Cleveland Clinic

Cleveland Clinic Laboratories

Technical Update • February 2022

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.

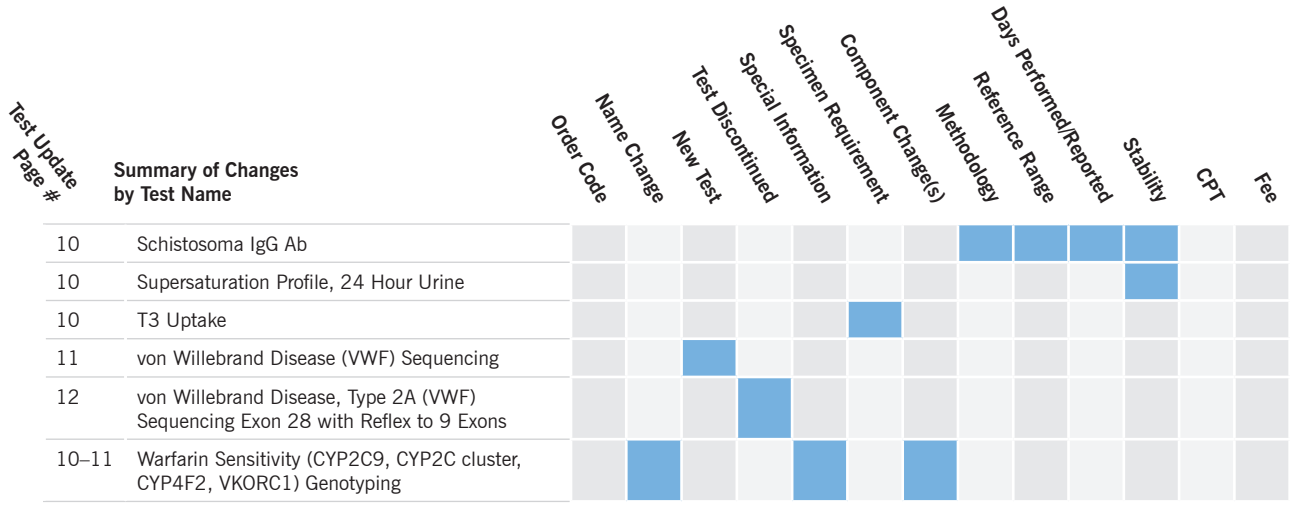
Recently changed tests are bolded, and they could include revisions to methodology, reference range, days performed, or CPT code. Deleted tests and new tests are listed separately. For your convenience, tests are listed alphabetically and order codes are provided.

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
3	5-Hydroxyindoleacetic Acid, Urine 24 Hour									■				
3	5-Hydroxyindoleacetic Acid, Urine Random									■				
12	Acetylcholine Receptor Antibodies with reflex				■									
3	Allergen, Rice IgG						■							
3	Amylase Isoenzymes						■			■				
12	Bartonella PCR, tissue													■
4	Beta hCG Quant Tumor Marker						■							
4	Beta-hCG, Quantitative (Tumor Marker), CSF						■							
4	Bioavailable Testosterone/SHBG, Female & Child					■				■				
5	C Telopeptide, Beta Cross Linked					■	■			■				
5	CK Isoenzymes									■				
5	Coxsackie B Abs										■			
6	CYP2C19 (Cytochrome P450 2C19)					■		■						
6–7	CYP2D6 (Cytochrome P450 2D6)					■		■	■					
11	Cytomegalovirus, Newborn Saliva												■	■
7	Echovirus Antibodies										■			
12	Familial Mediterranean Fever (MEFV) Sequencing				■									
7	FISH for Aggressive B-cell Lymphoma										■			
7	FISH for Aggressive B-Cell Lymphoma Blood										■			
7	FISH for Aggresive B-Cell Lymphoma Bone Marrow										■			

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
7	FISH for ALK Cyto Block										■			
7	FISH for BCL2 (18q21) Tissue										■			
7	FISH for BCL2 Blood										■			
7	FISH for BCL2 Bone Marrow										■			
7	FISH for BCL6 (3q27) Tissue										■			
7	FISH for BCL6 Blood										■			
7	FISH for BCL6 Bone Marrow										■			
7	FISH for CCND1 Blood										■			
7	FISH for CCND1 Bone Marrow										■			
7	FISH for CCND1 (Tissue)										■			
7	FISH for IgH/BCL2 Blood										■			
7	FISH for IGH/BCL2 Bone Marrow										■			
7	FISH for IGH/BCL2 Tissue										■			
7	FISH for IgH/CCND1 Blood										■			
8	FISH for IGH/CCND1 Bone Marrow										■			
8	FISH for IGH/CCND1 Tissue										■			
8	FISH for IGH/MYC/CEP8 Blood										■			
8	FISH for IGH/MYC/CEP8 Bone Marrow										■			
8	FISH for IGH/MYC/CEP8 Tissue										■			
8	FISH for MALT 1 (18q21)										■			
8	FISH for MYC (8q24) Blood										■			
8	FISH for MYC (8q24) Bone Marrow										■			
8	FISH for MYC (8q24) Tissue										■			
8, 12	FISH for YqH										■		■	■
12	Heterophile Ab (Inf. Mono) LA w/Titer RFLX				■									
8–9	Hirsutism Evaluation Panel									■				
9	HIV 1 Drug Resistance by Next Generation Sequencing						■							
9, 12	JAK2 V617F Mutation Detection Blood								■		■			■
9	JAK2 V617F Mutation Detection Bone Marrow								■		■			
9	Lead, Blood									■				
9	Lipoprotein Electrophoresis											■		
9	Mycoplasma Cult Non Urogenital					■					■			
9	MYD88 L265P Mutation Analysis								■		■			
9	MYD88 L265P Mutation Analysis Bone Marrow								■		■			
12	NAbFeron Ab				■									
9	OSHA Zinc Protoporphyrin; Test									■				
9	Polio Neutralization										■			
9	Polymyositis and Dermatomyositis Panel								■			■		
10	Polymyositis Panel								■			■		



Test Changes (Cont.)

Test Name	Order Code	Change	Effective Date
5-Hydroxyindoleacetic Acid, Urine 24 Hour	UHIAAD	**Reference Range: <7.7** mg/24 hrs	effective immediately
5-Hydroxyindoleacetic Acid, Urine Random	UHIAR2	**Reference Range: <6.7** mg/g crt	effective immediately
Allergen, Rice IgG	RICIGG	**Specimen Requirement: 0.3 mL** serum from Serum Separator (Gold) tube; **Minimum 0.2 mL**; Refrigerated; Transfer serum to a standard plastic aliquot tube. *OR* **0.3 mL** serum from No additive (Red) tube; **Minimum 0.2 mL**; Refrigerated; Transfer serum to a standard plastic aliquot tube.	2/26/22
Amylase Isoenzymes	AMYISO	**Specimen Requirement:** 1 mL serum from Serum Separator (Gold) tube; Minimum 0.5 mL; Refrigerated; Allow to clot completely at room temp. Separate serum from cells ASAP (within 2 hours of collection). *OR* 1 mL plasma from EDTA (Lavender) tube; Minimum 0.5mL; Refrigerated; Remove plasma ASAP (within 2 hours of collection).*OR* **Lithium heparin Plasma Separator (Light Green) tube;** Refrigerated; Remove plasma ASAP (within 2 hours of collection) **Note:** *Sodium heparin will no longer be an acceptable specimen* **Reference Range:** Pancreatic amylase (PANAMY) 6–35 Months: 2–28 U/L 3–6 Years: 8–34 U/L 7–17 Years: 9–39 U/L 18–99 Years: **13–53 U/L** Total amylase (TAMYIS) 3–90 Days: 0–30 U/L 3–6 Months: 7–40 U/L 7–8 Months: 7–57 U/L 9–11 Months: 11–70 U/L 12–17 Months: 11–79 U/L 18–35 Months: 19–92 U/L 3–4 Years: 26–106 U/L 5–12 Years: 30–119 U/L 13–99 Years: **28–100 U/L**	2/22/22

Test Changes (Cont.)

Test Name	Order Code	Change	Effective Date
Beta hCG Quant Tumor Marker	BHCG	**Specimen Requirement:** 1 mL serum from Serum Separator (Gold) tube; Minimum 0.4 mL; Refrigerated; Allow specimen to clot completely at room temperature. Separate serum from cells ASAP or within 2 hours of collection. Transfer serum to standard aliquot tube *OR* 1 mL plasma from EDTA (Lavender) tube; Minimum 0.4 mL; Refrigerated; Separate plasma from cells within 2 hours of collection and transfer to standard aliquot tube *OR* 1 mL plasma from Lithium heparin (Green) tube; Minimum 0.4 mL; Refrigerated; Separate plasma from cells within 2 hours of collection and transfer to standard aliquot tube. **Note:** *Sodium heparin will no longer be an acceptable specimen*	2/22/22
Beta-hCG, Quantitative (Tumor Marker), CSF	HCGCSF	**Specimen Requirement:** 0.5 mL Cerebrospinal fluid (CSF) in clean container; Minimum 0.3 mL; Refrigerated *OR* 0.5 mL Cerebrospinal fluid (CSF) in No additive (Red) tube; Minimum 0.3 mL; Refrigerated *OR* 0.5 mL Cerebrospinal fluid (CSF) in Lithium heparin (Green) tube; Minimum 0.3 mL; Refrigerated **Note:** *Sodium heparin will no longer be an acceptable specimen*	2/22/22
Bioavailable Testosterone/SHBG, Female & Child	BTSTFC	**Includes:** Testosterone Testosterone, Free Testosterone, Bioavailable **by Mass Spec** Sex Hormone Binding Globulin **Special Information:** Collection between 6–10 a.m. is preferred but not required. **Clinical Information: Bioavailable testosterone concentration is calculated using total testosterone (measured by mass spectrometry) and the binding constant of testosterone and sex hormone-binding globulin (SHBG) and/or albumin.** 6–10 a.m. collection is preferable since the reference ranges are determined based on collections during that time. Results for patients collected outside 6–10 a.m. will be reported but must be interpreted in the context of the alternate collection time. Samples collected after 10 a.m. could have falsely low testosterone, and results should be interpreted carefully. **For individuals on testosterone-suppressing hormone therapies (e.g., antiandrogens or estrogens), refer to cisgender female reference intervals.** **Reference Range:** Sex Hormone Binding Globulin (SHBG3) Female Tanner Stage I: 30–173 nmol/L Tanner Stage II: 16–127 nmol/L Tanner Stage III: 12–98 nmol/L Tanner Stage IV: 14–151 nmol/L Tanner Stage V: 23–165 nmol/L 1–30 Days: 14–60 nmol/L 31–364 Days: 60–215 nmol/L 1–3 Years: 60–190 nmol/L 4–6 Years: 55–170 nmol/L 7–9 Years: 35–170 nmol/L 10–12 Years: 17–155 nmol/L 13–15 Years: 11–120 nmol/L 16–17 Years: 19–145 nmol/L **18–49 Years: 25–122 nmol/L** **50–99 Years: 17–125 nmol/L** Male Tanner Stage I: 26–186 nmol/L Tanner Stage II: 22–169 nmol/L Tanner Stage III: 13–104 nmol/L Tanner Stage IV: 11–60 nmol/L Tanner Stage V: 11–71 nmol/L 1–30 Days: 13–85 nmol/L 31–364 Days: 70–250 nmol/L 1–3 Years: 50–180 nmol/L 4–6 Years: 45–175 nmol/L 7–9 Years: 28–190 nmol/L 10–12 Years: 23–160 nmol/L 13–15 Years: 13–140 nmol/L 16–17 Years: 10–60 nmol/L **18–49 Years: 17–56 nmol/L** **50–99 Years: 19–76 nmol/L** **Note:** *Other component ranges will not change*	2/22/22

Test Changes (Cont.)

Test Name	Order Code	Change	Effective Date
C Telopeptide, Beta Cross Linked	CTELO	**Special Information: Morning fasting specimen preferred.** Patient Prep: For patients receiving therapy with high biotin doses (e.g. greater than 5 mg/day), specimen should not be drawn until at least 8 hours after the last biotin administration. Hemolyzed specimens are unacceptable. This test is New York DOH approved. **Specimen Requirement:** 1 mL serum from Serum Separator (Gold) tube; Minimum 0.5 mL; Frozen; **Morning fasting specimen preferred.** Patient Prep: For patients receiving therapy with high biotin doses (e.g. greater than 5 mg/day), specimen should not be drawn until at least 8 hours after the last biotin administration. Allow tube to sit for 15–20 minutes at room temperature to form clot. Centrifuge and separate serum from cells ASAP or within 2 hours of collection. Transfer serum to standard aliquot tube. *OR* 1 mL plasma from Lithium heparin (Green) tube; Minimum 0.5 mL; Frozen; **Morning fasting specimen preferred.** Patient Prep: For patients receiving therapy with high biotin doses (e.g. greater than 5 mg/day), specimen should not be drawn until at least 8 hours after the last biotin administration. Allow tube to sit for 15–20 minutes at room temperature to form clot. Centrifuge and separate serum from cells ASAP or within 2 hours of collection. Transfer serum to standard aliquot tube. *OR* **1 mL plasma from EDTA (Lavender) tube; Minimum 0.5 mL; Frozen; Morning fasting specimen preferred. Patient Prep: For patients receiving therapy with high biotin doses (e.g. greater than 5 mg/day), specimen should not be drawn until at least 8 hours after the last biotin administration. Allow tube to sit for 15–20 minutes at room temperature to form clot. Centrifuge and separate serum from cells ASAP or within 2 hours of collection. Transfer serum to standard aliquot tube.** **Reference Range:** C Telopeptide, Beta Cross Linked (CTELOP) Female 6 Months–6 Years: 500–1800 pg/mL 7–9 Years: 566–1690 pg/mL 10–12 Years: 503–2077 pg/mL 13–15 Years: 160–1590 pg/mL 16–17 Years: 167–933 pg/mL 18–29 Years: 64–640 pg/mL 30–39 Years: 60–650 pg/mL 40–49 Years: 40–465 pg/mL **Premenopausal: 25–573 pg/mL** Postmenopausal: 104–1008 pg/mL Male 6 Months–6 Years: 500–1700 pg/mL 7–9 Years: 522–1682 pg/mL 10–12 Years: 553–2071 pg/mL 13–15 Years: 485–2468 pg/mL 16–17 Years: 276–1546 pg/mL 18–29 Years: 87–1200 pg/mL 30–39 Years: 70–780 pg/mL 40–49 Years: 60–700 pg/mL 50–69 Years: 40–840 pg/mL 70–99 Years: 52–847 pg/mL	2/22/22
CK Isoenzymes	CKISO	**Reference Range:** Creatine Kinase (CKISOT) Male 0–30 Days: 108–564 U/L 31 Days–5 Months: 72–367 U/L 6–35 Months: 50–272 U/L 3–6 Years: 56–281 U/L 7–17 Years: 60–393 U/L 18 Years and older: **39–308 U/L** Female 0–30 Days: 108–564 U/L 31 Days–5 Months: 72–367 U/L 6–35 Months: 38–261 U/L 3–6 Years: 40–222 U/L 7–17 Years: 46–250 U/L 18 Years and older: **26–192 U/L** **Note:** *Other component ranges will not change*	2/22/22
Coxsackie B Abs	COXBAB	**Reported:** 7–**13** days	2/22/22

Test Changes (Cont.)

Test Name	Order Code	Change	Effective Date
CYP2C19 (Cytochrome P450 2C19)	2C19CY	**For interface clients only: Test build may need to be modified** **Includes:** CYP2C19 Genotype **CYP2C19 Phenotype** Interpretation **Clinical Limitation:** Only the targeted CYP2C19 variants will be detected by this panel, and assumptions about phase and content are made to assign alleles. **Publicly** available sources such as the www.pharmvar.org or www.pharmgkb.org provide guidance on phenotype predictions and allele frequencies. Diagnostic errors can occur due to rare sequence variations. Risk of therapeutic failure or adverse reactions with CYP2C19 substrates may be affected by genetic and non-genetic factors that are not detected by this test. This result does not replace the need for therapeutic drug or clinical monitoring. **Clinical Information:** Background: Characteristics: The cytochrome P450 (CYP) isozyme 2C19 is involved in the metabolism of many drugs. Variants in the gene that codes for CYP2C19 will influence pharmacokinetics of CYP2C19 substrates, and may predict or explain non-standard dose requirements, therapeutic failure or adverse reactions. Inheritance: Autosomal co-dominant. Cause: CYP2C19 gene variants affect enzyme **function.** Variants tested: Negative: No variants detected is predictive of the *1 functional allele. *2 (rs4244285, c.681G>A), *3 (rs4986893, c.636G>A), *4 (rs28399504, c.1A>G), *5 (rs56337013, c.1297C>T), *6 (rs72552267, c.395G>A), *7 (rs72558186, c.819+2T>A, *8 (rs41291556, c.358T>C), *9 (rs17884712, c.431G>A), *10 (rs6413438, c.680C>T), *15 (rs17882687, c.55A>C), *17 (rs12248560, c.-806C>T), *35 (rs12769205, c.12662A>G) Clinical Sensitivity: Drug-dependent. Methodology: Polymerase chain reaction (PCR) and fluorescence monitoring. Analytical Sensitivity and Specificity: > 99%	2/22/22
CYP2D6 (Cytochrome P450 2D6)	2D6GTP	**For interface clients only: Test build may need to be modified** **Includes:** CYP2D6 Genotype **CYP2D6 Phenotype** Interpretation **Clinical Limitation:** Only the targeted CYP2D6 variants will be detected by this panel, and assumptions about phase and content are made to assign alleles. **Publicly** available sources such as the www.pharmvar.org or www.pharmgkb.org provide guidance on phenotype predictions and allele frequencies. A combination of the *5 (gene deletion) and a gene duplication cannot be specifically identified. This combination is not expected to adversely affect the phenotype prediction. Diagnostic errors can occur due to rare sequence variations. Risk of therapeutic failure or adverse reactions with CYP2D6 substrates may be affected by genetic and non-genetic factors that are not detected by this test. This result does not replace the need for therapeutic drug or clinical monitoring. **Clinical Information:** Background: Characteristics: The cytochrome P450 (CYP) isozyme 2D6 is involved in the metabolism of many drugs. Variants in the gene that codes for CYP2D6 may influence pharmacokinetics of CYP2D6 substrates, and may predict or explain non-standard dose requirement, therapeutic failure or adverse reactions. Inheritance: Autosomal co-dominant. Cause: CYP2D6 gene variants and copy number affect enzyme **function.** Variants tested: Negative: No variants detected is predictive of the *1 functional allele. *2 (rs16947, c.2850C>T; rs1135840, c.4180G>C), *2A (rs1080985, c.-1584C>G; rs16947, c.2850C>T; rs1135840, c.4180G>C), *3 (rs35743686, c.2549delA), *4 (rs1065852, c.100C>T; rs3892097, c.1846G>A; rs1135840, c.4180G>C), *5 (gene deletion), *6 (rs5030655, c.1707delT; rs1135840, c.4180G>C), *7 (rs5030867, c.2935A>C), *8 (rs5030865, c.1758G>T; rs16947, c.2850C>T; rs1135840, c.4180G>C), *9 (rs5030656, c.2615_2617delAAGA), *10 (rs1065852, c.100C>T; rs1135840, c.4180G>C), *11 (rs1080985, c.-1584C>G; rs201377835, c.883G>C; rs16947, c.2850C>T; rs1135840, c.4180G>C), *12 (rs5030862, c.124G>A; rs16947, c.2850C>T; rs1135840, c.4180G>C), *13 (a CYP2D7-derived exon 1 conversion), *14 (rs5030865, c.1758G>A; rs16947, c.2850C>T; rs1135840, c.4180G>C), *15 (rs774671100, c.137_138insT), *17 (rs28371706, c.1023C>T; rs16947, c.2850C>T; rs1135840, c.4180G>C), *29 (rs16947, c.2850C>T; rs59421388, *(continued on page 7)*	2/22/22

Test Changes (Cont.)

Test Name	Order Code	Change	Effective Date
CYP2D6 (Cytochrome P450 2D6) *(continued from page 6)*		c.3183G>A; rs1135840, c.4180G>C), *35 (rs769258, c.31G>A; rs16947, c.2850C>T; rs1135840, c.4180G>C), *36 (a CYP2D6*10 carrying a CYP2D7-derived exon 9 conversion), *36-*10 (a CYP2D6*36 and a CYP2D6*10 in tandem, *41 (rs16947, c.2850C>T; rs28371725, c.2988G>A; rs1135840, c.4180G>C), *45 (rs28371710, c.1716G>A; rs16947, c.2850C>T; rs1135840, c.4180G>C), *46 (rs28371696, c.77G>A; rs28371710, c.1716G>A; rs16947, c.2850C>T; rs1135840, c.4180G>C), *49 (rs1065852, c.100C>T; rs1135822, c.1611T>A; rs1135840, c.4180G>C), *53 (rs1135822, c.1611T>A), *69 (rs1065852, c.100C>T; rs16947, c.2850C>T; rs28371725, c.2988G>A; rs1135840, c.4180G>C), *114 (rs1065852, c.100C>T; rs5030865, c.1758G>A; rs16947, c.2850C>T; rs1135840, c.4180G>CDUP: complete gene duplications) Clinical Sensitivity: Drug-dependent. Methodology: Polymerase chain reaction (PCR) and fluorescence monitoring. **Sequencing is only performed if needed to characterize a duplicated CYP2D6 gene.** Analytical Sensitivity and Specificity: Greater than 99% **Methodology: Sequencing**	
Echovirus Antibodies	ECHOV	**Reported:** 7–**13** days	2/22/22
FISH for Aggressive B-cell Lymphoma	FABCEL	**Days Performed: 5** days per week **Reported: 3–5** days	effective immediately
FISH for Aggressive B-Cell Lymphoma Blood	FABCFP	**Days Performed: 5** days per week **Reported: 3–5** days	effective immediately
FISH for Aggresive B-Cell Lymphoma Bone Marrow	FABCBM	**Days Performed: 5** days per week **Reported: 3–5** days	effective immediately
FISH for ALK Cyto Block	ALKCB	**Reported: 5** days	effective immediately
FISH for BCL2 (18q21) Tissue	BCL2FT	**Days Performed: 5** days per week **Reported: 3**–5 days	effective immediately
FISH for BCL2 Blood	BCL2FH	**Days Performed: 5** days per week **Reported: 3**–5 days	effective immediately
FISH for BCL2 Bone Marrow	BCL2FM	**Days Performed: 5** days per week **Reported: 3**–5 days	effective immediately
FISH for BCL6 (3q27) Tissue	BCL6FT	**Days Performed: 5** days per week, **8:00 am–4:30 pm** **Reported: 3–5** days	effective immediately
FISH for BCL6 Blood	BCL6FH	**Days Performed: 5** days per week **Reported: 3**–5 days	effective immediately
FISH for BCL6 Bone Marrow	BCL6FM	**Days Performed: 5** days per week **Reported: 3**–5 days	effective immediately
FISH for CCND1 Blood	CCND1F	**Days Performed: 5** days per week **Reported: 3**–5 days	effective immediately
FISH for CCND1 Bone Marrow	CCND1M	**Days Performed: 5** days per week **Reported: 3**–5 days	effective immediately
FISH for CCND1 (Tissue)	CCND1T	**Days Performed: 5** days per week **Reported: 3**–5 days	effective immediately
FISH for IgH/BCL2 Blood	FSHFCL	**Days Performed: 5** days per week **Reported: 3**–5 days	effective immediately
FISH for IGH/BCL2 Bone Marrow	FSFCLM	**Reported: 3**–5 days	effective immediately
FISH for IGH/BCL2 Tissue	T1418	**Reported: 3**–5 days	effective immediately
FISH for IgH/CCND1 Blood	FSHMCL	**Days Performed: 5** days per week **Reported: 3**–5 days	effective immediately

Test Changes (Cont.)

Test Name	Order Code	Change	Effective Date
FISH for IGH/CCND1 Bone Marrow	FSMCLM	**Days Performed: 5** days per week **Reported: 3**–5 days	effective immediately
FISH for IGH/CCND1 Tissue	T1114	Reported: 3–5 days	effective immediately
FISH for IGH/MYC/ CEP8 Blood	814FSH	**Days Performed: 5** days per week **Reported: 3**–5 days	effective immediately
FISH for IGH/MYC/ CEP8 Bone Marrow	814FSM	**Days Performed: 5** days per week **Reported: 3**–5 days	effective immediately
FISH for IGH/MYC/ CEP8 Tissue	T814	**Days Performed: 5** days per week **Reported: 3**–5 days	effective immediately
FISH for MALT 1 (18q21)	MALT1	**Reported: 5** days	effective immediately
FISH for MYC (8q24) Blood	MYCFSH	**Days Performed: 5** days per week **Reported: 3**–5 days	effective immediately
FISH for MYC (8q24) Bone Marrow	MYCFSM	**Days Performed: 5** days per week **Reported: 3**–5 days	effective immediately
FISH for MYC (8q24) Tissue	MYC	**Days Performed: 5** days per week **Reported: 3**–5 days	effective immediately
FISH for YqH	YQHFSH	**Reported: 5** days **CPT:** 88273, 88271 **(x2)** **Price: $638.00**	2/3/22
Hirsutism Evaluation Panel	HIRSUT	**Reference Range:** Dehydroepiandrosterone Sulfate (DHEASA) Female 0–6 Days: 108–607 µg/dL 7–30 Days: 32–431 µg/dL 1–5 Months: 3–124 µg/dL 6–35 Months: 0–29 µg/dL 3–6 Years: 0–47 µg/dL 7–9 Years: 5–94 µg/dL 10–14 Years: 22–255 µg/dL 15–19 Years: 63–373 µg/dL **20–24 Years: 148–407 µg/dL** **25–34 Years: 99–340 µg/dL** **35–44 Years: 61–337 µg/dL** **45–54 Years: 35–256 µg/dL** **55–64 Years: 19–205 µg/dL** **65–74 Years: 9–246 µg/dL** **75–99 Years: 12–154 µg/dL** Tanner Stage I: 7–126 µg/dL Tanner Stage II: 13–241 µg/dL Tanner Stage III: 32–446 µg/dL Tanner Stage IV & V: 65–371 µg/dL Male 0–6 Days: 108–607 µg/dL 7–30 Days: 32–431 µg/dL 1–5 Months: 3–124 µg/dL 6–35 Months: 0–33 µg/dL 3–6 Years: 0–44 µg/dL 7–9 Years: 5–115 µg/dL 10–14 Years: 22–332 µg/dL 15–19 Years: 88–483 µg/dL **20–24 Years: 211–492 µg/dL** **25–34 Years: 160–449 µg/dL** **35–44 Years: 89–427 µg/dL** **45–54 Years: 44–331 µg/dL** *(continued on page 9)*	2/22/22

Test Changes (Cont.)

Test Name	Order Code	Change	Effective Date
Hirsutism Evaluation Panel *(continued from page 8)*		**55–64 Years: 52–295 µg/dL** **65–74 Years: 34–249 µg/dL** **75–99 Years: 16–123 µg/dL** Tanner Stage I: 7–209 µg/dL Tanner Stage II: 28–260 µg/dL Tanner Stage III: 39–390 µg/dL Tanner Stage IV & V: 81–488 µg/dL **Note:** *Other component ranges will not change*	
HIV 1 Drug Resistance by Next Generation Sequencing	HIVNGS	**Specimen Requirement: 3** mL plasma from EDTA (Lavender) tube; Minimum **2.5** mL; Frozen; Separate plasma from cells within 24 hours and transfer plasma to a standard aliquot tube. Please submit most recent viral load and test date, if available.	2/22/22
JAK2 V617F Mutation Detection Blood	JAK2	**Clinical Information:** This assay uses **Droplet Digital PCR** to detect a JAK2 V617F mutation in suspected non-CML myeloproliferative disorders or overlap myelodysplastic/myeloproliferative disease. **Methodology: Droplet Digital Polymerase Chain Reaction (PCR)** **Days Performed: 3** days per week **Reported: 5** days **Price: $561.00**	effective immediately
JAK2 V617F Mutation Detection Bone Marrow	JAK2M	**Clinical Information:** This assay uses **Droplet Digital PCR** to detect a JAK2 V617F mutation in suspected non-CML myeloproliferative disorders or overlap myelodysplastic/myeloproliferative disease. **Methodology: Droplet Digital Polymerase Chain Reaction (PCR)** **Days Performed: 3** days per week **Reported: 5** days	effective immediately
Lead, Blood	LEAD2	**Reference Range**: **<3.5** ug/dL	effective immediately
Lipoprotein Electrophoresis	LIPOEL	**Stability:** Ambient: After separation from cells: 1 day Refrigerated: After separation from cells: **7** days Frozen: Unacceptable	2/22/22
Mycoplasma Cult Non Urogenital	UMPLAS	**Clinical Information: Positives are reported as soon as detected.** **Reported: 11** days	2/22/22
MYD88 L265P Mutation Analysis	MYD88	**Methodology: Droplet Digital Polymerase Chain Reaction (PCR)** **Days Performed: 3** days per week **Reported: 5** days	effective immediately
MYD88 L265P Mutation Analysis Bone Marrow	MYD88M	**Methodology: Droplet Digital Polymerase Chain Reaction (PCR)** **Days Performed: 3** days per week **Reported: 5** days	effective immediately
OSHA Zinc Protoporphyrin; Test	OSHALZ	**Clinical Information: The Centers for Disease Control and Prevention (CDC) recommends a blood lead reference value of less than 3.5 µg/dL (Update of the Blood Lead Reference Value – United States, 2021). The CDC's updated "Recommended Actions Based on Blood Lead Level" can be accessed at www.cdc.gov. Consult your State Department of Health and/or applicable regulatory agencies for specific guidance on testing follow up and patient management.** **Reference Range:** **Lead (LEAD1): <3.5** ug/dL ZPP, whole blood (INDZP1): 0–40 ug/dL ZPP to heme ratio (INDZP2) 0–69 umol ZPP/mol heme	effective immediately
Polio Neutralization	PNEUT	**Reported:** 7–**13** days	2/22/22
Polymyositis and Dermatomyositis Panel	MYOSPL	**Stability:** Ambient: 48 hours Refrigerated: 2 weeks Frozen: **1 month** **Met0**oblot (IB), Qualitative Immunoprecipitation **Semi Quantitative Enzyme Linked Immunosorbent Assay** Semi-Quantitative Multiplex Bead Assay	2/22/22

Test Changes (Cont.)

Test Name	Order Code	Change	Effective Date
Polymyositis Panel	POLMYO	**Stability:** Ambient: 48 hours Refrigerated: 2 weeks Frozen: **1 month** **Methodology:** Immunoprecipitation **Semi Quantitative Enzyme Linked Immunosorbent Assay** Semi-Quantitative Multiplex Bead Assay	2/22/22
Schistosoma IgG Ab	SCHIST	**Stability:** Ambient: After separation from cells: **48 hours** Refrigerated: After separation from cells: **2 weeks** Frozen: After separation from cells: 1 month **Methodology: Semi Quantitative Enzyme Linked Immunosorbent Assay** **Reference Range: Less than 9 U: Negative–No significant level of Schistosoma IgG antibody detected.; 9–11 U: Equivocal–Recommend repeat testing in 2-4 weeks with fresh sample.; Greater than 11 U: Positive–IgG antibodies to Schistosoma detected, which may suggest current or past infection.** **Reported: 2–7** days	2/22/22
Supersaturation Profile, 24 Hour Urine	SSAT24	**Stability:** Ambient: Unacceptable Refrigerated: 14 days Frozen: **Unacceptable**	2/2/22
T3 Uptake	T3U	**Specimen Requirement:** 1 mL serum from Serum Separator (Gold) tube; Refrigerated *OR* 1 mL plasma from EDTA (Lavender) tube; Refrigerated *OR* 1 mL plasma from Lithium heparin Plasma Separator (Light Green) tube; Refrigerated **Note:** *Sodium or Lithium heparin (Green) tube and Sodium heparin Plasma Separator (Light Green) tube will no longer be accepable specimens*	2/22/22
Warfarin Sensitivity (CYP2C9, CYP2C cluster, CYP4F2, VKORC1) Genotyping	WRFSEN	**For interface clients only: Test build may need to be modified** **Includes:** CYP2C9 Genotype CYP4F2 Genotype VKORC1 Genotype **CYP2C Cluster Genotype** **CYP2C Cluster Phenotype** **CYP4F2 Phenotype** **VKORC1 Phenotype** Interpretation **Note:** *CYP2C8 Genotype will be removed* **Test Name:** Previously Warfarin Sensitivity (CYP2C8, CYP2C9, CYP4F2, VKORC1) Genotyping **Clinical Limitation:** Only the targeted CYP2C9, CYP2C cluster, CYP4F2, and VKORC1 variants will be detected by this panel, and assumptions about phase and content are made to assign alleles. Publicly available sources such as the www.pharmvar.org or www.pharmgkb.org provide guidance on phenotype predictions and allele frequencies. Diagnostic errors can occur due to rare sequence variations. Risk of therapeutic failure or adverse reactions with CYP2C9 substrates may be affected by genetic and nongenetic factors that are not detected by this test. This result does not replace the need for therapeutic drug or clinical monitoring. **Clinical Information**: Background Information **for Warfarin Sensitivity (CYP2C9, CYP2C cluster, CYP4F2, VKORC1) Genotyping:** Characteristics: Warfarin sensitivity can lead to a life-threatening overdose event such as excessive bleeding. Genetic variation is recognized to explain a large proportion of variability in warfarin dose requirements. This test may predict individual warfarin sensitivity and non-standard dose requirements. The cytochrome P450 (CYP) isozyme 2C9 is involved in the metabolism of many drugs. Variants in the gene that codes CYP2C9 may influence pharmacokinetics of substrates such as warfarin, and may predict or explain nonstandard dose requirements, therapeutic failure, or adverse reactions. Variants in the VKORC1 and CYP4F2 genes may predict sensitivity to warfarin. **The** *(continued on page 11)*	2/22/22

Test Changes (Cont.)

Test Name	Order Code	Change	Effective Date
Warfarin Sensitivity (CYP2C9, CYP2C cluster, CYP4F2, VKORC1) Genotyping *(continued from page 10)*	WRFSEN	**CYP2C cluster variant, rs12777823, common in people of African descent, with a minor allele frequency of approximately25 percent, is found to be associated with warfarin dose in this population.** Genetic information and nongenetic factors can be used in combination with warfarin dose calculators, such as through www.WarfarinDosing.org. Inheritance: Autosomal codominant. Cause: CYP2C9 and **CYP2C cluster variants are associated with reduced dose requirements.** The VKORC1*2 allele is associated with reduced expression of the warfarin target, vitamin K epoxide reductase (VKOR), and a reduced dose requirement. **The CYP4F2 variant is associated with an increased dose requirement. Clinical** Sensitivity: Genetic factors and known non-genetic factors account for approximately 50 percent of the variability in warfarin dose. Analytical Sensitivity and Specificity: Greater than 99 percent. **Please note the information contained in this report does not contain medication recommendations, and should not be interpreted as recommending any specific medications. Any dosage adjustments or other changes to medications should be evaluated in consultation with a medical provider.**	2/22/22

New Tests

Test Name	Order Code	Change	Effective Date
Cytomegalovirus, Newborn Saliva	CMVSAL	**Note: New test was announced in the November 2021 update, but financial information was not available at that time.** CPT: 87496 Price: $135.00	effectively immediately
von Willebrand Disease (VWF) Sequencing	VWFSEQ	**Includes:** von Willebrand Disease Interpretation **Special Information:** Serum, plasma, grossly hemolyzed or frozen specimens will be rejected. **Clinical Limitation:** Exons 26 and 34 are not covered by sequencing, and deletion/duplication analysis is not available for this gene. **Clinical Information:** Must submit Patient History for von Willebrand (VWD) Testing form with order. Informed consent forms are recommended and available through Client Services at 216.444.5755 or 800.628.6816. **Specimen Requirement:** 3 mL whole blood in EDTA (Lavender) tube; Minimum 3 mL; Refrigerated *OR* 3 mL whole blood in ACD A or B (Yellow) tube; Minimum 3 mL **Stability:** Ambient: 72 hours Refrigerated: 1 week Frozen: Unacceptable **Methodology:** Massive Parallel Sequencing **Days Performed:** Varies **Reported:** 3–4 weeks	2/26/22

Fee Increases

Test Name	Order Code	List Fee	CPT Code	Effective Date
Bartonella PCR, tissue	TBART	$535.00	87471	effective immediately

Fee Reductions

Test Name	Order Code	List Fee	CPT Code	Effective Date
FISH for YqH	YQHFSH	$638.00	"88273 (x1) 88271 (x2)"	2/3/22
JAK2 V617F Mutation Detection Blood	JAK2	$561.00		effective immediately

Discontinued Tests

Test Name	Order Code	Test Information	Effective Date
Acetylcholine Receptor Antibodies with reflex	ACHABS	Test will no longer be available. Recommended replacement tests: Acetylcholine Rec Binding Ab (ACHRAB), Acetylcholine Rec Blocking Ab (ACEBAB) and Acetylcho R Mod Ab (ACEMOD)	2/26/22
Familial Mediterranean Fever (MEFV) Sequencing	FAMMED	Test will no longer be orderable. For lab use only.	2/22/22
Heterophile Ab (Inf. Mono) LA w/Titer RFLX	HETAB	Test will no longer be available.	effective immediately
NAbFeron Ab	NABFAB	Test will no longer be available.	2/22/22
von Willebrand Disease, Type 2A (VWF) Sequencing Exon 28 with Reflex to 9 Exons	VWFE28	Test will no longer be available. Recommended new replacement test available 2/26/2022: von Willebrand Disease (VWF) Sequencing (VWFSEQ)	2/22/22