Cleveland Clinic

Cleveland Clinic Laboratories

Technical Update • April 2018

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

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

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

For additional detail, contact Client Services at 216.444.5755 or 800.628.6816, or via email at clientservices@ccf.org.

Test Update Page #	Summary of Changes by Test Name	Order Code	Name Change	New Test	Test Discontinued	Special Information	Specimen Requirement	Component Change(s)	Methodology	Reference Range	Days Performed/Reported	Stability	CPT	Fee
4	Adiponectin						■	■				■	■		
4	Beta-2 Glycoprotein, IgG											■		
4	Beta-2-Glycoprotein IgG and IgM											■		
4	Beta-2 Glycoprotein, IgM											■		
4, 16	BK Virus Quantitation, Urine						■	■	■	■		■	■		■
11	Borrelia burgdorferi Antibodies, IgG and IgM by Immunoblot (CSF)			■											
5	CA 19-9						■								
5	Diphtheria/Tetanus Antibody						■	■		■	■		■	■	
5	Direct Renin						■								
16	EBV by PCR Qualitative					■									
5	Erythropoietin										■				
5	Ethanol						■								
16	FirstScreen First Trimester Screening					■									
6	FISH for Plasma Cell Myeloma		■				■	■				■	■	■	
12	Folate RBC			■											
6	Gastrin						■								
6	Gastrin Secretin Stimulation						■								
6	Gentamicin, Post Dose											■			
6	Gentamicin, Pre Dose											■			
6	Gentamicin, Random											■			
16	Glomerular Basement Membrane Ab					■									
6	Glomerular Basement Membrane IgG						■								

Test Update Page #	Summary of Changes by Test Name	Order Code	Name Change	New Test	Test Discontinued	Special Information	Specimen Requirement	Component Change(s)	Methodology	Reference Range	Days Performed/Reported	Stability	CPT	Fee
6	Glutamic Acid Decarboxylase Antibody					■								
12	Glutathione Total			■										
13	Hepatitis C Virus (HCV) NS5A Drug Resistance by Sequencing			■										
7	Homocysteine					■								
13	HSV 1 & 2 / VZV Amplification-Herpes Simplex Virus and Varicella-Zoster Virus, Molecular Detection			■										
7	LMW Anti Xa Assay						■			■		■		
16	Lyme IgG & IgM Immunoblot, CSF				■									
7	Magnesium RBC					■	■			■	■	■		
14	Maternal Serum Screen, First Trimester, hCG, PAPP-A, NT			■										
8	MYD88 L265P Mutation Analysis						■				■	■		
8	Norovirus Group 1 and 2 Detection by PCR					■								
8	Parvovirus B-19 Antibodies					■								
8	Parvovirus B19 IgM Antibodies					■								
8	PTH, Intact					■						■		
16	RBC Folate				■									
9, 16	Risperidone & Metabolite					■	■			■	■	■		■
9	Salicylate											■		
9	T3					■								
9	Theophylline											■		
9	Thyroglobulin					■								
9	Tobramycin, Post Dose											■		
9	Tobramycin, Pre Dose											■		
9	Tobramycin, Random											■		
16	Torch Antibodies, IgG & IgM				■									
10	Torch Antibodies, IgM					■	■							
15	Torch Antibodies Panel, IgG & IgM			■										

Dear Valued Client,

For several molecular tests, modifications have been made to the turnaround time in the Test Directory. Please see the Reported field of each affected test in the Test Directory for test-specific details. The following tests are affected:

- Chromosomal Microarray SNP, Constitutional (CRMSNP)
- Chromosome Analysis, Blood (CHRBLD)
- Chromosome Analysis, Bone Marrow (CHRBMH)
- Chromosome Analysis, Leukemic Blood (CHRBLL)
- Chromosome Analysis, Solid Tumor (CHRSOL)
- Chromosome Analysis, Tissue (CHRTIS)
- Chromosome Analysis with Reflex AML FISH panel (CHRAML)
- Chromosome Analysis with Reflex MDS FISH (CHRMDS)
- FISH for 1p36
- FISH for 5q Abnormalities (5QFSH)
- FISH for 7q deletion (FISH7Q)
- FISH for 8;21 Translocation for AML (AMLFSH)
- FISH for 20q and CEP8 (20Q8FH)
- FISH for Acute Myeloid Leukemia Panel (FAMLPN)
- FISH for Aggressive B-Cell Lymphoma on Bone Marrow or Blood (FABCFP)
- FISH for ALK (2p23) FFPET NSCLC (FSHLNG)
- FISH for ALK (2P23) THINPREP NSCLC (FSHTPA)
- FISH for ALK (2p23) Translocation (ALKFSH)
- FISH for ALK Cyto Block (ALKCB)
- FISH for Angiosarcoma MYC Amplification (MYCAMP)
- FISH for BCL2 (18q21) Tissue (TBCL2F)
- FISH for BCL2 on Bone Marrow or Blood (BCL2FH)
- FISH for BCL6 (3q27) Tissue
- FISH for BCL6 blood or bone marrow (BCL6FH)
- FISH FOR BIRC3/MALT1 TRANSLOCATION
- FISH for B Lymphoblastic Leukemia Panel (FSHBLL)
- FISH for CCND1 (Blood or Bone Marrow) (CCND1F)
- FISH for CCND1 (Paraffin)
- FISH for Chromosome 19q
- FISH for Chronic Lymphocytic Leukemia (CLLFSH)
- FISH for Cutaneous Melanoma (CMFISH)
- FISH for DDIT3 (12q13)
- FISH for EGFR (EGFRFISH)
- FISH for Ewings Sarcoma
- FISH for FGFR1 (FGFR1F)
- FISH for FOXO1A gene (13q14)(FKHR)
- FISH for FUS gene (16p11)
- FISH for HER-2
- FISH for IgH/BCL2 blood or bone marrow (FSHFCL)
- FISH for IgH/CCND1 blood or bone marrow (FSHMCL)
- FISH for IGH/MYC/CEP8 Tissue (T814F)
- FISH for IGH/MYC Fixed Pellet (814FSH)
- FISH for IGH Translocations
- FISH for MALT 1 (18q21)
- FISH for MDM2
- FISH for MLL (MLLFSH)
- FISH for MYC (8q24) blood & bone marrow (MYCFSH)
- FISH for MYC (8q24) Tissue
- FISH for Myelodysplasia (FSHMDS)
- FISH for Myeloproliferative Neoplasms Panel (MPNFSH)
- FISH for PML/RARA (APLFSH)
- FISH for RARA (RARFSH)
- FISH for RET (10q11) (RET)
- FISH for RET Cyto Block (RETCB)
- FISH for ROS1 (6q22) (ROS1)
- FISH for ROS1 Cyto Block (ROS1CB)
- FISH for SRY (SRYFSH)
- FISH for SYT gene (18q11)
- FISH for t(12;21)(p13q;22) (1221FH)
- FISH for Trisomy 4 and 10 (FHT410)
- FISH for WWTR1/CAMTA1
- FISH for XIST (XSTFSH)
- FISH for XY (XYFSH)
- FISH for YqH (YQHFSH)

Test Changes

Test Name	Order Code	Change	Effective Date
Adiponectin	ADIP	**Special Information: Patient Prep: Overnight fasting prior to collection is required. Specimens from non-fasting patients, specimens not separated from the red cells, and lipemic specimens are unacceptable. This test is New York DOH approved.** **Specimen Requirement: 0.5 mL** serum from a serum separator (gold) tube; Minimum: **0.1 mL;** Overnight fasting is required; **Centrifuge and transfer serum into standard aliquot tube;** Refrigerated *OR* **0.5 mL** serum from a plain no additive (red) tube; Minimum: **0.1 mL;** Overnight fasting is required; **Centrifuge and transfer serum into standard aliquot tube;** Refrigerated **Stability:** Ambient: **After separation from cells:** 8 hours Refrigerated: **After separation from cells:** 1 week Frozen: **After separation from cells:** 1 month **Days Performed: Wednesday** **Reported:** 2–9 days	6/5/18
Beta-2 Glycoprotein, IgG	BETA2G	**Stability:** Ambient: **1 day** Refrigerated: 7 days Frozen: **14 days**	5/29/18
Beta-2-Glycoprotein IgG and IgM	B2GPGM	**Stability:** Ambient: **1 day** Refrigerated: 7 days Frozen: **14 days**	5/29/18
Beta-2 Glycoprotein, IgM	BETA2M	**Stability:** Ambient: **1 day** Refrigerated: 7 days Frozen: **14 days**	5/29/18
BK Virus Quantitation, Urine	UBKQT	**For Interfaced Clients Only: Test build may need to be modified** **Includes:** **BK Virus, Urine, Source** BK Virus Copies/mL Ur **BK Virus, Urine, log copy/mL** BK Virus Quantitation, Urine **Special Information: Must indicate specimen source. Plasma, serum or whole blood are unacceptable. This test is New York DOH approved.** **Clinical Information: Detect and quantify BK virus in urine. The quantitative range of this assay is 2.6–8.6 log copies/mL (390–390,000,000 copies/mL). A negative result (< 2.6 log copies/mL or < 390 copies/mL) does not rule out the presence of PCR inhibitors in the patient specimen or BK virus DNA concentrations below the level of detection of the assay. Inhibition may also lead to underestimation of viral quantitation. No international standard is currently available for calibration of this assay. Caution should be taken when interpreting results generated by different assay methodologies. If the assay did NOT detect the virus, the test result will be reported as "< 2.6 log copies/mL (< 390 copies/mL)." If the assay DETECTED the presence of the virus but was not able to accurately quantify the number of copies, the test result will be reported as "Not Quantified."** **Specimen Requirement:** 1 mL random urine in a sterile container; Minimum: **0.5 mL;** Send to Cleveland Clinic Laboratories on the day of collection; **Specimen source required; Frozen** **Stability:** Ambient: **24 hours** Refrigerated: **5** days Frozen: **1 month** **Methodology: Real-Time** Polymerase Chain Reaction **(RT-PCR)** **Days Performed: Sunday**–Saturday **Reported:** 2–4 days	6/5/18

Test Changes (Cont.)

Test Name	Order Code	Change	Effective Date
CA 19-9	CA199	**Special Information:** Patients taking a biotin dose of up to 5 mg/day should refrain from taking biotin for 1 hour prior to sample collection. Patients taking a biotin dose > 5 mg/day to 10 mg/day should refrain from taking biotin for 2 hours prior to sample collection. Patients taking a biotin dose > 10 mg/day should consult with their physician or the laboratory prior to having a sample taken. **Clinicians should consider biotin interference as a source of error, when clinically suspicious of the laboratory result.**	Effective immediately
Diphtheria/ Tetanus Antibody	DIPTET	**Special Information: 'Pre' and 'post' vaccination specimens should be submitted for testing. 'Post' specimen should be drawn 30 days following immunization. Label specimens clearly as 'pre-vaccine' or 'post-vaccine.' If shipped separately, 'post' specimen must be received within 60 days of 'pre' specimen. Plasma or other body fluids are unacceptable. This test is New York DOH approved.** **Clinical Information: Used to evaluate the ability of a patient to produce antibody to pure protein vaccines after vaccination to rule out antibody deficiency. Responder status is determined according to the ratio of a one-month post-vaccination sample to pre-vaccination concentration of IgG antibodies as follows: Diphtheria and tetanus:** **1. If the post-vaccination concentration is < 1.0 IU/mL, the patient is considered a nonresponder.** **2. If the post-vaccination concentration is ≥ 1.0 IU/mL, a patient with a ratio of < 1.5 is a nonresponder, a ratio of 1.5 to < 3.0 is a weak responder, and a ratio of ≥ 3.0 is a good responder.** **3. If the pre-vaccination concentration is > 1.0 IU/mL, it may be difficult to assess the response based on a ratio alone. A post-vaccination concentration above 2.5 IU in this case is adequate.** **Specimen Requirement: 1 mL** serum from a serum separator (gold) tube; Minimum: **0.15 mL; Submit 'pre' and 'post' vaccination specimens; 'Post' specimen should be drawn 30 days following immunization; Label as 'pre-vaccine' or 'post-vaccine;' Note: 'Post' specimen must be received within 60 days of 'pre' specimen; Separate serum from cells ASAP or within 2 hours of collection** and transfer into standard aliquot tube; 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)** **Methodology: Quantitative Multiplex Bead Assay** **Reference Range:** Diphtheria Antibody: **Antibody concentration of > 0.1 IU/mL is usually considered protective** Tetanus Antibody: **Antibody concentration of > 0.1 IU/mL is usually considered protective** **CPT: 86317 x 2**	7/10/18
Direct Renin	RENIND	**Special Information:** Fasting specimens are recommended but not required. Record the time of day and patient's posture during blood collection (supine or upright). DO NOT pre-chill collection tubes, store tubes on ice or refrigerate; cryoactivation of prorenin occurs when samples are refrigerated. Process blood at room temperature. Centrifuge samples in a non-refrigerated centrifuge, immediately aliquot and freeze at minus 20 °C or colder. Biotin levels of up to 100 mg/day have not shown interference with this assay. Patients taking > 100 mg/day to 300 mg/day should refrain from taking biotin for 1 hour prior to sample collection. Patients taking a biotin dose > 300 mg/day should consult with their physician or the laboratory prior to having a sample taken. **Clinicians should consider biotin interference as a source of error, when clinically suspicious of the laboratory result.**	Effective immediately
Erythropoietin	EPO	**Reference Range: 2.6–18.5 mIU/mL**	5/29/18
Ethanol	ALCO	**Special Information:** Do not use alcohol or other volatile disinfectants at the site of venipuncture. Aqueous Zephiran (benzalkonium chloride), aqueous Merthiolate (thimerosal), or povidone-iodine may be used. **Ethanol is not available for Add-On test orders.**	Effective immediately

Test Changes (Cont.)

Test Name	Order Code	Change	Effective Date
FISH for Plasma Cell Myeloma	FSHPCM	**Test Name:** Previously Plasma Cell Myeloma by FISH **Special Information:** FISH methods incorporating **10 or 14 probes** will be utilized for testing. **Ten probes** will be charged initially, but **4 more** may be performed and charged at an additional cost. **Clinical Information:** Bone marrow aspirate samples are evaluated for plasma cells, and FISH methodology is used to detect **abnormalities** of 13q, 17p, **1p/1q, CEP9/CEP15** and translocations of IGH **and IGH/CCND1.** If an IGH translocation is present **that does not represent an IGH/CCND1 translocation, additional reflex studies will be performed using probes** for IGH/MMSET and IGH/MAF. **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: **48 hours** Frozen: **Unacceptable** **Days Performed: Sunday–Thursday** **Reported: 7–10** days **CPT:** 88271 **x 10, 88275 x 5,** 88291 x 1	4/5/18
Gastrin	GAST	**Special Information:** Patient preparation: Preferably fasting for 12 hours or more. Patients taking a biotin dose of up to 5 mg/day should refrain from taking biotin for 4 days prior to sample collection. Patients taking a biotin dose > 5 mg/day to 10 mg/day should refrain from taking biotin for 7 days prior to sample collection. Patients taking a biotin dose > 10 mg/day should consult with their physician or the laboratory prior to having a sample taken. **Clinicians should consider biotin interference as a source of error, when clinically suspicious of the laboratory result.**	Effective immediately
Gastrin Secretin Stimulation	GASTST	**Special Information:** Patients taking a biotin dose of up to 5 mg/day should refrain from taking biotin for 4 days prior to sample collection. Patients taking a biotin dose > 5 mg/day to 10 mg/day should refrain from taking biotin for 7 days prior to sample collection. Patients taking a biotin dose > 10 mg/day should consult with their physician or the laboratory prior to having a sample taken. **Clinicians should consider biotin interference as a source of error, when clinically suspicious of the laboratory result.**	Effective immediately
Gentamicin, Post Dose	GENTPO	**Stability:** Ambient: **After separation from cells: 48 hours** Refrigerated: After separation from cells: 1 week Frozen: After separation from cells: 2 weeks	Effective immediately
Gentamicin, Pre Dose	GENTPR	**Stability:** Ambient: **After separation from cells: 48 hours** Refrigerated: After separation from cells: 1 week Frozen: After separation from cells: 2 weeks	Effective immediately
Gentamicin, Random	GENTRA	**Stability:** Ambient: **After separation from cells: 48 hours** Refrigerated: After separation from cells: 1 week Frozen: After separation from cells: 2 weeks	Effective immediately
Glomerular Basement Membrane IgG	GBMBG	**Note:** *Changes to this test were previously announced in the March 2018 Technical Update with an effective date of 5/8/18. Please note that changes to the special/clinical information, specimen requirement, stability, methodology, reference range and days performed/reported will occur on 4/26/18. We apologize for any inconvenience this may have caused.*	**4/26/18**
Glutamic Acid Decarboxylase Antibody	GADCAB	**Special Information: Biotin levels of up to 300 mg/day have not shown interference with this assay. Patients taking a biotin dose > 300 mg/day should consult with their physician or the laboratory prior to having a sample taken. Clinicians should consider biotin interference as a source of error, when clinically suspicious of the laboratory result.**	Effective immediately

Test Changes (Cont.)

Test Name	Order Code	Change	Effective Date
Homocysteine	HOMCYS	**Clinical Information: The assay can assist in the diagnosis of patients suspected of having hyperhomocysteinemia or homocystinuria. Elevated tHcy levels are caused by four major factors, including:** **1. Genetic deficiencies in enzymes involved in Hcy metabolism such as cystathionine beta-synthase (CBS), methionine synthase (MS), and methylenetetrahydrofolate reductase (MTHFR)** **2. Nutritional deficiency in B vitamins such as B6, B12 and folate** **3. Renal failure for effective amino acid clearance** **4. Drug interactions, such as with nitric oxide, methotrexate and phenytoin that interfere with Hcy metabolism** **Excess Hcy is related to a higher risk of coronary heart disease, stroke, and peripheral vascular disease (fatty deposits in peripheral arteries). Specimens from patients who are on drug therapy involving S-adenosylmethionine may show falsely elevated levels of homocysteine. Patients who are taking methotrexate, carbamazepine, phenytoin, nitrous oxide, anticonvulsants, or 6-azauridine triacetate may have elevated levels of homocysteine due to their effect on the pathway.**	3/29/18
LMW Anti Xa Assay	LMWHEP	**Specimen Requirement: 1 mL platelet-poor** plasma from a 3.2% sodium citrate (light blue) tube; Minimum: **0.5 mL;** Frozen **Stability:** Ambient: **Centrifuge within 1 hour of phlebotomy and test or freeze platelet-poor plasma within** 4 hours Refrigerated: Unacceptable Frozen: 2 weeks at ≤ **minus 20 °C;** 6 months at ≤ **minus 70 °C** **Reference Range:** 0–99 Years: **< 0.10 IU/mL** **0–99 Years: Therapeutic: 0.5–1.1 IU/mL**	4/12/18
Magnesium RBC	MAGRBC	**Special Information: Specimens that are not whole blood, improperly/inadequately labeled,** frozen, **or not processed within 4 hours of collection are unacceptable.** **Clinical Information:** Red blood cell (RBC) magnesium results reflect the intracellular stores and general homeostasis of magnesium. Results may be falsely low if RBCs in the submitted specimen are lysed or not promptly separated from plasma. **Specimen Requirement: 1 mL** red blood cells from an EDTA (royal blue) tube; Minimum: **0.5 mL** red blood cells; Centrifuge whole blood and separate red blood cells **(discard plasma) within 4 hours of collection; Pour red blood cells into transport tube;** Ambient *OR* **1 mL** red blood cells from an EDTA **(lavender) tube;** Minimum: **0.5 mL** red blood cells; Centrifuge whole blood and separate red blood cells **(discard plasma) within 4 hours of collection; Pour red blood cells into transport tube;** Ambient **Stability:** Ambient: After separation from plasma: 1 week Refrigerated: After separation from plasma: **1 month** Frozen: After separation from plasma: Unacceptable **Reference Range: 4.0–6.5 mg/dL** **Days Performed: Tuesday, Friday** **Reported: 3–5** days	5/29/18

Test Changes (Cont.)

Test Name	Order Code	Change	Effective Date
MYD88 L265P Mutation Analysis	MYD88	**Specimen Requirement:** One formalin-fixed paraffin-embedded (FFPE) tissue block; Ambient *OR* One FFPE bone marrow clot; Ambient *OR* 4 mL whole blood in an EDTA (lavender) tube; Minimum: **1 mL;** Refrigerated *OR* 2 mL bone marrow in an EDTA (lavender) tube; Minimum: **0.5 mL;** Refrigerated **Stability:** Ambient: Blood/bone marrow: 24 hours; Formalin-fixed paraffin-embedded tissue/bone marrow clot: Indefinitely Refrigerated: Blood/bone marrow: **7** days; Formalin-fixed paraffin-embedded tissue/bone marrow clot: Indefinitely Frozen: Blood/bone marrow: Unacceptable; Formalin-fixed paraffin-embedded tissue/bone marrow clot: Indefinitely **Days Performed: 2 days** per week **Reported:** 7 days	5/1/18
Norovirus Group 1 and 2 Detection by PCR	NORPCR	**Note:** *Changes to this test were previously announced in the March 2018 Technical Update with an effective date of 5/3/18. Please note that changes to the special/clinical information, specimen requirement, days performed/reported, CPT and price will occur on 4/26/18. We apologize for any inconvenience this may have caused.*	**4/26/18**
Parvovirus B-19 Antibodies	PARV	**Special Information:** Avoid using hemolyzed, icteric, lipemic or bacterially contaminated sera. **For the Parvo B19 IgM assay: Biotin levels of up to 10 mg/day have not shown interference with this assay. Patients taking a biotin dose > 10 mg/day should consult with their physician or the laboratory prior to having a sample taken. Clinicians should consider biotin interference as a source of error, when clinically suspicious of the laboratory result.**	Effective immediately
Parvovirus B19 IgM Antibodies	PARVOM	**Special Information:** Avoid using hemolyzed, icteric, lipemic or bacterially contaminated sera. **Biotin levels of up to 10 mg/day have not shown interference with this assay. Patients taking a biotin dose > 10 mg/day should consult with their physician or the laboratory prior to having a sample taken. Clinicians should consider biotin interference as a source of error, when clinically suspicious of the laboratory result.**	Effective immediately
PTH, Intact	PTHI	**Special Information:** Serum stability: Stable for 8 hours at 15–25 °C, 2 days at 2–8 °C, and 6 months at minus 20 °C. Note that the specimen needs to be spun after the specimen clots. Samples should not be taken from patients receiving therapy with high biotin doses (i.e., > 5 mg/day) until at least 8 hours following the most recent biotin administration. **Stability:** Ambient: **After separation from cells:** 8 hours Refrigerated: After separation from cells: 2 days Frozen: After separation from cells: 6 months	4/3/18

Test Changes (Cont.)

Test Name	Order Code	Change	Effective Date
Risperidone & Metabolite	RISPER	**Special Information: Patient Prep: Pre-dose (trough) draw–At steady state concentration. Gel separator tubes are not acceptable. Light blue (citrate) or yellow (SPS or ACD solution) tubes are unacceptable. This test is New York DOH approved.** **Clinical Information: Optimize drug therapy and monitor patient adherence. This test detects risperidone (parent) and paliperidone (9-hydroxyrisperidone, metabolite). Adverse effects to risperidone therapy may include headache, nausea, dizziness, tachycardia, orthostatic hypotension and dyskinesia.** **Specimen Requirement: 1 mL** serum from a plain no additive (red) tube; Minimum: **0.5 mL; Pre-dose (trough) draw–At steady state concentration;** Do not use serum separator tubes; **Separate serum from cells within 2 hours of collection and transfer into standard aliquot tube;** Refrigerated *OR* **1 mL** plasma from an **EDTA (lavender) tube;** Minimum: **0.5 mL; Pre-dose (trough) draw–At steady state concentration; Separate plasma from cells within 2 hours of collection and transfer into standard aliquot tube;** Refrigerated **Stability:** Ambient: **2 weeks** Refrigerated: 2 weeks Frozen: **2** months **Reference Range:** **Therapeutic range: Not well established** **Total (Risperidone & metabolite): 20–60 ng/mL** **Days Performed:** Sunday, **Wednesday** **Reported: 2**–6 days	5/29/18
Salicylate	SALI	**Stability:** Ambient: **After separation from cells: 3 days** Refrigerated: After separation from cells: 2 weeks Frozen: Unacceptable	Effective immediately
T3	T3	**Special Information: Patients taking a biotin dose of up to 5 mg/day should refrain from taking biotin for 4 hours prior to sample collection. Patients taking a biotin dose of 5 to 10 mg/day should refrain from taking biotin for 8 hours prior to sample collection. Patients taking a biotin dose > 10 mg/day should consult with their physician or the laboratory prior to having a sample taken. Clinicians should consider biotin interference as a source of error, when clinically suspicious of the laboratory result.**	Effective immediately
Theophylline	THEO	**Stability:** Ambient: **After separation from cells: 3 days** Refrigerated: After separation from cells: 1 week Frozen: After separation from cells: 60 days	Effective immediately
Thyroglobulin	TG	**Special Information:** Serum is the only acceptable specimen type. Patients taking a biotin dose of up to 5 mg/day should refrain from taking biotin for 2 days prior to sample collection. Patients taking a biotin dose > 5 mg/day to 10 mg/day should refrain from taking biotin for 4 days prior to sample collection. Patients taking a biotin dose > 10 mg/day should consult with their physician or the laboratory prior to having a sample taken. **Clinicians should consider biotin interference as a source of error, when clinically suspicious of the laboratory result.**	Effective immediately
Tobramycin, Post Dose	TOBRPO	**Stability:** Ambient: **After separation from cells: 48 hours** Refrigerated: After separation from cells: 3 days Frozen: After separation from cells: 1 month	Effective immediately
Tobramycin, Pre Dose	TOBRPR	**Stability:** Ambient: **After separation from cells: 48 hours** Refrigerated: After separation from cells: 3 days Frozen: After separation from cells: 1 month	Effective immediately
Tobramycin, Random	TOBRRA	**Stability:** Ambient: **After separation from cells: 48 hours** Refrigerated: After separation from cells: 3 days Frozen: After separation from cells: 1 month	Effective immediately

Test Changes (Cont.)

Test Name	Order Code	Change	Effective Date
Torch Antibodies, IgM	TORCHM	**Special Information:** Parallel testing is preferred and convalescent specimens must be received within 30 days from receipt of the acute specimens. **This test is New York DOH approved.** **Clinical Information: This test is not recommended for diagnosing congenital infections in newborns; tests should be selected individually to target the most likely infectious agents.** **Specimen Requirement:** 2 mL serum from a serum separator (gold) tube; Minimum: 1 mL; **Allow specimen to clot completely at room temperature; Separate from cells ASAP or within 2 hours of collection and transfer to 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;' Refrigerated	Effective immediately

New Tests

Test Name	Order Code	Change	Effective Date
Borrelia burgdorferi Antibodies, IgG and IgM by Immunoblot (CSF)	LYIBCS	**Includes:** B. burgdorferi IgG Abs + Bands (18, 23, 28, 30, 39, 41, 45, 58, 66, 93 kDa) B. burgdorferi IgM Abs + Bands (23, 39, 41 kDa) **Special Information:** Contaminated or heat-inactivated specimens are unacceptable. If possible, specimens from New York clients will be sent out to a New York DOH approved laboratory. **Clinical Information:** Use in conjunction with positive serologic testing for the workup of suspected acute Lyme neuroborreliosis. Do not order when clinical symptoms are absent. IgG: A positive result is reported when any 5 or more of the following 10 bands are present: 18, 23, 28, 30, 39, 41, 45, 58, 66, or 93 kDa. All other banding patterns are reported as negative. IgM: A positive result is reported when any 2 or more of the following bands are present: 23, 39, or 41 kDa. All other banding patterns are reported as negative. The detection of antibodies to B. burgdorferi in cerebrospinal fluid may indicate central nervous system infection. However, consideration must be given to possible contamination by blood or transfer of serum antibodies across the blood-brain barrier. A negative result indicates that the immunoblot evaluation for B. burgdorferi antibody demonstrates no antibodies unique to B. burgdorferi and is therefore not supportive of Lyme disease. A positive result indicates that the immunoblot evaluation for Lyme antibody is consistent with the presence of antibody produced by patients in response to infection by B. burgdorferi and suggests the presence of Lyme disease. Although the test has been shown to have a high degree of reliability for diagnostic purposes, laboratory data should always be correlated with clinical findings. The current CDC recommendations for the serological diagnosis of Lyme disease are to screen with a polyvalent ELISA test and confirm equivocals and positives with immunoblot. Both IgM and IgG immunoblots should be performed on samples obtained less than 4 weeks after appearance of erythema migrans. Only IgG immunoblot is to be performed on samples greater than 4 weeks after disease onset. IgM immunoblot in the chronic stage is not recommended and does not aid in the diagnosis of chronic Lyme disease or neuroborreliosis. **Specimen Requirement:** 3 mL cerebrospinal fluid (CSF) in a clean container; Minimum: 2 mL; Refrigerated **Stability:** Ambient: 8 hours Refrigerated: 2 weeks Frozen: 1 year (Avoid repeated freeze/thaw cycles) **Methodology:** Immunoblot (IB), Qualitative **Reference Range:** Negative **Days Performed:** Sunday–Saturday **Reported:** 2–4 days **CPT:** 86617 x 2 **Price:** $88.00 (non-discountable)	4/30/18

New Tests (Cont.)

Test Name	Order Code	Change	Effective Date
Folate RBC	RBCFLP	**Includes:** Folate RBC Hematocrit **Special Information:** Hematocrit must be performed and submitted with the order. If the patient has not received a transfusion or experienced excessive bleeding between the RBC folate draw and the hematocrit draw, any hematocrit drawn within 24 hours of the RBC folate draw is acceptable. Folate RBC tube only: Critical frozen and must be protected from light during collection, storage and shipment. Separate specimens must be submitted when multiple tests are ordered. Specimens that are clotted or non-frozen will be rejected. This test is New York DOH approved. **Clinical Information:** Aids in detecting folate deficiency. **Specimen Requirement:** 1 mL whole blood in an EDTA (lavender) tube; Minimum: 1 mL split between 2 aliquots of 0.5 mL each; THIS TEST REQUIRES MULTIPLE SPECIMEN TUBES; Protect from light during collection, storage, and shipment; Mix specimen well; Transfer 1 mL whole blood into an amber transport tube and freeze; Separate specimens must be submitted when multiple tests are ordered; Critical Frozen *AND* 2.5 mL whole blood in an EDTA (lavender) tube; Minimum: 1 mL split between 2 aliquots of 0.5 mL each; Fill tube to at least half of fill volume; Refrigerated **Stability:** Ambient: Folate RBC: 2 hours; Hematocrit: 24 hours Refrigerated: Folate RBC: 4 hours; Hematocrit: 48 hours Frozen: Folate RBC: 2 months; Hematocrit: Unacceptable **Methodology:** Automated Cell Counter Quantitative Chemiluminescent Immunoassay **Reference Range:** Folate RBC: ≥ 366 ng/mL Hematocrit 0–14 Days: 39.6–57.2% 15–30 Days: 30.5–45.0% 31–60 Days: 26.8–37.5% 61–179 Days: 28.6–37.2% 6–23 Months: 30.8–37.9% 2–5 Years: 31.0–37.8% 6–11 Years: 32.2–39.8% 12–14 Years: 33.4–46.0% 15–99 Years (Male): 39.0–51.0% 15–99 Years (Female): 36.0–46.0% **Days Performed:** Sunday–Saturday **Reported:** 2–3 days **CPT:** 82747 x 1, 85014 x 1 **Price:** $92.00	4/26/18
Glutathione Total	GLUTAT	**Special Information:** Hemolyzed specimens are unacceptable. This test is New York DOH approved. **Specimen Requirement:** 10 mL blood in an ACD A or B (yellow) tube; Minimum: 1 mL; Critical Refrigerated **Stability:** Ambient: Unacceptable Refrigerated: 3 weeks Frozen: Unacceptable **Methodology:** Quantitative, Kinetic **Reference Range:** Refer to report **Days Performed:** Varies **Reported:** 4–7 days **CPT:** 82978 x 1 **Price:** $103.00 (non-discountable)	4/10/18

New Tests (Cont.)

Test Name	Order Code	Change	Effective Date
Hepatitis C Virus (HCV) NS5A Drug Resistance by Sequencing	HCVNS5	**Special Information:** Heparinized specimens are unacceptable. This test is New York DOH approved. **Clinical Limitation:** This test may be unsuccessful if the hepatitis C virus (HCV) RNA viral load is < log 3.4 or 2500 IU/mL and/or if the HCV RNA genotype is not 1a or 1b. **Clinical Information:** Order before initiating treatment with NS5A inhibitors. Do not order prior to molecular confirmation of positive HCV screen and confirmation of genotype 1a or 1b. This assay detects resistance-associated variants in NS5A codons 20-101 for HCV genotypes 1a and 1b. Variants in viral sub-populations below 20% of total may not be detected. For more information, please refer to drug package inserts for the applicable direct-acting antiviral drug and current HCV treatment guidelines (e.g., AASLD/IDSA guidelines or EASL HCV treatment recommendations). **Specimen Requirement:** 2 mL plasma from an EDTA (lavender) tube; Minimum: 1 mL; Separate from cells ASAP or within 2 hours of collection and transfer into standard aliquot tube; Frozen *OR* 2 mL plasma from an EDTA (white) plasma preparation tube (PPT); Minimum: 1 mL; Separate from cells ASAP or within 2 hours of collection and transfer into standard aliquot tube; Frozen *OR* 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; Frozen **Stability:** Ambient: Unacceptable Refrigerated: 72 hours Frozen: 4 months **Methodology:** Polymerase Chain Reaction/Sequencing **Reference Range:** Refer to report **Days Performed:** Monday **Reported:** 11–14 days **CPT:** 87902 x 1 **Price:** $515.00 (non-discountable)	4/10/18
HSV 1 & 2 / VZV Amplification-Herpes Simplex Virus and Varicella-Zoster Virus, Molecular Detection	HSVVZV	**Note:** *This test was previously announced in the February 2018 Technical Update.* **Price:** $225.00 (non-discountable)	4/5/18

New Tests (Cont.)

Test Name	Order Code	Change	Effective Date
Maternal Serum Screen, First Trimester, hCG, PAPP-A, NT	MATFIR	**Special Information:** Patient Prep: Specimen must be drawn between 11 weeks, 0 days and 13 weeks, 6 days. Crown–Rump length (CRL) must be between 43–83.9 mm at time of specimen collection. Must submit Patient History for Maternal Serum Testing form with the specimen. The following information is required with the order: Patient's date of birth, current weight, number of fetuses present, patient's race, if the patient has had a previous pregnancy with a trisomy, if the patient is currently smoking, if this is a repeat sample, the age of the egg donor if in vitro fertilization, the date of ultrasound, the CRL measurement, the nuchal translucency (NT) measurement and the name and certification number of the sonographer. NT must be measured when the CRL is between 38–83.9 mm. Plasma or hemolyzed specimens are unacceptable. This test is New York DOH approved. **Clinical Information:** Used as a first-trimester screening test for trisomy 21 (Down syndrome) and trisomy 18. Does not include alpha fetoprotein for open neural tube defects. Requires nuchal translucency measurement performed by an ultrasonographer certified by the Fetal Medicine Foundation (FMF) or Nuchal Translucency Quality Review (NTQR). **Specimen Requirement:** 3 mL serum from a serum separator (gold) tube; Minimum: 1 mL; Patient Prep: Specimen must be drawn between 11 weeks, 0 days and 13 weeks, 6 days; (CRL must be between 43–83.9 mm at time of specimen collection); Separate from cells ASAP or within 2 hours of collection and transfer into standard aliquot tube; Must submit Patient History for Maternal Serum Testing form with specimen; The following information is required with the order: Patient's date of birth, current weight, number of fetuses present, patient's race, if the patient has had a previous pregnancy with a trisomy, if the patient is currently smoking, if this is a repeat sample, the age of the egg donor if in vitro fertilization, the date of ultrasound, the CRL measurement, the NT measurement and the name and certification number of the sonographer; NT must be measured when the CRL is between 38-83.9 mm; Refrigerated *OR* 3 mL serum from a plain no additive (red) tube; Minimum: 1 mL; Patient Prep: Specimen must be drawn between 11 weeks, 0 days and 13 weeks, 6 days; (CRL must be between 43–83.9 mm at time of specimen collection); Separate from cells ASAP or within 2 hours of collection and transfer into standard aliquot tube; Must submit Patient History for Maternal Serum Testing form with specimen; The following information is required with the order: Patient's date of birth, current weight, number of fetuses present, patient's race, if the patient has had a previous pregnancy with a trisomy, if the patient is currently smoking, if this is a repeat sample, the age of the egg donor if in vitro fertilization, the date of ultrasound, the CRL measurement, the NT measurement and the name and certification number of the sonographer; NT must be measured when the CRL is between 38-83.9 mm; Refrigerated **Stability:** Ambient: After separation from cells: 72 hours Refrigerated: After separation from cells: 2 weeks Frozen: After separation from cells: 3 months (Avoid repeated freeze/thaw cycles) **Methodology:** Quantitative Chemiluminescent Immunoassay **Reference Range:** Refer to report **Days Performed:** Sunday–Saturday **Reported:** 3–5 days **CPT:** 81508 x 1 **Price:** $156.00 (non-discountable)	6/12/18

New Tests (Cont.)

Test Name	Order Code	Change	Effective Date
Torch Antibodies Panel, IgG & IgM	TORGMP	**Special Information:** Grossly hemolyzed, icteric, lipemic and heat-inactivated samples are unacceptable. Samples containing particulate matter or exhibiting obvious microbial contamination will be rejected. **Clinical Information:** For toxoplasmosis IgM and IgG, Ab: Equivocal results should have a new sample collected and tested 3 weeks later. Rubella IgG Ab: If exposure to Rubella is suspected and a negative result is obtained, a second specimen should be collected and tested 1-2 weeks later. Equivocal results should have a second sample collected and tested. Rubella IgM Ab: Parallel testing is preferred and convalescent specimens MUST be received within 30 days from receipt of acute specimens. Herpes Simplex Type 1 and 2 IgG Antibodies: Equivocal results should be followed up by obtaining a new sample for re-testing. Herpes Simplex IgM, Abs: A negative result does not rule out a primary or reactivated infection with HSV1 or HSV2 because the sample may have been obtained too early in the course of infection. If a primary infection is suspected, obtain a new sample 1-2 weeks later. Patients with equivocal results should have a new sample collected and tested 1-3 weeks later. **Specimen Requirement:** 3 mL serum from a serum separator (gold) tube; Minimum: 3.5 mL (Total minimum volume is 3.5 mL split between 2 aliquot tubes: 3 mL for frozen specimen, 0.5 mL for refrigerated specimen); THIS TEST REQUIRES MULTIPLE SPECIMEN TUBES; Frozen *AND* 1 mL serum from a serum separator (gold) tube; Minimum: 3.5 mL (Total minimum volume is 3.5 mL split between 2 aliquot tubes: 3 mL for frozen specimen, 0.5 mL for refrigerated specimen); Separate serum from cells ASAP or within 2 hours of collection and transfer into standard aliquot tube; For Rubella IgM testing, parallel testing is preferred and convalescent specimens must be received within 30 days from receipt of acute specimens; Label specimens plainly as 'acute' or 'convalescent;' Refrigerated **Stability:** Ambient: After separation from cells: 8 hours Refrigerated: After separation from cells: 48 hours; Note: For Rubella IgM, 2 weeks Frozen: After separation from cells: 14 days **Methodology:** Chemiluminescence Immunoassay (CLIA) Chemiluminescent Microparticle Immunoassay (CMIA) Enzyme Immunoassay (EIA) Multiplex Semi-Quantitative Chemiluminescent Immunoassay **Reference Range:** Refer to report **Days Performed:** Refer to individual components **Reported:** Refer to individual components **CPT:** 86644 x 1, 86645 x 1, 86694 x 1, 86695 x 1, 86696 x 1, 86762 x 2, 86777 x 1, 86778 x 1 **Price:** $324.00 (non-discountable)	4/26/18

Fee Reductions

Test Name	Order Code	List Fee	CPT Code	Effective Date
BK Virus Quantitation, Urine	UBKQT	$195.00 (non-discountable)	87799	6/5/18
Risperidone & Metabolite	RISPER	$105.00 (non-discountable)	80342, (G0480, if appropriate)	5/29/18

Discontinued Tests

Test Name	Order Code	Test Information	Effective Date
EBV by PCR Qualitative	EBPCR	Note: *This test was previously announced in the March 2018 Technical Update with a discontinuation of 5/15/18. This test will be discontinued on 4/12/18, and we suggest ordering EBV by PCR Quantitative (EBVQNT). We apologize for any inconvenience this may have caused.*	4/12/18
FirstScreen First Trimester Screening	FIRSCN	This test will no longer be available. Suggest ordering Maternal Serum Screen, First Trimester, hCG, PAPP-A, NT (MATFIR).	6/12/18
Glomerular Basement Membrane Ab	GBM	This test will no longer be available. Suggest ordering Glomerular Basement Membrane IgG (GBMBG).	6/14/18
Lyme IgG & IgM Immunoblot, CSF	LYMIBC	This test will no longer be available. Suggest ordering Borrelia burgdorferi Antibodies, IgG and IgM by Immunoblot (CSF) (LYIBCS).	4/30/18
RBC Folate	FOLRBC	This test will no longer be available. Suggest ordering Folate RBC (RBCFLP).	4/26/18
Torch Antibodies, IgG & IgM	TORCH	This test will no longer be available. Suggest ordering Torch Antibodies Panel, IgG & IgM (TORGMP).	4/26/18