2015
Neosensory Neuropathy Paraneoplastic Profile	NEOSEN	82198	Specimen Requirement: 2 mL serum from a red top tube; Minimum: 0.5 mL ; Refrigerated *OR* 2 mL serum from a serum separator tube; Minimum: 0.5 mL; Refrigerated Stability: Ambient: 3 days Refrigerated: 3 weeks Frozen: 4 months Methodology: Enzyme-Linked Immunosorbent Assay (ELISA) Western Blot (WB) Immunoblot (IB) Days Performed: Monday–Friday Reported: 8–15 days	5/5/2015
Neurofibromatosis Type 2 DNA	NEUFIB	82303	Special Information: Higher blood volumes ensure adequate DNA quantity, which varies with WBC, specimen condition, and need for confirmatory testing. Patients, 0–3 years, have higher WBC, yielding more DNA per mL of blood. DNA yields and quality are better in fresh specimens. However, when necessary, most genetic tests are successful from DNA purified from whole blood that is several days old. Specimen Requirement: 8 mL whole blood in an EDTA lavender top tube; Minimum: 6 mL; Send to Cleveland Clinic Laboratories ASAP after collection to optimize DNA quality and quantity; Ambient Stability: Ambient: 10 days Refrigerated: 10 days Frozen: Unacceptable Methodology: Sanger Sequencing Days Performed: Varies Reported: 29–57 days	5/21/2015

Test Changes (Cont.)

Test Name	Order Code	Billing Code	Change	Effective Date
OPMD DNA Test	OPMD	82199	Specimen Requirement: 8 mL whole blood in an EDTA lavender top tube; Minimum: 6 mL; Send to Cleveland Clinic Laboratories ASAP after collection to optimize DNA quality and quantity; Ambient Stability: Ambient: 10 days Refrigerated: 10 days Frozen: Unacceptable Methodology: Repeat Expansion Detection by PCR Days Performed: Wednesday Reported: 15–29 days CPT: 81401	5/5/2015
Phencyclidine Confirmation, Urine	UPCPC	87652	Specimen Requirement: 1 mL random urine in a clean container; Minimum: 0.5 mL; Ambient Stability: Ambient: 1 week Refrigerated: 1 month Frozen: 3 years (avoid repeated freeze/thaw cycles) Methodology: High Performance Liquid Chromatography – Tandem Mass Spectrometry (LC-MS/MS) Days Performed: Monday Reported: 2–9 days	7/9/2015
Platelet Antibody Screen	PLTAB3	83391	Special Information: Samples should be spun down and taken off the clot. Samples should be less than 7 days old when tested. Older specimens are acceptable if they have been frozen.	5/1/2015
PMP22 DNA Sequencing Test	PMP22	82201	Special Information: Higher blood volumes ensure adequate DNA quantity, which varies with WBC, specimen condition, and need for confirmatory testing. Patients, 0–3 years, have higher WBC, yielding more DNA per mL of blood. DNA yields and quality are better in fresh specimens. However, when necessary, most genetic tests are successful from DNA purified from whole blood that is several days old. Specimen Requirement: 8 mL whole blood in an EDTA lavender top tube; Minimum: 6 mL; Send to Cleveland Clinic Laboratories ASAP after collection to optimize DNA quality and quantity; Ambient Stability: Ambient: 10 days Refrigerated: 10 days Frozen: Unacceptable Days Performed: Thursday Reported: 29–43 days	5/21/2015
PMP22 Duplication/Deletion DNA	PMPDEL	82200	Specimen Requirement: 8 mL whole blood in an EDTA lavender top tube; Minimum: 6 mL; Send to Cleveland Clinic Laboratories ASAP after collection to optimize DNA quality and quantity; Ambient Stability: Ambient: 10 days Refrigerated: 10 days Frozen: Unacceptable Days Performed: Monday, Wednesday Reported: 29–43 days	5/5/2015
Porphyrins, Urine Fractionated	UPORFR	84120	Stability: Ambient: Unacceptable Refrigerated: 4 days Frozen: 1 month	6/29/2015

Test Changes (Cont.)

Test Name	Order Code	Billing Code	Change	Effective Date
Recombx CV2 Autoantibody Test	CV2	82202	Specimen Requirement: 2 mL serum from a red top tube; Minimum: 0.5mL ; Refrigerated *OR* 2 mL cerebrospinal fluid (CSF) in a sterile container; Minimum: 0.5 mL; Refrigerated Stability: Ambient: 72 hours Refrigerated: 21 days Frozen: 4 months Days Performed: Tuesday, Thursday Reported: 8–15 days	5/5/2015
Recombx MaTa Autoantibody Test	MATA	82203	Specimen Requirement: 2 mL serum from a red top tube; Minimum: 0.5mL ; Refrigerated *OR* 2 mL cerebrospinal fluid (CSF) in a sterile container; Minimum: 0.5 mL; Refrigerated Stability: Ambient: 72 hours Refrigerated: 21 days Frozen: 4 months Days Performed: Tuesday, Thursday Reported: 8–15 days	5/5/2015
Respiratory Culture and Stain	RCULST	77914	Special Information: Patient Preparation: The patient should be instructed to remove dentures, rinse mouth and gargle with water. The patient should then be instructed to cough deeply and expectorate sputum into proper container. All fast-growing non-fastidious aerobic organisms which are clinically significant will be identified. MIC susceptibility testing will be performed, if relevant. Positive findings will include susceptibilities if appropriate. Pathogenic <i>Neisseria</i> species or <i>Haemophilus</i> species will be isolated only if requested. NOTE: BAL or Protected brush specimens should be ordered as a bronchoscopy culture (BALCSM) Specimen Requirement: 2 mL bronchial washings in a sterile container; Ambient *OR* 2 mL tracheal aspirate in a sterile container; If tracheal aspirate is microscopically deemed unsatisfactory, it will be rejected; Ambient *OR* 2 mL sputum in a sterile container; First morning specimen is preferred. If specimen is microscopically consistent with saliva, it will be rejected; Ambient	4/28/2015
RI Autoantibody	RIAUT	76515	Specimen Requirement: 2 mL serum from a red top tube; Minimum: 0.5 mL ; Refrigerated *OR* 2 mL serum from a serum separator tube; Minimum: 0.5 mL; Refrigerated Stability: Ambient: 3 days Refrigerated: 3 weeks Frozen: 4 months Days Performed: Tuesday, Thursday Reported: 8–15 days	5/5/2015
ROS1 gene rearrangement by FISH	ROS1	89243	Specimen Requirement: One formalin-fixed, paraffin-embedded tissue specimen block; Provide surgical path report; Refrigerated *OR* Four tissue slides (1 H&E cut at 4-5 microns and 3 unstained slides at 3-4 microns each); Provide surgical path report; Ambient Days Performed: Sunday–Saturday Reported: 4–7 days CPT: 88377	7/9/2015
SCA1 DNA Test	SCA1	89657	Special Information: Higher blood volumes ensure adequate DNA quantity, which varies with WBC, specimen condition, and need for confirmatory testing. Patients, 0–3 years, have higher WBC, yielding more DNA per mL of blood. DNA yields and quality are better in fresh specimens. However, when necessary, most genetic tests are successful from DNA purified from whole blood that is several days old. <i>continued on page 21</i>	6/1/2015

Test Changes (Cont.)

Test Name	Order Code	Billing Code	Change	Effective Date
SCA1 DNA Test (continued from page 20)			Specimen Requirement: 8 mL whole blood in an EDTA lavender top tube; Minimum: 6 mL; Send to Cleveland Clinic Laboratories ASAP after collection to optimize DNA quality and quantity; Ambient Stability: Ambient: 10 days Refrigerated: 10 days Frozen: Unacceptable Methodology: Repeat Expansion by PCR Days Performed: Monday–Friday Reported: 29–43 days	
SCA2 Expansion Analysis	SCA2	89650	Special Information: Higher blood volumes ensure adequate DNA quantity, which varies with WBC, specimen condition, and need for confirmatory testing. Patients, 0–3 years, have higher WBC, yielding more DNA per mL of blood. DNA yields and quality are better in fresh specimens. However, when necessary, most genetic tests are successful from DNA purified from whole blood that is several days old. Specimen Requirement: 8 mL whole blood in an EDTA lavender top tube; Minimum: 6 mL; Send to Cleveland Clinic Laboratories ASAP after collection to optimize DNA quality and quantity; Ambient Stability: Ambient: 10 days Refrigerated: 10 days Frozen: Unacceptable Methodology: Repeat Expansion Detection by PCR Days Performed: Monday–Friday Reported: 29–43 days	6/1/2015
SCA3 DNA Test	SCA3	89654	Special Information: Higher blood volumes ensure adequate DNA quantity, which varies with WBC, specimen condition, and need for confirmatory testing. Patients, 0–3 years, have higher WBC, yielding more DNA per mL of blood. DNA yields and quality are better in fresh specimens. However, when necessary, most genetic tests are successful from DNA purified from whole blood that is several days old. Specimen Requirement: 8 mL whole blood in an EDTA lavender top tube; Minimum: 6 mL; Send to Cleveland Clinic Laboratories ASAP after collection to optimize DNA quality and quantity; Ambient Stability: Ambient: 10 days Refrigerated: 10 days Frozen: Unacceptable Methodology: Repeat Expansion Detection by PCR Days Performed: Monday–Friday Reported: 29–43 days	6/1/2015
SCA6 DNA Test	SCA6	89655	Specimen Requirement: 8 mL whole blood in an EDTA lavender top tube; Minimum: 6 mL; Send to Cleveland Clinic Laboratories ASAP after collection to optimize DNA quality and quantity; Ambient Stability: Ambient: 10 days Refrigerated: 10 days Frozen: Unacceptable Methodology: Repeat Expansion Detection by PCR Days Performed: Monday–Friday Reported: 29–43 days CPT: 81401	6/1/2015

Test Changes (Cont.)

Test Name	Order Code	Billing Code	Change	Effective Date
SCA7 DNA Test	SCA7	89656	<p>Special Information: Higher blood volumes ensure adequate DNA quantity, which varies with WBC, specimen condition, and need for confirmatory testing. Patients, 0–3 years, have higher WBC, yielding more DNA per mL of blood. DNA yields and quality are better in fresh specimens. However, when necessary, most genetic tests are successful from DNA purified from whole blood that is several days old.</p> <p>Specimen Requirement: 8 mL whole blood in an EDTA lavender top tube; Minimum: 6 mL; Send to Cleveland Clinic Laboratories ASAP after collection to optimize DNA quality and quantity;</p> <p>Ambient</p> <p>Stability: Ambient: 10 days Refrigerated: 10 days Frozen: Unacceptable</p> <p>Methodology: Repeat Expansion by Polymerase Chain Reaction Days Performed: Monday–Friday Reported: 29–43 days CPT: 81479</p>	6/1/2015
SCA14 DNA Test	SCA14	83054	<p>Special Information: Higher blood volumes ensure adequate DNA quantity, which varies with WBC, specimen condition, and need for confirmatory testing. Patients, 0–3 years, have higher WBC, yielding more DNA per mL of blood. DNA yields and quality are better in fresh specimens. However, when necessary, most genetic tests are successful from DNA purified from whole blood that is several days old.</p> <p>Specimen Requirement: 8 mL whole blood in an EDTA lavender top tube; Minimum: 6 mL; Send to Cleveland Clinic Laboratories ASAP after collection to optimize DNA quality and quantity;</p> <p>Ambient</p> <p>Stability: Ambient: 10 days Refrigerated: 10 days Frozen: Unacceptable</p> <p>Methodology: Sanger Sequencing Days Performed: Monday Reported: 29–43 days</p>	5/5/2015
SCA17 DNA Test	SCA17	82204	<p>Special Information: Higher blood volumes ensure adequate DNA quantity, which varies with WBC, specimen condition, and need for confirmatory testing. Patients, 0–3 years, have higher WBC, yielding more DNA per mL of blood. DNA yields and quality are better in fresh specimens. However, when necessary, most genetic tests are successful from DNA purified from whole blood that is several days old.</p> <p>Specimen Requirement: 8 mL whole blood in an EDTA lavender top tube; Minimum: 6 mL; Send to Cleveland Clinic Laboratories ASAP after collection to optimize DNA quality and quantity;</p> <p>Ambient</p> <p>Stability: Ambient: 10 days Refrigerated: 10 days Frozen: Unacceptable</p> <p>Methodology: Repeat Expansion Detection by PCR Days Performed: Monday Reported: 29–43 days CPT: 81401</p>	6/1/2015

Test Changes (Cont.)

Test Name	Order Code	Billing Code	Change	Effective Date
SensoriMotor Neuropathy Profile Complete	SENMOT	82205	Specimen Requirement: 2 mL serum from a serum separator tube; Minimum: 0.5 mL ; Refrigerated *OR* 2 mL serum from a red top tube; Minimum: 0.5 mL ; Refrigerated Stability: Ambient: 3 days Refrigerated: 3 weeks Frozen: 4 months Reference Range: GD1a Titer: < 1:100 All other ranges are unchanged Days Performed: Sunday–Friday Reported: 8–15 days	5/5/2015
Sensory Neuropathy Profile xp	SENNRO	82206	Specimen Requirement: 2 mL serum from a red top tube; Minimum: 0.5 mL ; Refrigerated Stability: Ambient: 3 days Refrigerated: 3 weeks Frozen: 4 months Days Performed: Sunday–Saturday Reported: 8–15 days	5/5/2015
Streptococcus pneumoniae Antigen, CSF	SPACSF	89532	Clinical Information: False-positives may occur because of cross-reactivity with other members of <i>S. mitis</i> group. Clinical correlation is recommended. Patients who have received the <i>S. pneumoniae</i> vaccines may test positive in the 48 hours following the vaccination. It is recommended to avoid testing within 5 days of receiving vaccination. The College of American Pathologists (CAP) requires that bacterial antigen detection testing performed on CSF specimens be confirmed by culture (CAP MIC.22550). All CSF specimens will be processed with the assumption that a culture was performed before sending to ARUP unless a specific request for culture is included with the test order. Additional charges apply.	5/18/2015
Sulfatide Autoantibody	SULTID	76531	Specimen Requirement: 2 mL serum from a red top tube; Minimum: 0.5 mL ; Refrigerated *OR* 2 mL serum from a serum separator tube; Minimum: 0.5 mL ; Refrigerated Stability: Ambient: 3 days Refrigerated: 3 weeks Frozen: 4 months Reference Range: Sulfatide IgG Titer: < 1:2000 Sulfatide IgM Titer: < 1: 2000 Days Performed: Sunday, Tuesday, Thursday Reported: 8–15 days	5/5/2015
Torch Antibodies, IgG & IgM	TORCH	79189	Methodology: Enzyme Immunoassay (EIA) Enzyme-Linked Immunosorbent Assay (ELISA) Immunoassay (IA) Immunochemiluminometric Assay (ICMA) Chemiluminescence Immunoassay (CLIA)	6/16/2015

Test Changes (Cont.)

Test Name	Order Code	Billing Code	Change	Effective Date
Urine Culture	URCUL	76839	<p>Special Information: Specimen Collection Instructions</p> <p><i>Voided midstream clean catch method:</i> Instruct patients to wash hands prior to collection, offer exam gloves.</p> <p>a. Female patients should be instructed to sit on toilet with legs apart and spread labia with one hand. First void in toilet and then, continuing to void, hold specimen container in midstream to collect sample. b. Male patients should be instructed to retract foreskin if uncircumcised. First void in toilet and then, continuing to void, hold specimen container in midstream to collect sample.</p> <p><i>Indwelling (Foley) catheter or suprapubic tube (SPT):</i> Clamp catheter, separate the Foley from the bag, clean the hub with 70% alcohol and collect freshly voided urine. Transfer to sterile container. Do not collect urine from collection bag. Indwelling catheter specimens are treated as voided midstream specimens. NOTE: Catheter tips from urinary catheters will not be cultured.</p> <p><i>Straight catheter:</i> Thoroughly cleanse the urethral opening with betadine or chlorasept. Then pass catheter using sterile technique into the bladder. After discarding initial 15 to 30 ml of urine, collect urine for submission in a sterile container.</p> <p><i>Cystoscopy:</i> Label specimens obtained while cystoscope is in bladder CB for catheterized bladder. Label specimens of irrigated fluid passing from bladder through ureteral catheters WB (washed bladder urine). Label specimens collected with ureteral catheters passed to midureter or renal pelvis LK-1, RK-1, LK-2, and RK-2 (LK for left kidney, RK for right kidney). Submit all samples in a sterile container.</p> <p><i>Stoma (i.e., ileal conduit, nephrostomy, ureterostomy, cystostomy):</i> Remove the external device and discard urine within device. Gently cleanse the stoma. Using sterile technique, insert a catheter into the cleansed stoma, and collect the urine by aspirating back on the syringe. After discarding initial 15 to 30 ml of urine, transfer urine for submission in a sterile container.</p> <p><i>Prostatic secretions:</i> Multiple samples are cultured. If one specimen grows far more bacteria than others, the infection is localized to the urethra, bladder, or prostate. VB1 (voided bladder 1)—1st 10cc of urine represents urethra, VB2—midstream urine represents bladder EPS (expressed prostatic fluid)—Prostate massaged; represents prostate and VB3—also represents prostate.</p> <p>Additional billing is applied for identification and susceptibility testing. CPT codes vary based on methodology</p> <p>CPT: 87086</p>	4/30/2015
VAP	VAP	83811	<p>Special Information: Patient should fast 12 hours prior to sample collection</p> <p>Specimen Requirement: 2 mL serum from a serum separator tube; Patient should fast 12 hours prior to collection; Minimum: 1 mL; Refrigerated</p> <p>Reference Range:</p> <p>VAP VLDL 3:</p> <p>Goal: < 10 mg/dL</p> <p>Moderate Risk: 10–13 mg/dL</p> <p>High Risk: > 13 mg/dL</p> <p>All other ranges are unchanged</p>	5/7/2015
Vitamin B2	VITB2	83756	<p>Special Information: Critical frozen. Separate specimens must be submitted when multiple tests are requested. Testing is available for patients residing in New York state.</p> <p>Days Performed: Tuesday–Saturday</p> <p>Reported: 4–5 days</p>	6/1/2015
Voltage-Gated Calcium Channel IgG Autoantibodies	VOLTCA	82925	<p>Days Performed: Wednesday</p> <p>Reported: 4–11 days</p>	4/21/2015

Test Changes (Cont.)

Test Name	Order Code	Billing Code	Change	Effective Date
von Willebrand Disease Type 2N Sequence Analysis	TYPE2N	82906	Days Performed: Monday–Friday Reported: 23–24 days	5/28/2015
Warfarin Sensitivity Genotyping	WARSEN	88301	For Interfaced Clients Only: Test build may need to be modified Special Information: Aids in Warfarin dosage planning Includes: CYP2C9 2 Variants, VKORC1 Allele 1, VKORC1 Allele 2 Specimen Requirement: 3 mL whole blood in an EDTA lavender top tube; Minimum: 1 mL; Refrigerated (no alternate specimen type available)	7/14/2015
Whole Mitochondrial Genome with Haplotyping	GENHAP	84502	CPT: 81405, 81403, 81401x3	6/25/2015
Yo Autoantibody	ANTIYO	76159	Specimen Requirement: 2 mL serum from a red top tube; Minimum: 0.5 mL ; Refrigerated *OR* 2 mL serum from a serum separator tube; Minimum: 0.5 mL; Refrigerated Stability: Ambient: 3 days Refrigerated: 3 weeks Frozen: 4 months Days Performed: Monday, Wednesday, Friday Reported: 8–15 days	5/5/2015

New Tests

Test Name	Order Code	Billing Code	Test Information	Effective Date
Adenosine Deaminase, Pleural Fluid	PFAD	90597	Specimen Requirement: 0.3 mL centrifuged pleural fluid in a clean container; Minimum: 0.1 mL; Freeze ASAP; Transport Frozen Stability: Ambient: 2 hours Refrigerated: 1 week Frozen: 1 month Methodology: Spectrophotometry (S) Reference Range: 0.0–9.4 U/L Days Performed: Sunday, Tuesday, Thursday Reported: 2–5 days CPT: 84311 Price: \$68.00 (non-discountable)	5/11/2015
Adenosine Deaminase, RBC	RBCAD	90599	Specimen Requirement: 1 mL whole blood in an EDTA lavender top tube; Ambient *OR* 1 mL whole blood in a sodium or lithium heparin green top tube; Ambient Stability: Ambient: 15 days Refrigerated: 15 days Frozen: Unacceptable Methodology: Kinetic Spectrophotometry (KS) Reference Range: 400–900 mU/g Hb Days Performed: Sunday, Tuesday, Thursday Reported: 2–5 days CPT: 84311 Price: \$102.00 (non-discountable)	5/11/2015
Adenosine Deaminase, Serum	SAD	90581	Special Information: Testing not approved for patients residing in New York state. Specimen Requirement: 1 mL serum from a red top tube; Do not use serum separator tubes; Minimum: 0.3 mL; Centrifuge, aliquot and freeze ASAP; Transport Frozen Stability: Ambient: Unacceptable Refrigerated: 1 week Frozen: 3 months Methodology: Colorimetry Reference Range: 0–15 units/L Days Performed: Friday Reported: 10–11 days CPT: 84311 Price: \$138.00 (non-discountable)	5/11/2015
Admark Alzheimer's Evaluation	ADALZ	90601	Includes: ADmark ApoE Genotype, ADmark Phospho-Tau ADmark Total Tau, Ab42 Special Information: ApoE testing will not be performed on individuals under the age of 18. Patients must be symptomatic for Dementia. Specimen Requirement: 2 mL cerebrospinal fluid (CSF) in a sterile, polypropylene container; Minimum: 0.5 mL; Polystyrene and glass containers are not acceptable; Refrigerated *AND* 8 mL whole blood in an EDTA lavender top tube; Minimum: 6 mL; Refrigerated Stability: Ambient: CSF: 3 days, Whole blood: 10 days Refrigerated: CSF: 21 days; Whole blood: 10 days Frozen: CSF: 4 months; Whole blood: Not optimal Methodology: Enzyme-Linked Immunosorbent Assay (ELISA) Restriction Fragment Length Polymorphism (RFLP) Reference Range: Refer to report Days Performed: Monday–Saturday Reported: 15–22 days CPT: 81401, 83520x3 Price: \$1700.00 (non-discountable)	6/25/2015

New Tests

Test Name	Order Code	Billing Code	Test Information	Effective Date
Cytomegalovirus DNA Detection and Quantitation by PCR	CMVQNT	90605	<p>Specimen Requirement: 2 mL plasma from an EDTA lavender top tube; Minimum: 1 mL; Centrifuge, aliquot and refrigerate ASAP; Plasma must be separated from whole blood within 6 hours of collection by centrifugation at 800–1600 x g for 20 minutes at room temperature. Transfer plasma to a sterile, screw-capped polypropylene tube; Refrigerated</p> <p>*OR* 2 mL plasma from an EDTA pink top tube; Minimum: 1 mL; Centrifuge, aliquot and refrigerate ASAP; Plasma must be separated from whole blood within 6 hours of collection by centrifugation at 800–1600 x g for 20 minutes at room temperature. Transfer plasma to a sterile, screw-capped polypropylene tube; Refrigerated</p> <p>Stability:</p> <p><i>Ambient:</i> Whole blood must be transported at 2-25 C and centrifuged within 6 hours of collection</p> <p><i>Refrigerated:</i> Plasma specimens may be transported and stored at 2-8 C. Plasma specimens stored refrigerated (2-8 C) are stable for 7 days</p> <p><i>Frozen:</i> Plasma specimens may be transported and stored at < -20 C. Plasma specimens stored frozen (< -20 C) are stable for 6 weeks.</p> <p>Methodology: Polymerase Chain Reaction, Quant</p> <p>Days Performed: Monday–Friday</p> <p>Reported: 3–5 days</p> <p>CPT: 87497</p> <p>Price: \$248.00</p>	6/30/2015
Enterovirus PCR, Plasma	ENTPLA	90540	<p>Special Information: Enteroviruses are positive-sense RNA viruses in the Picornaviridae family. These viruses were initially classified by serotype as polioviruses (3 types), echoviruses (31 types, including types 22 and 23, which are now classified as parechoviruses), coxsackievirus A (23 types), and coxsackievirus B (6 types). However, genomic studies have demonstrated that there is significant overlap in the biological characteristics of different serotypes and, more recently, isolated Enteroviruses are now named with consecutive numbers (eg, EV68, EV69).</p> <p>The normal site of enterovirus replication is the gastrointestinal tract where the infection is typically subclinical. However, in a proportion of cases, the virus spreads to other organs, causing systemic manifestations, including mild respiratory disease (eg, common cold); conjunctivitis; hand, foot, and mouth disease; aseptic meningitis; myocarditis; and acute flaccid paralysis. Collectively, enteroviruses are the most common cause of upper respiratory tract disease in children. In addition, the enteroviruses are the most common cause of central nervous system (CNS) disease; they account for almost all viruses recovered in culture from spinal fluid. Differentiation of enteroviruses from other viruses and bacteria that cause CNS disease is important for the appropriate medical management of these patients.</p> <p>Traditional cell culture methods require 6 days, on average, for enterovirus detection. In comparison, real-time PCR allows same-day detection. Detection of enterovirus nucleic acid by PCR is also the most sensitive diagnostic method for the diagnosis of CNS infection caused by these viruses.</p> <p>Specimen Requirement: 1 mL plasma from an EDTA lavender top tube; Centrifuge promptly; Minimum: 0.3 mL; Refrigerated</p> <p>Stability:</p> <p><i>Ambient:</i> Unacceptable</p> <p><i>Refrigerated:</i> 7 days</p> <p><i>Frozen:</i> 7 days</p> <p>Methodology:</p> <p>Real-Time Polymerase Chain Reaction (RT-PCR)</p> <p>RNA Probe Hybridization</p> <p>Days Performed: Sunday–Saturday</p> <p>Reported: 2–6 days</p> <p>CPT: 87498</p> <p>Price: \$88.00 (non-discountable)</p>	5/19/2015

New Tests

Test Name	Order Code	Billing Code	Test Information	Effective Date
Helicobacter pylori Breath Test, Pediatric	HPYBRP	88834	<p>Specimen Requirement: Submit one baseline (blue) and one post dose (pink) breath sample bag; Transport Ambient; Contact the laboratory at 216-444-9033 for kits.</p> <p>Stability: Ambient: 7 days (Caps must remain on the bags) Refrigerated: Unacceptable Frozen: Unacceptable</p> <p>Methodology: Spectrophotometry (S)</p> <p>Reference Range: < 10.0 UHR</p> <p>Days Performed: Monday–Saturday</p> <p>Reported: 1–2 days</p> <p>CPT: 83013</p> <p>Price: \$248.00</p>	7/2/2015
HER2 FISH with D17S122 Reference Probe	REFD17	90577	<p>Special Information: Provide the surgical pathology report with each tissue specimen. The pathology report must include type of fixation used, the time to fixative (should be within 1 hour), and the fixation time (should be 6 to 72 hours). Original HER2/CEP17 report should accompany the slides.</p> <p>Specimen Requirement: 2 unstained slides; A hematoxylin and eosin-stained slide containing the section to be probed. Areas of invasive cancer must be clearly marked for probe application. Preferably the same areas probed in the initial HER2/CEP 17 test will be marked for this test. 2-3 consecutive, unstained positively charged slides with 4 micron sections should be included. Sample should be fixed in 10% neutral buffered formalin for 6 to 72 hours. Specimens fixed in Prefer or B5 solutions will not be accepted; Transport Ambient</p> <p>Stability: Ambient: sample is formalin fixed and must not be fixed in Prefer or B5</p> <p>Methodology: Fluorescent In-Situ Hybridization (FISH)</p> <p>Days Performed: 3 days per week</p> <p>Reported: 1–5 days</p> <p>CPT: 88377</p> <p>Price: \$645.00 (non-discountable)</p>	5/4/2015
NOD2 Genotyping	NODSEQ	90594	<p>Special Information: Variant changes in NOD2 introns, regulatory elements, large deletions or duplications, and splice site variants, may not be identified in this sequencing assay. Rare or unidentified variants in the PCR primer annealing sites may result in allele drop-out and may give false negative results. Inadequate DNA quantity or quality may give false negative results.</p> <p>Specimen Requirement: 5 mL whole blood in an EDTA lavender top tube; Minimum: 1 mL; Ambient</p> <p>Stability: Ambient: 24 hours Refrigerated: 5 days Frozen: Unacceptable</p> <p>Methodology: Polymerase Chain Reaction Sequencing Capillary Electrophoresis (CE)</p> <p>Reference Range: No variant identified</p> <p>Days Performed: 1 day per week</p> <p>Reported: 7–10 days</p> <p>CPT: 81401, G0452</p> <p>Price: \$748.00</p>	6/29/2015

New Tests

Test Name	Order Code	Billing Code	Test Information	Effective Date
SERPINA1 Genotyping	A1ASEQ	90535	<p>Special Information: Variant changes in SERPINA1 introns, regulatory elements, large deletions/duplications and splice site variants, may not be identified in this sequencing assay. Rare/unidentified variants in the PCR primer annealing sites may result in allele drop-out and may give false negative results. Inadequate DNA quantity/quality may give false negative results.</p> <p>Alpha-1 Antitrypsin Deficiency is caused by mutations in the SERPINA1 gene. The PI*ZZ allele accounts for 96% of all patients with Alpha-1 Antitrypsin Deficiency, with the remaining 4% of patients carrying the PI*SZ allele, the PI*MZ allele, or rare null and/or deficiency alleles. This assay is designed to detect missense/nonsense variants and/or small insertions and deletions that may be clinically significant but are not detected by targeted genotyping.</p> <p>Specimen Requirement: 5 mL whole blood in an EDTA lavender top tube; Minimum: 1 mL; Refrigerated</p> <p>Stability: Ambient: 24 hours Refrigerated: 5 days Frozen: Unacceptable</p> <p>Methodology: Electrophoresis (CE) Sequencing DNA Polymerase Chain Reaction</p> <p>Reference Range: No variant identified</p> <p>Days Performed: 1 day per week</p> <p>Reported: 7–14 days</p> <p>CPT: 81479, G0452</p> <p>Price: \$648.00</p>	6/30/2015

Fee Increases

Test Name	Order Code	Billing Code	List Fee	CPT Code	Effective Date
Alpha-1-Antitrypsin Clearance	A1ACL	87933	\$222.00 (non-discountable)	82103	5/1/2015
Bromide, Blood	BROMWB	90122	\$135.00 (non-discountable)	80375	5/1/2015
Cystinuria Profile, Quantitative 24 Hour Urine	UCYS24	90236	\$338.00 (non-discountable)	82136	5/1/2015
Drug Analysis, Comprehensive	DRANCO	82053	\$599.00	80302, 80326, 80301, 80331, 80334, 80337, 80338, 80341, 80344, 80346, 80348, 80353, 80354, 80355, 80357, 80358, 80359, 80360, 80361, 80364, 80365, 80366, 80367, 80368, 80370, 80371, 80372, 80373, 80377, 82570, 83992	4/9/2015
FISH Neuroblastoma 2p24 MYCN Amplification	MYCNFB	90081	\$702.00 (non-discountable)	88271x2, 88275	6/1/2015
Histoplasma Abs, CF+ID, CSF	CSFHAB	90150	\$222.00 (non-discountable)	86698x3	5/1/2015
HIV-2 Antibody Confirmation, Serum	HIV2CN	90312	\$99.00 (non-discountable)	86689	5/1/2015
HLA B*1502 Typing	B1502	89713	\$580.00 (non-discountable)	81381	5/1/2015
HLA B5701	B5701	84337	\$555.00 (non-discountable)	81381	5/1/2015
Hyperoxaluria, Urine	UHYPER	87816	\$415.00 (non-discountable)	82544	5/1/2015
Lysozyme	LYSO2	79801	\$66.00 (non-discountable)	85549	5/18/2015
MLH1 Hypermethylation and BRAF Mutation Analysis	MLBRF	90136	\$869.00 (non-discountable)	88381, 81210, 81479	5/1/2015
Plasminogen Activator Inhibitor Antigen	PAI1M	90107	\$365.00 (non-discountable)	83520	5/1/2015

Fee Reductions

Test Name	Order Code	Billing Code	List Fee	CPT Code	Effective Date
Aminolevulinic Acid Dehydratase (ALAD), Whole Blood	ALADWB	90109	\$345.00 (non-discountable)	82657	6/1/2015
Anti Mullerian Hormone	MULLER	84474	\$138.00 (discountable)	83520	8/4/2015
Aspergillus galactomannan BAL	ASGALB	88703	\$115.00	87305	6/2/2015
Aspergillus galactomannan Serum	ASGALS	88701	\$115.00 (discountable)	87305	6/2/2015
Benzoylcegonine Confirmation/Quantitation	BECGO	87675	\$105.00	80353	7/6/2015
Beta-2 Transferrin	B2TRAN	82885	\$205.00 (non-discountable)	86335	7/9/2015
Clomipramine	CLOM	79966	\$50.00 (non-discountable)	80335	7/2/2015
Cryptococcus Antibody	CRYPAB	89349	\$125.00 (non-discountable)	86403	5/1/2015
Fatty Acid Profile, Comprehensive	MCFA	90177	\$138.00 (non-discountable)	82544	5/1/2015
HLA-A, B, and C	HLABC	82817	\$926.00 (non-discountable)	81372	4/2/2015
Human Epididymis Protein 4	HEP4	88459	\$110.00 (discountable)	86305	7/7/2015
Insulin Like Growth Factor I	ILGF1	75072	\$108.00	84305	7/2/2015
KIT (D816V) Mutation by PCR	KITMST	84159	\$335.00 (non-discountable)	81402	4/2/2015
Testosterone, Free	FTESTO	75434	\$136.00	84402, 84403	5/7/2015
Whole Mitochondrial Genome with Haplotyping	GENHAP	84502	\$4300.00 (non-discountable)	81405, 81403, 81401x3	6/25/2015

Discontinued Tests

Test Name	Order Code	Billing Code	Test Information	Effective Date
Adenosine Deaminase	ADEAM	80372	This test will no longer be available. Suggest ordering Adenosine Deaminase, Serum (5/11/2015), Adenosine Deaminase, Pleural Fluid (5/11/2015), and/or Adenosine Deaminase, RBC (7/2/2015).	6/23/2015
Autosomal Dominant Ataxia Evaluation	AUTOAT	82179	This test will no longer be available.	6/1/2015
Blau Syndrome NOD2/CARD15 Complete Gene Analysis	BLAU	88320	This test will no longer be available. Suggest ordering NOD2 Genotyping.	6/9/2015
Blood Culture	BLCUL	79134	This test will no longer be available	4/20/2015
Blood Culture, Special	BLSP	79051	This test will no longer be available	4/20/2015
CMV Detection, Blood	CMVBLD	79819	This test will no longer be available. Suggest ordering Cytomegalovirus DNA Detection and Quantitation by PCR (CMVQNT)	
Gram Stain, Respiratory	RGMST	77752	This test will no longer be available.	7/9/2015
SETX DNA Sequencing	SETX	83050	This test will no longer be available.	6/1/2015
Staff Review	STFREV	77750	This test will no longer be available.	6/9/2015