



Cleveland Clinic Laboratories

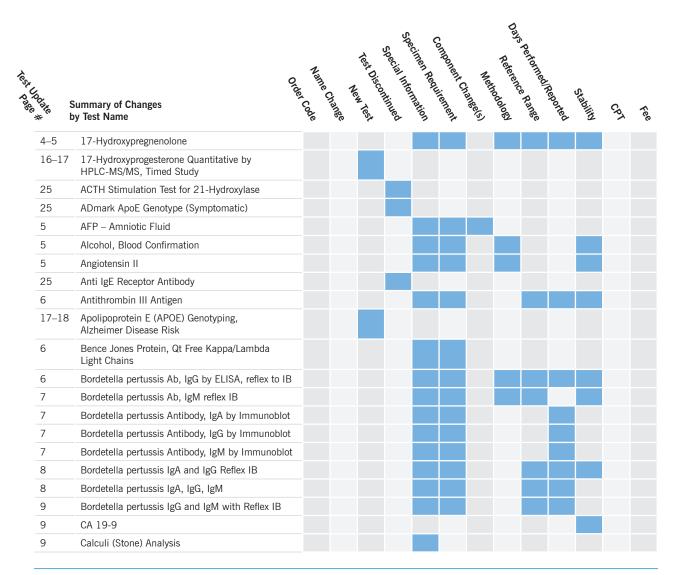
Technical Update • February 2018

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.



The common of Changes by Test Name Out to the common of t

Odake **	Summary of Changes by Test Name	Code	Change	ew lest	Minued	mation	Rement	angels	odology	Range	eported	Kability	Cox	Kee
9	Chromogranin A													
9	Chyloscreen, Body Fluid													
25	Cimetidine													
9	Cytology, SurePath Liquid-Based Pap Test													
10	Cytology, SurePath Liquid-Based Pap test and Human Papillomavirus (HPV), High Risk by PCR, SurePath (for routine co-testing in women over 30)													
10	Cytology, SurePath Liquid-Based Pap Test with Reflex to human Papillomavirus (HPV), High Risk by PCR, SurePath													
25	Dexamethasone Suppression 48-Hour													
10	DNAse-B Antibody													
11	Drug Detection Panel, TOF-MS, Umbilical Cord Tissue													
12	Ethyl glucuronide, Urine Confirm/Quant													
12	FISH for MLL													
12	FISH for XIST													
18	Fungal Antibodies with Reflex to Blastomyces dermatitidis Antibodies by Immunodiffusion, CSF													
12	HCG, Qualitative, Urine													
12	Hemoglobin A1C													
12	Hemoglobin Electrophoresis													
25	Herpes Simplex 1 & 2, Qt PCR, BAL													
25	Herpes Simplex Ag Detection													
25	Herpes Simplex by PCR													
25	Herpes Simplex Culture													
25	Herpes Simplex Virus by PCR, Ocular Fluid													
18	Herpes Simplex Virus Culture													
12	HIV 1 2 Combo (Antigen/Antibody)													
12, 25	Homocysteine													
25	Homocysteine, Plasma													
19	HSV $1\ \&\ 2\ /\ VZV$ Amplification-Herpes Simplex Virus and Varicella-Zoster Virus, Molecular Detection													
19	HSV PCR, Miscellaneous Specimen Types													
13	Inhibin A													
25	Inhibin A and B, Tumor Markers, Serum													
20	Inhibin A (Dimer) and Inhibin B, Tumor Markers, Serum													
13	Inhibin B													
14	JC Virus by PCR													
25	JC Virus DNA, PCR													
14	LDL Cholesterol, Direct													
25	LDLR Hypercholesterolemia Sequencing													
21	Lung Cancer Hotspot Gene Panel													

						Ş		2		Day	'n.				
NA JOHNA WAR	Summary of Changes by Test Name	Orde	Name Code	Change	Test Discon Test	Special Into	cimen Reduction	COMPONENT CHI	Men	Day Reference	Performed Le Range	Aeported	Stability	CPT	Kee
21	LYME AB Early Disease (≤ 30 days of signs and symptoms), with Reflex														
22	LYME AB Late Disease (> 30 days of signs or symptoms), with Reflex														
25	Lyme Antibodies, IgG, IgM														
25	Maprotiline														
25	Meperidine & Normeperidine														
26	Methsuximide/Normethsuximide														
22–23	Myelin Oligodendrocyte Glycoprotein (MOG-IgG1) Fluorescence-Activated Cell Sorting (FACS) Assay, Serum														
14	Polio Neutralization														
26	Poliovirus (Types 1,3) Antibodies, IFA														
14	Pregabalin														
15	Serotonin, Whole Blood														
26	ssDNA Antibody, IgG														
26	Streptococcal Antibodies Panel														
23	Streptococcal Antibody Panel														
15	TSH Receptor Antibody														
26	Varicella-Zoster DFA														
23–24	Vitamin B12 w/reflex														
24	West Nile Virus by PCR														
26	West Nile Virus PCR Plasma														
26	West Nile Virus RNA, Qualitative, RT PCR														

Dear Valued Client,

On 3/13/18, we will be changing laboratories for pancreatic polypeptide testing. Because pancreatic polypeptide assays are not standardized to a common reference material, the numerical values reported by different assays can vary significantly, and results from different methods or kits cannot be directly compared. Therefore, patients being followed using serial measurements may see changes in pancreatic polypeptide levels due to the assay change. Any such changes should be interpreted with caution. If possible, patients should be tested to re-establish their baseline values with the new assay. If you have questions about this change or would like information on how to rebaseline your patients, please contact Laboratory Client Services at 800.628.6816, and one of our representatives will be happy to assist you. If you have any medical questions, please contact Thomas Daly, MD at dalyt@ccf.org or 216.444.4547.

Test Changes

Test Name	Order Code	Change	Effective Date
17- Hydroxy- pregnenolone	PREG17	Special Information: CRITICAL FROZEN. Separate specimens must be submitted when multiple tests are ordered. Refrigerated or room temperature specimens are unacceptable. This test is New York DOH approved.	4/12/18
		Specimen Requirement: 1 mL serum from a serum separator (gold) tube; Minimum: 0.5 mL (Note: Minimum 0.25 mL per aliquot tube); Separate serum from cells ASAP or within 2 hours of collection; Transfer two 0.5 mL serum specimens into 2 separate standard aliquot tubes and freeze immediately; Separate specimens must be submitted when multiple tests are ordered; Critical Frozen	
		OR 1 mL serum from a plain no additive (red) tube; Minimum: 0.5 mL (Note: Minimum 0.25 mL per aliquot tube); Separate serum from cells ASAP or within 2 hours of collection; Transfer two 0.5 mL serum specimens into 2 separate standard aliquot tubes and freeze immediately; Separate specimens must be submitted when multiple tests are ordered; Critical Frozen	
		OR 1 mL plasma from an EDTA (lavender) tube; Minimum: 0.5 mL (Note: Minimum 0.25 mL per aliquot tube); Separate plasma from cells ASAP or within 2 hours of collection; Transfer two 0.5 mL plasma specimens into 2 separate standard aliquot tubes and freeze immediately; Separate specimens must be submitted when multiple tests are ordered; Critical Frozen	
		OR 1 mL plasma from a sodium or lithium heparin (green) tube; Minimum: 0.5 mL (Note: Minimum 0.25 mL per aliquot tube); Separate plasma from cells ASAP or within 2 hours of collection; Transfer two 0.5 mL plasma specimens into 2 separate standard aliquot tubes and freeze immediately; Separate specimens must be submitted when multiple tests are ordered; Critical Frozen	
		Stability: Ambient: After separation from cells: Unacceptable Refrigerated: After separation from cells: Unacceptable Frozen: After separation from cells: 6 months	
		Methodology: High Performance Liquid Chromatography/Tandem Mass Spectrometry (LC/MS/MS)	
		Reference Range: Male	
		Premature (26–28 Weeks): 1219–9799 ng/dL Premature (29–36 Weeks): 346–8911 ng/dL Full term (1–5 Months): 229–3104 ng/dL 6–12 Months: ≤ 917 ng/dL	
		13–23 Months: ≤ 592 ng/dL 2–4 Years: ≤ 249 ng/dL	
		5–6 Years: ≤ 319 ng/dL 7–9 Years: ≤ 187 ng/dL	
		10–12 Years: ≤ 392 ng/dL 13–15 Years: 35–465 ng/dL	
		16–17 Years: 32–478 ng/dL 18 Years and older: < 442 ng/dL	
		Tanner Stage I: ≤ 208 ng/dL Tanner Stage II: ≤ 355 ng/dL Tanner Stage III: ≤ 450 ng/dL Tanner Stage IV-V: 35-478 ng/dL	
		Female Premature (26–28 Weeks): 1219–9799 ng/dL	
		Premature (29–36 Weeks): 346–8911 ng/dL Full Term (1–5 Months): 229–3104 ng/dL 6–12 Months: ≤ 917 ng/dL	
		13–23 Months: ≤ 592 ng/dL 2–4 Years: ≤ 280 ng/dL 5–6 Years: ≤ 350 ng/dL 7–9 Years: ≤ 212 ng/dL	
		10-12 Years: ≤ 398 ng/dL 13-15 Years: ≤ 407 ng/dL 16-17 Years: ≤ 423 ng/dL 18 Years and older: < 226 ng/dL	
		(continued on page 5)	

Test Name	Order Code	Change	Effective Date
17- Hydroxy- pregnenolone (continued from page 4)		Tanner Stage I: ≤ 235 ng/dL Tanner Stage II: ≤ 367 ng/dL Tanner Stage III: ≤ 430 ng/dL Tanner Stage IV-V: ≤ 412 ng/dL Days Performed: Monday-Friday Reported: 2-5 days	
AFP-Amniotic Fluid	FAFPAM	For Interfaced Clients Only: Test build may need to be modified Special Information: Label tube "Amniotic Fluid for AFP." Include gestational age at time of collection or estimated due date, physician name and phone number. If Alpha Fetoprotein is elevated, then Acetylcholinesterase and Fetal Hemoglobin will be added at an additional cost. Add 3–11 days to the turnaround time. Unacceptable conditions: Specimens contaminated with fetal blood. This test is New York DOH approved. Specimen Requirement: 2.5 mL amniotic fluid in a clean container; Minimum: 1.5 mL; Must include gestational age at the time of collection or estimated due date; Submit Patient History for Prenatal Cytogenetics form; Patient Prep: Amniocentesis—Specimen must be drawn between 13 weeks, 0 days and 36 weeks, 6 days gestation; Ambient	2/20/18
Alcohol, Blood Confirmation	BALCO	Clinical Information: Therapy for methanol intoxication: 100–200 mg/dL; Critical: > 250 mg/dL. Inebriation, CNS depression, respiratory depression, mental and motor impairment, and liver damage may be caused by toxic concentrations. Ethanol ingestion may cause hypoglycemia in children. Specimen Requirement: 2 mL serum from a plain no additive (red) tube; Minimum: 0.5 mL; Separate serum from cells ASAP or within 2 hours of collection; Transfer 2 mL serum to a standard transport tube; Cap tube tightly to minimize alcohol loss; Do NOT draw serum separator tubes (SST); Refrigerated *OR* 2 mL plasma from a potassium oxalate/sodium fluoride (gray) tube; Minimum: 0.5 mL; Separate plasma from cells ASAP or within 2 hours of collection; Transfer 2 mL plasma to a standard transport tube; Cap tube tightly to minimize alcohol loss; Do NOT draw plasma separator tubes (PST); Refrigerated *OR* 2 mL plasma from an EDTA (lavender) tube; Minimum: 0.5 mL; Separate plasma from cells ASAP or within 2 hours of collection; Transfer 2 mL plasma to a standard transport tube; Cap tube tightly to minimize alcohol loss; Do NOT draw plasma separator tubes (PST); Refrigerated Stability: Ambient: After separation from cells in a tightly capped tube: 1 week Refrigerated: After separation from cells in a tightly capped tube: 2 weeks Frozen: After separation from cells in a tightly capped tube: 1 month Methodology: Quantitative Gas Chromatography	2/20/18
Angiotensin II	ANGII	Special Information: Hemolyzed specimens are unacceptable. This test is New York DOH approved. Specimen Requirement: 1 mL plasma from an EDTA (lavender) tube; Minimum: 0.3 mL; Remove plasma from cells ASAP or within 2 hours of collection and transfer into standard aliquot tube; Keep cold during centrifugation; Frozen Stability: Ambient: 12 hours Refrigerated: 24 hours Frozen: 28 days Methodology: Quantitative Radioimmunoassay	2/20/18

Test Name	Order Code	Change	Effective Date
Antithrombin III Antigen	AT3AG	Special Information: CRITICAL FROZEN. (Note: An attachment with detailed collection instructions will be available at www.clevelandcliniclabs.com). Separate specimens must be submitted when multiple tests are ordered. Serum, EDTA plasma, clotted or hemolyzed specimens are unacceptable. This test is New York DOH approved. Clinical Information: Not recommended as an initial test to detect antithrombin (AT) deficiency. Use to determine subtype in AT-deficient individuals. Specimen Requirement: 1 mL platelet-poor plasma from a sodium citrate (light blue) tube; Minimum: 0.5 mL; (Note: An attachment with detailed collection instructions will be available at www.clevelandcliniclabs.com); Do not use needles smaller than 23 gauge; Draw a pilot (light blue) tube and discard before drawing coagulation specimen; Tube must be completely filled; Mix gently by inversion 5–6 times; Centrifuge at 1700 g for 15 minutes or at a speed/time to produce platelet-poor plasma; Immediately remove top 2/3 of platelet-poor plasma and use plastic pipette to transfer 1 mL platelet-poor plasma into a standard plastic aliquot tube; Freeze immediately; Do not use glass vials; Separate specimens must be submitted when multiple tests are ordered; Critical Frozen Stability: Ambient: 8 hours Refrigerated: Unacceptable Frozen: 1 month Reference Range: 82–136% Days Performed: Sunday–Saturday Reported: 2–3 days	4/10/18
Bence Jones Protein, Qt Free Kappa/ Lambda Light Chains	UBJP	Special Information: Indicate total volume and collection time interval on aliquot tube and requisition. This test is New York DOH approved. Specimen Requirement: 8 mL 24-hour urine (well-mixed) in a clean container; Minimum: 4 mL; Refrigerate during collection; Split sample into two 4 mL aliquots; 24-hour volume and collection time interval must be included with the sample; Refrigerated *OR* 8 mL random urine in a clean container; Minimum: 4 mL; Split sample into two 4 mL aliquots; Record total volume; Refrigerated *OR* 8 mL urine supernate in a clean container; Minimum: 4 mL; Split sample into two 4 mL aliquots; Record total volume; Refrigerated	2/20/18
Bordetella pertussis Ab, IgG by ELISA, reflex to IB	BPGESA	Special Information: If Bordetella pertussis Antibody, IgG by ELISA is 1.05 IV or greater, then Bordetella pertussis IgG Immunoblot testing will be added at an additional cost. Contaminated, heat-inactivated, hemolyzed, or severely lipemic specimens are unacceptable. If possible, specimens from New York clients will be sent out to a New York DOH approved laboratory. Specimen Requirement: 1 mL serum from a serum separator (gold) tube; Minimum: 0.1 mL; Separate serum from cells ASAP or within 2 hours of collection 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; Please mark specimens plainly as 'acute' or 'convalescent;' Refrigerated Stability: Ambient: After separation from cells: 48 hours Refrigerated: After separation from cells: 2 weeks Frozen: After separation from cells: 1 year (Avoid repeated freeze/thaw cycles) Methodology: Semi-Quantitative Enzyme-Linked Immunosorbent Assay Reference Range: B. pert IgG ≤ 0.94 IV: Negative − No significant level of detectable B. pertussis IgG antibody 0.95−1.04 IV: Equivocal − Repeat testing in 10−14 days may be helpful ≥ 1.05 IV: Positive − IgG antibody to B. pertussis detected, which may indicate a current or recent exposure/immunization to B. pertussis	2/20/18

Test Name	Order Code	Change	Effective Date
Bordetella pertussis Ab, IgM reflex IB	BPMESA	Special Information: If Bordetella pertussis IgM antibody is 1.2 IV or greater, then Bordetella pertussis IgM Immunoblot testing will be added at an additional cost. Contaminated, heat-inactivated, or severely lipemic specimens are unacceptable. If possible, specimens from New York clients will be sent out to a New York DOH approved laboratory, and an approved Non-Permitted Laboratory (NPL) form must be submitted with the specimen. Specimen Requirement: 1 mL serum from a serum separator (gold) tube; Minimum: 0.1 mL; Separate serum 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; Please mark specimens plainly as 'acute' or 'convalescent;' Refrigerated Stability: Ambient: After separation from cells: 48 hours Refrigerated: After separation from cells: 2 weeks Frozen: After separation from cells: 1 year (Avoid repeated freeze/thaw cycles) Methodology: Semi-Quantitative Enzyme-Linked Immunosorbent Assay Reference Range: B. pert IgM ≤ 0.9 IV: Negative − No significant level of detectable B. pertussis IgM	2/20/18
		antibody 1.0–1.1 IV: Equivocal – Repeat testing in 10–14 days may be helpful ≥ 1.2 IV: Positive – IgM antibody to B. pertussis detected, which may indicate a current or recent exposure/immunization to B. pertussis	
Bordetella pertussis Antibody, IgA by Immunoblot	ВРАА	Special Information: Contaminated or heat-inactivated specimens are unacceptable. This test is New York DOH approved. Specimen Requirement: 1 mL serum from a serum separator (gold) tube; Minimum: 0.15 mL; Separate serum from cells ASAP or within 2 hours of collection and transfer into standard aliquot tube; Refrigerated Days Performed: Tuesday, Friday Reported: 2–6 days	2/20/18
Bordetella pertussis Antibody, IgG by Immunoblot	BPAG	Special Information: Heat-inactivated specimens are unacceptable. This test is New York DOH approved. Specimen Requirement: 1 mL serum from a serum separator (gold) tube; Minimum: 0.15 mL; Separate serum from cells ASAP or within 2 hours of collection and transfer into standard aliquot tube; Refrigerated Days Performed: Tuesday, Friday, Sunday Reported: 2–5 days	2/20/18
Bordetella pertussis Antibody, IgM by Immunoblot	BPAM	Special Information: Heat-inactivated specimens are unacceptable. If possible, specimens from New York clients will be sent out to a New York DOH approved laboratory, and an approved Non-Permitted Laboratory (NPL) form must accompany specimen. Specimen Requirement: 1 mL serum from a serum separator (gold) tube; Minimum: 0.15 mL; Separate serum from cells ASAP or within 2 hours of collection and transfer into standard aliquot tube; Refrigerated Days Performed: Tuesday, Friday Reported: 2–6 days	2/20/18

Test Name	Order Code	Change	Effective Date
Bordetella pertussis IgA and IgG Reflex IB	BPIAG	Special Information: If Bordetella pertussis Antibody, IgA by ELISA is 1.2 IV or greater, then B. pertussis IgA Immunoblot testing will be added at an additional charge. If Bordetella pertussis Antibody, IgG by ELISA is 1.05 IV or greater, then B. pertussis IgG Immunoblot testing will be added at an additional charge. Contaminated, heat-inactivated, or severely lipemic specimens are unacceptable. If possible, specimens from New York clients will be sent out to a New York DOH approved laboratory. Specimen Requirement: 1 mL serum from a serum separator (gold) tube; Minimum: 0.3 mL; Separate serum from cells ASAP or within 2 hours of collection 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; Please mark specimens plainly as 'acute' or 'convalescent;' Refrigerated Stability: Ambient: After separation from cells: 48 hours Refrigerated: After separation from cells: 2 weeks Frozen: After separation from cells: 1 year (Avoid repeated freeze/thaw cycles) Reference Range: B. pertussis IgA ≤ 0.9 IV: Negative − No significant level of detectable B. pertussis IgA antibody 1.0−1.1 IV: Equivocal − Repeat testing in 10−14 days may be helpful ≥ 1.2 IV: Positive − IgA antibody to B. pertussis detected, which may indicate a current or past exposure/immunization to B. pertussis IgG antibody 0.95−1.04 IV: Regative − No significant level of detectable B. pertussis IgG antibody 0.95−1.04 IV: Equivocal − Repeat testing in 10−14 days may be helpful ≥ 1.05 IV: Positive − IgG antibody to B. pertussis detected, which may indicate a current or recent exposure/immunization to B. pertussis	2/20/18
Bordetella pertussis IgA, IgG, IgM	BPPABS	Special Information: If Bordetella pertussis Antibody, IgA by ELISA is 1.2 IV or greater, then B. pertussis IgA Immunoblot testing will be added at an additional cost. If Bordetella pertussis Antibody, IgG by ELISA is 1.05 IV or greater, then B. pertussis IgG Immunoblot testing will be added at an additional cost. If Bordetella pertussis Antibody, IgM by ELISA is 1.2 IV or greater, then B. pertussis IgM Immunoblot testing will be added at an additional cost. Contaminated, heat-inactivated, or severely lipemic specimens are unacceptable. If possible, specimens from New York clients will be sent out to a New York DOH approved laboratory. Specimen Requirement: 1 mL serum from a serum separator (gold) tube; Minimum: 0.3 mL; Separate serum 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; Please mark specimens plainly as 'acute' or 'convalescent;' Refrigerated Reference Range: B. pertussis IgA ≤ 0.9 IV: Negative − No significant level of detectable B. pertussis IgA antibody 1.0−1.1 IV: Equivocal − Repeat testing in 10−14 days may be helpful ≥ 1.2 IV: Positive − IgA antibody to B. pertussis detected, which may indicate a current or past exposure/immunization to B. pertussis IgG antibody 0.95−1.04 IV: Equivocal − Repeat testing in 10−14 days may be helpful ≥ 1.05 IV: Positive − IgG antibody to B. pertussis detected, which may indicate a current or recent exposure/immunization to B. pertussis IgM ≤ 0.9 IV: Negative − No significant level of detectable B. pertussis IgM antibody 1.0−1.1 IV: Equivocal − Repeat testing in 10−14 days may be helpful ≥ 1.05 IV: Positive − IgG antibody to B. pertussis detected, which may indicate a current or recent exposure/immunization to B. pertussis IgM antibody 1.0−1.1 IV: Equivocal − Repeat testing in 10−14 days may be helpful ≥ 1.2 IV: Positive − IgM antibody to B. pertussis detected, which may indicate a curre	2/20/18

Test Name	Order Code	Change	Effective Date
Bordetella pertussis IgG and IgM with Reflex IB	BPIMG	Special Information: If Bordetella pertussis Antibody, IgG by ELISA is 1.05 IV or greater, then B. pertussis IgG Immunoblot testing will be added at an additional charge. If Bordetella pertussis Antibody, IgM by ELISA is 1.2 IV or greater, then Bordetella pertussis IgM Immunoblot will be added at an additional charge. Contaminated, heat-inactivated, or severely lipemic specimens are unacceptable. If possible, specimens from New York clients will be sent out to a New York DOH approved laboratory. Specimen Requirement: 1 mL serum from a serum separator (gold) tube; Minimum: 0.3 mL; Separate serum from cells ASAP or within 2 hours of collection 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; Please mark specimens plainly as 'acute' or 'convalescent;' Refrigerated Reference Range: B. pertussis IgG ≤ 0.94 IV: Negative − No significant level of detectable B. pertussis IgG antibody 0.95−1.04 IV: Equivocal − Repeat testing in 10−14 days may be helpful ≥ 1.05 IV: Positive − IgG antibody to B. pertussis detected, which may indicate a current or recent exposure/immunization to B. pertussis IgM antibody 1.0−1.1 IV: Equivocal − Repeat testing in 10−14 days may be helpful ≥ 1.2 IV: Positive − IgM antibody to B. pertussis detected, which may indicate a current or recent exposure/immunization to B. pertussis	2/20/18
		Days Performed: Tuesday, Friday Reported: 2–6 days	
CA 19-9	CA199	Stability: Ambient: 24 hours Refrigerated: 7 days Frozen: 6 months	Effective immediately
Calculi (Stone) Analysis	CSA	Special Information: Air-dry and submit entire calculi specimen. Specimens will be subject to rejection if submitted improperly. Do NOT submit in formalin, urine or other liquid. Do NOT submit stone on tape, wrapped in gauze, fixed in a gel or glue, or embedded in wax. Orders will be cancelled and credited if specimens are rejected.	2/28/18
Chromogranin A	CHROMA	Specimen Requirement: 1 mL serum from a serum separator (gold) tube; Minimum: 0.5 mL; Only one tube to be collected; Refrigerated *OR* 1 mL serum from a plain no additive (red) tube; Minimum: 0.5 mL; Only one tube to be collected; Refrigerated	2/5/18
Chyloscreen, Body Fluid	FCHYLO	Special Information: Do not freeze. Cerebrospinal fluid (CSF), plasma, serum or whole blood are unacceptable. This test is New York DOH approved. Stability: Ambient: Unacceptable Refrigerated: 3 weeks Frozen: Unacceptable	2/20/18
Cytology, SurePath Liquid-Based Pap Test	SPPAP	For Interfaced Clients Only: Test build may need to be modified Special Information: Transport cervical specimen in the original collection kit. For specific instructions regarding collection, contact Client Services at 800.628.6816 or 216.444.5755. Note: This test does not include HPV testing. If atypical cells are noted, Pap Test Pathology Review reflex testing may be added. The Pap test is a screening test for cervical cancer and its precursors with an inherent false-negative rate. Unacceptable conditions: Specimens not collected in a SurePath collection kit. Expired preservative vials or vials received without the collection devices.	2/20/18

Test Name	Order Code	Change	Effective Date
Cytology, SurePath Liquid-Based Pap test and Human Papillomavirus (HPV), High Risk by PCR, SurePath (for routine co-testing in women over 30)	SPHPV	For Interfaced Clients Only: Test build may need to be modified Special Information: Transport cervical specimen in the original collection kit. For specific collection instructions, contact Client Services at 800.628.6816 or 216.444.5755. Note: If the SurePath Liquid-Based Pap Test is interpreted as Satisfactory, then Human Papillomavirus (HPV) High Risk by PCR, SurePath will be added. Pap Test Pathology Review reflex testing may also be added. Additional charges apply. Unsatisfactory SurePath Liquid-Based Pap test specimens will not be tested for HPV. The Pap test is a screening test for cervical cancer and its precursors with an inherent false-negative rate. Unacceptable conditions: Specimens not collected in a SurePath collection kit. Expired preservative vials or vials received without the collection devices.	2/20/18
Cytology, SurePath Liquid-Based Pap Test with Reflex to human Papillomavirus (HPV), High Risk by PCR, SurePath	SPLBP	For Interfaced Clients Only: Test build may need to be modified Special Information: Transport cervical specimen in the original collection kit. For specific collection instructions, contact Client Services at 800.628.6816 or 216.444.5755. If the SurePath Liquid-Based Pap Test is interpreted as atypical squamous cells of undetermined significance (ASC-US), then Human Papillomavirus (HPV) High Risk by PCR, SurePath will be added. Pap Test Pathology Review reflex testing may also be added. Additional charges apply. Unacceptable conditions: Specimens not collected in a SurePath collection kit. Expired preservative vials or vials received without the collection devices.	2/20/18
DNAse-B Antibody	DASEAB	Special Information: Plasma or severely hemolyzed specimens are unacceptable. This test is New York DOH approved. Clinical Information: Confirm current or recent infection with group A Streptococcus in patients suspected of having a nonsuppurative complication such as acute glomerulonephritis (AGN) or acute rheumatic fever (ARF). DNase-B Antibody and Anti-Streptolysin O (ASO) are generally ordered concurrently. Preferred test for rheumatic chorea since it remains elevated longer. Specimen Requirement: 1 mL serum from a serum separator (gold) tube; Minimum: 0.4 mL; Separate serum from cells ASAP or within 2 hours of collection and transfer to 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 Methodology: Quantitative Nephelometry	4/17/18

Test Name Order	de Change	Effective Date
Drug Detection DRGT	For Interfaced Clients Only: Test build may need to be modified	2/20/18
Drug Detection Panel, TOF-MS, Umbilical Cord Tissue	For Interfaced Clients Only: Test build may need to be modified Note: Marijuana metabolite will be removed Includes: Buprenorphine Norbuprenorphine Buprenorphine Buprenorphine Buprenorphine Buprenorphine Fentanyl Hydrocodone Fentanyl Hydrocodone Hydromorphone Meperidine Methadone EDDP G-Acetylmorphine Morphine Morphine Morphine Naloxone Oxycodone Oxymorphone Noroxymorphone Noroxymorphone Noroxymorphone Propoxyphene Tapentadol Tramadol N-desmethyltramadol O-desmethyltramadol O-desmethyltramadol O-desmethyltramadol Amphetamine Benzoylecgonine	r

Test Name	Order Code	Change	Effective Date
Ethyl glucuronide, Urine Confirm/Quant	UEGQNT	Days Performed: Monday, Wednesday, Saturday Reported: 2–7 days	2/20/18
FISH for MLL	MLLFSH	Note: KMT2A has been added as an alias name. Other alias names include FISH for Mixed Lineage Leukemia and FISH for MLL (11q23) Translocation.	Effective immediately
FISH for XIST	XSTFSH	Test Name: Previously FISH for XST	Effective immediately
HCG, Qualitative, Urine	UHCG	Note: The CPT code for this test was previously announced in the January 2018 Technical Update with a go-live date of 3/1/2018. Effective immediately, the CPT code has been changed. We apologize for any inconvenience this may have caused. Methodology: Immunochromatography CPT: 81025 x 1	Effective immediately
Hemoglobin A1C	НВА1С	Specimen Requirement: 2 mL whole blood in an EDTA (lavender) tube; Minimum: 0.1 mL; Refrigerated *OR* 2 mL whole blood in a lithium heparin (green) tube; Minimum: 0.1 mL; Gel separator tubes are NOT acceptable; Refrigerated	Effective immediately
Hemoglobin Electrophoresis	HBELSA	Note: This test will have an order code change (previously HBELEC).	4/10/18
HIV 1 2 Combo (Antigen/Antibody)	HIV12C	Special Information: Note: If results are inconsistent with an individual's clinical presentation or risk profile for HIV infection, a repeat specimen is suggested. A repeat specimen is also recommended for any individual identified reactive for the first time. All repeat reactive HIV Antibody tests will have supplemental testing with an immunoassay that differentiates HIV-1 from HIV-2 antibodies performed at an additional charge. Patients who are screen positive and differentiation negative must be tested with HIV RNA test to rule out an acute infection.	Effective immediately
Homocysteine	HOMCYS	Test Name: Previously Homocysteine, Serum 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). Specimen Requirement: 1 mL serum from a serum separator (gold) tube; Minimum: 0.5 mL; Centrifuge and separate serum from cells immediately; If collected in a non-gel separator tube, centrifuge and transfer serum to a CCL tube and refrigerate; Refrigerated *OR* 1 mL plasma from a lithium heparin (light green) plasma separator tube (PST); Minimum: 0.5 mL; Centrifuge and separate plasma from cells immediately; If collected in a non-gel separator tube, centrifuge and transfer plasma to a CCL tube and refrigerate; Refrigerated Stability: Ambient: After separation from cells: 4 days Refrigerated: After separation from cells: 4 weeks Frozen: After separation from cells: 10 months Methodology: Enzymatic Reference Range: 18–99 Years: < 15.1 μmol/L Days Performed: Sunday–Saturday Reported: 8 hours	3/29/18

Test Name	Order Code	Change	Effective Date
Inhibin A	INHIBA	Special Information: Patient Prep: Fasting is recommended, but not required. Plasma is not acceptable. Hemolyzed or severely lipemic specimens are unacceptable. This test is New York DOH approved.	4/3/18
		Clinical Information: Aids in the diagnosis and monitoring of various hormonal reproductive disorders. This assay is performed using the Beckman Coulter Unicel DxI assay. Values may be elevated during normal pregnancy. Some cancers, preeclampsia, and Down Syndrome may increase Inhibin A values.	
		Specimen Requirement: 1 mL serum from a serum separator (gold) tube; Minimum: 0.5 mL; Patient Prep: Fasting is recommended, but not required; Transfer 1 mL serum into standard aliquot tube; Refrigerated	
		Stability: Ambient: After separation from cells: 24 hours Refrigerated: After separation from cells: 1 week Frozen: After separation from cells: 1 year (Avoid repeated freeze/thaw cycles)	
		Methodology: Quantitative Chemiluminescent Immunoassay	
		Reference Range: Female	
		Normal Cycling Early Follicular Phase (-14 to -10): 1.8–17.3 pg/mL Mid Follicular Phase (-9 to -4): 3.5–31.7 pg/mL Late Follicular Phase (-3 to -1): 9.8–90.3 pg/mL	
		Mid Cycle (Day 0): 16.9–91.8 pg/mL Early Luteal (1 to 3): 16.1–97.5 pg/mL Mid Luteal (4 to 11): 3.9–87.7 pg/mL Late Luteal (12 to 14): 2.7–47.1 pg/mL	
		IVF-Peak Levels: 354.2–1690.0 pg/mL PCOS-Ovulatory: 5.7–16.0 pg/mL Postmenopausal: < 6.9 pg/mL	
		Male (Normal): < 2.1 pg/mL	
		Days Performed: Sunday—Saturday Reported: 2–3 days	
Inhibin B	INHIBB	Special Information: Room temperature specimens, and hemolyzed or lipemic specimens are unacceptable. This test is New York DOH approved.	4/3/18
		Clinical Information: Use to differentiate ovarian tumor with normal CA 125 as stromal or mucinous epithelial tumor. May be used for monitoring recurrence of stromal ovarian tumors. This test is performed using the Beckman Coulter Inhibin B ELISA kit. Values obtained with different methodologies or kits cannot be used interchangeably.	
		Specimen Requirement: 0.5 mL serum from a serum separator (gold) tube; Minimum: 0.2 mL; Centrifuge and transfer serum into standard aliquot tube; Frozen	
		OR 0.5 mL serum from a plain no additive (red) tube; Minimum: 0.2 mL; Centrifuge and transfer serum into standard aliquot tube; Frozen	
		Stability: Ambient: After separation from cells: Unacceptable Refrigerated: After separation from cells: 48 hours Frozen: After separation from cells: 1 month	
		Reference Range: Female	
		0-6 Years: < 73 pg/mL 7-10 Years: < 130 pg/mL 11-12 Years: < 186 pg/mL 13-18 Years: < 360 pg/mL	
		Pre-menopausal: < 290 pg/mL Follicular phase: 10–290 pg/mL Post-menopausal: ≤ 16 pg/mL Male	
		0-6 Years: 40-630 pg/mL 7-10 Years: 35-170 pg/mL 11-18 Years: 50-475 pg/mL 19-45 Years: 40-450 pg/mL	
		46 Years and older: < 200 pg/mL Days Performed: Wednesday, Friday	
		Reported: 2–9 days	

Test Name	Order Code	Change	Effective Date
JC Virus by PCR	JCPCRB	Special Information: Must indicate source of specimen. Heparinized specimens are unacceptable. This test is New York DOH approved. Clinical Information: Detects JC virus in cerebrospinal fluid (CSF), plasma, serum, or urine specimens. Specimen Requirement: 1 mL plasma from an EDTA (lavender) tube; Minimum: 0.5 mL; Transfer 1 mL plasma to sterile aliquot tube; Specimen source required; Frozen *OR* 1 mL random urine in a sterile container; Minimum: 0.5 mL; Specimen source required; Frozen *OR* 1 mL serum from a serum separator (gold) tube; Minimum: 0.5 mL; Transfer 1 mL serum to sterile aliquot tube; Specimen source required; Frozen *OR* 1 mL cerebrospinal fluid (CSF) in a sterile container; Minimum: 0.5 mL; Specimen source required; Frozen	4/5/18
LDL Cholesterol, Direct	LDLDCT	Reference Range: Direct LDL-Chol 0-19 Years: < 110 mg/dL 20-99 Years: < 100 mg/dL VLDL-Cholesterol 0-9 Years: < 15 mg/dL 10-19 Years: < 18 mg/dL 20-99 Years: < 30 mg/dL	Effective immediately
Polio Neutralization	PNEUT	Days Performed: Monday–Friday Reported: 7–10 days	4/19/18
Pregabalin	PBALIN	For Interfaced Clients Only: Test build may need to be modified Special Information: Please indicate in the supplied fields: 1. Dose–List drug amount and include the units of measure 2. Route–List the route of administration (IV, oral, etc.) 3. Dose Frequency–Indicate how often the dose is administered (per day, per week, as needed, etc.) 4. Type of Draw–Indicate the type of blood draw (Peak, Trough, Random, etc.). Citrated plasma is unacceptable. This test is New York DOH approved. Clinical Information: Useful to optimize drug therapy and monitor patient adherence. The therapeutic range is based on serum pre-dose (trough) draw at steady-state concentration. Therapeutic and toxic ranges are not well established. Proposed Dose-Related Range: 2–10 µg/mL. Adverse effects may include peripheral edema, allergic reactions, dizziness and somnolence. Specimen Requirement: 1 mL serum from a plain no additive (red) tube; Minimum: 0.2 mL; Pre-dose (trough) draw–At a steady state concentration; Separate serum from cells ASAP or within 2 hours of collection and transfer into standard aliquot tube; Refrigerated *OR* 1 mL plasma from an EDTA (lavender) tube; Minimum: 0.2 mL; Pre-dose (trough) draw–At a steady state concentration; Separate plasma from cells ASAP or within 2 hours of collection and transfer into standard aliquot tube; Refrigerated Stability: Ambient: 1 month Refrigerated: 1 month Frozen: 2 months Methodology: Quantitative Liquid Chromatography–Tandem Mass Spectrometry Reference Range: Not well established Days Performed: Tuesday, Saturday Reported: 2–7 days	4/17/18

Test Name	Order Code	Change	Effective Date
Serotonin, Whole Blood	SEROWB	Special Information: Patient Prep: Abstain from medications for 72 hours prior to collection. CRITICAL FROZEN. Separate specimens must be submitted when multiple tests are ordered. Non-frozen specimens and specimens other than whole blood are unacceptable. This test is New York DOH approved.	4/17/18
		Clinical Information: Used to diagnose and monitor carcinoid tumors. Preferred serotonin test since most of the blood serotonin resides in the platelets. Medications that may affect serotonin concentrations include lithium, monoamine oxidase (MAO) inhibitors, methyldopa, morphine, and reserpine. Foods that contain serotonin do not interfere significantly, in general. Slight increases may be seen in acute intestinal obstruction, acute myocardial infarction (MI), cystic fibrosis, dumping syndromes, and nontropical sprue. Metastasizing abdominal carcinoid tumors often show serotonin concentrations > 400 ng/mL.	
		Specimen Requirement: 3 mL whole blood in an EDTA (lavender) tube; Minimum: 1 mL; Patient Prep: Abstain from medications for 72 hours prior to collection; Place on ice after draw; Transfer 3 mL whole blood to a serotonin transport tube containing ascorbic acid (ARUP supply #16568); Mix well and freeze; Must preserve and freeze specimen within 2 hours of collection; Separate specimens must be submitted when multiple tests are ordered; Critical Frozen	
		Stability: Ambient: After transfer to serotonin transport tube: Unacceptable Refrigerated: After transfer to serotonin transport tube: Unacceptable Frozen: After transfer to serotonin transport tube: 1 month	
		Methodology: High Performance Liquid Chromatography (HPLC)	
		Reference Range: 50–200 ng/mL Days Performed: Sunday, Tuesday—Friday	
		Reported: 2–6 days	
TSH Receptor Antibody	TRAB	Note: Clinical Information (Diagnosis and management of patients with Graves disease) for this test will be removed.	2/1/18

New Tests

Test Name	Order Code	Change	Effective Date
17-Hydroxy- progesterone Quantitative by HPLC-MS/MS, Timed Study	HPROGT	Special Information: Grossly hemolyzed specimens are unacceptable. This test is New York DOH approved. Clinical Information: Note: Reference ranges for 17-Hydroxyprogesterone following stimulation are not well defined and are dependent on the stimulation method utilized.	4/5/18
		Specimen Requirement: 2 mL serum from a serum separator (gold) tube; Minimum: 0.6 mL (Total minimum volume is 0.6 mL sample split into two 0.3 mL aliquots); THIS TEST REQUIRES TWO SPECIMEN TUBES; Split sample into two 1 mL serum aliquots and refrigerate; Refrigerated	
		OR 2 mL serum from a plain no additive (red) tube; Minimum: 0.6 mL (Total minimum volume is 0.6 mL sample split into two 0.3 mL aliquots); THIS TEST REQUIRES TWO SPECIMEN TUBES; Split sample into two 1 mL serum aliquots and refrigerate; Refrigerated	
		OR 2 mL plasma from a lithium heparin (light green) plasma separator tube (PST); Minimum: 0.6 mL (Total minimum volume is 0.6 mL sample split into two 0.3 mL aliquots); THIS TEST REQUIRES TWO SPECIMEN TUBES; Split sample into two 1 mL plasma aliquots and refrigerate; Refrigerated	
		OR 2 mL plasma from a sodium heparin (light green) plasma separator tube (PST); Minimum: 0.6 mL (Total minimum volume is 0.6 mL sample split into two 0.3 mL aliquots); THIS TEST REQUIRES TWO SPECIMEN TUBES; Split sample into two 1 mL plasma aliquots and refrigerate; Refrigerated	
		OR 2 mL plasma from a sodium or lithium heparin (green) tube; Minimum: 0.6 mL (Total minimum volume is 0.6 mL sample split into two 0.3 mL aliquots); THIS TEST REQUIRES TWO SPECIMEN TUBES; Split sample into two 1 mL plasma aliquots and refrigerate; Refrigerated	
		Stability: Ambient: After separation from cells: Unacceptable Refrigerated: After separation from cells: 1 week Frozen: After separation from cells: 6 months	
		Methodology: High Performance Liquid Chromatography/Tandem Mass Spectrometry (LC/MS/MS)	
		Reference Range: 17-Hydroxyprogesterone (Baseline) Female	
		Premature (26–28 Weeks): 124–841 ng/dL Premature (29–35 Weeks): 26–568 ng/dL Full term Day 3: 7–77 ng/dL 4–30 Days: 7–106 ng/dL	
		1-2 Months: 13-106 ng/dL 3-5 Months: 13-106 ng/dL 6 Months-1 Year: ≤ 148 ng/dL 2-3 Years: ≤ 256 ng/dL	
		4-6 Years: ≤ 299 ng/dL 7-9 Years: ≤ 71 ng/dL 10-12 Years: ≤ 129 ng/dL 13-15 Years: 9-208 ng/dL	
		13-13 feals: 9-208 fig/dL 16-17 Years: ≤ 178 ng/dL 18 Years and older: < 207 ng/dL Follicular: 15-70 ng/dL Luteal: 35-290 ng/dL	
		Tanner Stage II: ≤ 74 ng/dL Tanner Stage II: ≤ 164 ng/dL Tanner Stage III: 13–209 ng/dL Tanner Stage IV–V: 7–170 ng/dL	
		Male Premature (26–28 Weeks): 124–841 ng/dL Premature (29–35 Weeks): 26–568 ng/dL Full term Day 3: 7–77 ng/dL 4–30 Days: < 200 ng/dL	
		(continued on page 17)	

Test Name	Order Code	Change	Effective Date
17-Hydroxy- progesterone Quantitative by HPLC-MS/MS, Timed Study (continued from page 16)		1–2 Months: < 200 ng/dL 3–5 Months: 3–90 ng/dL 6 Months–1 Year: ≤ 148 ng/dL 2–3 Years: ≤ 228 ng/dL 4–6 Years: ≤ 208 ng/dL 7–9 Years: ≤ 63 ng/dL 10–12 Years: ≤ 79 ng/dL 13–15 Years: 9–140 ng/dL 16–17 Years: 24–192 ng/dL 18 Years and older: < 139 ng/dL Tanner Stage I!: ≤ 62 ng/dL Tanner Stage II!: ≤ 104 ng/dL Tanner Stage III: ≤ 151 ng/dL Tanner Stage IV–V: 20–173 ng/dL 17-Hydroxyprogesterone (60–Minute) Not well defined Days Performed: Sunday–Saturday Reported: 2–5 days CPT: 83498 x 2 Price: \$80.00 (non-discountable)	

Apolipoprotein E (APOE) Genotyping, Alzheimer Disease Risk ALZHEI

Special Information: Genetic counseling and informed consent are strongly recommended prior to ordering and post test to discuss results. NOTE: Testing of fetal specimens or specimens from patients under the age of 18 years is not offered. If possible, specimens from New York clients will be sent out to a New York DOH approved laboratory.

Clinical Limitation: Only the APOE alleles e2, e3 and e4 will be detected; rare alleles are not detected by this test. Diagnostic errors can occur due to rare sequence variations.

Clinical Information: Supports a clinical diagnosis of Alzheimer disease (AD) in symptomatic individuals. Use for AD risk assessment only. Background Information: Characteristics: Alzheimer disease, the most common cause of dementia, is characterized by progressive cognitive decline including memory, problem-solving skills, multi-step tasks, planning, and changes in personality. A clinical diagnosis of probable AD can be made based on clinical signs and neuroimaging, and the diagnosis is confirmed postmortem based on neuropathologic findings. The e4 allele of the APOE gene has been widely demonstrated to be associated with increased risk of AD. In individuals with a clinical diagnosis of AD, the presence of the e4 allele increases the likelihood that the diagnosis is correct, but is not diagnostic alone. APOE genotyping is not recommended for predicting AD risk in asymptomatic individuals. Prevalence of APOE e4: Heterozygosity and homozygosity for the e4 allele is present in approximately 25% and 1-2% of the general population, respectively. Inheritance of APOE e4: Semi-dominant. Penetrance of APOE e4: Incomplete and influenced by age, gender, ethnicity, family history and environmental factors. The e4 allele is neither necessary nor sufficient for diagnosing AD; therefore, not all individuals with AD have the e4 allele and not all individuals with the e4 allele will develop AD. Cause: Multi-factorial.

Variants Tested: Two single nucleotide polymorphisms in the APOE gene at codons 130 (rs429358) and 176 (rs7412). The e3 allele (Cysteine at 130 and Arginine at 176) is the most common in the general population. The e4 allele (Arginine at 130 and 176) is associated with increased AD risk. The e2 allele (Cysteine at codons 130 and 176) may be associated with a lower risk for AD, but homozygosity has been associated with increased risk for type III hyperlipoproteinemia. Clinical Sensitivity: Approximately 30–60% of individuals diagnosed with AD carry at least one e4 allele. The e4/e4 genotype is found in approximately 13% of the AD population and 20% of the familial AD population. Methodology: Polymerase chain reaction (PCR) and fluorescence monitoring using hybridization probes. Analytical Sensitivity and Specificity: 99%

(continued on page 18)

4/10/18

Test Name	Order Code	Change	Effective Date
Apolipoprotein E (APOE) Genotyping, Alzheimer Disease Risk (continued from page 17)		Specimen Requirement: 3 mL whole blood in an EDTA (lavender) tube; Minimum: 1 mL; Refrigerated *OR* 3 mL whole blood in an ACD A or B (yellow) tube; Minimum: 1 mL; Refrigerated Stability: Ambient: 72 hours Refrigerated: 2 weeks Frozen: 1 month Methodology: Fluorescence Monitoring Polymerase Chain Reaction (PCR) Reference Range: Homozygous apo e3 (e3/e3): This genotype is the most common (normal) genotype Days Performed: Monday, Thursday Reported: 3–8 days CPT: 81401 x 1 Price: \$104.00 (non-discountable)	
Fungal Antibodies with Reflex to Blastomyces dermatitidis Antibodies by Immunodiffusion, CSF	FANCSF	Note: This test was previously announced in the January 2018 Technical Update. Price: \$90.00 (non-discountable)	Effective immediately
Herpes Simplex Virus Culture	HSVCUL	Special Information: Indicate specimen source. Blood, cerebrospinal fluid (CSF), plasma or serum are unacceptable. Calcium alginate, eSwab, dry or wood swabs will be rejected. This test is New York DOH approved. Clinical Information: Traditional gold standard test for identifying acute herpes simplex virus (HSV) infection in active lesions (e.g., vesicles, ulcers, inflamed mucous membranes). Molecular testing is generally preferred. Specimen Requirement: Buccal swab in 3 mL Viral Transport Media (VTM) (ARUP supply #12884); Minimum: 0.5 mL; Indicate specimen source; Refrigerated *OR* Eye swab in 3 mL Viral Transport Media (VTM) (ARUP supply #12884); Minimum: 0.5 mL; Indicate specimen source; Refrigerated *OR* Genital swab in 3 mL Viral Transport Media (VTM) (ARUP supply #12884); Minimum: 0.5 mL; Indicate specimen source; Refrigerated *OR* Rectal swab in 3 mL Viral Transport Media (VTM) (ARUP supply #12884); Minimum: 0.5 mL; Indicate specimen source; Refrigerated *OR* Throat swab in 3 mL Viral Transport Media (VTM) (ARUP supply #12884); Minimum: 0.5 mL; Indicate specimen source; Refrigerated *OR* Vesicle swab in 3 mL Viral Transport Media (VTM) (ARUP supply #12884); Minimum: 0.5 mL; Indicate specimen source; Refrigerated *OR* 3 mL bronchoalveolar lavage (BAL) specimen in a sterile container; Minimum: 0.5 mL; Indicate specimen source; Refrigerated *OR* Tissue in 3 mL Viral Transport Media (VTM) (ARUP supply #12884); Minimum: 0.5 mL; Indicate specimen source; Refrigerated *OR* Tissue in 3 mL Viral Transport Media (VTM) (ARUP supply #12884); Minimum: 0.5 mL; Indicate specimen source; Refrigerated *OR* Tissue in 3 mL Viral Transport Media (VTM) (ARUP supply #12884); Minimum: 0.5 mL; Indicate specimen source; Refrigerated *OR* Tissue in 3 mL Viral Transport Media (VTM) (ARUP supply #12884); Minimum: 0.5 mL; Indicate specimen source; Refrigerated *OR* Tissue in 3 mL Viral Transport Media (VTM) (ARUP supply #12884); Minimum: 0.5 mL; Indicate specimen source; Refrigerated *OR* Tissue in 3 mL Viral Transport Media (VTM)	4/5/18

Test Name	Order Code	Change	Effective Date
HSV 1 & 2 / VZV Amplification-Herpes Simplex Virus and Varicella-Zoster Virus, Molecular Detection	HSVVZV	Special Information: Testing will be performed daily, 7 days per week. Results should generally be available within 1–2 days of receipt in Cleveland Clinic Laboratories (Microbiology). Clinical Information: This multiplex assay has been designed to aid in diagnosis of viral infections in cutaneous and mucocutaneous active lesions obtained from symptomatic patients. The FDA approved assay will differentiate Herpes Simplex Virus types 1 and 2 plus Varicella-Zoster Virus. Negative results do not preclude infection with one of these three viruses and should not be used as the sole basis for diagnosis, treatment or other management decisions. This assay is not intended for use in prenatal screening. Specimen Requirement: Swab(s) in Universal Transport Media (UTM); Only swabs collected from active cutaneous lesions (vesicles of any skin site) and mucocutaneous lesions are acceptable and include the following specimen sources: genital (penis or vaginal/cervical), skin, nares, ocular and oral lesions; The following specimen sources are not validated and could be sent out for testing if desired: plasma, serum, amniotic fluid, BAL, and tissue; Refer to test code PCRHSV (HSV PCR, Miscellaneous Specimen Types); For cerebrospinal fluid (CSF) specimens, refer to test code HSPCRC (Herpes Simplex Virus by PCR on CSF); Transport at ambient temperature up to 30 °C for up to 48 hours; Transport on ice pack if warmer temperatures are to be expected; Ambient Stability: Ambient: 48 hours (Up to 30 °C) Refrigerated: 7 days (2–8 °C) Frozen: 7 days (Minus 20 °C) Methodology: Probe Amplification Reference Range: Herpes Simplex Virus Type 1, HDA: Negative Herpes Simplex Virus Type 2, HDA: Negative Varicella-Zoster Virus, HDA: Negative Days Performed: 7 days per week Reported: 0–3 days	4/5/18
HSV PCR, Miscellaneous Specimen Types	PCRHSV	Special Information: Specimen source is required. Heparinized specimens are unacceptable. This test is New York DOH approved. Clinical Information: Preferred test for detecting herpes simplex virus (HSV) infection in neonates or when rapid diagnostic test for suspected HSV infection is necessary. Specimen Requirement: 1 mL plasma from an EDTA (lavender) tube; Minimum: 0.5 mL; Separate plasma from cells and transfer into sterile aliquot tube; Specimen source required; Frozen *OR* 1 mL serum from a serum separator (gold) tube; Minimum: 0.5 mL; Separate serum from cells and transfer into sterile aliquot tube; Specimen source required; Frozen *OR* 1 mL amniotic fluid in a sterile container; Minimum: 0.5 mL; Specimen source required; Frozen *OR* 1 mL bronchoalveolar lavage (BAL) specimen in a sterile container; Minimum: 0.5 mL; Specimen source required; Frozen *OR* Tissue in a sterile container; Freeze immediately; Specimen source required; Frozen *OR* Tissue: Unacceptable; Plasma, serum, amniotic fluid, BAL, tissue: 8 hours Refrigerated: Tissue: Unacceptable; Plasma, serum, amniotic fluid, BAL, tissue: 72 hours Frozen: 3 months Methodology: Qualitative Polymerase Chain Reaction Days Performed: Sunday–Saturday Reported: 2–4 days CPT: 87529 x 1 Price: \$114.00 (non-discountable)	4/5/18

Test Name	Order Code	Change	Effective Date
Inhibin A (Dimer) and Inhibin B, Tumor Markers, Serum	INHABP	Special Information: Room temperature or plasma specimens will be rejected. Hemolyzed or lipemic samples are also unacceptable. Values obtained with different methodologies or kits cannot be used interchangeably. This test is New York DOH approved.	4/3/18
		Specimen Requirement: 2 mL serum from a serum separator (gold) tube; Minimum: 1 mL (Total minimum volume is 1 mL serum split into two 0.5 mL aliquots); THIS TEST REQUIRES TWO SPECIMEN TUBES; Patient Prep: Fasting is recommended, but not required; Split sample into two 1 mL serum aliquots and freeze; Frozen	
		Stability: Ambient: After separation from cells: Unacceptable Refrigerated: After separation from cells: 48 hours Frozen: After separation from cells: 1 month	
		Methodology: Enzyme-Linked Immunosorbent Assay (ELISA) Quantitative Chemiluminescent Immunoassay	
		Reference Range: Inhibin A Female Normal Cycling Early Follicular Phase (-14 to -10): 1.8–17.3 pg/mL Mid Follicular Phase (-9 to -4): 3.5–31.7 pg/mL Late Follicular Phase (-3 to -1): 9.8–90.3 pg/mL Mid Cycle (Day 0): 16.9–91.8 pg/mL Early Luteal (1 to 3): 16.1–97.5 pg/mL Mid Luteal (4 to 11): 3.9–87.7 pg/mL Late Luteal (12 to 14): 2.7–47.1 pg/mL IVF-Peak Levels: 354.2–1690.0 pg/mL PCOS-Ovulatory: 5.7–16.0 pg/mL Postmenopausal: < 6.9 pg/mL Male (Normal): < 2.1 pg/mL Inhibin B Female 0–6 Years: < 73 pg/mL 11–12 Years: < 186 pg/mL 13–18 Years: < 360 pg/mL Pre-menopausal: < 290 pg/mL	
		Follicular phase: 10–290 pg/mL Post-menopausal: ≤ 16 pg/mL Male 0-6 Years: 40–630 pg/mL 7-10 Years: 35-170 pg/mL 11-18 Years: 50–475 pg/mL 19–45 Years: 40–450 pg/mL 46 Years and older: < 200 pg/mL	
		Days Performed: Refer to individual components	
		Reported: Refer to individual components CPT: 83520 x 1, 86336 x 1	
		Price: \$186.00 (non-discountable)	

Test Name	Order Code	Change	Effective Date
Lung Cancer Hotspot Gene Panel	LNG550	Specimen Requirement: 10 mm square formalin-fixed paraffin-embedded (FFPE) tissue block; Formalin-fixed paraffin-embedded tissue slides; Transport and store slides at ambient temperature; 10 sections FFPE tissue on charged, unbaked slides plus one H&E stained section with best tumor area circled by a pathologist; Provide the percentage of tumor cells present; Ambient *OR* 10 mm square formalin-fixed paraffin-embedded (FFPE) tissue block; Cell block specimens; Formalin-fixed paraffin-embedded tissue slides; Transport and store slides at ambient temperature; 10 sections FFPE tissue on charged, unbaked slides plus one H&E stained section with best tumor area circled by a pathologist; Provide the percentage of tumor cells present; Ambient *OR* 3–5 mL fine needle aspirate (FNA) in CytoLyt solution; FNA specimens are preserved in CytoLyt solution and should be stored at 4 °C until DNA extraction can be performed; Transport to lab at ambient temperature is acceptable; Provide the percentage of tumor cells present; Ambient Stability: Ambient: Indefinitely for FFPE slides; FFPE slides and FNA can be transported at ambient temperature Refrigerated: 2 weeks for FNA samples Frozen: Unacceptable Methodology: Next Generation DNA Sequencing Days Performed: Twice per week	Effective immediately
		Reported: 10–14 days	
		CPT: 81445 x 1, G0452 x 1	
		Price: \$1739.00 (non-discountable)	
LYME AB Early Disease (≤ 30 days of signs and symptoms), with Reflex	LMERLY	Clinical Limitation: Grossly hemolyzed, icteric or lipemic samples as well as samples containing particulate matter or exhibiting obvious microbial contamination should not be tested. The results are not by themselves diagnostic and should be considered in association with the second step Western Blot and other clinical data and symptoms. This assay should not be used for general population screening. It should be used only for patients with signs and symptoms consistent with Lyme disease. Potential assay interference due to circulating antibodies against Human Ehrlichiosis and Tick Borne Relapsing Fever has been found.	4/3/18
		Clinical Information: Qualitative test for the presence of IgG and IgM antibodies to Borrelia burgdorferi, the causative agent of Lyme disease. Positive or equivocal results will automatically reflex to an IgG and IgM Western Blot for confirmation and will be billed accordingly.	
		Specimen Requirement: 0.5 mL serum from a serum separator (gold) tube; Minimum: 0.4 mL; Refrigerated	
		Stability: Ambient: 48 hours Refrigerated: 5 days Frozen: 15 days at minus 20 °C or below (Avoid multiple freeze/thaw cycles)	
		Methodology: Chemiluminescence Immunoassay (CLIA)	
		Reference Range: Negative	
		Days Performed: Monday–Saturday	
		Reported: 1–2 days	
		CPT: 86618 x 1	
		Price: \$87.00 (non-discountable)	

Test Name	Order Code	Change	Effective Date
LYME AB Late Disease (> 30 days of signs or symptoms), with Reflex	LMLATE	Clinical Limitation: Grossly hemolyzed, icteric or lipemic samples as well as samples containing particulate matter or exhibiting obvious microbial contamination should not be tested. The results are not by themselves diagnostic and should be considered in association with the second step Western Blot and other clinical data and symptoms. This assay should not be used for general population screening. It should be used only for patients with signs and symptoms consistent with Lyme disease. Potential assay interference due to circulating antibodies against Human Ehrlichiosis and Tick Borne Relapsing Fever has been found. Clinical Information: Qualitative test for the presence of IgG and IgM antibodies to Borrelia burgdorferi, the causative agent of Lyme disease. Positive or equivocal results will automatically reflex to IgG Western Blot for confirmation and be billed accordingly. Specimen Requirement: 0.5 mL serum from a serum separator (gold) tube; Minimum: 0.4 mL; Refrigerated Stability: Ambient: 48 hours Refrigerated: 5 days Frozen: 15 days at minus 20 °C or below (Avoid multiple freeze/thaw cycles) Methodology: Chemiluminescence Immunoassay (CLIA) Reference Range: Negative Days Performed: Monday–Saturday Reported: 1–2 days CPT: 86618 x 1 Price: \$87.00 (non-discountable)	4/3/18
Myelin Oligodendrocyte Glycoprotein (MOG- IgG1) Fluorescence- Activated Cell Sorting (FACS) Assay, Serum	MOGFAC	Special Information: Patient Prep: For optimal antibody detection, the recommendation is to draw the specimen before initiation of immunosuppressant medication. The reflex titer test will be performed at an additional charge when the results of this assay require further evaluation. Grossly hemolyzed, grossly lipemic and grossly icteric specimens will be rejected. Clinical Information: Useful for diagnosis of inflammatory demyelinating diseases (IDD) with similar phenotype to neuromyelitis optica spectrum disorder (NMOSD), including optic neuritis (single or bilateral) and transverse myelitis. Diagnosis of autoimmune myelin oligodendrocyte glycoprotein (MOG)-opathy. Diagnosis of neuromyelitis optica (NMO). Distinguishing NMOSD, acute disseminated encephalomyelitis (ADEM), optic neuritis, and transverse myelitis from multiple sclerosis (MS) early in the course of disease. Diagnosis of ADEM. Prediction of a relapsing disease course. A positive value for myelin oligodendrocyte glycoprotein (MOG)-IgG is consistent with a neuromyelitis optica (NMO)-like phenotype, and in the setting of acute disseminated encephalomyelitis (ADEM), optic neuritis and transverse myelitis indicates an autoimmune oligodendrogliopathy with potential for relapsing course. Identification of MOG-IgG allows distinction from MS and may justify initiation of appropriate immunosuppressive therapy (not MS disease-modifying agents) at the earliest possible time. This allows early initiation and maintenance of optimal therapy. Recommend follow-up in 3 to 6 months as persistence of MOG-IgG seropositivity predicts a relapsing course. This autoantibody is not found in healthy subjects. Note of caution: (MOG)-IgG, specifically MOG-IgG1, may drop below detectable levels in setting of therapies for acute attack (IV methylprednisolone or plasmapheresis) or attack prevention (immunosuppressants). Specimen Requirement: 2 mL serum from a plain no additive (red) tube; Minimum: 1 mL; Patient Prep: Recommend drawing the specimen before initiation of immunosup	3/13/18

Test Name	Order Code	Change	Effective Date
Myelin Oligodendrocyte Glycoprotein (MOG- IgG1) Fluorescence- Activated Cell Sorting (FACS) Assay, Serum (continued from page 22)		Methodology: Fluorescent Activated Cell Sorting Assay (FACS) Reference Range: Negative Days Performed: Monday, Tuesday, Thursday Reported: 6–9 days CPT: 86255 x 1 Price: \$595.00 (non-discountable)	
Streptococcal Antibody Panel	ASODNA	Special Information: Plasma or severely hemolyzed specimens are unacceptable. Specimen Requirement: 2 mL serum from a serum separator (gold) tube; Minimum: 1 mL (Total minimum volume is 1 mL serum split into two 0.5 mL aliquots); THIS TEST REQUIRES TWO SPECIMEN TUBES; Separate from cells ASAP or within 2 hours of collection; Split sample into two 1 mL serum aliquots; Refrigerated Stability: Ambient: After separation from cells: 2 days Refrigerated: After separation from cells: 8 days Frozen: After separation from cells: 6 months Methodology: Immunoturbidimetric Assay Quantitative Nephelometry Reference Range: Anti-Streptolysin 0 0-17 Years: < 151 IU/mL 18-99 Years: < 201 IU/mL DNAse B Ab 0-6 Years: < 250 U/mL 7-17 Years: < 310 U/mL 18-99 Years: < 260 U/mL Days Performed: Refer to individual components Reported: Refer to individual components CPT: 86060 x 1, 86215 x 1 Price: \$77.00	4/17/18
Vitamin B12 w/reflex	B12RFX	Special Information: A fasting sample is preferred but not required. 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. Clinical Information: Vitamin B12 (cobalamin) is important for maintaining metabolism, brain and nervous system functions, and the formation of red blood cells. Vitamin B12 is not produced by the human body, so it must be obtained through eating animal proteins such as meat, dairy, or eggs. Although the body can store sufficient vitamin B12 reserves for 2 to 5 years, deficiency can develop due to extended nutritional insufficiency among strict vegetarians, vegans, or elderly patients with limited diets. Vitamin B12 deficiency is also caused by malaborption issues such as pernicious anemia or underlying disorders or damage to the stomach, small bowel, or pancreas. Testing for vitamin B12 is performed to detect deficiency and monitor vitamin B12 therapy. Symptoms of vitamin B12 deficiency include macrocytic megaloblastic anemia, peripheral neuropathy, glossitis, hyperreflexia, ataxia, poor coordination, deficient proprioception, affective behavioral disorder, weakness, and fatigue. Some patients may show the neurological behavioral disorder, weakness, and fatigue. Some patients may show the neurological behavioral disorder, weakness, and fatigue. Some patients may show the neurological behavioral disorder median to 150 pg/mL, but less than or equal to 400 pg/mL, methylmalonic acid (MMA) and homocysteine (HOMCYS) will be performed and billed. Specimen Requirement: 3 mL serum from a serum separator (gold) tube; Minimum: 2 mL; Separate serum from cells within 6 hours of draw and aliquot into CCL aliquot tube; Frozen Stability: Ambient: 24 hours Frozen: 7 days	3/1/18

Test Name	Order Code	Change	Effective Date
Vitamin B12 w/reflex (continued from page 23)		Methodology: Electro Chemiluminescence Immunoassay (ECLIA) Reference Range: 232–1245 pg/mL Days Performed: Sunday–Saturday Reported: 8 hours CPT: 82607 x 1 Price: \$62.00	
West Nile Virus by PCR	WNVPCR	Special Information: Must indicate specimen source. Heparinized specimens are unacceptable. This test is New York DOH approved.	4/12/18
		Clinical Information: Used to confirm positive West Nile antibodies test or clarify equivocal serologic test results.	
		Specimen Requirement: 1 mL plasma from an EDTA (lavender) tube; Minimum: 0.5 mL; Separate plasma from cells, transfer to sterile aliquot tube and freeze; Specimen source required; Frozen	
		OR 1 mL serum from a serum separator (gold) tube; Minimum: 0.5 mL; Separate serum from cells, transfer to sterile aliquot tube and freeze; Specimen source required; Frozen	
		OR 1 mL cerebrospinal fluid (CSF) in a sterile container; Minimum: 0.5 mL; Specimen source required; Frozen	
		Stability: Ambient: 8 hours Refrigerated: 24 hours Frozen: 3 months	
		Methodology: Qualitative Polymerase Chain Reaction	
		Days Performed: Monday–Friday	
		Reported: 2–5 days	
		CPT: 87798 x 1	
		Price: \$136.00 (non-discountable)	

Fee Reductions

Test Name	Order Code	List Fee	CPT Code	Effective Date
Homocysteine	HOMCYS	\$82.00	83090	3/29/18

Discontinued Tests

Test Name	Order Code	Test Information	Effective Date
ACTH Stimulation Test for 21-Hydroxylase	AS21	This test will no longer be available. Suggest ordering 17-Hydroxyprogesterone Quantitative by HPLC-MS/MS, Timed Study (HPROGT) and ACTH Stimulation, 2 Time Points (ACTHS2).	4/5/18
ADmark ApoE Genotype (Symptomatic)	APOALZ	This test will no longer be available. Suggest ordering Apolipoprotein E (APOE) Genotyping, Alzheimer Disease Risk (ALZHEI).	4/10/18
Anti IgE Receptor Antibody	ANTIE	This test will no longer be available. Suggest ordering Urticaria-Induced Basophil Activation (UTBAS).	Effective immediately
Cimetidine	CIMET	This test will no longer be available.	2/20/18
Dexamethasone Suppression 48-Hour	DXSUPP	This test will no longer be available.	4/3/18
Herpes Simplex 1 & 2, Qt PCR, BAL	HSVBAL	This test will no longer be available. Suggest ordering HSV PCR, Miscellaneous Specimen Types (PCRHSV).	4/5/18
Herpes Simplex Ag Detection	DHSV	This test will no longer be available. Suggest ordering HSV 1 $\&$ 2 / VZV Amplification-Herpes Simplex Virus and Varicella-Zoster Virus, Molecular Detection (HSVVZV).	4/5/18
Herpes Simplex by PCR	HSPCR	This test will no longer be available. Suggest ordering HSV PCR, Miscellaneous Specimen Types (PCRHSV).	4/5/18
Herpes Simplex Culture	VHSV	This test will no longer be available. Suggest ordering HSV 1 $\&$ 2 / VZV Amplification-Herpes Simplex Virus and Varicella-Zoster Virus, Molecular Detection (HSVVZV) or Herpes Simplex Virus Culture (HSVCUL).	4/5/18
Herpes Simplex Virus by PCR, Ocular Fluid	OCHSV	This test will no longer be available. Suggest ordering HSV 1 $\&$ 2 / VZV Amplification-Herpes Simplex Virus and Varicella-Zoster Virus, Molecular Detection (HSVVZV).	4/5/18
Homocysteine, Plasma	HCYPL	This test will no longer be available. Suggest ordering Homocysteine (HOMCYS).	3/29/18
Inhibin A and B, Tumor Markers, Serum	INHAB	This test will no longer be available. Suggest ordering Inhibin A (Dimer) and Inhibin B, Tumor Markers, Serum (INHABP).	4/3/18
JC Virus DNA, PCR	JCPCR	This test will no longer be available. Suggest ordering JC Virus by PCR (JCPCRB).	4/5/18
LDLR Hypercholesterol- emia Sequencing	LDLR	This test will no longer be available.	2/26/18
Lyme Antibodies, IgG, IgM	LYMEGM	This test will no longer be available. Suggest ordering LYME AB Early Disease (\leq 30 days of signs and symptoms), with Reflex (LMERLY) or LYME AB Late Disease ($>$ 30 days of signs or symptoms), with Reflex (LMLATE).	4/3/18
Maprotiline	MAPRO	This test will no longer be available.	2/20/18
Meperidine & Normeperidine	MEPNO	This test will no longer be available.	2/20/18

Discontinued Tests (Cont.)

Test Name	Order Code	Test Information	Effective Date
Methsuximide/ Normethsuximide	METHSU	This test will no longer be available.	2/20/18
Poliovirus (Types 1,3) Antibodies, IFA	POLIO	This test will no longer be available. Suggest ordering Polio Neutralization (PNEUT).	4/19/18
ssDNA Antibody, IgG	SSDNA	This test will no longer be available. Suggest ordering alternative test "dsDNA: DNA Antibody with Confirmation (test code DNA)."	2/20/18
Streptococcal Antibodies Panel	STRAB	This test will no longer be available. Suggest ordering Streptococcal Antibody Panel (ASODNA).	4/17/18
Varicella-Zoster DFA	DVZV	This test will no longer be available. Suggest ordering HSV 1 $\&$ 2 / VZV Amplification-Herpes Simplex Virus and Varicella-Zoster Virus, Molecular Detection (HSVVZV).	4/5/18
West Nile Virus PCR Plasma	WNVPLS	This test will no longer be available. Suggest ordering West Nile Virus by PCR (WNVPCR).	4/12/18
West Nile Virus RNA, Qualitative, RT PCR	NILEPC	This test will no longer be available. Suggest ordering West Nile Virus by PCR (WNVPCR).	4/12/18