

Technical Update • January 2016

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

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

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

Deleted tests and new tests are listed separately. Please update your database as necessary. For additional detail, contact Client Services at 216.444.5755 or 800.628.6816 or via email at clientservices@ccf.org.

Test Update Page #	Summary of Changes by Test Name	Order Code	Billing Code	Name Change	New Test	Special Information	Specimen Requirement	Component(s)	Methodology	Reference Range	Days Performed/Reported	Stability	CPT	Fee
3	Acanthamoeba Culture													
3	Allergen, Cranberry IgE													
3	BCR-ABL Qualitative Multiplex RT-PCR													
8	Bone Marrow Cancer Chromosome Microarray & SNP													
8	BRAF Gene Analysis													
3	CMV by PCR, CSF/FLD/Tissue													
3	COL1A1/COL1A2 DNA Sequencing													
3, 4	Cystic Fibrosis Screen 139 Variant Assay													
4	Date Rape Panel													
13	Diagnostic CF Test													
9	EGFR Gene Analysis													
4	FISH for FGFR1													
4	FISH for PDGFRA													
4	FISH for RARA													
9, 10	FLT3 Mutation Detection by PCR													
4	G-6-PD Quantitative													
10	Herpes Simplex Virus by PCR, Ocular Fluid													
4	Herpesvirus 6 IgM Antibody													
13	HIV-1 PCR													
10	HPV DNA, High Risk, Anal-Rectal													
13	Immune Activation Markers													

Test Update Page #	Summary of Changes by Test Name	Order Code	Billing Code	Name Change	New Test	Test Discontinued	Special Information	Specimen Requirement	Component(s)	Methodology	Reference Range	Days Performed/Reported	Stability	CPT	Fee
4	Influenza Detection														
5	Influenza/RSV Detection														
11	KIT Gene Analysis														
11	KRAS Gene Analysis														
5	Myoglobin, Urine														
12	NRAS Gene Analysis														
13	Ocular Cytomegalovirus PCR														
13	Ocular Herpes Simplex 1 and 2 PCR														
13	Ocular Toxoplasma gondii PCR														
13	Ocular Varicella Zoster Virus PCR														
5	Oxalate, Serum														
5	PML/RARA RTPCR														
12	Rapid PCR Assay for Influenza/RSV														
13	Trimethylamine N-oxide														
6	Thyroglobulin, FNA														
6	Thyroid Cancer Mutation Panel														
6	Toxoplasma PCR														
7	Varicella Zoster by PCR														
7	Vascular Endothelial Growth Factor														

Test Change: High Risk HPV DNA Anal Pap/Rectal Testing

Effective January 4, high-risk HPV DNA testing performed on anal pap/rectal specimens will be temporarily performed at Quest diagnostics. Requests for HPV testing on anal and rectal samples should be ordered using the new test code "HPV,DNA, High-Risk,Anal-Rectal." HPV testing on cervical specimens will continue to be performed in-house, and can be ordered using the test code currently in use (HPV DNA assay). It is the intention of the Cleveland Clinic Laboratories to resume performing this test on site following the transition of testing to PCR, which should occur in early 2016.

Questions? Contact Client Services at 800.628.6816 or 216.444.5755.

HIV-1 PCR Assay Discontinuation

The qualitative HIV DNA assay is being replaced by the manufacturer with a qualitative HIV DNA/RNA assay. Both assays will yield qualitative results, but the new assay will detect both integrated virus (i.e. DNA) and actively replicating virus (i.e. RNA). It is, therefore, considered superior to the former assay. The indications for this assay remain unchanged from those of the former assay.

Test Changes

Test Name	Order Code	Billing Code	Change	Effective Date
Acanthamoeba Culture	AMBCUL	89737	Special Information: Samples should be collected aseptically, transferred to Page's Amoeba saline and promptly submitted to Cleveland Clinic Laboratories. Store Page's saline at ambient temperature and is available through the department of Microbiology 216.444.1092. Specimens should not be frozen. Formalinized tissue will be rejected.	1/18/16
Allergen, Cranberry IgE	CRANBY	89665	For Interfaced Clients Only: Test build may need to be modified Clinical Information: Allergen results of 0.10-0.34 kU/L are intended for specialist use as the clinical relevance is undetermined. Even though increasing ranges are reflective of increasing concentrations of allergen-specific IgE, these concentrations may not correlate with the degree of clinical response or skin testing results when challenged with a specific allergen. The correlation of allergy laboratory results with clinical history and in vivo reactivity to specific allergens is essential. A negative test may not rule out clinical allergy or even anaphylaxis. Specimen Requirement: 0.25 mL serum from a serum separator tube; Minimum: 0.25 mL; Separate serum from cells within 2 hours of collection; Multiple specimen tubes should be avoided; Refrigerated Stability: Ambient: 48 hours Refrigerated: 2 weeks Frozen: 1 year Reference Range: ≤ 0.34 kU/L Days Performed: Sunday–Saturday Reported: 2–3 days	2/22/16
BCR-ABL Qualitative Multiplex RT-PCR	BCRQL	90167	CPT: 81206, 81207, 81208, G0452	3/3/16
CMV by PCR, CSF/FLD/Tissue	CMVCSF	79779	Specimen Requirement: 1 mL cerebrospinal fluid (CSF) in sterile container; Minimum: 0.5 mL; Frozen *OR* 1 mL bronchoalveolar lavage (BAL) in a sterile container; Minimum; 0.5 mL; Frozen *OR* 1 mL random urine in a sterile container; Minimum: 0.5 mL; Frozen *OR* Snap frozen tissue in a sterile container; Frozen *OR* 1 mL ocular fluid; Minimum: 0.5 mL; Frozen	12/21/15
COL1A1/COL1A2 DNA Sequencing	COLA12	84273	Specimen Requirement: 7 mL whole blood in an EDTA lavender top tube; Minimum: 3 mL; Collect Monday–Thursday only; Send to Cleveland Clinic Laboratories on the day of collection. Store in refrigerator, if must be sent next day; Refrigerated	3/10/16
Cystic Fibrosis Screen 139 Variant Assay	CFNGS	90638	Clinical Limitation: The results should be used and interpreted in the context of a full clinical evaluation. The assay does not include all variants identified in the CFTR gene. Therefore, the failure to identify a variant does not guarantee that other CFTR variants are not present in the samples being analyzed. Variants identified by this assay vary in frequency among different populations. As with any hybridization-based assay, underlying variants in oligonucleotide-binding regions can affect the alleles being probed and, consequently, the calls made. The orientation of the PolyTG/ PolyT variant, whether in cis/trans to the R117H variant, cannot be ascertained. PolyTG/PolyT are homopolymeric regions known to be difficult to interpret with sequence-based assays due to polymerase slippage. A 0.9% (4/448) miscall rate is reported for PolyTG/PolyT results. <i>(continued on page 4)</i>	3/3/16

Test Changes (Cont.)

Test Name	Order Code	Billing Code	Change	Effective Date
Cystic Fibrosis Screen 139 Variant Assay <i>(continued from page 3)</i>			<p>Clinical Information: Cystic fibrosis has a disease incidence estimated at one in 2,000 to 4,000 live births and a prevalence of approximately 30,000 individuals in the US population. It occurs in all ethnic and racial populations, at various frequencies: one in 3,000 Caucasians; one in 9,200 Hispanic Americans; one in 10,900 Native Americans; one in 15,000 African Americans; and one in 31,000 Asian Americans.</p> <p>Specimen Requirement: 4.5 mL whole blood in an EDTA lavender top tube; Minimum: 2 mL; Ambient</p> <p>Methodology: Next Gen Sequencing</p>	
Date Rape Panel	UDRPAN	82125	<p>For Interfaced Clients Only: Test build may need to be modified</p> <p>Methodology: Gas Chromatography/Flame Ion Detection (GC-FID) Enzymatic Immunoassay (IA)</p> <p>Days Performed: Sunday–Saturday</p> <p>Reported: 2–5 days</p>	1/1/16
FISH for FGFR1	FGFR1F	88770	<p>Clinical Information: This assay employs a break-apart probe to detect rearrangements of the FGFR1 locus on chromosome 8p11. Myeloid neoplasms with FGFR1 rearrangements are often associated with eosinophilia and represent a distinct clinicopathologic entity in the WHO classification of hematolymphoid neoplasms. This assay is useful for the evaluation of unexplained eosinophilia and to assist in the diagnosis and classification of myeloproliferative neoplasms.</p>	1/4/16
FISH for PDGFRA	PDGFRA	88699	<p>Clinical Information: This assay employs a tri-color probe to detect rearrangements of the PDGFRA locus on chromosome 4q12. Myeloid neoplasms with PDGFRA rearrangements are often associated with eosinophilia and represent a distinct clinicopathologic entity in the WHO classification of hematolymphoid neoplasms. This assay is useful for the evaluation of unexplained eosinophilia and to assist in the diagnosis and classification of myeloproliferative neoplasms.</p>	1/4/16
FISH for RARA	RARFSH	82695	<p>Clinical Information: This assay employs a dual color, break-apart FISH probe to detect translocations involving the RARA gene at chromosome 17q21, as seen in acute promyelocytic leukemia.</p>	1/4/16
G-6-PD Quantitative	G6PDQT	30039	<p>Reference Range: 9.9–16.6 U/g Hb</p>	1/4/16
Herpesvirus 6 IgM Antibody	HHV6M	81735	<p>Stability: (After separation from cells) Ambient: 48 hours Refrigerated: 2 weeks Frozen: 6 months</p> <p>Reference Range: <1:10</p>	3/3/16
Influenza Detection	FLU	83313	<p>Specimen Requirement: One nasopharyngeal swab in M4 or Universal Transport Media (UTM); Refrigerated</p> <p>*OR* One throat swab in M4 or Universal Transport Media (UTM); Refrigerated</p> <p>*OR* Nasopharyngeal aspirate in sterile container; Refrigerated</p> <p>*OR* Nasopharyngeal washings in sterile container; Refrigerated</p> <p>*OR* Bronchoalveolar lavage (BAL) in sterile container; Refrigerated</p> <p>CPT: 87502x1</p>	1/1/16

Test Changes (Cont.)

Test Name	Order Code	Billing Code	Change	Effective Date
Influenza/RSV Detection	FLURSV	83314	<p>Specimen Requirement: One nasopharyngeal swab in M4 or Universal Transport Media (UTM); Refrigerated</p> <p>*OR* One throat swab in M4 or Universal Transport Media (UTM); Refrigerated</p> <p>*OR* Nasopharyngeal aspirate in sterile aspirate in sterile container; Refrigerated</p> <p>*OR* Nasopharyngeal washings in sterile container; Refrigerated</p> <p>*OR* Bronchoalveolar lavage (BAL) in sterile container; Refrigerated</p>	1/1/16
Myoglobin, Urine	UMYO	83875	<p>For Interfaced Clients Only: Test build may need to be modified</p> <p>Clinical Information: Patients with urine myoglobin greater than 15 mg/L are at risk of acute renal failure. Usual results are less than 1 mg/L. Results between 1 and 15 mg/L are associated with vigorous exercise, myocardial infarct, mild muscle injury, and other conditions.</p> <p>Specimen Requirement: 4 mL random urine in a clean container; Immediately after collection, transfer a maximum of 4 mL urine to an ARUP Standard Transport Tube prefilled with sodium carbonate (ARUP supply #48096); Tubes are available through Client Services at 800-628-6816; Frozen</p> <p>Stability: (pH 8–9) Ambient: 1 hour Refrigerated: 72 hours Frozen: 1 month</p> <p>Reference Range: 0–1 mg/L</p> <p>Days Performed: Sunday–Saturday</p> <p>Reported: 2–3 days</p>	3/4/16
Oxalate, Serum	OXLATE	82970	<p>Specimen Requirement: 2 mL serum from a red top tube; Minimum: 1.2 mL; Do not use serum separator tubes; Separate serum from cells ASAP; Refrigerated</p> <p>*OR* 2 mL plasma from an EDTA lavender top tube; Minimum: 1.2 mL; Do not use plasma separator tubes; Separate plasma from cells ASAP; Refrigerated</p> <p>Stability: Ambient: 30 days Refrigerated: 30 days Frozen: 30 days</p> <p>Reference Range: 2.5 mcmol/L Critical: 0–99 years: 200 mcmol/L</p>	3/7/16
PML/RARA RTPCR	APLPCR	82570	<p>For Interfaced Clients Only: Test build will need to be modified</p> <p>Special Information: RNA isolation is performed Sunday–Saturday</p> <p>Specimen Requirement: 5 mL whole blood in an EDTA lavender top tube; Minimum: 1 mL; Specimen MUST be delivered to Cleveland Clinic Laboratories by 3 PM EST on the day of collection. Do not collect the day before or the day of a major holiday; Refrigerated</p> <p>*OR* 3 mL bone marrow in an EDTA lavender top tube; Minimum: 3 mL; Specimen MUST be delivered to Cleveland Clinic Laboratories by 3 PM EST on the day of collection. Do not collect the day before or the day of a major holiday; Refrigerated</p> <p>Days Performed: Sunday, Tuesday, Thursday</p> <p>Reported: 3–8 days</p> <p>CPT: 81315</p>	3/4/16

Test Changes (Cont.)

Test Name	Order Code	Billing Code	Change	Effective Date
Thyroglobulin, FNA	FTHYG	88199	<p>For Interfaced Clients Only: Test build may need to be modified</p> <p>Specimen Requirement: 0.5 mL fine needle aspirate rinse in saline in a clean container; Minimum: 0.5 mL; Centrifuge to remove cellular material; Specimen must be non-viscous and free of particulate matter; Frozen</p> <p>*OR* 0.5 mL fine needle aspirate rinse in a sodium or lithium heparin green top tube; Minimum: 0.5 mL; Centrifuge to remove cellular material; Specimen must be non-viscous and free of particulate matter; Frozen</p> <p>Stability: Ambient: 8 hours Refrigerated: 48 hours Frozen: 6 months</p> <p>Days Performed: Sunday-Saturday</p> <p>Reported: 2-3 days</p>	2/22/16
Thyroid Cancer Mutation Panel	TYMUT	89918	<p>Specimen Requirement: 4 slides from fine needle aspirate (FNA), 3 of which should be without coverslips (cover slipped slides will delay reporting of result); Minimum: 4 slides; A pathology report is also required; Ambient</p> <p>*OR* Formalin-fixed paraffin-embedded tissue block; Minimum: 2 slides; A pathology report is also required; Ambient</p> <p>*OR* Needle washings in alcohol based fixative (e.g. Cytolyt); A pathology report is also required; Ambient</p> <p>Days Performed: 7 days a week</p> <p>Reported: 6-7 days</p>	1/1/16
Toxoplasma PCR	TXPCR	81737	<p>For Interfaced Clients Only: The test build will need to be modified</p> <p>Specimen Requirement: 1 mL plasma from an EDTA lavender top tube; Minimum: 0.5 mL; Frozen</p> <p>*OR* 1 mL ocular fluid in a sterile container; Minimum: 0.5 mL; Frozen</p> <p>*OR* 25 mg tissue in a sterile container; Frozen</p> <p>*OR* 1 mL cerebrospinal fluid (CSF) in a sterile container; Minimum: 0.5 mL; Frozen</p> <p>*OR* 1 mL amniotic fluid in a sterile container; Minimum: 0.5 mL; Frozen</p> <p>*OR* 1 mL serum from a serum separator tube; Minimum: 0.5 mL; Frozen</p> <p>Stability: Ambient: Tissue: Unacceptable All other specimen types: 8 hours</p> <p>Refrigerated: Tissue: Unacceptable All other specimen types: 5 days</p> <p>Frozen: All specimen types: 3 months</p> <p>Methodology: Qualitative Polymerase Chain Reaction (PCR)</p> <p>Days Performed: Tuesday, Friday</p> <p>Reported: 2-6 days</p>	12/21/15

Test Changes (Cont.)

Test Name	Order Code	Billing Code	Change	Effective Date
Varicella Zoster by PCR	VZPCR	77127	<p>Specimen Requirement: 1 mL cerebrospinal fluid (CSF) in sterile container; Minimum: 0.5 mL; Specimen source is required; Frozen</p> <p>*OR* 1 mL plasma from an EDTA lavender top tube; Minimum: 0.5 mL; Specimen source is required; Frozen</p> <p>*OR* 1 mL serum from a serum separator tube; Minimum: 0.5 mL; Specimen source is required; Frozen</p> <p>*OR* Tissue, snap frozen, in a sterile container; Frozen</p> <p>*OR* Vesicle fluid swab in M4 or Universal Transport Media (UTM); Place swab into transport media ASAP and freeze; Frozen</p> <p>*OR* 1 mL ocular fluid in a sterile container; Minimum: 0.5 mL; Frozen</p>	12/21/15
Vascular Endothelial Growth Factor	VEGF	84201	<p>For Interfaced Clients Only: Test build may need to be modified</p> <p>Specimen Requirement: 1 mL plasma from an EDTA lavender top tube; Minimum: 0.3 mL; Separate plasma from cells ASAP or within 2 hours of collection. Additional specimens must be submitted when multiple tests are ordered; Critical Frozen</p> <p>Stability: (After separation from cells) Ambient: 4 hours Refrigerated: 6 hours Frozen: 6 months</p> <p>Methodology: Quantitative Chemiluminescent Immunoassay</p> <p>Reference Range: 9–86 pg/mL</p> <p>Days Performed: Tuesday</p> <p>Reported: 2–9 days</p> <p>CPT: 82397</p>	3/17/16

New Tests

Test Name	Order Code	Billing Code	Test Information	Effective Date
Bone Marrow Cancer Chromosome Microarray & SNP	BMHNSP	90814	<p>Clinical Information: To detect copy number changes and loss of heterozygosity (LOH)/copy neutral LOH in hematological malignancies at diagnosis, prognostication or disease progression for clinically relevant chromosomal abnormalities.</p> <p>Special Information: The following specimens are considered unacceptable: 1. Clotted or frozen Bone Marrow 2. Samples collected in the incorrect anticoagulant 3. Improperly labeled specimen.</p> <p>Specimen Requirement: 4 mL bone marrow in an EDTA lavender top tube; Collect specimen Monday–Friday only; 50 ng/μL of extracted DNA in TE buffer will be sent for analysis; Ambient</p> <p>Stability: Ambient: 48 hours Refrigerated: Undetermined Frozen: Unacceptable</p> <p>Methodology: Microarray</p> <p>Days Performed: Monday–Friday</p> <p>Reported: 10–14 days</p> <p>CPT: 81406</p> <p>Price: \$1450.00</p>	2/22/16
BRAF Gene Analysis	BRAFGN	90820	<p>Clinical Information: NGS is primary method of testing. Sanger sequencing is a secondary method. The lab will report which method was used (NGS or Sanger sequencing) in body of report. The CPT code doesn't change regardless of the method.</p> <p>Specimen Requirement: 10 mm square formalin-fixed paraffin-embedded tissue block; Formalin-fixed paraffin-embedded tissue slides; Transport and store slides at ambient temperature. 10 unstained sections FFPE tissue on uncharged, unbaked slides plus one H&E stained section with best tumor area circled by pathologist; Ambient</p> <p>*OR* 3–5 mL fine needle aspirate (FNA) in CytoLyt solution and should be stored at 4°C until DNA extraction can be performed; Ambient</p> <p>*OR* Tissue pellets from an FFPE block. Ambient</p> <p>Stability: Ambient: Tissue block: Indefinitely Fine needle aspirate: 24 hours</p> <p>Refrigerated: Tissue block: Unacceptable Fine needle aspirate: 6 weeks</p> <p>Frozen: Tissue block: Unacceptable Fine needle aspirate: Unacceptable</p> <p>Methodology: Sequencing Polymerase Chain Reaction (PCR) Next Generation DNA Sequencing</p> <p>Days Performed: 1 day per week</p> <p>Reported: 14–21 days</p> <p>CPT: 80210, G0452</p>	3/13/16

New Tests (Cont.)

Test Name	Order Code	Billing Code	Test Information	Effective Date
EGFR Gene Analysis	EGFRGN	90815	<p>Special Information: NGS testing is primary method of testing, allele-specific PCR is secondary. The lab will report which method was used (NGS or allele-specific PCR) in body of the report. The CPT code doesn't change regardless of method.</p> <p>Specimen Requirement: 10 mm square formalin-fixed paraffin-embedded tissue block; Formalin-fixed paraffin-embedded tissue slides; Transport and store slides at ambient temperature. 10 unstained sections FFPE tissue on uncharged, unbaked slides plus one H&E stained section with best tumor area circled by pathologist; Ambient</p> <p>*OR* 3–5 mL fine needle aspirate (FNA) in CytoLyt solution and should be stored at 4°C until DNA extraction can be performed; Ambient</p> <p>*OR* Tissue pellets from an FFPE block. Ambient</p> <p>Stability: Ambient: Tissue block: Indefinitely Fine needle aspirate: 24 hours</p> <p>Refrigerated: Tissue block: Unacceptable Fine needle aspirate: 6 weeks</p> <p>Frozen: Tissue block: Unacceptable Fine needle aspirate: Unacceptable</p> <p>Methodology: Allele-specific Polymerase Chain Reaction (PCR) Next Generation DNA Sequencing Real-time Polymerase Chain Reaction (PCR)</p> <p>Days Performed: 1 day per week</p> <p>Reported: 14-21 days</p> <p>CPT: 81235, G0452</p> <p>Price: \$528.00 (non-discountable), Test will be Client Bill Only</p>	2/1/16
FLT3 Mutation Detection by PCR	FLT3MD	90818	<p>Clinical Information: First-line test for prognostication of CN-AML</p> <p>Specimen Requirement: 5 mL whole blood in an EDTA lavender top tube; Minimum: 1 mL; Separate specimens must be submitted when multiple tests are ordered; Refrigerated</p> <p>*OR* 5 mL whole blood in an ACD A or B yellow top tube; Minimum: 1 mL; Separate specimens must be submitted when multiple tests are ordered; Refrigerated</p> <p>*OR* 5 mL whole blood in a sodium or lithium heparin green top tube; Minimum: 1 mL; Separate specimens must be submitted when multiple tests are ordered; Refrigerated</p> <p>*OR* 3 mL bone marrow in an EDTA lavender top tube; Minimum: 1 mL; Separate specimens must be submitted when multiple tests are ordered; Refrigerated</p> <p>*OR* 3 mL bone marrow in an ACD A or B yellow top tube; Minimum: 1 mL; Separate specimens must be submitted when multiple tests are ordered; Refrigerated</p> <p>*OR* 3 mL bone marrow in a sodium or lithium heparin green top tube; Minimum: 1 mL; Separate specimens must be submitted when multiple tests are ordered; Refrigerated</p> <p>Stability: Ambient: 1 week Refrigerated: 1 week Frozen: Unacceptable</p> <p>Methodology: Qualitative Polymerase Chain Reaction/Capillary Electrophoresis</p> <p><i>(continued on page 10)</i></p>	3/9/16

New Tests (Cont.)

Test Name	Order Code	Billing Code	Test Information	Effective Date
FLT3 Mutation Detection by PCR <i>(continued from page 9)</i>			Days Performed: Varies Reported: 4–9 days CPT: 81479, 81245 Price: \$395.00	
Herpes Simplex Virus by PCR, Ocular Fluid	OCHSV	90812	Specimen Requirement: 1 mL ocular fluid in a sterile container; Minimum: 0.5 mL; Frozen Stability: Ambient: 8 hours Refrigerated: 72 hours Frozen: 3 months Methodology: Qualitative Polymerase Chain Reaction (PCR) Days Performed: Sunday–Saturday Reported: 2–4 days CPT: 87529 Price: \$88.00 (non-discountable)	12/21/15
HPV DNA, High Risk, Anal-Rectal	HPVAR	90813	Specimen Requirement: Dacron swab in 1 mL Digene standard transport medium (STM). To collect an anal-rectal sample, a tap water-moistened Dacron swab is used. The Dacron swab is inserted about 5-6 cm into the anal canal past the anal verge, into the rectal vault. This is done without direct visualization of the anal canal. Firm lateral pressure is applied to the swab handle as it is rotated and slowly withdrawn from the anal canal, inscribing a cone-shaped arc. Avoid using cotton swabs on a wooden stick because the handle may break and splinter during collection. Swab that is grossly contaminated with feces should be discarded and the collection repeated. Remove the cap from the Digene standard transport medium (STM) supplied with the collection kit. Immediately insert swab to the bottom of the transport tube. Snap off shaft at score line and cap tube securely. Transport Frozen *OR* Anal-rectal brush in 1 mL Digene standard transport medium (STM). To collect an anal-rectal sample, a tap water-moistened anal-rectal brush is used. The anal-rectal brush is inserted about 5-6 cm into the anal canal past the anal verge, into the rectal vault. This is done without direct visualization of the anal canal. Firm lateral pressure is applied to the swab handle as it is rotated and slowly withdrawn from the anal canal, inscribing a cone-shaped arc. Avoid using cotton swabs on a wooden stick because the handle may break and splinter during collection. Brush that is grossly contaminated with feces should be discarded and the collection repeated. Remove the cap from the Digene standard transport medium (STM) supplied with the collection kit. Immediately insert brush to the bottom of the transport tube. Snap off shaft at score line and cap tube securely. Transport Frozen Stability: Ambient: 14 days Refrigerated: 21 days Frozen: 90 days Methodology: Hybrid capture II Reference Range: Not detected Days Performed: Tuesday–Saturday Reported: 3–6 days CPT: 87624 Price: \$130.00 (non-discountable)	1/4/16

New Tests (Cont.)

Test Name	Order Code	Billing Code	Test Information	Effective Date
KIT Gene Analysis	KITGN	90821	<p>Specimen Requirement: 10 mm square formalin-fixed paraffin-embedded tissue block; Formalin-fixed paraffin-embedded tissue slides; Transport and store slides at ambient temperature. 10 unstained sections FFPE tissue on uncharged, unbaked slides plus one H&E stained section with best tumor area circled by pathologist; Ambient</p> <p>*OR* 3–5 mL fine needle aspirate (FNA) in CytoLyt solution and should be stored at 4°C until DNA extraction can be performed; Ambient</p> <p>*OR* Tissue pellets from an FFPE block. Ambient</p> <p>Stability: Ambient: Tissue block: Indefinitely Fine needle aspirate: 24 hours</p> <p>Refrigerated: Tissue block: Unacceptable Fine needle aspirate: 6 weeks</p> <p>Frozen: Tissue block: Unacceptable Fine needle aspirate: Unacceptable</p> <p>Methodology: Next Generation DNA Sequencing</p> <p>Days Performed: 1 day per week</p> <p>Reported: 14-21 days</p>	3/10/16
KRAS Gene Analysis	KRASGN	90816	<p>Specimen Requirement: 10 mm square formalin-fixed paraffin-embedded tissue block; Formalin-fixed paraffin-embedded tissue slides; Transport and store slides at ambient temperature. 10 unstained sections FFPE tissue on uncharged, unbaked slides plus one H&E stained section with best tumor area circled by pathologist; Ambient</p> <p>*OR* 3–5 mL fine needle aspirate (FNA) in CytoLyt solution and should be stored at 4°C until DNA extraction can be performed; Ambient</p> <p>*OR* Tissue pellets from an FFPE block. Ambient</p> <p>Stability: Ambient: Tissue block: Indefinitely Fine needle aspirate: 24 hours</p> <p>Refrigerated: Tissue block: Unacceptable Fine needle aspirate: 6 weeks</p> <p>Frozen: Tissue block: Unacceptable Fine needle aspirate: Unacceptable</p> <p>Methodology: Allele-specific Polymerase Chain Reaction (PCR) Next Generation DNA Sequencing Real-time Polymerase Chain Reaction (PCR)</p> <p>Days Performed: 1 day per week</p> <p>Reported: 14–21 days</p> <p>CPT: 81275, 81276, G0452</p>	3/10/16

New Tests (Cont.)

Test Name	Order Code	Billing Code	Test Information	Effective Date
NRAS Gene Analysis	NRASGN	90817	<p>Clinical Information: NRAS mutations in codons 12, 13, or 61 are identified in colorectal cancers, melanoma, and other tumors. Activating mutations in NRAS in metastatic colon cancer are associated with resistance to anti-EGFR monoclonal antibody therapy and are an adverse prognostic marker in melanoma</p> <p>Specimen Requirement: 10 mm square formalin-fixed paraffin-embedded tissue block; Formalin-fixed paraffin-embedded tissue slides; Transport and store slides at ambient temperature. 10 unstained sections FFPE tissue on uncharged, unbaked slides plus one H&E stained section with best tumor area circled by pathologist; Ambient</p> <p>*OR* 3–5 mL fine needle aspirate (FNA) in CytoLyt solution and should be stored at 4°C until DNA extraction can be performed; Ambient</p> <p>*OR* Tissue pellets from an FFPE block. Ambient</p> <p>Stability: Ambient: Tissue block: Indefinitely Fine needle aspirate: 24 hours</p> <p>Refrigerated: Tissue block: Unacceptable Fine needle aspirate: 6 weeks</p> <p>Frozen: Tissue block: Unacceptable Fine needle aspirate: Unacceptable</p> <p>Methodology: Next Generation Sequencing</p> <p>Days Performed: 1 day per week</p> <p>Reported: 14–21 days</p> <p>CPT: 81311, G0452</p> <p>Price: \$63.00 (non-discountable), Test will be Client Bill Only</p>	3/10/16
Rapid PCR Assay for Influenza/RSV	FLRSV	90811	<p>Clinical Information: Possible interfering substances include blood, mucus, FLU Mist, or other live attenuated influenza vaccines. This assay is qualitative only and does not differentiate subtypes or lineages. This test is only approved for testing of nasopharyngeal specimens if placed in UTM transport media. Other sample types including lower respiratory tract specimens and nasal aspirates/wash specimens have not been validated. M4 transport is NOT acceptable (please order FLURSV if M4 is used or alternative sites are submitted).</p> <p>Includes: Flu A by PCR Flu B by PCR RSV by PCR</p> <p>Specimen Requirement: Nasopharyngeal swab in 3 mL UTM transport tube; Refrigerated</p> <p>Stability: Ambient: 24 hours Refrigerated: 7 days Frozen: Unacceptable</p> <p>Methodology: Polymerase Chain Reaction (PCR)</p> <p>Reference Range: Negative</p> <p>Days Performed: 7 days per week</p> <p>Reported: 1–2 days</p> <p>CPT: 87631</p> <p>Price: \$215.00</p>	1/5/16

New Tests (Cont.)

Test Name	Order Code	Billing Code	Test Information	Effective Date
Trimethylamine N-oxide	TMAO	90822	<p>Specimen Requirement: 1 mL serum from a serum separator tube; Minimum: 0.5 mL; Patients should fast overnight and refrain from consuming fish or other seafood the day before the blood draw to avoid false elevations in TMAO; Refrigerated</p> <p>Stability: Ambient: Unacceptable Refrigerated: 7 days Frozen -20° C: 3 weeks Frozen -70° C: 3 weeks</p> <p>Methodology: Liquid Chromatography–Tandem Mass Spectrometry (LC-MS/MS)</p> <p>Reference Range: Refer to report</p> <p>Days Performed: Tuesday</p> <p>Reported: 8–11 days</p> <p>CPT: 82542</p> <p>Price: \$75.00</p>	1/18/16

Discontinued Tests

Test Name	Order Code	Billing Code	Test Information	Effective Date
Diagnostic CF Test	CFDNA	80939	This test will no longer be available. Suggest ordering Cystic Fibrosis Screen 139 Variant (CFNGS)	3/3/16
HIV-1 PCR	HIVPCR	50197	This test will no longer be available.	2/29/16
Immune Activation Markers	IMACTV	26	This test will no longer be available.	3/1/16
Ocular Cytomegalovirus PCR	VITCMV	84523	This test will no longer be available. Suggest ordering CMV by PCR, CSF/FLD/Tissue (CMVCSF)	12/21/15
Ocular Herpes Simplex 1 and 2 PCR	VITHSV	84525	This test will no longer be available. Suggest ordering Herpes Simplex Virus by PCR, Ocular Fluid (OCHSV)	12/21/15
Ocular Toxoplasma gondii PCR	VITTXO	84524	This test will no longer be available. Suggest ordering Toxoplasma PCR (TXPCR)	12/21/15
Ocular Varicella Zoster Virus PCR	VITVZV	84526	This test will no longer be available. Suggest ordering Varicella Zoster by PCR (VZPCR)	12/21/15