

Technical Update • June 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
4	(1,3) B-D Glucan													
4	Abscess and Wound Culture with Gram Stain													
4	Acetylcholine Receptor Binding Aby													
4	Adenosine Deaminase, Serum													
5	Alkaline Phosphatase Isoenzymes													
5	Allergen, Brazil Nut Component IgE													
5	Allergen, Bromelain IgE													
5	Allergen, Cashew Component IgE													
5	Allergen, Cat Components IgE													
5	Allergen, Cow Milk Components IgE													
5	Allergen, Dog Components IgE													
5	Allergen, Dust Mite Components IgE													
5	Allergen, Egg Components IgE													
5	Allergen, Hazelnut Components IgE													
5	Allergen, Profilin, Birch IgE													
6	Allergen, Soybean Components IgE													
6	Allergen, Walnut Components IgE													
16	Aluminum, Urine 24 Hour													
6	Amphetamine Confirmation/quant, serum/plasma													
6	ANA													

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6	ANA Panel I												
6	Aspergillus galactomannan BAL												
6	Aspergillus galactomannan Serum												
6	Barbiturates												
7	Bioavailable Testosterone, SHBG, Adult Male												
7	Biotinidase Serum												
16	BRAF Gene Analysis												
7	Buprenorphine and Metabolites, Quant, serum/plasma												
7	Clozapine												
16	Colon Cancer Hotspot Gene Panel Cytology												
16	Colon Cancer Hotspot Gene Panel Tissue												
8	Cryptosporidia Examination												
8	Cryptosporidium & Giardia Antigens by EIA												
15	Cytomegalovirus Antiviral Drug Resistance by Sequencing												
16	Desmoid NGS Hotspot												
13	Drug Screen 9 Panel, Serum or Plasma												
8	Echinococcus Ab, IgG												
16	EGFR Gene Analysis												
16	FISH for DDIT3 (12q13)												
13	FISH for DDIT3/GLI1 (12q13.3)												
16	Gastrointestinal Stromal Tumor (GIST) Hotspot Panel Cytology												
16	Gastrointestinal Stromal Tumor (GIST) Hotspot Panel Tissue												
8	Glutamic Acid Decarboxylase Antibody												
8	Hepatitis A Antibody, IgG												
9	Hepatitis B Surface Ab												
9-10	Hepatitis C Virus (HCV) Genotyping, Reverse Transcription PCR												
16	IDH1 Gene Analysis												
16	IDH1 & IDH2 Hotspot Gene Panel Cytology												
16	IDH1 & IDH2 Hotspot Gene Panel Tissue												
16	IDH2 Gene Analysis												
16	KIT Gene Analysis												
16	KRAS Gene Analysis												
10	Liver Fibrosis, FibroTest-ActiTest												
10	LPT to Beryllium, BAL												
10	LPT to Beryllium, Blood												
16	Lung Cancer Hotspot Gene Panel Cytology												

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16	Lung Cancer Hotspot Gene Panel Tissue													
16	Melanoma Hotspot Gene Panel Cytology													
16	Melanoma Hotspot Gene Panel Tissue													
16	MET Gene Analysis													
10	Methadone & Metabolite													
11	Microsporidia Examination													
16	NRAS Gene Analysis													
11	Opiates Confirmation, Quantitation Serum/Plasma													
11	Ova and Parasite Examination													
12	Oxalate, Plasma													
16	PDGFRA Gene Analysis NGS Hotspot													
16	PIK3CA Gene Analysis NGS Hotspot													
14	Steroid Panel, Congenital Adrenal Hyperplasia (CAH)													
14	Targeted Oncology Panel Next Generation Sequencing Bone Marrow													
14-15	Targeted Oncology Panel Next Generation Sequencing Cytology													
15	Targeted Oncology Panel Next Generation Sequencing Other													
15	Targeted Oncology Panel Next Generation Sequencing Peripheral Blood													
12	Testosterone													
12	Testosterone, Total and Free, Serum													
12, 15	Tissue Culture & Stain													
12	Urogenital Ureaplasma and Mycoplasma Species by PCR, for Genital, Rectal, Urine Samples													

Test Changes

Test Name	Order Code	Change	Effective Date
(1,3) B-D Glucan	BDGLUC	<p>Special Information: Certain fungi, such as the genus <i>Cryptococcus</i> which produces very low levels of (1,3)-β-D-glucan, may not result in serum (1,3)-β-D-glucan sufficiently elevated so as to be detected by the assay. Infections with fungi of the order Mucorales such as <i>Absidia</i>, <i>Mucor</i> and <i>Rhizopus</i> which are not known to produce (1,3)-β-D-glucan, are also observed to yield low serum (1,3)-β-D-glucan titers. In addition, the yeast phase of <i>Blastomyces dermatitidis</i> produces little (1,3)-β-D-glucan and may not be detected by the assay.</p> <p>Clinical Limitation: Samples obtained by heel or finger stick methods are unacceptable as the alcohol-soaked gauze used to prepare the site (and, potentially, the skin surface-pooling of blood) has been shown to contaminate the specimens. **The following sample conditions can interfere with an accurate result: hemolysis, turbidity caused by lipemia, visual bilirubin, turbid serum, and elevated levels of Immunoglobulin G.</p> <p>Clinical Information: Some individuals have elevated levels of (1,3)-β-D-glucan that fall into the indeterminate zone. In such cases, additional surveillance testing is recommended. The frequency of patient testing will depend upon the relative risk of fungal infection.</p> <p>Specimen Requirement: 0.5 mL serum from serum separator (Gold) tube; Refrigerated; Sample should be collected in a sterile container using aseptic technique. If aliquoting is necessary, sterile aliquot tubes must be used. The sample should be transported to the laboratory as soon as possible or within 2 hours of collection. The sample should be centrifuged to separate the serum from the cells and then immediately placed into refrigerated storage pending delivery to the testing laboratory. Heel and fingerstick collections are unacceptable. This test cannot be added on to other testing. Sample cannot be shared with other testing.</p>	effective immediately
Abscess and Wound Culture with Gram Stain	WCUL	<p>Special Information: Media and incubation conditions are employed for the recovery of aerobic bacteria from an abscess, lesion or wound. Aspirates of purulent material are superior to swab specimens. Prior to specimen collection, remove surface exudate by cleansing with sterile saline or 70% alcohol and then aspirate with needle and syringe. Transfer aspirate fluid to a sterile container (or Port-A-Cul vial if anaerobic culture is also ordered). If a swab specimen must be used, a flocced swab (e.g., Eswab) is preferred because it collects more material than standard swabs. If culture is positive, identification will be performed on clinically significant organisms at an additional charge. Identification CPT codes that may apply include: 87206, 87077, 87106, 87107, 87153, 87158. Antimicrobial susceptibilities are performed when indicated, and the following CPT codes may apply: 87181, 87184, 87185, 87186.</p>	6/20/23
Acetylcholine Receptor Binding Aby	ACHRAB	Days Performed: Mon, Wed, Fri	effective immediately
Adenosine Deaminase, Serum	SAD	<p>Special Information: This test is New York DOH approved.</p> <p>Clinical Information: This test can be used to evaluate liver function in conjunction with alanine aminotransferase (ALT) or gammaglutamyl transferase (GGT). May also be useful to evaluate tuberculosis pleuritis or extrapulmonary tuberculosis.</p> <p>Specimen Requirement: 0.5 mL serum from no additive (Red) tube; Minimum 0.2 mL; Frozen; Allow serum tube to clot completely at room temperature. Separate serum from cells within 4 hours of collection and transfer to standard aliquot tube. Freeze aliquot and keep frozen until received in performing lab. *OR* 0.5 mL serum from serum separator (Gold) tube; Minimum 0.2 mL; Frozen; Allow serum tube to clot completely at room temperature. Separate serum from cells within 4 hours of collection and transfer to standard aliquot tube. Freeze aliquot and keep frozen until received in performing lab. *OR* 0.5 mL plasma from sodium or lithium heparin (Green) tube; Minimum 0.2 mL; Frozen; Separate plasma from cells within 4 hours of collection and transfer to standard aliquot tube. Freeze aliquot and keep frozen until received in performing lab.</p> <p>Stability: Ambient: After separation from cells: 24 hours Refrigerated: After separation from cells: 1 week Frozen: After separation from cells: 3 months (specimen must remain frozen until received in performing lab)</p> <p>Methodology: Spectrophotometry (S)</p> <p>Days Performed: Sun, Tue, Thu</p> <p>Reported: 2–5 days</p>	7/18/23

Test Changes (Cont.)

Test Name	Order Code	Change	Effective Date
Alkaline Phosphatase Isoenzymes	ALKISO	<p>For interface clients only–Test build may need to be modified</p> <p>Reference Range: Bone % (ALKBO): 10.7-68.3 % Bone Fraction (ALKBF): 12.9-52.6 U/L Liver % (ALKLIV): 26.0-86.2 % Liver Fraction (ALKLF): 16.0-69.3 U/L Alkaline Phosphatase Macrohepatic Isoenzymes (ALKMH): 0 U/L Alkaline Phosphatase Macrohepatic Fraction (ALKMHF): 0 % Intestinal % (ALKINT): 0.0-24.2 % Intestine Fraction (ALKINF): 0.0-16.3 U/L Alkaline Phosphatase (ALKPS): 0 Days to 14 Days: 83–248 U/L 15 Days to 364 Days: 122–469 U/L 1 Year to 9 Years: 142–335 U/L 10 Years to 12 Years: 129–417 U/L Male 13 Years to 14 Years: 116–468 U/L Female 13 Years to 14 Years: 57–254 U/L Male 15 Years to 16 Years: 82–331 U/L Female 15 Years to 16 Years: 50–117 U/L Male 17 Years to 18 Years: 55–149 U/L Female 17 Years to 18 Years: 45–87 U/L Male 19 Years to 99 Years: 38–113 U/L Female 19 Years to 99 Years: 34–123 U/L</p>	7/18/23
Allergen, Brazil Nut Component IgE	BRAZCP	Reference Range: <0.10 kU/L	7/20/23
Allergen, Bromelain IgE	BROMLN	Reference Range: <0.10 kU/L	7/20/23
Allergen, Cashew Component IgE	CASHCP	Reference Range: <0.10 kU/L	7/20/23
Allergen, Cat Components IgE	CATCP	<p>Reference Range: nFel d1 (CAT1): <0.10 kU/L nFel d2 (CAT2): <0.10 kU/L nFel d4 (CAT4): <0.10 kU/L nFel d7 (CAT7): <0.10 kU/L Allergen class guide (ALGNG6): Note</p>	7/20/23
Allergen, Cow Milk Components IgE	MILKE	<p>Reference Range: Allergen, Casein IgE (CAT1): <0.10 kU/L Allergen, Alpha Lactalbumin IgE (ALCALB): <0.10 kU/L Allergen, Beta Lactoglobulin IgE (BLACTG): <0.10 kU/L Allergen class guide (ALGNG1): Note</p>	7/20/23
Allergen, Dog Components IgE	DOGCP	<p>Reference Range: rCan f1 (DOG1): <0.10 kU/L rCan f2 (DOG2): <0.10 kU/L rCan f3 (DOG3): <0.10 kU/L rCan f4 (DOG4): <0.10 kU/L rCan f5 (DOG5): <0.10 kU/L rCan f6 (DOG6): <0.10 kU/L Allergen class guide (ALGNG5): Note</p>	7/20/23
Allergen, Dust Mite Components IgE	DUSTCP	<p>Reference Range: rDer p2 (DUST2): <0.10 kU/L rDer p10 (DUST10): <0.10 kU/L rDer p1 (DUST1): <0.10 kU/L</p>	7/20/23
Allergen, Egg Components IgE	EGGIGE	<p>Reference Range: Ovomuroid (OVOMCD): <0.10 kU/L Ovalbumin (OVALB): <0.10 kU/L Allergen Class Guide (ALGNGD): Note</p>	7/20/23
Allergen, Hazelnut Components IgE	HZNTCP	<p>Reference Range: Cor a1 (HZNT1): <0.10 kU/L Cor a8 (HZNT8): <0.10 kU/L Cor a9 (HZNT9): <0.10 kU/L Cor a14 (HZNT14): <0.10 kU/L</p>	7/20/23
Allergen, Profilin, Birch IgE	PROFLN	Reference Range: <0.10 kU/L	7/20/23

Test Changes (Cont.)

Test Name	Order Code	Change	Effective Date
Allergen, Soybean Components IgE	SYBNCP	Reference Range: nGly m5 (SYBN5): <0.10 kU/L nGly m6 (SYBN6): <0.10 kU/L nGly m4 (SYBN4): <0.10 kU/L	7/20/23
Allergen, Walnut Components IgE	WLNTCP	Reference Range: Jug r1 (WLNT1): <0.10 kU/L Jug r3 (WLNT3): <0.10 kU/L	7/20/23
Amphetamine Confirmation/quant, serum/plasma	AMPCQ	Special Information: For medical purposes only; not valid for forensic use. This test is a reflex from Drug Screen 9 Panel, Serum or Plasma (DRGSC9). Stability: Ambient: After separation from cells: 1 week Refrigerated: After separation from cells: 2 weeks Frozen: After separation from cells: 3 years (Avoid repeated freeze/thaw cycles)	6/22/23
ANA	ANAS	Clinical Information: The test is used as an aid in screening for anti-nuclear antibodies. Where clinically warranted, correlation with the clinical picture, and other autoimmune serology results is recommended. The test is performed using multiplex flow immunoassay. Stability: Ambient: 24 hours Refrigerated: 7 days Frozen: 14 days Methodology: Multiplex	effective immediately
ANA Panel I	ANA1	Special Information: If ANA screen by multiplex flow immunoassay is positive, ANA titer and pattern, DNA, SSA Ab, SSB Ab, Smith Ab, JO-1 Ab, Chromatin, Scleroderma, RNP Ab, Ribosomal RNP, and Centromere will be performed and billed. For ANA screen: Avoid using hemolyzed, lipemic or bacterially contaminated sera. Do not use heat inactivated sera. Stability: Ambient: 24 hours Refrigerated: 7 days Frozen: 14 days Methodology: Multiplex	effective immediately
Aspergillus galactomannan BAL	ASGALB	Days Performed: Tue, Thu	effective immediately
Aspergillus galactomannan Serum	ASGALS	Special Information: Send specimen in original tube. Avoid exposure of specimen to atmosphere. Sample can not be shared with multiple tests. Add on testing not acceptable. Specimen Requirement: 1.5 mL serum from serum separator (Gold) tube; Refrigerated; Collect sample in a sterile container using aseptic technique. Sample cannot be shared with other testing. This test cannot be added on to other testing. *OR* 1.5 mL serum from no additive (Red) tube; Refrigerated; Collect sample in a sterile container using aseptic technique. Sample cannot be shared with other testing. This test cannot be added on to other testing. Days Performed: Tue, Thu	effective immediately
Barbiturates	BARBS	Special Information: All drugs will be quantified if positive. Positive cutoff for all drugs: 50 ng/mL. Separator tubes will be rejected. Hemolyzed specimens will be rejected. Specimens exposed to repeated freeze/thaw cycles are unacceptable. Plasma or whole blood collected in sodium citrate (light blue) tubes will be rejected. This test is a reflex from Drug Screen 9 Panel, Serum or Plasma (DRGSC9). This test is New York DOH approved. Clinical Limitation: For medical purposes only; not valid for forensic use. Clinical Information: This test can be useful to optimize drug therapy, monitor patient adherence, or rule out barbiturate exposure. The absence of expected drug(s) and/or drug metabolite(s) may indicate non-compliance, inappropriate timing of specimen collection relative to drug administration, poor drug absorption, or limitations of testing. Stability: Ambient: After separation from cells: 1 week Refrigerated: After separation from cells: 2 weeks Frozen: After separation from cells: 3 years (Avoid repeated freeze/thaw cycles)	6/22/23

Test Changes (Cont.)

Test Name	Order Code	Change	Effective Date
Bioavailable Testosterone, SHBG, Adult Male	BTESTO	<p>Special Information: Patients taking a biotin dose of up to 5 mg/day should refrain from taking biotin for 4 hours prior to sample collection. Patients taking a biotin dose of 5 to 10 mg/day should refrain from taking biotin for 8 hours prior to sample collection. Patients taking a biotin dose > 10 mg/day should consult with their physician or the laboratory prior to having a sample taken. Clinicians should consider biotin interference as a source of error, when clinically suspicious of the laboratory result.</p> <p>Specimen Requirement: 2 mL plasma from lithium heparin plasma separator (Light Green) tube; Centrifuge and refrigerate. Submit in original tube or aliquot specimen into CCL aliquot tube *OR* 2 mL serum from serum separator (Gold) tube; Centrifuge and refrigerate.</p> <p>Stability: Ambient: 5 days Refrigerated: 7 days Frozen: 4 months</p>	7/25/23
Biotinidase Serum	BIOTIN	<p>Special Information: Centrifuge, remove from cells, aliquot and freeze ASAP. Transport frozen.</p> <p>Clinical Limitation: With respect to the reference interval, neonates and infants younger than 6 months of age generally have activities that are lower than those of normal adults.</p> <p>Clinical Information: Evaluation of individuals with: 1) unexplained seizures; 2) unexplained ataxia or marked clumsiness; 3) unexplained hearing loss, especially if on a sensorineural basis and especially if accompanied by neurological abnormalities and/or dermatitis; 4) unexplained dermatitis, especially if accompanied by epilepsy, ataxia, intellectual disability and/or hearing loss. Partial deficiencies and carriers may occur at the low end of the reference range; retesting of the biotinidase activity and/or determination of possible mutations of the biotinidase gene may be indicated if the reported enzyme activity is < 4.5 U/L, depending on the enzyme level and clinical context.</p> <p>Specimen Requirement: 1 mL serum from serum separator (Gold) tube; Centrifuge, aliquot and freeze ASAP. Centrifuge and remove serum ASAP or within 30 minutes of collection. Freeze immediately. Transport frozen specimen to testing laboratory. *OR* 1 mL plasma from green lithium heparin no-gel tube; Centrifuge, aliquot and freeze ASAP. Centrifuge and remove plasma ASAP or within 30 minutes of collection. Freeze immediately. Transport frozen specimen to testing laboratory. *OR* 1 mL serum from red plain tube; Centrifuge, aliquot and freeze ASAP. Centrifuge and remove serum from clot ASAP and then freeze immediately. Transport frozen to testing laboratory. *OR* 1 mL plasma from lithium heparin plasma separator (Light Green) tube; Centrifuge, aliquot and freeze ASAP. Centrifuge and remove plasma ASAP or within 30 minutes of collection. Freeze immediately. Transport frozen specimen to testing laboratory. *OR* 1 mL plasma from sodium heparin (Green) tube; Centrifuge, aliquot and freeze ASAP. Centrifuge and remove plasma ASAP or within 30 minutes of collection. Freeze immediately. Transport frozen specimen to testing laboratory.</p> <p>Stability: Ambient: 4 hours, after separation from cells Refrigerated: 4 hours, after separation from cells Frozen: 7 days, after separation from cells, at < -20 degrees Celsius</p> <p>Reference Range: 4.4–12.0 U/L Reported: 1–7 days</p>	7/20/23
Buprenorphine and Metabolites, Quant, serum/plasma	SBUP	<p>Special Information: This test is a reflex from Drug Screen 9 Panel, Serum or Plasma (DRGSC9). This test is New York DOH approved.</p> <p>Clinical Limitation: For medical purposes only; not valid for forensic use.</p> <p>Stability: Ambient: After separation from cells: 1 week Refrigerated: After separation from cells: 2 weeks Frozen: After separation from cells: 3 years (Avoid repeated freeze/thaw cycles)</p>	6/22/23
Clozapine	CLOZA	<p>Reference Range: 350–600 ng/mL; Urgent > 1000 ng/mL</p>	effective immediately

Test Changes (Cont.)

Test Name	Order Code	Change	Effective Date
Cryptosporidia Examination	CRYSPO	<p>Special Information: Testing performed only on stool specimens. Do not send swabs. Ecofix preserved stool is preferred. Fresh specimens must be less than 6 hours old. Patient Preparation: No administration of barium, bismuth, psyllium (Metamucil), castor oil, mineral oil, or administration of antiamoebic drugs within one week prior to the test. Positive Cryptosporidium results are confirmed with microscopy after concentration of the specimen. CPT codes that may apply include: 87015, 87206, 87207.</p> <p>Specimen Requirement: 5 g stool in EcoFix fixative; Ambient; Specimen preserved in Ecofix vial. *OR* 5 g stool; Specimen preserved in 10% formalin or SAF. Unpreserved specimen collected in a clean container. Unpreserved specimens must be delivered within 6 hours of collection.</p> <p>Stability: Ambient: Preserved: 2 months; Unpreserved: 6 hours Refrigerated: Preserved: 2 months; Unpreserved: 6 hours Frozen: Preserved: Unacceptable; Unpreserved: Unacceptable</p> <p>Days Performed: Mon–Fri 7:30 am–4:00 pm</p>	7/18/23
Cryptosporidium & Giardia Antigens by EIA	OVAPSC	<p>Special Information: Average TAT for this assay is 20 hrs. The Ova and Parasite Screen is a screening test for Giardia lamblia and Cryptosporidium species only. This test replaces the traditional Ova and Parasite Exam. Ideally, fresh stool should be collected and immediately placed into 2 vial system: C/S/Cary-Blair and EcoFix vials. Preserved stool should be transported at ambient and/or refrigerated temperature. Unpreserved stool should not be submitted unless it can be delivered to the laboratory within 6 hours in a clean leakproof container. Unpreserved stool should be transported at either ambient or refrigerator temperature but never frozen. Cary-Blair, MIF or C & S diluted samples may interfere with confirmatory test methods. Interfering substances include barium, bismuth, metamucil, castor oil, mineral oil, or antiamoebic drugs within one week prior to specimen collection.</p> <p>Specimen Requirement: 5 mL stool in C/S/Cary Blair; Ambient; Outpatient locations should submit stool preserved in 2 vial system: C/S/Cary-Blair and EcoFix vials. Stool can be transported at ambient temperature or refrigerated. Do not freeze. *OR* 5 mL stool in formalin 10%; Ambient; Outpatient locations should submit stool preserved in 10% formalin vial. Transport at ambient temperature preferred.</p> <p>Stability: Ambient: Preserved: 2 months; Unpreserved: 6 hours Refrigerated: Preserved: 2 months; Unpreserved: 6 hours Frozen: Preserved: 2 months; Unpreserved: Unacceptable</p> <p>Days Performed: Mon–Fri 7:30 am–4:00 pm</p> <p>Reported: 1–3 days</p>	7/18/23
Echinococcus Ab, IgG	ECHINO	<p>Clinical Information: Patients with collagen vascular diseases, hepatic cirrhosis, schistosomiasis, and other parasitic infections can produce false-positive results. There is a strong cross-reaction between echinococcosis and cysticercosis-positive sera. Seroconversion between acute and convalescent sera is considered strong evidence of recent infection. The best evidence for infection is a significant change on two appropriately timed specimens where both tests are done in the same laboratory at the same time.</p> <p>Stability: Ambient: After separation from cells: 48 hours Refrigerated: After separation from cells: 2 weeks Frozen: After separation from cells: 1 year (Avoid repeated freeze/thaw cycles)</p> <p>Methodology: Semi Quantitative Enzyme Linked Immunosorbent Assay</p> <p>Reference Range: Refer to report</p>	effective immediately
Glutamic Acid Decarboxylase Antibody	GADCAB	Days Performed: Tue, Fri	effective immediately
Hepatitis A Antibody, IgG	AHAVG	<p>Clinical Information: The test is used to determine the immune status to Hepatitis A Virus (HAV) as a result of vaccination or past infection. Should recent infection be suspected, this test needs to be ordered along with HAV IgM test.</p> <p>Reference Range: reference range has been removed</p>	7/27/23

Test Changes (Cont.)

Test Name	Order Code	Change	Effective Date
Hepatitis B Surface Ab	AHBSAG	<p>Special Information: The assay does not differentiate Hepatitis B surface antibody from vaccination or natural infection.</p> <p>Clinical Information: To assess immune status to HBV due to past infection or vaccination. Negative values: No evidence of antibodies to Hepatitis B surface antigen. Equivocal values: Indeterminate result. In patients who were vaccinated 6–8 weeks prior to this draw or previously infected with HBV, repeat testing is suggested. Those who were vaccinated for Hepatitis B virus years ago, may fall into this category due to waning immunity over time. Clinical correlation is required. Positive values: These results are consistent with immunity to the hepatitis B virus due to previous exposure to Hepatitis B virus or Hepatitis B vaccination.</p> <p>Reference Range: <i>reference range has been removed</i></p>	7/27/23
Hepatitis C Virus (HCV) Genotyping, Reverse Transcription PCR	HEPGEN	<p>Name: Previously Hepatitis C Genotyping</p> <p>Special Information: This assay usually requires a viral load of at least 500 IU/mL to obtain a genotype. If a genotype is unable to be determined using this assay on two consecutive specimens, and the viral load is >500 IU/mL, the second specimen will be sent out to a reference laboratory for genotyping by an alternative method (ARUP Hepatitis C Virus Genotype by Sequencing: https://ltd.aruplab.com/Tests/Pub/0055593).</p> <p>Clinical Limitation: 1. Multiple genotype assay results may be caused by a mixed genotype infection, recombination of HCV genotypes, or assay probe cross-reactivity.</p> <p>2. The Abbott RealTime HCV Genotype II assay is capable of detecting both genotypes in a genotype mixture when the concentrations of both genotypes are near equal; however, the assay may not detect the lower concentration genotype.</p> <p>3. Performance has not been established with the Abbott RealTime HCV Genotype II assay for HCV genotype 6 specimens. HCV genotype 6 specimens may generate a HCV genotype 1 result with the Abbott RealTime HCV Genotype II assay based on probe cross-reactivity of the HCV genotype 1 probe.</p> <p>4. A specimen with a result of “HCV not detected” cannot be presumed to be negative for HCV RNA. A specimen with an interpretation of “No Genotype Result” can not be presumed to be negative for the tested genotypes.</p> <p>Clinical Information: The Hepatitis C virus (HCV), a significant cause of blood-borne hepatitis, is an enveloped virus containing a single-stranded positive sense RNA genome of approximately 9,500 nucleotides. It has been identified as the major etiological agent for post-transfusion non-A and non-B hepatitis worldwide. Based on genetic similarity, HCV has been classified into six major genotypes (1-6) and numerous subtypes (1a, 1b, etc.). Genotypes 1a, 1b, 2, and 3 are the most common HCV genotypes in the United States.</p> <p>HCV genotype testing may be considered for those in whom it may alter treatment recommendations. With the advent of pangenotypic HCV treatment regimens, HCV genotyping is no longer required prior to treatment initiation for all individuals. In those with evidence of cirrhosis and/or past unsuccessful HCV treatment, treatment regimens may differ by genotype and thus pretreatment genotyping is recommended. For noncirrhotic treatment-naive patients, although genotyping may impact the preferred treatment approach, it is not required if a pangenotypic regimen is used. HCV genotyping may also be ordered to obtain insurance pre-authorization for medications.</p> <p>The Abbott RealTime HCV Genotype II is an FDA-cleared in vitro reverse transcription-polymerase chain reaction (RT-PCR) assay used for the qualitative identification of hepatitis C virus (HCV) genotypes 1, 1a, 1b, and 2-5 in plasma or serum from individuals chronically infected with HCV. The Abbott RealTime HCV Genotype II is intended for use as an aid in the management of HCV-infected individuals and in guiding the selection of therapeutic treatment indicated for the above listed genotypes. The assay is intended for use on patients who are chronically infected with HCV, are being considered for antiviral treatment, and are positive for HCV RNA. The Abbott RealTime HCV Genotype II assay is not for screening blood, plasma, serum or tissue donors for HCV.</p> <p><i>(continued on page 10)</i></p>	7/18/23

Test Changes (Cont.)

Test Name	Order Code	Change	Effective Date
Hepatitis C Virus (HCV) Genotyping, Reverse Transcription PCR <i>(continued from page 9)</i>	HEPGEN	<p>Clinical Reference: 1. AASLD-IDS. HCV testing and linkage to care. Recommendations for testing, managing, and treating hepatitis C. http://www.hcvguidelines.org/full-report/hcv-testing-and-linkage-care. [Last Accessed: 4/28/2023].</p> <p>2. US Food and Drug Administration. Abbott RealTime HCV Genotype II: Summary of Safety and Effectiveness Data. Approved June 20, 2013. https://www.accessdata.fda.gov/cdrh_docs/pdf12/P120012b.pdf. [Last Accessed: 4/28/2023].</p> <p>Specimen Requirement: 2 mL plasma from EDTA plasma preparation (White) tube; Refrigerated; Separate plasma from whole blood within 6 hours of collection by centrifugation at 800-1600 x g for 20 minutes at room temperature. Transport using cold packs. *OR* 2 mL plasma from EDTA (Lavender) tube; Refrigerated; Separate plasma 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 polypropylene screw-cap vial. Transport using cold packs. *OR* 2 mL serum from serum separator (Gold) tube; Refrigerated; Separate serum from whole blood within 6 hours of collection by centrifugation at 800-1600 x g for 20 minutes at room temperature. Transport using cold packs. *OR* 2 mL serum from no additive (Red) tube; Refrigerated; Separate serum from whole blood within 6 hours of collection by centrifugation at 800-1600 x g for 20 minutes at room temperature. Transfer serum to a sterile polypropylene screw-cap vial. Transport using cold packs.</p> <p>Stability: Ambient: 24 hours Refrigerated: 3 days Frozen: 60 days</p>	7/18/23
Liver Fibrosis, FibroTest-ActiTest	LIVFIB	<p>Specimen Requirement: 2 mL serum from serum separator (Gold) tube; Refrigerated; Centrifuge within 2 hours from collection. Protect serum from light after centrifugation. Overnight fasting is preferred. *OR* 2 mL serum from no additive (Red) tube; Refrigerated; Centrifuge within 2 hours from collection. Transfer serum into a standard or amber aliquot tube. Protect serum from light after centrifugation. Overnight fasting is preferred.</p>	7/27/23
LPT to Beryllium, BAL	BALBE	<p>Special Information: Contact testing laboratory at least one week prior to collecting specimen at (216) 444-2502. Specimen should not be collected or delivered on weekends or holidays.</p> <p>Clinical Information: Lymphocyte proliferation test to Beryllium is a cellular assay used as an aid in diagnosis of prior sensitization to Beryllium in the environment. Beryllium-sensitized individuals may remain asymptomatic for extended periods and never develop chronic berylliosis. Clinical, epidemiological, and radiological correlation is required. Bronchoalveolar lavage testing may offer higher sensitivity than whole blood testing where pulmonary disease is present.</p>	6/15/23
LPT to Beryllium, Blood	BLDBE	<p>Special Information: Contact testing laboratory at least 48 hours prior to collecting specimen at (216) 444-2502. Specimen should not be collected or delivered on weekends or holidays.</p> <p>Clinical Information: Lymphocyte proliferation test to Beryllium is a cellular assay used as an aid in diagnosing prior sensitization to Beryllium in the environment. Beryllium-sensitized individuals may remain asymptomatic for extended periods and never develop chronic berylliosis. Clinical, epidemiological, and radiological correlation is required. Bronchoalveolar lavage testing may offer higher sensitivity than whole blood testing where pulmonary disease is suspected.</p> <p>Specimen Requirement: 80 mL whole blood from sodium heparin (Green) tube; Minimum 80 mL; Ambient; Collect Monday–Wednesday only. Deliver the specimen to the lab within 48 hours post collection. Do not aliquot. Specimen must remain at ambient temperature. Do not refrigerate. Do not freeze. Collect sample in a sterile container using aseptic technique. Sample cannot be shared with other testing. This test cannot be added on to other testing.</p>	6/15/23
Methadone & Metabolite	MMTAB	<p>Special Information: Separator tubes, plasma or whole blood collected in sodium citrate (light blue) tubes, specimens exposed to repeated freeze/thaw cycles, and hemolyzed specimens will be rejected. This test is a reflex from Drug Screen 9 Panel, Serum or Plasma (DRGSC9). This test is New York DOH approved.</p> <p>Clinical Limitation: For medical purposes only; not valid for forensic use.</p> <p>Stability: Ambient: After separation from cells: 1 week Refrigerated: After separation from cells: 2 weeks Frozen: After separation from cells: 3 years (Avoid repeated freeze/thaw cycles)</p> <p>Methodology: Liquid Chromatography-Tandem Mass Spectrometry (LC-MS/MS)</p>	6/22/23

Test Changes (Cont.)

Test Name	Order Code	Change	Effective Date
Microsporidia Examination	MICSP0	<p>Special Information: Transfer approximately 1 gram of feces to Eco fix vial or 10% formalin or SAF vial. Fluid levels should reach line on vial. Mix each specimen with the preservative. Indicate on vial label whether stool is formed (soft or hard) or diarrheal. Stool must be received in the Laboratory within 6 hours of collection if unpreserved.</p> <p>Specimen Requirement: 2 g stool in EcoFix fixative; Ambient; Specimen collected in EcoFix vial. *OR* 2 g stool in clean, leakproof container; Ambient; Stool must be received in the Laboratory within 6 hours of collection. *OR* 2 g stool; Ambient; Specimen collected in 10% formalin or SAF vial.</p> <p>Stability: Ambient: Preserved: 1 week; Unpreserved: 6 hours Refrigerated: Preserved: 1 week; Unpreserved: 6 hours Frozen: Preserved: Unacceptable; Unpreserved: Unacceptable</p> <p>Days Performed: Mon–Fri 7:30 am–4:00 pm</p>	7/18/23
Opiates Confirmation, Quantitation Serum/ Plasma	OPISEC	<p>Special Information: Separator tubes or hemolyzed specimens will be rejected. Specimens exposed to repeated freeze/thaw cycles are unacceptable. Plasma or whole blood collected in sodium citrate (light blue) tubes will be rejected. This test is a reflex from Drug Screen 9 Panel, Serum or Plasma (DRGSC9). This test is New York DOH approved.</p> <p>Stability: Ambient: After separation from cells: 1 week Refrigerated: After separation from cells: 2 weeks Frozen: After separation from cells: 3 years (Avoid repeated freeze/thaw cycles)</p>	6/22/23
Ova and Parasite Examination	OVAP	<p>Clinical Information: The Ova and Parasite screen (OVAPSC) is more sensitive than the Ova and Parasite exam (OVAP) for the detection of Giardia, the most commonly encountered enteric parasite in this locale. The Ova and Parasite screen (OVAPSC) should be used, rather than the Ova and Parasite exam (OVAP), unless other enteric parasites are suspected.</p> <p>The Ova and Parasite exam (OVAP) should be ordered to detect and identify the presence of enteric protozoa and the eggs of helminths. This test should be reserved for individuals with significant risk factors for enteric parasitosis (eg, immigration from or travel to an endemic area). In such cases, a minimum of 3 specimens collected over 3–10 days are recommended. Stool should be collected using the Cleveland Clinic Universal Stool Collection Kit available in Oracle (includes 1 EcoFix vial, 1 C/S vial, and 1 sterile container).</p> <p>Special studies are needed for the detection of Cryptosporidium, Cyclospora, Cystoisospora, microsporidia, pinworm, worm identification, and parasites in unusual locations. Non-stool specimens should be collected using a sterile screw-top transport container.</p> <p>Specimen Requirement: Unspecified respiratory specimen in sterile container; Ambient; Sterile leakproof container should be used with transport at room temperature. *OR* 3-5 mL body fluid in sterile container; Ambient; Sterile leakproof container should be used with transport at room temperature. *OR* 15 mL random urine in sterile container; Ambient; Urine specimens should be freshly voided and submitted in a sterile leakproof container. Transport at ambient temperature. *OR* 5 mL stool in EcoFix fixative; Ambient; 1 vial of EcoFix preservative (OVAP). If an OVAPSC is ordered simultaneously 1 vial C/S/Cary-Blair is needed. Recommended screening procedure is 3 stool specimens, 1 per day for each of 3 days. *OR* 5 mL sputum in clean container; Ambient; Sterile leakproof container should be used with transport at room temperature. *OR* 5 mL stool in clean container; If stool cannot be transported to the laboratory within 6 hours, stool should be placed into 1 vial EcoFix (OVAP) and 1 vial C/S/Cary-Blair (OVAPSC). Recommended screening procedure is 3 stool specimens, 1 per day for each of 3 days. *OR* 5 mL stool in other container; Alternative Collection: 2 vial system: 1 vial of 10% formalin and 1 vial of PVA or 1 vial system: 1 vial of SAF. Recommended screening procedure is 3 stool specimens, 1 per day for each of 3 days.</p> <p>Stability: Ambient: Preserved: 2 months; Unpreserved: 6 hours Refrigerated: Preserved: 2 months; Unpreserved: 6 hours Frozen: Preserved: Unacceptable; Unpreserved: Unacceptable</p> <p>Days Performed: 5 days per week 7:30 am–4:00 pm</p>	7/18/23

Test Changes (Cont.)

Test Name	Order Code	Change	Effective Date
Oxalate, Plasma	OXLATE	<p>For interface clients only—Test build may need to be modified</p> <p>Name: Previously Oxalate</p> <p>Special Information: CRITICAL FROZEN. Patient Prep: Patient should avoid ingestion of vitamin C for 24 hours prior to sample collection. Fasting for 8 hours is recommended, but not required, to avoid lipemia. Samples that are not plasma will be rejected.</p> <p>Clinical Limitation: Patient should avoid ingestion of vitamin C for 24 hours prior to sample collection. Fasting for 8 hours is recommended, but not required, to avoid lipemia.</p> <p>Clinical Information:</p> <p>Specimen Requirement: 2.5 mL plasma from lithium heparin no-gel (Green) tube; Place specimen on ice after draw. Critical Frozen; Patient should avoid ingestion of vitamin C for 24 hours prior to sample collection. Fasting for 8 hours is recommended, but not required. Separate plasma from cells ASAP or within 1 hour of collection, transfer to standard aliquot tube, and freeze immediately.</p> <p>Stability: Ambient: After separation from cells: Unacceptable Refrigerated: After separation from cells: Unacceptable Frozen: After separation from cells: 24 hours at <-15 degrees C and 4 weeks at < -60 degrees C.</p> <p>Methodology: Colorimetric Enzyme Assay</p> <p>Reference Range: < 2.0 umol/L</p> <p>Days Performed: Mon, Wed, Fri</p> <p>Reported: 1–4 days</p>	7/18/23
Testosterone	TESTO	Special Information: Note: <i>biotin comment has been removed</i>	7/25/23
Testosterone, Total and Free, Serum	TFTEST	Reported: 4–8 days	effective immediately
Tissue Culture & Stain	TISCUL	<p>Special Information: Add drops of sterile saline to keep small pieces of tissue moist. If culture is positive, identification will be performed on clinically significant organisms at an additional charge. Identification CPT codes that may apply include: 87206, 87077, 87106, 87107, 87153, 87158. Antimicrobial susceptibilities are performed when indicated, and the following CPT codes may apply: 87181, 87184, 87185, 87186.</p> <p>CPT: 87205; 87176; 87070</p> <p>Price: \$116.00</p>	6/20/23
Urogenital Ureaplasma and Mycoplasma Species by PCR, for Genital, Rectal, Urine Samples	URMPCR	<p>Specimen Requirement: 1 mL random urine in viral transport media; Frozen; Transfer 1 mL urine to VTm. Specimen source required. *OR* One genital swab in viral transport media; Frozen; Transfer genital swab to VTm. Specimen source required. *OR* One rectal swab in viral transport media; Frozen; Transfer rectal swab to VTm. Specimen source required. Note: <i>Thin prep has been removed.</i></p>	effective immediately

New Tests

Test Name	Order Code	Change	Effective Date
Drug Screen 9 Panel, Serum or Plasma	DRGSC9	<p>Includes:</p> <ul style="list-style-type: none"> Amphetamines, S/P, Screen Methamphetamine, S/P, Screen Barbiturates, S/P, Screen Benzodiazepines, S/P, Screen Buprenorphine, S/P, Screen Cannabinoids, S/P, Screen Cocaine, S/P, Screen Methadone, S/P, Screen Opiates, S/P, Screen Oxycodone, S/P, Screen Phencyclidine, S/P, Screen Drug Screen Comments, Serum or Plasma <p>Special Information: Specimens which are hemolyzed, exposed to repeated freeze/thaw cycles, or collected in gel separator tubes will be rejected. This test is New York DOH approved.</p> <p>Clinical Limitation: This test is for medical purposes only; not valid for forensic use. Cocaine and cocaethylene are more stable in fluoride-preserved plasma than serum.</p> <p>Clinical Information: This test is useful to monitor patient compliance. This test does not distinguish between the delta-8 and delta-9 forms of THC or their metabolites. Drugs/Drug classes reported as "Positive" are automatically reflexed to mass spectrometry confirmation/quantitation testing. An immunoassay unconfirmed positive screen result may be useful for medical purposes but does not meet forensic standards. The absence of expected drug(s) and/or drug metabolite(s) may indicate noncompliance, inappropriate timing of specimen collection relative to drug administration, poor drug absorption, or limitations of testing.</p> <p>The concentration at which the screening test can detect a drug or metabolite varies within a drug class. Specimens for which drugs or drug classes are detected by the screen are automatically reflexed to a second, more specific technology (mass spectrometry) at additional cost. The concentration value must be greater than or equal to the cutoff to be reported as positive.</p> <p>Specimen Requirement: 4 mL plasma from potassium oxalate/sodium fluoride (Gray) tube; Minimum 3 mL; Refrigerated; Draw 2 tubes to ensure adequate plasma volume. Do not use gel separator tubes. Separate plasma from cells ASAP or within 2 hours of collection. Transfer plasma to standard aliquot tube. *OR* 4 mL serum from no additive (Red) tube; Minimum 3 mL; Refrigerated; Draw 2 tubes to ensure adequate serum volume. Do not use gel separator tubes. Separate serum from cells ASAP or within 2 hours of collection. Transfer serum to standard aliquot tube. *OR* 4 mL plasma from sodium heparin (Green) tube; Minimum 3 mL; Refrigerated; Draw 2 tubes to ensure adequate plasma volume. Do not use gel separator tubes. Separate plasma from cells ASAP or within 2 hours of collection. Transfer plasma to standard aliquot tube. *OR* 4 mL plasma from EDTA (Lavender) tube; Minimum 3 mL; Refrigerated; Draw 2 tubes to ensure adequate plasma volume. Do not use gel separator tubes. Separate plasma from cells ASAP or within 2 hours of collection. Transfer plasma to standard aliquot tube.</p> <p>Stability:</p> <ul style="list-style-type: none"> Ambient: After separation from cells: 1 week Refrigerated: After separation from cells: 2 weeks Frozen: After separation from cells: 3 years (Avoid repeated freeze/thaw cycles) <p>Methodology: Qualitative Enzyme-linked Immunosorbent Assay</p> <p>Days Performed: Sun–Sat</p> <p>Reported: 2–11 days</p>	6/22/23
FISH for DDIT3/GLI1(12q13.3)	DDIT3	<p>Clinical Information: Assists in the diagnosis of Myxoid Liposarcoma (MLS)</p> <p>Specimen Requirement: 6 unstained slides; 4 um formalin fixed paraffin-embedded tissue sections on electrostatically charged slides containing representative tumor. Samples must not be fixed in Prefer or B5.</p> <p>Methodology: Fluorescent In-Situ Hybridization (FISH)</p> <p>Days Performed: 5 days per week 8:00 am–4:30 pm</p> <p>Reported: 5–7 days</p>	effective immediately

New Tests (Cont.)

Test Name	Order Code	Change	Effective Date
Steroid Panel, Congenital Adrenal Hyperplasia (CAH)	CAHSP	<p>Includes:</p> <ul style="list-style-type: none"> Androstenedione 11-Deoxycortisol Cortisol DHEA, Unconjugated 17-Hydroxypregnenolone Progesterone 17-Hydroxyprogesterone Testosterone, Total, LC/MS/MS Deoxycorticosterone <p>Special Information: Specimens that are hemolyzed, icteric or collected in separator gel tubes will be rejected.</p> <p>Clinical Information: This test can be useful for the diagnosis/management of patients with the most common forms (21-hydroxylase or 11-hydroxylase deficiency) of congenital adrenal hyperplasia.</p> <p>Specimen Requirement: 0.5 mL serum from no additive (Red) tube; Minimum 0.25 mL; Frozen; Do not use serum separator gel tubes. Separate serum from cells ASAP and transfer to standard aliquot tube.</p> <p>Stability:</p> <ul style="list-style-type: none"> Ambient: After separation from cells: 6 hours Refrigerated: After separation from cells: 72 hours Frozen: After separation from cells: 28 days <p>Methodology: Chromatography with Mass Spectrometry</p> <p>Days Performed: Sun, Tue</p> <p>Reported: 5–10 days</p>	6/15/23
Targeted Oncology Panel Next Generation Sequencing Bone Marrow	TOPBM	<p>Special Information: The following genes are interrogated: ABL1, AKT, AKT1, AKT3, AR, AXL, BRAF, C11orf95, CCND1, CDK4, CDK6, CTNNB1, DDR2, EGFR, ERBB2, ERBB3, ERBB4, ERG, ESR1, ETV1, ETV4, ETV5, FGFR1, FGFR2, FGFR3, FGFR4, GLI1, GNA11, GNAQ, GNAS, H3-3A, H3-3B, HRAS, IDH1, IDH2, INHBE, JAK1, JAK2, JAK3, KIT, KRAS, MAP2K1, MAP2K2, MET, MTOR, MYC, MYCN, NRAS, NTRK1, NTRK2, NTRK3, PDGFA, PIK3CA, PPARG, RAF1, RELA, RET, ROS1, SMO, TERT AND TP53.</p> <p>Clinical Information: This pan-cancer assay evaluates tumor hotspots, SNVs, indels, CNVs, and gene fusions from DNA and RNA. This information can be used for diagnostic, prognostic and therapeutic purposes across a variety of solid and liquid tumors.</p> <p>Specimen Requirement: 2 mL bone marrow aspirate in EDTA (Lavender) tube; Ambient</p> <p>Stability:</p> <ul style="list-style-type: none"> Ambient: Stable at ambient temperature for 48 hours. Refrigerated: Refrigerate at 2–8 C for up to 7 days. Frozen: Unacceptable <p>Methodology: Next Gen Sequencing</p> <p>Days Performed: 3 days per week 8:00 am–4:30 pm</p> <p>Reported: 8 days</p> <p>CPT: 81455</p>	6/20/23
Targeted Oncology Panel Next Generation Sequencing Cytology	TOPCY	<p>Special Information: The following genes are interrogated: ABL1, AKT, AKT1, AKT3, AR, AXL, BRAF, C11orf95, CCND1, CDK4, CDK6, CTNNB1, DDR2, EGFR, ERBB2, ERBB3, ERBB4, ERG, ESR1, ETV1, ETV4, ETV5, FGFR1, FGFR2, FGFR3, FGFR4, GLI1, GNA11, GNAQ, GNAS, H3-3A, H3-3B, HRAS, IDH1, IDH2, INHBE, JAK1, JAK2, JAK3, KIT, KRAS, MAP2K1, MAP2K2, MET, MTOR, MYC, MYCN, NRAS, NTRK1, NTRK2, NTRK3, PDGFA, PIK3CA, PPARG, RAF1, RELA, RET, ROS1, SMO, TERT AND TP53.</p> <p>Clinical Information: This pan-cancer assay evaluates tumor hotspots, SNVs, indels, CNVs, and gene fusions from DNA and RNA. This information can be used for diagnostic, prognostic and therapeutic purposes across a variety of solid and liquid tumors.</p> <p>Specimen Requirement: 8 slides from formalin fixed paraffin cell block; Ambient (continued on page 15)</p>	6/20/23

New Tests (Cont.)

Test Name	Order Code	Change	Effective Date
Targeted Oncology Panel Next Generation Sequencing Cytology <i>(continued from page 14)</i>		<p>Stability: Ambient: Stable at ambient temperature for 48 hours. Refrigerated: Refrigerate at 2–8 C for up to 7 days. Frozen: Unacceptable</p> <p>Days Performed: 3 days per week 8:00 am–4:30 pm</p> <p>Reported: 8 days</p> <p>CPT: 81455</p>	
Targeted Oncology Panel Next Generation Sequencing Other	TOPTO	<p>Special Information: The following genes are interrogated: ABL1, AKT, AKT1, AKT3, AR, AXL, BRAF, C11orf95, CCND1, CDK4, CDK6, CTNNB1, DDR2, EGFR, ERBB2, ERBB3, ERBB4, ERG, ESR1, ETV1, ETV4, ETV5, FGFR1, FGFR2, FGFR3, FGFR4, GLI1, GNA11, GNAQ, GNAS, H3-3A, H3-3B, HRAS, IDH1, IDH2, INHBE, JAK1, JAK2, JAK3, KIT, KRAS, MAP2K1, MAP2K2, MET, MTOR, MYC, MYCN, NRAS, NTRK1, NTRK2, NTRK3, PDGRFA, PIK3CA, PPARG, RAF1, RELA, RET, ROS1, SMO, TERT AND TP53.</p> <p>Clinical Information: This pan-cancer assay evaluates tumor hotspots, SNVs, indels, CNVs, and gene fusions from DNA and RNA. This information can be used for diagnostic, prognostic and therapeutic purposes across a variety of solid and liquid tumors.</p> <p>Specimen Requirement: 10 mm square formalin fixed paraffin block; Formalin-fixed paraffin-embedded tissue slides. Transport and store slides at ambient temperature. 15 unstained sections FFPE tissue on charged, unbaked slides plus one H&E stained section with best tumor area circled by a pathologist. Provide the percentage of tumor cells present.</p> <p>Stability: Ambient: FFPET slides are stable at ambient temperature indefinitely. Refrigerated: FFPET slides are stable at 2–8C indefinitely. Frozen: Unacceptable</p> <p>Days Performed: 3 days per week 8:00 am–4:30 pm</p> <p>Reported: 8 days</p> <p>CPT: 81455</p>	6/20/23
Targeted Oncology Panel Next Generation Sequencing Peripheral Blood	TOPPB	<p>Special Information: The following genes are interrogated: ABL1, AKT, AKT1, AKT3, AR, AXL, BRAF, C11orf95, CCND1, CDK4, CDK6, CTNNB1, DDR2, EGFR, ERBB2, ERBB3, ERBB4, ERG, ESR1, ETV1, ETV4, ETV5, FGFR1, FGFR2, FGFR3, FGFR4, GLI1, GNA11, GNAQ, GNAS, H3-3A, H3-3B, HRAS, IDH1, IDH2, INHBE, JAK1, JAK2, JAK3, KIT, KRAS, MAP2K1, MAP2K2, MET, MTOR, MYC, MYCN, NRAS, NTRK1, NTRK2, NTRK3, PDGRFA, PIK3CA, PPARG, RAF1, RELA, RET, ROS1, SMO, TERT AND TP53.</p> <p>Clinical Information: This pan-cancer assay evaluates tumor hotspots, SNVs, indels, CNVs, and gene fusions from DNA and RNA. This information can be used for diagnostic, prognostic and therapeutic purposes across a variety of solid and liquid tumors.</p> <p>Specimen Requirement: 4 mL peripheral blood from EDTA (Lavender) tube; Ambient</p> <p>Stability: Ambient: Stable at ambient temperature for 48 hours. Refrigerated: Refrigerate at 2–8 C for up to 7 days. Frozen: Unacceptable</p> <p>Methodology: Next Gen Sequencing</p> <p>Days Performed: 3 days per week 8:00 am–4:30 pm</p> <p>Reported: 8 days</p> <p>CPT: 81455</p>	6/20/23

Fee Increases

Test Name	Order Code	List Fee	CPT Code	Effective Date
Cytomegalovirus Antiviral Drug Resistance by Sequencing	CYTSEQ	\$914.00	87900; 87910	effective immediately
Tissue Culture & Stain	TISCUL	\$116.00	87205; 87176; 87070	6/20/23

Discontinued Tests

Test Name	Order Code	Test Information	Effective Date
Aluminum, Urine 24 Hour	UAL24	Test will no longer be orderable. There is no recommended replacement test, however preferred specimen type is serum, and the recommended alternative serum test is Aluminum (ALUM).	effective immediately
BRAF Gene Analysis	BRAFGN	Test will no longer be orderable. Recommended replacement test is Targeted Oncology Panel Next Generation Sequencing Other (TOPTO).	6/20/23
Colon Cancer Hotspot Gene Panel Cytology	NGSCCY	Test will no longer be orderable. Recommended replacement test is Targeted Oncology Panel Next Generation Sequencing Cytology (TOPCY).	6/20/23
Colon Cancer Hotspot Gene Panel Tissue	NGSCOL	Test will no longer be orderable. Recommended replacement test is Targeted Oncology Panel Next Generation Sequencing Other (TOPTO).	6/20/23
Desmoid NGS Hotspot	DESMHS	Test will no longer be orderable. Recommended replacement test is Targeted Oncology Panel Next Generation Sequencing Other (TOPTO).	6/20/23
EGFR Gene Analysis	EGFRGN	Test will no longer be orderable. Recommended replacement test is Targeted Oncology Panel Next Generation Sequencing Other (TOPTO).	6/20/23
FISH for DDIT3 (12q13)	CHOP	Test will no longer be orderable. Recommended replacement test is FISH for DDIT3/GLI1(12q13.3) (DDIT3)	effective immediately
Gastrointestinal Stromal Tumor (GIST) Hotspot Panel Cytology	GISTCY	Test will no longer be orderable. Recommended replacement test is Targeted Oncology Panel Next Generation Sequencing Cytology (TOPCY).	6/20/23
Gastrointestinal Stromal Tumor (GIST) Hotspot Panel Tissue	GISTHS	Test will no longer be orderable. Recommended replacement test is Targeted Oncology Panel Next Generation Sequencing Other (TOPTO).	6/20/23
IDH1 Gene Analysis	IDH1GN	Test will no longer be orderable. Recommended replacement test is Targeted Oncology Panel Next Generation Sequencing Other (TOPTO).	6/20/23
IDH1 & IDH2 Hotspot Gene Panel Cytology	IDHCY	Test will no longer be orderable. Recommended replacement test is Targeted Oncology Panel Next Generation Sequencing Cytology (TOPCY).	6/20/23
IDH1 & IDH2 Hotspot Gene Panel Tissue	IDH12G	Test will no longer be orderable. Recommended replacement test is Targeted Oncology Panel Next Generation Sequencing Other (TOPTO).	6/20/23
IDH2 Gene Analysis	IDH2GN	Test will no longer be orderable. Recommended replacement test is Targeted Oncology Panel Next Generation Sequencing Other (TOPTO).	6/20/23
KIT Gene Analysis	KITGN	Test will no longer be orderable. Recommended replacement test is Targeted Oncology Panel Next Generation Sequencing Other (TOPTO).	6/20/23
KRAS Gene Analysis	KRASGN	Test will no longer be orderable. Recommended replacement test is Targeted Oncology Panel Next Generation Sequencing Other (TOPTO).	6/20/23
Lung Cancer Hotspot Gene Panel Cytology	LUNGCY	Test will no longer be orderable. Recommended replacement test is Targeted Oncology Panel Next Generation Sequencing Cytology (TOPCY).	6/20/23
Lung Cancer Hotspot Gene Panel Tissue	LNG550	Test will no longer be orderable. Recommended replacement test is Targeted Oncology Panel Next Generation Sequencing Other (TOPTO).	6/20/23
Melanoma Hotspot Gene Panel Cytology	NGSMCY	Test will no longer be orderable. Recommended replacement test is Targeted Oncology Panel Next Generation Sequencing Cytology (TOPCY).	6/20/23
Melanoma Hotspot Gene Panel Tissue	NGSMEL	Test will no longer be orderable. Recommended replacement test is Targeted Oncology Panel Next Generation Sequencing Other (TOPTO).	6/20/23
MET Gene Analysis	METGN	Test will no longer be orderable. Recommended replacement test is Targeted Oncology Panel Next Generation Sequencing Other (TOPTO).	6/20/23
NRAS Gene Analysis	NRASGN	Test will no longer be orderable. Recommended replacement test is Targeted Oncology Panel Next Generation Sequencing Other (TOPTO).	6/20/23
PDGFRA Gene Analysis NGS Hotspot	PDGFGN	Test will no longer be orderable. Recommended replacement test is Targeted Oncology Panel Next Generation Sequencing Other (TOPTO).	6/20/23
PIK3CA Gene Analysis NGS Hotspot	PIK3GN	Test will no longer be orderable. Recommended replacement test is Targeted Oncology Panel Next Generation Sequencing Other (TOPTO).	6/20/23