

# Cleveland Clinic Laboratories

## Technical Update • July 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](http://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](mailto:clientservices@ccf.org).

| Test Update Page # | Summary of Changes by Test Name                     | Name Change Order Code | New Test | Test Discontinued | Special Information | Specimen Requirement | Component Change(s) | Days Performed/Reported | Reference Range Methodology | Stability | CPT | Fee |
|--------------------|---|------------------------|----------|-------------------|---------------------|----------------------|---------------------|-------------------------|-----------------------------|-----------|-----|-----|
| 3                  | 17-Hydroxyprogesterone, Urine                       |                        |          |                   |                     |                      |                     |                         |                             |           |     |     |
| 10                 | Allergen, NW Carolina Regional Panel                |                        |          |                   |                     |                      |                     |                         |                             |           |     |     |
| 6                  | BCR-ABL Qualitative Multiplex RT-PCR Bone Marrow    |                        |          |                   |                     |                      |                     |                         |                             |           |     |     |
| 10                 | Beta Galactosidase, Leukocytes                      |                        |          |                   |                     |                      |                     |                         |                             |           |     |     |
| 3, 9               | BRAF Gene Analysis                                  |                        |          |                   |                     |                      |                     |                         |                             |           |     |     |
| 10                 | BRAF V600E Blood, Bone Marrow                       |                        |          |                   |                     |                      |                     |                         |                             |           |     |     |
| 10                 | Cadmium Exposure Panel, OSHA                        |                        |          |                   |                     |                      |                     |                         |                             |           |     |     |
| 3                  | Chromosome Analysis, Chorionic Villus               |                        |          |                   |                     |                      |                     |                         |                             |           |     |     |
| 3, 9               | Colon Cancer Hotspot Panel v2 NGS                   |                        |          |                   |                     |                      |                     |                         |                             |           |     |     |
| 3, 9               | EGFR Gene Analysis                                  |                        |          |                   |                     |                      |                     |                         |                             |           |     |     |
| 3, 9               | EGFR Mutation Analysis, Tissue                      |                        |          |                   |                     |                      |                     |                         |                             |           |     |     |
| 9                  | FISH for 8;21 Translocation for AML Blood           |                        |          |                   |                     |                      |                     |                         |                             |           |     |     |
| 6                  | FISH for 8;21 Translocation for AML Bone Marrow     |                        |          |                   |                     |                      |                     |                         |                             |           |     |     |
| 6                  | FISH for Acute Myeloid Leukemia Bone Marrow         |                        |          |                   |                     |                      |                     |                         |                             |           |     |     |
| 9                  | FISH for Acute Myeloid Leukemia Panel Blood         |                        |          |                   |                     |                      |                     |                         |                             |           |     |     |
| 9                  | FISH for Aggressive B-Cell Lymphoma Blood           |                        |          |                   |                     |                      |                     |                         |                             |           |     |     |
| 6                  | FISH for Aggressive B-Cell Lymphoma Bone Marrow     |                        |          |                   |                     |                      |                     |                         |                             |           |     |     |
| 9                  | FISH for B Lymphoblastic Leukemia Panel Blood       |                        |          |                   |                     |                      |                     |                         |                             |           |     |     |
| 6                  | FISH for B Lymphoblastic Leukemia Panel Bone Marrow |                        |          |                   |                     |                      |                     |                         |                             |           |     |     |
| 9                  | FISH for CBFβ/MYH11 Blood                           |                        |          |                   |                     |                      |                     |                         |                             |           |     |     |
| 6                  | FISH for CBFβ/MYH11 Bone Marrow                     |                        |          |                   |                     |                      |                     |                         |                             |           |     |     |

Test Update  
Page #

Summary of Changes  
by Test Name

| Order Code | Name Change  | Test Discontinued | Special Information | Specimen Requirement | Component Change(s) | Methodology | Days Performed/Reported | Reference Range | Stability | CPT | Fee |
|------------|--|-------------------|---------------------|----------------------|---------------------|-------------|-------------------------|-----------------|-----------|-----|-----|
| 6          |  |                   |                     |                      |                     |             |                         |                 |           |     |     |
| 6          | FISH for IGH/BCL2 Bone Marrow  |                   |                     |                      |                     |             |                         |                 |           |     |     |
| 9          | FISH for MLL Blood   |                   |                     |                      |                     |             |                         |                 |           |     |     |
| 6          | FISH for MLL Bone Marrow   |                   |                     |                      |                     |             |                         |                 |           |     |     |
| 9          | FISH for Myelodysplasia Blood  |                   |                     |                      |                     |             |                         |                 |           |     |     |
| 6          | FISH for Myelodysplasia Bone Marrow                                    |                   |                     |                      |                     |             |                         |                 |           |     |     |
| 6          | FISH for Myeloproliferative Neoplasm Panel Bone Marrow                 |                   |                     |                      |                     |             |                         |                 |           |     |     |
| 9          | FISH for Myeloproliferative Neoplasms Panel Blood                      |                   |                     |                      |                     |             |                         |                 |           |     |     |
| 9          | FISH for PDGFRA Blood  |                   |                     |                      |                     |             |                         |                 |           |     |     |
| 6          | FISH for PDGFRA Bone Marrow  |                   |                     |                      |                     |             |                         |                 |           |     |     |
| 6          | FISH for PDGFRB Rearrangement Bone Marrow                              |                   |                     |                      |                     |             |                         |                 |           |     |     |
| 9          | FISH for PML/RARA Blood  |                   |                     |                      |                     |             |                         |                 |           |     |     |
| 6          | FISH for PML/RARA Bone Marrow  |                   |                     |                      |                     |             |                         |                 |           |     |     |
| 9          | FISH for RARA Blood  |                   |                     |                      |                     |             |                         |                 |           |     |     |
| 6          | FISH for RARA Bone Marrow  |                   |                     |                      |                     |             |                         |                 |           |     |     |
| 10         | FISH for Trisomy 4 and 10 Blood  |                   |                     |                      |                     |             |                         |                 |           |     |     |
| 6          | FISH for Trisomy 4 and 10 Bone Marrow                                  |                   |                     |                      |                     |             |                         |                 |           |     |     |
| 3          | Hematologic Neoplasm Next Generation Sequencing Panel Marrow           |                   |                     |                      |                     |             |                         |                 |           |     |     |
| 3          | Hematologic Neoplasm Next Generation Sequencing Panel Peripheral Blood |                   |                     |                      |                     |             |                         |                 |           |     |     |
| 3, 10      | IDH1 & IDH2 Gene Analysis  |                   |                     |                      |                     |             |                         |                 |           |     |     |
| 3          | IDH1 Gene Analysis   |                   |                     |                      |                     |             |                         |                 |           |     |     |
| 3          | IDH2 Gene Analysis   |                   |                     |                      |                     |             |                         |                 |           |     |     |
| 4, 10      | Islet antigen-2 antibody   |                   |                     |                      |                     |             |                         |                 |           |     |     |
| 4, 10      | KIT Gene Analysis  |                   |                     |                      |                     |             |                         |                 |           |     |     |
| 4, 10      | KRAS Gene Analysis   |                   |                     |                      |                     |             |                         |                 |           |     |     |
| 4          | Liver Fibrosis, FibroTest-ActiTest                                     |                   |                     |                      |                     |             |                         |                 |           |     |     |
| 4, 10      | Lung Cancer Hotspot Gene Panel   |                   |                     |                      |                     |             |                         |                 |           |     |     |
| 4          | Melanocyte Stimulation Hormone, Alpha (a-MSH)                          |                   |                     |                      |                     |             |                         |                 |           |     |     |
| 4, 10      | Melanoma Hotspot Panel v2 NGS  |                   |                     |                      |                     |             |                         |                 |           |     |     |
| 4, 10      | Mucopolysaccharides, Urine   |                   |                     |                      |                     |             |                         |                 |           |     |     |
| 6          | Next Generation Sequencing Hotspot GIST                                |                   |                     |                      |                     |             |                         |                 |           |     |     |
| 4, 10      | NRAS Gene Analysis   |                   |                     |                      |                     |             |                         |                 |           |     |     |
| 7          | Oligoclonal Banding  |                   |                     |                      |                     |             |                         |                 |           |     |     |
| 10         | Oligoclonal Banding – RL   |                   |                     |                      |                     |             |                         |                 |           |     |     |
| 4-5        | Pan-Solid Tumor NGS Panel  |                   |                     |                      |                     |             |                         |                 |           |     |     |
| 7          | PDGFRA Gene Analysis NGS Hotspot                                       |                   |                     |                      |                     |             |                         |                 |           |     |     |
| 5          | Primidone  |                   |                     |                      |                     |             |                         |                 |           |     |     |
| 7-8        | Prostatic Secretions Culture   |                   |                     |                      |                     |             |                         |                 |           |     |     |
| 5          | Rubella IgG Antibody   |                   |                     |                      |                     |             |                         |                 |           |     |     |
| 5          | Spinal Muscular Atrophy Carrier Screening and Diagnostic               |                   |                     |                      |                     |             |                         |                 |           |     |     |
| 5          | STRATIFY JCV Antibody and Index with Reflex to Inhibition Assay        |                   |                     |                      |                     |             |                         |                 |           |     |     |

## Test Changes

| Test Name  | Order Code | Change  | Effective Date        |
|--|------------|---|-----------------------|
| 17-Hydroxy-progesterone, Urine   | U17OHP     | <p><b>Specimen Requirement: 10 mL</b> 24-hour urine (well-mixed) in a clean container; Minimum: <b>5 mL</b>; Refrigerate during collection; Patient should not be on any corticosteroid, ACTH, estrogen, or gonadotropin medications, if possible, for at least 48 hours prior to start of urine collection; Transfer <b>10 mL</b> aliquot to standard transport tube; Submit total volume; Transport on dry ice is preferred; Separate specimens must be submitted when multiple tests are ordered; Frozen</p> <p><b>Days Performed:</b> Varies</p> <p><b>Reported:</b> 8–11 days</p>  | Effective immediately |
| BRAF Gene Analysis   | BRAFGN     | <b>CPT:</b> 81210 x 1   | 7/9/19                |
| Chromosome Analysis, Chorionic Villus                                  | CVCYTO     | <p><b>For Interfaced Clients Only: Test build may need to be modified</b></p> <p><b>Special Information: Do NOT freeze.</b> Frozen specimens, specimens placed in fixative, improper labeling, and no villi submitted in specimen are unacceptable conditions.</p> <p><b>Clinical Information: Chorionic villi sampling (CVS) chromosome analysis is recommended to be offered to all pregnant women by the American College of Obstetricians and Gynecologists (ACOG) for diagnostic testing (as opposed to just screening) for chromosome abnormalities. Additional specific indications for cytogenetic analysis include abnormal maternal serum screening results, abnormalities seen on ultrasound, family history of a chromosome abnormality, or known parental balanced chromosome rearrangement.</b></p> <p><b>Specimen Requirement: 15–30 mg</b> chorionic villus in <b>RPMI media</b>; Do NOT freeze or place in <b>fixative</b>; Deliver specimen to Cleveland Clinic Laboratories on the day of collection; Ambient</p> <p><b>Stability:</b><br/>           Ambient: <b>5 days (Preferred)</b><br/>           Refrigerated: <b>5 days</b><br/>           Frozen: Unacceptable</p> <p><b>Days Performed: Monday–Saturday</b></p> <p><b>Reported: 6–9 days</b></p> <p><b>CPT:</b> 88235 x 1, 88267 x 1, <b>88280 x 1</b></p> | 8/27/19               |
| Colon Cancer Hotspot Panel v2 NGS                                      | NGSCOL     | <b>CPT:</b> 81210 x 1, 81275 x 1, 81276 x 1, 81311 x 1  | 7/9/19                |
| EGFR Gene Analysis   | EGFRGN     | <b>CPT:</b> 81235 x 1   | 7/9/19                |
| EGFR Mutation Analysis, Tissue   | EGFRTI     | <b>CPT:</b> 81235 x 1   | 7/9/19                |
| Hematologic Neoplasm Next Generation Sequencing Panel Marrow           | HNMNGS     | <b>Special Information: Interrogated genes: ABL1, ASXL1, BCOR, BCORL1, BRAF, CALR, CBL, CDKN2A, CDKN2A, CEBPA, CSF3R, CUX1, DDX41, DNMT3A, EED, ETNK1, ETV6, EZH2, FBXW7, FLT3, GATA1, GATA2, GNAS, IDH1, IDH2, IKZF1, JAK2, JAK3, KDM6A, KIT, KMT2A, KRAS, LUC7L2 (C7orf55), MPL, MYD88, NF1, NOTCH1, NPM1, NRAS, PHF6, PIGA, PPM1D, PRPF8, PTEN, PTPN11, RAD21, RIT1, RUNX1, SETBP1, SF3B1, SH2B3, SMC1A, SMC3, SRSF2, STAG2, STAT3, STAT5B, SUZ12, TET2, TP53, U2AF1, WT1, ZRSR2</b>   | 7/30/19               |
| Hematologic Neoplasm Next Generation Sequencing Panel Peripheral Blood | HNPNGS     | <b>Special Information: Interrogated genes: ABL1, ASXL1, BCOR, BCORL1, BRAF, CALR, CBL, CDKN2A, CDKN2A, CEBPA, CSF3R, CUX1, DDX41, DNMT3A, EED, ETNK1, ETV6, EZH2, FBXW7, FLT3, GATA1, GATA2, GNAS, IDH1, IDH2, IKZF1, JAK2, JAK3, KDM6A, KIT, KMT2A, KRAS, LUC7L2 (C7orf55), MPL, MYD88, NF1, NOTCH1, NPM1, NRAS, PHF6, PIGA, PPM1D, PRPF8, PTEN, PTPN11, RAD21, RIT1, RUNX1, SETBP1, SF3B1, SH2B3, SMC1A, SMC3, SRSF2, STAG2, STAT3, STAT5B, SUZ12, TET2, TP53, U2AF1, WT1, ZRSR2</b>   | 7/30/19               |
| IDH1 & IDH2 Gene Analysis  | IDH12GN    | <b>CPT:</b> 81120 x 1, 81121 x 1  | 7/9/19                |
| IDH1 Gene Analysis   | IDH1GN     | <b>CPT:</b> 81120 x 1   | 7/9/19                |
| IDH2 Gene Analysis   | IDH2GN     | <b>CPT:</b> 81121 x 1   | 7/9/19                |

## Test Changes (Cont.)

| Test Name                                     | Order Code | Change   | Effective Date        |
|---|------------|--|-----------------------|
| Islet antigen-2 antibody                      | IA2AB      | <b>Clinical Information:</b> Anti-insulinoma associated antigen 2 (IA-2) antibody test is used as an aid in diagnosis of type I diabetes mellitus, <b>to predict the risk of progression to type I diabetes mellitus among susceptible individuals, and to predict the necessity of insulin therapy in adult-onset diabetes mellitus. Clinical correlation is required.</b>  | Effective immediately |
| KIT Gene Analysis                             | KITGN      | <b>CPT:</b> 81272 x 1  | 7/9/19                |
| KRAS Gene Analysis                            | KRASGN     | <b>CPT:</b> 81275 x 1, 81276 x 1   | 7/9/19                |
| Liver Fibrosis, FibroTest-ActiTest            | LIVFIB     | <b>Methodology:</b><br>Nephelometry (NEPH)<br>Spectrophotometry (S)<br><b>Reference Range:</b><br>Apolipoprotein A1<br><b>0–17 Years: Not established</b><br><b>18–99 Years (Male): 94–176 mg/dL</b><br><b>18–99 Years (Female): 101–198 mg/dL</b><br>(Note: There are no other reference range changes)   | Effective immediately |
| Lung Cancer Hotspot Gene Panel                | LNG550     | <b>CPT:</b> 81445 x 1  | 7/9/19                |
| Melanocyte Stimulation Hormone, Alpha (a-MSH) | MSHA       | <b>Days Performed:</b> Varies<br><b>Reported:</b> 11–14 days   | Effective immediately |
| Melanoma Hotspot Panel v2 NGS                 | NGSMEL     | <b>CPT:</b> 81210 x 1, 81272 x 1, 81311 x 1  | 7/9/19                |
| Mucopolysaccharides, Urine                    | UMUCPO     | <b>CPT:</b> 82664 x 1, 83864 x 3, <b>84311 x 3</b>   | 7/2/19                |
| NRAS Gene Analysis                            | NRASGN     | <b>CPT:</b> 81311 x 1  | 7/9/19                |
| Pan-Solid Tumor NGS Panel                     | PSTNGS     | <b>Clinical Information: Interrogated Genes–Single Nucleotide Variants (SNV) &amp; Small Insertions or Deletions (indels) [DNA]:</b> AKT1, AKT2, AKT3, ALK, APC, AR, ARID1A, ATM, ATR, BAP1, BARD1, BCL2, BCL6, BRAF, BRCA1, BRCA2, BRIP1, BTK, CARD11, CCND1, CCND2, CCND3, CCNE1, CD79A, CD79B, CDH1, CDK12, CDK4, CDK6, CDKN2A, CEBPA, CHEK1, CHEK2, CREBBP, CSF1R, CTNNB1, DDR2, DNMT3A, EGFR, EP300, ERBB2, ERBB3, ERBB4, ERCC1, ERCC2, ERG, ESR1, EZH2, FAM175A, FANCI, FANCL, FBXW7, FGF10, FGF14, FGF19, FGF2, FGF23, FGF3, FGF4, FGF5, FGF6, FGF7, FGF8, FGF9, FGFR1, FGFR2, FGFR3, FGFR4, FLT1, FLT3, FOXL2, GEN1, GNA11, GNAQ, GNAS, HNF1A, HRAS, IDH1, IDH2, INPP4B, JAK2, JAK3, KDR, KIT, KMT2A, KRAS, LAMP1, MAP2K1, MAP2K2, MCL1, MDM2, MDM4, MET, MLH1, MLLT3, MPL, MRE11A, MSH2, MSH3, MSH6, MTOR, MUTYH, MYC, MYCL, MYCN, MYD88, NBN, NF1, NOTCH1, NOTCH2, NOTCH3, NPM1, NRAS, NRG1, PALB2, PDGFRA, PDGFRB, PIK3CA, PIK3CB, PIK3CD, PIK3CG, PIK3R1, PMS2, PPP2R2A, PTCH1, PTEN, PTPN11, RAD51, RAD51B, RAD51C, RAD51D, RAD54L, RAF1, RB1, RET, RICTOR, ROS1, RPS6KB1, SLX4, SMAD4, SMARCB1, SMO, SRC, STK11, SYNE1, TERT, TET2, TFRC, TP53, TSC1, TSC2, VHL, XRCC2. <b>Copy Number Variation (CNV) [DNA]:</b> AKT2, ALK, AR, ATM, BRAF, BRCA1, BRCA2, CCND1, CCND3, CCNE1, CDK4, CDK6, CHEK1, CHEK2, EGFR, ERBB2, ERBB3, ERCC1, ERCC2, ESR1, FGF1, FGF10, FGF14, FGF19, FGF2, FGF23, FGF3, FGF4, FGF5, FGF6, FGF7, FGF8, FGF9, FGFR1, FGFR2, FGFR3, FGFR4, JAK2, KIT, KRAS, LAMP1, MDM2, MDM4, MET, MYC, MYCL, MYCN, NRAS, NRG1, PDGFRA, PDGFRB, PIK3CA, PIK3CB, PTEN, RAF1, RET, RICTOR, RPS6KB1, TFRC. <b>Gene Fusions [RNA]:</b> ABL1, AKT3, ALK, AR, AXL, BCL2,<br><br>(continued on page 5) | 7/30/19               |

## Test Changes (Cont.)

| Test Name   | Order Code | Change   | Effective Date        |
|---|------------|--|-----------------------|
| Pan-Solid Tumor NGS Panel<br><i>(continued from page 4)</i>     |            | <p><b>BRAF, BRCA1, BRCA2, CDK4, CSF1R, EGFR, EML4, ERBB2, ERG, ESR1, ETS1, ETV1, ETV4, ETV5, EWSR1, FGFR1, FGFR2, FGFR3, FGFR4, FLI1, FLT1, FLT3, JAK2, KDR, KIF5B, KIT, KMT2A, MET, MLLT3, MSH2, MYC, NOTCH1, NOTCH2, NOTCH3, NRG1, NTRK1, NTRK2, NTRK3, PAX3, PAX7, PDGFRA, PDGFRB, PIK3CA, PPARG, RAF1, RET, ROS1, RPS6KB1, TMPRSS2</b></p> <p><b>Clinical Limitation:</b> This test does not differentiate between somatic and germline variants.</p> <p><b>Specimen Requirement:</b> 10 mm square formalin-fixed paraffin-embedded (FFPE) tissue block; FFPE tissue slides; 10 unstained section FFPE tissue on charged, unbaked slides plus one H&amp;E stained section with best tumor area circled by a pathologist (<b>minimum of 20% tumor content is required</b>); <b>Ambient</b></p> <p>*OR* 10 unstained slides cut at 7 microns AND 8 unstained slides cut at 4 microns</p> |                       |
| Primidone   | PRIM       | <p><b>Stability:</b><br/>           Ambient: After separation from cells: 48 hours<br/>           Refrigerated: After separation from cells: 7 days<br/>           Frozen: After separation from cells: <b>30</b> days</p>   | Effective immediately |
| Rubella IgG Antibody  | RUBIGG     | <p><b>Clinical Information:</b> A negative result suggests no history of Rubella vaccination or exposure to Rubella virus; however, some individuals with past history of Rubella vaccination may test negative using this test as immunity to Rubella virus wanes over time after vaccination. Please correlate with vaccination history if applicable. Equivocal results cannot exclude non-specific reactivity or recent or past exposure to Rubella virus including vaccination. Equivocal result may also be seen due to waning immunity to Rubella virus or presence of passively-transferred antibodies. Please correlate with patient's history.</p> <p><b>Stability:</b><br/>           Ambient: 48 hours<br/>           Refrigerated: 7 days<br/>           Frozen: <b>14</b> days</p>   | 8/5/19                |
| Spinal Muscular Atrophy Carrier Screening and Diagnostic        | SMAGEN     | <b>For Interfaced Clients Only: Test build may need to be modified</b>   | 7/22/19               |
| STRATIFY JCV Antibody and Index with Reflex to Inhibition Assay | JCVIDX     | <p><b>Special Information:</b> The STRATIFY JCV Antibody and Index with Reflex to Inhibition will be performed at no charge. Interpretive criteria: Negative: &lt; 0.20; Indeterminate: 0.20–0.40; Positive: &gt; 0.40. <b>Hemolyzed specimens will be rejected.</b></p> <p><b>Specimen Requirement:</b> 0.5 mL serum from a serum separator (gold) tube; Minimum: <b>0.25 mL</b>; Ambient</p> <p>*OR* 0.5 mL serum from a plain no additive (red) tube; Minimum: <b>0.25 mL</b>; Ambient</p> <p>*OR* 0.5 mL plasma from an EDTA (lavender) tube; Minimum: <b>0.25 mL</b>; Ambient</p> <p><b>Days Performed:</b> Tuesday–Saturday</p> <p><b>Reported:</b> 2–5 days</p>   | 7/29/19               |

# New Tests

| Test Name  | Order Code | Change  | Effective Date        |
|--|------------|---|-----------------------|
| BCR-ABL Qualitative Multiplex RT-PCR Bone Marrow       | BCRQLM     | <b>Note:</b> This test was previously announced in the June Technical Update.<br><b>CPT:</b> 81206 x 1, 81207 x 1, 81208 x 1, G0452 x 1<br><b>Price:</b> \$704.00 (non-discountable)  | 8/6/19                |
| FISH for 8;21 Translocation for AML Bone Marrow        | AMLFBM     | <b>Note:</b> This test was previously announced in the June Technical Update.<br><b>Price:</b> \$656.00 (non-discountable)  | 8/6/19                |
| FISH for Acute Myeloid Leukemia Bone Marrow            | FAMLPM     | <b>Note:</b> This test was previously announced in the June Technical Update.<br><b>Price:</b> \$2355.00 (non-discountable)   | 8/6/19                |
| FISH for Aggressive B-Cell Lymphoma Bone Marrow        | FABCBM     | <b>Note:</b> This test was previously announced in the June Technical Update.<br><b>Price:</b> \$1275.00 (non-discountable)   | 8/6/19                |
| FISH for B Lymphoblastic Leukemia Panel Bone Marrow    | FSBLLM     | <b>Note:</b> This test was previously announced in the June Technical Update.<br><b>Price:</b> \$2495.00 (non-discountable)   | 8/6/19                |
| FISH for CBF/ MYH11 Bone Marrow                        | INV16M     | <b>Note:</b> This test was previously announced in the June Technical Update.<br><b>Price:</b> \$656.00 (non-discountable)  | 8/6/19                |
| FISH for IGH/BCL2 Bone Marrow                          | FSFCLM     | <b>Note:</b> This test was previously announced in the June Technical Update.<br><b>Price:</b> \$495.00 (non-discountable)  | 8/6/19                |
| FISH for MLL Bone Marrow                               | MLLFBM     | <b>Note:</b> This test was previously announced in the June Technical Update.<br><b>Price:</b> \$735.00 (non-discountable)  | 8/6/19                |
| FISH for Myelodysplasia Bone Marrow                    | FSMDSM     | <b>Note:</b> This test was previously announced in the June Technical Update.<br><b>Price:</b> \$1245.00 (non-discountable)   | 8/6/19                |
| FISH for Myeloproliferative Neoplasm Panel Bone Marrow | MPNFMSM    | <b>Note:</b> This test was previously announced in the June Technical Update.<br><b>CPT:</b> 88237 x 1, 88271 x 9, 88275 x 4, 88291 x 1<br><b>Price:</b> \$1365.00 (non-discountable) | 8/6/19                |
| FISH for PDGFRA Bone Marrow                            | PGFRAM     | <b>Note:</b> This test was previously announced in the June Technical Update.<br><b>Price:</b> \$656.00 (non-discountable)  | 8/6/19                |
| FISH for PDGFRB Rearrangement Bone Marrow              | PDGFBM     | <b>Note:</b> This test was previously announced in the June Technical Update.<br><b>Price:</b> \$656.00 (non-discountable)  | 8/6/19                |
| FISH for PML/RARA Bone Marrow                          | APLFBM     | <b>Note:</b> This test was previously announced in the June Technical Update.<br><b>Price:</b> \$656.00 (non-discountable)  | 8/6/19                |
| FISH for RARA Bone Marrow                              | RARFSM     | <b>Note:</b> This test was previously announced in the June Technical Update.<br><b>Price:</b> \$656.00 (non-discountable)  | 8/6/19                |
| FISH for Trisomy 4 and 10 Bone Marrow                  | FT410M     | <b>Note:</b> This test was previously announced in the June Technical Update.<br><b>Price:</b> \$795.00 (non-discountable)  | 8/6/19                |
| Next Generation Sequencing Hotspot GIST                |            | <b>Note:</b> This test was previously announced in the June Technical Update.<br><b>CPT:</b> 81210 x 1, 81272 x 1, 81314 x 1, 81479 x 1<br><b>Price:</b> \$1165.00 (non-discountable) | Effective immediately |

## New Tests (Cont.)

| Test Name                        | Order Code | Change   | Effective Date        |
|----------------------------------|------------|--|-----------------------|
| Oligoclonal Banding              | OLIGO      | <p><b>Clinical Information:</b> The test is used as an aid in diagnosis and monitoring of multiple sclerosis. Clinical correlation is required.</p> <p><b>Specimen Requirement:</b> 1 mL cerebrospinal fluid (CSF) in a clean container; Minimum: 0.5 mL; Collect blood and cerebrospinal fluid (CSF) within same 24-hour period; Refrigerated</p> <p>*AND* 1 mL serum from a serum separator (gold) tube; Minimum: 0.5 mL; Collect blood and cerebrospinal fluid (CSF) within same 24-hour period; Refrigerated</p> <p><b>Stability:</b><br/>           Ambient: 1 day<br/>           Refrigerated: 7 days<br/>           Frozen: 14 days</p> <p><b>Methodology:</b> Isoelectric Focusing</p> <p><b>Reference Range:</b> Oligoclonal bands are not seen in the CSF</p> <p><b>Days Performed:</b> 3 days per week</p> <p><b>Reported:</b> 2–5 days</p> <p><b>CPT:</b> 83916 x 1</p> <p><b>Price:</b> \$112.00</p>  | 8/27/19               |
| PDGFRA Gene Analysis NGS Hotspot |            | <p><b>Note:</b> <i>This test was previously announced in the June Technical Update.</i></p> <p><b>Days Performed:</b> 3 days per week</p> <p><b>Reported:</b> 8 days</p> <p><b>CPT:</b> 81314 x 1</p> <p><b>Price:</b> \$595.00 (non-discountable)</p>   | Effective immediately |
| Prostatic Secretions Culture     | PSCUL      | <p><b>Special Information:</b> Prostatic secretions: Multiple samples are cultured. If one specimen grows far more bacteria than others, the infection is localized to the urethra, bladder, or prostate. VB1 (voided bladder 1)—First 10 cc of urine represents urethra, VB2—midstream urine represents bladder EPS (expressed prostatic fluid)—Prostate massaged; represents prostate and VB3—also represents prostate.</p> <p><b>Clinical Information:</b> To transfer urine into C&amp;S preservative tube: Submerge the tip of transfer straw into urine specimen. Push the gray top C&amp;S preservative tube into the transfer straw. Hold in position until flow stops. It must be filled to the minimum fill line on the tube (3 mL). Remove tube leaving transfer straw in urine specimen container. Shake tube vigorously to mix sample. If both a UA (red/yellow) and C&amp;S tube (gray top) are being collected, transfer urine to C&amp;S tube first. Urine specimens are processed based on whether the specimen was collected with an invasive (straight catheter, suprapubic aspirate, cystoscopy) or noninvasive (midstream clean catch, indwelling catheter, stoma) method. A low colony count is performed on urine specimens collected via invasive methods. Normal flora from the urethra, vagina and perineum often contaminate urine specimens. Quantitation of bacteria helps to distinguish contaminated specimens from those representing infection. The most common uropathogens are normal intestinal flora organisms such as <i>Escherichia coli</i>, <i>Klebsiella</i> spp., <i>Enterobacter</i> spp., <i>Proteus</i> spp. and <i>Enterococcus</i> spp. The level of work-up is based on the specimen type, number of different organisms growing, and the quantity of potential uropathogens in relation to urogenital flora. If culture is positive, identification will be performed on clinically significant organisms at an additional charge. Identification CPT codes that may apply include: 87077, 87088, 87106, 87107, 87153. Antimicrobial susceptibilities are performed when indicated, and the following CPT codes may apply: 87181, 87184, 87185, 87186</p> <p><b>Specimen Requirement:</b> 4 mL random urine in a BD Vacutainer C&amp;S preservative (gray) tube; Minimum: 3 mL; Ambient</p> <p>*OR* 4 mL random urine in a sterile container; Minimum: 3 mL; Urine collected without preservative should be refrigerated within 30 minutes and transported to the Microbiology Laboratory at Cleveland Clinic Laboratories within 24 hours; Refrigerated</p> <p><i>(continued on page 8)</i></p> | 7/9/19                |

## New Tests (Cont.)

| Test Name  | Order Code | Change  | Effective Date |
|--|------------|---|----------------|
| Prostatic Secretions Culture<br><i>(continued from page 7)</i> |            | <p><b>Stability:</b><br/>                     Ambient: Preserved: 48 hours; Unpreserved: 2 hours<br/>                     Refrigerated: Preserved: 48 hours; Unpreserved: 24 hours<br/>                     Frozen: Unacceptable</p> <p><b>Methodology:</b> Culture</p> <p><b>Reference Range:</b> No growth</p> <p><b>Days Performed:</b> Sunday–Saturday</p> <p><b>Reported:</b> 6 days</p> <p><b>CPT:</b> 87086 x 1</p> <p><b>Price:</b> \$46.00</p> |                |

## Fee Reductions

| Test Name   | Order Code | List Fee                     | CPT Code                                    | Effective Date |
|---|------------|------------------------------|---|----------------|
| BRAF Gene Analysis                                | BRAFGN     | \$430.00 (non-discountable)  | 81210                                       | 7/9/19         |
| Colon Cancer Hotspot Panel v2 NGS                 | NGSCOL     | \$926.00                     | 81210,<br>81275,<br>81276,<br>81311         | 7/9/19         |
| EGFR Gene Analysis                                | EGFRGN     | \$625.00 (non-discountable)  | 81235                                       | 7/9/19         |
| EGFR Mutation Analysis, Tissue                    | EGFRTI     | \$858.00 (non-discountable)  | 81235                                       | 7/9/19         |
| FISH for 8;21 Translocation for AML Blood         | AMLFSH     | \$656.00 (non-discountable)  | 88237,<br>88271 x 2,<br>88275,<br>88291     | 8/6/19         |
| FISH for Acute Myeloid Leukemia Panel Blood       | FAMLPN     | \$2355.00 (non-discountable) | 88237,<br>88271 x 8,<br>88275 x 4,<br>88291 | 8/6/19         |
| FISH for Aggressive B-Cell Lymphoma Blood         | FABCFP     | \$1275.00 (non-discountable) | 88237,<br>88271 x 8,<br>88275 x 4,<br>88291 | 8/6/19         |
| FISH for B Lymphoblastic Leukemia Panel Blood     | FSHBLL     | \$2495.00 (non-discountable) | 88237,<br>88271 x 9,<br>88275 x 4,<br>88291 | 8/6/19         |
| FISH for CBF/ MYH11 Blood                         | INV16F     | \$656.00 (non-discountable)  | 88237,<br>88271 x 2,<br>88275,<br>88291     | 8/6/19         |
| FISH for MLL Blood                                | MLLFSH     | \$735.00 (non-discountable)  | 88237,<br>88271 x 2,<br>88275,<br>88291     | 8/6/19         |
| FISH for Myelodysplasia Blood                     | FSHMDS     | \$1245.00 (non-discountable) | 88237,<br>88271 x 6,<br>88275 x 3,<br>88291 | 8/6/19         |
| FISH for Myeloproliferative Neoplasms Panel Blood | MPNFSH     | \$1275.00 (non-discountable) | 88237,<br>88271 x 9,<br>88275 x 4,<br>88291 | 8/6/19         |
| FISH for PDGFRA Blood                             | PDGFRA     | \$656.00 (non-discountable)  | 88237,<br>88271 x 2,<br>88275,<br>88291     | 8/6/19         |
| FISH for PML/RARA Blood                           | APLFSH     | \$656.00 (non-discountable)  | 88237,<br>88271 x 2,<br>88275,<br>88291     | 8/6/19         |
| FISH for RARA Blood                               | RARFSH     | \$656.00 (non-discountable)  | 88237,<br>88271 x 2,<br>88275,<br>88291     | 8/6/19         |

## Fee Reductions (Cont.)

| Test Name                       | Order Code | List Fee                    | CPT Code                                | Effective Date        |
|---------------------------------|------------|-----------------------------|---|-----------------------|
| FISH for Trisomy 4 and 10 Blood | FHT410     | \$795.00 (non-discountable) | 88237,<br>88271 x 2,<br>88275,<br>88291 | 8/6/19                |
| IDH1 & IDH2 Gene Analysis       | IDH12GN    | \$740.00 (non-discountable) | 81120,<br>81121                         | 7/9/19                |
| Islet antigen-2 antibody        | IA2AB      | \$108.00 (non-discountable) | 86341                                   | Effective immediately |
| KIT Gene Analysis               | KITGN      | \$630.00 (non-discountable) | 81272                                   | 7/9/19                |
| KRAS Gene Analysis              | KRASGN     | \$676.00 (non-discountable) | 81275,<br>81276                         | 7/9/19                |
| Lung Cancer Hotspot Gene Panel  | LNG550     | \$915.00 (non-discountable) | 81445                                   | 7/9/19                |
| Melanoma Hotspot Panel v2 NGS   | NGSMEL     | \$874.00                    | 81210,<br>81272,<br>81311               | 7/9/19                |
| Mucopolysaccharides, Urine      | UMUCPO     | \$700.00 (non-discountable) | 82664,<br>83864 x 3,<br>84311 x 3       | 7/2/19                |
| NRAS Gene Analysis              | NRASGN     | \$665.00 (non-discountable) | 81311                                   | 7/9/19                |

## Discontinued Tests

| Test Name                            | Order Code | Test Information   | Effective Date |
|--------------------------------------|------------|--|----------------|
| Allergen, NW Carolina Regional Panel | NWCAR      | This test will no longer be available. Suggest ordering individual allergens.        | 8/29/19        |
| Beta Galactosidase, Leukocytes       | BGALA      | This test will no longer be available.   | 8/29/19        |
| BRAF V600E Blood, Bone Marrow        | BRAFBM     | This test will no longer be available.   | 8/27/19        |
| Cadmium Exposure Panel, OSHA         | CADEXR     | This test will no longer be available.   | 8/29/19        |
| Oligoclonal Banding – RL             | OLIGOR     | This test will no longer be available. Suggest ordering Oligoclonal Banding (OLIGO). | 8/27/19        |