

Cleveland Clinic Laboratories

Technical Update • June 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.



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Test Changes

Test Name	Order Code	Change	Effective Date
Aspirin/Clopidogrel Resistance (Aggregation) Panel	ASPCLP	Reference Range: Arach Max Aggreg (0–99 Years): 75–100% Max ADP Aggregation (0–99 Years): 65–93% Max	7/30/19
BCR-ABL Qualitative Multiplex RT-PCR	BCRQL	Specimen Requirement: 10 mL blood in an EDTA (lavender) tube; Minimum: 4 mL; Ambient	8/6/19
Cysticercus IgG Ab, Serum	CYSGBL	Special Information: Parallel testing is preferred and convalescent specimens must be received within 30 days from receipt of the acute specimens. Label specimens plainly as 'acute' or 'convalescent.' Cerebrospinal fluid (CSF) is unacceptable. Contaminated, heat-inactivated, hemolyzed, icteric, or lipemic specimens will be rejected. This test is New York DOH approved.	Effective immediately
		Specimen Requirement: I mL serum from a serum separator (gold) tube; Minimum: 0.1 mL; Label specimen as acute or convalescent; Refrigerated Stability: Ambient: After separation from cells: 48 hours Refrigerated: After separation from cells: 2 weeks	
		Frozen: After separation from cells: 1 year (Avoid repeated freeze/thaw cycles) Reference Range: ≤ 0.8 IV: Negative–No significant level of cysticercosis IgG antibody detected 0.9–1.1 IV: Equivocal–Questionable presence of cysticercosis IgG antibody	
		detected; Repeat testing in 10–14 days may be helpful \geq 1.2 IV: Positive–IgG antibodies to cysticercosis detected, which may suggest current or past infection	
FISH for 5q	5QFSH	Test Name: Previously FISH for 5q Abnormalities	8/6/19
Abnormalities Blood		Note: Special Information will be removed.	
		Clinical Information: Deletions of chromosome 5q or monosomy of chromosome 5 may be seen in acute myeloid leukemia, myelodysplastic syndromes, or other neoplasms.	
		Specimen Requirement: 5–7 mL peripheral blood in an EDTA (lavender) tube; Ambient	
		OR 5–7 mL peripheral blood in a sodium heparin (green) tube; Ambient Stability: Ambient: 48 hours	
		Refrigerated: Acceptable Frozen: Not acceptable	
		Days Performed: 3 days per week	
		CPT: 88237 x 1, 88271 x 2, 88275 x 1, 88291 x 1	
FISH for 7q Deletion	FISH7Q	Test Name: Previously FISH for 7q deletion	8/6/19
Blood		Clinical Information: Deletions of chromosome 7q or monosomy of chromosome 7 may be seen in acute myeloid leukemia, myelodysplastic syndromes, or other neoplasms.	
		Specimen Requirement: 5–7 mL peripheral blood in an EDTA (lavender) tube; Ambient	
		OR 5–7 mL peripheral blood in a sodium heparin (green) tube; Ambient	
		Stability: Ambient: 48 hours Refrigerated: Acceptable	
		Prozen: Unacceptable	
		Reported: 5 days	
		CPT: 88237 x 1, 88271 x 2, 88275 x 1, 88291 x 1	

Test Name	Order Code	Change	Effective Date
FISH for 8;21 Translocation for AML Blood	AMLFSH	Test Name: Previously FISH for 8;21 Translocation for AML Specimen Requirement: 5–7 mL peripheral blood in an EDTA (lavender) tube; Ambient *OR* 5–7 mL peripheral blood in a sodium heparin (green) tube; Ambient Stability: Ambient: 48 hours Refrigerated: Acceptable Frozen: Not acceptable Days Performed: 4 days per week Reported: 5 days CPT: 88237 x 1, 88271 x 2, 88275 x 1, 88291 x 1	8/6/19
FISH for 20q and CEP8 Blood	20Q8FH	Test Name: Previously FISH for 20q and CEP8 Specimen Requirement: 5–7 mL peripheral blood in an EDTA (lavender) tube; Ambient *OR* 5–7 mL peripheral blood in a sodium heparin (green) tube; Ambient Stability: Ambient: 48 hours Refrigerated: Acceptable Frozen: Unacceptable Days Performed: 3 days per week Reported: 5 days CPT: 88237 x 1, 88271 x 2, 88275 x 1, 88291 x 1	8/6/19
FISH for Acute Myeloid Leukemia Panel Blood	FAMLPN	Test Name: Previously FISH for Acute Myeloid Leukemia Panel Specimen Requirement: 5–7 mL peripheral blood in an EDTA (lavender) tube; Ambient *OR* 5–7 mL peripheral blood in a sodium heparin (green) tube; Ambient Stability: Ambient: 48 hours Refrigerated: Acceptable Frozen: Not acceptable Days Performed: 4 days per week Reported: 5 days CPT: 88237 x 1, 88271 x 8, 88275 x 4, 88291 x 1	8/6/19
FISH for Aggressive B-Cell Lymphoma Blood	FABCFP	Test Name: Previously FISH for Aggressive B-Cell Lymphoma on Bone Marrow or BloodSpecimen Requirement: 5–7 mL peripheral blood in an EDTA (lavender) tube; Ambient*OR* 5–7 mL peripheral blood in a sodium heparin (green) tube; AmbientDays Performed: 4 days per weekReported: 5 daysCPT: 88237 x 1, 88271 x 8, 88275 x 4, 88291 x 1	8/6/19
FISH for BCL2 Blood	BCL2FH	Test Name: Previously FISH for BCL2 on Bone Marrow or Blood Clinical Information: This assay uses a dual color, break-apart probe to detect BCL2 translocations. Specimen Requirement: 5–7 mL peripheral blood in an EDTA (lavender) tube; Ambient *OR* 5–7 mL peripheral blood in a sodium heparin (green) tube; Ambient Stability: Ambient: 48 hours Refrigerated: Acceptable Frozen: Unacceptable Days Performed: 3 days per week Reported: 5 days CPT: 88237 x 1, 88271 x 2, 88275 x 1, 88291 x 1	8/6/19

Test Name	Order Code	Change	Effective Date
FISH for BCL6 Blood	BCL6FH	Test Name: FISH for BCL6 blood or bone marrow Specimen Requirement: 5–7 mL peripheral blood in an EDTA (lavender) tube; Ambient *OR* 5–7 mL peripheral blood in a sodium heparin (green) tube; Ambient Stability: Ambient: 48 hours Refrigerated: Acceptable Frozen: Not acceptable Days Performed: 3 days per week Reported: 5 days CPT: 88237 x 1, 88271 x 2, 88275 x 1, 88291 x 1	8/6/19
FISH for B Lymphoblastic Leukemia Panel Blood	FSHBLL	Test Name: Previously FISH for B Lymphoblastic Leukemia Panel Note: The directory will be updated to show that Trisomy 17 is not included. This is not a build change. Includes: FISH for BCR/ABL FISH for BCR/ABL FISH for t(12;21)(p13q;22) FISH for Trisomy 4 and 10 Specimen Requirement: 5–7 mL peripheral blood in an EDTA (lavender) tube; Ambient *OR* 5–7 mL peripheral blood in a sodium heparin (green) tube; Ambient Stability: Ambient: 48 hours Refrigerated: Acceptable Frozen: Not acceptable Days Performed: 4 days per week Reported: 5 days CPT: 88237 x 1, 88271 x 9, 88275 x 4, 88291 x 1	8/6/19
FISH for CBFB/ MYH11 Blood	INV16F	Test Name: Previously FISH for CBFB/MYH11 Specimen Requirement: 5–7 mL peripheral blood in an EDTA (lavender) tube; Ambient *OR* 5–7 mL peripheral blood in a sodium heparin (green) tube; Ambient Stability: Ambient: 40 hours Refrigerated: Acceptable Frozen: Not acceptable Days Performed: 4 days per week Reported: 5 days CPT: 88237 x 1, 88271 x 2, 88275 x 1, 88291 x 1	8/6/19
FISH for CCND1 Blood	CCND1F	Test Name: Previously FISH for CCND1 (Blood or Bone Marrow) Note: Special Information will be removed. Specimen Requirement: 5–7 mL peripheral blood in an EDTA (lavender) tube; Ambient *OR* 5–7 mL peripheral blood in a sodium heparin (green) tube; Ambient Stability: Ambient: 48 hours Refrigerated: Acceptable Frozen: Not acceptable Days Performed: 3 days per week Reported: 5 days CPT: 88237 x 1, 88271 x 2, 88275 x 1, 88291 x 1	8/6/19

Test Name	Order Code	Change	Effective Date
FISH for FGFR1 Blood	FGFR1F	Test Name: Previously FISH for FGFR1 Specimen Requirement: 5–7 mL peripheral blood in an EDTA (lavender) tube; Ambient *OR* 5–7 mL peripheral blood in a sodium heparin (green) tube; Ambient Stability: Ambient: 48 hours Refrigerated: Acceptable Frozen: Not acceptable Days Performed: 3 days per week Reported: 5 days CPT: 88237 x 1, 88271 x 2, 88275 x 1, 88291 x1	8/6/19
FISH for IgH/BCL2 Blood	FSHFCL	Test Name: Previously FISH for IgH/BCL2 blood or bone marrow Note: <i>FISH for t(14;18) translocation will be added as an alias name.</i> Specimen Requirement: 5–7 mL peripheral blood in an EDTA (lavender) tube; Specimens which will not be processed by the performing laboratory within 72 hours of draw are considered unsatisfactory; Ambient *OR* 5–7 mL peripheral blood in a sodium heparin (green) tube; Specimens which will not be processed by the performing laboratory within 72 hours of draw are considered unsatisfactory; Ambient Stability: Ambient: 48 hours Refrigerated: Acceptable Frozen: Not acceptable Days Performed: 3 days per week Reported: 5 days CPT: 88237 x 1, 88271 x 2, 88275 x 1, 88291 x 1	8/6/19
FISH for IgH/ CCND1 Blood	FSHMCL	Test Name: Previously FISH for IgH/CCND1 blood or bone marrow Specimen Requirement: 5–7 mL peripheral blood in an EDTA (lavender) tube; Specimens which will not be processed by the performing laboratory within 72 hours of draw are considered unsatisfactory; Ambient *OR* 5–7 mL peripheral blood in a sodium heparin (green) tube; Specimens which will not be processed by the performing laboratory within 72 hours of draw are considered unsatisfactory; Ambient Stability: Ambient: Preferred Refrigerated: Acceptable Frozen: Not acceptable Days Performed: 3 days per week Reported: 5 days CPT: 88237 x 1, 88271 x 2, 88275 x 1, 88291 x 1	8/6/19
FISH for IGH/MYC Blood	814FSH	Test Name: Previously FISH for IGH/MYC Fixed Pellet Note: <i>FISH for t(8;14) translocation will be added as an alias name.</i> Clinical Information: The dual fusion probe was used in this interphase FISH assay to detect the presence of the IGH/MYC translocation. Specimen Requirement: 5–7 mL peripheral blood in an EDTA (lavender) tube; Ambient *OR* 5–7 mL peripheral blood in a sodium heparin (green) tube; Ambient Stability: Ambient: 48 hours Refrigerated: Acceptable Frozen: Unacceptable Days Performed: 3 days per week Reported: 5 days CPT: 88237 x 1, 88271 x 2, 88275 x 1, 88291 x 1	8/6/19

Test Name	Order Code	Change	Effective Date
FISH for MLL Blood	MLLFSH	Test Name: Previously FISH for MLL Note: Special Information will be removed. Specimen Requirement: 5–7 mL peripheral blood in an EDTA (lavender) tube; Ambient *OR* 5–7 mL peripheral blood in a sodium heparin (green) tube; Ambient Stability: Ambient: 48 hours Refrigerated: Acceptable Frozen: Not acceptable Days Performed: 4 days per week Reported: 5 days CPT: 88237 x 1, 88271 x 2, 88275 x 1, 88291 x 1	8/6/19
FISH for MYC (8q24) Blood	MYCFSH	Test Name: Previously FISH for MYC (8q24) blood & bone marrow Specimen Requirement: 5–7 mL peripheral blood in an EDTA (lavender) tube; Ambient *OR* 5–7 mL peripheral blood in a sodium heparin (green) tube; Ambient Stability: Ambient: 48 hours Refrigerated: Acceptable Frozen: Not acceptable Frozen: Not acceptable Days Performed: 3 days per week Reported: 5 days CPT: 88237 x 1, 88271 x 2, 88275 x 1, 88291 x 1	8/6/19
FISH for Myelodysplasia Blood	FSHMDS	Test Name: Previously FISH for Myelodysplasia Note: The directory has been updated to show the tests that are included. This is not a build change. Includes: FISH for 5q deletion FISH for 7q deletion FISH for 20q8 Specimen Requirement: 5–7 mL peripheral blood in an EDTA (lavender) tube; Ambient *OR* 5–7 mL peripheral blood in a sodium heparin (green) tube; Ambient Days Performed: 4 days per week Reported: 5 days CPT: 88237 x 1, 88271 x 6, 88275 x 3, 88291 x 1	8/6/19
FISH for Myeloproliferative Neoplasms Panel Blood	MPNFSH	Test Name: Previously FISH for Myeloproliferative Neoplasms Panel Specimen Requirement: 5–7 mL peripheral blood in an EDTA (lavender) tube; Ambient *OR* 5–7 mL peripheral blood in a sodium heparin (green) tube; Ambient Stability: Ambient: 48 hours Refrigerated: Acceptable Frozen: Not acceptable Days Performed: 4 days per week Reported: 5 days CPT: 88237 x 1, 88271 x 9, 88275 x 4, 88291 x 1	8/6/19
FISH for PDGFRA Blood	PDGFRA	Test Name: Previously FISH for PDGFRA Note: <i>FISH for 4q12 will be added as an alias name.</i> Specimen Requirement: 5–7 mL peripheral blood in an EDTA (lavender) tube; Ambient *OR* 5–7 mL peripheral blood in a sodium heparin (green) tube; Ambient (continued on page 9)	8/6/19

Test Name	Order Code	Change	Effective Date
FISH for PDGFRA Blood (continued from page 8)		Stability: Ambient: 48 hours Refrigerated: Acceptable Frozen: Not acceptableDays Performed: 3 days per weekReported: 5 daysCPT: 88237 x 1, 88271 x 2, 88275 x 1, 88291 x 1	
FISH for PDGFRB Rearrangement Blood	PDGFRB	Test Name: Previously PDGFRB Rearrangement by FISH Clinical Information: A dual color, break-apart probe flanking the centromeric and telomeric sides of the PDGFRB locus is used to evaluate for a translocation involving the PDGFRB gene. Specimen Requirement: 5–7 mL peripheral blood in an EDTA (lavender) tube; Ambient *OR* 5–7 mL peripheral blood in a sodium heparin (green) tube; Ambient Days Performed: 3 days per week Reported: 5 days CPT: 88237 x 1, 88271 x 2, 88275 x 1, 88291 x 1	8/6/19
FISH for PML/RARA Blood	APLFSH	Test Name: Previously FISH for PML/RARA Specimen Requirement: 5–7 mL peripheral blood in an EDTA (lavender) tube; Ambient *OR* 5–7 mL peripheral blood in a sodium heparin (green) tube; Ambient Stability: Ambient: 48 hours Refrigerated: Acceptable Frozen: Not acceptable Days Performed: 4 days per week Reported: 5 days CPT: 88237 x 1, 88271 x 2, 88275 x 1, 88291 x 1	8/6/19
FISH for RARA Blood	RARFSH	Test Name: Previously FISH for RARA Note: FISH for RARA Translocation for APL will be added as an alias name. Specimen Requirement: 5–7 mL peripheral blood in an EDTA (lavender) tube; Ambient *OR* 5–7 mL peripheral blood in a sodium heparin (green) tube; Ambient Stability: Ambient: 48 hours Refrigerated: Acceptable Frozen: Not acceptable Days Performed: 3 days per week Reported: 5 days CPT: 88237 x 1, 88271 x 2, 88275 x 1, 88291 x 1	8/6/19
FISH for t(12;21) (p13;q22) Blood	1221FH	Test Name: Previously FISH for t(12;21)(p13q;22) Note: FISH for ETV6/RUNX1 (TEL/AML1) will be added as an alias name. Specimen Requirement: 5–7 mL peripheral blood in an EDTA (lavender) tube; Ambient *OR* 5–7 mL peripheral blood in a sodium heparin (green) tube; Ambient Stability: Ambient: 48 hours Refrigerated: Acceptable Frozen: Not acceptable Days Performed: 3 days per week Reported: 5 days CPT: 88237 x 1, 88271 x 2, 88275 x 1, 88291 x 1	8/6/19

Test Name	Order Code	Change	Effective Date
FISH for Trisomy 4 and 10 Blood	FHT410	Test Name: Previously FISH for Trisomy 4 and 10 Clinical Information: Two color interphase FISH analysis is performed using centromeric probes for chromosomes 4 and 10. In precursor B-cell lymphoblastic leukemia, the simultaneous presence of trisomy for chromosomes 4 and 10 has been associated with a favorable prognosis. Specimen Requirement: 5–7 mL peripheral blood in an EDTA (lavender) tube; Ambient *OR* 5–7 mL peripheral blood in a sodium heparin (green) tube; Ambient Stability: Ambient: 48 hours Refrigerated: Acceptable Frozen: Unacceptable Days Performed: 3 days per week Reported: 5 days CPT: 88237 x 1, 88271 x 2, 88275 x 1, 88291 x 1	8/6/19
Galactose Quant, Plasma	GALAC	Special Information: The Biochemical Genetics Patient Information form is required for testing. Clinical Information: Screening for galactosemia. Elevated plasma galactose values are found in individuals with galactosemia. This test is not recommended for follow-up of positive newborn screening results. This test is not appropriate for the diagnosis of galactosemia. Specimen Requirement: 0.5 mL plasma from a sodium heparin (green) tube; Minimum: 0.2 mL; Centrifuge and transfer plasma into a standard aliquot tube; Must submit the Biochemical Genetics Patient Information form; Frozen Reference Range: ≤ 7 days: < 5.4 mg/dL	6/4/19
Hemoglobin A2	HBA2	Reference Range: 2.0–3.1%	7/2/19
Hemoglobin A2 and F	A2F	Reference Range: Hemoglobin Fetal: 0.0–0.9% Hemoglobin A2 Percent: 2.0–3.1%	7/2/19
Hemoglobin Fetal	HBF	Reference Range: 0.0–0.9%	7/2/19
Ketones, Urine	UKET	Specimen Requirement: 10 mL random urine in a clean container; Minimum: 5 mL; Refrigerated *OR* 7 mL random urine in a BD Urine Preservative tube (yellow); Minimum: 7 mL; Ambient Stability: Ambient: Clean container–2 hours; BD Urine Preservative tube (yellow)– 72 hours Refrigerated: Clean container–24 hours; BD Urine Preservative tube (yellow)– 72 hours	7/30/19
Liver Fibrosis, FibroTest-ActiTest	LIVFIB	Methodology: Immunoassay (IA) Nephelometry (NEPH) Spectrophotometry (S) Reference Range: Apolipoprotein A1 Male: ≥ 115 mg/dL Female: ≥ 125 mg/dL (Note: There will be no other range changes)	6/3/19

Test Name	Order Code	Change	Effective Date
Mycoplasma pneumoniae IgA	MYCIGA	Special Information: Critical frozen. Separate specimens must be submitted when multiple tests are ordered. Thawed specimens are unacceptable. This test is New York DOH approved. Specimen Requirement: 1 mL serum from a plain no additive (red) tube; Minimum: 0.6 mL; Transfer serum to a standard aliquot tube and freeze immediately; Separate specimens must be submitted when multiple tests are ordered; Critical Frozen *OR* 1 mL serum from a serum separator (gold) tube; Minimum: 0.6 mL; Transfer serum to a standard aliquot tube and freeze immediately; Separate specimens must be submitted when multiple tests are ordered; Critical Frozen Methodology: Semi-Quantitative Enzyme-Linked Immunosorbent Assay Reference Range: Refer to report Days Performed: Varies Reported: 4–10 days	6/3/19
Parainfluenza 1,2,3 Abs	PAR123	Special Information: Collection of an acute and convalescent pair is recommended. Clinical Information: Parainfluenza viruses can cause upper and lower respiratory tract infections, especially in children. Specimen Requirement: 1 mL serum from a serum separator (gold) tube; Minimum: 0.5 mL; Aliquot serum into a plastic vial; Ambient *OR* 1 mL serum from a plain no additive (red) tube; Minimum: 0.5 mL; Aliquot serum into a plastic vial; Ambient Days Performed: Tuesday–Saturday Reported: 3–6 days	7/2/19
Paraneoplastic Autoantibody Evaluation, CSF	PARCSF	For Interfaced Clients Only: Test build may need to be modified Special Information: Include name, phone number, mailing address, and email address (if applicable) of ordering physician. Reflex algorithm: If indirect immunofluorescence assay (IFA) (ANN1C, ANN2C, ANN3C, PCA1C, PCA2C, PCTRC, AMPHC, CRMC, AGN1C) is indeterminate, then paraneoplastic autoantibody Western blot is performed at an additional charge. If IFA patterns suggest CRMP- 5-IgG, then CRMP-5-IgG Western blot is performed at an additional charge. If IFA patterns suggest GAD65 antibody, then GAD65 antibody radioimmunoassay is performed at an additional charge. If IFA patterns suggest neuronal voltage-gated potassium channel-complex autoantibody, then VGKC-complex antibody IPA is performed at an additional charge. If VGKCC > 0.00 nmol/L, LGI1-IgG CBA, CSF (Leucine-Rich Glioma Inactivated Protein-1 IgG, CSF) and CASPR2-IgG CBA, CSF (Contactin-Associated Protein-Like-2-IgG, CSF) are performed at an additional charge. If IFA patterns suggest amphiphysin antibody, then amphiphysin Western blot is performed at an additional charge. If IFA patterns suggest NMDA-Receptor antibody and NMDA-Receptor Ab antibody Cell-binding assay (CBA) are positive, NMDA-Receptor Ab antibody IF titer assay is performed at an additional charge. If IFA patterns suggest AMPA-Receptor antibody and AMPA-Receptor antibody CBA are positive, AMPA-Receptor antibody and AMPA-Receptor antibody CBA are positive, AMPA-Receptor antibody and AMPA-Receptor antibody IF titer assay is performed at an additional charge. If IFA patterns suggest mGluR1, then mGluR1 antibody CBA and mGluR1 titer is performed at an additional charge. In patients with a history of tobacco use or other lung cancer risk, or if thymoma is suspected, PAVAL/ Paraneoplastic Autoantibody Evaluation, Serum is also recommended. Causes for rejection: Grossly hemolyzed, grossly lipemic, grossly icteric. Methodology: Cell Binding Assay (CBA), if indicated Immunoprecipitation Indirect Immunofluor	6/11/2019

Test Name	Order Code	Change	Effective Date
Platelet Aggregation	AGGPLP	Reference Range: ADP Aggregation (0–99 Years): 65–93% Max ATP Rel by ADP: 0.1–1.3 nM ADP 20 Max Aggreg: 71–94% Max ATP Rel by ADP 20: 0.1–1.4 nM Arach Max Aggreg (0–99 Years): 75–100% Max ATP Rel by Aracha: 0.4–2.0 nM Collagen Max Aggreg: 74–99% Max ATP Rel by Collagen: 0.4–1.7 nM EPIN Max Aggreg: 70–97% Max ATP Rel by Epineph: 0.2–1.6 nM Epin 100 Max Aggreg: 70–99% Max ATP Rel by Epineph 100: 0.2–1.7 nM Risto 1500 Max Agg: 76–100% Max Risto 1200 Max Agg: 76–100% Max Risto 600 Max Agg: 0–9% Max	7/30/19
Prolactin, Dilution Study	PROLM	Test Name: Previously Prolactin Macroadenoma Note: Prolactin Dilution Study and Prolactin Macroadenoma are new alias names. Special Information: EDTA plasma is unacceptable. This test is New York DOH approved. Specimen Requirement: 1 mL serum from a serum separator (gold) tube; Minimum: 1 mL; Allow specimen to clot completely at room temperature, then transfer serum into standard aliquot tube; Frozen *OR* 1 mL plasma from a lithium heparin (light green) plasma separator tube (PST); Minimum: 1 mL; Frozen *OR* 1 mL plasma from a sodium heparin (light green) plasma separator tube (PST); Minimum: 1 mL; Frozen *OR* 1 mL plasma from a sodium or lithium heparin (green) tube; Minimum: 1 mL; Frozen *OR* 1 mL plasma from a sodium or lithium heparin (green) tube; Minimum: 1 mL; Frozen Stability Ambient: After separation from cells: 8 hours Refrigerated: After separation from cells: 48 hours Frozen: After separation from cells: 3 months	Effective immediately
Propafenone	PROPA	Specimen Requirement: 1 mL serum from a plain no additive (red) tube; Minimum: 0.21 mL; Do not use serum separator tubes; Transfer serum into standard aliquot tube; Refrigerated *OR* 1 mL plasma from an EDTA (lavender) tube; Minimum: 0.21 mL; Do not use plasma separator tubes; Transfer plasma into standard aliquot tube; Refrigerated Methodology: High Performance Liquid Chromatography/Tandem Mass Spectrometry (LC/MS/MS) Days Performed: Varies Reported: 8–11 days	Effective immediately
SHOX DNA Diagnostic	SHOX	For Interfaced Clients Only: Test build may need to be modified Special Information: Store specimen at room temperature (preferred). Clinical Information: This test identifies mutations causing short stature related to SHOX deficiency. SHOX deficiency is an indication for somatotropin (Humatrope). Specimen Requirement: 3 mL whole blood in an EDTA (lavender) tube; Minimum: 1 mL (This volume does not allow for repeat testing); Ambient *OR* 3 mL whole blood in an ACD A or B (yellow) tube; Minimum: 1 mL (This volume does not allow for repeat testing); Ambient Stability: Ambient: 28 days Refrigerated: 28 days Frozen: Unacceptable Methodology: Denaturing High Performance Liquid Chromatography CPT: 81479 x 1	8/1/19

Test Name	Order Code	Change	Effective Date
Test Name Trypsin	Order Code TRYPSI	Change Test Name: Previously Trypsinogen Note: <i>Trypsinogen will be added as an alias name, and Trypsin and Trypsin-like</i> <i>Immunoreactiv/Trypsinogen will no longer be alias names.</i> Special Information: Cord blood or plasma will be rejected. Grossly hemolyzed or lipemic specimens are unacceptable. This test is New York DOH approved. Clinical Information: Specific indicator of pancreatic damage. Patients with acute pancreatitis have significantly elevated concentrations. For the diagnosis of pancreatitis, results should be correlated with clinical presentation and other diagnostic data. Individuals with acute pancreatitis have significantly elevated trypsin concentrations. Concentrations in those with chronic pancreatitis are variable and may be below, within, or above the reference interval. Trypsin concentrations are not diagnostic for carcinoma of the pancreas. Results obtained with different assay methods or kits cannot be used interchangeably. Specimen Requirement: 1 mL serum from a plain no additive (red) tube; Minimum: 0.3 mL; Allow specimen to clot for 15–20 minutes at room temperature; Separate from cells ASAP or within 2 hours of collection and transfer into standard aliquot tube; Frozen *OR* 1 mL serum from a serum separator (gold) tube; Minimum: 0.3 mL; Allow specimen to clot for 15–20 minutes at room temperature; Separate from cells ASAP or within 2 hours of collection and transfer into standard aliquot tube; Prozen	Effective Date
		Frozen Stability: Ambient: After separation from cells: 2 hours Refrigerated: After separation from cells: 24 hours Frozen: After separation from cells: 3 months Methodology: Quantitative Radioimmunoassay Days Performed: Tuesday, Friday Reported: 2–6 days CPT: 83519 x 1	
Urinalysis Only	UA	Stability: Ambient: Clean container–2 hours; BD Urine Preservative tube–72 hours Refrigerated: Clean container–24 hours; BD Urine Preservative tube–72 hours	7/2/19
Vancomycin	VANCRA	Reference Range: 0–99 Years: 10.0 –20.0 μg/mL	7/9/19

New Tests

Test Name	Order Code	Change	Effective Date
Anti-Alpha Fodrin Ab, IgA	FODIGA	Clinical Information: According to the latest findings, the routine screening for antibodies directed against alpha-fodrin can be a useful tool in diagnosing early stage Sjogren's syndrome. Specimen Requirement: 1 mL serum from a serum separator (gold) tube; Refrigerated *OR* 1 mL serum from a plain no additive (red) tube; Refrigerated Stability: Ambient: 5 days Refrigerated: 14 days Frozen: 60 days Methodology: Enzyme Immunoassay (EIA) Days Performed: Varies Reported: 11–12 days CPT: 83520 x 1 Price: \$85.00 (non-discountable)	6/18/19
Anti-Alpha Fodrin Ab, IgG	FODIGG	Clinical Information: According to the latest findings, the routine screening for antibodies directed against alpha-fodrin can be a useful tool in diagnosing early stage Sjogren's syndrome. Specimen Requirement: 1 mL serum from a serum separator (gold) tube; Refrigerated *OR* 1 mL serum from a plain no additive (red) tube; Refrigerated Stability: Ambient: 5 days Refrigerated: 14 days Frozen: 60 days Methodology: Enzyme Immunoassay (EIA) Days Performed: Varies Reported: 11–12 days CPT: 83520 x 1 Price: \$85.00 (non-discountable)	6/18/19
Anti Alpha Fodrin Ab, IgG & IgA	FODAG	Clinical Information: According to the latest findings, the routine screening for antibodies directed against alpha-fodrin can be a useful tool in diagnosing early stage Sjogren's syndrome. Specimen Requirement: 2 mL serum from a serum separator (gold) tube; Collect 2 specimen tubes to ensure adequate specimen volume; Refrigerated *OR* 2 mL serum from a plain no additive (red) tube; Collect 2 specimen tubes to ensure adequate specimen volume; Refrigerated Stability: Ambient: 5 days Refrigerated: 14 days Frozen: 60 days Methodology: Enzyme Immunoassay (EIA) Days Performed: Varies Reported: 11–12 days CPT: 83520 x 2 Price: \$170.00 (non-discountable)	6/18/19

Test Name	Order Code	Change	Effective Date
BCR-ABL Qualitative Multiplex RT-PCR Bone Marrow	BCRQLM	 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: 5 mL bone marrow in an EDTA (lavender) tube; Minimum: 2 mL; Ambient Methodology: Capillary Electrophoresis (CE) Reverse Transcription/Polymerase Chain Reaction (RT/PCR) Days Performed: 3 days per week Reported: 5 days 	8/6/19
Bone Marrow Chromosome Analysis with Reflex SNP Array	BMCHF	Note: This test was previously announced in the April Technical Update with a go- live date of 5/19/19. Please note that the go-live date has been changed to TBD. We apologize for any inconvenience this may have caused.	TBD
FISH for 5q Abnormalities Bone Marrow	5QFSBM	 Clinical Information: Deletions of chromosome 5q or monosomy of chromosome 5 may be seen in acute myeloid leukemia, myelodysplastic syndromes, or other neoplasms. Specimen Requirement: 2–3 mL bone marrow in an EDTA (lavender) tube; Ambient *OR* 2–3 mL bone marrow in a sodium heparin (green) tube; Ambient Stability: Ambient: 48 hours Refrigerated: Acceptable Frozen: Not acceptable Methodology: Fluorescent In-Situ Hybridization (FISH) Days Performed: 3 days per week Reported: 5 days CPT: 88237 x 1, 88271 x 2, 88275 x 1, 88291 x 1 Price: \$800.00 (non-discountable) 	8/6/19
FISH for 7q Deletion Bone Marrow	FSH7QM	Clinical Information: Deletions of chromosome 7q or monosomy of chromosome 7 may be seen in acute myeloid leukemia, myelodysplastic syndromes, or other neoplasms. Specimen Requirement: 2–3 mL bone marrow in an EDTA (lavender) tube; Ambient *OR* 2–3 mL bone marrow in a sodium heparin (green) tube; Ambient Stability: Ambient: 48 hours Refrigerated: Acceptable Frozen: Not acceptable Methodology: Fluorescent In-Situ Hybridization (FISH) Days Performed: 3 days per week Reported: 5 days CPT: 88237 x 1, 88271 x 2, 88275 x 1, 88291 x 1 Price: \$675.00 (non-discountable)	8/6/19

Test Name	Order Code	Change	Effective Date
FISH for 8;21 Translocation for AML Bone Marrow	AMLFBM	Clinical Information: Used in the diagnosis of acute myelogenous leukemia (AML). FISH analysis with the AML1 and ETO probes is valuable in cases of AML M2 because of its ability to reveal masked or variant, t(8;21) (q22;q22) translocations. Specimen Requirement: 2–3 mL bone marrow in an EDTA (lavender) tube; Ambient *OR* 2–3 mL bone marrow in a sodium heparin (green) tube; Ambient Stability: Ambient: 48 hours Refrigerated: Acceptable Frozen: Not acceptable Methodology: Fluorescent In-Situ Hybridization (FISH) Days Performed: 4 days per week Reported: 5 days CPT: 88237 x 1, 88271 x 2, 88275 x 1, 88291 x 1	8/6/19
FISH for 20q and CEP8 Bone Marrow	20Q8BM	 Specimen Requirement: 2–3 mL bone marrow in an EDTA (lavender) tube; Ambient *OR* 2–3 mL bone marrow in a sodium heparin (green) tube; Ambient Stability: Ambient: 48 hours Refrigerated: Acceptable Frozen: Not acceptable Methodology: Fluorescent In-Situ Hybridization (FISH) Days Performed: 3 days per week Reported: 5 days CPT: 88237 x 1, 88271 x 2, 88275 x 1, 88291 x 1 Price: \$735.00 (non-discountable) 	8/6/19
FISH for Acute Myeloid Leukemia Bone Marrow	FAMLPM	Includes: FISH for MLL FISH for 8,21 Translocation for AML FISH for CBFB/MYH11 FISH for CBFB/MYH11 FISH for PML/RARA Specimen Requirement: 2–3 mL bone marrow in an EDTA (lavender) tube; Ambient *OR* 2–3 mL bone marrow in a sodium heparin (green) tube; Ambient Stability: Ambient: 48 hours Refrigerated: Acceptable Frozen: Not acceptable Methodology: Fluorescent In-Situ Hybridization (FISH) Days Performed: 4 days per week Reported: 5 days CPT: 88237 x 1, 88271 x 8, 88275 x 4, 88291 x 1	8/6/19
FISH for Aggressive B-Cell Lymphoma Bone Marrow	FABCBM	Includes: FISH for BCL2 FISH for BCL6 FISH for c-MYC FISH for t(8;14)(q24;q32) Specimen Requirement: 2–3 mL bone marrow in an EDTA (lavender) tube; Ambient *OR* 2–3 mL bone marrow in a sodium heparin (green) tube; Ambient Stability: Ambient: 48 hours Refrigerated: Acceptable Frozen: Not acceptable Frozen: Not acceptable Methodology: Fluorescent In-Situ Hybridization (FISH) Days Performed: 4 days per week Reported: 5 days CPT: 88237 x 1, 88271 x 8, 88275 x 4, 88291 x 1	8/6/19

Test Name	Order Code	Change	Effective Date
FISH for BCL2 Bone Marrow	BCL2FM	Clinical Information: This assay uses a dual color, break-apart probe to detect BCL2 translocations. Specimen Requirement: 2 -3 mL bone marrow in an EDTA (lavender) tube; Ambient *OR* 2–3 mL bone marrow in a sodium heparin (green) tube; Ambient Stability: Ambient: 48 hours Refrigerated: Acceptable Frozen: Not acceptable Frozen: Not acceptable Methodology: Fluorescent In-Situ Hybridization (FISH) Days Performed: 3 days per week Reported: 5 days CPT: 88237 x 1, 88271 x 2, 88275 x 1, 88291 x 1 Price: \$495.00 (non-discountable)	8/6/19
FISH for BCL6 Bone Marrow	BCL6FM	Clinical Information: This assay uses a dual color, break-apart probe to detect BCL6 translocations. Specimen Requirement: 2–3 mL bone marrow in an EDTA (lavender) tube; Ambient *OR* 2–3 mL bone marrow in a sodium heparin (green) tube; Ambient Stability: Ambient: 48 hours Refrigerated: Acceptable Frozen: Not acceptable Methodology: Fluorescent In-Situ Hybridization (FISH) Days Performed: 3 days per week Reported: 5 days CPT: 88237 x 1, 88271 x 2, 88275 x 1, 88291 x 1 Price: \$600.00 (non-discountable)	8/6/19
FISH for B Lymphoblastic Leukemia Panel Bone Marrow	FSBLLM	Includes: FISH for BCRABL FISH for MLL FISH for MLL FISH for t(12;21)(p13q22) FISH for Trisomy 4 and 10 Specimen Requirement: 2–3 mL bone marrow in an EDTA (lavender) tube; Ambient *OR* 2–3 mL bone marrow in a sodium heparin (green) tube; Ambient Stability: Ambient: 48 hours Refrigerated: Acceptable Frozen: Not acceptable Methodology: Fluorescent In-Situ Hybridization (FISH) Days Performed: 4 days per week Reported: 5 days CPT: 88237 x 1, 88271 x 9, 88275 x 4, 88291 x 1	8/6/19

Test Name	Order Code	Change	Effective Date
FISH for CBFB/ MYH11 Bone Marrow	INV16M	Clinical Information: To assist in the diagnosis of acute myelocytic leukemia, specifically acute myelomonocytic leukemia. This chromosome abnormality is usually associated with increased number of immature eosinophils in the bone marrow and often with peripheral blood eosinophilia. Specimen Requirement: 2–3 mL bone marrow in an EDTA (lavender) tube; Ambient *OR* 2–3 mL bone marrow in a sodium heparin (green) tube; Ambient Stability: Ambient: 48 hours Refrigerated: Acceptable Frozen: Not acceptable Methodology: Fluorescent In-Situ Hybridization (FISH) Days Performed: 4 days per week Reported: 5 days CPT: 88237 x 1, 88271 x 2, 88275 x 1, 88291 x 1	8/6/19
FISH for CCND1 Bone Marrow	CCND1M	Clinical Information: The identification of a translocation involving the CCND1 locus at chromosome 11q13 assists in the diagnosis and classification of non-Hodgkin lymphomas. Specimen Requirement: 2–3 mL bone marrow in an EDTA (lavender) tube; Ambient *OR* 2–3 mL bone marrow in a sodium heparin (green) tube; Ambient Stability: Ambient: 48 hours Refrigerated: Acceptable Frozen: Not acceptable Frozen: Not acceptable Methodology: Fluorescent In-Situ Hybridization (FISH) Days Performed: 3 days per week Reported: 5 days CPT: 88237 x 1, 88271 x 2, 88275 x 1, 88291 x 1 Price: \$675.00 (non-discountable)	8/6/19
FISH for FGFR1 Bone Marrow	FGFR1M	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 World Health Organization (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. Specimen Requirement: 2–3 mL bone marrow in an EDTA (lavender) tube; Ambient *OR* 2–3 mL bone marrow in a sodium heparin (green) tube; Ambient Stability: Ambient: 48 hours Refrigerated: Acceptable Frozen: Not acceptable Methodology: Fluorescent In-Situ Hybridization (FISH) Days Performed: 3 days per week Reported: 5 days CPT: 88237 x 1, 88271 x 2, 88275 x 1, 88291 x 1 Price: \$722.00 (non-discountable)	8/6/19

Test Name	Order Code	Change	Effective Date
FISH for IGH/BCL2 Bone Marrow	FSFCLM	Clinical Information: This assay uses a dual color, dual fusion probe to detect the IGH/BCL2 translocation that is associated with follicular lymphoma and diffuse large B-cell lymphoma. This test should not be used to monitor minimal residual disease. Specimen Requirement: 2–3 mL bone marrow in an EDTA (lavender) tube; Refrigerated *OR* 2–3 mL bone marrow in a sodium heparin (green) tube; Refrigerated Stability: Ambient: 48 hours Refrigerated: Acceptable Frozen: Not acceptable Methodology: Fluorescent In-Situ Hybridization (FISH) Days Performed: 3 days per week Reported: 5 days CPT: 88237 x 1, 88271 x 2, 88275 x 1, 88291 x 1	8/6/19
FISH for IGH/CCND1 Bone Marrow	FSMCLM	Clinical Information: This assay uses a dual color, dual fusion probe to detect the IGH/CCND1 translocation associated with mantle cell lymphoma. This test should not be used to monitor minimal residual disease. Specimen Requirement: 2–3 mL bone marrow in an EDTA (lavender) tube; Ambient *OR* 2–3 mL bone marrow in a sodium heparin (green) tube; Ambient Stability: Ambient: 48 hours Refrigerated: Acceptable Frozen: Unacceptable Methodology: Fluorescent In-Situ Hybridization (FISH) Days Performed: 3 days per week Reported: 5 days CPT: 88237 x 1, 88271 x 2, 88275 x 1, 88291 x 1 Price: \$495.00 (non-discountable)	8/6/19
FISH for IGH/MYC Bone Marrow	814FSM	Clinical Information: The dual fusion probe was used in this interphase FISH assay to detect the presence of the IGH/MYC translocation. Specimen Requirement: 2–3 mL bone marrow in an EDTA (lavender) tube; Ambient *OR* 2–3 mL bone marrow in a sodium heparin (green) tube; Ambient Stability: Ambient: 48 hours Refrigerated: Acceptable Frozen: Not acceptable Methodology: Fluorescent In-Situ Hybridization (FISH) Days Performed: 3 days per week Reported: 5 days CPT: 88237 x 1, 88271 x 2, 88275 x 1, 88291 x 1 Price: \$600.00 (non-discountable)	8/6/19
FISH for MLL Bone Marrow	MLLFBM	Clinical Information: For diagnosis and classification of patients with acute myeloid and acute lymphoblastic leukemia. Specimen Requirement: 2–3 mL bone marrow in an EDTA (lavender) tube; Ambient *OR* 2–3 mL bone marrow in a sodium heparin (green) tube; Ambient Stability: Ambient: 48 hours Refrigerated: Acceptable Frozen: Not acceptable Methodology: Fluorescent In-Situ Hybridization (FISH) Days Performed: 4 days per week Reported: 5 days CPT: 88237 x 1, 88271 x 2, 88275 x 1, 88291 x 1	8/6/19

Test Name	Order Code	Change	Effective Date
FISH for MYC (8q24) Bone Marrow	MYCFSM	 Special Information: Specimens submitted for MYC amplification should not use this test code. Clinical Information: This assay uses a dual color, break-apart probe to detect translocations involving the MYC gene. MYC translocations are seen in a wide variety of malignant lymphomas including Burkitt lymphoma, diffuse large B-cell lymphoma, and others. Specimen Requirement: 2–3 mL bone marrow in an EDTA (lavender) tube; Ambient *OR* 2–3 mL bone marrow in a sodium heparin (green) tube; Ambient Stability: Ambient: 48 hours Refrigerated: Acceptable Frozen: Not acceptable Methodology: Fluorescent In-Situ Hybridization (FISH) Days Performed: 3 days per week Reported: 5 days CPT: 88237 x 1, 88271 x 2, 88275 x 1, 88291 x 1 Price: \$600.00 (non-discountable) 	8/6/19
FISH for Myelodysplasia Bone Marrow	FSMDSM	Includes: FISH for 5q deletion FISH for 7q deletion FISH for 20q8 Specimen Requirement: 2–3 mL bone marrow in an EDTA (lavender) tube; Ambient *OR* 2–3 mL bone marrow in a sodium heparin (green) tube; Ambient Stability: Ambient: 48 hours Refrigerated: Acceptable Frozen: Not acceptable Methodology: Fluorescent In-Situ Hybridization (FISH) Days Performed: 4 days per week Reported: 5 days CPT: 88237 x 1, 88271 x 6, 88275 x 3, 88291 x 1	8/6/19
FISH for Myeloproliferative Neoplasm Panel Bone Marrow	MPNFSM	Includes: FISH for BCL/ABL1 FISH for PDGFRA FISH for PDGFRB FISH for FGFR1 Specimen Requirement: 2–3 mL bone marrow in an EDTA (lavender) tube; Ambient *OR* 2–3 mL bone marrow in a sodium heparin (green) tube, Ambient Stability: Ambient: 48 hours Refrigerated: Acceptable Frozen: Not acceptable Methodology: Fluorescent In-Situ Hybridization (FISH) Days Performed: 4 days per week Reported: 5 days	8/6/19

Test Name	Order Code	Change	Effective Date
FISH for PDGFRA Bone Marrow	PGFRAM	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 World Health Organization (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. Specimen Requirement: 2–3 mL bone marrow in an EDTA (lavender) tube; Ambient *OR* 2–3 mL bone marrow in a sodium heparin (green) tube; Ambient Stability: Ambient: 48 hours Refrigerated: Acceptable Frozen: Not acceptable Days Performed: 3 days per week Reported: 5 days CPT: 88237 x 1, 88271 x 3, 88275 x 1, 88291 x 1	8/6/19
FISH for PDGFRB Rearrangement Bone Marrow	PDGFBM	Clinical Information: A dual color, break-apart probe flanking the centromeric and telomeric sides of the PDGFRB locus is used to evaluate for a translocation involving the PDGFRB gene. Specimen Requirement: 2–3 mL bone marrow in an EDTA (lavender) tube; Ambient *OR* 2–3 mL bone marrow in a sodium heparin (green) tube; Ambient Stability: Ambient: 48 hours Refrigerated: Acceptable Frozen: Not acceptable Methodology: Fluorescent In-Situ Hybridization (FISH) Days Performed: 3 days per week Reported: 5 days CPT: 88237 x 1, 88271 x 2, 88275 x 1, 88291 x 1	8/6/19
FISH for PML/RARA Bone Marrow	APLFBM	Specimen Requirement: 2–3 mL bone marrow in an EDTA (lavender) tube; Ambient *OR* 2–3 mL bone marrow in a sodium heparin (green) tube; Ambient Stability: Ambient: 48 hours Refrigerated: Acceptable Frozen: Not acceptable Methodology: Fluorescent In-Situ Hybridization (FISH) Days Performed: 4 days per week Reported: 5 days CPT: 88237 x 1, 88271 x 2, 88275 x 1, 88291 x 1	8/6/19
FISH for RARA Bone Marrow	RARFSM	 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. Specimen Requirement: 2–3 mL bone marrow in an EDTA (lavender) tube; Ambient *OR* 2–3 mL bone marrow in a sodium heparin (green) tube; Ambient Stability: Ambient: 48 hours Refrigerated: Acceptable Frozen: Not acceptable Methodology: Fluorescent In-Situ Hybridization (FISH) Days Performed: 3 days per week Reported: 5 days CPT: 88237 x 1, 88271 x 2, 88275 x 1, 88291 x 1 	8/6/19

Test Name	Order Code	Change	Effective Date
FISH for t(12;21) (p13;q22) Bone Marrow	1221FM	Clinical Information: To assist in the diagnosis of precursor B-cell lymphoblastic leukemia Specimen Requirement: 2–3 mL bone marrow in an EDTA (lavender) tube; Ambient *OR* 2–3 mL bone marrow in a sodium heparin (green) tube; Ambient Stability: Ambient: 48 hours Refrigerated: Acceptable Frozen: Not acceptable Methodology: Fluorescent In-Situ Hybridization (FISH) Days Performed: 3 days per week Reported: 5 days CPT: 88237 x 1, 88271 x 2, 88275 x 1, 88291 x 1 Price: \$735.00 (non-discountable)	8/6/19
FISH for Trisomy 4 and 10 Bone Marrow	FT410M	Clinical Information: Two color interphase FISH analysis was performed using centromeric probes for chromosomes 4 and 10. In precursor B-cell lymphoblastic leukemia, the simultaneous presence of trisomy for chromosomes 4 and 10 has been associated with a favorable prognosis. Specimen Requirement: 2–3 mL bone marrow in an EDTA (lavender) tube; Ambient *OR* 2–3 mL bone marrow in a sodium heparin (green) tube; Ambient Stability: Ambient: 48 hours Refrigerated: Acceptable Frozen: Not acceptable Methodology: Fluorescent In-Situ Hybridization (FISH) Days Performed: 3 days per week Reported: 5 days CPT: 88237 x 1, 88271 x 2, 88275 x 1, 88291 x 1	8/6/19
Heinz Body Stain	HNZBSN	Special Information: Samples > 96 hours old will be rejected. Specimens from infants < 6 months of age are unacceptable; test results are unreliable. This test is New York DOH approved. Clinical Information: Useful as a nonspecific screen for hemolysis due to drugs/ toxins, enzyme deficiencies, thalassemias, and unstable hemoglobins. Specimen Requirement: 5 mL whole blood in an EDTA (lavender) tube; Minimum: 2 mL; Refrigerated *OR* 5 mL whole blood in a sodium or lithium heparin (green) tube; Minimum: 2 mL; Refrigerated Stability: Ambient: Unacceptable Refrigerated: 96 hours Frozen: Unacceptable Methodology: Stain Reference Range: Direct: Negative Induced: Normal Days Performed: Monday–Friday Reported: 2–5 days CPT: 85441 x 1, 85445 x 1 Price: \$130.00 (non-discountable)	7/30/19

Test Name	Order Code	Change	Effective Date
JC Virus DNA, Ultrasensitive (LLOQ 10 copies/mL), Quantitative, Real- Time PCR, CSF	JCVPCR	Clinical Information: JC polyoma virus is the cause of progressive multifocal leukoencephalopathy (PML), a demyelinating neurologic disease of immunocompromised patients and patients on certain medications. This test detects and quantifies JC virus (JCV) in cerebrospinal fluid (CSF), and detection of the virus in CSF may indicate infection. Specimen Requirement: 1 mL cerebrospinal fluid (CSF) in a sterile container; Minimum: 0.5 mL; Frozen Stability: Ambient: 48 hours Refrigerated: 7 days Frozen: 30 days Methodology: Real-Time Polymerase Chain Reaction (RT-PCR) Reference Range: < 10 copies/mL Days Performed: Monday–Saturday Reported: 2–4 days CPT: 87799 x 1 Price: \$330.00 (non-discountable)	6/27/19
Leukocyte Alkaline Phosphatase	LAPSN	 Special Information: Specimens collected in EDTA or specimens that have been spun will be rejected. Poorly prepared smears (e.g., too thick or no feather edge), broken or fixed smears are unacceptable. Smears made from anything other than heparin, smears made from blood older than 24 hours, and smears not protected from light are unacceptable. Whole blood not protected from light will be rejected. This test is New York DOH approved. Clinical Information: Aids in differential diagnosis of neutrophilia, including chronic myeloid leukemia (CML) and leukemoid reaction. Specimen Requirement: 5 mL whole blood in a sodium or lithium heparin (green) tube and 6 unfixed, well-prepared smears; Minimum: 1 mL whole blood and 6 smears; Protect both smears and whole blood from light; Package carefully to avoid breakage; Send both whole blood and 6 smears; Collect Monday–Wednesday only; Whole blood must be received within 24 hours of collection; Smears must be made within 24 hours of collection; ambient Stability: Ambient: Blood: 24 hours; Unfixed smears: 1 week Refrigerated: Blood: Unacceptable; Unfixed smears: Unacceptable Frozen: Blood: Unacceptable; Unfixed smears: Unacceptable Methodology: Stain Days Performed: Monday–Friday Reported: 2–6 days CPT: 85540 x 1 Price: \$76.00 (non-discountable) 	6/18/19
Next Generation Sequencing Hotspot GIST		 Specimen Requirement: 3–5 mL fine needle aspirate (FNA) in CytoLyt solution; FNA specimens are preserved in CytoLyt solution and should be stored at 4 °C until DNA extraction can be performed; Transport to Cleveland Clinic Laboratories at ambient temperature is acceptable; Ambient *OR* 10 mm square formalin-fixed paraffin-embedded tissue (FFPET) block slides; Transport and store slides at ambient temperature; 10 unstained sections FFPET on charged, unbaked slides, plus one H&E stained section with best tumor area circled by a pathologist; Ambient Stability: Ambient: Indefinitely for FFPET slides; FFPET and FNA can be transported at ambient temperature Refrigerated: 2 weeks for FNA samples Frozen: Unacceptable Methodology: Next Generation DNA Sequencing Days Performed: 3 days per week Reported: 8 days 	6/4/19

Test Name	Order Code	Change	Effective Date
Orexin-A/ Hypocretin-1, Spinal Fluid	ORXCSF	Special Information: Hemolyzed specimens are unacceptable due to false-positive results. Patient Preparation: Patient should not have recently received radioisotopes, either therapeutically or diagnostically, due to potential assay interference.	6/11/19
		Clinical Information: Aids in the diagnosis and differentiation of type 1 narcolepsy from other types of narcolepsy. This assay is not intended for use as a screening test. Narcolepsy affects 0.02% to 0.05% of the population, and the onset of symptoms often occurs in adolescence. Orexin (also known as orexin-A or hypocretin-1) is a neuropeptide produced in the hypothalamus and is involved in the sleep/wake cycle in humans. Impairment of orexin production and orexin-modulated neurotransmission is associated with narcolepsy with cataplexy (episodes of muscle weakness in response to emotional stimuli). An abnormally low concentration of orexin-A in cerebrospinal fluid (CSF) is indicative of what is termed type 1 narcolepsy. Survey of the literature reveals that approximately 85% to 95% of randomly selected individuals with type 1 narcolepsy and typical cataplexy exhibit low (< 110 pg/mL) CSF orexin concentrations.	
		 In one large study, the sensitivity of this cutoff was found to be 87% with a specificity of 99%. 	
		2. Orexin deficiency and type 1 narcolepsy are closely associated with HLA complex DQB1 *0602. It is estimated that only 1 in 500 HLA DQB1*0602-negative individuals exhibit low CSF orexin concentrations. CSF concentrations have been found to almost always be above 200 pg/mL in healthy individuals and those with non-type 1-narcoleptic sleep disorders such as narcolepsy type 2 and idiopathic hypersomnia.	
		Specimen Requirement: 1.5 mL cerebrospinal fluid (CSF) in a sterile container; Minimum: 0.5 mL; Obtain aliquot from second collection vial (preferred, not required); Specimens should be centrifuged to remove any red cells before shipping; Frozen	
		Stability: Ambient: Unacceptable Refrigerated: Unacceptable Frozen: 120 days	
		Methodology: Radioimmunoassay (RIA)	
		Davs Performed: Tuesdav	
		Reported: 4–29 days	
		CPT: 83519 x 1	
		Price: \$845.00 (non-discountable)	
PDGFRA Gene Analysis NGS Hotspot		Specimen Requirement: 3–5 mL fine needle aspirate (FNA) in CytoLyt solution; FNA specimens are preserved in CytoLyt solution and should be stored at 4 °C until DNA extraction can be performed; Transport to Cleveland Clinic Laboratories at ambient temperature is acceptable; Ambient	6/4/19
		OR 10 mm square formalin-fixed paraffin-embedded tissue (FFPET) block slides; Transport and store slides at ambient temperature; 10 unstained sections FFPET on charged, unbaked slides, plus one H&E stained section with best tumor area circled by a pathologist; Ambient	
		Stability: Ambient: Indefinitely for FFPET slides; FFPET slides and FNA can be transported at ambient temperature Refrigerated: 2 weeks for FNA samples Frozen: Unacceptable	
		Methodology: Next Generation DNA Sequencing	
		Days Performed: 3 days per week	

Test Name	Order Code	Change	Effective Date
Urine Kappa/Lambda Free Light Chains (FLC) with Ratio	UKLFRE	Clinical Information: The results of urine kappa and lambda free light chains and ratio must be interpreted in conjunction with urine immunofixation electrophoresis. The free light chain quantitative values may be inaccurate in specimens with high levels of Bence Jones proteins; therefore, correlation with urine immunofixation electrophoresis is required to identify inconsistent results. Specimen Requirement: 1.5 mL random urine in a clean container; Minimum: 1 mL; Urine supernate is also acceptable; Refrigerated Stability: Ambient: 2 hours Refrigerated: 1 week Frozen: Unacceptable Methodology: Quantitative Nephelometry Days Performed: Monday–Friday Reported: 2–6 days CPT: 83883 × 2 Price: \$48.00 (non-discountable)	7/30/19
Warfarin Sensitivity (CYP2C8, CYP2C9, CYP4F2, VKORC1) Genotyping	WRFSEN	Note: This test was previously announced in the May Technical Update. Price: \$300.00 (non-discountable)	Effective immediately
Zika Virus by PCR, Blood	ZKAPCR	 Special Information: Testing should only be performed on individuals meeting Centers for Disease Control and Prevention (CDC) clinical criteria for Zika virus (e.g., clinical signs and symptoms associated with Zika virus infection) and/or CDC epidemiological criteria for Zika virus (e.g., history of residence in or travel to a geographic region with active Zika transmission at the time of travel, or other epidemiological criteria for which Zika virus testing may be indicated). A positive RT-PCR result confirms Zika virus infection, and no additional testing is indicated. When test results are negative, the serum should be tested as outlined in the current CDC-issued algorithm (http://www.cdc.gov/zika/laboratories/lab- guidance.html). The Zika Virus by PCR test is for in vitro diagnostic use under the FDA Emergency Use Authorization (EUA). This test has not been FDA cleared or approved. Specimen source is required. Urine is unacceptable; refer to Zika Virus by PCR, Urine (UZKPCR). This test is New York DOH approved. Specimen Requirement: 2 mL serum from a serum separator (gold) tube; Minimum: 1 mL; Separate serum from cells and transfer to a sterile aliquot tube; Specimen source is required; Frozen Stability: Ambient: Unacceptable Refrigerated: 5 days Frozen: 6 weeks Methodology: Qualitative Polymerase Chain Reaction Days Performed: Monday, Wednesday, Friday Reported: 2–5 days CPT: 87662 x 1 Price: \$169.00 (non-discountable) 	8/1/19

Test Name	Order Code	Change	Effective Date
Zika Virus by PCR, Urine	UZKPCR	 Special Information: Testing should only be performed on individuals meeting Centers for Disease Control and Prevention (CDC) clinical criteria for Zika virus (e.g., clinical signs and symptoms associated with Zika virus infection) and/or CDC epidemiological criteria for Zika virus (e.g., history of residence in or travel to a geographic region with active Zika transmission at the time of travel, or other epidemiological criteria for which Zika virus testing may be indicated). Health care providers are strongly encouraged to collect serum specimens alongside other specimen types to provide additional opportunities for diagnosing Zika. A positive RT-PCR result confirms Zika virus infection, and no additional testing is indicated. When test results are negative for urine, serum should be tested as outlined in the current CDC-issued algorithm (http://www.cdc.gov/zika/laboratories/lab-guidance.html). The Zika Virus by PCR test is for in vitro diagnosing Zika. A positive SPCR, Blood (ZKAPCR). This test is New York DOH approved. Specimen Requirement: 1 mL random urine in a sterile container; Minimum: 0.5 mL; Specimen source is required; Frozen Stability: Mabient: Unacceptable Refrigerated: 5 days Frozen: 6 weeks Methodology: Qualitative Polymerase Chain Reaction Days Performed: Monday, Wednesday, Friday. Reported: 2–5 days CPT: 87662 x 1 Price: \$169.00 (non-discountable). 	8/1/19
Zika Virus IgM Antibody Capture (MAC), by ELISA	ZKAIGM	 Special Information: Use for patients whose symptoms began, or whose documented exposure occurred, at least 14 days prior to testing. Should also be used as follow-up for patients with negative serum and urine results from molecular testing performed less than 14 days after symptom onset. This ELISA assay is intended for in vitro diagnostic use under FDA Emergency Use Authorization (EUA). This test has not been FDA cleared or approved. The possibility of false-positive or false-negative results must be considered. RT-PCR testing on both a serum and urine specimen is recommended by the Centers for Disease Control and Prevention (CDC) to rule out false-negative IgM results in patients experiencing symptoms for less than 2 weeks. Specimens collected for IgM testing greater than or equal to 2 weeks after symptom onset do not require any additional testing. For more information, please review the current clinical guidelines for Zika virus testing at: www.cdc.gov/zika/. Parallel testing is preferred and convalescent specimens must be received within 30 days from receipt of the acute specimens. Label specimens plainly as 'acute' or 'convalescent,' and submit Patient History for Zika Virus testing form with the specimen. Contaminated, heat-inactivated, hemolyzed, or severely lipemic specimens are unacceptable. This test is New York DOH approved. Specimen Requirement: 2 mL serum from a serum separator (gold) tube; Minimum: 1 mL; Separate from cells ASAP or within 2 hours of collection and transfer into standard aliquot tube; Parallel testing is preferred and convalescent specimens; Label specimens; Label specimen plainly as 'acute' or 'convalescent,' It is recommended that the Patient History for Zika Virus Testing form is submitted with the specimen; Refrigerated Stability Ambient: After separation from cells: 1 year (Avoid repeated freeze/thaw cycles) Methodology: Semi-Quantitative Enzyme-Linked Immunosorbent Assay Days Performed: Monday, We	8/1/19

Fee Increases

Test Name	Order Code	List Fee	CPT Code	Effective Date
FISH for BCL6 Blood	BCL6FH	\$600.00 (non-discountable)	88237, 88271 x 2, 88275, 88291	8/6/19
Universal PCR, Acid Fast Bacilli	AFBPCR	\$570.00 (non-discountable)	87551, 87556	Effective immediately
Universal PCR, Fungal	FUNPCR	\$510.00 (non-discountable)	87801	Effective immediately

Fee Reductions

Test Name	Order Code	List Fee	CPT Code	Effective Date
FISH for 5q Abnormalities Blood	5QFSH	\$800.00 (non-discountable)	88237, 88271 x 2, 88275, 88291	8/6/19
FISH for 7q Deletion Blood	FISH7Q	\$675.00 (non-discountable)	88237, 88271 x 2, 88275, 88291	8/6/19
FISH for 20q and CEP8 Blood	20Q8FH	\$735.00 (non-discountable)	88237, 88271 x 2, 88275, 88291	8/6/19
FISH for BCL2 Blood	BCL2FH	\$675.00 (non-discountable)	88237, 88271 x 2, 88275, 88291	8/6/19
FISH for CCND1 Blood	CCND1F	\$675.00 (non-discountable)	88237, 88271 x 2, 88275, 88291	8/6/19
FISH for FGFR1 Blood	FGFR1F	\$722.00 (non-discountable)	88237, 88271 x 2, 88275, 88291	8/6/19
FISH for IGH/MYC Blood	814FSH	\$600.00 (non-discountable)	88237, 88271 x 2, 88275, 88291	8/6/19
FISH for t(12;21)(p13;q22) Blood	1221FH	\$735.00 (non-discountable)	88237, 88271 x 2, 88275, 88291	8/6/19
SHOX DNA Diagnostic	SHOX	\$450.00 (non-discountable)	81479	8/1/19
Trypsin	TRYPSI	\$110.00	83519	6/4/19

Discontinued Tests

Test Name	Order Code	Test Information	Effective Date
Amoxapine & Metabolite	AMOX	This test will no longer be available.	8/1/19
Antimony, Urine	ANTIMU	This test will no longer be available.	8/1/19
Autoimmune Polyglandular Syndrome Eval	AIRE	This test will no longer be available.	8/1/19
Degradation Products	FDP	This test will no longer be available. Suggest ordering D-Dimer (DDMER).	Effective immediately
Heinz Bodies Stain	HNZSTN	This test will no longer be available. Suggest ordering Heinz Body Stain (HNZBSN).	7/30/19
Kappa/Lambda Light Chains, Free with Ratio, Urine	UKLFR	This test will no longer be available. Suggest ordering Urine Kappa/Lambda Free Light Chains (FLC) with Ratio (UKLFRE).	7/30/19
Kappa Light Chain, Free, Urine	UFKAPP	This test will no longer be available. Suggest ordering Urine Kappa/Lambda Free Light Chains (FLC) with Ratio (UKLFRE).	7/30/19
Lambda Light Chain, Free, Urine	UFLAMB	This test will no longer be available. Suggest ordering Urine Kappa/Lambda Free Light Chains (FLC) with Ratio (UKLFRE).	7/30/19