

# Cleveland Clinic Laboratories

## Technical Update • February 2019

Cleveland Clinic Laboratories is dedicated to keeping you updated and informed about recent testing changes. This Technical Update is provided on a monthly basis to notify you of any changes to the tests in our catalog.

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

To compare the new information with previous test information, refer to the online Test Directory at [clevelandcliniclabs.com](http://clevelandcliniclabs.com). Test information is updated in the online Test Directory on the Effective Date stated in the Technical Update. Please update your database as necessary.

For additional detail, contact Client Services at 216.444.5755 or 800.628.6816, or via email at [clientservices@ccf.org](mailto:clientservices@ccf.org).

Test Update Page #	Summary of Changes by Test Name	Order Code	Name Change	New Test	Test Discontinued	Special Information	Specimen Requirement	Component Change(s)	Methodology	Days Performed/Reported	Reference Range	Stability	CPT	Fee
4	Adenovirus Antigen Detection, Gastroenteritis, EIA													
18	Allergen, Ampicilloyl IgE													
4	Allergen, Cat Components IgE													
4	Allergen, Cow Milk Components IgE													
4	Allergen, Dog Components IgE													
4	Allergen, Dust Mite Components IgE													
4	Allergen, Egg Components IgE													
4	Allergen, Hazelnut Components IgE													
4	Allergen, Soybean Components IgE													
5	Allergen, Walnut Components IgE													
5	Alpha-1-Antitrypsin Clearance, Timed													
5	Alpha-1-Antitrypsin Phenotype by Electrophoresis													
5-6	Antimony, Blood													
6	Barbiturates													
6	Bartonella PCR, tissue													
18	Benzoylcegonine Confirmation/Quantitation													
18	Beta Galactosidase, Leukocytes													
6	Bromide													
7	C1Q Binding Assay													
7	C2 Complement, Functional with Reflex, Serum													
7	Chromium, Blood													
7	CK													
7	CK Isoenzymes													

Test Update  
Page #

Summary of Changes  
by Test Name

Order Code	Name Change	New Test	Special Information	Specimen Requirement	Component Change(s)	Methodology	Days Performed/Reported	Reference Range	Stability	CPT	Fee
7	CKMB										
7	CK, Total and CKMB										
18	Clobazam										
7	CMV by PCR, non-blood specimens										
7	Copper										
8	Copper/Zinc										
8	Cyanide, Blood										
8	Ehrlichia chaffeensis IgG & IgM Abs by IFA										
8	Ethyl Glucuronide, Urine Confirm/Quant										
8	Fentanyl and Metabolite										
8	Flecainide										
16	FLT3 ITD and TKD Mutation Detection by PCR										
18	FLT3 Mutation Detection by PCR										
16	Fluid Hematocrit										
16	Fluid Hemoglobin										
9	FSHD DNA Test										
9	Gabapentin										
9	Gabitril										
9	Galactocerebrosidase										
9, 18	Herpesvirus 6 IgM Antibody										
9	Ibuprofen										
10	IgA										
10	IgG										
10	IgM										
10	JC Polyoma Virus Quantitative PCR										
18	Kappa, Serum										
18	Kidney Anti-A Titer										
18	Lambda, Serum										
10	Lead, Blood										
10	Lithium										
11	Manganese										
18	Mephenytoin & Normephenytoin										
11	Mexiletine										
11	Mycophenolic Acid and Metabolite										
18	Mycoplasma pneumoniae IgA										
11, 18	Neisseria gonorrhoea Antibodies, Total										
18	Niacin										
11	Nickel, Serum										
11	Organic Acids, Plasma										
17	Pan-Solid Tumor NGS Panel										
12	Platelet Function Screen										
12	Pregabalin										

Test Update Page #	Summary of Changes by Test Name	Name Change	Order Code	New Test	Special Information	Specimen Requirement	Component Change(s)	Methodology	Days Performed/Reported	Reference Range	Stability	CPT	Fee
12	Primidone												
12	Rheumatoid Factor												
12	Risperidone & Metabolite												
18	Rotavirus and Adenovirus 40-41 Antigens												
12	Selenium Blood												
12	Sertraline												
12, 18	S-Sulfocysteine, Urine												
18	Strychnine												
13	Sulfonamides												
13	Sulfonylurea Hypoglycemics												
13	Synthetic Cannabinoid Metabolites – Expanded, Urine (Qualitative)												
13	Tapentadol and Metabolite Confirm/Quantitation, Urine												
14	Thallium, Blood												
14	Thiocyanate, Urine Random												
14	TTR Gene, Full Gene Analysis												
14–15	Vitamin B6												
15	Voltage-Gated Potassium Channel (VGKC) Antibody												
15	Zinc												
15	Zinc, Whole Blood												

**Dear Valued Client,**

As part of an ongoing effort to standardize the specimen requirement for certain trace/heavy metals tests in our directory, the verbiage for “navy blue” tube will be replaced by “royal blue” tube. Please note that the specimen collection tube will remain the same in these instances.

## Test Changes

Test Name	Order Code	Change	Effective Date
Adenovirus Antigen Detection, Gastroenteritis, EIA	SADNO	<p><b>Test Name:</b> Previously Adenovirus 40-41 Antigens by EIA</p> <p><b>Special Information:</b> Stool should be collected in a sterile, leak-proof container without preservatives, media, or metal ions. For patients using diapers, first line the diaper with clean plastic to prevent absorption. Transfer 5 g or 5 mL of the stool specimen from the plastic-lined diaper to the sterile container and cap securely. Do NOT submit the diaper. Do not use M4 media or any type of media. Do not use preservatives or additives. Unacceptable Conditions: Diapers. Stool in transport media or preservatives. Specimens other than stool. Insufficient specimen on swab. M4 medium</p> <p><b>Clinical Information:</b> Adenovirus causes respiratory tract infections, conjunctivitis, and diarrhea. Infections are most common in young children and immunocompromised individuals. Adenovirus antigen detection is useful to confirm the diagnosis of adenovirus infection in patients with gastroenteritis.</p> <p><b>Specimen Requirement:</b> 5 g stool in a sterile container; Minimum: 1 g (Pea-sized portion of stool); Collect fresh stool in a sterile, leak-proof container; Do NOT use any preservatives, additives, or media; Do not submit diapers, and do not use M4 transport media or metal-ion containers; Refer to Special Information; Frozen</p> <p>*OR* 5 mL stool in a sterile container; Minimum: 1 mL; Collect fresh stool in a sterile, leak-proof container; Do NOT use any preservatives, additives, or media; Do not submit diapers, and do not use M4 transport media or metal-ion containers; Refer to Special Information; Frozen</p> <p>*OR* One rectal swab in a sterile container; Stool collection should be visible on swab; Do NOT use any preservatives, additives, or media; Do not submit diapers, and do not use M4 transport media or metal-ion containers; Refer to Special Information; Frozen</p> <p>*OR* One swab(s) in a sterile container; Stool collection should be visible on swab; Do NOT use any preservatives, additives, or media; Do not submit diapers, and do not use M4 transport media or metal-ion containers; Refer to Special Information; Frozen</p> <p><b>Stability:</b>            Ambient: Unacceptable            Refrigerated: 72 hours            Frozen: 30 days</p> <p><b>Reference Range:</b> Refer to report</p> <p><b>Days Performed:</b> Monday, Wednesday, Friday</p> <p><b>Reported:</b> 2–5 days</p>	2/19/19
Allergen, Cat Components IgE	CATCP	<p><b>Clinical Limitation:</b> The correlation of allergy laboratory results with clinical history and in vivo reactivity to specific allergens is essential. A negative test may not rule out clinical allergy or even anaphylaxis.</p>	2/5/19
Allergen, Cow Milk Components IgE	MILKE	<p><b>Clinical Information:</b> Alpha-lactalbumin, beta-lactoglobulin, and casein are the allergens included in this panel. The correlation of allergy laboratory results with clinical history and in vivo reactivity to specific allergens is essential. A negative test may not rule out clinical allergy or even anaphylaxis.</p>	2/5/19
Allergen, Dog Components IgE	DOGCP	<p><b>Clinical Information:</b> The correlation of allergy laboratory results with clinical history and in vivo reactivity to specific allergens is essential. A negative test may not rule out clinical allergy or even anaphylaxis.</p>	2/5/19
Allergen, Dust Mite Components IgE	DUSTCP	<p><b>Clinical Information:</b> The correlation of allergy laboratory results with clinical history and in vivo reactivity to specific allergens is essential. A negative test may not rule out clinical allergy or even anaphylaxis.</p>	2/5/19
Allergen, Egg Components IgE	EGGIGE	<p><b>Clinical Information:</b> Ovomuroid and ovalbumin are the allergens included in this panel. The correlation of allergy laboratory results with clinical history and in vivo reactivity to specific allergens is essential. A negative test may not rule out clinical allergy or even anaphylaxis.</p>	2/5/19
Allergen, Hazelnut Components IgE	HZNTCP	<p><b>Clinical Information:</b> The correlation of allergy laboratory results with clinical history and in vivo reactivity to specific allergens is essential. A negative test may not rule out clinical allergy or even anaphylaxis.</p>	2/5/19
Allergen, Soybean Components IgE	SYBNCP	<p><b>Clinical Information:</b> The correlation of allergy laboratory results with clinical history and in vivo reactivity to specific allergens is essential. A negative test may not rule out clinical allergy or even anaphylaxis.</p>	2/5/19

## Test Changes (Cont.)

Test Name	Order Code	Change	Effective Date
Allergen, Walnut Components IgE	WLNTCP	<b>Clinical Information:</b> The correlation of allergy laboratory results with clinical history and in vivo reactivity to specific allergens is essential. A negative test may not rule out clinical allergy or even anaphylaxis.	2/5/19
Alpha-1-Antitrypsin Clearance, Timed	A1ACL	<p><b>Special Information:</b> If no specimen is obtained in 24 hours, extend collection to 48 or 72 hours. Note collection time frame. Serum must be collected during the stool collection period. <b>Stool and serum should be shipped together.</b></p> <p><b>Clinical Information:</b> This test is useful for diagnosing protein-losing enteropathies. <b>Cautions:</b> In the absence of either a 24-hour fecal collection or a contemporary serum specimen, the fecal concentration of alpha-1-antitrypsin (A1A) can be used as a surrogate marker. The clearance is preferred in order to normalize the large range of serum A1A concentrations and the variability in random fecal A1A concentration.</p> <p><b>Specimen Requirement:</b> 1 mL serum from a serum separator (gold) tube; Minimum: 0.5 mL; MULTIPLE SPECIMENS ARE REQUIRED FOR THIS TEST; <b>Centrifuge within 2 hours of collection and transfer serum into a standard plastic aliquot tube; Blood must be drawn during the stool collection period;</b> Frozen</p> <p>*AND* Entire collection of 24-hour stool in a clean container; Minimum: 1 mL homogenized stool; MULTIPLE SPECIMENS ARE REQUIRED FOR THIS TEST; Frozen</p> <p>*OR* 1 mL serum from a plain no additive (red) tube; Minimum: 0.5 mL; MULTIPLE SPECIMENS ARE REQUIRED FOR THIS TEST; <b>Centrifuge within 2 hours of collection and transfer serum into a standard plastic aliquot tube; Blood must be drawn during the stool collection period;</b> Frozen</p> <p>*AND* Entire collection of 24-hour stool in a clean container; Minimum: 1 mL homogenized stool; MULTIPLE SPECIMENS ARE REQUIRED FOR THIS TEST; Frozen</p> <p><b>Stability:</b>            Ambient: <b>Serum: 28 days; Stool: 14 days</b>            Refrigerated: <b>Serum: 28 days; Stool: 14 days</b>            Frozen: <b>Serum: 28 days; Stool: 14 days</b></p> <p><b>CPT:</b> 82103 x 2</p>	Effective immediately
Alpha-1-Antitrypsin Phenotype by Electrophoresis	A1APHE	<b>Special Information:</b> Grossly hemolyzed specimens will be rejected. This test is New York DOH approved.	2/19/19
Antimony, Blood	ANTMBL	<p><b>Special Information:</b> Diet, medication, and nutritional supplements may introduce interfering substances. Patient should be encouraged to discontinue nutritional supplements, vitamins, minerals, and non-essential over-the-counter medications (upon the advice of their physician). <b>Specimens collected in tubes other than royal blue (EDTA), or specimens transported in containers other than a royal blue (EDTA) tube or trace element-free transport tube will be rejected.</b> Heparin anticoagulant is unacceptable. <b>Clotted specimens will also be rejected.</b> This test is New York DOH approved.</p> <p><b>Clinical Information:</b> Blood antimony levels predominantly reflect recent exposure and are most useful in the diagnosis of acute poisoning. Blood concentrations in unexposed individuals rarely exceed 10 µg/L. The form of antimony greatly influences distribution and elimination. Trivalent antimony readily enters red blood cells, has an extended half-life on the order of weeks to months, and is eliminated predominantly through the bile. Pentavalent antimony resides in the plasma, has a relatively short half-life on the order of hours to days, and is eliminated predominantly through the kidneys. Reported symptoms after toxic antimony exposure vary based upon route of exposure, duration and antimony source and may include abdominal pain, dyspnea, nausea, vomiting, dermatitis and eye irritation. Clinical presentation is similar to that of inorganic arsenic exposure. <b>Elevated results may be due to skin or collection-related contamination, including the use of a noncertified metal-free collection/transport tube. If contamination concerns exist due to elevated levels of blood antimony, confirmation with a second specimen collected in a certified metal-free tube is recommended.</b></p>	2/19/19

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## Test Changes (Cont.)

Test Name	Order Code	Change	Effective Date
Antimony, Blood <i>(continued from page 5)</i>		<b>Stability:</b> Ambient: <b>Indefinitely</b> Refrigerated: <b>Indefinitely</b> Frozen: Unacceptable  <b>Reference Range:</b> ≤ 6.0 µg/L  <b>Days Performed:</b> Sunday–Saturday  <b>Reported:</b> 2–4 days	
Barbiturates	BARBS	<b>For Interfaced Clients Only: Test build may need to be modified</b>  <b>Special Information:</b> All drugs will be quantified if positive. Positive cutoff for all drugs: 50 ng/mL. <b>For medical purposes only; not valid for forensic use. Separator tubes will be rejected. Hemolyzed specimens will be rejected. Specimens exposed to repeated freeze/thaw cycles are unacceptable. Plasma or whole blood collected in sodium citrate (light blue) tubes will be rejected. This test is New York DOH approved.</b>  <b>Clinical Information:</b> Optimize drug therapy. Monitor patient adherence. Rule out barbiturate exposure. The absence of expected drug(s) and/or drug metabolite(s) may indicate non-compliance, inappropriate timing of specimen collection relative to drug administration, poor drug absorption, or limitations of testing.  <b>Specimen Requirement:</b> 3.5 mL plasma from a potassium oxalate/sodium fluoride (gray) tube; Minimum: 1.5 mL; Do not use separator tubes; Separate plasma from cells ASAP or within 2 hours of collection <b>and transfer into standard aliquot tube;</b> Refrigerated  *OR* 3.5 mL plasma from an EDTA (lavender) tube; Minimum: 1.5 mL; Do not use separator tubes; Separate plasma from cells ASAP or within 2 hours of collection <b>and transfer into standard aliquot tube;</b> Refrigerated  *OR* 3.5 mL serum from a plain no additive (red) tube; Minimum: 1.5 mL; Do not use separator tubes; Separate serum from cells ASAP or within 2 hours of collection <b>and transfer into standard aliquot tube;</b> Refrigerated  *OR* 3.5 mL plasma from a sodium heparin (green) tube; Minimum: 1.5 mL; Do not use separator tubes; Separate plasma from cells ASAP or within 2 hours of collection <b>and transfer into standard aliquot tube;</b> Refrigerated  <b>Reference Range:</b> Amobarbital: <b>Cutoff: 50 ng/mL</b> Butalbital: <b>Cutoff: 50 ng/mL</b> Pentobarbital: <b>Cutoff: 50 ng/mL</b> Phenobarbital: <b>Cutoff: 50 ng/mL</b> Secobarbital: <b>Cutoff: 50 ng/mL</b>	4/4/19
Bartonella PCR, tissue	TBART	<b>Special Information:</b> Citrated or heparinized solutions are not acceptable. Tissues floating in excess formalin are not acceptable. Direct blood, plasma, serum and stool specimens will be rejected.  <b>Specimen Requirement:</b> Frozen tissue in a sterile container; Minimum: 5 mm; <b>Ship on dry ice;</b> Frozen  *OR* Body fluid in a sterile container; <b>Ship on dry ice;</b> Frozen  *OR* Isolate of organism in an agar slant; Pure culture, slant or plate; Ambient  <b>Stability:</b> Ambient: <b>Tissue &amp; Body fluid: 4–6 hours; Cultures should be sent ambient</b> Refrigerated: <b>Tissue &amp; Body fluid: 24 hours; Culture: Unacceptable</b> Frozen: <b>Tissue &amp; Body fluid: 1–2 months; Culture: Unacceptable</b>	4/2/19
Bromide	BROM	<b>For Interfaced Clients Only: Test build may need to be modified</b>  <b>Special Information:</b> Draw specimen prior to next dose—at steady state concentration. <b>Whole blood, gel separator tubes, sodium citrate (light blue) tubes, and SPS or ACD solution (yellow) tubes are unacceptable. This test is New York DOH approved.</b>  <b>Clinical Information:</b> Monitor drug therapy or use when bromide toxicity is suspected (e.g., hyperchloremia with negative anion gap and altered mental status). Value > 50 mg/dL may be associated with mild toxicity.	2/19/19

## Test Changes (Cont.)

Test Name	Order Code	Change	Effective Date
C1Q Binding Assay	C1Q2	<p><b>Special Information: CRITICAL FROZEN. Separate specimens must be submitted when multiple tests are ordered. Non-frozen specimens will be rejected. This test is New York DOH approved.</b></p> <p><b>Clinical Information: Less than or equal to 3.9 µg Eq/mL is considered negative for circulating complement binding immune complexes. Circulating immune complexes may be found without any evident pathology, and positive results do not necessarily implicate the immune complex in a disease process.</b></p> <p><b>Specimen Requirement:</b> 1 mL serum from a serum separator (gold) tube; Minimum: 0.3 mL; Allow complete clotting of red blood cells (up to 1 hour), then separate serum from cells within 30 minutes and freeze immediately <b>in a standard aliquot tube; Separate specimens must be submitted when multiple tests are ordered;</b> Critical Frozen</p> <p>*OR* 1 mL serum from a <b>plain no additive (red) tube;</b> Minimum: 0.3 mL; Allow complete clotting of red blood cells (up to 1 hour), then separate serum from cells within 30 minutes and freeze immediately <b>in a standard aliquot tube; Separate specimens must be submitted when multiple tests are ordered;</b> Critical Frozen</p> <p><b>Stability:</b>            Ambient: After separation from cells: 2 hours            Refrigerated: <b>After separation from cells:</b> Unacceptable            Frozen: After separation from cells: 2 weeks (<b>Avoid repeated freeze/thaw cycles</b>)</p> <p><b>Methodology: Semi-Quantitative</b> Enzyme-Linked Immunosorbent Assay</p> <p><b>Reference Range: ≤ 3.9 µg Eq/mL</b></p>	2/19/19
C2 Complement, Functional with Reflex, Serum	C2COM	<p><b>For Interfaced Clients Only: Test build may need to be modified</b></p> <p><b>Note:</b> C2 Complement, Antigen has been removed from the reflex algorithm. The reflexes for Complement C3, Serum and Complement C4, Serum will still be performed, if indicated.</p> <p><b>Special Information:</b> Testing Algorithm: If the C2 result is &lt; 15 U/mL, then C3 and C4 will be performed at an additional cost. <b>Grossly lipemic specimens are unacceptable. Serum gel tubes will be rejected.</b></p>	Effective immediately
Chromium, Blood	CHROM	<p><b>Specimen Requirement:</b> 2 mL whole blood in an <b>EDTA (royal blue) tube;</b> Minimum: 1 mL; Refrigerated</p>	4/13/19
CK	CK	<p><b>Specimen Requirement:</b> 1 mL serum from a serum separator (gold) tube; Minimum: 0.4 mL; Submit in original tube or aliquot into CCL aliquot tube; Centrifuge and refrigerate</p> <p>*OR* 1 mL plasma from a lithium heparin (light green) plasma separator tube; Minimum: 0.4 mL; Centrifuge and refrigerate</p>	4/2/19
CK Isoenzymes	CKISO	<p><b>Special Information:</b> This test will detect CK macroenzymes. Specimens preserved in citrate, EDTA, fluoride, heparin, or iodoacetate are unacceptable. <b>Grossly hemolyzed specimens will be rejected.</b> This test is New York DOH approved.</p>	2/19/19
CKMB	MBE	<p><b>Reference Range:</b>            Male: &lt; <b>7.8 ng/mL</b>            Female: &lt; <b>4.4 ng/mL</b></p>	4/2/19
CK, Total and CKMB	CKCKMB	<p><b>Reference Range:</b>            CK            Male: 51–298 U/L            Female: 42–196 U/L            CK-MB            Male: &lt; <b>7.8 ng/mL</b>            Female: &lt; <b>4.4 ng/mL</b>            CK MB%: 0.0–4.0%</p>	4/2/19
<b>CMV by PCR, non-blood specimens</b>	CMVCSF	<p><b>Test Name:</b> Previously CMV by PCR, CSF/FLD/Tissue/Bone Marrow</p>	2/12/19
Copper	COPPER	<p><b>Specimen Requirement:</b> 1 mL plasma from an <b>EDTA (royal blue) tube;</b> Minimum: 0.5 mL; Do not allow specimen to come into contact with polystyrene, metal or rubber; Centrifuge and transfer plasma to a polypropylene tube using a plastic transfer pipette; Do not use glass pipettes; Refrigerated</p> <p><b>Days Performed: Monday–Friday, excluding major holidays</b></p> <p><b>Reported: 1–7 days</b></p>	4/13/19

## Test Changes (Cont.)

Test Name	Order Code	Change	Effective Date
Copper/Zinc	CUZN	<b>Specimen Requirement:</b> 1 mL plasma from an <b>EDTA (royal blue) tube</b> ; Minimum: 0.5 mL; Do not allow plasma to remain on red cells; Do not allow specimen to come into contact with polystyrene, glass, metal or rubber; Centrifuge and transfer plasma to a polypropylene tube using a plastic transfer pipette; Refrigerated <b>Days Performed: Monday–Friday, excluding major holidays</b> <b>Reported:</b> 1–7 days	4/13/19
Cyanide, Blood	CYANID	<b>Days Performed:</b> Sunday, <b>Tuesday</b> , Friday <b>Reported:</b> 2–6 days	2/19/19
Ehrlichia chaffeensis IgG & IgM Abs by IFA	ECHAFF	<b>Specimen Requirement:</b> 1 mL serum from a serum separator (gold) tube; Minimum: 0.1 mL; Separate serum from cells ASAP or within 2 hours of collection <b>and transfer into standard aliquot tube; 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';</b> Refrigerated <b>Reference Range:</b> E. chaffeensis Ab IgG < 1:64– <b>Negative: No significant level of E. chaffeensis IgG antibody detected</b> <b>1:64–1:128–Equivocal: Questionable presence of E. chaffeensis IgG antibody detected; Repeat testing in 10-14 days may be helpful</b> ≥ 1:256– <b>Positive: Presence of IgG antibody to E. chaffeensis detected, suggestive of current or past infection</b> E. chaffeensis Ab IgM < 1:16– <b>Negative: No significant level of E. chaffeensis IgM antibody detected</b> ≥ 1:16– <b>Positive: Presence of IgM antibody to E. chaffeensis detected, suggestive of current or recent infection</b> <b>Days Performed:</b> Tuesday, Friday <b>Reported:</b> 2–6 days	2/19/19
Ethyl Glucuronide, Urine Confirm/Quant	UEGQNT	<b>Methodology: Quantitative</b> Liquid Chromatography–Tandem Mass Spectrometry <b>Days Performed: Sunday, Tuesday, Wednesday, Friday, Saturday</b> <b>Reported:</b> 2–7 days	2/19/19
Fentanyl and Metabolite	FENTYL	<b>For Interfaced Clients Only: Test build may need to be modified</b> <b>Special Information:</b> Monitor patient adherence. <b>Whole blood, serum separator tubes, sodium citrate (light blue) tubes, or plasma separator tubes will be rejected. Specimens exposed to repeated freeze/thaw cycles are unacceptable. This test is New York DOH approved.</b>	2/19/19
Flecainide	FLEC	<b>Special Information: Timing of specimen collection: Pre-dose (trough) draw–At steady state concentration. Gel separator tubes or gels of any kind will be rejected; drug loss is immediate, and no testing will be performed. This test is New York DOH approved.</b> <b>Clinical Information: Useful to optimize drug therapy and monitor patient adherence. Toxic concentrations may cause cardiac abnormalities, hypotension and seizure.</b> <b>Specimen Requirement:</b> 2 mL serum from a plain no additive (red) tube; Minimum: 0.5 mL; Do not use serum separator tubes; <b>Pre-dose (trough) draw–At steady state concentration;</b> Remove serum from cells within 6 hours of collection <b>and transfer into standard aliquot tube;</b> Refrigerated <b>*OR*</b> 2 mL plasma from an EDTA (lavender) tube; Minimum: 0.5 mL; Do not use plasma separator tubes; <b>Pre-dose (trough) draw–At steady state concentration;</b> Remove plasma from cells within 6 hours of collection <b>and transfer into standard aliquot tube;</b> Refrigerated <b>*OR*</b> 2 mL plasma from a sodium or lithium heparin (green) tube; Minimum: 0.5 mL; Do not use plasma separator tubes; <b>Pre-dose (trough) draw–At steady state concentration;</b> Remove plasma from cells within 6 hours of collection <b>and transfer into standard aliquot tube;</b> Refrigerated <b>*OR*</b> 2 mL plasma from a <b>potassium oxalate/sodium fluoride (gray) tube;</b> Minimum: 0.5 mL; Do not use plasma separator tubes; <b>Pre-dose (trough) draw–At steady state concentration;</b> Remove plasma from cells within 6 hours of collection <b>and transfer into standard aliquot tube;</b> Refrigerated <b>Days Performed: Monday, Thursday, Saturday</b> <b>Reported:</b> 2–6 days	2/19/19



## Test Changes (Cont.)

Test Name	Order Code	Change	Effective Date
FSHD DNA Test	FSHDNA	<p><b>Specimen Requirement:</b> 10 mL whole blood in an EDTA (lavender) tube; Minimum: 7 mL; Collect Monday–Wednesday only; Send to Cleveland Clinic Laboratories on the day of collection; <b>Do not store specimen;</b> Collect <b>two</b> EDTA (lavender) tubes to ensure adequate specimen volume; Ambient</p> <p><b>Stability:</b>                      Ambient: 72 hours                      Refrigerated: <b>72 hours</b>                      Frozen: Unacceptable</p> <p><b>Days Performed: Varies</b>  <b>Reported: 15–22 days</b></p>	2/11/19
Gabapentin	GABA	<p><b>Days Performed: Monday, Wednesday–Saturday</b>  <b>Reported: 2–5 days</b></p>	2/19/19
Gabitril	GABIT	<p><b>Special Information: Patient Prep: Pre-dose (trough) draw. Separator tubes will be rejected.</b></p> <p><b>Specimen Requirement: 1 mL</b> serum from a plain no additive (red) tube; Minimum: <b>0.4 mL; Pre-dose (trough) draw;</b> Do not use serum separator tubes; <b>Separate from cells ASAP or within 2 hours of collection and transfer into standard aliquot tube;</b> Refrigerated</p> <p>*OR* 1 mL plasma from an <b>EDTA (lavender) tube;</b> Minimum: <b>0.4 mL; Pre-dose (trough) draw; Separate from cells ASAP or within 2 hours of collection and transfer into standard aliquot tube;</b> Refrigerated</p> <p><b>Stability:</b>                      Ambient: <b>1 month</b>                      Refrigerated: <b>1 month</b>                      Frozen: <b>48 months</b></p> <p><b>Methodology: High Performance</b> Liquid Chromatography/Tandem Mass Spectrometry (LC/MS/MS)  <b>Days Performed: Varies</b>  <b>Reported: 8–11 days</b></p>	2/19/19
Galactocerebrosidase	GALSYL	<b>CPT: 82658 x 1</b>	1/31/19
Herpesvirus 6 IgM Antibody	HHV6M	<p><b>For Interfaced Clients Only: Test build may need to be modified</b></p> <p><b>Note: Special Information will be removed.</b></p> <p><b>Specimen Requirement:</b> 0.5 mL serum from a serum separator (gold) tube; Minimum: <b>0.1 mL; Transfer 0.5 mL serum to standard aliquot tube;</b> Refrigerated</p> <p>*OR* 0.5 mL serum from a plain no additive (red) tube; Minimum: <b>0.1 mL; Transfer 0.5 mL serum to standard aliquot tube;</b> Refrigerated</p> <p><b>Stability:</b>                      Ambient: <b>1 week</b>                      Refrigerated: 2 weeks                      Frozen: <b>1 month</b></p> <p><b>Methodology: Semi-Quantitative</b> Indirect <b>Fluorescent Antibody</b>  <b>Reference Range: &lt; 1:20</b>  <b>Days Performed: Varies</b>  <b>Reported: 4–8 days</b></p>	2/19/19
Ibuprofen	IBUPRO	<p><b>Specimen Requirement:</b> 1 mL serum from a plain no additive (red) tube; Minimum: <b>0.21 mL;</b> Do not use serum separator tubes; Separate serum from cells ASAP or within 2 hours of collection and transfer to aliquot tube; Refrigerated</p> <p>*OR* 1 mL plasma from an EDTA (lavender) tube; Minimum: <b>0.21 mL;</b> Do not use plasma separator tubes; Separate plasma from cells ASAP or within 2 hours of collection and transfer to aliquot tube; Refrigerated</p> <p><b>Stability:</b>                      Ambient: <b>15 days</b>                      Refrigerated: <b>15 days</b>                      Frozen: <b>15 days</b></p> <p><b>Methodology: High Performance</b> Liquid Chromatography/Tandem Mass Spectrometry (LC/MS/MS)</p>	2/19/19

## Test Changes (Cont.)

Test Name	Order Code	Change	Effective Date
IgA	IGA	<b>Stability:</b> Ambient: <b>1 day</b> Refrigerated: <b>7 days</b> Frozen: <b>14 days</b>	4/9/19
IgG	IGG	<b>Stability:</b> Ambient: <b>1 day</b> Refrigerated: <b>7 days</b> Frozen: <b>14 days</b>	4/9/19
IgM	IGM	<b>Stability:</b> Ambient: <b>1 day</b> Refrigerated: <b>7 days</b> Frozen: <b>14 days</b>	4/9/19
JC Polyoma Virus Quantitative PCR	JCQNT	<p><b>Special Information: Avoid repeated freezing and thawing of specimens. Cerebrospinal fluid (CSF) and urine specimens will be rejected.</b></p> <p><b>Clinical Information:</b> JC virus is the cause of progressive multifocal leukoencephalopathy (PML), a severe demyelinating disease of the central nervous system. PML is a particular concern to individuals infected with the human immunodeficiency virus. Quantification of JC virus DNA is based upon real-time PCR amplification and detection of JCV genomic DNA. <b>The quantitative range of the assay is 500–35,000,000 JCV DNA copies/mL.</b></p> <p><b>Specimen Requirement: 0.7 mL plasma from an EDTA (lavender) tube; Minimum: 0.3 mL; Separate plasma from cells within 2 hours of collection, and transfer into a sterile aliquot tube; Do not clarify plasma by filtration or further centrifugation; Frozen</b></p> <p><b>*OR* 0.7 mL plasma from an EDTA (white) plasma preparation tube (PPT); Minimum: 0.3 mL; Centrifuge within 2 hours of collection; The plasma is not required to be transferred to an aliquot tube; Frozen</b></p> <p><b>*OR* 0.7 mL plasma from an ACD A (yellow) tube; Minimum: 0.3 mL; Separate plasma from cells within 2 hours of collection, and transfer into a sterile aliquot tube; Do not clarify plasma by filtration or further centrifugation; Frozen</b></p> <p><b>*OR* 0.7 mL serum from a serum separator (gold) tube; Minimum: 0.3 mL; Allow blood to clot at room temperature; Separate serum from cells within 1 hour of collection, and transfer into a sterile aliquot tube; Frozen</b></p> <p><b>*OR* 0.7 mL serum from a plain no additive (red) tube; Minimum: 0.3 mL; Allow blood to clot at room temperature; Separate serum from cells within 1 hour of collection, and transfer into a sterile aliquot tube; Frozen</b></p> <p><b>Stability:</b> Ambient: <b>48 hours</b> Refrigerated: <b>7 days</b> Frozen: <b>30 days (Avoid repeated freeze/thaw cycles)</b></p> <p><b>Methodology: Real-Time Polymerase Chain Reaction (RT-PCR)</b></p> <p><b>Days Performed: Monday–Saturday</b></p> <p><b>Reported: 2–4 days</b></p>	4/2/19
Lead, Blood	LEAD2	<p><b>Specimen Requirement: 1 mL whole blood in an EDTA (royal blue) tube; Minimum: 0.5 mL; Refrigerated</b></p> <p><b>*OR* 1 mL whole blood in an EDTA (lavender) tube; Minimum: 0.5 mL; Lavender top tubes are acceptable, but not recommended; Refrigerated</b></p>	Effective immediately
Lithium	LI	<p><b>Specimen Requirement: 1 mL serum from a serum separator (gold) tube; Minimum: 0.5 mL; Specimen should be separated from cells within 4 hours; Centrifuge and refrigerate</b></p> <p><b>*OR* 1 mL plasma from a sodium heparin (green) tube; Minimum: 0.5 mL; If collected in a non-gel separator tube: Centrifuge and transfer plasma to a CCL tube and refrigerate; Specimen should be separated from cells within 4 hours; Refrigerated</b></p> <p><b>*OR* 1 mL plasma from an EDTA (lavender) tube; Minimum: 0.5 mL; If collected in a non-gel separator tube: Centrifuge and transfer plasma to a CCL tube and refrigerate; Specimen should be separated from cells within 4 hours; Refrigerated</b></p>	4/2/19

## Test Changes (Cont.)

Test Name	Order Code	Change	Effective Date
Manganese	MANGAN	<b>Specimen Requirement:</b> 2 mL whole blood in an <b>EDTA (royal blue) tube</b> ; Minimum: 1 mL; Refrigerated	4/13/19
Mexiletine	MEX	<b>For Interfaced Clients Only: Test build may need to be modified</b> <b>Special Information:</b> Draw specimen prior to next dose—at steady state concentration. Unacceptable conditions: Whole blood, gel separator tubes, light blue (sodium citrate), or yellow (SPS or ACD Solution) tubes. This test is New York DOH approved. <b>Days Performed: Monday, Thursday, Saturday</b> <b>Reported: 2–6 days</b>	2/19/19
Mycophenolic Acid and Metabolite	MYCMET	<b>Days Performed: Sunday–Saturday</b> <b>Reported: 2–4 days</b>	2/19/19
Neisseria gonorrhoea Antibodies, Total	NGAB	<b>Note: Special Information and Clinical Information will be removed.</b> <b>Specimen Requirement:</b> 1 mL serum from a serum separator (gold) tube; Minimum: <b>0.5 mL</b> ; Transfer 1 mL serum to standard aliquot tube; Refrigerated <b>*OR*</b> 1 mL serum from a <b>plain no additive (red) tube</b> ; Minimum: <b>0.5 mL</b> ; Transfer 1 mL serum to standard aliquot tube; Refrigerated <b>Stability:</b> Ambient: <b>1 week</b> Refrigerated: 2 weeks Frozen: <b>1 month</b> <b>Days Performed: Varies</b> <b>Reported: 4–8 days</b>	2/19/19
Nickel, Serum	NICKEL	<b>Special Information:</b> Diet, medication, and nutritional supplements may introduce interfering substances. Patients should be encouraged to discontinue nutritional supplements, vitamins, minerals, and non-essential over-the-counter medications (upon the advice of their physician). <b>Specimens collected in tubes other than navy blue (no additive) will be rejected. Specimens transported in containers other than a navy blue (no additive) tube or trace element-free transport tube are unacceptable. Heparin anticoagulant is unacceptable. Specimens that are not separated from the red cells or clot within 2 hours are not acceptable.</b> <b>Clinical Information:</b> Serum nickel testing is intended to detect potentially toxic exposure. Elevated results may be due to skin or collection-related contamination, including the use of a noncertified metal-free collection/transport tube. If contamination concerns exist due to elevated levels of serum nickel, confirmation with a second specimen collected in a certified metal-free tube is recommended. <b>Specimen Requirement:</b> 2 mL serum from a no additive (navy blue) tube; Minimum: 0.5 mL; Separate serum from cells <b>within 2 hours of collection</b> and aliquot into a trace metal-free transport tube (ARUP # 43116); Ambient <b>Stability:</b> Ambient: <b>After separation from cells: Indefinitely</b> Refrigerated: <b>After separation from cells: Indefinitely</b> Frozen: <b>After separation from cells: Indefinitely</b> <b>Days Performed: Sunday–Saturday</b> <b>Reported: 2–4 days</b>	2/19/19
Organic Acids, Plasma	ORGACS	<b>For Interfaced Clients Only: Test build may need to be modified</b> <b>Includes:</b> Lactic Acid Pyruvic Acid Succinic Acid 3-OH-Butyric Acid Acetoacetic Acid 2-Keto-3-methylvaleric Acid 2-Ketoisocaproic Acid 2-Ketoisovaleric Acid <b>Glutaric Acid</b> <b>Stability:</b> Ambient: <b>After separation from cells: Unacceptable</b> Refrigerated: <b>After separation from cells: Unacceptable</b> Frozen: <b>After separation from cells: 1 month</b>	2/19/19

## Test Changes (Cont.)

Test Name	Order Code	Change	Effective Date
Platelet Function Screen	PLTSCP	<b>Reference Range:</b> COL/EPI closure time: < <b>194 CT sec</b> COL/ADP closure time: < 118 CT sec	3/18/19
Pregabalin	PBALIN	<b>For Interfaced Clients Only: Test build may need to be modified</b> <b>Special Information:</b> Citrated plasma is unacceptable. This test is New York DOH approved. <b>Days Performed:</b> Wednesday, Saturday <b>Reported:</b> 2–7 days	2/19/19
Primidone	PRIM	<b>Specimen Requirement:</b> 1 mL plasma from a <b>lithium heparin (green) tube</b> ; Minimum: 0.5 mL; Collect immediately prior to next dose; <b>Do not collect in a gel separator tube; Centrifuge and transfer plasma to a CCL tube and transport refrigerated</b> ; Refrigerated <b>*OR*</b> 1 mL serum from a <b>plain no additive (red) tube</b> ; Minimum: 0.5 mL; Collect immediately prior to next dose; <b>Do not collect in a gel separator tube; Centrifuge and transfer serum to a CCL tube and transport refrigerated</b> ; Refrigerated <b>*OR*</b> 1 mL plasma from an <b>EDTA (lavender) tube</b> ; Minimum: 0.5 mL; Collect immediately prior to next dose; <b>Do not collect in a gel separator tube; Centrifuge and transfer plasma to a CCL tube and transport refrigerated</b> ; Refrigerated <b>Stability:</b> Ambient: After separation from cells: 48 hours Refrigerated: After separation from cells: <b>7 days</b> Frozen: After separation from cells: 14 days	4/2/19
Rheumatoid Factor	RF	<b>Stability:</b> Ambient: 24 hours Refrigerated: <b>8 days</b> Frozen: <b>3 months</b>	Effective immediately
Risperidone & Metabolite	RISPER	<b>Days Performed:</b> Monday, Wednesday, Saturday <b>Reported:</b> 2–6 days	2/19/19
Selenium Blood	SELEN	<b>Specimen Requirement:</b> 2 mL whole blood in an <b>EDTA (royal blue) tube</b> ; Minimum: 1 mL; Refrigerated	4/10/19
Sertraline	SERTRA	<b>Special Information:</b> Specimen should be collected prior to next dose—at steady state concentration. <b>Whole blood is unacceptable. Gel separator tubes, light blue (citrate) tubes, and SPS or ACD solution (yellow) tubes will be rejected. This test is New York DOH approved.</b> <b>Clinical Information:</b> Anti-depressant therapeutic drug monitoring. Sertraline doses ranging from 50–200 mg/d produce serum concentrations ranging from 30–200 ng/mL. Dosing above 200 mg/d is associated with increased adverse effects and decreased efficacy. <b>Adverse effects may include dry mouth, headache, dizziness, somnolence, nausea and diarrhea.</b> <b>Days Performed:</b> Wednesday <b>Reported:</b> 2–9 days	2/19/19
S-Sulfocysteine, Urine	USULFC	<b>Specimen Requirement:</b> 1 mL random urine in a clean container ( <b>No preservatives</b> ); Minimum: <b>0.25 mL</b> ; <b>Ship frozen on dry ice</b> ; Frozen <b>Stability:</b> Ambient: <b>15 days</b> Refrigerated: <b>15 days</b> Frozen: <b>7 months</b> <b>Methodology:</b> Ultra Performance Liquid Chromatography-Tandem Mass Spectrometry (UPLC-MS/MS) <b>CPT:</b> 82131 x 1, 82570 x 1	1/31/19

## Test Changes (Cont.)

Test Name	Order Code	Change	Effective Date
Sulfonamides	SULFA	<p><b>Special Information:</b> Indicate which sulfa drugs are being administered. Draw peak sample 2 hours post dose. <b>Whole blood is unacceptable. Gel separator tubes, light blue (citrate) tubes, or yellow (SPS or ACD solution) tubes will be rejected. This test is New York DOH approved.</b></p> <p><b>Clinical Information:</b> Monitor drug therapy. This assay is designed to measure sulfamethoxazole. Peak sulfonamide (total) blood levels of <b>5.0–15.0 mg/dL</b> may be effective for most infections, with concentrations of <b>12.0–15.0 mg/dL</b> being optimal for serious infections. Levels should not exceed <b>20.0 mg/dL. Adverse effects may include blood dyscrasias, skin rash, nausea, vomiting and fever.</b></p> <p><b>Methodology: Quantitative Colorimetric</b></p> <p><b>Days Performed: Monday</b></p> <p><b>Reported: 2–9 days</b></p>	2/19/19
Sulfonylurea Hypoglycemics	SULFON	<p><b>Clinical Information:</b> Preferred test for evaluating if etiology of hypoglycemia is sulfonylurea ingestion. <b>The assay is used to evaluate hypoglycemia that may be caused from the ingestion of sulfonylurea drugs. Hypoglycemic drugs are detected if the drug concentration is greater than the limit of detection (cut-off). The presence of hypoglycemic drug(s) indicates a recent ingestion.</b></p> <p><b>Methodology:</b> Liquid Chromatography-Tandem Mass Spectrometry (LC-MS/MS)</p> <p><b>Reference Range:</b>            Acetohexamide: <b>Cutoff: 100 ng/mL</b>            Chlorpropamide: <b>Cutoff: 100 ng/mL</b>            Glimepiride: <b>Cutoff: 5 ng/mL</b>            Glipizide: <b>Cutoff: 5 ng/mL</b>            Glyburide: <b>Cutoff: 5 ng/mL</b>            Nateglinide: <b>Cutoff: 5 ng/mL</b>            Repaglinide: <b>Cutoff: 5 ng/mL</b>            Tolazamide: <b>Cutoff: 100 ng/mL</b>            Tolbutamide: <b>Cutoff: 100 ng/mL</b></p> <p><b>Days Performed: Sunday, Tuesday, Thursday</b></p> <p><b>Reported: 2–7 days</b></p>	2/19/19
Synthetic Cannabinoid Metabolites - Expanded, Urine (Qualitative)	K2	<p><b>Note:</b> <i>The scope of analysis is changing. JWH-018 N-pentanoic acid, UR-144 N-pentanoic acid, AKB48 N-pentanoic acid, AB-FUBINACA oxobutanoic acid, AB-CHMINACA 3-methyl-butanoic acid, PB-22 3-Carboxyindole, 5-Fluoro-PB-22 3-Carboxyindole, BB-22 3-Carboxyindole, ADB-PINACA N-pentanoic acid, AB-PINACA N-pentanoic acid, ADBICA N-pentanoic acid, ADB-CHMINACA 3,3-dimethyl-butanoic acid, 5F-AMB 3-methyl-butanoic acid, 5F-ADB 3,3-dimethyl-butanoic acid, FUB-AMB 3-methyl-butanoic acid and MDMB-FUBINACA 3,3-dimethyl-butanoic acid will be removed.</i></p> <p><i>4-carboxy-NA-PIM, FUBIC-ACID, 5-fluoro-PICA 3,3-dimethylbutanoic acid, CHMINACA-3-methylbutanoic acid, FUBICA 3,3-dimethylbutanoic acid, 5-fluoro-PIC-ACID, CHMIC-ACID, 4-carboxy-CUMYL-BINACA, 4-carboxy-AMB-PINACA, 5-fluoro-PINAC-ACID, CHMINACA 3,3-dimethylbutanoic acid, 5-fluoro-PINACA 3-methylbutanoic acid, 5-fluoro-PINACA 3,3-dimethylbutanoic acid, FUBINACA 3-methylbutanoic acid and FUBINACA 3,3-dimethylbutanoic acid will be added.</i></p> <p><b>Days Performed: Monday–Sunday</b></p> <p><b>Reported: 6–7 days</b></p>	2/25/19
Tapentadol and Metabolite Confirm/ Quantitation, Urine	TAPENU	<p><b>Special Information: Specimens exposed to repeated freeze/thaw cycles will be rejected.</b></p> <p><b>Days Performed: Sunday, Wednesday, Friday</b></p> <p><b>Reported: 2–7 days</b></p>	2/19/19

## Test Changes (Cont.)

Test Name	Order Code	Change	Effective Date
Thallium, Blood	THALL	<p><b>Special Information:</b> Diet, medication, and nutritional supplements may introduce interfering substances. Patients should be encouraged to discontinue nutritional supplements, vitamins, minerals, and non-essential over-the-counter medications (upon the advice of their physician). <b>Specimens collected in tubes other than royal blue (EDTA), or specimens transported in containers other than a royal blue (EDTA) tube or trace element-free transport tube will be rejected.</b> Heparin anticoagulant is unacceptable. <b>Clotted specimens will be rejected. This test is New York DOH approved.</b></p> <p><b>Clinical Information:</b> Blood thallium levels reflect recent exposure as thallium has a biological half-life of approximately 2–4 days. Blood levels greater than 100 µg/L are considered toxic and greater than 300 µg/L indicate severe ingestion. After severe thallium poisonings, reported symptoms have varying times of onset and include gastroenteritis, multi-organ failure and neurologic injury. Peripheral neuropathy and alopecia are well-documented effects of acute and chronic exposure. Human health effects from low-level thallium exposure are unknown. Elevated results <b>may be due to skin or collection-related contamination, including the use of a noncertified metal-free collection/transport tube. If contamination concerns exist due to elevated levels of blood thallium, confirmation with a second specimen collected in a certified metal-free tube is recommended.</b></p> <p><b>Reference Range:</b> ≤ 2.0 µg/L</p> <p><b>Days Performed:</b> Sunday–Saturday</p> <p><b>Reported:</b> 2–4 days</p>	2/19/19
Thiocyanate, Urine Random	UTHIOC	<p><b>Days Performed:</b> Sunday, Thursday</p> <p><b>Reported:</b> 2–6 days</p>	2/19/19
TTR Gene, Full Gene Analysis	TTRGEN	<p><b>Stability:</b>            Ambient: <b>Preferred; Specimen preferred to arrive at performing lab within 96 hours of draw</b>            Refrigerated: <b>Acceptable</b>            Frozen: <b>Acceptable</b></p> <p><b>Days Performed:</b> Varies</p> <p><b>Reported:</b> 15–21 days</p>	Effective immediately
Vitamin B6	VITB6	<p><b>Special Information:</b> Collect specimen after an overnight fast. <b>Whole blood will be rejected.</b> Specimens not protected from light, <b>or icteric specimens</b> are unacceptable. This test is New York DOH approved.</p> <p><b>Specimen Requirement:</b> 1 mL plasma from a sodium or lithium heparin (green) tube; Minimum: 0.5 mL; Collect after an overnight fast; Place specimen on ice after draw; Separate plasma from cells within 1 hour of collection and freeze; Protect specimen from light; Use amber transport tubes; Frozen</p> <p>*OR* 1 mL plasma from a lithium heparin (light green) plasma separator tube (PST); Minimum: 0.5 mL; Collect after an overnight fast; Place specimen on ice after draw; Separate plasma from cells within 1 hour of collection and freeze; Protect specimen from light; Use amber transport tubes; Frozen</p> <p>*OR* 1 mL serum from a plain no additive (red) tube; Minimum: 0.5 mL; Collect after an overnight fast; Place specimen on ice after draw; Separate serum from cells within 1 hour of collection and freeze; Protect specimen from light; Use amber transport tubes; Frozen</p> <p>*OR* 1 mL plasma from a sodium heparin (light green) plasma separator tube (PST); Minimum: 0.5 mL; Collect after an overnight fast; Place specimen on ice after draw; Separate plasma from cells within 1 hour of collection and freeze; Protect specimen from light; Use amber transport tubes; Frozen</p> <p>*OR* 1 mL plasma from an <b>EDTA (lavender) tube</b>; Minimum: 0.5 mL; Collect after an overnight fast; Place specimen on ice after draw; Separate plasma from cells within 1 hour of collection and freeze; Protect specimen from light; Use amber transport tubes; Frozen</p>	2/19/19

(continued on page 15)

## Test Changes (Cont.)

Test Name	Order Code	Change	Effective Date
Vitamin B6 <i>(continued from page 14)</i>		<p>*OR* 1 mL serum from a <b>serum separator (gold) tube</b>; Minimum: 0.5 mL; Collect after an overnight fast; Place specimen on ice after draw; Separate serum from cells within 1 hour of collection and freeze; Protect specimen from light; Use amber transport tubes; Frozen</p> <p><b>Stability:</b>            Ambient: After separation from cells: Unacceptable            Refrigerated: After separation from cells: <b>1 week</b>            Frozen: After separation from cells: 2 months</p> <p><b>Methodology:</b> High Performance Liquid Chromatography/<b>Tandem Mass Spectrometry (LC/MS/MS)</b></p>	
Voltage-Gated Potassium Channel (VGKC) Antibody	VGKCAB	<p><b>Special Information:</b> Screening test for Voltage-Gated Potassium Channel (VGKC) antibody receptor complex-associated autoantibodies. Assay does not identify Contactin Associated Protein 2 (CASPR2) Antibody or Leucine-rich Glioma Inactivated 1 Protein (LGI1) antibodies individually. <b>Plasma is unacceptable. Grossly lipemic or icteric specimens will be rejected.</b></p> <p><b>Stability:</b>            Ambient: <b>After separation from cells:</b> 72 hours            Refrigerated: <b>After separation from cells:</b> 2 weeks            Frozen: <b>After separation from cells:</b> 1 month (<b>Avoid repeated freeze/thaw cycles</b>)</p>	2/19/19
Zinc	ZINC	<p><b>Specimen Requirement:</b> 1 mL plasma from an <b>EDTA (royal blue) tube</b>; Minimum: 0.5 mL; Do not allow specimen to come into contact with polystyrene, glass, metal or rubber; Centrifuge and transfer plasma to a polypropylene tube; Do not allow plasma to remain on red cells; Refrigerated</p> <p><b>Days Performed: Monday–Friday, excluding major holidays</b></p> <p><b>Reported: 1–7 days</b></p>	4/13/19
Zinc, Whole Blood	ZINCWB	<p><b>Special Information:</b> Diet, medication, and nutritional supplements may introduce interfering substances. Patient should be encouraged to discontinue nutritional supplements, vitamins, minerals, and non-essential over the counter medications (upon the advice of their physician). <b>Specimens collected in tubes other than royal blue (EDTA), or specimens transported in containers other than a royal blue (EDTA) tube or trace element-free transport tube are unacceptable. Heparin anticoagulant is not acceptable. Clotted specimens will be rejected. This test is New York DOH approved.</b></p> <p><b>Clinical Information:</b> Zinc concentration in blood has not been shown to change significantly in deficiency or with supplementation. Elevated results may be due to skin or collection-related contamination, including the use of a noncertified metal-free collection/transport tube. If contamination concerns exist due to elevated levels of blood zinc, confirmation with a second specimen collected in a certified metal-free tube is recommended.</p> <p><b>Specimen Requirement:</b> 2 mL whole blood in an <b>EDTA (royal blue) tube</b>; Minimum: 0.5 mL; Transport blood in original tube; Ambient</p> <p><b>Reference Range: 440.0–860.0 µg/dL</b></p> <p><b>Days Performed: Sunday–Saturday</b></p> <p><b>Reported: 2–4 days</b></p>	2/19/19

# New Tests

Test Name	Order Code	Change	Effective Date
FLT3 ITD and TKD Mutation Detection by PCR	FLT3IT	<p><b>Special Information:</b> DNA isolation is performed Sunday–Saturday. Fresh-frozen paraffin-embedded (FFPE) tumor tissue or fresh tissue are not acceptable. Grossly hemolyzed or clotted specimens will be rejected.</p> <p><b>Specimen Requirement:</b> 5 mL whole blood in an EDTA (lavender) tube; Minimum: 1 mL; Refrigerated</p> <p>*OR* 3 mL bone marrow in an EDTA (lavender) tube; Minimum: 1 mL; Refrigerated</p> <p><b>Stability:</b>            Ambient: 24 hours            Refrigerated: 5 days            Frozen: Unacceptable</p> <p><b>Methodology:</b> Polymerase Chain Reaction (PCR)</p> <p><b>Days Performed:</b> Monday, Wednesday, Friday</p> <p><b>Reported:</b> 3–8 days</p> <p><b>CPT:</b> 81245 x 1, 81246 x 1</p> <p><b>Price:</b> \$298.00 (non-discountable)</p>	2/19/19
Fluid Hematocrit	FLDHCT	<p><b>Specimen Requirement:</b> 2.5 mL fluid in an EDTA (lavender) tube; Minimum: 0.5 mL; To be ordered for pleural or peritoneal/ascites fluids only; Indicate the fluid type; Fill tube to at least half of fill volume; Refrigerated</p> <p><b>Stability:</b>            Ambient: 24 hours            Refrigerated: 48 hours            Frozen: Unacceptable</p> <p><b>Methodology:</b> Automated Cell Counter</p> <p><b>Interpretive Data:</b> The reference interval and other method performance specifications are unavailable for this body fluid. Comparison of this result with the concentration in the blood, serum, or plasma is recommended.</p> <p><b>Days Performed:</b> 7 days per week</p> <p><b>Reported:</b> 8 hours</p>	Effective immediately
Fluid Hemoglobin	FLDHGB	<p><b>Specimen Requirement:</b> 2.5 mL fluid in an EDTA (lavender) tube; Minimum: 0.5 mL; To be ordered for pleural or peritoneal/ascites fluids only; Indicate the fluid type; Refrigerated</p> <p><b>Stability:</b>            Ambient: 24 hours            Refrigerated: 48 hours            Frozen: Unacceptable</p> <p><b>Methodology:</b> Automated Cell Counter</p> <p><b>Interpretive Data:</b> The reference interval and other method performance specifications are unavailable for this body fluid. Comparison of this result with the concentration in the blood, serum, or plasma is recommended.</p> <p><b>Days Performed:</b> 7 days per week</p> <p><b>Reported:</b> 8 hours</p>	Effective immediately



## New Tests (Cont.)

Test Name	Order Code	Change	Effective Date
Pan-Solid Tumor NGS Panel	PST	<p><b>Specimen Requirement:</b> 10 mm square formalin-fixed paraffin-embedded (FFPE) tissue block; FFPE slides; Transport and store slides at ambient temperature; 10 unstained section FFPE tissue on charged, unbaked slides plus one H&amp;E stained section with best tumor area circled by a pathologist; Ambient</p> <p><b>Stability:</b>                      Ambient: Indefinitely for FFPE slides; FFPE slides can be transported at ambient temperature                      Frozen: Unacceptable</p> <p><b>Methodology:</b> Next Gen Sequencing</p> <p><b>Interpretive Data:</b> The Pan-Solid Tumor (PST) NGS Panel uses next generation sequencing (NGS) technology to assess wide variant types including single nucleotide variants, insertion/deletions, amplifications, and fusions in a total of 170 genes in key pathways, as well as genomic signatures including microsatellite instability and tumor mutation burden, from formalin-fixed paraffin embedded tissue specimens. The demonstration of clinically significant genomic variations can aid the therapeutic, prognostic, and/or diagnostic guidance for oncologists managing patients with solid tumor.</p> <p><b>Days Performed:</b> 2 days per week</p> <p><b>Reported:</b> 14 days</p> <p><b>CPT:</b> 81455 x 1</p>	3/29/19

## Fee Increases

Test Name	Order Code	List Fee	CPT Code	Effective Date
Clobazam	CLOBAZ	\$126.00 (non-discountable)	80339, (G0480, if appropriate)	2/5/19
Herpesvirus 6 IgM Antibody	HHV6M	\$166.00 (non-discountable)	86790	2/19/19
Mycoplasma pneumoniae IgA	MYCIGA	\$142.00 (non-discountable)	86738	2/5/19
Neisseria gonorrhoea Antibodies, Total	NGAB	\$166.00 (non-discountable)	86609	2/19/19
Niacin	B3VIT	\$131.00 (non-discountable)	84591	2/5/19

## Fee Reductions

Test Name	Order Code	List Fee	CPT Code	Effective Date
Beta Galactosidase, Leukocytes	BGALA	\$225.00 (non-discountable)	82657	Effective immediately
S-Sulfocysteine, Urine	USULFC	\$185.00 (non-discountable)	82131, 82570	1/31/19

## Discontinued Tests

Test Name	Order Code	Test Information	Effective Date
Allergen, Ampicilloyl IgE	AMPCIL	This test will no longer be available.	2/19/19
Benzoylcegonine Confirmation/Quantitation	BECCO	This test will no longer be available. Suggest ordering Cocaine Confirmation, Urine (UCOCC).	4/2/19
FLT3 Mutation Detection by PCR	FLT3MD	This test will no longer be available. Suggest ordering FLT3 ITD and TKD Mutation Detection by PCR (FLT3IT).	2/19/19
Kappa, Serum	KAPPA	This test will no longer be available. Suggest ordering Kappa, Free, Serum (FKAPPS).	4/2/19
Kidney Anti-A Titer	KIDTT	This test will no longer be available.	3/28/19
Lambda, Serum	LAMBDA	This test will no longer be available. Suggest ordering Lambda, Free, Serum (FLAMBS).	4/2/19
Mephenytoin & Normephenytoin	MEPNOR	This test will no longer be available.	2/25/19
Rotavirus and Adenovirus 40-41 Antigens	ROTAD	This test will no longer be available. Suggest ordering Adenovirus Antigen Detection, Gastroenteritis, EIA (SADNO) and Rotavirus Antigen Detection (EROTA).	2/19/19
Strychnine	STRYCH	This test will no longer be available.	2/19/19