Cleveland Clinic

Cleveland Clinic Laboratories

Technical Update • January 2019

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
11	Acylcarnitines, Plasma w/ No Interpretation			■										
4	AFP, Serum (Tumor Marker)									■		■		
4	Alpha-1 Antitrypsin Genotyping								■					
11	Amino Acids, CSF w/ Basic Interpretation			■										
11	Amino Acids, CSF w/ No Interpretation			■										
11	Amino Acids, Plasma w/ Basic Interpretation			■										
11	Amino Acids, Plasma w/ No Interpretation			■										
11	Amino Acids, Urine w/ Basic Interpretation			■										
11	Amino Acids, Urine w/ No Interpretation			■										
11	BCR/ABL1 p190 Quantitative PCR Blood			■										
11	BCR/ABL1 p190 Quantitative PCR Bone Marrow			■										
12	BCR/ABL1 p210 Quantitative PCR Blood			■										
12	BCR/ABL1 p210 Quantitative PCR Bone Marrow			■										
13	BCR/ABL p190 RT-PCR, Quantitative				■									
13	BCRABL p210 RTPCR Quantitative				■									
4	BCR-ABL Qualitative Multiplex RT-PCR					■	■							
4	BRAF Gene Analysis	■									■	■		
4	Calculi (Stone) Analysis					■								
4	Candida Profile with Immune Complex		■			■								
4	Coenzyme Q10					■					■	■		
4	Colon Cancer Hotspot Panel v2 NGS	■				■					■			
4, 13	Creutzfeldt-Jakob Disease					■							■	■
4	Cutaneous Immunofluorescence Antibodies (IgG)					■						■		

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
5	EGFR Gene Analysis	■									■	■		
5	Factor V Leiden										■			
5	Flow Cytometric Immunophenotyping for Lymphoma, Tissue												■	
5	HFE (Hemochromatosis)								■		■			
5	HIV-1/2 Ab Confirmatory		■											
5	HIV-1 p24 Ag +HIV-1-2 Ab, with reflex to differentiation		■			■								
5	IDH1 & IDH2 Gene Analysis										■			
5	IDH1 Gene Analysis										■			
5	IDH2 Gene Analysis										■			
5	Insulin					■				■				
5	Insulin Antibody											■		
5	Iron						■							
5	Iron and TIBC						■							
6	Islet antigen-2 antibody		■			■	■		■	■		■	■	
6	JAK2 Exon 12–15 Sequencing Blood					■	■							
6	JAK2 V617F Mutation Detection Blood						■		■		■			
6	JAK2 V617F Mutation Detection Bone Marrow						■				■			
6	Kappa, Free, Serum					■						■		
7	Kappa/Lambda, Free, Serum					■						■		
7	KIT Gene Analysis	■									■	■		
7	KRAS Gene Analysis	■									■	■		
7	Lambda, Free, Serum					■						■		
7	Lung Cancer Hotspot Gene Panel					■					■			
7	LYME AB Early Disease (≤ 30 days of signs and symptoms), with Reflex										■			
8	LYME AB Late Disease (> 30 days of signs or symptoms), with Reflex										■			
8	Measles IgG Antibody										■			
8	Melanoma Hotspot Panel v2 NGS	■									■			
8	MET Gene Analysis	■				■					■			
8	MGMT Methylation	■				■					■			
8	MLH1 Promoter Hypermethylation	■									■			
8	MSI (PCR) X 2											■		
8	MTHFR Gene Analysis					■	■		■		■	■		
8	Mumps IgG Antibody										■			
9	Mycobacterium tuberculosis (MTB) and Rifampin Resistance Detection by PCR					■					■			
9	NRAS Gene Analysis	■									■	■		
12	NTRK Gene Analysis			■										
12	Organic Acids Ur, Quant w/ No Interpretation			■										
9	PNH Panel by FCM											■		
9	PSA											■		

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
9	PSA, Free											■		
9	PSA, Screening											■		
13	Respiratory Panel by PCR			■										
13	Respiratory Viral Panel by PCR				■									
9	Reticulin IgA and IgG Antibodies						■							
10	Rubella IgG Antibody										■			
10	Spinal Muscular Atrophy Carrier Screening and Diagnostic						■				■	■		
10	Varicella-Zoster IgG Ab										■			

Dear Valued Client,

For several molecular tests, CPT code G0452 will be removed. The following tests are affected:

Effective 1/3/19:

- Bone marrow Cancer Chromosome Microarray + SNP (BMHSNP)
- Chromosomal Microarray SNP, Constitutional (CRMSNP)
- Leukemic Blood Cancer Chromosome Microarray + SNP (BLLSNP)

Effective 2/1/19:

- Alpha-1 Antitrypsin Genotyping (HA1AT)
- Alpha 1 Antitrypsin Phenotype and Genotype (A1ATPG)
- Alpha Thalassemia Gene Deletion (ATHALS)
- BRAF Gene Analysis (BRAFGN)
- Colon Cancer Hotspot Panel v2 NGS (NGSCOL)
- EGFR Gene Analysis (EGFRGN)
- EGFR Mutation Analysis, Cell Pellet (EGFRCP)
- EGFR Mutation Analysis, Tissue (EGFRTI)
- Factor V Leiden (FVLEI)
- Fragile X Syndrome DNA Analysis by PCR, Blood (FRAX)
- HFE (Hemochromatosis) (HEMDNA)
- IDH1 & IDH2 Gene Analysis (IDH12GN)
- IDH1 Gene Analysis (IDH1GN)
- IDH2 Gene Analysis (IDH2GN)
- KIT Gene Analysis (KITGN)
- KRAS Gene Analysis (KRASGN)
- Lung Cancer Hotspot Gene Panel (LNG550)
- Melanoma Hotspot Panel v2 NGS (NGSMEL)
- MET Gene Analysis (METNGS)
- MGMT Methylation (MGMT)
- MLH1 Promoter Hypermethylation (MLH1PH)
- MSI (PCR) X 2 (MSICCT)
- MTHFR Gene Analysis (MTHF)
- NRAS Gene Analysis (NRASGN)
- Prothrombin Gene Mutation (PTGEN)

Test Changes

Test Name	Order Code	Change	Effective Date
AFP, Serum (Tumor Marker)	AFP	**Stability:** Ambient: 8 hours Refrigerated: **48 hours** Frozen: **14 days** **Reference Range: < 11.00 ng/mL**	2/28/19
Alpha-1 Antitrypsin Genotyping	HA1AT	**Methodology:** **Fluorescence Monitoring** High Resolution Melt Analysis Real-Time Polymerase Chain Reaction (RT-PCR)	2/1/19
BCR-ABL Qualitative Multiplex RT-PCR	BCRQL	**Clinical Information:** This assay detects and differentiates all known BCR/ABL1 splice variants, including the p190, p210 and p230 isoforms as well as other rare variants. This assay is intended for initial diagnosis in suspected cases of chronic myeloid leukemia or acute lymphoblastic leukemia. **When p190 or p210 BCR/ABL1 transcripts are detected by this test, reflex quantitative analysis will also be performed.** **Specimen Requirement:** 10 mL blood in an EDTA (lavender) tube; Minimum: **4 mL;** Ambient *OR* 5 mL bone marrow in an EDTA (lavender) tube; Minimum: **2 mL;** Ambient	2/28/19
BRAF Gene Analysis	**BRAFGN**	**For Interfaced Clients Only: Test build may need to be modified** **Note:** *This test will have a new order code.* **Stability:** Ambient: **Indefinitely for fresh-frozen paraffin-embedded (FFPE) slides; FFPE slides can be transported at ambient temperatures** Refrigerated: **Up to 2 weeks for fine-needle aspirate (FNA) samples** Frozen: **Unacceptable** **Days Performed:** 3 days per week **Reported: 8** days	2/1/19
Calculi (Stone) Analysis	CSA	**Note:** *Changes to Calculi (Stone) Analysis were previously announced in the October and December Technical Updates. Please note that the new go-live date for changes will be **3/19/19.***	3/19/19
Candida Profile with Immune Complex	CNDIMM	**Test Name:** Previously Candida Immune Complex **Note:** *Candida Immune Complex has been added as an alias name.*	Effective immediately
Coenzyme Q10	COEQ10	**Special Information:** Freeze plasma within 3 hours of collection. Failure to follow specimen handling guidelines may lead to false positive results. **Hemolyzed, lipemic and grossly icteric specimens will be rejected.** **Stability:** Ambient: Unacceptable Refrigerated: 8 hours Frozen: **14 days** **Days Performed: Varies** **Reported:** 4–8 days	Effective immediately
Colon Cancer Hotspot Panel v2 NGS	**NGSCOL**	**For Interfaced Clients Only: Test build may need to be modified** **Note:** *This test will have a new order code. NGSCOLON will be added as an alias name.* **Days Performed:** 3 days per week **Reported: 8** days	2/1/19
Creutzfeldt-Jakob Disease	CJD	**Note:** *Clinical Information will be removed.* **CPT: 0035U x 1,** 84182 x 1, **86317 x 1**	1/2/19
Cutaneous Immunofluorescence Antibodies (IgG)	CIFAB	**Special Information: Specimens that are grossly hemolyzed, grossly lipemic or grossly icteric will be rejected.** **Stability:** Ambient: **14** days Refrigerated: 14 days Frozen: **30** days	Effective immediately

Test Changes (Cont.)

Test Name	Order Code	Change	Effective Date
EGFR Gene Analysis	**EGFRGN**	**For Interfaced Clients Only: Test build may need to be modified** **Note:** *This test will have a new order code.* **Stability:** Ambient: **Indefinitely for fresh-frozen paraffin-embedded (FFPE) slides; FFPE slides can be transported at ambient temperatures** Refrigerated: **Up to 2 weeks for fine-needle aspirate (FNA) samples** Frozen: **Unacceptable** **Days Performed:** 3 days per week **Reported: 8** days	2/1/19
Factor V Leiden	FVLEI	**Days Performed: 3** days per week **Reported:** 5 days	2/1/19
Flow Cytometric Immunophenotyping for Lymphoma, Tissue	RLLYMP	**CPT:** 88184 x 1, 88185 **x 17,** 88189 x 1	2/24/19
HFE (Hemochromatosis)	HEMDNA	**Methodology:** Fluorescence Monitoring Real-Time Polymerase Chain Reaction (RT-PCR) **Days Performed: 2 days per week** **Reported:** 7 days	2/1/19
HIV-1/2 Ab Confirmatory	HIV12M	**Test Name:** Previously Human Immunodeficiency Virus Types 1 and 2 Antibody	1/31/19
HIV-1 p24 Ag +HIV-1-2 Ab, with reflex to differentiation	HIV12C	**Test Name:** Previously HIV 1 2 Combo (Antigen/Antibody) **Note:** *Changes to HIV 1 2 Combo (Antigen/Antibody) were previously announced in the December Technical Update. Please note that the test name will be changed to HIV-1 p24 Ag +HIV-1-2 Ab, with reflex to differentiation. We apologize for any inconvenience this may have caused.*	1/31/19
IDH1 & IDH2 Gene Analysis	IDH12GN	**Days Performed:** 3 days per week **Reported: 8** days	2/1/19
IDH1 Gene Analysis	IDH1GN	**Days Performed:** 3 days per week **Reported: 8** days	2/1/19
IDH2 Gene Analysis	IDH2GN	**Days Performed:** 3 days per week **Reported: 8** days	2/1/19
Insulin	INSULN	**Note:** *Changes to Insulin were published in the November Technical Update with a go-live date of 1/3/19. Please note that the go-live date has been changed to* ***2/28/19****. We apologize for any inconvenience this may have caused.* **Reference Range: 3.0–25.0 mU/L**	2/28/19
Insulin Antibody	INSAB	**Stability:** Ambient: **1 day** Refrigerated: **7 days** Frozen: **14 days**	2/28/19
Iron	IRN1	**Specimen Requirement:** 1 mL plasma from a lithium heparin (light green) plasma separator tube (PST); Minimum: 0.4 mL; **Separate from cells within 1 hour;** Submit in original tube or aliquot specimen into CCL aliquot tube; Ambient *OR* 1 mL serum from a serum separator (gold) tube; Minimum: 0.4 mL; **Separate from cells within 1 hour;** Ambient	2/19/19
Iron and TIBC	IRON	**Specimen Requirement:** 1 mL plasma from a lithium heparin (light green) plasma separator tube (PST); Minimum: 0.5 mL; **Separate from cells within 1 hour;** Submit in original tube or aliquot specimen into CCL aliquot tube; Ambient *OR* 1 mL serum from a serum separator (gold) tube; Minimum: 0.5 mL; **Separate from cells within 1 hour;** Ambient	2/19/19

Test Changes (Cont.)

Test Name	Order Code	Change	Effective Date
Islet antigen-2 antibody	IA2AB	**Test Name:** Previously Insulinoma Associated Antibody 2 **Note:** *The following alias names will be added: Anti-IA2 antibodies, IA-2 antibody, Insulinoma-associated antibody 2, Islet antigen-2 antibody, Islet cell antigen antibody, Tyrosine phosphatase-related islet antigen 2 antibody. The following alias names will be removed: Beta Cell Autoantibody to IA2, Insulinoma Associated 2 Antibody, Islet Cell Antigen (ICA)* **Special Information: The test is not to be used alone and is to be used in conjunction with other clinical and laboratory findings.** **Clinical Limitation: Plasma is unacceptable. Lipemic and grossly hemolyzed samples should not be tested. Visibly turbid samples will have interference with this assay.** **Clinical Information: The test is used for the quantitative determination of antibodies to Islet Antigen-2 (IA-2) in human serum. It may be useful as an aid in the diagnosis of Type 1 diabetes mellitus.** **Specimen Requirement:** 0.5 mL serum from a serum separator (gold) tube; Minimum: 0.1 mL; **Frozen** **Stability:** Ambient: **8 hours** Refrigerated: **48 hours** Frozen: 14 days **Methodology: Enzyme-Linked Immunosorbent Assay (ELISA)** **Reference Range: < 7.5 U/mL** **CPT: 86341 x 1**	1/11/19
JAK2 Exon 12–15 Sequencing Blood	JAKNON	**Note:** *JAKNON will be added as an alias name.* **Specimen Requirement: 4 mL** whole blood in an EDTA (lavender) tube; Minimum: **1 mL;** Ambient	2/1/19
JAK2 V617F Mutation Detection Blood	JAK2	**Specimen Requirement:** 4 mL whole blood in an EDTA (lavender) tube; Minimum: **1 mL;** Refrigerated **Methodology:** Next Gen Sequencing **Days Performed:** 2 days per week **Reported: 7** days	2/1/19
JAK2 V617F Mutation Detection Bone Marrow	JAK2M	**Specimen Requirement:** 2 mL bone marrow aspirate in an EDTA (lavender) tube; Minimum: **0.5 mL;** Ambient **Days Performed:** 2 days per week **Reported: 7** days	2/1/19
Kappa, Free, Serum	FKAPPS	**Clinical Limitation: The Kappa free light chain results for a given specimen determined with assays from different manufacturers or on different systems can vary due to differences in assay methods and reagent specificity. Values obtained with different assays or systems cannot be used interchangeably. If, in the course of serially monitoring a patient, the assay or system used for determining Kappa free light chain levels is changed, additional sequential testing should be performed. Turbidimetric assays are not suitable for the measurement of highly lipemic or hemolyzed samples or samples containing high levels of circulating immune complexes (CICs) due to the unpredictable degree of non-specific scatter these samples types may generate. Unexpected results should be confirmed using an alternative assay method. This assay has not been validated for the pediatric population.** **Stability:** Ambient: 24 hours Refrigerated: 21 days Frozen: **30** days	2/5/19

Test Changes (Cont.)

Test Name	Order Code	Change	Effective Date
Kappa/Lambda, Free, Serum	KLFRS	**Clinical Limitation: The Kappa/Lambda free light chain results for a given specimen determined with assays from different manufacturers or on different systems can vary due to differences in assay methods and reagent specificity. Values obtained with different assays or systems cannot be used interchangeably. If, in the course of serially monitoring a patient, the assay or system used for determining Kappa/Lambda free light chain levels is changed, additional sequential testing should be performed. Turbidimetric assays are not suitable for the measurement of highly lipemic or hemolyzed samples or samples containing high levels of circulating immune complexes (CICs) due to the unpredictable degree of non-specific scatter these samples types may generate. Unexpected results should be confirmed using an alternative assay method. This assay has not been validated for the pediatric population.** **Stability:** Ambient: 24 hours Refrigerated: 21 days Frozen: **30** days	2/5/19
KIT Gene Analysis	**KITGN**	**For Interfaced Clients Only: Test build may need to be modified** **Note:** *This test will have a new order code.* **Stability:** Ambient: **Indefinitely for fresh-frozen paraffin-embedded (FFPE) slides; FFPE slides can be transported at ambient temperatures** Refrigerated: **2 weeks for fine-needle aspirate (FNA) samples** Frozen: **Unacceptable** **Days Performed:** 3 days per week **Reported: 8** days	2/1/19
KRAS Gene Analysis	**KRASGN**	**For Interfaced Clients Only: Test build may need to be modified** **Note:** *This test will have a new order code.* **Stability:** Ambient: **Indefinitely for fresh-frozen paraffin-embedded (FFPE) slides; FFPE slides can be transported at ambient temperatures** Refrigerated: **2 weeks for fine-needle aspirate (FNA) samples** Frozen: **Unacceptable** **Days Performed:** 3 days per week **Reported: 8** days	2/1/19
Lambda, Free, Serum	FLAMBS	**Clinical Limitation: The Lambda free light chain results for a given specimen determined with assays from different manufacturers or on different systems can vary due to differences in assay methods and reagent specificity. Values obtained with different assays or systems cannot be used interchangeably. If, in the course of serially monitoring a patient, the assay or system used for determining Kappa free light chain levels is changed, additional sequential testing should be performed. Turbidimetric assays are not suitable for the measurement of highly lipemic or hemolyzed samples or samples containing high levels of circulating immune complexes (CICs) due to the unpredictable degree of non-specific scatter these samples types may generate. Unexpected results should be confirmed using an alternative assay method. This assay has not been validated for the pediatric population.** **Stability:** Ambient: 24 hours Refrigerated: 21 days Frozen: **30** days	2/5/19
Lung Cancer Hotspot Gene Panel	LNG550	**Note:** *NGSLUNG will be added as an alias name.* **Days Performed:** 3 days per week **Reported: 8** days	2/1/19
LYME AB Early Disease (≤ 30 days of signs and symptoms), with Reflex	LMERLY	**Days Performed:** Monday–**Friday** **Reported:** 1–**4** days	1/3/19

Test Changes (Cont.)

Test Name	Order Code	Change	Effective Date
LYME AB Late Disease (> 30 days of signs or symptoms), with Reflex	LMLATE	**Days Performed:** Monday–**Friday** **Reported:** 1–**4** days	1/3/19
Measles IgG Antibody	MEASLG	**Days Performed: Monday–Friday** **Reported:** 1–**4** days	1/3/19
Melanoma Hotspot Panel v2 NGS	**NGSMEL**	**For Interfaced Clients Only: Test build may need to be modified** **Note:** *This test will have a new order code.* **Days Performed:** 3 days per week **Reported: 8** days	2/1/19
MET Gene Analysis	**METNGS**	**For Interfaced Clients Only: Test build may need to be modified** **Note:** *This test will have a new order code. METNGS will be added as an alias name.* **Days Performed:** 3 days per week **Reported: 8** days	2/1/19
MGMT Methylation	**MGMT**	**For Interfaced Clients Only: Test build may need to be modified** **Note:** *This test will have a new order code. MGMT will be added as an alias name.* **Days Performed: 2 days per week** **Reported:** 7 days	2/1/19
MLH1 Promoter Hypermethylation	**MLH1PH**	**For Interfaced Clients Only: Test build may need to be modified** **Note:** *This test will have a new order code.* **Days Performed: 2 days per week** **Reported:** 7 days	2/1/19
MSI (PCR) X 2	MSICCT	**Stability:** Ambient: Whole Blood–**48 hours;** Paraffin-embedded tissue–Indefinitely Refrigerated: Whole blood–7 days Frozen: Unacceptable	2/1/19
MTHFR Gene Analysis	MTHF	**Clinical Information:** May be used for evaluation of hyperhomocysteinemia. **Specimen Requirement:** 4 mL whole blood in an EDTA (lavender) tube; Minimum: 1 mL; **Ambient** **Stability:** Ambient: **48** hours Refrigerated: **7** days Frozen: Unacceptable **Methodology:** High Resolution Melt Analysis **Real-Time** Polymerase Chain Reaction (**RT-**PCR) **Days Performed:** 1 day per week **Reported: 8** days	2/1/19
Mumps IgG Antibody	MUMPSG	**Days Performed: Monday–Friday** **Reported:** 1–**4** days	1/3/19

Test Changes (Cont.)

Test Name	Order Code	Change	Effective Date
Mycobacterium tuberculosis (MTB) and Rifampin Resistance Detection by PCR	MTBRIF	**Special Information: Species and subspecies within the M. tuberculosis complex are not distinguished. If positive for M. tuberculosis complex, a result for rifampin resistance is reported. Although 95% of mutations conferring rifampin resistance will be detected, other resistance mutations are possible. In vitro susceptibility testing is required. Similarly, false positive rifampin resistance may occur due to mutations that do not confer resistance. Culture is always performed when Polymerase Chain Reaction (PCR) is requested because culture is more sensitive. Additionally, culture provides organisms for susceptibility testing and optimizes detection of non-tuberculous mycobacteria.** **Clinical Information: This order code includes 6 week acid fast culture and stain as well as Cepheid GeneXpert MTB/RIF assay testing performed on original sample within 1–2 days of submission. The Xpert MTB/RIF assay should be performed on specimens from patients for whom there is clinical suspicion of tuberculosis and who have received less than 3 days of anti-tuberculosis therapy. Since M. tuberculosis typically takes 2 to 3 weeks to grow in conventional culture, PCR is recommended for rapid detection of M. tuberculosis in sputum specimens. PCR is 98% sensitive for detection of smear positive/culture positive pulmonary infection. M. tuberculosis may also be detected in smear-negative sputum samples because of the greater sensitivity of the MTB/RIF assay compared to acid fast microscopy. A positive result may occur in the presence of non-viable M. tuberculosis. A negative result does not rule out infection. The predictive value for the absence of smear positive/culture positive tuberculosis is 99.7% for one negative Xpert PCR assay and 100% for two negative Xpert PCR assays. Therefore, the Xpert assay can be used to help determine if continued isolation is warranted in patients with suspected pulmonary tuberculosis. (Steingart Cochran Rev 2013; Luetkemeyer CID 2016)** **Days Performed:** 7 days per week **Reported: 8 weeks**	Effective immediately
NRAS Gene Analysis	**NRASGN**	**For Interfaced Clients Only: Test build may need to be modified** **Note:** *This test will have a new order code.* **Stability:** Ambient: **Indefinitely for fresh-frozen paraffin-embedded (FFPE) slides; FFPE slides can be transported at ambient temperatures** Refrigerated: **2 weeks for fine-needle aspirate (FNA) samples** Frozen: **Unacceptable** **Days Performed:** 3 days per week **Reported: 8** days	2/1/19
PNH Panel by FCM	PNHPNL	**Stability:** Ambient: 48 hours Refrigerated: **Unacceptable** Frozen: Unacceptable	1/15/19
PSA	PSA	**Stability:** Ambient: 24 hours Refrigerated: **5** days Frozen: 24 weeks	1/22/19
PSA, Free	PSATF	**Stability:** Ambient: 8 hours Refrigerated: **5** days Frozen: 12 weeks	1/22/19
PSA, Screening	PSAS1	**Stability:** Ambient: 24 hours Refrigerated: **5** days Frozen: 24 weeks	1/22/19
Reticulin IgA and IgG Antibodies	RETAB	**Specimen Requirement: 0.8 mL** serum from a serum separator (gold) tube; Minimum: **0.4 mL;** Centrifuge and aliquot serum into standard transport tube; Refrigerated *OR* **0.8 mL** serum from a plain no additive (red) tube; Minimum: **0.4 mL;** Centrifuge and aliquot serum into standard transport tube; Refrigerated	12/31/18

Test Changes (Cont.)

Test Name	Order Code	Change	Effective Date
Rubella IgG Antibody	RUBIGG	**Days Performed: Monday–Friday** **Reported:** 1–**4** days	1/3/19
Spinal Muscular Atrophy Carrier Screening and Diagnostic	SMAGEN	**Specimen Requirement:** 4 mL peripheral blood in an EDTA (lavender) tube; Minimum: 0.5 mL; Newborn and infant draws are especially arduous, but a minimum of 0.5 mL is imposed; Blood specimens are transported and stored at room temperature no longer than **48 hours; Ambient** **Stability:** Ambient: Blood may be transported ambient temperature within **48 hours** Refrigerated: Blood may be transported ambient temperature within **48 hours;** After **48 hours** blood must be stored at 2–8 °C for up to 7 days Frozen: Frozen samples will be rejected **Days Performed:** 2 days per week **Reported:** 7 days	1/2/19
Varicella-Zoster IgG Ab	VZVG2	**Days Performed: Monday–Friday** **Reported:** 1–**4** days	1/3/19

New Tests

Test Name	Order Code	Change	Effective Date
Acylcarnitines, Plasma w/ No Interpretation	ACYLNI	**Note:** *This test was previously announced in the December Technical Update.* **Price:** $416.00	1/29/19
Amino Acids, CSF w/ Basic Interpretation	CAABI	**Note:** *This test was previously announced in the December Technical Update.* **Price:** $404.00 (non-discountable)	1/29/19
Amino Acids, CSF w/ No Interpretation	CAANI	**Note:** *This test was previously announced in the December Technical Update.* **Price:** $275.00 (non-discountable)	1/29/19
Amino Acids, Plasma w/ Basic Interpretation	PAABI	**Note:** *This test was previously announced in the December Technical Update.* **Price:** $404.00 (non-discountable)	1/29/19
Amino Acids, Plasma w/ No Interpretation	PAANI	**Note:** *This test was previously announced in the December Technical Update.* **Price:** $275.00 (non-discountable)	1/29/19
Amino Acids, Urine w/ Basic Interpretation	UAABI	**Note:** *This test was previously announced in the December Technical Update.* **Price:** $404.00 (non-discountable)	1/29/19
Amino Acids, Urine w/ No Interpretation	UAANI	**Note:** *This test was previously announced in the December Technical Update.* **Price:** $275.00 (non-discountable)	1/29/19
BCR/ABL1 p190 Quantitative PCR Blood	P190PB	**Special Information:** Clearly indicate specimen type on label. External client shipping instructions: Ship "Priority Overnight;" do not ship on Fridays or the day preceding a holiday. **Clinical Limitation:** This assay does not detect minor or micro breakpoints, microdeletions, or mutations. Some specimens with very high levels of BCR/ABL1 major transcript (e13a2 and/or e14a2) may be displayed as a low p190 positive. **Specimen Requirement:** 10 mL whole blood in an EDTA (lavender) tube; Minimum: 4 mL; Ambient **Stability:** Ambient: 48 hours Refrigerated: 7 days Frozen: Unacceptable **Methodology:** Polymerase Chain Reaction (PCR), Quant **Interpretive Data:** p190 BCR/ABL1 transcripts are not detected **Days Performed:** 4 days per week **Reported:** 5 days **CPT:** 81207 x 1 **Price:** $863.00 (non-discountable)	2/28/19
BCR/ABL1 p190 Quantitative PCR Bone Marrow	P190BM	**Special Information:** Clearly indicate specimen type on label. External client shipping instructions: Ship "Priority Overnight;" do not ship on Fridays or the day preceding a holiday. **Clinical Limitation:** This assay does not detect minor or micro breakpoints, microdeletions, or mutations. Some specimens with very high levels of BCR/ABL1 major transcript (e13a2 and/or e14a2) may be displayed as a low p190 positive. **Specimen Requirement:** 5 mL bone marrow in an EDTA (lavender) tube; Minimum: 2 mL; Ambient **Stability:** Ambient: 48 hours Refrigerated: 7 days Frozen: Unacceptable **Methodology:** Polymerase Chain Reaction (PCR), Quant **Interpretive Data:** p190 BCR/ABL1 transcripts are not detected **Days Performed:** 4 days per week **Reported:** 5 days **CPT:** 81207 x 1 **Price:** $863.00 (non-discountable)	2/28/19

New Tests (Cont.)

Test Name	Order Code	Change	Effective Date
BCR/ABL1 p210 Quantitative PCR Blood	P210PB	**Special Information:** Clearly indicate specimen type on label. External client shipping instructions: Ship "Priority Overnight;" do not ship on Fridays or the day preceding a holiday. **Clinical Limitation:** This assay is designed to detect, but not distinguish between the BCR/ABL1 fusion transcripts e13a2 (b2a2) and e14a2 (b3a2). This assay does not detect minor or micro breakpoints, microdeletions, or mutations. **Specimen Requirement:** 10 mL whole blood in an EDTA (lavender) tube; Minimum: 4 mL; Ambient **Stability:** Ambient: 48 hours Refrigerated: 7 days Frozen: Unacceptable **Methodology:** Polymerase Chain Reaction (PCR), Quant **Interpretive Data:** p210 BCR/ABL1 transcripts are not detected **Days Performed:** 4 days per week **Reported:** 5 days **CPT:** 81206 x 1 **Price:** $746.00 (non-discountable)	2/28/19
BCR/ABL1 p210 Quantitative PCR Bone Marrow	P210BM	**Special Information:** Clearly indicate specimen type on label. External client shipping instructions: Ship "Priority Overnight;" do not ship on Fridays or the day preceding a holiday. **Clinical Limitation:** This assay is designed to detect, but not distinguish between the BCR/ABL1 fusion transcripts e13a2 (b2a2) and e14a2 (b3a2). This assay does not detect minor or micro breakpoints, microdeletions, or mutations. **Specimen Requirement:** 4 mL bone marrow in an EDTA (lavender) tube; Minimum: 2 mL; Ambient **Stability:** Ambient: 48 hours Refrigerated: 7 days Frozen: Unacceptable **Methodology:** Polymerase Chain Reaction (PCR), Quant **Interpretive Data:** p210 BCR/ABL1 transcripts are not detected **Days Performed:** 5 days per week **Reported:** 5 days **CPT:** 81206 x 1 **Price:** $1180.00 (non-discountable)	2/28/19
NTRK Gene Analysis	NTRKGN	**Specimen Requirement:** 10 mm square formalin-fixed paraffin-embedded (FFPE) tissue block; FFPE tissue slides; Transport and store slides at ambient temperature; 10 unstained sections FFPE tissue on charged, unbaked slides plus one H&E stained slide with best tumor area circled by pathologist; Ambient **Stability:** Ambient: Formalin-fixed paraffin-embedded tissue slides; Transport and store slides at ambient temperature Refrigerated: Unacceptable Frozen: Unacceptable **Methodology:** Next Gen Sequencing **Days Performed:** 1 day per week **Reported:** 14 days **CPT:** 81445 x 1, 88381 x 1 **Price:** $1942.00 (non-discountable)	1/22/19
Organic Acids Ur, Quant w/ No Interpretation	UORANI	**Note:** *This test was previously announced in the December Technical Update.* **Price:** $85.00 (non-discountable)	1/29/19

New Tests (Cont.)

Test Name	Order Code	Change	Effective Date
Respiratory Panel by PCR	RPPCR	**Note:** *The Respiratory Panel by PCR was previously announced in the November Technical Update with a go-live date of 1/8/19. Due to unforeseen circumstances, the go-live date has been changed to 2/26/19. We apologize for any inconvenience this may have caused.*	2/26/19

Fee Increases

Test Name	Order Code	List Fee	CPT Code	Effective Date
Creutzfeldt-Jakob Disease	CJD	$170.00 (non-discountable)	0035U, 84182, 86317	1/2/19

Discontinued Tests

Test Name	Order Code	Test Information	Effective Date
BCR/ABL p190 RT-PCR, Quantitative	190PCR	This test will no longer be available. Suggest ordering BCR/ABL1 p190 Quantitative PCR Blood (P190PB) or BCR/ABL1 p190 Quantitative PCR Bone Marrow (P190BM).	2/28/19
BCRABL p210 RTPCR Quantitative	BCRPCR	This test will no longer be available. Suggest ordering BCR/ABL1 p210 Quantitative PCR Blood (P210PB) or BCR/ABL1 p210 Quantitative PCR Bone Marrow (P210BM).	2/28/19
Respiratory Viral Panel by PCR	RVPPCR	**Note:** *This test was previously announced in the November Technical Update with a discontinuation date of 1/8/19. Due to unforeseen circumstances, the date for discontinuation has been changed to 2/26/19. We apologize for any inconvenience this may have caused.*	2/26/19