Cleveland Clinic

Cleveland Clinic Laboratories

Technical Update • July 2023

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

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

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

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

Test Update Page #	Summary of Changes by Test Name	Order Code	Name Change	New Test	Test Discontinued	Special Information	Specimen Requirement	Component Change(s)	Methodology	Reference Range	Days Performed/Reported	Stability	CPT	Fee
10	1,5 Anhydroglucitol												■	■
3, 13	16s rDNA Bacterial Identification, Sanger Sequencing, Fresh Tissue												■	■
3	5-Methyltetrahydrofolate					■	■	■	■	■	■	■		
13	Allergen, Expanded Respiratory Disease Profile Region 5													■
10	B-Cell Clonality Using BIOMED-2 PCR Primers Other			■										
3	Blastomyces dermatitidis Antibodies by Immunoassay with Reflex to Immunodiffusion		■				■	■	■		■	■		
3	Blood Parasite Microscopy Only		■											
14	CALR (Calreticulin) Exon 9 Mutation Analysis Marrow				■									
14	CALR (Calreticulin) Exon 9 Mutation Blood				■									
14	Campylobacter jejuni Antibody, IgG				■									
14	CEBPA Mutation Analysis Blood				■									
14	CEBPA Mutation Analysis Marrow				■									
14	Coccidioides Ab, CF				■									
4	Coccidioides IgG and IgM Antibodies with Reflex to Immunodiffusion		■				■	■	■		■	■		
4	Coenzyme Q10 Leukocytes					■		■		■	■			
14	CSF3R Mutation Analysis Blood				■									
14	CSF3R Mutation Analysis Bone Marrow				■									

Test Update Page #	Summary of Changes by Test Name	Order Code	Name Change	New Test	Test Discontinued	Special Information	Specimen Requirement	Component Change(s)	Methodology	Reference Range	Days Performed/Reported	Stability	CPT	Fee
4	Cytomegalovirus (CMV) DNA, Qualitative PCR, Non-Plasma						■							
5	Cytomegalovirus (CMV) DNA, Quantitative PCR, Plasma		■			■								
14	Cytomegalovirus, Newborn Saliva				■									
5	Ethyl Glucuronide, Urine reflex to Confirm/Quant					■	■			■	■	■		
5	FISH for 20q and CEP8 Blood					■					■			
10	FISH for DDIT3/GLI1(12q13.3)												■	■
5	FISH for t(12;21)(p13;q22) Blood										■			
14	Fungal Antibodies				■									
11	Fungal Antibodies Panel			■										
5–6	Hypercoagulation Diagnostic Interpretive Panel						■	■					■	
11	Immunoglobulin Heavy Chain Using Biomed-2 PCR Primers Other			■										
12	Immunoglobulin Kappa Chain using Biomed-2 PCR Primers Other			■										
6	Iodide					■	■							
14	JAK2 Exon 12 – 16 Mutation Detection Bone Marrow				■									
14	JAK2 Exon 12 – 16 Sequencing Blood				■									
14	MPL Mutation Analysis Blood				■									
14	MPL Mutation Analysis Marrow				■									
14	Natural Killer Cells, Functional				■									
6–7	Neopterin, CSF					■	■	■	■	■	■	■		
7	Neurotransmitter Metabolites/Amines					■	■	■	■	■	■	■		
14	NPM1 Mutation Detection Bone Marrow				■									
14	Nucleophosmin Gene (NPM1) Mutation Blood				■									
8	Pancreatic Elastase, Fecal						■	■	■	■	■	■		
8	Plasma Thymidine Determination					■		■		■		■		
8	Pyridoxal 5 phosphate, CSF					■	■	■	■	■	■	■		
14	SF3B1 Mutation Analysis Blood				■									
14	SF3B1 Mutation Analysis Bone Marrow				■									
12	Steroid Panel, Congenital Adrenal Hyperplasia (CAH)												■	■
9	Succinyladenosine, CSF					■	■	■	■	■	■	■		
12	T-Cell Clonality Using Biomed-2 PCR Primers Other			■										
13	T-Cell Receptor Beta Biomed-2 PCR Other			■										
13	TCR-G (PCR) Other			■										
9–10	Tetrahydrobiopterin & Neopterin, CSF					■	■	■	■	■	■	■		
14	Transglutaminase IgA Abs													■
14	Transglutaminase IgG Abs													■
14	Transglutaminase IgG and IgA													■

Test Changes

Test Name	Order Code	Change	Effective Date
16s rDNA Bacterial Identification, Sanger Sequencing, Fresh Tissue	BCTSEQ	**CPT: 87153** **Price: $333.00**	effective immediately
5-Methyltetra-hydrofolate	5MTH	**For interface clients only – Test build may need to be modified** **Includes:** **5-MTHF Result** **5-MTHF Interpretation** **Special Information: Bloody CSF specimens will be rejected.** **Clinical Information: CSF 5-Methyltetrahydrofolate (5-MTFH) is useful for determining a deficiency of folate in the central nervous system. 5-MTHF is the predominant form of folate in cerebrospinal fluid (CSF). Low CSF 5-MTHF levels are associated with inborn errors of metabolism affecting folate metabolism, dietary deficiency of folate, cerebral folate syndromes and Kearns-Sayre syndrome. Symptoms may include, anemia, developmental delay, seizures, depression and dementia.** **Specimen Requirement: 1** mL cerebrospinal fluid (CSF) in **CSF tube;** Place specimen on ice after draw. Frozen; **Minimum 0.5 mL** **Stability:** Ambient: Unacceptable Refrigerated: **24 hours** Frozen: **-20°C 72 hours; -80°C** Indefinitely **Methodology: High Performance Liquid Chromatography (HPLC)** **Reference Range: Refer to report** **Days Performed: Varies** **Reported: 11–15** days	8/22/23
Blastomyces dermatitidis Antibodies by Immunoassay with Reflex to Immunodiffusion	BLASAB	**For interface clients only – Test build may need to be modified** **Name:** Previously Blastomyces dermatitidis Antibodies by Immunoassay with Reflex to Immunodiffusion (Serum) **Special Information:** Contaminated, hemolyzed, or severely lipemic specimens will be rejected. **Clinical Information:** This immunoassay detects total antibodies against yeast-phase antigens from Blastomyces dermatitidis. Negative fungal serology does not rule out the possibility of current infection. If Blastomyces antibodies are positive by EIA then Blastomyces Immunodiffusion will be added at additional cost. **Specimen Requirement: 2** mL serum from serum separator (Gold) tube; Refrigerated; Separate serum from cells ASAP or within 2 hours of collection and transfer into standard aliquot tube. **Stability:** Ambient: 48 hours Refrigerated: **7 days** Frozen: **14 days** **Methodology:** **Enzyme-Linked Immunosorbent Assay (ELISA)** Immunodiffusion (ID) **Reference Range:** **Blastomyces dermatitidis Total Antibody Qualitative Result (BLSTAB): Negative** **Days Performed: Tue, Fri 7:00 am** **Reported:** 3–**4** days	8/22/23
Blood Parasite Microscopy Only	BABESI	**Name:** Previously Babesia Microscopy	effective immediately

Test Changes (Cont.)

Test Name	Order Code	Change	Effective Date
Coccidioides IgG and IgM Antibodies with Reflex to Immunodiffusion	COCIMG	**For interface clients only – Test build may need to be modified** **Name:** Previously Coccidioides IgG and IgM Antibodies **Special Information:** Non-serum specimens and serum that is contaminated, hemolyzed, icteric or lipemic will be rejected. **Clinical Information: As an** aid in the diagnosis of coccidioidomycosis (Valley fever). Negative fungal serology does not rule out the possibility of current infection. **Positive results will reflex Coccidioides immunodiffusion testing.** Note: This immunoassay uses recombinant and native Coccidioides antigens, including CF and TP antigens, **typically detecting IgG and IgM, respectively.** **Specimen Requirement:** 2 mL serum from serum separator (Gold) tube; Refrigerated; Separate serum from cells ASAP or within 2 hours of collection. **Stability:** Ambient: 48 hours Refrigerated: **7 days** Frozen: **14 days** **Reference Range:** Coccidioides IgM Ab Qualitative Result (COCIMQ): Negative Coccidioides IgG Ab Qualitative Result (COCIGQ): Negative Overall Coccidioides Antibody Result (COCCIO): Negative **Days Performed: Tue, Fri 7:00 am**	8/22/23
Coenzyme Q10 Leukocytes	LEUK10	**For interface clients only – Test build may need to be modified** **Special Information: Hemolyzed specimens will be rejected.** **Reference Range: Refer to report** **Days Performed: Varies**	8/22/23
Cytomegalovirus (CMV) DNA, Qualitative PCR, Non-Plasma	CMVQL	**Specimen Requirement:** 3 mL saliva in Universal Transport Media (UTM); Collect Ambient; Transport Refrigerated; **Newborn saliva collection: * Saliva swab specimens are only accepted from infants less than 21 days of age. 1. Obtain a regular or mini-tip flocked swab and tube containing 3 mL Universal Transport Medium (Oracle #1063581/1035694; Diagnostic Hybrids #402C/403C). 2. Confirm that the baby was breastfed > 1 hour before specimen collection. 3. Baby can be held or remain in the bassinet for specimen collection. 4. Wash hands and put gloves on. 5. Remove the sterile flocked swab from its wrapping. 6. Place the swab between the baby's cheek and gum on one side of the mouth. Keep the swab in place for 10-15 seconds. 7. Move the swab to the other side of the mouth for another 10-15 seconds. Make sure the swab appears moist when removed. 8. Remove the swab from the mouth and insert it into the UTM tube. 9. Break off the swab tip. Close the cap.** *OR* 5 mL random urine in sterile container; Collect Ambient; Transport Refrigerated; **Urine collection: 1. Collect or transfer at least 1 mL of urine into a sterile container.** 2. Specimen must be transferred into cobas PCR Urine Sample Kit within 24 hours of collection. **The correct volume of urine has been added when the fluid level is between the two black lines on the tube label.** **Stability:** Ambient: 24 hours for neat urine; 90 days for urine stabilized in cobas PCR media; 48 hours for saliva in UTM Refrigerated: 24 hours for neat urine; 90 days for urine stabilized in cobas PCR media; 7 days for saliva in UTM Frozen: 14 days if frozen immediately for saliva; Not acceptable for urine	8/22/23

Test Changes (Cont.)

Test Name	Order Code	Change	Effective Date
Cytomegalovirus (CMV) DNA, Quantitative PCR, Plasma	CMVQNT	**Name:** Previously Cytomegalovirus DNA Detection and Quantitation by PCR **Special Information:** Store and transport whole blood at 2-25 degrees Celsius for no longer than 36 hours. Plasma must be separated from whole blood within 36 hours of collection by centrifugation for samples stored at 2-25 degrees Celsius. Sterile plasma should be transferred to a sterile screw-capped polypropylene tube. Amplification occurs during testing, all handling of specimens must be performed in a sterile manner. Please order **in-house CMVQL for qualitative CMV PCR on saliva and urine.** Please order **send-out** CMVCSF **for qualitative CMV PCR all other specimen types including CSF, tissue, and bone marrow.** **Clinical Information: Cytomegalovirus (CMV) is a common viral pathogen that can cause severe disease in immunocompromised patients. The quantitative cobas CMV is an FDA-approved in vitro quantitative real time PCR (qPCR) assay that targets highly-conserved regions of the CMV DNA polymerase (UL54) gene, and is reported out in international units (IU/mL). It is intended for use as an aid in the management of CMV in solid organ transplant patients and in hematopoietic stem cell transplant patients. In patients receiving anti-CMV therapy, serial DNA measurements can be used to assess viral response to treatment. The results from cobas CMV must be interpreted within the context of all relevant clinical and laboratory findings.**	8/22/23
Ethyl Glucuronide, Urine reflex to Confirm/Quant	UEGLUC	**Special Information: Cutoff concentration:** 500 ng/mL. **The concentration value must be greater than or equal to the cutoff to be reported as positive. All** positive Ethyl Glucuronide results will be sent for confirmation by Liquid Chromatography -Tandem Mass Spectrometry (LC-MS/MS) at an additional cost. **Clinical Limitation: Unintentional exposure to ethanol by other means such as hand sanitizers and other products or foods containing ethanol can result in detectable levels of ethyl glucuronide.** **Specimen Requirement:** 4 mL random urine in clean container; **Minimum 1.5** mL; Refrigerated **Stability:** Ambient: **7 days** Refrigerated: **30 days** Frozen: **30 days** **Reference Range: Negative** **Days Performed:** Mon–**Sat** **Reported: 1–3** days	8/22/23
FISH for 20q and CEP8 Blood	20Q8FH	**Special Information:** Ambient transport temperature. If aliquoting is necessary, sterile aliquot tubes **of whole blood** must be used. **Days Performed: 5** days per week	effective immediately
FISH for t(12;21) (p13;q22) Blood	1221FH	**Days Performed: 5** days per week	effective immediately
Hypercoagulation Diagnostic Interpretive Panel	HYPER	**Includes:** Prothrombin Time (PT) APTT Fibrinogen Cardiolipin Antibodies C-Reactive Protein APTTSC TT ANTIXA Protein C Functional PTGEN **FVIIIC** **APCR** **Antithrombin Assay** **PROT S Clot** **STACLOT LA** *(continued on page 6)*	8/22/23

Test Changes (Cont.)

Test Name	Order Code	Change	Effective Date
Hypercoagulation Diagnostic Interpretive Panel *(continued from page 5)*		**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. 3.2% sodium citrate is the preferred anticoagulant recommended by CLSI. Per Pathologist review, the following tests may be ordered and billed: ATIII Antigen (85301); PTT Incubated Mixing Add On (85730, 85732 x2); Dilute Russell Viper Venom (85613); Platelet Neutralization (85597); Factor V Leiden (81241); Reptilase (85635); Fibrinogen Antigen (85385); D-Dimer (85379); Prot C Immunologic (85302); Factor 8 chromogenic (85240); Sample must be accompanied by the completed Clinical History Form for Hemostasis and Thrombosis Evaluation and a medication list. **Specimen Requirement:** 2 mL serum from serum separator (Gold) tube; Minimum 1 mL; Frozen; Indicate clearly which tube is plasma and which tube is serum. Submit Coagulation Consultation Patient History Form. AND 4 mL whole blood in EDTA (Lavender) tube; Minimum 2 mL; Refrigerated AND 6 mL plasma from sodium citrate (Light Blue) tube; Minimum 3 mL **NOTE: If only the minimum volume is received, some reflex testing may not be able to be performed. Collection tubes must be filled to total fill volume. Inadequately filled and clotted tubes will be rejected. Non-testing sites: Centrifuge samples; Aliquot plasma into separate tubes and label with Epic Beaker labels, DO NOT POUR SPECIMENS TOGETHER. Specimens should be frozen (-20C or colder). Centrifuge, aliquot and freeze ASAP.** **Stability:** Ambient: **Main campus: ACCEPTABLE for Whole Blood. (Must be delivered ambient to testing lab less than** 4 hours **post collection.) Non-Testing Sites: UNACCEPTABLE.** Refrigerated: Unacceptable Frozen: **For Non-Testing sites, Frozen Plasma is ACCEPTABLE. Centrifuge samples, then aliquot plasma into separate tubes and label with Epic Beaker labels. DO NOT COMBINE TUBES. Specimens should be frozen (-20° C or colder) and they are stable for 2 weeks. (6 months at -70° C)**	
Iodide	BIODIN	**Special Information:** Allow specimen to clot for 30 minutes then centrifuge. **Carefully pour serum into metal-free, polypropylene vial, avoiding transfer of the cellular components of blood. Do not insert a pipet into the serum to accomplish transfer, and do not ream the specimen with a wooden stick to assist with serum transfer.** High concentrations of gadolinium and iodine are known to interfere with most metals tests. If gadolinium-containing or iodine-containing contrast media have been administered, a specimen cannot be collected for 96 hours. **Clinical Information: This test is useful for determination of iodine overload and monitoring iodine levels in individuals taking iodine-containing drugs.** Values between 80 ng/mL and 250 ng/mL have been reported to indicate hyperthyroidism. Values > 250 ng/mL may indicate iodine overload. **Specimen Requirement:** 1 mL serum from no additive (Navy Blue) tube; Refrigerated; Do not use betadine during venipuncture. **Patient should have no gadolinium- or iodine-containing contrast media administered in the previous 96 hours. Allow specimen to clot for 30 minutes then pour serum into metal-free, screw-capped, polypropylene vial.** **Days Performed: Tue**, Fri **Reported:** 2–**5** days	effective immediately
Neopterin, CSF	NEOCSF	**For interface clients only – Test build may need to be modified** **Special Information: Bloody CSF specimens will be rejected.** **Clinical Information: CSF Neopterin is useful for diagnosis of certain disorders of neurotransmitter metabolism. Neopterin is also useful as a marker for immune system stimulation. Tetrahydrobiopterin (BH4) serves as a cofactor for the hydroxylation of phenylalanine and in the biosynthesis of biogenic amines. Deficiency of BH4 may occur as a result of mutations causing a reduction in one of the three biosynthetic enzymes (guanosine triphosphate cyclohydrolase, 6-pyruvoyl-tetrahydropterin synthase, sepiapterin reductase) or the two regenerating enzymes (pterin-4-carbinolamine dehydratase, dihydropteridine reductase). Defects in BH4 metabolism can result in hyperphenylalaninemia and** *(continued on page 7)*	8/22/23

Test Changes (Cont.)

Test Name	Order Code	Change	Effective Date
Neopterin, CSF *(continued from page 6)*		**deficiency of the neurotransmitters dopamine and serotonin. Changes in CSF neopterin may also occur in deficiency of the BH4 synthesis pathway. Disorders of BH4 metabolism are characterized by a wide range of symptoms that may include developmental delay, intellectual disability, behavioral disturbances, dystonia, Parkinsonian symptoms, gait disturbances, speech delay, psychomotor impairment and ptosis. In guanosine triphosphate (GTP) cyclohydrolase I (GTPCH) deficiency, neopterin and biopterin levels are low. In 6-pyruvoyl-tetrahydropterin synthesis (PTPS) deficiency, the neopterin level is high and the biopterin level is low. In dihydropteridine reductase (DHPR) deficiency, the neopterin level is in the reference range or slightly increased, and the biopterin level is high. In carbinolamine-4a-dehydratase (PCD) deficiency, the neopterin level is initially high, the biopterin level is in the subnormal range, and a primapterin level (7-substituted biopterin) is present. Neopterin is released from macrophages and astrocytes following stimulation by interferon gamma. It is a non-specific marker for immune system stimulation. An elevation in cerebrospinal fluid can be useful to help differentiate between immune problems and other causes of neurological disease.** **Specimen Requirement: 1** mL cerebrospinal fluid (CSF) in **CSF tube;** Place specimen on ice after draw. Frozen; **Minimum 0.5 mL** **Stability:** Ambient: Unacceptable Refrigerated: **24 hours** Frozen: **-20°C 72 hours; -80°C** Indefinitely **Methodology: High Performance Liquid Chromatography (HPLC)** **Reference Range: Refer to report** **Days Performed: Varies** **Reported: 11–15** days	
Neurotransmitter Metabolites/Amines	NEUR	**For interface clients only – Test build may need to be modified** **Includes:** **Neurotrans Met Panel Result** **5-MTHF Result** **Neopterin Result** **Neurotrans Met Panel Int** **Special Information: Bloody CSF specimens will be rejected.** **Clinical Information: CSF Neurotransmitter Metabolites (5HIAA, HVA, 3OMD) is useful for diagnosis of certain disorders of neurotransmitter metabolism. Monoamine metabolite testing includes homovanillic acid (HVA), 3-O-methyl-Dopa (3-OMD), and 5-hydroxyindole acetic acid (5-HIAA). This test is useful in diagnosing pediatric neurotransmitter diseases affecting dopamine and serotonin metabolism in the brain. Inborn errors of metabolism and and various drugs may lead to severe imbalances and disturbances in these neurotransmitter systems that are reflected by changes in the concentration of monoamines metabolites in CSF. Primary inherited defects involve deficiencies in tyrosine and tryptophan hydroxylase, aromatic amino acid decarboxylase, monoamine oxidase, dopamine beta hydroxylase and the dopamine transporter. Other defects in the biopterin synthesis pathway may also affect dopamine and serotonin metabolism. These disorders are characterized by a wide range of symptoms that may include developmental delay, mental disability, behavioral disturbances, dystonia, seizures, encephalopathy, athetosis and ptosis.** **Specimen Requirement: 0.5** mL cerebrospinal fluid (CSF) in **CSF tube;** Place specimen on ice after draw. Frozen; **Minimum 0.25 mL** **Stability:** Ambient: Unacceptable Refrigerated: **24 hours** Frozen: **-20°C 72 hours; -80°C** Indefinitely **Methodology: High Performance Liquid Chromatography (HPLC)** **Reference Range:** ***reference ranges have been removed*** **Days Performed: Varies** **Reported: 11–15** days	8/22/23

Test Changes (Cont.)

Test Name	Order Code	Change	Effective Date
Pancreatic Elastase, Fecal	PANCEF	**For interface clients only – Test build may need to be modified** **Specimen Requirement:** 5 g **random** stool in sterile container; Refrigerated; **Container should be preservative free.** **Stability:** Ambient: **8 hours** Refrigerated: **7 days** Frozen: **12 months** **Methodology: Chemiluminescence Immunoassay (CLIA)** **Reference Range:** **Elastase-1 Concentration (ELASTA): >= 200 ug/g** **Elastase Interpretation (ELASIN): Normal** **Days Performed: Mon–Fri**	8/29/23
Plasma Thymidine Determination	PLTHY	**For interface clients only – Test build may need to be modified** **Clinical Information:** Plasma Thymidine/Deoxyuridine analyte is used for diagnosis of Mitochondrial neurogastrointestinal encephalomyopathy (MNGIE). MNGIE is an autosomal recessive disorder caused by mutations in the gene encoding thymidine phosphorylase (TP). The disease is characterized clinically by impaired eye movements, gastrointestinal dysmotility, cachexia, peripheral neuropathy, myopathy and leukoencephalopathy. Molecular genetic studies of MNGIE patients\tissues have revealed multiple deletions, depletion, and site-specific point mutations of mitochrondrial DNA. TP is a cytosolic enzyme required for nucleoside homeostatis. In MNGIE, TP activity is severely reduced and consequently levels of thymidine and deoxyuridine in plasma are dramatically elevated. MNGIE patients may benefit from hematopoietic stem cell transplantation. **Stability:** Ambient: Unacceptable Refrigerated: After separation from cells: 24 hours Frozen: After separation from cells: **Indefinitely (Avoid freeze/thaw cycles)** **Reference Range: Refer to report**	8/22/23
Pyridoxal 5 phosphate, CSF	P5PCSF	**For interface clients only – Test build may need to be modified** **Includes:** **PLPCSF Results** **PLPCSF Interpretation** **Special Information: Bloody CSF specimens will be rejected.** **Clinical Information:CSF Pyridoxal 5'-phosphate is useful for diagnosis of disorders leading to low CSF levels of this cofactor. Pyridoxal 5' phosphate (PLP) (a member of the vitamin B6 family) is required as a cofactor for more than 100 different enzymes in the body. These may involve the metabolism of various neurotransmitters and amino acids. Inadequate PLP may occur due to genetic, nutritional deficiencies as well as reaction with various drugs. Inherited disorders that affect the CSF PLP level include pyridoxamine-5'-phosphate oxidase deficiency, alpha aminoadipic semialdehyde dehydrogenase deficiency, hyperprolinemia type 2 and hypophosphatasia due to alkaline phosphatase deficiency.** **Specimen Requirement:** 1 mL cerebrospinal fluid (CSF) in **CSF tube;** Frozen, **Critical**; Minimum 0.5 mL **Stability:** Ambient: Unacceptable Refrigerated: Unacceptable Frozen: **-20°C 72 hours; -80°C** Indefinitely **Methodology: High Performance Liquid Chromatography (HPLC)** **Reference Range: Refer to report** **Reported: 11–15** days	8/22/23

Test Changes (Cont.)

Test Name	Order Code	Change	Effective Date
Succinyladenosine, CSF	CSUCCN	**For interface clients only – Test build may need to be modified** **Includes:** **ASLCSF Results** **ASLCSF Interpretation** **Special Information: Bloody CSF specimens will be rejected.** **Clinical Information: CSF Succinyladenosine is useful for diagnosing Adenylosuccinate Lyase Deficiency (ADSL). Succinyladenosine is elevated in ADSL and results in succinylpurinemic autism, intellectual disability, and, in some cases, growth restriction associated with muscle wasting and epilepsy. Adenylosuccinate lyase is involved in both denovo synthesis of purines and formation of adenosine monophosphate from inosine monophosphate by catalyzing two reactions in AMP biosynthesis: the removal of a fumarate from succinylaminoimidazole carboxamide (SAICA) ribotide to give aminoimidazole carboxamide ribotide (AICA) and removal of fumarate from adenylosuccinate to give AMP. In the absence of ADSL deficiency, succinyladenosine is either not detected or at very low levels in the CSF. Small elevations of succinyladenosine in spinal fluid have been reported in AICARibosiduria (deficiency of AICAR transformylase) a devastating condition involving profound intellectual disability, epilepsy, dysmorphic features and congenital blindness. Small elevations are also seen secondary to fumarase deficiency.** **Specimen Requirement: 1 mL** cerebrospinal fluid (CSF) in **CSF Tube; Minimum 0.5 mL;** Place specimen on ice after draw. **Frozen, Critical** **Stability:** Ambient: Unacceptable Refrigerated: Unacceptable Frozen: **-20°C 72 hours; -80°C** Indefinitely **Methodology: High Performance Liquid Chromatography (HPLC** **Reference Range: Refer to report** **Days Performed: Varies** **Reported: 11–15** days	8/22/23
Tetrahydrobiopterin & Neopterin, CSF	TBIOPT	**For interface clients only – Test build may need to be modified** **Includes:** Tetrahydrobiopterin Neopterin **Neopterin BH4 Interpretation** **Special Information:** Call **Laboratory Customer Service** to obtain appropriate sample collection kit. Each **kit** consists of 5 numbered centrifuge tubes in a small plastic bag. Tube #3 contains antioxidants necessary to protect the sample from oxidation. One set of tubes is required per patient. **Bloody CSF specimens will be rejected.** **Clinical Information: CSF Neopterin/Tetrahydrobiopterin is useful for diagnosis of certain disorders of neurotransmitter metabolism. Tetrahydrobiopterin (BH4) serves as a cofactor for the hydroxylation of phenylalanine and in the biosynthesis of biogenic amines. Deficiency of BH4 may occur as a result of mutations causing a reduction in one of the three biosynthetic enzymes, guanosine triphosphate cyclohydrolase. 6-pyruvoyl-tetrahydropterin synthase, sepiapterin reductase, or the two regenerating enzymes, pterin-4-carbinolamine dehydratase, and dihydropteridine reductase. Defects in BH4 metabolism can result in hyperphenylalaninemia and deficiency of the neurotransmitters dopamine and serotonin. Changes in CSF neopterin may also occur in deficiency of the BH4 synthesis pathway. Disorders of BH4 metabolism are characterized by a wide range of symptoms that may include developmental delay, intellectual disability, behavioral disturbances, dystonia, Parkinsonian symptoms, gait disturbances, speech delay, psychomotor impairment and ptosis.** **Specimen Requirement: 1** mL cerebrospinal fluid (CSF) from set of 5 MNG Collection Tubes; Frozen; **Sample must be collected in tube no. 3 from kit. Minimum 0.5 mL** *(continued on page 10)*	8/22/23

Test Changes (Cont.)

Test Name	Order Code	Change	Effective Date
Tetrahydrobiopterin & Neopterin, CSF *(continued from page 9)*	TBIOPT	**Stability:** Ambient: Unacceptable Refrigerated: **24 hours** Frozen: **-20°C 72 hours; -80°C** Indefinitely **Methodology:** High Performance Liquid Chromatography (HPLC) **Reference Range:** Tetrahydobiopterin (TBIOPT02): **Refer to report** Neopterin (TBIOPT01): **Refer to report** **Days Performed: Varies** **Reported: 11–15 days**	8/22/23

New Tests

Test Name	Order Code	Change	Effective Date
1,5 Anhydroglucitol	15AGTL	**Note: New test was announced in the May update, but financial information was not available at that time** **CPT:** 84378 **Price:** $40.00	effective immediately
B-Cell Clonality Using BIOMED-2 PCR Primers Other	BCBMDO	**Special Information:** Frozen tissue should be delivered to Surgical Pathology for accessioning and cutting. Frozen tissue unacceptable; Paraffin-embedded tissue indefinitely **Specimen Requirement:** 10 mm square formalin fixed paraffin block in clean container; Ambient; Paraffin-embedded tissue should be delivered to Surgical Pathology for accessioning and cutting. **Stability:** Ambient: Frozen tissue unacceptable; Paraffin-embedded tissue indefinitely Refrigerated: Frozen tissue unacceptable; Paraffin-embedded tissue unacceptable Frozen: Frozen tissue indefinitely; Paraffin-embedded tissue unacceptable **Methodology:** Capillary Electrophoresis (CE) Polymerase Chain Reaction (PCR) **Days Performed:** 2 days per week **Reported:** 7 days **CPT:** 81261; 81264; G0452 **Price:** $709.00	effective immediately
FISH for DDIT3/ GLI1(12q13.3)	DDIT3	**Note: New test was announced in the June update, but financial information was not available at that time** **CPT:** 88271x2; 88275x1; 88291x1 **Price:** $640.00	effective immediately

New Tests (Cont.)

Test Name	Order Code	Change	Effective Date
Fungal Antibodies Panel	FUNPAN	**Includes:** Blastomyces dermatitidis Total Antibody Coccidioides IgG Antibody Coccidioides IgM Antibody Aspergillus Antibody by CF Histoplasma Mycelia Antibodies by CF Histoplasma Yeast Antibodies by CF **Special Information:** Performing Labs: Immunopathology (x49026), Client Services (x45755)–Vendor ARUP. Refer to individual tests Blastomyces dermatitidis Antibodies by Immunoassay with Reflex to Immunodiffusion (BLASAB), Coccidioides IgG and IgM Antibodies with Reflex to Immunodiffusion (COCIMG), Aspergillus Ab, CF (ASPRCF) and Histoplasma Ab, CF (HISTCF). Refer to individual tests for days performed and expected TAT. **Clinical Information:** See individual tests. **Specimen Requirement:** 4 mL serum from serum separator (Gold) tube AND 2 mL serum from serum separator (Gold) tube; Refrigerated; Multiple specimen tubes must be collected for this panel. 4 mL tube is for test: Blastomyces dermatitidis Antibodies by Immunoassay with Reflex to Immunodiffusion (BLASAB) and Coccidioides IgG and IgM Antibodies with Reflex to Immunodiffusion (COCIMG). Separate serum from cells ASAP or within 2 hours of collection and transfer into standard aliquot tube. 2 mL tube is for test: Aspergillus Ab, CF (ASPRCF) and Histoplasma Ab, CF (HISTCF). Separate serum from cells ASAP or within 2 hours of collection and transfer to standard aliquot tube. Parallel testing is preferred and convalescent specimens must be received within 30 days from receipt of the acute specimens. Label specimens plainly as 'acute' and 'convalescent.'. Minimum 1.7 mL; Submitting the minimum volume will not allow for repeat testing or add-ons. The aliquot for Blastomyces dermatitidis Antibodies by Immunoassay with Reflex to Immunodiffusion (BLASAB) and Coccidioides IgG and IgM Antibodies with Reflex to Immunodiffusion (COCIMG) must have a minimum volume of 0.9 mL. The aliquot for Aspergillus Ab, CF (ASPRCF) and Histoplasma Ab, CF (HISTCF) must have a minimum volume of 0.8 mL. **Stability:** Ambient: After separation from cells: 48 hours Refrigerated: After separation from cells: 7 days Frozen: After separation from cells: 14 days **Methodology:** Enzyme-Linked Immunosorbent Assay (ELISA) Immunodiffusion (ID) Semi-Quantitative Complement Fixation **Days Performed:** Refer to Special Info **Reported:** Refer to individual components	8/22/23
Immunoglobulin Heavy Chain Using Biomed-2 PCR Primers Other	IGHO	**Special Information:** Frozen tissue should be delivered to Surgical Pathology for accessioning and cutting. Paraffin-embedded tissue should be delivered to Surgical Pathology for accessioning and cutting. **Specimen Requirement:** 10 mm square formalin fixed paraffin block in clean container; Ambient; Paraffin-embedded tissue should be delivered to Surgical Pathology for accessioning and cutting. *OR* 6 ug extracted DNA in clean container; Ambient; Please indicate the tissue source of the DNA. **Stability:** Ambient: Frozen tissue- unacceptable; Paraffin-embedded tissue- indefinitely; Extracted DNA- 24 hours Refrigerated: Frozen tissue- unacceptable; Paraffin-embedded tissue- unacceptable; Extracted DNA- 3 years Frozen: Frozen tissue- indefinitely; Paraffin-embedded tissue- unacceptable; Extracted DNA unacceptable **Methodology:** Capillary Electrophoresis (CE) Polymerase Chain Reaction (PCR) **Reference Range:** Negative **Days Performed:** 2 days per week **Reported:** 7 days **CPT:** 81261; G0452 **Price:** $725.00	effective immediately

New Tests (Cont.)

Test Name	Order Code	Change	Effective Date
Immunoglobulin Kappa Chain using Biomed-2 PCR Primers Other	IGKO	**Specimen Requirement:** 10 mm square paraffin block in clean container; Ambient; Paraffin-embedded tissue should be delivered to Surgical Pathology for accessioning and cutting. *OR* 6 ug extracted DNA in clean container; Ambient; Please indicate the tissue source for the DNA. **Stability:** Ambient: Frozen tissue- unacceptable; Paraffin-embedded tissue- indefinitely; Extracted DNA- 24 hours Refrigerated: Frozen tissue- unacceptable; Paraffin-embedded tissue- unacceptable; Extracted DNA- 3 years Frozen: Frozen tissue- indefinitely; Paraffin-embedded tissue- unacceptable; Extracted DNA unacceptable **Methodology:** Capillary Electrophoresis (CE) Polymerase Chain Reaction (PCR) **Reference Range:** Negative **Days Performed:** 2 days per week **Reported:** 7 days **CPT:** 81264; G0452 **Price:** $725.00	effective immediately
Steroid Panel, Congenital Adrenal Hyperplasia (CAH)	CAHSP	**Note: New test was announced in the June update, but financial information was not available at that time** **CPT:** 82157; 82634; 82533; 82626; 84143; 84144; 83498; 84403; 82633 **Price:** $580.00	effective immediately
T-Cell Clonality Using Biomed-2 PCR Primers Other	TCBMDO	**Special Information:** Disclaimer: The performance characteristics of this LDT were established at the Molecular Pathology Section of the Pathology and Laboratory Medicine Institute at the Cleveland Clinic. The Food and Drug Administration (FDA) of the USA has not approved this test nor is it required for clinical use. **Specimen Requirement:** 10 mm square formalin fixed paraffin block in clean container; Ambient; Paraffin-embedded tissue should be delivered to Anatomic Pathology for accessioning and cutting. **Stability:** Ambient: Paraffin-embedded tissue-indefinitely Refrigerated: Paraffin-embedded tissue-unacceptable Frozen: Paraffin-embedded tissue-unacceptable **Methodology:** Capillary Electrophoresis (CE) Polymerase Chain Reaction (PCR) **Days Performed:** 2 days per week **Reported:** 7 days **CPT:** 81342; 81340; G0452 **Price:** $1472.00	effective immediately

New Tests (Cont.)

Test Name	Order Code	Change	Effective Date
T-Cell Receptor Beta Biomed-2 PCR Other	TCRBO	**Special Information:** Paraffin-embedded Tissue should be delivered to Surgical Pathology for accessing and cutting. Frozen Tissue should be delivered to Surgical Pathology for accessing and cutting. **Specimen Requirement:** 10 mm square formalin fixed paraffin block in clean container; Ambient; Frozen Tissue should be delivered to Surgical Pathology for accessing and cutting. *OR* 6 ug extracted DNA in clean container; Ambient; Please indicate the tissue source of the DNA. **Stability:** Ambient: Paraffin-embedded tissue- indefinitely; Extracted DNA- 24 hours Refrigerated: Paraffin-embedded tissue- unacceptable; Extracted DNA- 3 years Frozen: Frozen tissue- indefinitely; Paraffin-embedded tissue- unacceptable; Extracted DNA- unacceptable **Methodology:** Capillary Electrophoresis (CE) Polymerase Chain Reaction (PCR) **Reference Range:** Negative **Days Performed:** 2 days per week **Reported:** 7 days **CPT:** 81340; G0452 **Price:** $725.00	effective immediately
TCR-G (PCR) Other	TCRGO	**Special Information:** Frozen tissue should be delivered to Surgical Pathology for accessioning and cutting. Paraffin-embedded tissue should be delivered to Surgical Pathology for accessioning and cutting. **Specimen Requirement:** 10 mm square formalin fixed paraffin block in clean container; Ambient; Paraffin-embedded tissue should be delivered to Surgical Pathology for accessioning and cutting. *OR* 6 ug extracted DNA in clean container; Ambient; Please indicate the tissue source of the DNA. **Stability:** Ambient: Frozen tissue- unacceptable; Paraffin-embedded Tissue- indefinitely; Extracted DNA- 24 hours Refrigerated: Frozen tissue- unacceptable; Paraffin-embedded tissue- unacceptable; Extracted DNA- 3 years Frozen: Frozen tissue- indefinitely; Paraffin-embedded tissue- unacceptable; Extracted DNA- unacceptable **Methodology:** Capillary Electrophoresis (CE) Polymerase Chain Reaction (PCR) **Reference Range:** Negative **Days Performed:** 2 days per week **Reported:** 7 days **CPT:** 81342; G0452 **Price:** $810.00	effective immediately

Fee Increases

Test Name	Order Code	List Fee	CPT Code	Effective Date
16s rDNA Bacterial Identification, Sanger Sequencing, Fresh Tissue	BCTSEQ	$333.00	87153x1	effective immediately
Allergen, Expanded Respiratory Disease Profile Region 5	RESPR5	$924.00	86003x28	effective immediately

Fee Reductions

Test Name	Order Code	List Fee	CPT Code	Effective Date
Transglutaminase IgA Abs	TGIGA	$103.00	86364	effective immediately
Transglutaminase IgG Abs	TGIGG	$103.00	86364	effective immediately
Transglutaminase IgG and IgA	TGLGMA	$206.00	86364x2	effective immediately

Discontinued Tests

Test Name	Order Code	Test Information	Effective Date
CALR (Calreticulin) Exon 9 Mutation Analysis Marrow	CALRM	Test will no longer be orderable. Recommended replacement test is Myeloproliferative Neoplasm Panel Marrow (MPNM).	effective immediately
CALR (Calreticulin) Exon 9 Mutation Blood	CALR	Test will no longer be orderable. Recommended replacement test is Myeloproliferative Neoplasm Panel Peripheral Blood (MPNP).	effective immediately
CEBPA Mutation Analysis Blood	CEBPA	Test will no longer be orderable. Recommended replacement test is Acute Leukemia NGS Panel, Blood (HDPNGS).	effective immediately
CEBPA Mutation Analysis Marrow	CEBPAM	Test will no longer be orderable. Recommended replacement test is Acute Leukemia NGS Panel, Bone Marrow (HDMNGS).	effective immediately
Campylobacter jejuni Antibody, IgG	CAMIGG	Test will no longer be orderable. There is no recommended replacement.	effective immediately
Coccidioides Ab, CF	COCICF	Test will no longer be orderable. Recommended replacement test is Coccidioides IgG and IgM Antibodies with Reflex to Immunodiffusion (COCIMG).	8/22/23
CSF3R Mutation Analysis Blood	CSF3RP	Test will no longer be orderable. Recommended replacement test is Acute Leukemia NGS Panel, Blood (HDPNGS).	effective immediately
CSF3R Mutation Analysis Bone Marrow	CSF3RM	Test will no longer be orderable. Recommended replacement test is Acute Leukemia NGS Panel, Bone Marrow (HDMNGS).	effective immediately
Cytomegalovirus, Newborn Saliva	CMVSAL	Test will no longer be orderable. Recommended replacement test is Cytomegalovirus (CMV) DNA, Qualitative PCR, Non-Plasma (CMVQL).	8/22/23
Fungal Antibodies	FUNCF	Test will no longer be orderable. Recommended replacement test is Fungal Antibodies Panel (FUNPAN).	8/22/23
JAK2 Exon 12-16 Mutation Detection Bone Marrow	JAK2NM	Test will no longer be orderable. Recommended replacement test is Myeloproliferative Neoplasm Panel Marrow (MPNM).	effective immediately
JAK2 Exon 12 - 16 Sequencing Blood	JAKNON	Test will no longer be orderable. Recommended replacement test is Myeloproliferative Neoplasm Panel Peripheral Blood (MPNP).	effective immediately
MPL Mutation Analysis Blood	MPL	Test will no longer be orderable. Recommended replacement test is Myeloproliferative Neoplasm Panel Peripheral Blood (MPNP).	effective immediately
MPL Mutation Analysis Marrow	MPLM	Test will no longer be orderable. Recommended replacement test is Myeloproliferative Neoplasm Panel Marrow (MPNM).	effective immediately
Natural Killer Cells, Functional	NKFUNC	Test will no longer be orderable. There is no recommended replacement.	effective immediately
NPM1 Mutation Detection Bone Marrow	NPM1M	Test will no longer be orderable. Recommended replacement test is Acute Leukemia NGS Panel, Bone Marrow (HDMNGS).	effective immediately
Nucleophosmin Gene (NPM1) Mutation Blood	NPM1	Test will no longer be orderable. Recommended replacement test is Acute Leukemia NGS Panel, Blood (HDPNGS).	effective immediately
SF3B1 Mutation Analysis Blood	SF3B1P	Test will no longer be orderable. Recommended replacement test is Acute Leukemia NGS Panel, Blood (HDPNGS).	effective immediately
SF3B1 Mutation Analysis Bone Marrow	SF3B1M	Test will no longer be orderable. Recommended replacement test is Acute Leukemia NGS Panel, Bone Marrow (HDMNGS).	effective immediately