Cleveland Clinic

Cleveland Clinic Laboratories

Technical Update • January 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
2	Allergen, Beta Lactoglobulin IgE						■	■						
2	Allergen, Tree Aspen IgE						■	■		■				
3	Bartonella Antibody Panel (IFA)						■	■		■	■		■	
3	Beta-2 Glycoprotein 1 Antibodies, IgA						■	■						
5	Bone marrow Cancer Chromosome Microarray + SNP													■
3	Carboxyhemoglobin										■			
3	D-Dimer											■		
5	DNA Extraction Blood			■										
3	DNA Extraction Bone Marrow (Buffy Coat)		■				■	■						
4	FISH for Plasma Cell Myeloma							■				■		
5	GCH1 Gene Analysis					■								
5	GCK (CH) DNA Sequencing Test					■								
5	GCK (NDM) DNA Sequencing Test					■								
4	Hematologic Neoplasm Next Generation Sequencing Panel Marrow						■							
4	Hematologic Neoplasm Next Generation Sequencing Panel Peripheral Blood						■							
5	Homocysteine, Total, Urine					■								
4	JAK2 Exon 12 – 16 Sequencing Blood												■	
4	Mitotane							■			■	■		
4, 5	MPL Mutation Analysis Blood												■	■
4, 5	Myeloid NGS Panel Peripheral Blood												■	■
4	Sex Hormone Binding Globulin										■	■		

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4	Synovial Fluid, Crystals ID and Staff Review							■						
4	Synovial Fluid, Routine Analysis							■						
4	Widal Panel						■							

Test Changes

Test Name	Order Code	Change	Effective Date
Allergen, Beta Lactoglobulin IgE	BLACGL	**Special Information: Multiple patient encounters/multiple specimen tubes should be avoided. Hemolyzed, icteric, or lipemic specimens will be rejected. This test is New York DOH approved.** **Clinical Information:** Reference Interval: Less than 0.10 kU/L–No significant level detected **(Class 0);** 0.10–0.34 kU/L–Clinical relevance undetermined **(Class 0/1);** 0.35–0.70 kU/L–Low **(Class 1);** 0.71–3.50 kU/L–Moderate **(Class 2);** 3.51–17.50 kU/L–High **(Class 3); 17.51–50.00 kU/L–Very High (Class 4); 50.01–100.00 kU/L–Very High (Class 5); > 100 kU/L–Very high (Class 6). Allergen results of 0.10–0.34 kU/L are intended for specialist use as the clinical relevance is undetermined. Even though increasing ranges are reflective of increasing concentrations of allergen-specific IgE, these concentrations may not correlate with the degree of clinical response or skin testing results when challenged with a specific allergen. The correlation of allergy laboratory results with clinical history and in vivo reactivity to specific allergens is essential. A negative test may not rule out clinical allergy or even anaphylaxis.** **Specimen Requirement: 0.25 mL** serum from a serum separator (gold) tube; Minimum: **0.25 mL plus 0.04 mL for each allergen ordered;** Remove serum from cells **ASAP or** within 2 hours of collection; **Transfer 0.25 mL serum plus 0.1 mL for each additional allergen ordered to a standard aliquot tube;** Refrigerated	1/21/20
Allergen, Tree Aspen IgE	ASPEN	**Special Information:** Hemolyzed, icteric or lipemic specimens will not be accepted. **This test is New York DOH approved.** **Specimen Requirement:** 0.5 mL serum from a plain no additive (red) tube; Minimum: **0.34 mL plus 0.04 mL for each allergen ordered; Separate serum from cells ASAP or within 2 hours of collection; Transfer 0.5 mL serum plus 0.1 mL for each additional allergen ordered to a standard aliquot tube; Ambient** *OR* 0.5 mL serum from a serum separator (gold) tube; Minimum: **0.34 mL plus 0.04 mL for each allergen ordered; Separate serum from cells ASAP or within 2 hours of collection; Transfer 0.5 mL serum plus 0.1 mL for each additional allergen ordered to a standard aliquot tube; Ambient** **Methodology: Enzyme Immunoassay (EIA)**	3/5/20

Test Changes (Cont.)

Test Name	Order Code	Change	Effective Date
Bartonella Antibody Panel (IFA)	BARTAB	**Special Information: Parallel testing is preferred, and convalescent specimens must be received within 30 days from receipt of acute specimens. Label specimens plainly as 'acute' or 'convalescent.' Hemolyzed, severely lipemic, or contaminated specimens will be rejected. This test is New York DOH approved.** **Clinical Information: May confirm a current or past exposure to B. henselae or B. quintana in a patient with typical signs and symptoms and a compatible exposure history.** **Specimen Requirement:** 1 mL serum from a **serum separator (gold)** tube; Minimum: 0.3 mL; **Parallel testing is preferred, and convalescent specimens must be received within 30 days from receipt of acute specimens; Label specimens plainly as 'acute' or 'convalescent;'** Separate serum from cells ASAP **or within 2 hours of collection and transfer into a standard aliquot tube;** Refrigerated **Stability:** Ambient: After separation from cells: **48 hours** Refrigerated: After separation from cells: 2 weeks Frozen: After separation from cells: 1 year **(Avoid repeated freeze/thaw cycles)** **Methodology:** Indirect **Fluorescent Antibody** (IFA) **Reference Range:** B. henselae IgG Ab Negative: < 1:64–**No significant level of Bartonella henselae IgG antibody detected** **Equivocal: 1:64–1:128–Questionable presence of Bartonella henselae IgG antibody detected; Repeat testing in 10–14 days may be helpful** **Positive: ≥ 1:256–Presence of IgG antibody to Bartonella henselae detected, suggestive of current or past infection** B. henselae IgM Ab Negative: < 1:16–**No significant level of Bartonella henselae IgM antibody detected** **Positive: ≥ 1:16–Presence of IgM antibody to Bartonella henselae detected, suggestive of current or recent infection** B. quintana IgG Ab Negative: < 1:64–No significant level of Bartonella quintana IgG antibody detected Equivocal: 1:64–1:128–Questionable presence of Bartonella quintana IgG antibody detected; Repeat testing in 10–14 days may be helpful Positive: ≥ 1:256–Presence of IgG antibody to Bartonella quintana detected, suggestive of current or past infection B. quintana IgM Ab Negative: < 1:16–No significant level of Bartonella quintana IgM antibody detected Positive: ≥ 1:16–Presence of IgM antibody to Bartonella quintana detected, suggestive of current or recent infection	3/5/20
Beta-2 Glycoprotein 1 Antibodies, IgA	BETAA	**Special Information: Contaminated, hemolyzed, grossly icteric, or severely lipemic specimens will be rejected. Plasma or other body fluids are unacceptable. This test is New York DOH approved.** **Specimen Requirement:** 0.5 mL serum from a **serum separator (gold)** tube; Minimum: 0.3 mL; Remove serum from cells ASAP or within 2 hours of collection **and transfer into a standard aliquot tube;** Refrigerated	3/5/20
Carboxyhemoglobin	CO	**Reference Range:** Carboxyhemoglobin 0–99 Years: **< 2.1%** **0–99 Years (Smokers): 2.0–8.0%**	Effective immediately
D-Dimer	DDMER	**Stability:** Ambient: 4 hours Frozen: 4 weeks **at < minus 18 °C,** if frozen at 4 hours	Effective immediately
DNA Extraction Bone Marrow (Buffy Coat)	NUCBUF	**Test Name:** Previously DNA Extraction (Buffy Coat) **Note:** *RNA Extraction will be removed as an alias name.* **Special Information: Bone marrow** specimen will be held in the laboratory for 3 years. If additional testing is needed, please order DNA and RNA Extraction for Clinical Testing and answer all required questions. **Specimen Requirement:** 3 mL **bone marrow** in an EDTA (lavender) tube; Ambient	1/7/20

Test Changes (Cont.)

Test Name	Order Code	Change	Effective Date
FISH for Plasma Cell Myeloma	FSHPCM	**Specimen Requirement:** 2–3 mL bone marrow in an **EDTA (lavender)** tube; Ambient *OR* 2–3 mL bone marrow in a sodium heparin (green) tube; Ambient **Stability:** Ambient: 48 hours Refrigerated: **Acceptable** Frozen: Unacceptable **Days Performed: 4 days per week** **Reported: 5** days	Effective immediately
Hematologic Neoplasm Next Generation Sequencing Panel Marrow	HNMNGS	**Note:** *Changes to this test were announced in the October and November Technical Updates.*	Effective immediately
Hematologic Neoplasm Next Generation Sequencing Panel Peripheral Blood	HNPNGS	**Note:** *Changes to this test were announced in the October and November Technical Updates.*	Effective immediately
JAK2 Exon 12–16 Sequencing Blood	JAKNON	**CPT:** 81403 x 1	Effective immediately
Mitotane	MTANE	**Specimen Requirement:** 2 mL serum from a plain no additive (red) tube; Minimum: **0.5 mL;** Refrigerated *OR* 2 mL plasma from a sodium or lithium heparin (green) tube; Minimum: **0.5 mL;** Refrigerated **Stability:** Ambient: 3 days Refrigerated: 2 weeks Frozen: **Acceptable** **Days Performed:** Monday, **Wednesday, Friday** **Reported:** 6–7 days	Effective immediately
MPL Mutation Analysis Blood	MPL	**CPT:** 81403 x 1	Effective immediately
Myeloid NGS Panel Peripheral Blood	MYPNGS	**CPT:** 81450 x 1	Effective immediately
Sex Hormone Binding Globulin	SHBG2	**Stability:** Ambient: **5 days** Refrigerated: **7** days Frozen: **12** months **Reference Range:** Male (18–99 Years): 14–82 nmol/L Female **21**–49 Years: **25–122 nmol/L** 50–99 Years: 17–125 nmol/L	3/3/20
Synovial Fluid, Crystals ID and Staff Review	SFCRID	**Specimen Requirement:** 2 mL synovial fluid in an EDTA (lavender) tube; Ambient *OR* 2 mL synovial fluid in a sodium or lithium heparin (green) tube; **Accepted but not preferred;** Ambient *OR* 2 mL synovial fluid in a **clean container (No preservatives);** Ambient	3/2/20
Synovial Fluid, Routine Analysis	RTSYNF	**Specimen Requirement:** 2 mL synovial fluid in an EDTA (lavender) tube; Ambient *OR* 2 mL synovial fluid in a sodium or lithium heparin (green) tube; **Sodium or lithium heparin are accepted but not preferred;** Ambient *OR* 2 mL synovial fluid in a **clean container (No preservatives);** Ambient	3/2/20
Widal Panel	SALM	**Special Information:** This assay detects antibodies directed against five Salmonella typhi and paratyphi antigens: O Type D, O Type Vi, H Type A, H Type B, or H Type D. **Hemolyzed, icteric, contaminated, heat-inactivated, lipemic, or turbid specimens will be rejected. This test is New York DOH approved.**	1/7/20

New Tests

Test Name	Order Code	Change	Effective Date
DNA Extraction Blood	NUCBLD	**Special Information:** Extracted DNA will be held in the laboratory for 3 years. If additional testing is needed, please order DNA and RNA Extraction for Clinical Testing and answer all required questions. **Specimen Requirement:** 5 mL blood in an EDTA (lavender) tube; Ambient **Stability:** Ambient: Transport within 48 hours Refrigerated: Refrigerated specimens are acceptable Frozen: Will be rejected **Methodology:** Extraction (EXT) **Days Performed:** 5 days per week **CPT:** 81479 x 1	1/7/20

Fee Increases

Test Name	Order Code	List Fee	CPT Code	Effective Date
Bone marrow Cancer Chromosome Microarray + SNP	BMHSNP	$1660.00 (non-discountable)	81277	1/1/20
MPL Mutation Analysis Blood	MPL	$942.00 (non-discountable)	81403	Effective immediately

Fee Reductions

Test Name	Order Code	List Fee	CPT Code	Effective Date
Myeloid NGS Panel Peripheral Blood	MYPNGS	$1337.00 (non-discountable)	81450	Effective immediately

Discontinued Tests

Test Name	Order Code	Test Information	Effective Date
GCH1 Gene Analysis	GCH1	This test will no longer be available.	3/3/20
GCK (CH) DNA Sequencing Test	GCKCH	This test will no longer be available.	3/3/20
GCK (NDM) DNA Sequencing Test	GCKNDM	This test will no longer be available.	3/3/20
Homocysteine, Total, Urine	UHCYS	This test will no longer be available. Suggest ordering Homocysteine (HOMCYS).	1/6/20