Cleveland Clinic

Cleveland Clinic Laboratories

Technical Update • September 2018

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

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

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

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

Test Update Page #	Summary of Changes by Test Name	Order Code	Name Change	New Test	Test Discontinued	Special Information	Specimen Requirement	Component Change(s)	Methodology	Reference Range	Days Performed/Reported	Stability	CPT	Fee
11	Acetylcholinesterase and Fetal Hemoglobin, Amniotic Fluid			■										
11	Acylcarnitines, Plasma w/ Basic Interpretation			■										
3, 16	Adrenal Antibody					■	■	■	■	■	■	■		■
3	AFP–Maternal						■							
3	Aminolevulinic Acid Dehydratase (ALAD), Whole Blood							■						
3	Apolipoprotein A-1 & B										■			
16	Calprotectin, Fecal													■
17	CDKL5-Related Atypical Rett Syndrome				■									
3	Chlamydia pneumoniae IgG, IgM, IgA Abs						■				■			
3	Chlamydia psittaci IgG, IgM, IgA Abs						■		■		■			
3–4	Chromosome Analysis, Chorionic Villus					■	■	■	■		■	■	■	
11	Circulating Tumor Cell Count			■										
17	Circulating Tumor Cells for Breast Cancer				■									
17	Circulating Tumor Cells for Prostate Cancer				■									
11–12	Copper, Liver			■										
17	Copper, Tissue				■									
16	Coxsackie A Abs													■
4, 16	Cyanide, Blood					■								■
12	Dihydropyrimidine Dehydrogenase (DPYD), 3 Variants			■										
4, 16	Diphtheria/Tetanus Antibody							■						■
17	DPD 5-FU GenotypR				■									

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
4–5	Drug Detection Panel, TOF-MS, Umbilical Cord Tissue									■				
13–14	Drug Detection Panel, Umbilical Cord Tissue, with Marijuana Metabolite			■										
17	EPM1 DNA Test				■									
17	Fatty Acid Profile, Comprehensive				■									
5	FISH for PML/RARA						■							
5, 16	Flow Cytometric Immunophenotyping for Leukemia/Lymphoma					■							■	■
17	GLUD1 (CH) DNA Sequencing Test				■									
5, 16	HPV DNA, High Risk, Anal-Rectal					■	■	■	■		■	■		■
6–8	Insulin Like Growth Factor 1					■				■		■		
17	IPF1 (MODY4) DNA Sequencing Test				■									
8	Kappa/Lambda Light Chains, Free with Ratio, Urine										■			
8	Kappa Light Chain, Free, Urine						■							
9	Lambda Light Chain, Free, Urine						■				■			
14	Leukemic Blood Cancer Chromosome Microarray + SNP			■										
14	Marijuana Metabolite, Umbilical Cord Tissue, Qualitative			■										
17	Molecular Detection of TSHR				■									
9, 16	Narcolepsy Associated Ag, HLA-DQB1 Typing					■	■	■	■		■	■	■	■
17	Niemann-Pick Disease Type A Mutation, Whole Blood				■									
14	Organic Acids Ur, Quant w/ Basic Interpretation			■										
16	Organic Acids Ur, Quant wo/ Interpretation													■
17	P53 Mutation Analysis				■									
14	Products of Conception Microarray + SNP			■										
17	Rickettsia Antibodies, IgG & IgM				■									
10, 16	Toxoplasma Antibody Evaluation, CSF					■	■	■	■	■	■	■		■
15	TP53 Somatic Mutation, Prognostic			■										
10	Trypsinogen					■								

Test Changes

Test Name	Order Code	Change	Effective Date
Adrenal Antibody	ADRENL	**For Interfaced Clients Only: Test build may need to be modified** **Special Information: If Adrenal Antibody screen is positive, Adrenal Antibody Titer will be performed at an additional cost.** **Clinical Information: Adrenal antibody is detected in patients with autoimmune adrenal disease** (e.g., Addison's disease). **Specimen Requirement: 2 mL** serum from a **plain no additive (red) tube;** Minimum: **0.5 mL; Do not use serum separator (gold) tubes; Send using cold packs;** Refrigerated **Stability:** Ambient: **48 hours** Refrigerated: **14 days** Frozen: **30 days** **Methodology:** Immunofluorescence **Reference Range: Negative (in normal individuals)** **Days Performed:** Wednesday, **Friday** **Reported: 3–8** days	9/10/18
AFP–Maternal	AFPMAT	**Specimen Requirement:** 2 mL serum from a serum separator (gold) tube; Minimum: 0.5 mL; **Specimen must be drawn between 15.0 weeks–21.6 weeks gestation;** Refrigerated	Effective immediately
Aminolevulinic Acid Dehydratase (ALAD), Whole Blood	ALADWB	**For Interfaced Clients Only: Test build may need to be modified**	Effective immediately
Apolipoprotein A-1 & B	APOAB	**Days Performed: Monday**–Saturday **Reported:** 1–**3 days**	9/24/18
Chlamydia pneumoniae IgG, IgM, IgA Abs	CHLPNE	**Specimen Requirement:** 1 mL serum from a serum separator (gold) tube; Minimum: 0.1 mL; **Transfer into plastic screw-cap vial; Ambient** *OR* 1 mL serum from a plain no additive (red) tube; Minimum: 0.1 mL; **Transfer into plastic screw-cap vial; Ambient** **Days Performed:** Monday–Saturday **Reported:** 2–**3** days	9/10/18
Chlamydia psittaci IgG, IgM, IgA Abs	CHLPSI	**Specimen Requirement:** 1 mL serum from a serum separator (gold) tube; Minimum: 0.1 mL; **Transfer into plastic screw-cap vial; Ambient** *OR* 1 mL serum from a plain no additive (red) tube; Minimum: 0.1 mL; **Transfer into plastic screw-cap vial; Ambient** **Methodology:** Immunofluorescence **Days Performed:** Monday–Saturday **Reported:** 2–**3** days	9/10/18
Chromosome Analysis, Chorionic Villus	CVCYTO	**For Interfaced Clients Only: Test build may need to be modified** **Includes:** **Chromosome Analysis, Chorionic Villus** **EER Chromosome Analysis Chorionic Villus** **Special Information: Frozen specimens or specimens preserved in formalin will be rejected. Thaw media prior to specimen collection. If cytogenetics tissue media is not available, collect in plain RPMI, Hanks solution, saline, or ringers. Please submit Patient History for Prenatal Cytogenetics form with specimen for proper interpretation of results. Counseling and informed consent are recommended for genetic testing. Note: These studies involve culturing of living cells; therefore, turnaround times given represent average times which are subject to multiple variables. After specimen receipt, results are generally available in an average of 12 days. A processing fee to cover sex confirmation and rule out maternal contamination by FISH is added to all Chromosome Analysis, Chorionic Villus Sampling (CVS) tests. An additional processing fee will be charged if this procedure is canceled at the client's request, after the test has been set up, or if the specimen integrity is inadequate to allow culture growth. This test is New York DOH approved.** *(continued on page 4)*	11/8/18

Test Changes (Cont.)

Test Name	Order Code	Change	Effective Date
Chromosome Analysis, Chorionic Villus *(continued from page 3)*		**Clinical Information: Order prenatal chromosome analysis on chorionic villi when individual:** **1) Is at increased risk for fetal aneuploidy based on maternal age, abnormal noninvasive prenatal testing (NIPT), abnormal multiple marker screening, or abnormal fetal ultrasound** **2) Has a family history of chromosome abnormality or genetic disorder** **3) Desires diagnostic testing instead of screening** **Specimen Requirement:** Chorionic villus **placed in a sterile, screw-top container filled with tissue culture transport medium (ARUP Supply #32788); Thaw media prior to collection; If cytogenetics tissue media is not available, collect in plain** RPMI, **Hanks solution, saline, or ringers; Please submit Patient History for Prenatal Cytogenetics form with specimen; Do NOT freeze; Do NOT place in formalin; MUST deliver specimen to Cleveland Clinic Laboratories on the day of collection; Ambient** **Stability:** Ambient: **48 hours** Refrigerated: **48 hours** Frozen: Unacceptable **Methodology: Giemsa-Band Analysis** **Days Performed: Sunday–Saturday** **Reported: 8–15** days **CPT:** 88235 x 1, 88267 x 1	
Cyanide, Blood	CYANID	**Note:** *Changes for this test were announced in the July Technical Update with a go-live date of 9/4/18. Due to unforeseen circumstances, changes for this test are effective immediately. We apologize for any inconvenience this may have caused.*	Effective immediately
Diphtheria/Tetanus Antibody	DIPTET	**For Interfaced Clients Only: Test build may need to be modified**	Effective immediately
Drug Detection Panel, TOF-MS, Umbilical Cord Tissue	DRGTOF	**Reference Range:** Buprenorphine: cutoff 1 ng/g Norbuprenorphine: cutoff 0.5 ng/g Buprenorphine-G: cutoff 1 ng/g Codeine: cutoff 0.5 ng/g Dihydrocodeine: cutoff 1 ng/g Fentanyl: cutoff 0.5 ng/g Hydrocodone: cutoff 0.5 ng/g Norhydrocodone: cutoff 1 ng/g Hydromorphone: cutoff 0.5 ng/g Meperidine: cutoff 2 ng/g Methadone: cutoff 2 ng/g EDDP: cutoff 1 ng/g 6-Acetylmorphine: cutoff 1 ng/g Morphine: cutoff 0.5 ng/g Naloxone: cutoff 1 ng/g Oxycodone: cutoff 0.5 ng/g Noroxycodone: cutoff 1 ng/g Oxymorphone: cutoff 0.5 ng/g Noroxymorphone: **cutoff 0.5 ng/g** Propoxyphene: cutoff 1 ng/g Tapentadol: cutoff 2 ng/g Tramadol: cutoff 2 ng/g N-desmethyltramadol: cutoff 2 ng/g O-desmethyltramadol: cutoff 2 ng/g Amphetamine: cutoff 5 ng/g Benzoylecgonine: cutoff 0.5 ng/g m-OH-Benzoylecgonine: cutoff 1 ng/g Cocaine: cutoff 0.5 ng/g Cocaethylene: cutoff 1 ng/g MDMA–Ecstasy: cutoff 5 ng/g *(continued on page 5)*	Effective immediately

Test Changes (Cont.)

Test Name	Order Code	Change	Effective Date
Drug Detection Panel, TOF-MS, Umbilical Cord Tissue *(continued from page 4)*		Methamphetamine: cutoff 5 ng/g Phentermine: cutoff 8 ng/g Alprazolam: cutoff 0.5 ng/g Alpha-OH-Alprazolam: cutoff 0.5 ng/g Butalbital: cutoff 25 ng/g Clonazepam: cutoff 1 ng/g Diazepam: cutoff 1 ng/g 7-Aminoclonazepam: cutoff 1 ng/g Lorazepam: cutoff 5 ng/g Midazolam: cutoff 1 ng/g Alpha-OH-Midazolam: cutoff 2 ng/g Nordiazepam: cutoff 1 ng/g Oxazepam: cutoff 2 ng/g Phenobarbital: cutoff 75 ng/g Temazepam: cutoff 1 ng/g Zolpidem: cutoff 0.5 ng/g Phencyclidine-PCP: cutoff 1 ng/g	
FISH for PML/RARA	APLFSH	**Specimen Requirement:** 8 mL whole blood in an EDTA (lavender) tube; Minimum: 2 mL; **Specimen must be received in Molecular FISH laboratory at Cleveland Clinic Laboratories prior to 9 a.m. EST (Monday–Friday) to receive result same day; Specimens received in Molecular FISH laboratory after 9 a.m. EST will receive result by end of next day;** Refrigerated *OR* 5 mL bone marrow in an EDTA (lavender) tube; Minimum: 2 mL; **Specimen must be received in Molecular FISH laboratory at Cleveland Clinic Laboratories prior to 9 a.m. EST (Monday–Friday) to receive result same day; Specimens received in Molecular FISH laboratory after 9 a.m. EST will receive result by end of next day;** Refrigerated	9/4/18
Flow Cytometric Immunophenotyping for Leukemia/ Lymphoma	RLLLIP	**Special Information:** Flow Cytometry will be performed using the following antibodies: CD3, CD4, CD5, CD8, CD13, CD16/56, CD19, CD34, CD45, KAPPA, LAMBDA. Based on review of the flow cytometry results, the following tests may be ordered and billed: Additional Flow Cytometry markers, Molecular and FISH assays. **Note: If 16 or more markers are interpreted, then CPT 88188 will change to 88189.** **CPT:** 88184 x 1, 88185 **x 10, 88188 x 1**	9/4/18
HPV DNA, High Risk, Anal-Rectal	HPVAR	**For Interfaced Clients Only: Test build may need to be modified** **Special Information: Specimens not in PreservCyt media will be rejected. Bloody or dark brown specimens are unacceptable. Must indicate specimen source. This test is New York DOH approved.** **Clinical Information: This test is FDA-approved for routine cervical cancer screening in combination with cervical cytology (Pap smear) for women 30 years or older. Used as a follow-up test for abnormal cytology results in women 21 years or older. This test amplifies DNA of 14 high-risk HPV types associated with cervical cancer and its precursor lesions (HPV types 16, 18, 31, 33, 35, 39, 45, 51, 52, 56, 58, 59, 66, and 68). Sensitivity may be affected by specimen collection methods, stage of infection, and the presence of interfering substances. Results should be interpreted in conjunction with other available laboratory and clinical data. A negative high-risk HPV result does not exclude the possibility of future cytologic high-grade squamous intraepithelial lesion (HSIL) or underlying CIN2-3 or cancer. This test is intended for medical purposes only and is not valid for the evaluation of suspected sexual abuse or for other forensic purposes. HPV testing should not be used for screening or management of atypical squamous cells of undetermined significance (ASCUS) in women under age 21.** **Specimen Requirement: Collect anal-rectal specimen using brush or spatula from ThinPrep kit and place in PreservCyt media; Transfer 3 mL into standard aliquot tube;** Minimum: **1.5 mL; Specimen source is required; Refrigerated** **Stability:** Ambient: **6 months** Refrigerated: **6 months** Frozen: **Unacceptable** **Methodology: Qualitative Polymerase Chain Reaction** **Days Performed: Monday, Wednesday, Friday** **Reported: 2**–6 days	Effective immediately

Test Changes (Cont.)

Test Name	Order Code	Change	Effective Date
Insulin Like Growth Factor 1	ILGF1	**Special Information: Grossly hemolyzed or lipemic samples are not recommended and should not be tested.** **Clinical Limitation: Bacterial contamination or heat inactivation of the specimen may affect test results.** **Note:** *Clinical Information will be removed for this test.* **Stability:** Ambient: **24 hours** Refrigerated: **7** days Frozen: **14 days** **Reference Range:** Male 0–11 Months: **11**–100 **ng/m**L **1–2 Years: 12–120 ng/mL** **2–3 Years: 13–143 ng/mL** **3–4 Years: 14–169 ng/mL** 4–5 Years: **15–200 ng/mL** **5–6 Years: 16–233 ng/mL** **6–7 Years: 17–269 ng/mL** **7–8 Years: 18–307 ng/mL** **8–9 Years: 20–347 ng/mL** 9–10 Years: **23–386 ng/mL** **10–11 Years: 29–424 ng/mL** **11–12 Years: 37–459 ng/mL** **12–13 Years: 49–487 ng/mL** **13–14 Years: 64–508 ng/mL** **14–15 Years: 83–519 ng/mL** **15–16 Years: 102–520 ng/mL** **16–17 Years: 119–511 ng/mL** **17–18 Years: 131–490 ng/mL** **18–19 Years: 137–461 ng/mL** 19–20 Years: **137–428 ng/mL** **20–21 Years: 133–395 ng/mL** **21–22 Years: 127–364 ng/mL** **22–23 Years: 120–338 ng/mL** **23–24 Years: 112–316 ng/mL** **24–25 Years: 105–298 ng/mL** **25–26 Years: 99–283 ng/mL** **26–27 Years: 94–271 ng/mL** **27–28 Years: 90–262 ng/mL** **28–29 Years: 87–255 ng/mL** **29–30 Years: 84–250 ng/mL** **30–31 Years: 83–246 ng/mL** **31–32 Years: 82–244 ng/mL** **32–33 Years: 82–243 ng/mL** **33–34 Years: 82–242 ng/mL** **34–35 Years: 82–242 ng/mL** **35–36 Years: 83–241 ng/mL** **36–37 Years: 83–240 ng/mL** **37–38 Years: 83–239 ng/mL** **38–39 Years: 83–238 ng/mL** **39–40 Years: 83–238 ng/mL** **40–41 Years: 82–237 ng/mL** **41–42 Years: 81–236 ng/mL** **42–43 Years: 80–235 ng/mL** **43–44 Years: 78–233 ng/mL** **44–45 Years: 76–230 ng/mL** **45–46 Years: 74–227 ng/mL** **46–47 Years: 72–225 ng/mL** **47–48 Years: 71–224 ng/mL** **48–49 Years: 69–224 ng/mL** **49–50 Years: 68–225 ng/mL** **50–51 Years: 67–225 ng/mL** **51–52 Years: 66–225 ng/mL** *(continued on page 7)*	10/29/18

Test Changes (Cont.)

Test Name	Order Code	Change	Effective Date
Insulin Like Growth Factor 1 *(continued from page 6)*		**52–53 Years: 65–222 ng/mL** **53–54 Years: 64–218 ng/mL** **54–55 Years: 62–214 ng/mL** **55–56 Years: 61–210 ng/mL** **56–57 Years: 59–206 ng/mL** **57–58 Years: 58–204 ng/mL** **58–59 Years: 56–203 ng/mL** **59–60 Years: 55–203 ng/mL** **60–61 Years: 53–206 ng/mL** **61–62 Years: 51–209 ng/mL** **62–63 Years: 49–214 ng/mL** **63–64 Years: 46–219 ng/mL** **64–65 Years: 43–225 ng/mL** **65–66 Years: 40–231 ng/mL** **66–67 Years: 37–236 ng/mL** **67–68 Years: 34–240 ng/mL** **68–69 Years: 31–243 ng/mL** **69–70 Years: 29–245 ng/mL** **70–71 Years: 27–246 ng/mL** **71–72 Years: 26–245 ng/mL** **72–73 Years: 25–242 ng/mL** **73–74 Years: 24–236 ng/mL** **74–75 Years: 23–229 ng/mL** **75–76 Years: 22–221 ng/mL** **76–77 Years: 22–212 ng/mL** **77–78 Years: 21–204 ng/mL** **78–79 Years: 20–196 ng/mL** **79–80 Years: 19–189 ng/mL** **80–81 Years: 18–184 ng/mL** **81–82 Years: 17–180 ng/mL** **82–83 Years: 16–177 ng/mL** **83–84 Years: 16–176 ng/mL** **84–85 Years: 16–176 ng/mL** **85–86 Years: 15–177 ng/mL** **> 86 Years: Not Established** Female 0–11 Months: **8**–131 **ng/mL** **1–2 Years: 9–146 ng/mL** **2–3 Years: 11–165 ng/mL** **3–4 Years: 13–187 ng/mL** 4–5 Years: **15–216 ng/mL** **5–6 Years: 19–251 ng/mL** **6–7 Years: 24–293 ng/mL** **7–8 Years: 30–342 ng/mL** **8–9 Years: 39–396 ng/mL** 9–10 Years: **49–451 ng/mL** **10–11 Years: 62–504 ng/mL** **11–12 Years: 76–549 ng/mL** **12–13 Years: 90–581 ng/mL** **13–14 Years: 104–596 ng/mL** **14–15 Years: 115–591 ng/mL** **15–16 Years: 121–564 ng/mL** **16–17 Years: 122–524 ng/mL** **17–18 Years: 120–479 ng/mL** **18–19 Years: 117–436 ng/mL** 19–20 Years: **113–399 ng/mL** **20–21 Years: 109–372 ng/mL** **21–22 Years: 107–351 ng/mL** **22–23 Years: 105–337 ng/mL** **23–24 Years: 103–326 ng/mL** **24–25 Years: 102–317 ng/mL** **25–26 Years: 100–311 ng/mL** **26–27 Years: 98–305 ng/mL** **27–28 Years: 96–301 ng/mL** *(continued on page 8)*	

Test Changes (Cont.)

Test Name	Order Code	Change	Effective Date
Insulin Like Growth Factor 1 *(continued from page 7)*		**28–29 Years: 93–297 ng/mL** **29–30 Years: 91–293 ng/mL** **30–31 Years: 89–290 ng/mL** **31–32 Years: 87–286 ng/mL** **32–33 Years: 85–283 ng/mL** **33–34 Years: 83–280 ng/mL** **34–35 Years: 82–279 ng/mL** **35–36 Years: 81–278 ng/mL** **36–37 Years: 80–277 ng/mL** **37–38 Years: 80–277 ng/mL** **38–39 Years: 79–276 ng/mL** **39–40 Years: 78–274 ng/mL** **40–41 Years: 76–271 ng/mL** **41–42 Years: 75–267 ng/mL** **42–43 Years: 73–263 ng/mL** **43–44 Years: 71–258 ng/mL** **44–45 Years: 69–253 ng/mL** **45–46 Years: 66–249 ng/mL** **46–47 Years: 64–246 ng/mL** **47–48 Years: 62–243 ng/mL** **48–49 Years: 60–240 ng/mL** **49–50 Years: 59–238 ng/mL** **50–51 Years: 57–236 ng/mL** **51–52 Years: 55–235 ng/mL** **52–53 Years: 53–234 ng/mL** **53–54 Years: 52–233 ng/mL** **54–55 Years: 51–233 ng/mL** **55–56 Years: 49–234 ng/mL** **56–57 Years: 48–235 ng/mL** **57–58 Years: 47–236 ng/mL** **58–59 Years: 46–238 ng/mL** **59–60 Years: 44–240 ng/mL** **60–61 Years: 43–241 ng/mL** **61–62 Years: 41–243 ng/mL** **62–63 Years: 40–244 ng/mL** **63–64 Years: 38–244 ng/mL** **64–65 Years: 36–244 ng/mL** **65–66 Years: 34–241 ng/mL** **66–67 Years: 32–238 ng/mL** **67–68 Years: 30–235 ng/mL** **68–69 Years: 28–231 ng/mL** **69–70 Years: 27–228 ng/mL** **70–71 Years: 26–226 ng/mL** **71–72 Years: 24–224 ng/mL** **72–73 Years: 24–222 ng/mL** **73–74 Years: 23–221 ng/mL** **74–75 Years: 22–220 ng/mL** **75–76 Years: 21–218 ng/mL** **76–77 Years: 20–216 ng/mL** **77–78 Years: 20–214 ng/mL** **78–79 Years: 19–210 ng/mL** **79–80 Years: 18–206 ng/mL** **80–81 Years: 18–200 ng/mL** **81–82 Years: 18–193 ng/mL** **82–83 Years: 17–186 ng/mL** **83–84 Years: 17–179 ng/mL** **84–85 Years: 17–173 ng/mL** **85–86 Years: 17–167 ng/mL** **> 86 Years: Not Established**	
Kappa/Lambda Light Chains, Free with Ratio, Urine	UKLFR	**Days Performed:** Monday–Saturday **Reported:** 2–**3** days	9/10/18
Kappa Light Chain, Free, Urine	UFKAPP	**Specimen Requirement:** 2 mL random urine **collected** in a clean, **leak-proof plastic** container; Minimum: 1 mL; **Ambient** *OR* 2 mL 24-hour urine (well-mixed) in a clean container (No preservatives); Minimum: 1 mL; **Ambient**	9/10/18

Test Changes (Cont.)

Test Name	Order Code	Change	Effective Date
Lambda Light Chain, Free, Urine	UFLAMB	**Specimen Requirement:** 2 mL random urine **collected** in a clean, **leak-proof plastic** container; Minimum: 1 mL; **Ambient** *OR* 2 mL 24-hour urine (well-mixed) in a clean container (No preservatives); Minimum: 1 mL; **Ambient** **Days Performed:** Monday–Saturday **Reported:** 2–**4** days	9/10/18
Narcolepsy Associated Ag, HLA-DQB1 Typing	NARCAB	**For Interfaced Clients Only: Test build may need to be modified** **Special Information: Counseling and informed consent are recommended for genetic testing. This test is New York DOH approved.** **Clinical Limitation: This methodology will not differentiate between individuals who are heterozygous (one copy) and those who are homozygous (two copies) for the HLA-DQB1*06:02 allele. Rare diagnostic errors may occur due to primer site mutations. Alleles other than HLA-DQB1*06:02 are not identified. Other genetic and non-genetic factors that influence narcolepsy are not evaluated.** **Clinical Information: May help rule out narcolepsy when clinical history and sleep studies are inconclusive. Background Information: Characteristics: Narcolepsy is a sleep disorder associated with invalidating excessive daytime sleepiness and cataplexy. Disturbed nighttime sleep, sleep paralysis, and hypnagogic hallucinations (occurring in the period between sleep and wakefulness) are common. Incidence: Narcolepsy affects approximately 1 in 2,000 individuals. Inheritance: Multifactorial. Cause: The HLA-DQB1*06:02 allele is strongly associated with narcolepsy, but by itself is not causative. Recent studies indicate HLA-DRB1*15 is not associated with narcolepsy. Mutations Tested: HLA-DQB1*06:02 allele. Clinical Sensitivity: 85-95% depending on ethnicity. Greater than 99% of affected Caucasians with cataplexy have the HLA-DQB1*06:02 allele. Clinical Specificity: < 1%; 15-25% of unaffected Caucasians have the HLA-DQB1*06:02 allele. Methodology: PCR with melting curve analysis. Analytical Sensitivity and Specificity: 99%** **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: **1 week** Frozen: **Unacceptable** **Methodology:** **Fluorescence Monitoring** Polymerase Chain Reaction (PCR) **Days Performed: Varies** **Reported: 8–11** days **CPT: 81383 x 1**	11/13/18

Test Changes (Cont.)

Test Name	Order Code	Change	Effective Date
Toxoplasma Antibody Evaluation, CSF	CSFTOX	**For Interfaced Clients Only: Test build may need to be modified** **Includes:** Toxoplasma IgG Ab **Toxoplasma IgM** **Special Information: Please include disclaimer to indicate that it is acceptable to perform testing on cerebrospinal fluid (CSF) specimen. This test should not be used for blood donor screening, associated re-entry protocols, or for screening Human Cell, Tissues and Cellular and Tissue-Based Products (HCT/P). Contaminated, heat-inactivated or grossly hemolyzed specimens will be rejected. Plasma and urine are unacceptable. Parallel testing is preferred and convalescent specimens must be received within 30 days from receipt of the acute specimens. Label specimen as CSF and mark plainly as 'acute' or 'convalescent.'** **Clinical Information: This is a first-line test for identifying visceral Toxoplasma gondii infection. CDC suggests equivocal or positive results should be retested using a different assay from another reference laboratory specializing in toxoplasmosis testing (IgG dye test, IgM ELISA, reflex to avidity and/or other tests).** **Specimen Requirement: 2 mL** cerebrospinal fluid (CSF) in a **clean** container; Minimum: 0.5 mL; **Parallel testing is preferred and convalescent specimens must be received within 30 days from receipt of the acute specimens; Label specimen as CSF and mark plainly as 'acute' or 'convalescent;' Note: Please include disclaimer to indicate that it is acceptable to perform testing on CSF specimen;** Refrigerated **Stability:** Ambient: **Undetermined** Refrigerated: **Preferred** Frozen: **Undetermined** **Methodology: Semi-Quantitative Chemiluminescent Immunoassay** **Reference Range: Refer to report** **Days Performed: Sunday–Saturday** **Reported:** 2–**3** days	10/30/18
Trypsinogen	TRYPSI	**Clinical Information: Aids in diagnosis of acute and chronic pancreatitis.**	Effective immediately

New Tests

Test Name	Order Code	Change	Effective Date
Acetylcholinesterase and Fetal Hemoglobin, Amniotic Fluid	ACHFHB	**Note:** *This test was previously announced in the August Technical Update. Please note that there is a new order code, ACHFHB. We apologize for any inconvenience this may have caused.*	10/2/18
Acylcarnitines, Plasma w/ Basic Interpretation	ACYLBI	**Note:** *This test was previously announced in the August Technical Update.* **Price:** $416.00	9/25/18
Circulating Tumor Cell Count	CTCBPC	**Special Information:** Patient Prep: If the patient is on doxorubicin therapy, allow at least 7 days following administration of a dose of doxorubicin before drawing blood. MUST indicate source of metastatic cancer with order. Frozen or refrigerated specimens will be rejected. Specimens not collected in the CellSave™ tube or collected in expired CellSave™ tubes are unacceptable. Short draws will also be rejected. This assay is FDA approved only for breast, prostate, or colorectal metastatic cancers; other types will not be tested. This test is New York DOH approved. **Clinical Information:** The CellSearch™ Circulating Tumor Cell kit is intended for the quantification of circulating tumor cells (CTC) of epithelial origin for metastatic breast, prostate, or colon cancer in whole blood. This assay can be used to predict progression-free and overall survival in patients treated for metastatic cancer, and it may be used to evaluate response to therapy. Results should be interpreted with caution if specimens are drawn within 7 days of administration of doxorubicin therapy. **Specimen Requirement:** 20 mL whole blood in CellSave™ Preservative tubes; Minimum: 10 mL; Collecting the minimum volume will not allow for repeat testing; Patient Prep: If patient is on doxorubicin therapy, allow at least 7 days following administration of a dose of doxorubicin before blood draw; Draw two tubes (CellSave™ Preservative Tube, ARUP supply #44867) and fill completely; Do NOT refrigerate or freeze; Send specimen to Cleveland Clinic Laboratories on the day of collection; Source of metastatic cancer is REQUIRED with the order; Ambient **Stability:** Ambient: 4 days Refrigerated: Unacceptable Frozen: Unacceptable **Methodology:** Immunomagnetic Separation Immunofluorescent Stain Computer Assisted Analysis **Reference Range:** Refer to report **Days Performed:** Sunday–Saturday **Reported:** 2–6 days **CPT:** 86152 x 1 **Price:** $505.00 (non-discountable)	11/8/18
Copper, Liver	LIVCOP	**Special Information:** Specimens less than 0.25 mg (dry weight) are unacceptable. Paraffin blocks that have been processed with Hollandes or other copper-containing stain will be rejected. This test is New York DOH approved. **Clinical Information:** This test may be useful when related serum or urine assessments are inconclusive. Hepatic copper concentrations approach or exceed 250 µg/g in untreated Wilson disease. Elevated hepatic copper is also seen with chronic biliary obstruction and cholestasis. Results inconsistent with other findings may reflect heterogeneity in hepatic copper distribution. **Specimen Requirement:** 1 cm long liver tissue specimen; Minimum: 1 cm long; Obtain liver tissue with an 18 gauge needle; At least 1 cm long is required; Tissue can be fresh, dried or paraffin-embedded; Formalin-fixed is also acceptable; Specimens other than paraffin-embedded should be stored and transported in a metal-free container (e.g., royal blue with no additive); Refrigerated	11/6/18

(continued on page 12)

New Tests (Cont.)

Test Name	Order Code	Change	Effective Date
Copper, Liver *(continued from page 11)*		**Stability:** Ambient: Paraffin block, preserved (formalin), or dried: Indefinitely; Fresh tissue: Unacceptable Refrigerated: Paraffin block, preserved (formalin), or dried: Indefinitely; Fresh tissue: 1 week Frozen: Paraffin block, preserved (formalin), or dried: Indefinitely; Fresh tissue: Indefinitely **Methodology:** Inductively Coupled Plasma / Mass Spectrometry (ICP-MS) **Reference Range:** Refer to report **Days Performed:** Monday, Wednesday, Thursday, Friday, Saturday **Reported:** 3–7 days **CPT:** 82525 x 1 **Price:** $114.00 (non-discountable)	
Dihydropyrimidine Dehydrogenase (DPYD), 3 Variants	5FUDPD	**Special Information:** Plasma or serum will be rejected. Heparinized specimens are unacceptable. This test is New York DOH approved. **Clinical Limitation:** Only the targeted DPYD variants will be detected by this panel. Diagnostic errors can occur due to rare sequence variations. 5-FU drug metabolism, efficacy and risk for toxicity may be affected by genetic and non-genetic factors that are not evaluated by this test. Genotyping does not replace the need for therapeutic drug monitoring or clinical observation. **Clinical Information:** Used to predict risk of dose-related toxicity to 5-FU therapy. Background information: Characteristics: 5-FU is the most frequently used chemotherapeutic drug for the treatment of many types of cancer, particularly colorectal adenocarcinoma. Grade III-IV drug toxicity attributed to 5-FU occurs in approximately 16% of patients, and may include hematologic, gastrointestinal, and dermatologic complications. In some cases, this toxicity can cause death. When 5-FU is metabolized in the body, approximately 80% is catabolized by the dihydropyrimidine dehydrogenase (DPD) enzyme. Variants in the DPYD gene can lead to reduced 5-FU catabolism, resulting in the aforementioned toxicity complications. Inheritance: Autosomal codominant. Cause: DPYD gene mutations. DPYD Variants Tested: Non-functional alleles and toxicity risk: *13 (rs55886062, c.1679T>G)–Increased risk; *2A (rs3918290, c.1905+1G>A)–Greatly increased risk; c.2846A>T (rs67376798)–Increased risk; A negative result indicates no variants detected and is predictive of *1 functional alleles and normal enzymatic activity. Allele Frequency by Population: *13: Caucasian–0.1%; Asian–absent; African American–absent; *2A: Caucasian–0.47-2.2%; Asian–absent; African American–absent; c.2846A>T: Caucasians–1.1%; Asian–absent; African American–absent. Clinical Sensitivity: Estimated at 31% for the DPYD variants analyzed. Methodology: Polymerase chain reaction (PCR) and fluorescence monitoring. Analytical Sensitivity and Specificity: 99% **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) **Days Performed:** Monday, Thursday **Reported:** 6–11 days **CPT:** 81232 x 1 **Price:** $266.00 (non-discountable)	11/6/18

New Tests (Cont.)

Test Name	Order Code	Change	Effective Date
Drug Detection Panel, Umbilical Cord Tissue, with Marijuana Metabolite	DTOFMP	**Special Information:** Cords soaking in blood, saline or other fluids will be rejected. Formalin-fixed specimens or tissue that is obviously decomposed will not be accepted. For medical purposes only; not valid for forensic use unless testing was performed within Chain of Custody process. This test is New York DOH approved. **Clinical Information:** Used to detect and document maternal drug use during approximately the last trimester of a full term birth. The pattern and frequency of drug(s) used by the mother cannot be determined by this test. A negative result does not exclude the possibility that a mother used drugs during pregnancy. Detection of drugs in umbilical cord tissue depends on extent of maternal drug use, as well as drug stability, unique characteristics of drug deposition in umbilical cord tissue, and the performance of the analytical method. Drugs administered during labor and delivery may be detected. Detection of drugs in umbilical cord tissue does not insinuate impairment and may not affect outcomes for the infant. Glucuronide metabolites are indicated as -G. **Specimen Requirement:** At least 6 inches of umbilical cord (approximately the length of an adult hand) in a clean container; Minimum: 6 inches (Absolute minimum); Drain and discard any blood; Rinse the exterior of the cord segment with normal saline or sterile water; Pat the cord dry and transport at least 6 inches of umbilical cord in a routine urine collection cup or use the Security Kit for Meconium/Umbilical Drug Detection (ARUP supply #51548); NOTE: 8 inches is preferred; Only a single sample is required; Frozen **Stability:** Ambient: 3 days Refrigerated: 2 weeks Frozen: 1 year **Methodology:** Liquid Chromatography-Tandem Mass Spectrometry (LC-MS/MS) **Reference Range:** Buprenorphine: cutoff 1 ng/g Norbuprenorphine: cutoff 0.5 ng/g Buprenorphine-G: cutoff 1 ng/g Codeine: cutoff 0.5 ng/g Dihydrocodeine: cutoff 1 ng/g Fentanyl: cutoff 0.5 ng/g Hydrocodone: cutoff 0.5 ng/g Norhydrocodone: cutoff 1 ng/g Hydromorphone: cutoff 0.5 ng/g Meperidine: cutoff 2 ng/g Methadone: cutoff 2 ng/g EDDP: cutoff 1 ng/g 6-Acetylmorphine: cutoff 1 ng/g Morphine: cutoff 0.5 ng/g Naloxone: cutoff 1 ng/g Oxycodone: cutoff 0.5 ng/g Noroxycodone: cutoff 1 ng/g Oxymorphone: cutoff 0.5 ng/g Noroxymorphone: cutoff 0.5 ng/g Propoxyphene: cutoff 1 ng/g Tapentadol: cutoff 2 ng/g Tramadol: cutoff 2 ng/g N-desmethyltramadol: cutoff 2 ng/g O-desmethyltramadol: cutoff 2 ng/g Amphetamine: cutoff 5 ng/g Benzoylecgonine: cutoff 0.5 ng/g m-OH-Benzoylecgonine: cutoff 1 ng/g Cocaine: cutoff 0.5 ng/g Cocaethylene: cutoff 1 ng/g MDMA–Ecstasy: cutoff 5 ng/g Methamphetamine: cutoff 5 ng/g Phentermine: cutoff 8 ng/g Alprazolam: cutoff 0.5 ng/g Alpha-OH-Alprazolam: cutoff 0.5 ng/g *(continued on page 14)*	9/6/18

New Tests (Cont.)

Test Name	Order Code	Change	Effective Date
Drug Detection Panel, Umbilical Cord Tissue, with Marijuana Metabolite *(continued from page 13)*		Butalbital: cutoff 25 ng/g Clonazepam: cutoff 1 ng/g Diazepam: cutoff 1 ng/g 7-Aminoclonazepam: cutoff 1 ng/g Lorazepam: cutoff 5 ng/g Midazolam: cutoff 1 ng/g Alpha-OH-Midazolam: cutoff 2 ng/g Nordiazepam: cutoff 1 ng/g Oxazepam: cutoff 2 ng/g Phenobarbital: cutoff 75 ng/g Temazepam: cutoff 1 ng/g Zolpidem: cutoff 0.5 ng/g Phencyclidine-PCP: cutoff 1 ng/g THC-COOH: cutoff 0.2 ng/g **Days Performed:** Sunday–Saturday **Reported:** 2–4 days **CPT:** 80307 x 1, 80349 x 1, (G0480, if appropriate) **Price:** $197.00 (non-discountable)	
Leukemic Blood Cancer Chromosome Microarray + SNP	BLLSNP	**Note:** *This test was previously announced in the August Technical Update with a go-live date of 8/30/18. Due to unforeseen circumstances, the go-live date has been changed to 9/27/18. We apologize for any inconvenience this may have caused.*	9/27/18
Marijuana Metabolite, Umbilical Cord Tissue, Qualitative	DRGTHC	**Special Information:** Cords soaking in saline or other solutions will be rejected. For medical purposes only; not valid for forensic use unless testing was performed within Chain of Custody process. This test is New York DOH approved. **Clinical Information:** Used to detect in utero exposure to cannabis (marijuana) in neonates, consistent with maternal use during approximately the last trimester of pregnancy. Other drug exposures can be detected by alternative testing. The pattern and frequency of drug(s) used by the mother cannot be determined by this test. A negative result does not exclude the possibility that a mother used drugs during pregnancy. Detection of drugs in umbilical cord tissue depends on the extent of maternal drug use, as well as drug stability, unique characteristics of drug deposition in umbilical cord tissue, and the performance of the analytical method. Drugs administered during labor and delivery may be detected. Detection of drugs in umbilical cord tissue does not insinuate impairment and may not affect outcomes for the infant. **Specimen Requirement:** At least 6 inches of umbilical cord (approximately the length of an adult hand) in a clean container; Minimum: 6 inches (Absolute minimum); Drain and discard any blood; Rinse the exterior of the cord segment with normal saline or sterile water; Pat the cord dry and transport at least 6 inches of umbilical cord in a routine urine collection cup or use the Security Kit for Meconium/Umbilical Drug Detection (ARUP supply #51548); Frozen **Stability:** Ambient: 3 days Refrigerated: 2 weeks Frozen: 1 year **Methodology:** Liquid Chromatography-Tandem Mass Spectrometry (LC-MS/MS) **Reference Range:** cutoff 0.2 ng/g **Days Performed:** Sunday–Saturday **Reported:** 2–4 days **CPT:** 80349 x 1, (G0480, if appropriate) **Price:** $120.00 (non-discountable)	9/6/18
Organic Acids Ur, Quant w/ Basic Interpretation	UORABI	**Note:** *This test was previously announced in the August Technical Update.* **Price:** $258.00 (non-discountable)	9/25/18
Products of Conception Microarray + SNP	POCSNP	**Note:** *This test was previously announced in the August Technical Update with a go-live date of 8/30/18. Due to unforeseen circumstances, the go-live date has been changed to 9/27/18. We apologize for any inconvenience this may have caused.*	9/27/18

New Tests (Cont.)

Test Name	Order Code	Change	Effective Date
TP53 Somatic Mutation, Prognostic	TP53MU	**Includes:** TP53 Somatic Mutation, Prognostic TP53 Exon 4 Mutation TP53 Exon 5 Mutation TP53 Exon 6 Mutation TP53 Exon 7 Mutation TP53 Exon 8 Mutation TP53 Exon 9 Mutation TP53 Somatic Mutation, Interpretation **Special Information:** This test is New York DOH approved. **Clinical Information:** This testing may be useful in clinical research settings to evaluate progression of certain cancers. **Specimen Requirement:** 6 mL whole blood in an EDTA (lavender) tube; Minimum: 3 mL; Refrigerated *OR* 3 mL bone marrow in an EDTA (lavender) tube; Minimum: 1 mL; Refrigerated *OR* Formalin-fixed, paraffin-embedded (FFPE) tissue block; Refrigerated **Stability:** Ambient: Whole blood or bone marrow: 72 hours; Paraffin-embedded tissue: Indefinitely Refrigerated: Whole blood or bone marrow: 1 week; Paraffin-embedded tissue: Indefinitely Frozen: Unacceptable **Methodology:** Polymerase Chain Reaction/Sequencing **Days Performed:** Varies **Reported:** 5–11 days **CPT:** 81405 x 1 **Price:** $1285.00 (non-discountable)	10/30/18

Fee Increases

Test Name	Order Code	List Fee	CPT Code	Effective Date
Adrenal Antibody	ADRENL	$125.00 (non-discountable)	86255	9/10/18
Narcolepsy Associated Ag, HLA-DQB1 Typing	NARCAB	$215.00 (non-discountable)	81383	11/13/18

Fee Reductions

Test Name	Order Code	List Fee	CPT Code	Effective Date
Calprotectin, Fecal	CALPRO	$100.00 (non-discountable)	83993	9/6/18
Coxsackie A Abs	COXAAB	$68.00 (non-discountable)	86658	9/6/18
Cyanide, Blood	CYANID	$129.00	82600	Effective immediately
Diphtheria/Tetanus Antibody	DIPTET	$86.00 (non-discountable)	86317 x 2	Effective immediately
Flow Cytometric Immunophenotyping for Leukemia/Lymphoma	RLLLIP	$1060.00 (non-discountable)	88184, 88185 x 10, 88188	9/4/18
HPV DNA, High Risk, Anal-Rectal	HPVAR	$130.00	87624	Effective immediately
Organic Acids Ur, Quant wo/ Interpretation	UORA	$191.00 (non-discountable)	83918	9/25/18
Toxoplasma Antibody Evaluation, CSF	CSFTOX	$110.00	86777, 86778	10/30/18

Discontinued Tests

Test Name	Order Code	Test Information	Effective Date
CDKL5-Related Atypical Rett Syndrome	CDKL5	This test will no longer be available.	11/1/18
Circulating Tumor Cells for Breast Cancer	CTC	This test will no longer be available. Suggest ordering Circulating Tumor Cell Count (CTCBPC).	11/8/18
Circulating Tumor Cells for Prostate Cancer	CTCP	This test will no longer be available. Suggest ordering Circulating Tumor Cell Count (CTCBPC).	11/8/18
Copper, Tissue	TISCOP	This test will no longer be available. Suggest ordering Copper, Liver (LIVCOP).	11/6/18
DPD 5-FU GenotypR	5FU	This test will no longer be available. Suggest ordering Dihydropyrimidine Dehydrogenase (DPYD), 3 Variants (5FUDPD).	11/6/18
EPM1 DNA Test	EPMDNA	This test will no longer be available.	11/1/18
Fatty Acid Profile, Comprehensive	MCFA	This test will no longer be available. Suggest ordering Fatty Acids Profile, Essential Serum or Plasma (CFAPRO).	11/1/18
GLUD1 (CH) DNA Sequencing Test	GLUD1	This test will no longer be available.	11/1/18
IPF1 (MODY4) DNA Sequencing Test	MODY4	This test will no longer be available.	11/1/18
Molecular Detection of TSHR	TSHR	This test will no longer be available.	10/1/18
Niemann-Pick Disease Type A Mutation, Whole Blood	NIEMAN	This test will no longer be available.	11/1/18
P53 Mutation Analysis	P53MUT	This test will no longer be available. Suggest ordering TP53 Somatic Mutation, Prognostic (TP53MU).	10/30/18
Rickettsia Antibodies, IgG & IgM	RICKGM	This test will no longer be available. Suggest ordering Rickettsia rickettsii IgG & IgM Abs (ROCKY) and Rickettsia Typhi IgG & IgM Abs (TYPHUS).	9/10/18