Cleveland Clinic

Cleveland Clinic Laboratories

Technical Update • September 2019

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

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

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

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

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	Aldolase										■	■	■	
8–9	Autoimmune Dysautonomia Evaluation, Serum			■										
4, 13	BCR/ABL1 p190 Quantitative PCR Blood												■	■
4, 13	BCR/ABL1 p190 Quantitative PCR Bone Marrow												■	■
4, 13	BCR/ABL1 p210 Quantitative PCR Blood												■	■
4, 13	BCR/ABL1 p210 Quantitative PCR Bone Marrow												■	■
13	CMV Culture					■								
9	Cytomegalovirus Rapid Culture			■										
13	DRPLA DNA Test					■								
13	Dystrophin					■								
10	Ehrlichia and Anaplasma Species by PCR			■										
13	FBN1 Gene Deletion/Duplication Analysis					■								
13	FISH for ALK (2p23) Translocation					■								
4	FISH for Cutaneous Melanoma											■		
4	HCG, Qualitative, Urine										■			
4	Helicobacter pylori Breath Test, Pediatric						■							
4	Hemoglobin Electrophoresis								■					
4	Hemoglobin Evaluation Cascade								■					
4	Hemoglobin S and F Monitoring								■					
13	HER2 FISH with D17S122 Reference Probe					■								
13	High Sensitivity Total Testosterone					■								
5	Lactate, Precipitated										■			
5	Lactate/Pyruvate										■			

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
5–6	Levetiracetam						■	■						
6	MALE OXIDATIVE STRESS INFERTILITY TEST		■											
6	Measles IgG Antibody					■								
6, 13	MSI (PCR) X 2												■	■
6, 13	MYD88 L265P Mutation Analysis												■	■
6, 13	NTRK Plus Gene Fusion NGS Panel												■	■
6–7	Paraneoplastic Autoantibody Evaluation, Serum					■		■	■				■	
13	RET Sequencing and Deletion/Duplication				■									
7	Sm/RNP Antibody					■					■			
13	Testosterone, Free and Total				■									
10–12	Testosterone, Total and Free, Serum			■										
7	TSH									■				
7	West Nile Virus Antibody Panel CSF							■						

FISH TESTING UPDATE

The following test changes and new tests were previously announced in the June *Technical Update* with an effective date of 8/6/19. Due to unforeseen circumstances, the effective date has been changed to TBD. We apologize for any inconvenience this may have caused.

TEST CHANGES

FISH for 5q Abnormalities Blood (5QFSH)

FISH for 7q Deletion Blood (FISH7Q)

FISH for 8;21 Translocation for AML Blood (AMLFSH)

FISH for 20q and CEP8 Blood (20Q8FH)

FISH for Acute Myeloid Leukemia Panel Blood (FAMLPN)

FISH for Aggressive B-Cell Lymphoma Blood (FABCFP)

FISH for BCL2 Blood (BCL2FH)

FISH for BCL6 Blood (BCL6FH)

FISH for B Lymphoblastic Leukemia Panel Blood (FSHBLL)

FISH for CBFB/MYH11 Blood (INV16F)

FISH for CCND1 Blood (CCND1F)

FISH for FGFR1 Blood (FGFR1F)

FISH for IgH/BCL2 Blood (FSHFCL)

FISH for IgH/CCND1 Blood (FSHMCL)

FISH for IGH/MYC Blood (814FSH)

FISH for MLL Blood (MLLFSH)

FISH for MYC (8q24) Blood (MYCFSH)

FISH for Myelodysplasia Blood (FSHMDS)

FISH for Myeloproliferative Neoplasms Panel Blood (MPNFSH)

FISH for PDGFRA Blood (PDGFRA)

FISH for PDGFRB Rearrangement Blood (PDGFRB)

FISH for PML/RARA Blood (APLFSH)

FISH for RARA Blood (RARFSH)

FISH for t(12;21)(p13;q22) Blood (1221FH)

FISH for Trisomy 4 and 10 Blood (FHT410)

NEW TESTS

FISH for 5q Abnormalities Bone Marrow (5QFSBM)

FISH for 7q Deletion Bone Marrow (FSH7QM)

FISH for 8;21 Translocation for AML Bone Marrow (AMLFBM)

FISH for 20q and CEP8 Bone Marrow (20Q8BM)

FISH for Acute Myeloid Leukemia Bone Marrow (FAMLPM)

FISH for Aggressive B-Cell Lymphoma Bone Marrow (FABCBM)

FISH for BCL2 Bone Marrow (BCL2FM)

FISH for BCL6 Bone Marrow (BCL6FM)

FISH for B Lymphoblastic Leukemia Panel Bone Marrow (FSBLLM)

FISH for CBFB/MYH11 Bone Marrow (INV16M)

FISH for CCND1 Bone Marrow (CCND1M)

FISH for FGFR1 Bone Marrow (FGFR1M)

FISH for IGH/BCL2 Bone Marrow (FSFCLM)

FISH for IGH/CCND1 Bone Marrow (FSMCLM)

FISH for IGH/MYC Bone Marrow (814FSM)

FISH for MLL Bone Marrow (MLLFBM)

FISH for MYC (8q24) Bone Marrow (MYCFSM)

FISH for Myelodysplasia Bone Marrow (FSMDSM)

FISH for Myeloproliferative Neoplasm Panel Bone Marrow (MPNFSM)

FISH for PDGFRA Bone Marrow (PGFRAM)

FISH for PDGFRB Rearrangement Bone Marrow (PDGFBM)

FISH for PML/RARA Bone Marrow (APLFBM)

FISH for RARA Bone Marrow (RARFSM)

FISH for t(12;21)(p13;q22) Bone Marrow (1221FM)

FISH for Trisomy 4 and 10 Bone Marrow (FT410M)

Test Changes

Test Name	Order Code	Change	Effective Date
Aldolase	ALD	**Stability:** Ambient: **3 days** Refrigerated: 5 days Frozen: 6 months **Reference Range:** 0–30 Days: 6.0–32.0 U/L 1 Month–**16 Years: 3.0–12.0 U/L** **17–99 Years: 1.5–8.1 U/L** **Days Performed: Monday–Friday, excluding major holidays** **Reported:** 1–2 days	10/29/19
BCR/ABL1 p190 Quantitative PCR Blood	P190PB	**CPT:** 81207 x 1	10/31/19
BCR/ABL1 p190 Quantitative PCR Bone Marrow	P190BM	**CPT:** 81207 x 1	10/31/19
BCR/ABL1 p210 Quantitative PCR Blood	P210PB	**CPT:** 81206 x 1	10/31/19
BCR/ABL1 p210 Quantitative PCR Bone Marrow	P210BM	**CPT:** 81206 x 1	10/31/19
FISH for Cutaneous Melanoma	CMFISH	**Days Performed: 5** days per week **Reported: 6** days	9/10/19
HCG, Qualitative, Urine	UHCG	**Reference Range:** 0–99 Years: Negative	10/29/19
Helicobacter pylori Breath Test, Pediatric	HPYBRP	**Note:** *Breath Test for H pylori, Pediatric (3 to 17 years) and H pylori Breath Test, Pediatric (3 to 17 years) will be added as alias names. The alias names Breath Test for H pylori, Pediatric (< 18 years of age) and H pylori Breath Test, Pediatric (< 18 years of age) will be removed.* **Special Information: Performance characteristics** have not been assessed in children below the age of three. Collection of breath samples should be performed by trained healthcare personnel only. Gender, age, height and weight are required. Pregnancy/Lactation: The safety of the BreathTek UBT kit during pregnancy and lactation is not established. If particulate matter is visible in the reconstituted Pranactin-Citric solution after thorough mixing, the solution should not be used. Fast at least 1 hour prior to administering the BreathTek UBT. Patient should not have taken antibiotics, proton pump inhibitors or bismuth preparations within 2 weeks prior to administrating the BreathTek UBT. The effect of histamine receptor type 2 **(H2)** antagonists may reduce urease activity on urea breath tests. They may be discontinued for 24–48 hours before the BreathTek UBT. Do not use any straw other than the straw provided in the kit. If repeat testing is needed, BreathTek UBT can be administered the following day. Additional kits can be obtained by contacting Cleveland Clinic Laboratories at 800.628.6816. **Clinical Information: Urea Breath Test is used as an aid in diagnosis of current infection with Helicobacter pylori. False positive results may occur in infection with Helicobacter heilmannii or contamination with other urease-producing bacteria during specimen collection. False negative results may be seen in patients with hypochlorhydria. Clinical correlation is required.**	9/4/19
Hemoglobin Electrophoresis	HBELSA	**For Interfaced Clients Only: Test build may need to be modified**	10/29/19
Hemoglobin Evaluation Cascade	HBEVAL	**For Interfaced Clients Only: Test build may need to be modified**	10/29/19
Hemoglobin S and F Monitoring	HBSFMO	**For Interfaced Clients Only: Test build may need to be modified**	10/29/19

Test Changes (Cont.)

Test Name	Order Code	Change	Effective Date
Lactate, Precipitated	LACPRE	**Reference Range:** 0–90 Days: 1.0–3.5 mmol/L 3–24 Months: 1.0–3.3 mmol/L 2–17 Years: 1.0–2.4 mmol/L 18–99 Years: 0.5–2.2 mmol/L **Urgent Range:** 0–99 Years: **> 4.0 mmol/L**	10/29/19
Lactate/Pyruvate	LACPYR	**Reference Range:** Lactate 0–90 Days: 1.0–3.5 mmol/L 3–24 Months: 1.0–3.3 mmol/L 2–17 Years: 1.0–2.4 mmol/L 18–99 Years: 0.5–2.2 mmol/L Pyruvate 0–99 Years: 0.03–0.08 mmol/L **Urgent Range:** Lactate 0–99 Years: **> 4.0 mmol/L**	10/29/19
Levetiracetam	LEVET	**Special Information:** Collect specimen immediately prior to next dose. Remove plasma/serum from whole blood as soon as possible, preferably within 1 hour after collection. Hydrolysis of levetiracetam may occur in the presence of whole blood. **Levetiracetam samples that are not separated from red cells within 48 hours of collection or hemolyzed samples not analyzed within 48 hours are rejected and credited.** This test is not suitable for patients receiving treatment with the drug brivaracetam (Briviact). The drug causes an interference that may lead to falsely elevated levetiracetam results. Brivaracetam (Briviact) interferes with measurements of levetiracetam (Keppra) in the levetiracetam assay. Patients undergoing a switch in drug therapy involving Keppra and Briviact should not be monitored for levetiracetam using the assay. Brivaracetam is a chemical analog of levetiracetam. They are structurally similar and thus immunochemical crossreactivity is possible. The circulating half-life of each drug is approximately 8 to 9 hours. Sufficient time should be allowed for clearance prior to using the Levetiracetam Assay. Please contact Cleveland Clinic Laboratories at 800.628.6816 for suitable testing. **Specimen Requirement:** 1 mL serum from a plain no additive (red) tube; Minimum: 0.5 mL; Do not use tubes containing cell separator gel; Centrifuge and transfer serum to a clean, tightly sealed tube **as soon as possible after collection; Refrigerate sample for transport;** Refrigerated *OR* 1 mL plasma from an EDTA (navy blue) tube; Minimum: 0.5 mL; Do not use tubes containing cell separator gel; Centrifuge and transfer plasma to a clean, tightly sealed tube **as soon as possible after collection; Refrigerate sample for transport;** Refrigerated *OR* 1 mL plasma from a plain no additive (navy blue) tube; Minimum: 0.5 mL; Do not use tubes containing cell separator gel; Centrifuge and transfer plasma to a clean, tightly sealed tube **as soon as possible after collection; Refrigerate sample for transport;** Refrigerated *OR* 1 mL plasma from an EDTA (pink) tube; Minimum: 0.5 mL; Do not use tubes containing cell separator gel; Centrifuge and transfer plasma to a clean, tightly sealed tube **as soon as possible after collection; Refrigerate sample for transport;** Refrigerated *OR* 1 mL plasma from a sodium heparin (navy) tube; Minimum: 0.5 mL; Do not use tubes containing cell separator gel; Centrifuge and transfer plasma to a clean, tightly sealed tube **as soon as possible after collection; Refrigerate sample for transport;** Refrigerated *OR* 1 mL plasma from an EDTA (royal blue) tube; Minimum: 0.5 mL; Do not use tubes containing cell separator gel; Centrifuge and transfer plasma to a clean, tightly sealed tube **as soon as possible after collection; Refrigerate sample for transport;** Refrigerated *(continued on page 6)*	11/3/19

Test Changes (Cont.)

Test Name	Order Code	Change	Effective Date
Levetiracetam *(continued from page 5)*		*OR* 1 mL plasma from a sodium or lithium heparin (green) tube; Minimum: 0.5 mL; Do not use tubes containing cell separator gel; Centrifuge and transfer plasma to a clean, tightly sealed tube **as soon as possible after collection; Refrigerate sample for transport;** Refrigerated *OR* 1 mL plasma from an EDTA (lavender) tube; Minimum: 0.5 mL; Do not use tubes containing cell separator gel; Centrifuge and transfer plasma to a clean, tightly sealed tube **as soon as possible after collection; Refrigerate sample for transport;** Refrigerated	
MALE OXIDATIVE STRESS INFERTILITY TEST	ORP	**Test Name:** Previously Oxidation and Reduction Potential	9/5/19
Measles IgG Antibody	MEASLG	**Clinical Limitation:** Bacterial contamination or heat inactivation of the specimens may affect the test result. **Clinical Information: The test may be used for determination of immune status, response to Measles vaccine, or confirmation of positive Measles IgM result post infection. This test does not detect neutralizing antibodies, and some individuals with past history of Measles vaccination may test negative using this test. It is typically used as a surrogate of immunity virus.** **Note:** *Interpretation of AU/mL values will be as follows: Negative < 13.5 AU/mL; Equivocal ≥ 13.5 AU/mL and < 16.5 AU/mL; Positive ≥ 16.5 AU/mL*	10/29/19
MSI (PCR) X 2	MSICCT	**CPT:** 81301 x 1	9/3/19
MYD88 L265P Mutation Analysis	MYD88	**CPT:** 81305 x 1	10/31/19
NTRK Plus Gene Fusion NGS Panel		**CPT:** 81445 x 1	9/3/19
Paraneoplastic Autoantibody Evaluation, Serum	PARNEO	**For Interfaced Clients Only: Test build may need to be modified** **Includes:** AChR Ganglionic Neuronal Ab Anti-neuronal Nuclear Ab, Type 1, 2, & 3 Purkinje Cell Cytoplasmic Ab Type 1, 2, & Tr Amphiphysin Ab CRMP-5-IgG Striational (Striated muscle) Ab Calcium Channel Bind Ab, P/Q Type and N-Type Anti-Glial Nuclear Ab, Type 1 Neuronal (V-G) K+ Channel Ab **Special Information:** Reflex Algorithm: If IFA (ANN1S, ANN2S, ANN3S, PCABP, PCAB2, PCATR, AMPHS, CRMS, AGN1S) patterns are indeterminate, paraneoplastic autoantibody Western blot is performed at an additional charge. If client requests or if IFA patterns suggest CRMP-5-IgG, CRMP-5-IgG Western blot is performed at an additional charge. If IFA patterns suggest amphiphysin antibody, amphiphysin Western blot is performed at an additional charge. If IFA patterns suggest GAD65 antibody, GAD65 antibody radioimmunoassay is performed at an additional charge. If IFA pattern suggests NMDA-R, NMDA-R Ab CBA and/or NMDA-R Ab IF Titer Assay is performed at an additional charge. If IFA pattern suggests AMPA-R, AMPA-R Ab CBA and/or AMPA-R Ab IF Titer Assay is performed at an additional charge. If IFA pattern suggests GABA-B-R, GABA-B-R Ab CBA and/or GABA-B-R Ab IF Titer Assay is performed at an additional charge. **If IFA pattern suggests DPPX, then DPPX antibody CBA and DPPX antibody titer are performed at an additional charge. If IFA pattern suggests mGluR1, then mGluR1 antibody CBA and mGluR1 antibody titer are performed at an additional charge. If CRMP IFA is positive, then ACh receptor binding antibody, CRMP-5-IgG Western blot, and ACh receptor (muscle) modulating antibody will be performed at an additional charge. If striational striated muscle antibody is 1:7,680 or greater, then ACh receptor binding antibody, CRMP-5-IgG Western blot, and ACh receptor (muscle) modulating antibody will be performed at an additional charge.** *(continued on page 7)*	9/5/19

Test Changes (Cont.)

Test Name	Order Code	Change	Effective Date
Paraneoplastic Autoantibody Evaluation, Serum *(continued from page 6)*		CRMP-5-IgG Western blot is also performed by specific request for more sensitive detection of CRMP-5-IgG. Testing should be requested in cases of subacute basal ganglionic disorders (chorea, Parkinsonism), cranial neuropathies (especially loss of vision, taste, or smell) and myelopathies. If VGKC > 0.00, LGI1-IgG CBA, S (Leucine-Rich Glioma Inactivated Protein-1 IgG, Serum) and CASPR2-IgG CBA, S (Contactin-Associated Protein-Like-2-IgG, Serum) are performed at an additional charge. **Provide relevant clinical information and name, phone number, mailing address, and email address of ordering provider. Patient Prep: For optimal antibody detection, it is recommended to collect the specimen prior to initiation of immunosuppressant medication. This test should not be requested in patients who have recently received radioisotopes, therapeutically or diagnostically, because of potential assay interference. The specific waiting period before specimen collection will be dependent upon the isotope administered, the dose given, and the clearance rate in the individual patient. Specimens will be screened for radioactivity prior to analysis. Radioactive specimens received in the laboratory will be held for 1 week and assayed if sufficiently decayed, or canceled if radioactivity remains. Patient should have no general anesthetic or muscle-relaxant drugs in the previous 24 hours.** Causes for specimen rejection: Grossly hemolyzed, grossly lipemic, grossly icteric **Methodology:** Cell Binding Assay (CBA), if indicated Enzyme-**Linked Immunosorbent Assay (ELISA)** IFA Titer Assay (if indicated) Indirect Immunofluorescence Assay (IFA) Radioimmunoassay (RIA) Western Blot (WB), if indicated **CPT:** 83519 **x 4,** 83520 x 1, 86255 x 9	
Sm/RNP Antibody	NRNP	**Special Information: Grossly hemolyzed, grossly lipemic, or grossly icteric specimens will be rejected.** **Days Performed: Monday–Saturday** **Reported: 3**–5 days	9/9/19
TSH	TSH	**Reference Range:** 0–5 Days: 0.700–15.200 uU/mL 6–90 Days: 0.720–11.000 uU/mL 4–12 Months: 0.730–8.350 uU/mL 1–6 Years: 0.700–5.970 uU/mL 7–11 Years: 0.600–4.840 uU/mL 12–20 Years: 0.510–4.300 uU/mL 21–99 Years: **0.270–4.200 uU/mL** Pregnancy first trimester **(9–12 weeks): 0.180–2.900 uU/mL** Pregnancy second trimester: **0.110–3.980 uU/mL** Pregnancy third trimester: **0.480–4.710 uU/mL**	10/29/19
West Nile Virus Antibody Panel CSF	CNILE	**For Interfaced Clients Only: Test build may need to be modified**	10/29/19

New Tests

Test Name	Order Code	Change	Effective Date
Autoimmune Dysautonomia Evaluation, Serum	AIDYSA	**Includes:** ACh Receptor (Muscle) Binding Ab AChR Ganglionic Neuronal Ab ANNA-1 DPPX Ab IFA GAD65 Ab Assay Neuronal (V-G) K+ Channel Ab N-Type Calcium Channel Ab P/Q-Type Calcium Channel Ab Striational (Striated Muscle) Ab Dysautonomia, Interpretation **Special Information:** Reflex Algorithm: If indirect immunofluorescence assay (IFA) (ANN1S) patterns are indeterminate, then paraneoplastic autoantibody Western blot is performed at an additional charge. If IFA patterns suggest CRMP-5-IgG, then CRMS and/or CRMP-5-IgG Western blot is performed at an additional charge. If IFA patterns suggest amphiphysin antibody, then AMPHS and/or amphiphysin Western blot is performed at an additional charge. If IFA patterns suggest antineuronal nuclear antibody type 2 or type 3, Purkinje cell cytoplasmic antibody type 1, type 2, or type trace, and/or anti-glial nuclear antibody type 1, then ANN2S, ANN3S, PCABP, PCAB2, PCATR, and/or AGN1S is performed at an additional charge. If IFA pattern suggests NMDA-R, then NMDA-R cell-binding assay (CBA) and NMDA-R titer are performed at an additional charge. If IFA pattern suggests AMPA-R, then AMPA-R CBA and AMPA-R titer are performed at an additional charge. If IFA pattern suggests GABA-B-R, then GABA-B-R CBA and GABA-B-R titer are performed at an additional charge. If IFA pattern suggests DPPX antibody, then DPPX antibody CBA and DPPX titer are performed at an additional charge. If acetylcholine (ACh) receptor binding antibody is > 0.02, then ACh receptor modulating antibodies and CRMP-5-IgG Western blot are performed at an additional charge. If VGKC is above 0.00, LGI1-IgG CBA and CASPR2-IgG CBA are performed at an additional charge. Include ordering provider name, phone number, mailing address and email address. Also include relevant clinical information. Patient Prep: For optimal antibody detection, collection of specimen before initiation of immunosuppressant medication is recommended. This test should not be requested in patients who have recently received radioisotopes, therapeutically or diagnostically, because of potential assay interference. The specific waiting period before specimen collection will depend on the isotope administered, the dose given, and the clearance rate in the individual patient. Specimens will be screened for radioactivity prior to analysis. Radioactive specimens received in the laboratory will be held 1 week and assayed if sufficiently decayed, or canceled if radioactivity remains. Patient should have no general anesthetic or muscle-relaxant medications in the previous 24 hours. Grossly hemolyzed, grossly lipemic, or grossly icteric specimens will be rejected. **Clinical Information:** Investigation of idiopathic dysautonomic symptoms. In patients with idiopathic dysautonomia, directing a focused search for cancer. Investigation of autonomic symptoms that appear in the course or wake of cancer therapy and are not explainable by recurrent cancer or metastasis; detection of autoantibodies in this profile helps differentiate autoimmune dysautonomia from the effects of chemotherapy. Caution: Negative results do not exclude autoimmune dysautonomia or cancer. Note: CRMP-5 titers < 1:240 are detectable by recombinant CRMP-5 Western blot analysis, which can be done upon request on stored serum (held 4 weeks). This supplemental testing is recommended in cases of chorea, vision loss, cranial neuropathy, and myelopathy. **Specimen Requirement:** 4 mL serum from a plain no additive (red) tube; Minimum: 2.5 mL; Patient should have no general anesthetic or muscle-relaxant medications in the previous 24 hours; Specimen collection is recommended before initiation of immunosuppressant medication; This test should not be requested in patients who have recently received radioisotopes (refer to Special Information); Include ordering provider name, phone number, mailing address, and email address; Also provide relevant clinical information; Refrigerated *(continued on page 9)*	9/5/19

New Tests (Cont.)

Test Name	Order Code	Change	Effective Date
Autoimmune Dysautonomia Evaluation, Serum *(continued from page 8)*		*OR* 4 mL serum from a serum separator (gold) tube; Minimum: 2.5 mL; Patient should have no general anesthetic or muscle-relaxant medications in the previous 24 hours; Specimen collection is recommended before initiation of immunosuppressant medication; This test should not be requested in patients who have recently received radioisotopes (refer to Special Information); Include ordering provider name, phone number, mailing address, and email address; Also provide relevant clinical information; Refrigerated **Stability:** Ambient: 72 hours Refrigerated: 28 days (preferred) Frozen: 28 days **Methodology:** Cell Binding Assay (CBA), if indicated Cell-Based Assay Enzyme Immunoassay (EIA) Immunoprecipitation Indirect Immunofluorescence Assay (IFA) Radioimmunoassay (RIA) Western Blot (WB), if indicated **Days Performed:** Monday–Sunday **Reported:** 8–11 days **CPT:** 83519 x 5, 83520 x 1, 86255 x 2, 86341 x 1 **Price:** $490.00 (non-discountable)	
Cytomegalovirus Rapid Culture	CMVCUL	**Special Information:** Specimen source is preferred. Whole blood in viral transport media, cerebrospinal fluid (CSF), rectal swabs, or stool specimens are unacceptable. Calcium alginate, eSwab, dry, or wood swabs will be rejected. This test is New York DOH approved. **Clinical Information:** Useful as an aid in the diagnosis of active cytomegalovirus (CMV) infection. Molecular testing by polymerase chain reaction (PCR) is a more sensitive method for the detection of CMV viremia and central nervous system infections, especially in the immunocompromised patient. **Specimen Requirement:** 5 mL whole blood in an EDTA (lavender) tube; Minimum: 1 mL; Please indicate specimen source; Refrigerated *OR* 2 mL bronchoalveolar lavage (BAL) specimen in a sterile container; Minimum: 0.5 mL; It is also acceptable to transfer to viral transport media; Please indicate specimen source; Refrigerated *OR* One throat swab in viral transport media in an individually sealed bag; Please indicate specimen source; Refrigerated *OR* Tissue in viral transport media; Place specimen in an individually sealed bag; Please indicate specimen source; Refrigerated *OR* 2 mL random urine in a sterile container; Minimum: 0.5 mL; It is also acceptable to transfer to viral transport media; Please indicate specimen source; Refrigerated **Stability:** Ambient: 2 hours Refrigerated: 72 hours Frozen: Unacceptable **Methodology:** Cell culture Immunofluorescence **Reference Range:** Culture negative for CMV by early antigen test **Days Performed:** Sunday–Saturday **Reported:** 2–6 days **CPT:** 87254 x 1 **Price:** $87.00 (non-discountable)	10/29/19

New Tests (Cont.)

Test Name	Order Code	Change	Effective Date
Ehrlichia and Anaplasma Species by PCR	EHRANA	**Special Information:** Serum, plasma and heparinized specimens are unacceptable. This test is New York DOH approved. **Clinical Limitation:** This test detects and speciates Anaplasma phagocytophilum; Ehrlichia chaffeensis; E. ewingii/E. canis; E. muris-like. The nucleic acid detected from E. ewingii and E. canis cannot be differentiated by this test. A result of 'Detected' for E. ewingii/canis indicates the presence of either of these two organisms in the specimen. **Clinical Information:** This is the preferred panel for diagnosing possible tick-borne disease (i.e., Anaplasmosis or Ehrlichiosis) during the acute phase of the disease. A negative result does not rule out the presence of PCR inhibitors in the patient specimen or test-specific nucleic acid in concentrations below the level of detection by this test. **Specimen Requirement:** 1 mL whole blood in an EDTA (lavender) tube; Minimum: 0.6 mL; Refrigerated **Stability:** Ambient: 24 hours Refrigerated: 1 week Frozen: 1 week **Methodology:** Qualitative Polymerase Chain Reaction **Days Performed:** Sunday–Saturday **Reported:** 2–4 days **CPT:** 87798 x 1 **Price:** $208.00 (non-discountable)	9/10/19
Testosterone, Total and Free, Serum	TFTEST	**Includes:** Testosterone, Free Testosterone, Total **Special Information:** NOTE: Patient's age and sex are required. Serum gel tubes are NOT acceptable. Grossly hemolyzed specimens will be rejected. **Clinical Information:** Useful as a second-level test for suspected increases or decreases in physiologically active testosterone. Indications: Assessment of androgen status in cases with suspected or known sex hormone-binding globulin-binding abnormalities; assessment of functional circulating testosterone in early pubertal boys and older men; assessment of functional circulating testosterone in women with symptoms or signs of hyperandrogenism, but normal total testosterone levels; monitoring of testosterone therapy or antiandrogen therapy in older men and in females. Cautions: Early-morning testosterone levels in young male individuals are 50% higher than p.m. levels, on average. Reference ranges have been derived from a.m. specimens. Testosterone levels can fluctuate substantially between different days, and sometimes even more rapidly. Assessment of androgen status should be based on more than a single measurement. The low end of the normal reference range for total testosterone in prepubertal subjects is not yet established. While free testosterone can be used for the same indications as bioavailable testosterone, determination of bioavailable testosterone levels may be superior to free testosterone measurement in most situations. **Specimen Requirement:** 2.5 mL serum from a plain no additive (red) tube; Minimum: 1 mL; Do NOT draw serum gel tubes; Refrigerated **Stability:** Ambient: Unacceptable Refrigerated: 14 days Frozen: 60 days **Methodology:** Equilibrium Dialysis Liquid Chromatography-Tandem Mass Spectrometry (LC-MS/MS) *(continued on page 11)*	8/29/19

New Tests (Cont.)

Test Name	Order Code	Change	Effective Date
Testosterone, Total and Free, Serum *(continued from page 10)*		**Reference Range:** Testosterone, Free Male 1–15 Days: 0.20–3.10 ng/dL 16–364 Days: Values decrease gradually from newborn (0.20–3.10 ng/dL) to prepubertal levels. Citation: J Clin Endocrinol Metab 1973;36(6):1132-1142 1–8 Years: < 0.04–0.11 ng/dL 9 Years: < 0.04–0.45 ng/dL 10 Years: < 0.04–1.26 ng/dL 11 Years: < 0.04–5.52 ng/dL 12 Years: < 0.04–9.28 ng/dL 13 Years: < 0.04–12.6 ng/dL 14 Years: 0.48–15.3 ng/dL 15 Years: 1.62–17.7 ng/dL 16 Years: 2.93–19.5 ng/dL 17 Years: 4.28–20.9 ng/dL 18 Years: 5.40–21.8 ng/dL 19 Years: 5.36–21.2 ng/dL 20–24 Years: 5.25–20.7 ng/dL 25–29 Years: 5.05–19.8 ng/dL 30–34 Years: 4.85–19.0 ng/dL 35–39 Years: 4.65–18.1 ng/dL 40–44 Years: 4.46–17.1 ng/dL 45–49 Years: 4.26–16.4 ng/dL 50–54 Years: 4.06–15.6 ng/dL 55–59 Years: 3.87–14.7 ng/dL 60–64 Years: 3.67–13.9 ng/dL 65–69 Years: 3.47–13.0 ng/dL 70–74 Years: 3.28–12.2 ng/dL 75–79 Years: 3.08–11.3 ng/dL 80–84 Years: 2.88–10.5 ng/dL 85–89 Years: 2.69–9.61 ng/dL 90–94 Years: 2.49–8.76 ng/dL 95–100 Years: 2.29–7.91 ng/dL Female 1–15 Days: 0.06–0.25 ng/dL 16–364 Days: Values decrease gradually from newborn (0.06–0.25 ng/dL) to prepubertal levels. Citation: J Clin Endocrinol Metab 1973;36(6):1132-1142 1–4 Years: < 0.04 ng/dL 5 Years: < 0.04–0.07 ng/dL 6 Years: < 0.04–0.14 ng/dL 7 Years: < 0.04–0.23 ng/dL 8 Years: < 0.04–0.34 ng/dL 9 Years: < 0.04–0.46 ng/dL 10 Years: < 0.04–0.59 ng/dL 11 Years: < 0.04–0.72 ng/dL 12 Years: < 0.04–0.84 ng/dL 13 Years: < 0.04–0.96 ng/dL 14 Years: < 0.04–1.06 ng/dL 15–18 Years: < 0.04–1.09 ng/dL 19 Years: 0.06–1.08 ng/dL 20–24 Years: 0.06–1.08 ng/dL 25–29 Years: 0.06–1.06 ng/dL 30–34 Years: 0.06–1.03 ng/dL 35–39 Years: 0.06–1.00 ng/dL 40–44 Years: 0.06–0.98 ng/dL 45–49 Years: 0.06–0.95 ng/dL 50–54 Years: 0.06–0.92 ng/dL 55–59 Years: 0.06–0.90 ng/dL 60–64 Years: 0.06–0.87 ng/dL 65–69 Years: 0.06–0.84 ng/dL 70–74 Years: 0.06–0.82 ng/dL 75–79 Years: 0.06–0.79 ng/dL *(continued on page 12)*	

New Tests (Cont.)

Test Name	Order Code	Change	Effective Date
Testosterone, Total and Free, Serum *(continued from page 11)*		80–84 Years: 0.06–0.76 ng/dL 85–89 Years: 0.06–0.73 ng/dL 90–94 Years: 0.06–0.71 ng/dL 95–100 Years: 0.06–0.68 ng/dL Testosterone, Total Male 0–5 Months: 75–400 ng/dL 6 Months–9 Years: < 7–20 ng/dL 10–11 Years: < 7–130 ng/dL 12–13 Years: < 7–800 ng/dL 14 Years: < 7–1200 ng/dL 15–16 Years: 100–1200 ng/dL 17–18 Years: 300–1200 ng/dL 19–99 Years: 240–950 ng/dL Tanner Stage I (prepubertal): < 7–20 ng/dL Tanner Stage II: 8–66 ng/dL Tanner Stage III: 26–800 ng/dL Tanner Stage IV: 85–1200 ng/dL Tanner Stage V (young adult): 300–950 ng/dL Female 0–5 Months: 20–80 ng/dL 6 Months–9 Years: < 7–20 ng/dL 10–11 Years: < 7–44 ng/dL 12–16 Years: < 7–75 ng/dL 17–18 Years: 20–75 ng/dL 19–99 Years: 8–60 ng/dL Tanner Stage I (prepubertal): < 7–20 ng/dL Tanner Stage II: < 7–47 ng/dL Tanner Stage III: 17–75 ng/dL Tanner Stage IV: 20–75 ng/dL Tanner Stage V (young adult): 12–60 ng/dL Note: Puberty onset (transition from Tanner stage I to Tanner stage II) occurs for boys at a median age of 11.5 (+/- 2) years and for girls at a median age of 10.5 (+/-2) years. There is evidence that it may occur up to 1 year earlier in obese girls and in African American girls. For boys, there is no definite proven relationship between puberty onset and body weight or ethnic origin. Progression through Tanner stages is variable. Tanner stage V (young adult) should be reached by age 18. **Days Performed:** Monday–Sunday **Reported:** 4–6 days **CPT:** 84402 x 1, 84403 x 1 **Price:** $136.00 (non-discountable)	

Fee Reductions

Test Name	Order Code	List Fee	CPT Code	Effective Date
BCR/ABL1 p190 Quantitative PCR Blood	P190PB	$863.00 (non-discountable)	81207	10/31/19
BCR/ABL1 p190 Quantitative PCR Bone Marrow	P190BM	$863.00 (non-discountable)	81207	10/31/19
BCR/ABL1 p210 Quantitative PCR Blood	P210PB	$746.00 (non-discountable)	81206	10/31/19
BCR/ABL1 p210 Quantitative PCR Bone Marrow	P210BM	$1180.00 (non-discountable)	81206	10/31/19
MSI (PCR) X 2	MSICCT	$803.00 (non-discountable)	81301	9/3/19
MYD88 L265P Mutation Analysis	MYD88	$437.00 (non-discountable)	81305	10/31/19
NTRK Plus Gene Fusion NGS Panel		$1694.00 (non-discountable)	81445	9/3/19

Discontinued Tests

Test Name	Order Code	Test Information	Effective Date
CMV Culture	VCMV	This test will no longer be available. Suggest ordering Cytomegalovirus Rapid Culture (CMVCUL).	10/29/19
DRPLA DNA Test	DRPLA	This test will no longer be available.	11/5/19
Dystrophin	DYSTRO	This test will no longer be available.	11/5/19
FBN1 Gene Deletion/ Duplication Analysis	FBN1DD	This test will no longer be available.	11/5/19
FISH for ALK (2p23) Translocation	ALKFSH	This test will no longer be available.	11/4/19
HER2 FISH with D17S122 Reference Probe		This test will no longer be available.	11/4/19
High Sensitivity Total Testosterone	HSTSTO	This test will no longer be available.	Effective immediately
RET Sequencing and Deletion/Duplication	MEN2	This test will no longer be available.	10/29/19
Testosterone, Free and Total	FTESTO	This test will no longer be available. Suggest ordering Testosterone, Total and Free, Serum (TFTEST).	8/29/19