



## Cleveland Clinic Laboratories

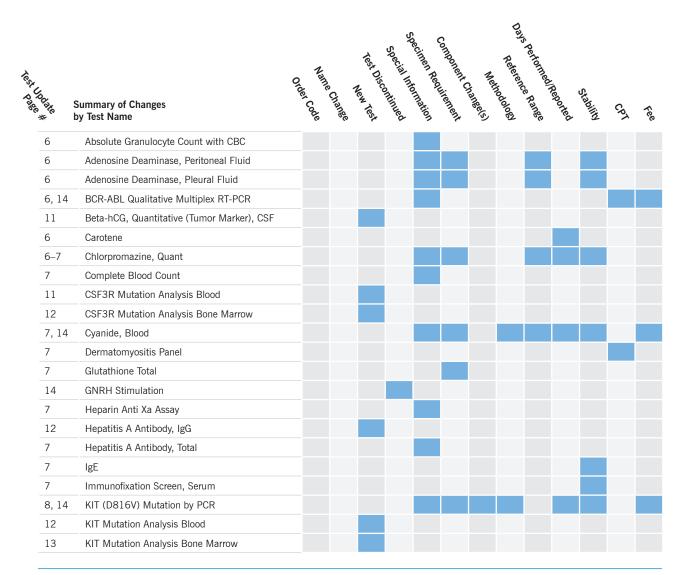
#### Technical Update • November 2020

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.



#### **Summary of Changes** by Test Name

Dodate *	Summary of Changes by Test Name	det Code	Change	lew test	Minued	Hunation	Hement	nangels	odology	e Range	teported	Stability	CRY	Fee
14	KIT Mutation Exons 8-11 and 17, Hematologic Neoplasms, Sequencing													
8	LMW Anti Xa Assay													
8	LYME AB Early Disease (≤ 30 days of signs and symptoms), with Reflex													
9	LYME AB Late Disease (> 30 days of signs or symptoms), with Reflex													
9	Monoclonal Protein, 24 Hour Urine													
9	Monoclonal Protein, Urine													
9	Monoclonal Protein with Immunoglobulins and Free Light Chains, serum													
9	Myelin Basic Protein, CSF													
9	pH, Fecal													
14	Pituitary Evaluation													
9, 14	Polymyositis and Dermatomyositis Panel													
9	Protein Electrophoresis, Serum													
10	Protein Electrophoresis, Serum, with IFE													
10	Protein Electrophoresis, Ur 24 Hr w/M Protein Quant													
10	Protein Electrophoresis, Urine Random													
10	Protein Electrophoresis, Urine, with IFE													
10	PTH Intact, Fluid													
13	SF3B1 Mutation Analysis Blood													
13	SF3B1 Mutation Analysis Bone Marrow													
10	Urticaria-Inducing Activity													

#### **Dear Valued Client,**

Effective immediately, frozen stability has increased to 30 days for the following allergens:

Allergen, Acacia IgE (ACACIA) Allergen, Chick Pea IgE (CPEA)

Allergen, Acremonium kiliense IgE (CACREM)

Allergen, Almond IgE (ALMOND)

Allergen, Alternaria tenuis (alternata) IgE (ATENS)

Allergen, Amoxicilloyl IgE (MOXCIL) Allergen, Ampicilloyl (IgE) (AMPCYL) Allergen, Animals Group (ANIMLS) Allergen, Apple IgE (APPLES)

Allergen, Aspergillus fumigatus IgE (AFUMIG) Allergen, Aspergillus niger IgE (ASPNI) Allergen, Australian Pine IgE (APINE) Allergen, Avocado IgE (AVOCAD) Allergen, Bahia Grass IgE (BAHIA) Allergen, Banana IgE (BNANA) Allergen, Barley IgE (BARLEY) Allergen, Basil IgE (BASIL)

Allergen, Bermuda Grass IgE (BRMUDA) Allergen, Birch Tree IgE (BIRCHT) Allergen, Black Pepper IgE (BLAPEP) Allergen, Blueberry IgE (BLUBRY) Allergen, Blue Mussel IgE (BLUMUS)

Allergen, Beech IgE (BEECH)

Allergen, Beef IgE (BEEFMT)

Allergen, Box Elder (Maple) Tree IgE (BELDR) Allergen, Brazil Nut Component IgE (BRAZCP)

Allergen, Brazil Nut IgE (BRAZIL) Allergen, Broccoli IgE (BROCCI) Allergen, Buckwheat IgE (BUKWHT) Allergen, Cabbage IgE (CABBAG)

Allergen, Cacao (Chocolate) IgE (CACAO) Allergen, Candida albicans IgE (CNDIDA)

Allergen, Carrot IgE (CARROT)

Allergen, Cashew Component IgE (CASHCP) Allergen, Cashew Nut IgE (CASHEW) Allergen, Cat Dander IgE (CATDND) Allergen, Catfish IgE (CTFISH) Allergen, Celery IgE (CELERY) Allergen, Cereal Group (CEREAL)

Allergen, Cheese Cheddar Type IgE (CHEDCH) Allergen, Cheese Mold Type IgE (MLDCHS)

Allergen, Cherry IgE (CHERRY) Allergen, Chestnut IgE (CHESNT)

Allergen, Chicken Feathers IgE (CHCKF) Allergen, Chicken Meat IgE (CHCKN) Allergen, Chili Pepper IgE (CHILI) Allergen, Cinnamon IgE (CINAMN)

Allergen, Cladosporium herbarum (Hormodendrum) IgE

(CHERB)

Allergen, Clam IgE (CLAM)

Allergen, Cocklebur IgE (COKBUR) Allergen, Cockroach IgE (CROACH) Allergen, Coconut IgE (COCNUT) Allergen, Codfish IgE (CODFSH) Allergen, Coffee IgE (COFFEE) Allergen, Corn IgE (CORNS)

Allergen, Cottonwood Tree IgE (COTTWD)

Allergen, Cow Epithelium (Dander) IgE (COWEPI) Allergen, Cow Milk Components IgE (MILKE)

Allergen, Cow's Milk IgE (MILKC)

Allergen, Crab IgE (CRAB)

Allergen, Cucumber IgE (CUCUM) Allergen, Dandelion IgE (DELION)

Allergen, Dermatophagoides farinae IgE (DFARN) Allergen, Dermatophagoides pteronyssinus IgE

(DPTERN)

Allergen, Dog Dander IgE (K9DND) Allergen, Duck Feathers IgE (DUCKFR)

Allergen, Dust Mite Components IgE (DUSTCP) Allergen, Egg Components IgE (EGGIGE) Allergen, Egg White IgE (EGGWHT) Allergen, Egg Yolk IgE (EGYOLK) Allergen, Elm Tree IgE (ELM)

Allergen, English Plantain (Ribwort) IgE (ENGPLT) Allergen, Epicoccum purpurascens IgE (EPIP)

Allergen, False Ragweed IgE (FSRAG) Allergen, Feather Mix IgE (FETHMX) Allergen, Firebush (Kocia) IgE (FIRBSH) Allergen, Florida Perennial (FLPER) Allergen, Flounder IgE (FLOUND) Allergen, Food Adult/Child (FOODAD) Allergen, Food Panel Adult ACA (FODACA)

Allergen, Food Panel RL (FOODRL) Allergen, Foods Group (FOODS)

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Allergen, Macadamia Nut IgE (MACADA)

Allergen, Mackerel IgE (MACKEL)

Allergen, Fusarium proliferatum IgE (FUSAR) Allergen, Malt IgE (MLTIGE) Allergen, Garlic IgE (GARLIC) Allergen, Mango IgE (MANGO) Allergen, Meadow Fescue IgE (MFESCU) Allergen, Gelatin IgE (GELATN) Allergen, Melaleuca (Cajeput) Tree IgE (MLALUC) Allergen, Giant Ragweed IgE (GRAGWD) Allergen, Gluten IgE (GLUTEN) Allergen, Melon IgE (MELON) Allergen, Goldenrod IgE (GOLDRD) Allergen, Mini Screen (MINI) Allergen, Goose Feathers IgE (GOOSEF) Allergen, Mold Group (MOLDS) Allergen, Grape IgE (GRAPE) Allergen, Mountain Juniper IgE (MTJUNI) Allergen, Grapefruit IgE (GRAFRU) Allergen, Mouse Epithelium IgE (MOUEPI) Allergen, Grasses Group (GRASS) Allergen, Mouse Proteins IgE (MOUSE) Allergen, Great Lakes Group (GRTLKS) Allergen, Mouse Urine Proteins IgE (MOUUR) Allergen, Green Bean IgE (GRBEAN) Allergen, Mucor racemosus IgE (MUCOR) Allergen, Guinea Pig Epithelium IgE (GPIG) Allergen, Mugwort IgE (MUGWRT) Allergen, Halibut IgE (HALIBT) Allergen, Mulberry IgE (MULBRY) Allergen, Hamster Epithelium IgE (HMSTR) Allergen, Mushroom IgE (MUSHRM) Allergen, Hazelnut Components IgE (HZNTCP) Allergen, Mustard IgE (MUSTD) Allergen, Hazel Nut IgE (HAZEL) Allergen, Nettle IgE (NETTLE) Allergen, Hazel Nut Tree IgE (HZNTTR) Allergen, Nut Panel Group (NUTPNL) Allergen, Helminthosporium halodes IgE (HELMIN) Allergen, Oak Tree IgE (OAK) Allergen, Hickory/Pecan Tree IgE (HIKPEC) Allergen, Oat IgE (OAT) Allergen, Honeybee IgE (HONBEE) Allergen, Onion IgE (ONIONS) Allergen, Horse Dander IgE (HORSE) Allergen, Orange IgE (ORNGE) Allergen, House Dust (Greer) IgE (DUSTG) Allergen, Orchard Grass IgE (ORCHRD) Allergen, House Dust (Hollister-Stier) IgE (DUST) Allergen, Oyster IgE (OYSTER) Allergen, Indoor Allergy Panel (INDOOR) Allergen, Paper Wasp IgE (PAWASP) Allergen, Parsley IgE (PARSLY) Allergen, Inhalants Group (INHALE) Allergen, Insect Group (INSECT) Allergen, Pea IgE (PEES) Allergen, Japanese Cedar IgE (JAPCED) Allergen, Peach IgE (PEACH) Allergen, Johnson Grass IgE (JONSON) Allergen, Peanut Components IgE (PNUTCP) Allergen, June Grass (Kentucky Blue, Meadow) IgE Allergen, Peanut IgE (PEANUT) (JUNEGR) Allergen, Peanut IgE with Reflex to Peanut Components, Allergen, Kidney Bean IgE (KDBEAN) IgE (PNTRFX) Allergen, Kiwi IgE (KIWI) Allergen, Pear IgE (PEARS) Allergen, Pecan Nut IgE (PECAN) Allergen, Lamb's Quarters (Goosefoot) IgE (LAMBQU) Allergen, Latex IgE (LATEXA) Allergen, Pediatric Group (PEDTRC) Allergen, Lemon IgE (LEMON) Allergen, Pediatric Profile (SCRPED) Allergen, Lentil IgE (LENTIL) Allergen, Penicillins IgE (PENCLS) Allergen, Lettuce IgE (LETUCE) Allergen, Penicillium chrysogenum IgE (PNOTAT) Allergen, Lime IgE (LIME) Allergen, Penicilloyl G IgE (PENG) Allergen, Linseed IgE (LINSED) Allergen, Penicilloyl V IgE (PENV) Allergen, Lobster IgE (LOBSTR) Allergen, Phoma Betae IgE (PHOMAB)

(continued on page 5)

Allergen, Pigweed IgE (PGWEED)

Allergen, Pine Nut IgE (PINENT)

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Allergen, Pineapple IgE (PINEAP)
Allergen, Pistachio IgE (PISTAC)
Allergen, Plum IgE (PLUMM)
Allergen, Poppy Seed IgE (POPSED)

Allergen, Pork IgE (PORK)
Allergen, Potato IgE (POTATO)

Allergen, Pumpkin Seed IgE (PUMKSD) Allergen, Rabbit Epithelium IgE (RABEPI)

Allergen, Raspberry IgE (RASPBY)
Allergen, Red Cedar Tree IgE (RDCEDR)

Allergen, Red Dye IgE (REDDYE)
Allergen, Redtop Grass IgE (REDTOP)

Allergen, Respiratory Disease Profile Region 4

(RESPR4)

Allergen, Respiratory Disease Profile Region 5 (RESPR5)

Allergen, Respiratory Disease Profile Region 7 (RESPR7)

Allergen, Respiratory Region 8 (RESPR8)
Allergen, Rhizopus nigricans IgE (RHIZOP)

Allergen, Rice IgE (RICE)

Allergen, Rough Marshelder IgE (RMELDR)
Allergen, Russian Thistle IgE (THISTL)
Allergen, Rye Grass IgE (RYEGRS)

Allergen, Rye IgE (RYE)

Allergen, Salad Mix Group (SALAD) Allergen, Salmon IgE (SMON) Allergen, Scallop IgE (SCALOP)

Allergen, Screen (SCR)

Allergen, Screen Panel RL (SCRNRL)
Allergen, Seafood Group (SEFOOD)
Allergen, Seafood Panel (SEAFOD)
Allergen, Sesame Seed IgE (SESAME)
Allergen, Sheep Epithelium IgE (SHEEP)
Allergen, Sheep Sorrel IgE (SORREL)
Allergen, Shellfish Panel IgE (SHLFSH)

Allergen, Short (Common) Ragweed IgE (SRAGWD)

Allergen, Shrimp IgE (SHRIMP) Allergen, Sole IgE (SOLE)

Allergen, South Florida Long Panel (SFLONG)
Allergen, South Florida Short Panel (SFSHRT)
Allergen, Soybean Components IgE (SYBNCP)

Allergen, Soybean IgE (SOYBN)

Allergen, Squid IgE (SQUID)

Allergen, Stemphylium herbarum IgE (SBOTRY)

Allergen, Strawberry IgE (STRBRY)
Allergen, Sunflower Seed IgE (SUNFLR)
Allergen, Sweet Gum IgE (SWEGUM)
Allergen, Sweet Potato IgE (SWEPOT)
Allergen, Sweet Vernal Grass IgE (SWVERN)
Allergen, Sycamore Tree IgE (SYCMOR)

Allergen, Tilapia IgE (TILAPI)

Allergen, Timothy Grass IgE (TIMTHY)
Allergen, Tomato IgE (TOMATO)
Allergen, Tree Group (TREES)

Allergen, Tree, Hackberry IgE (HCKBRY)
Allergen, Trichophyton rubrum IgE (RUBRUM)

Allergen, Trout IgE (TROUT) Allergen, Tuna IgE (TUNA) Allergen, Turkey IgE (TURKEY) Allergen, Vanilla IgE (VANILA)

Allergen, Vegetables Group (VEGGIE)

Allergen, Walnut Components IgE (WLNTCP)

Allergen, Walnut IgE (WALNUT)
Allergen, Walnut Tree IgE (WNUTTR)
Allergen, Watermelon IgE (WATMEL)

Allergen, Weed, Careless Weed IgE (CRLSWD)

Allergen, Weed Group (WEEDS)

Allergen, Weed, Yellow Dock (Rumex crispus) IgE

(YELDOK)

Allergen, Wheat IgE (WHEAT)
Allergen, Whey IgE (MWHEY)

Allergen, White Ash Tree IgE (WHTASH)
Allergen, White Bean IgE (WTBEAN)

Allergen, White Faced Hornet IgE (WHORNT)

Allergen, Whitefish IgE (WHIFSH)
Allergen, White Hickory IgE (WHICK)
Allergen, White Pine Tree IgE (WTPINE)
Allergen, Whole Egg IgE (WHOEGG)
Allergen, Willow Tree IgE (WILLOW)

Allergen, Yeast IgE (BYEAST)

Allergen, Yellow Hornet IgE (YLHORN)

Allergen, Yellow Jacket (Common Wasp) IgE (YELJAK)

Allergen, Zone 8 Panel (ZONE8)

# Test Changes

Test Name	Order Code	Change	Effective Date
Absolute Granulocyte Count with CBC	AGCCBC	Special Information: If blasts, atypical lymphocytes, or lymphoma cells are seen by manual review of peripheral blood smear, a differential is performed and billed.	12/24/20
Adenosine Deaminase, Peritoneal Fluid	PERAD	Special Information: Indicate source. Whole blood, bronchoalveolar lavage (BAL) specimens, and turbid specimens will be rejected.	11/16/20
Peritorieai Fiuld		Specimen Requirement: 0.5 mL peritoneal fluid in a clean container; Minimum: 0.2 mL; Use leak-proof container; Centrifuge sample, then aliquot and freeze; Frozen  Stability: Ambient: 24 hours Refrigerated: 1 week Frozen: 1 month	
		Reference Range: 0–30 U/L	
Adenosine Deaminase, Pleural	PFAD	Special Information: Indicate source. Whole blood, bronchoalveolar lavage (BAL) specimens, and turbid specimens will be rejected.	11/16/20
Fluid		Specimen Requirement: 0.5 mL pleural fluid in a clean container; Minimum:  0.2 mL; Use leak-proof container; Centrifuge specimen, transfer to a clean container and freeze; Frozen  Stability:  Ambient: 24 hours Refrigerated: 1 week Frozen: 1 month  Reference Range: 0–30 U/L	
BCR-ABL Qualitative	BCRQL	Clinical Information: This assay detects and differentiates all known BCR/ABL1	11/3/20
Multiplex RT-PCR	BONGE	splice variants, including the p190, p210 and 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. When transcripts of other rare variants are detected by this test, BCRABL1 FISH testing will be performed prior to reporting if specimen is available.  CPT: 81206 x 1, 81207 x 1, 81208 x 1	11/5/20
Carotene	CAROT	Days Performed: Monday, Thursday, Saturday	11/16/20
		Reported: 2–5 days	
Chlorpromazine, Quant	CLORPR	Special Information: Draw trough specimen before the next dose at steady state concentration. Whole blood, gel separator tubes, hemolyzed samples, citrate (light blue) tube, and tubes with SPS or ACD (yellow) solution will be rejected.	11/16/20
		Clinical Information: Chlorpromazine is a neuroleptic drug indicated for the treatment of schizophrenia, psychotic disorders and intractable hiccup. Chlorpromazine should not be used in patients who have epilepsy, Parkinson's disease, hypoparathyroidism, myasthenia gravis, and prostatic hypertrophy. Adverse effects may include drowsiness, hypotension, agranulocytosis, cardiac abnormalities, seizures and rare life-threatening effects, such as phenothiazine sudden death syndrome, and neuroleptic malignant syndrome.	
		Specimen Requirement: 2 mL serum from a plain no additive (red) tube; Minimum: 0.5 mL; Predose (trough) draw—At steady state concentration; Do NOT draw separator tubes; Remove serum from cells ASAP or within 2 hours of collection and transfer into a standard aliquot tube; Frozen	
		*OR* 2 mL plasma from an EDTA (lavender) tube; Minimum: <b>0.5 mL; Predose (trough) draw–At steady state concentration; Do NOT draw separator tubes;</b> Remove plasma from cells ASAP or within 2 hours of collection <b>and transfer into a standard aliquot tube;</b> Frozen	
		*OR* 2 mL plasma from a sodium or lithium heparin (green) tube; Minimum: 0.5 mL; Predose (trough) draw—At steady state concentration; Do NOT draw separator tubes; Remove plasma from cells ASAP or within 2 hours of collection and transfer into a standard aliquot tube; Frozen	
		*OR* 2 mL plasma from a potassium oxalate/sodium fluoride (gray) tube; Minimum: 0.5 mL; Predose (trough) draw-At steady state concentration; Do NOT draw separator tubes; Remove plasma from cells ASAP or within 2 hours of collection and transfer into a standard aliquot tube; Frozen	
		(continued on page 7)	

Test Name	Order Code	Change	Effective Date
Chlorpromazine, Quant (continued from page 6)		Stability: Ambient: After separation from cells: Unacceptable Refrigerated: After separation from cells: 14 days Frozen: After separation from cells: 14 days Reference Range: 30–300 ng/mL Days Performed: Monday Reported: 9–10 days	
Complete Blood Count	CBC	Special Information: For outpatients and emergency department (ED) patients only: If the white blood cell (WBC) count is $<$ 2.01 k/ $\mu$ L or $>$ 19.99 k/ $\mu$ L, a differential will be performed and billed.	12/27/20
Cyanide, Blood	CYANID	Special Information: Critical frozen. This test is New York DOH approved.  Clinical Information: Studies have shown that cyanide has variable instability in biological specimens and is particularly unstable in some postmortem specimens. The loss of cyanide can be minimized by shipping the sample to the laboratory for analysis as soon as possible using potassium oxalate/sodium fluoride (gray) tubes. The potential for increases in cyanide concentrations, although rare, have also been demonstrated and may be due to microbial action. Preservation with sodium fluoride may reduce this possibility.  Specimen Requirement: 1 mL whole blood in a potassium oxalate/sodium fluoride (gray) tube; Minimum: 0.4 mL; Separate specimens must be submitted when multiple tests are ordered; Critical Frozen  Stability:  Ambient: Undetermined Refrigerated: 24 hours Frozen: 3 months  Methodology: High Performance Liquid Chromatography/Tandem Mass Spectrometry (LC/MS/MS)  Reference Range: Refer to report  Days Performed: Varies	11/16/20
Dermatomyositis Panel	DERMYO	Reported: 9–12 days  CPT: 83516 x 2, 84182 x 4	11/16/20
Glutathione Total	GLUTAT	Specimen Requirement: 10 mL or 8 mL blood in an ACD A (yellow) or ACD B (yellow) tube; Minimum volume is 8.5 mL or 6.5 mL depending on tube size used; Separate specimens must be submitted when multiple tests are ordered; Critical Refrigerated	Effective immediately
Heparin Anti Xa Assay	HEPASY	Special Information: 3.2% sodium citrate is the preferred anticoagulant recommended by Clinical and Laboratory Standards Institute (CLSI). Patient samples should be centrifuged by the laboratory < 1 hour from collection time to prevent falsely decreased Heparin Anti Xa values due to heparin neutralization by in vitro release of platelet factor 4. Samples that are centrifuged > 1 and < 4 hours from collection will have the following comment attached: Interpret with caution. Sample centrifuged greater than 1 hour from collection time. According to Clinical and Laboratory Standards Institute guidelines, results could be falsely decreased due to heparin neutralization by in vitro release of platelet factor 4. Suggest correlation with clinical findings and redraw if indicated.	11/3/20
Hepatitis A Antibody, Total	AHAVT	Clinical Limitation: The test is not approved for donor testing.  Note: Clinical Information will be removed.	11/24/20
lgE	IGE	Stability: Ambient: 1 day Refrigerated: 7 days Frozen: <b>30</b> days	Effective immediately
Immunofixation Screen, Serum	IFESC	Stability: Ambient: 1 day Refrigerated: 14 days Frozen: 30 days	12/8/20

Test Name	Order Code	Change	Effective Date
KIT (D816V) Mutation by PCR  KIT816		For Interfaced Clients Only: Test build may need to be modified  Special Information: DNA isolation is performed Sunday—Saturday. Plasma, serum, formalin-fixed paraffin-embedded (FFPE) tissue blocks/slides, fresh or frozen tissue, or DNA extracted by a non-CLIA lab will be rejected. Specimens collected in anticoagulants other than EDTA or sodium heparin are unacceptable. Clotted or grossly hemolyzed specimens will be rejected.  Note: Clinical Information will be removed.  Specimen Requirement: 5 mL whole blood in an EDTA (lavender) tube; Minimum: 1 mL; Do not freeze; Refrigerated  *OR* 3 mL bone marrow in an EDTA (lavender) tube; Minimum: 1 mL; Do not freeze; Refrigerated  *OR* 5 mL whole blood in a sodium heparin (green) tube; Minimum: 1 mL; Do not freeze; Refrigerated  *OR* 3 mL bone marrow in a sodium heparin (green) tube; Minimum: 1 mL; Do not freeze; Refrigerated  *OR* 3 mL bone marrow in a sodium heparin (green) tube; Minimum: 1 mL; Do not freeze; Refrigerated  *OR* 3 mL bone marrow in a sodium heparin (green) tube; Minimum: 1 mL; Do not freeze; Refrigerated  *OR* 3 mL bone marrow in a sodium heparin (green) tube; Minimum: 1 mL; Do not freeze; Refrigerated  *OR* 3 mL bone marrow in a sodium heparin (green) tube; Minimum: 1 mL; Do not freeze; Refrigerated  *OR* 3 mL bone marrow in a sodium heparin (green) tube; Minimum: 1 mL; Do not freeze; Refrigerated  *OR* 3 mL bone marrow in a sodium heparin (green) tube; Minimum: 1 mL; Do not freeze; Refrigerated  *OR* 3 mL bone marrow in a sodium heparin (green) tube; Minimum: 1 mL; Do not freeze; Refrigerated	11/16/20
LMW Anti Xa Assay	LMWHEP	Special Information: 3.2% sodium citrate is the preferred anticoagulant recommended by Clinical and Laboratory Standards Institute (CLSI). Patient samples should be centrifuged by the laboratory < 1 hour from collection time to prevent falsely decreased Low Molecular Weight Anti Xa values due to heparin neutralization by in vitro release of platelet factor 4. Samples that are centrifuged > 1 and < 4 hours from collection will have the following comment attached: Interpret with caution. Sample centrifuged greater than 1 hour from collection time. According to Clinical and Laboratory Standards Institute guidelines, results could be falsely decreased due to heparin neutralization by in vitro release of platelet factor 4. Suggest correlation with clinical findings and redraw if indicated.	11/3/20
LYME AB Early Disease (≤ 30 days of signs and symptoms), with Reflex	LMERLY	Clinical Limitation: Grossly hemolyzed, icteric, or lipemic samples, as well as samples containing particulate matter or exhibiting obvious microbial contamination, should not be tested. The results are not by themselves diagnostic and should be considered in association with the second step Western Blot and other clinical data and symptoms. This assay should not be used for general population screening. It should be used only for patients with signs and symptoms suggestive of Lyme disease. Potential assay interference due to circulating antibodies against Human Ehrlichiosis, Tick Borne Relapsing Fever, Babesiosis, Parvovirus and Epstein-Barr Virus (EBV) infections has been found.  Clinical Information: Qualitative test for the presence of IgG and IgM antibodies to Borrelia burgdorferi, the causative agent of Lyme disease. Positive or equivocal results will automatically reflex to an IgG and IgM Western Blot for confirmation and will be billed accordingly. Recent infection with B. burgdorferi sensu lato cannot be excluded if the specimen is collected within four weeks after the onset of signs and symptoms or within six weeks after a known tick exposure. Clinical and epidemiological correlation is required.  Stability:  Ambient: 48 hours Refrigerated: 14 days Frozen: 15 days at minus 20 °C or below (Avoid multiple freeze/thaw cycles)	11/19/20

Test Name	Order Code	Change	Effective Date
LYME AB Late Disease (> 30 days of signs or symptoms), with Reflex	LMLATE	Clinical Limitation: Grossly hemolyzed, icteric, or lipemic samples, as well as samples containing particulate matter or exhibiting obvious microbial contamination, should not be tested. The results are not by themselves diagnostic and should be considered in association with the second step Western Blot and other clinical data and symptoms. This assay should not be used for general population screening. It should be used only for patients with signs and symptoms consistent with Lyme disease. Potential assay interference due to circulating antibodies against Human Ehrlichiosis, Tick Borne Relapsing Fever, Babesiosis, Parvovirus and Epstein-Barr Virus (EBV) infections has been found.  Clinical Information: Qualitative test for the presence of IgG and IgM antibodies to Borrelia burgdorferi, the causative agent of Lyme disease. Positive or equivocal results will automatically reflex to an IgG and IgM Western Blot for confirmation, and will be billed accordingly. Recent infection with B. burgdorferi sensu lato cannot be excluded if the specimen is collected within four weeks after the onset of signs and symptoms or within six weeks after a known tick exposure. Clinical and epidemiological correlation is required.  Stability:  Ambient: 48 hours Refrigerated: 14 days Frozen: 15 days at minus 20 °C or below (Avoid multiple freeze/thaw cycles)	11/19/20
Monoclonal Protein, 24 Hour Urine	U24MPA	Stability: Ambient: 1 day Refrigerated: 14 days Frozen: 30 days	12/8/20
Monoclonal Protein, Urine	URMPA	Stability: Ambient: 1 day Refrigerated: 14 days Frozen: 30 days	12/8/20
Monoclonal Protein with Immunoglobulins and Free Light Chains, serum	SERMPA	Stability: Ambient: 1 day Refrigerated: 14 days Frozen: 30 days	12/8/20
Myelin Basic Protein, CSF	СМВР	Special Information: Hemolysis is unacceptable and is associated with falsely- elevated levels of myelin basic protein (MBP) in the cerebrospinal fluid (CSF). CSF should be free from contamination with blood, if possible. If CSF is bloody, centrifuge the sample and separate supernatant from cells prior to freezing the sample. This test is New York DOH approved.  Clinical Information: Not recommended for the workup of suspected multiple sclerosis.  Methodology: Enzyme-Linked Immunosorbent Assay (ELISA)	11/16/20
pH, Fecal	FECLPH	Special Information: Unacceptable: Specimens containing barium, diapers, stool in media or preservatives, grossly bloody specimens. This test is New York DOH approved.  Specimen Requirement: 5 g stool in a clean container (No preservatives); Minimum: 1 g; Frozen, ASAP  Stability: Ambient: 1 hour Refrigerated: 2 weeks Frozen: 2 weeks  Days Performed: Sunday–Saturday Reported: 2–4 days	11/16/20
Polymyositis and Dermatomyositis Panel	MYOSPL	<b>CPT</b> : 83516 <b>x 7, 84182 x 4,</b> 86235 x 1	11/16/20
Protein Electrophoresis, Serum	SEPG	Stability: Ambient: 4 days Refrigerated: 14 days Frozen: 30 days	12/8/20

Test Name	Order Code	Change	Effective Date
Protein Electrophoresis, Serum, with IFE	SEPGRX	Stability: Ambient: 4 days Refrigerated: 14 days Frozen: 30 days	12/8/20
Protein Electrophoresis, Ur 24 Hr w/M Protein Quant	UEPG24	Stability: Ambient: 4 days Refrigerated: 14 days Frozen: 30 days	12/8/20
Protein Electrophoresis, Urine Random	UEPG	Stability: Ambient: 4 days Refrigerated: 14 days Frozen: 30 days	12/8/20
Protein Electrophoresis, Urine, with IFE	UEPGRX	Stability: Ambient: 4 days Refrigerated: 14 days Frozen: 30 days	12/8/20
PTH Intact, Fluid	FLPTH	Special Information: Unacceptable conditions: Specimen types other than those listed, specimens too viscous to be aspirated by the instrument, grossly hemolyzed samples, grossly lipemic samples. Indicate source on test request form.  Specimen Requirement: 0.5 mL fine needle aspirate (FNA) in a clean container with saline; Minimum: 0.5 mL; Specimen must be non-viscous, non-hemolyzed, and free of particulate matter; Centrifuge to remove cellular material and visible hemolysis; Indicate source of specimen; Transfer 0.5 mL saline needle rinse to a standard transport tube; Frozen  *OR* 0.5 mL body fluid in an EDTA (lavender) tube; Minimum: 0.5 mL; Specimen must be non-viscous, non-hemolyzed, and free of particulate matter; Centrifuge to remove cellular material and visible hemolysis; Indicate source of specimen; Transfer 0.5 mL saline needle rinse to a standard transport tube; Frozen  *OR* 0.5 mL body fluid in a lithium heparin (green) tube; Minimum: 0.5 mL; Specimen must be non-viscous, non-hemolyzed, and free of particulate matter; Centrifuge to remove cellular material and visible hemolysis; Indicate source of specimen; Transfer 0.5 mL saline needle rinse to a standard transport tube; Frozen  *OR* 0.5 mL body fluid in a sodium heparin (green) tube; Minimum: 0.5 mL; Specimen must be non-viscous, non-hemolyzed, and free of particulate matter; Centrifuge to remove cellular material and visible hemolysis; Indicate source of specimen; Transfer 0.5 mL saline needle rinse to a standard transport tube; Frozen	11/16/20
Urticaria-Inducing Activity	UTACT	Special Information: Critical frozen. Patients taking calcineurin inhibitors should stop their medications for 72 hours prior to draw. Patients on prednisone should be off medication for 2 weeks prior to draw. Separate specimens must be submitted when multiple tests are ordered. Specimens other than serum are unacceptable. Grossly hemolyzed, lipemic, or contaminated specimens will be rejected. This test is New York DOH approved.  Days Performed: Monday, Friday  Reported: 12–15 days	11/16/20

## New Tests

Test Name	Order Code	Change	Effective Date
Beta-hCG, Quantitative (Tumor	HCGCSF	<b>Special Information:</b> Body fluids other than cerebrospinal fluid (CSF) will be rejected. This test is New York DOH approved.	11/19/20
Marker), CSF		Clinical Information: Human chorionic gonadotropin (hCG) is a valuable aid in the management of patients with trophoblastic tumors, nonseminomatous testicular tumors, and seminomas when used in conjunction with information available from the clinical evaluation and other diagnostic procedures. Increased hCG concentrations have also been observed in melanoma, carcinomas of the breast, gastrointestinal tract, lung, and ovaries, and in benign conditions including cirrhosis, duodenal ulcer, and inflammatory bowel disease. The result cannot be interpreted as absolute evidence of the presence or absence of malignant disease. The result is not interpretable as a tumor marker in pregnant females. The combination of the specific monoclonal antibodies used in the Roche Beta HCG electrochemiluminescent immunoassay recognizes the holo-hormone, 'nicked' forms of hCG, the beta-core fragment, and the free beta-subunit. Results obtained with different test methods or kits cannot be used interchangeably.	
		Specimen Requirement: 0.5 mL cerebrospinal fluid (CSF) in a clean container; Minimum: 0.3 mL; Refrigerated	
		*OR* 0.5 mL cerebrospinal fluid (CSF) in a sodium or lithium heparin (green) tube; Minimum: 0.3 mL; Refrigerated	
		$^{\star}\text{OR}^{\star}$ 0.5 mL cerebrospinal fluid (CSF) in a plain no additive (red) tube; Minimum: 0.3 mL; Refrigerated	
		Stability: Ambient: 5 days Refrigerated: 2 weeks Frozen: 1 year	
		Methodology: Electro Chemiluminescence Immunoassay (ECLIA)	
		Days Performed: Sunday–Saturday Reported: 2–3 days	
		<b>CPT:</b> 84702 x 1	
		Price: \$47.00 (non-discountable)	
CSF3R Mutation	CSF3RP	Special Information: The following genes are interrogated: CSF3R	11/3/20
Analysis Blood		Clinical Information: For evaluation of BCR/ABL1 negative unexplained leukocytosis. The majority of patients (~90%) with chronic neutrophilic leukemia (CNL) have CSF3R mutations (PMID: 26700908). Although highly enriched in CNL, CSF3R mutations can rarely occur in other hematologic malignancies such as BCR/ABL1 negative atypical chronic myeloid leukemia (aCML), acute myeloid leukemia (AML), and chronic myelomonocytic leukemia (CMML).	
		Specimen Requirement: 4 mL blood in an EDTA (lavender) tube; Ambient	
		Stability: Ambient: 48 hours Refrigerated: 7 days Frozen: Unacceptable	
		Methodology: Next Generation DNA Sequencing	
		Days Performed: 2 days per week	
		Reported: 10 days	
		CPT: 81403 x 1	
		Price: \$1136.00 (non-discountable)	

# New Tests (Cont.)

Test Name	Order Code	Change	Effective Date
Test Name  CSF3R Mutation  Analysis Bone Marrow	CSF3RM  Special Information: The following genes are interrogated: CSF3R  Clinical Information: For evaluation of BCR/ABL1 negative unexplained leukocytosis. The majority of patients (~90%) with chronic neutrophilic leukemia (CNL) have CSF3R mutations (PMID: 26700908). Although highly enriched in CNL, CSF3R mutations can rarely occur in other hematologic malignancies such as BCR/ABL1 negative atypical chronic myeloid leukemia (aCML), acute myeloid leukemia (AML), and chronic myelomonocytic leukemia (CMML).  Specimen Requirement: 2 mL bone marrow aspirate in an EDTA (lavender) tube; Ambient  Stability: Ambient: 48 hours Refrigerated: 7 days Frozen: Unacceptable		Effective Date 11/3/20
		Methodology: Next Generation DNA Sequencing  Days Performed: 2 days per week  Reported: 10 days  CPT: 81403 x 1  Price: \$1136.00 (non-discountable)	
Hepatitis A Antibody, IgG	AHAVG	Clinical Limitation: Serum is the only acceptable sample type. Performance has not been established for the use of cadaveric specimens or other body fluids. Do not use specimens with the following conditions: heat-inactivated, grossly hemolyzed or obvious microbial contamination. This assay has not been FDA cleared or approved for the screening of blood or plasma donors. This assay cannot be used for the diagnosis of acute Hepatitis A Virus (HAV) infection. Specimens from individuals with anti-E. coli, anti-CMV, or hemodialysis patients may cross-react with this assay.  Clinical Information: The test is used to determine immune status to Hepatitis A Virus (HAV) as a result of vaccination or past infection. Should recent infection be suspected, this test needs to be ordered along with HAV IgM test.  Specimen Requirement: 0.5 mL serum from a serum separator (gold) tube; Minimum: 0.3 mL; Refrigerated  Stability:  Ambient: 4 days  Refrigerated: 8 days  Frozen: 14 days  Methodology: Chemiluminescent Microparticle Immunoassay (CMIA)  Reference Range: Negative  Days Performed: Sunday–Saturday  Reported: 1–2 days  CPT: 86708 x 1  Price: \$42.00	11/24/20
KIT Mutation Analysis Blood	KITPB	Special Information: The following genes are interrogated: KIT Clinical Information: For use in evaluation of acute myeloid leukemia. Coverage includes exons 2, 8-11, 13 and 17.  Specimen Requirement: 4 mL whole blood in an EDTA (lavender) tube; Ambient Stability: Ambient: 48 hours Refrigerated: 7 days Frozen: Unacceptable Methodology: Next Generation DNA Sequencing Days Performed: 2 days per week Reported: 10 days CPT: 81272 x 1, 81273 x 1 Price: \$965.00 (non-discountable)	11/3/20

# New Tests (Cont.)

Test Name	Order Code	Change	Effective Date
KIT Mutation Analysis Bone Marrow	KITBM	Special Information: The following genes are interrogated: KIT  Clinical Information: For use in evaluation of acute myeloid leukemia. Coverage includes exons 2, 8-11, 13 and 17.  Specimen Requirement: 2 mL bone marrow aspirate in an EDTA (lavender) tube; Ambient  Stability:  Ambient: 48 hours Refrigerated: 7 days Frozen: Unacceptable  Methodology: Next Generation DNA Sequencing	11/3/20
		Days Performed: 2 days per week  Reported: 10 days  CPT: 81272 x 1, 81273 x 1  Price: \$965.00 (non-discountable)	
SF3B1 Mutation Analysis Blood	SF3B1P	Special Information: The following genes are interrogated: SF3B1  Clinical Information: Somatic mutations in SF3B1 have been reported in 15-30% of myelodysplastic syndrome (MDS) cases, including the vast majority of MDS cases with ring sideroblasts phenotype (70-80%), in chronic lymphocytic leukemia (CLL, 15%), and, at a lower rate, in other myeloid neoplasms and some solid tumors (PMID: 21909114, PMID: 24523246).  Specimen Requirement: 4 mL blood in an EDTA (lavender) tube; Ambient Stability:  Ambient: 48 hours Refrigerated: 7 days Frozen: Unacceptable  Methodology: Next Generation DNA Sequencing  Days Performed: 2 days per week  Reported: 10 days  CPT: 81403 x 1  Price: \$1136.00 (non-discountable)	11/3/20
SF3B1 Mutation Analysis Bone Marrow	SF3B1M	Special Information: The following genes are interrogated: SF3B1  Clinical Information: Somatic mutations in SF3B1 have been reported in 15-30% of myelodysplastic syndrome (MDS) cases, including the vast majority of MDS cases with ring sideroblasts phenotype (70-80%), in chronic lymphocytic leukemia (CLL, 15%), and, at a lower rate, in other myeloid neoplasms and some solid tumors (PMID: 21909114, PMID: 24523246).  Specimen Requirement: 2 mL bone marrow aspirate in an EDTA (lavender) tube; Ambient  Stability:  Ambient: 48 hours Refrigerated: 7 days Frozen: Unacceptable  Methodology: Next Generation DNA Sequencing  Days Performed: 2 days per week  Reported: 10 days  CPT: 81403 x 1  Price: \$1136.00 (non-discountable)	11/3/20

### Fee Increases

Test Name	Order Code	List Fee	CPT Code	Effective Date
Cyanide, Blood	CYANID	\$129.00 (non-discountable)	82600	11/16/20
KIT (D816V) Mutation by PCR	KIT816	\$350.00 (non-discountable)	81273	11/16/20
Polymyositis and Dermatomyositis Panel	MYOSPL	\$604.00 (non-discountable)	83516 x 7, 84182 x 4, 86235	11/16/20

### Fee Reductions

Test Name	Order Code	List Fee	CPT Code	Effective Date
BCR-ABL Qualitative Multiplex RT-PCR	BCRQL	\$641.00 (non-discountable)	81206, 81207, 81208	11/3/20

### **Discontinued Tests**

Test Name	Order Code	Test Information	Effective Date
GNRH Stimulation	GNRSTM	This test will no longer be available.	11/10/20
KIT Mutation Exons 8-11 and 17, Hema- tologic Neoplasms, Sequencing	KITEML	This test will no longer be available. Suggest ordering KIT Mutation Analysis Blood (KITPB) or KIT Mutation Analysis Bone Marrow (KITBM)	12/1/20
Pituitary Evaluation	PTEVAL	This test will no longer be available.	11/10/20