Cleveland Clinic

Cleveland Clinic Laboratories

Technical Update • September 2020

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
12	Alpha-2-Antiplasmin				■									
5	Amikacin, Random					■								
12	ANA, Body Fluid				■									
5	Anti-Alpha Fodrin Ab, IgA					■	■		■		■	■		
5	Anti-Alpha Fodrin Ab, IgG					■	■		■		■	■		
5	Anti Alpha Fodrin Ab, IgG & IgA					■	■		■		■	■		
10	Anti-Nuclear Antibodies by IFA, Body Fluid			■										
6	Antithrombin Assay									■				
6	Arsenic, Hair						■			■				
6	Blastomyces Antigen							■						
6	Cardiolipin Antibodies					■				■				
6	Cardiolipin IgA Antibodies					■				■				
6	Cardiolipin IgG Antibodies					■				■				
6	Cardiolipin IgM Antibodies					■				■				
6	Catecholamines Fractionated by LC-MS/MS, Urine Free					■								
7	CD19 Count						■	■				■	■	
7	Digoxin					■								
7	DNA Autoantibodies, Double Stranded					■	■				■	■		
7	Factor II Assay									■				
7	Factor V Assay									■				
8	Factor VII Assay									■				

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
8	Factor VIII Assay									■				
8	Factor IX Assay									■				
8	Factor X Assay									■				
8	Factor XI Assay									■				
8	Factor XII Assay									■				
12	Factor XIII Assay				■									
10	FISH for DUSP22-IRF4 Tissue			■										
11	FISH for TP63 and DUSP22-IRF4 Panel			■										
11	FISH for TP63 Tissue			■										
9	Gentamicin, Random					■								
9	Helicobacter pylori Ab, IgA											■		
11	Histone IgG Aby			■										
12	Histone IgG Antibody				■									
9	HLA-B*58:01		■											
9	Hypercoagulation Diagnostic Interpretive Panel									■				
9, 12	JAK2 Exon 12-16 Mutation Detection Bone Marrow												■	■
9	Lithium					■								
9	Lupus Anticoagulant Diagnostic Interpretive Panel									■				
9	Phenobarbital					■								
9	Plasminogen Functional									■				
9	Protein C Functional									■				
12	Prothrombin Time and PTT Elevation Diagnostic Panel													■
12	PTT Elevation Diagnostic Panel													■
9	Th/To Antibody					■					■			
10	Tobramycin, Random					■								
10	Von Willebrand Factor Antigen									■				

Cytogenetic Karyotyping & Chromosomal Microarray Testing

Cleveland Clinic Laboratories (CCL) remains committed to supporting patients and providers during the COVID-19 pandemic.

To meet the current demands for COVID-19 PCR testing, Cleveland Clinic Laboratories is temporarily reassigning some of our molecular pathology technologists to this effort.

As a result, cytogenetic karyotyping and chromosomal microarray testing will temporarily be sent out to a partnered reference laboratory. This will allow COVID-19 testing to continue uninterrupted while we increase our testing capacity.

What Tests Are Affected

If you have any questions, please contact your CCL Account Manager or Client Services at 800.628.6818.

CCF Test	CCF Test Code	CCF TAT
1. Chromosome Analysis, Bone Marrow	CHRBMH	8–12 Days
2. Chromosome Analysis, Bone Marrow w/ Reflex SNP Array	BMCHF	28–30 Days
3. Chromosome Analysis, Leukemic Blood	CHRBLL	8–12 Days
4. Chromosome Analysis, Tissue (Fibroblasts)	CHRTIS	21 Days
5. Chromosome Analysis, Solid Tumor (Lymph Nodes)	CHRSOL	10 Days
6. Chromosomal Microarray, Constitutional Blood	CRMSNP	14 Days
7. Chromosomal Microarray, Leukemic Blood	BLLSNP	14 Days
8. Chromosomal Microarray, Products of Conception	POCSNP	14 Days
9. Chromosomal Microarray, Bone Marrow	BMHSNP	14 Days

(continued on page 4)

Special Communication (continued from page 3)

Send-Out Test Details

Quest – Test Name	Quest Test Code	Expected TAT
1. Chromosome Analysis, Hematologic Malignancy	14600	9 Days
2. Chromosome Analysis, Hematologic Malignancy; Chromosomal Microarray, Hematologic Malignancy, ClariSure® Oligo-SNP	14600 90961	9 Days 13 Days
3. Chromosome Analysis, Hematologic Malignancy	14600	9 Days
4. Chromosome Analysis, Tissue	14593	16 Days
5. Chromosome Analysis, Solid Tumor Chromosome Analysis, Lymph Node	14603 (solid tumor) 14602 (lymph node)	22 Days 11 Days
6. Chromosomal Microarray, Postnatal, ClariSure® Oligo-SNP	16478	13–16 Days
7. Chromosomal Microarray, Hematologic Malignancy, ClariSure® Oligo-SNP	90961	13 Days
8. Chromosomal Microarray, POC, ClariSure® Oligo-SNP	90929	13 Days
9. Chromosomal Microarray, Hematologic Malignancy, ClariSure® Oligo-SNP	90961	13 Days

Timing

On Monday, August 24, 2020, Cleveland Clinic Laboratories will temporarily send these tests to Quest Diagnostics.

CCL estimates that this process will continue for several months. We will return these tests in-house as soon as possible and communicate any changes once they are available.

Test Turnaround Time

In some instances, we anticipate that turnaround times (TAT) may be impacted. CCL will do everything possible to minimize delays.

Ordering & Results

There are no changes to the ordering process.

Test results will continue to be available via the Atlas portal or faxed results. Please contact your CCL Sales representative as necessary for further support in retrieving these results.

Billing

At this time, we do not anticipate any changes to the billing process.

Pricing will reflect costs associated with sending out these tests. A Cleveland Clinic Laboratories representative will communicate any price changes directly to clients.

Test Changes

Test Name	Order Code	Change	Effective Date
Amikacin, Random	AMIKRA	**Special Information:** Do not collect in a gel separator tube. **Intended for collections outside of pre or post-dose. Please utilize the time specific assay (e.g., pre-dose amikacin or post-dose amikacin) when applicable.**	9/8/20
Anti-Alpha Fodrin Ab, IgA	FODIGA	**Special Information: Grossly hemolyzed specimens will be rejected. Lipemic specimens and icteric specimens are unacceptable. Other causes for rejection include bacterial contamination and non-serum specimen types.** **Specimen Requirement: 2 mL** serum from a serum separator (gold) tube; Minimum: **0.5 mL (Note: This volume does NOT allow for repeat testing); Separate serum from cells within 1 hour of collection, transfer into a standard plastic aliquot tube and freeze; Separate specimens should be submitted when multiple tests are ordered; Frozen** *OR* **2 mL** serum from a plain no additive (red) tube; Minimum: **0.5 mL (Note: This volume does NOT allow for repeat testing); Separate serum from cells within 1 hour of collection, transfer into a standard plastic aliquot tube and freeze; Separate specimens should be submitted when multiple tests are ordered; Frozen** **Stability:** Ambient: **7** days Refrigerated: 14 days Frozen: 60 days; **Stable x 1 freeze/thaw cycle** **Methodology:** Enzyme-**Linked Immunosorbent Assay (ELISA)** **Days Performed: Monday–Friday** **Reported: 13–14** days	9/24/20
Anti-Alpha Fodrin Ab, IgG	FODIGG	**Special Information: Grossly hemolyzed specimens will be rejected. Lipemic specimens and icteric specimens are unacceptable. Other causes for rejection include bacterial contamination and non-serum specimen types.** **Specimen Requirement: 2 mL** serum from a serum separator (gold) tube; Minimum: **0.5 mL (Note: This volume does NOT allow for repeat testing); Separate from cells within 1 hour of collection, transfer to a standard plastic aliquot tube and freeze; Separate specimens should be submitted when multiple tests are ordered; Frozen** *OR* **2 mL** serum from a plain no additive (red) tube; Minimum: **0.5 mL (Note: This volume does NOT allow for repeat testing); Separate from cells within 1 hour of collection, transfer to a standard plastic aliquot tube and freeze; Separate specimens should be submitted when multiple tests are ordered; Frozen** **Stability:** Ambient: **7** days Refrigerated: 14 days Frozen: 60 days; **Stable x 1 freeze/thaw cycle** **Methodology:** Enzyme-**Linked Immunosorbent Assay (ELISA)** **Days Performed: Monday–Friday** **Reported: 13–14** days	9/24/20
Anti Alpha Fodrin Ab, IgG & IgA	FODAG	**Special Information: Grossly hemolyzed specimens will be rejected. Lipemic specimens and icteric specimens are unacceptable. Other causes for rejection are bacterial contamination and non-serum specimen types.** **Specimen Requirement:** 2 mL serum from a serum separator (gold) tube; Minimum: **0.5 mL (Note: This volume does NOT allow for repeat testing); Separate serum from cells within 1 hour of collection, transfer into a standard plastic aliquot tube and freeze; Separate specimens should be submitted when multiple tests are ordered; Frozen** *OR* 2 mL serum from a plain no additive (red) tube; Minimum: **0.5 mL (Note: This volume does NOT allow for repeat testing); Separate serum from cells within 1 hour of collection, transfer into a standard plastic aliquot tube and freeze; Separate specimens should be submitted when multiple tests are ordered; Frozen** **Stability:** Ambient: **7** days Refrigerated: 14 days Frozen: 60 days; **Stable x 1 freeze/thaw cycle** **Methodology:** Enzyme-**Linked Immunosorbent Assay (ELISA)** **Days Performed: Monday–Friday** **Reported: 8–15** days	9/24/20

Test Changes (Cont.)

Test Name	Order Code	Change	Effective Date
Antithrombin Assay	AT3ASY	**Reference Range:** 0–1 Days: **42–92%** 2–5 Days: **44–98%** 6–30 Days: 51–114% 1–3 Months: **78–128%** 4–11 Months: 89–131% 1–5 Years: **93–152%** 6–10 Years: 102–144% 11–16 Years: 87–145% 17–99 Years: 84–138%	Effective immediately
Arsenic, Hair	ARSHR	**Specimen Requirement: 0.2 g** hair in a clean container; Minimum: 0.05 g; HEAVY METALS FORM REQUIRED to meet State Health Department requirements; Cut hair near scalp, at least 3 inches long and the width of a pencil; Do not apply tape to hair; Specimen source is required; Ambient **Reference Range:** 0–15 Years: Not established 16 Years and older: **< 1.0 mcg/g hair**	9/3/20
Blastomyces Antigen	BLAS	**For Interfaced Clients Only: Test build may need to be modified**	Effective immediately
Cardiolipin Antibodies	CARDIO	**Note:** *Special Information will be removed.* **Clinical Information: This test is used as an aid in diagnosis of anti-phospholipid syndrome. The test may occasionally be positive in patients with a range of underlying conditions, secondary syphilis, HIV infection, active Hepatitis C, endocarditis, among others. Clinical correlation is required.** **Reference Range:** Cardiolipin IgG Antibodies: **< 15.0 GPL** Cardiolipin IgM Antibodies: **< 12.5 MPL** Cardiolipin IgA Antibodies: **< 12.0 APL**	9/3/20
Cardiolipin IgA Antibodies	CARDIA	**Note:** *Special Information will be removed.* **Clinical Information: This test is used as an aid in diagnosis of anti-phospholipid syndrome. The test may occasionally be positive in patients with a range of underlying conditions, secondary syphilis, HIV infection, active Hepatitis C, endocarditis, among others. Clinical correlation is required. Negative: < 12.0 APL; Indeterminate: 12.1 to 20.0 APL; Positive: > 20.0 APL** **Reference Range: < 12.0 APL**	9/3/20
Cardiolipin IgG Antibodies	CARDIG	**Note:** *Special Information will be removed.* **Clinical Information: This test is used as an aid in diagnosis of anti-phospholipid syndrome. The test may occasionally be positive in patients with a range of underlying conditions, secondary syphilis, HIV infection, active Hepatitis C, endocarditis, among others. Clinical correlation is required. Negative: < 15.0 GPL; Indeterminate: 15.1 to 20.0 GPL; Positive: > 20.0 GPL** **Reference Range: < 15.0 GPL**	9/3/20
Cardiolipin IgM Antibodies	CARDIM	**Note:** *Special Information will be removed.* **Clinical Information: This test is used as an aid in diagnosis of anti-phospholipid syndrome. The test may occasionally be positive in patients with a range of underlying conditions, secondary syphilis, HIV infection, active Hepatitis C, endocarditis, among others. Clinical correlation is required. Negative: < 12.5 MPL; Indeterminate: 12.5 to 20.0 MPL; Positive: > 20.0 MPL** **Reference Range: < 12.5 MPL**	9/3/20
Catecholamines Fractionated by LC-MS/MS, Urine Free	URCAT2	**Note:** *Catecholamines, 24-hour or random urine will be added as an alias name.*	9/3/20

Test Changes (Cont.)

Test Name	Order Code	Change	Effective Date
CD19 Count	ABS19	**For Interfaced Clients Only: Test build may need to be modified** **Includes:** CD19% CD19 absolute number **Specimen Requirement:** 4 mL whole blood in an EDTA (lavender) tube; Draw **one** 2 mL EDTA tube; Ambient **Stability:** Ambient: Maintain at room temperature when transporting to laboratory. **Specimen stability is < 72 hours old. Samples > 72 hours old will be rejected.** **CPT:** 86355 x 1	9/1/20
Digoxin	DIG	**Special Information:** Do not collect in a gel separator tube. **A specimen should be collected at least 6 to 8 hours after drug administration. By this time, serum digoxin levels are expected to be in equilibrium with tissue levels and should correlate with pharmacologic effects.**	9/8/20
DNA Autoantibodies, Double Stranded	DSDNA	**Special Information: Grossly hemolyzed specimens will be rejected. Lipemic specimens and icteric specimens are unacceptable. Other causes for rejection include bacterial contamination and non-serum specimen types.** **Specimen Requirement:** 1 mL serum from a serum separator (gold) tube; Minimum: **0.3 mL (Note: This volume does NOT allow for repeat testing); Separate serum from cells within 1 hour of collection, transfer into a standard plastic aliquot tube and freeze; Separate specimens should be submitted when multiple tests are ordered; Frozen** *OR* 1 mL serum from a plain no additive (red) tube; Minimum: **0.3 mL (Note: This volume does NOT allow for repeat testing); Separate serum from cells within 1 hour of collection, transfer into a standard plastic aliquot tube and freeze; Separate specimens should be submitted when multiple tests are ordered; Frozen** **Stability:** Ambient: 7 days Refrigerated: **14 days** Frozen: **60 days; Stable x 1 freeze/thaw cycle** **Days Performed:** Monday–Friday **Reported:** 8–**15** days	9/24/20
Factor II Assay	FIIC	**Reference Range:** 0–1 Days: **29–72%** 2–5 Days: **36–96%** 6–30 Days: 37–106% 1–3 Months: **50–109%** 4–11 Months: 66–120% **1–5 Years: 78–120%** **6–10 Years: 74–111%** **11–16 Years: 67–108%** **17–99 Years: 77–151%**	Effective immediately
Factor V Assay	FVC	**Reference Range:** 0–1 Days: **42–100%** 2–5 Days: **53–134%** 6–30 Days: **73–124%** 1–3 Months: **57–122%** 4–11 Months: **65–118%** **1–5 Years: 93–118%** **6–10 Years: 74–108%** **11–16 Years: 65–92%** **17–99 Years: 73–139%**	Effective immediately

Test Changes (Cont.)

Test Name	Order Code	Change	Effective Date
Factor VII Assay	FVIIC	**Reference Range:** 0–1 Days: **23–116%** 2–5 Days: **29–160%** 6–30 Days: **35–154%** 1–3 Months: 32–160% 4–11 Months: **39–142%** 1–5 Years: 45–130% 6–10 Years: **43–134%** 11–16 Years: **48–129%** 17–99 Years: 55–160%	Effective immediately
Factor VIII Assay	FVIIIC	**Reference Range:** 0–1 Days: 22–207% 2–5 Days: 22–179% 6–30 Days: **26–182%** 1–3 Months: **34–145%** 4–11 Months: **38–127%** **1–5 Years: 59–165%** **6–10 Years: 58–153%** **11–16 Years: 53–152%** **17–99 Years: 50–173%**	Effective immediately
Factor IX Assay	FIXC	**Reference Range:** 0–1 Days: 21–97% 2–5 Days: 21–97% 6–30 Days: 29–86% 1–3 Months: 29–120% 4–11 Months: **50–144%** 1–5 Years: **66–110%** 6–10 Years: 88–95% 11–16 Years: **83–130%** 17–99 Years: 77–173%	Effective immediately
Factor X Assay	FXC	**Reference Range:** 0–1 Days: **15–73%** 2–5 Days: 23–85% 6–30 Days: **38–93%** 1–3 Months: **43–115%** 4–11 Months: 46–127% 1–5 Years: **61–124%** 6–10 Years: **57–108%** 11–16 Years: 52–126% 17–99 Years: 73–163%	Effective immediately
Factor XI Assay	FXIC	**Reference Range:** 0–1 Days: 10–91% 2–5 Days: 23–120% 6–30 Days: 27–109% 1–3 Months: **42–134%** 4–11 Months: **39–185%** 1–5 Years: **57–207%** 6–10 Years: **53–165%** 11–16 Years: **51–134%** 17–99 Years: 68–175%	Effective immediately
Factor XII Assay	FXIIC	**Reference Range:** 0–1 Days: **15–124%** **2–5 Days: 12–110%** 6–30 Days: **19–108%** **1–3 Months: 28–145%** **4–11 Months: 44–153%** **1–5 Years: 71–172%** **6–10 Years: 67–186%** **11–16 Years: 38–182%** **17–999 Years: 58–218%**	Effective immediately

Test Changes (Cont.)

Test Name	Order Code	Change	Effective Date
Gentamicin, Random	GENTRA	**Special Information:** Do not collect in a gel separator tube. **Intended for collections outside of pre or post-dose. Please utilize the time specific assay (e.g., pre-dose gentamicin or post-dose gentamicin) when applicable.** The aminoglycoside sisomicin cross-reacts with the QMS Gentamicin assay due to its structural similarity. Therefore, the results of this assay cannot be used to accurately quantify gentamicin serum or plasma levels in patients on sisomicin in combination with gentamicin.	9/8/20
Helicobacter pylori Ab, IgA	HPYLRA	**Stability:** Ambient: 1 day Refrigerated: 7 days Frozen: **1 year; 2 freeze/thaw cycles are acceptable**	9/1/20
HLA-B*58:01	HLAB58	**Test Name:** Previously HLA-B58	Effective immediately
Hypercoagulation Diagnostic Interpretive Panel	HYPER	**Reference Range:** *Please refer to reference range changes for Cardiolipin Antibodies (CARDIO).*	9/3/20
JAK2 Exon 12-16 Mutation Detection Bone Marrow	JAK2NM	**CPT:** 81403 x 1	Effective immediately
Lithium	LI	**Special Information: Draw immediately before next dose or at least 12 hours after dosing.**	9/8/20
Lupus Anticoagulant Diagnostic Interpretive Panel	LUPUSP	**Reference Range:** *Please refer to reference range changes for Cardiolipin Antibodies (CARDIO).*	9/3/20
Phenobarbital	PHEN	**Special Information:** Do not collect in a gel separator tube. **Draw once steady state is achieved.**	9/8/20
Plasminogen Functional	PLGFUN	**Reference Range:** 0–1 Days: **35–86%** 2–5 Days: 39–95% 6–30 Days: **35–87%** 1–3 Months: 48–104% 4–11 Months: **62–123%** **1–5 Years: 70–133%** **6–10 Years: 67–121%** **11–16 Years: 61–116%** **17–99 Years: 69–137%**	Effective immediately
Protein C Functional	PRCFUN	**Reference Range:** 0–1 Days: 20–61% 2–5 Days: **24–74%** 6–30 Days: **25–75%** 1–3 Months: 33–92% 4–11 Months: **44–93%** 1–5 Years: **48–106%** 6–10 Years: 53–107% 11–16 Years: 65–128% 17–99 Years: 76–147%	Effective immediately
Th/To Antibody	THTO	**Clinical Information:** The Th/To is a component of the 7-2/MRP RNP. Most of the 7-2/MRP RNP is found in the GC region of the nucleolus and < 1% of this snoRNP appears located in mitochondria. The Th/To antibodies are present in 10–19% of patients with limited SSc, in 11% of patients with diffuse cutaneous SSc, and in 3% of patients with primary Raynaud's disease. Anti-Th/To antibody has been shown to be highly specific for patients with SSc. The anti-Th/To antibody detection is an in-house bioassay performed at **Esoterix** for a qualitative determination of Th/To antibody in serum by immunoprecipitation. The Th/To antibody assay will be labeled as an "Analytic Specific Reagent (ASR)." **Days Performed: Monday–Thursday** **Reported:** 11–15 days	Effective immediately

Test Changes (Cont.)

Test Name	Order Code	Change	Effective Date
Tobramycin, Random	TOBRRA	**Special Information:** Do not collect in a gel separator tube. **Intended for collections outside of pre or post-dose. Please utilize the time specific assay (e.g., pre-dose tobramycin or post-dose tobramycin) when applicable.** Samples that contain tobramycin in combination with either amikacin or kanamycin cannot be reliably quantitated by this assay.	9/8/20
Von Willebrand Factor Antigen	VWF	**Reference Range:** **0–1 Days: 37–314%** **2–5 Days: 50–278%** 6–30 Days: 19–**269%** **1–3 Months: 58–226%** **4–11 Months: 33–216%** **1–5 Years: 60–131%** **6–10 Years: 44–158%** **11–16 Years: 46–168%** 17–99 Years: 50–173%	Effective immediately

New Tests

Test Name	Order Code	Change	Effective Date
Anti-Nuclear Antibodies by IFA, Body Fluid	BFANA	**Special Information:** This test reflexes to ANA Titer and Pattern Body Fluid at no additional charge if ANA by IFA is positive; this is to rule out false positive ANA by IFA. Bacterial contamination, gross hemolysis, lipemic or icteric specimens, and specimens other than indicated are unacceptable. **Clinical Information:** Anti-nuclear antibodies (ANA) are commonly found in a variety of autoimmune diseases. Antibody frequency increases with age in apparently healthy people. ANA patterns on HEp-2 slides provide only general clues about particles (chromatin, nucleosomes, and spliceosomes). ANA patterns (other than centromere pattern) are not reliably correlated with the presence of specific antibodies and must be further evaluated by enzyme immunoassay using individual extractable nuclear antigens (ENA). **Specimen Requirement:** 1 mL body fluid in a sterile container; Minimum: 0.3 mL (Note: This volume does NOT allow for repeat testing); Frozen **Stability:** Ambient: 7 days Refrigerated: 14 days Frozen: 60 days; Stable x 1 freeze/thaw cycle **Methodology:** Indirect Fluorescent Antibody (IFA) **Days Performed:** 7 days per week **Reported:** 8–15 days **CPT:** 86038 x 1 **Price:** $75.00 (non-discountable)	Effective immediately
FISH for DUSP22-IRF4 Tissue	DUIRFH	**Clinical Information:** This test is used for the identification of DUSP22-IRF4 rearrangements, as seen in various T-cell lymphomas. This assay employs a break-apart probe strategy and does not identify the translocation partner gene. **Specimen Requirement:** 4 μm formalin-fixed paraffin-embedded (FFPE) block; Minimum: 4 μm; Pre and post H&E with four unstained slides with defined marked areas for analysis; Ambient **Stability:** Ambient: FFPE slides at room temperature **Methodology:** Fluorescent In-Situ Hybridization (FISH) **Days Performed:** Monday–Friday **Reported:** 5 days **CPT:** 88377 x 1 **Price:** $588.00 (non-discountable)	10/6/20

New Tests (Cont.)

Test Name	Order Code	Change	Effective Date
FISH for TP63 and DUSP22-IRF4 Panel	TPDUFP	**Clinical Information:** This test is used for the identification of TP63 rearrangements and DUSP22-IRF4 rearrangements, as seen in various T-cell lymphomas. Both assays employ a break-apart probe strategy and do not identify the translocation partner gene. **Specimen Requirement:** 4 μm formalin-fixed paraffin-embedded (FFPE) block; Minimum: 4 μm; Pre and post H&E with six unstained slides with defined marked areas for analysis; Ambient **Stability:** Ambient: FFPE slides at room temperature **Methodology:** Fluorescent In-Situ Hybridization (FISH) **Days Performed:** Monday–Friday **Reported:** 5 days **CPT:** 88377 x 2 **Price:** $900.00 (non-discountable)	10/6/20
FISH for TP63 Tissue	TP63FH	**Clinical Information:** This test is used for the identification of TP63 rearrangements, as seen in various T-cell lymphomas. This assay employs a break-apart probe strategy and does not identify the translocation partner gene. **Specimen Requirement:** 4 μm formalin-fixed paraffin-embedded (FFPE) block; Minimum: 4 μm; Pre and post H&E with four unstained slides with defined marked areas for analysis; Ambient **Stability:** Ambient: FFPE slides at room temperature **Methodology:** Fluorescent In-Situ Hybridization (FISH) **Days Performed:** Monday–Friday **Reported:** 5 days **CPT:** 88377 x 1 **Price:** $588.00 (non-discountable)	10/6/20
Histone IgG Aby	HISTN	**Special Information:** Negative: < 1.0 units, Weak positive: 1.0–1.5 units, Moderate positive: 1.6–2.5 units, Strong positive: > 2.5 units. Results are obtained with the Inova QUANTA Lite Histone Enzyme-Linked Immunosorbent Assay (ELISA) kit. Histone values obtained with different manufacturers' assay methods may not be used interchangeably. The magnitude of the reported IgG levels cannot be correlated to an endpoint titer. **Clinical Information:** Anti-histone IgG antibody test is used as an aid in the diagnosis of idiopathic and drug-induced systemic lupus erythematosus. It may be positive in other systemic autoimmune diseases. Clinical correlation is required. **Specimen Requirement:** 1 mL serum from a serum separator (gold) tube; Minimum: 0.5 mL; Refrigerated **Stability:** Ambient: 24 hours Refrigerated: 7 days Frozen: 1 year; 2 freeze/thaw cycles are acceptable **Methodology:** Enzyme-Linked Immunosorbent Assay (ELISA) **Days Performed:** Thursday **Reported:** 1–8 days **CPT:** 86235 x 1 **Price:** $53.00 (non-discountable)	10/6/20

Fee Reductions

Test Name	Order Code	List Fee	CPT Code	Effective Date
JAK2 Exon 12-16 Mutation Detection Bone Marrow	JAK2NM	$542.00 (non-discountable)	81403	Effective immediately
Prothrombin Time and PTT Elevation Diagnostic Panel	PTPTTE	$511.00	85025, 85060, 85390, 85520, 85610, 85611, 85670, 85730, 85732 x 2	Effective immediately
PTT Elevation Diagnostic Panel	PTTEPL	$380.00	85390, 85520, 85610, 85670, 85730, 85732	Effective immediately

Discontinued Tests

Test Name	Order Code	Test Information	Effective Date
Alpha-2-Antiplasmin	A2PI	This test will no longer be available.	Effective immediately
ANA, Body Fluid	FANA	This test will no longer be available. Suggest ordering Anti-Nuclear Antibodies by IFA, Body Fluid (BFANA)	Effective immediately
Factor XIII Assay	FXIII	This test will no longer be available. Suggest ordering Factor XIII Antigen (F13AG)	10/13/20
Histone IgG Antibody	HISTON	This test will no longer be available. Suggest ordering Histone IgG Aby (HISTN)	10/6/20