Cleveland Clinic

Cleveland Clinic Laboratories

Technical Update • August 2023

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	Aldosterone/Direct Renin Ratio						■							
7	Allergen, Sesame Seed rSes i 1 Component			■										
7	Allergen, Sesame Seed with Component Reflex			■										
7	Allergen, Wheat, rTri a Omega-5-gliadin Component			■										
7	Allergen, Wheat with Component Reflex			■										
9	Biotinidase Serum													■
2–3	C-Telopeptide, Beta Cross Linked						■	■	■		■	■	■		
7	C3 Nephritic Factor			■										
3	Direct Renin						■							
3	Drug Analysis, Urine						■	■				■			
3	Drug Screen 9 Panel, Serum or Plasma						■						■	■
3	Drug Screen, Blood							■							
4	LPT to Beryllium, Blood								■						
4	Magnesium RBC						■	■							
4	Methylmalonic Acid Blood								■		■				
4	Platelet Aggregation								■						
5	Pneumocystis jirovecii, Real-Time PCR	■	■				■	■			■	■			
5	Rapamune							■							
5	Targeted Oncology Panel Next Generation Sequencing Bone Marrow						■								■

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6	Targeted Oncology Panel Next Generation Sequencing Cytology						■	■						■
6	Targeted Oncology Panel Next Generation Sequencing Other						■							■
6	Targeted Oncology Panel Next Generation Sequencing Peripheral Blood						■							■
8–9	TMA Complement Panel			■										
9	UBA1 Mutation Testing for VEXAS Syndrome			■										

Test Changes

Test Name	Order Code	Change	Effective Date
Aldosterone/Direct Renin Ratio	ALDREN	**Special Information:** Fasting specimens are recommended but not required. Record the time of day and patient's posture during blood collection (supine or upright). DO NOT pre-chill collection tubes, store tubes on ice or refrigerate; cryoactivation of prorenin occurs when samples are refrigerated. **Biotin levels of up to 100 mg/day have not shown interference with this assay. Patients taking >100 mg/day to 300 mg/day should refrain from taking Biotin for 1 hour prior to sample collection. Patients taking a Biotin dose >300 mg/day should consult with their physician or the laboratory prior to having a sample taken. Clinicians should consider biotin interference as a source of error, when clinically suspicious of the laboratory result.** **Specimen Requirement:** 2 mL plasma from EDTA (Lavender) tube; **Collection Ambient;** Transport Critical Frozen; **Centrifuge and remove plasma from cells within 2 hours of collection. Freeze plasma immediately after separation from cells.** **Stability:** Ambient: Unacceptable Refrigerated: Unacceptable Frozen: **30 days**	8/15/23
C-Telopeptide, Beta Cross Linked	CTELO	**For interface clients only–Test build may need to be modified** **Special Information:** CRITICAL FROZEN. Morning fasting specimen preferred. **Specimen Requirement:** 1 mL serum from serum separator (Gold) tube; **Collection Centrifuge, aliquot and freeze ASAP.** Transport Critical Frozen; Morning fasting specimen is preferred. Separate specimens must be submitted when multiple tests are ordered. 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 **and freeze.** *OR* 1 mL plasma from lavender EDTA tube; **Collection Centrifuge, aliquot and freeze ASAP.** Transport Critical Frozen; Morning fasting specimen is preferred. Separate specimens must be submitted when multiple tests are ordered. Centrifuge and separate plasma from cells ASAP or within 2 hours of collection. Transfer plasma to standard aliquot tube **and freeze.** **Stability:** Ambient: After separation from cells: **6** hours Refrigerated: After separation from cells: **8** hours Frozen: After separation from cells: 3 months **at–20 C** *(continued on page 3)*	9/14/23

Test Changes (Cont.)

Test Name	Order Code	Change	Effective Date
C-Telopeptide, Beta Cross Linked *(continued from page 2)*	CTELO	**Reference Range:** **Female 0 Years to 29.9 Years: 148-967 pg/mL** **Female 30 Years to 39.9 Years: 150-635 pg/mL** **Female 40 Years to 49.9 Years: 131-670 pg/mL** **Female 50 Years to 59.9 Years: 183-1060 pg/mL** **Female 60 Years to 69.9 Years: 171-970 pg/mL** **Female 70 Years and older: 152-858 pg/mL** Female: Premenopausal: **138**–689 pg/mL Female: Postmenopausal: 177–1015 pg/mL **Male 0 Years to 29.9 Years: 238-1019 pg/mL** Male 30 Years to 39.9 Years: 225-936 pg/mL Male 40 Years to 49.9 Years: 182-801 pg/mL Male 50 Years to 59.9 Years: 161-737 pg/mL Male 60 Years to 69.9 Years: 132-752 pg/mL Male 70 Years and older: 118-776 pg/mL **Days Performed: Mon–Fri** **Reported:** 1–**3** days	9/14/23
Direct Renin	RENIND	**Special Information:** Fasting specimens are recommended but not required. Record the time of day and patient's posture during blood collection (supine or upright). DO NOT pre-chill collection tubes, store tubes on ice or refrigerate; cryoactivation of prorenin occurs when samples are refrigerated. Biotin levels of up to 100 mg/day have not shown interference with this assay. Patients taking >100 mg/day to 300 mg/day should refrain from taking Biotin for 1 hour prior to sample collection. Patients taking a Biotin dose >300 mg/day should consult with their physician or the laboratory prior to having a sample taken. Clinicians should consider biotin interference as a source of error, when clinically suspicious of the laboratory result. **Clinical Limitation:** Criteria for Rejection: Refrigerated, grossly hemolyzed, grossly lipemic, and obviously microbially contaminated samples will be rejected. **Specimen Requirement:** 1 mL plasma from EDTA (Lavender) tube; **Collection Ambient;** Transport Critical Frozen; **Centrifuge and remove plasma from cells within 2 hours of collection. Freeze plasma immediately after separation from cells.**	8/15/23
Drug Analysis, Urine	UDRUGC	**Special Information:** Cautions: Not intended for therapeutic compliance testing. Not intended for use in employment-related testing. Test results are qualitative. This test is New York State approved. **Specimen Requirement: 5** mL random urine in clean container (no preservatives); Refrigerated **Reported: 3–5** days	9/12/23
Drug Screen 9 Panel, Serum or Plasma	DRGSC9	**Note: New test was announced in the June update, but financial information was not available at that time** **Clinical Limitation: This is a blood drug screen. In most situations, urine drug screening is recommended due to the longer window of detection, faster turnaround time, and ability to test without invasive sampling. If your patient is not anuric or oliguric, please consider ordering Toxicology Screen, Urine (UTOX2) or an appropriate confirmation test.** This test is for medical purposes only; not valid for forensic use. Cocaine and cocaethylene are more stable in fluoride-preserved plasma than serum. **CPT:** 80307 **Price:** $155.00	effective immediately
Drug Screen, Blood	BDRUG	**Specimen Requirement:** 2.75 mL serum from no additive (Red) tube; Refrigerated; Do not draw serum separator tubes (SST). **Separate serum from cells ASAP or within 2 hours of collection. Transfer serum to standard aliquot tube.** **Stability:** Ambient: 3 hours Refrigerated: **14 days** Frozen: **14 days**	9/12/23

Test Changes (Cont.)

Test Name	Order Code	Change	Effective Date
LPT to Beryllium, Blood	BLDBE	**For interface clients only–Test build may need to be modified** **Reference Range:** PHA Stimulation Index: > 50.0 SI Beryllium 1.0 uM D5: < 3.0 SI Beryllium 1.0 uM D6: < 3.0 SI Beryllium 10 uM D5: < 3.0 SI Beryllium 10 uM D6: < 3.0 SI Beryllium 100 uM D5: < 3.0 SI **Note:** *Candida Albicans result component has been removed*	9/12/23
Magnesium RBC	MAGRBC	**Special Information:** Specimens that are not processed within 4 hours of collection are not acceptable **(whole blood specimens must be centrifuged and all plasma must be removed from the red blood cells). In addition, specimens that are improperly/inadequately labeled or frozen are not acceptable.** **Specimen Requirement:** 1 mL red blood cells from EDTA (Royal blue) tube; Ambient; Centrifuge whole blood and separate Red Blood Cells (discard plasma) within 4 hours of collection. **All plasma must be removed from Red Blood Cells. Keep Red Blood Cells in original collection tube or** pour Red Blood Cells into transport tube. *OR* 1 mL red blood cells from EDTA (Lavender) tube; Ambient; Centrifuge whole blood and separate Red Blood Cells (discard plasma) within 4 hours of collection. **All plasma must be removed from Red Blood Cells. Keep Red Blood Cells in original collection tube or** pour Red Blood Cells into transport tube.	8/15/23
Methylmalonic Acid Blood	MMA	**For interface clients only–Test build may need to be modified** **Reference Range:** **0 Years to 99 Years: <= 0.40 umol/L** Urgent: **> 50.00 umol/L**	9/14/23
Platelet Aggregation	AGGPLP	**Reference Range:** ADP Aggregation (ADP): 65-93 % Max ATP Rel by ADP (ADPREL): 0.1-1.3 nM ADP 20 Max Aggreg (ADP20): 71-94 % Max ATP Rel by ADP 20 (AD20RE): 0.1-1.4 nM Arach Max Aggreg (ARACA): 75-100 % Max ATP Rel by Aracha (ARAREL): 0.4-2.0 nM Collagen Max Aggreg (COLLAG): 74-99 % Max ATP Rel by Collagen (COLREL): 0.4-1.7 nM EPIN Max Aggreg (EPIN): 70-97 % Max ATP Rel by Epineph (EPIREL): 0.2-1.6 nM Epin 100 Max Aggreg (EPI100): 70-99 % Max ATP Rel by Epineph 100 (EP100R): 0.2-1.7 nM Thromboxane A2 **3** uM Max Aggregation (THRMBXAG): 58-93 ATP Release by Thromboxane A2 (THRMBXREL): 0.2-1.4 nM Thrombin **1** Unit ATP Release (THROMBREL): >0.5 Risto 1500 Max Agg (RIST15): 76-100 % Max Risto 1200 Max Agg (RIST12): 76-100 % Max Risto 900 Max Agg (RIST9): 50-100 % Max Risto 500 Max Agg (RIST5): 0-9 % Max	9/12/23

Test Changes (Cont.)

Test Name	Order Code	Change	Effective Date
Pneumocystis jirovecii, Real-Time PCR	PJPCR	**For interface clients only–Test build may need to be modified** **Name:** Previously Pneumocystis jiroveci PCR **Special Information: Test performed Monday through Friday and Saturday or Sunday.** **Clinical Limitation: This assay is intended for use as a lab-developed test for the detection of Pneumocystis jirovecii DNA from lower respiratory specimens. It is meant to be used as an aid in the diagnosis of Pneumocystis pneumonia (PCP), in conjunction with other clinical and laboratory information. The test should only be ordered in individuals suspected to have PCP, as the assay has been described to be positive in some colonized individuals without presenting features of PCP disease. Although a negative result does not entirely rule out the presence of Pneumocystis, the negative predictive value of this test is very high. Test results should be interpreted alongside clinical history, imaging findings, and ancillary laboratory data if available.** **Clinical Information: Pneumocystis jirovecii is an atypical fungus that causes Pneumocystis pneumonia (PCP) in patients with a compromised immune system. Transplant recipients and those with poorly controlled HIV are at highest risk, but those receiving chemotherapy for malignant diseases and others with immunosuppression may also develop the disease. PCP is an important cause of morbidity and mortality in immunocompromised patients. The diagnosis of PCP is a challenge since the microorganism does not grow in conventional culture, and direct microscopy methods have suboptimal sensitivity. Molecular methods of detection are preferred due to their superior sensitivity, but these assays can be positive in colonized individuals without overt clinical disease. This updated Pneumocystis jirovecii real-time polymerase chain reaction (RT-PCR) assay targets the mitochondrial large ribosomal subunit gene (mtLSU rRNA), which is present in multiple copies per organism, to optimize assay sensitivity.** **Specimen Requirement:** 2 mL bronch (BAL) in sterile container; Refrigerated; **Collect and submit the specimen in a sterile container (ie. Oracle #1012787, Covidien #2200SA).** If aliquoting is necessary, sterile tubes must be used. *OR* 2 mL sputum in sterile container; Refrigerated; **Collect and submit the specimen in a sterile container (ie. Oracle #1012787, Covidien #2200SA).** If aliquoting is necessary, sterile tubes must be used. *OR* lung tissue in sterile container; Refrigerated; **Collect and submit the specimen in a sterile container (ie. Oracle #1012787, Covidien #2200SA). If aliquoting is necessary, sterile tubes must be used.** *OR* **2 mL bronch washings in sterile container; Collect and submit the specimen in a sterile container (ie. Oracle #1012787, Covidien #2200SA). If aliquoting is necessary, sterile tubes must be used.** *OR* tracheal **aspiriate** in sterile container; **Collect and submit the specimen in a sterile container (ie. Oracle #1012787, Covidien #2200SA).** If aliquoting is necessary, sterile tubes must be used. **Reference Range: Pneumocystis jirovecii Not Detected by PCR** **Days Performed:** 6 days per week **8:00** am **Reported:** 3 days	9/14/23
Rapamune	RAPAM	**Specimen Requirement:** 2.5 mLwhole blood from EDTA (Lavender) tube; Refrigerated; Collect immediately prior to next dose. **Note:** *EDTA (Royal blue) tube is no longer acceptable.*	9/14/23
Targeted Oncology Panel Next Generation Sequencing Bone Marrow	TOPBM	**Note: New test was announced in the June update, but financial information was not available at that time** **Special Information:** The following genes are interrogated: ABL1, AKT, AKT1, AKT3, AR, AXL, BRAF, C11orf95, CCND1, CDK4, CDK6, CTNNB1, DDR2, EGFR, ERBB2, ERBB3, ERBB4, ERG, ESR1, ETV1, ETV4, ETV5, FGFR1, FGFR2, FGFR3, FGFR4, GNA11, GNAQ, GNAS, H3-3A, H3-3B, HRAS, IDH1, IDH2, JAK1, JAK2, JAK3, KIT, KRAS, MAP2K1, MAP2K2, MET, MTOR, MYC, MYCN, NRAS, NTRK1, NTRK2, NTRK3, PDGRFA, PIK3CA, PPARG, RAF1, RELA, RET, ROS1, SMO, TERT AND TP53. **Note:** *GLI1 and INHBE genes have been removed* **CPT:** 81455 **Price:** $3,000.00	effective immediately

Test Changes (Cont.)

Test Name	Order Code	Change	Effective Date
Targeted Oncology Panel Next Generation Sequencing Cytology	TOPCY	**Note: New test was announced in the June update, but financial information was not available at that time** **Special Information:** The following genes are interrogated: ABL1, AKT, AKT1, AKT3, AR, AXL, BRAF, C11orf95, CCND1, CDK4, CDK6, CTNNB1, DDR2, EGFR, ERBB2, ERBB3, ERBB4, ERG, ESR1, ETV1, ETV4, ETV5, FGFR1, FGFR2, FGFR3, FGFR4, GNA11, GNAQ, GNAS, H3-3A, H3-3B, HRAS, IDH1, IDH2, JAK1, JAK2, JAK3, KIT, KRAS, MAP2K1, MAP2K2, MET, MTOR, MYC, MYCN, NRAS, NTRK1, NTRK2, NTRK3, PDGRFA, PIK3CA, PPARG, RAF1, RELA, RET, ROS1, SMO, TERT AND TP53. **Note:** *GLI1 and INHBE genes have been removed* **Specimen Requirement: 10 slides from alcohol fixed cell block; Ambient; 10 slides from a cell block and 1 H&E stained slide** *OR* **10** slides from formalin fixed paraffin cell block; Ambient; **10 slides from a cell block** **CPT:** 81455 **Price:** $3,000.00	effective immediately
Targeted Oncology Panel Next Generation Sequencing Other	TOPTO	**Note: New test was announced in the June update, but financial information was not available at that time** **Special Information:** The following genes are interrogated: ABL1, AKT, AKT1, AKT3, AR, AXL, BRAF, C11orf95, CCND1, CDK4, CDK6, CTNNB1, DDR2, EGFR, ERBB2, ERBB3, ERBB4, ERG, ESR1, ETV1, ETV4, ETV5, FGFR1, FGFR2, FGFR3, FGFR4, GNA11, GNAQ, GNAS, H3-3A, H3-3B, HRAS, IDH1, IDH2, JAK1, JAK2, JAK3, KIT, KRAS, MAP2K1, MAP2K2, MET, MTOR, MYC, MYCN, NRAS, NTRK1, NTRK2, NTRK3, PDGRFA, PIK3CA, PPARG, RAF1, RELA, RET, ROS1, SMO, TERT AND TP53. **Note:** *GLI1 and INHBE genes have been removed* **CPT:** 81455 **Price:** $3,000.00	effective immediately
Targeted Oncology Panel Next Generation Sequencing Peripheral Blood	TOPPB	**Note: New test was announced in the June update, but financial information was not available at that time** **Special Information:** The following genes are interrogated: ABL1, AKT, AKT1, AKT3, AR, AXL, BRAF, C11orf95, CCND1, CDK4, CDK6, CTNNB1, DDR2, EGFR, ERBB2, ERBB3, ERBB4, ERG, ESR1, ETV1, ETV4, ETV5, FGFR1, FGFR2, FGFR3, FGFR4, GNA11, GNAQ, GNAS, H3-3A, H3-3B, HRAS, IDH1, IDH2, JAK1, JAK2, JAK3, KIT, KRAS, MAP2K1, MAP2K2, MET, MTOR, MYC, MYCN, NRAS, NTRK1, NTRK2, NTRK3, PDGRFA, PIK3CA, PPARG, RAF1, RELA, RET, ROS1, SMO, TERT AND TP53. **Note:** *GLI1 and INHBE genes have been removed* **CPT:** 81455 **Price:** $3,000.00	effective immediately

New Tests

Test Name	Order Code	Change	Effective Date
Allergen, Sesame Seed rSes i 1 Component	SESMCP	**Clinical Information:** As an aid in diagnosing allergy to sesame seed. **Specimen Requirement:** 0.5 mL serum from serum separator (Gold) tube; Minimum 0.3 mL; Submitting the minimum volume will not allow for repeat or add on testing. Required volume of 0.5 mL is preferred when possible. Refrigerated; An extra 50 uL will be required for each additional allergen ordered. *OR* 0.5 mL plasma from sodium heparin (Green) tube; Minimum 0.3 mL; Submitting the minimum volume will not allow for repeat or add on testing. Required volume of 0.5 mL is preferred when possible. Refrigerated *OR* 0.5 mL plasma from EDTA (Lavender) tube; Minimum 0.3 mL; Submitting the minimum volume will not allow for repeat or add on testing. Required volume of 0.5 mL is preferred when possible. Refrigerated **Stability:** Ambient: 1 Day Refrigerated: 30 Days Frozen: 30 Days **Methodology:** Quantitative ImmunoCAP Fluorescent Enzyme Immunoassay **Reference Range:** <0.10 kU/L **Days Performed:** Sun–Sat 7:00 am–11:00 pm **Reported:** 1–2 days	9/12/23
Allergen, Sesame Seed with Component Reflex	SESMRX	**Clinical Information:** As an aid in diagnosing allergy to Sesame seed. IgE (kU/L) Interpretation: <0.35, Class 0–Below Detection; 0.35–0.69, Class 1–Low; 0.70–3.49, Class 2–Moderate; 3.50–17.49, Class 3–High; 17.50–49.99, Class 4–Very High; 50–99.99, Class 5–Very High; >=100, Class 6–Very High **Specimen Requirement:** 0.75 mL serum from serum separator (Gold) tube; Minimum 0.5 mL; Submitting the minimum volume will not allow for repeat or add on testing. Required volume of 0.5 mL is preferred when possible. Refrigerated; An extra 50 uL will be required for each additional allergen ordered. *OR* 0.75 mL plasma from sodium heparin (Green) tube; Minimum 0.5 mL; Submitting the minimum volume will not allow for repeat or add on testing. Required volume of 0.5 mL is preferred when possible. Refrigerated *OR* 0.75 mL plasma from EDTA (Lavender) tube; Minimum 0.5 mL; Submitting the minimum volume will not allow for repeat or add on testing. Required volume of 0.5 mL is preferred when possible. Refrigerated **Stability:** Ambient: 1 Day Refrigerated: 30 Days Frozen: 30 Days **Methodology:** Quantitative ImmunoCAP Fluorescent Enzyme Immunoassay **Reference Range:** Allergen, Sesame Seed IgE: < 0.35 kU/L Allergen, Sesame Seed Class: 0 **Days Performed:** Sun–Sat 7:00 am–11:00 pm **Reported:** 1–2 days	9/12/23
Allergen, Wheat, rTri a Omega-5-gliadin Component	OMEGA5	**Clinical Information:** As an aid in diagnosing wheat-dependent exercise-induced allergy/anaphylaxis **Specimen Requirement:** 0.5 mL serum from serum separator (Gold) tube; Minimum 0.3 mL; Submitting the minimum volume will not allow for repeat or add on testing. Required volume of 0.5 mL is preferred when possible. Refrigerated; An extra 50 uL will be required for each additional allergen ordered. *OR* 0.5 mL plasma from sodium heparin (Green) tube; Minimum 0.3 mL; Submitting the minimum volume will not allow for repeat or add on testing. Required volume of 0.5 mL is preferred when possible. Refrigerated *OR* 0.5 mL plasma from EDTA (Lavender) tube; Minimum 0.3 mL; Submitting the minimum volume will not allow for repeat or add on testing. Required volume of 0.5 mL is preferred when possible. Refrigerated **Stability:** Ambient: 1 Day Refrigerated: 30 Days Frozen: 30 Days **Methodology:** Quantitative ImmunoCAP Fluorescent Enzyme Immunoassay **Reference Range:** <0.10 kU/L **Days Performed:** Sun–Sat 7:00 am–11:00 pm **Reported:** 1–2 days	9/12/23

New Tests (Cont.)

Test Name	Order Code	Change	Effective Date
Allergen, Wheat with Component Reflex	WHTRFX	**Clinical Information:** As an aid in diagnosing wheat-dependent exercise-induced allergy/anaphylaxis. IgE (kU/L) Interpretation: <0.35, Class 0–Below Detection; 0.35–0.69, Class 1–Low; 0.70–3.49, Class 2–Moderate; 3.50–17.49, Class 3–High; 17.50–49.99, Class 4–Very High; 50–99.99, Class 5–Very High; >=100, Class 6–Very High **Specimen Requirement:** 0.75 mL serum from serum separator (Gold) tube; Minimum 0.5 mL; Submitting the minimum volume will not allow for repeat or add on testing. Required volume of 0.5 mL is preferred when possible. Refrigerated; An extra 50 uL will be required for each additional allergen ordered. *OR* 0.75 mL plasma from sodium heparin (Green) tube; Minimum 0.5 mL; Submitting the minimum volume will not allow for repeat or add on testing. Required volume of 0.5 mL is preferred when possible. Refrigerated *OR* 0.75 mL plasma from EDTA (Lavender) tube; Minimum 0.5 mL Submitting the minimum volume will not allow for repeat or add on testing. Required volume of 0.5 mL is preferred when possible. Refrigerated **Stability:** Ambient: 1 Day Refrigerated: 30 Days Frozen: 30 Days **Methodology:** Quantitative ImmunoCAP Fluorescent Enzyme Immunoassay **Reference Range:** Allergen, Sesame Seed IgE: < 0.35 kU/L Allergen, Sesame Seed Class: 0 **Days Performed:** Sun–Sat 7:00 am–11:00 pm **Reported:** 1–2 days	9/12/23
C3 Nephritic Factor	C3NEPH	**Note:** Orders restricted to Nephrology and Hematology for inpatients and outpatients. **Includes:** C3 Nephritic Factor Interpretation **Clinical Information:** Detection of C3 Nephritic Factor aids in the guidance of therapy and prognosis of Membranoproliferative Glomerular Nephritis and partial Lypodystrophy. **Specimen Requirement:** 1 mL serum from serum separator (Gold) tube; Minimum 0.5 mL; Frozen; Separate serum from cells ASAP or within 2 hours of collection. Transfer serum to standard aliquot tube and freeze. *OR* 1 mL serum from no additive (Red) tube; Minimum 0.5 mL; Frozen; Separate serum from cells ASAP or within 2 hours of collection. Transfer serum to standard aliquot tube and freeze. **Stability:** Ambient: After separation from cells: Unacceptable Refrigerated: After separation from cells: Unacceptable Frozen: After separation from cells: Acceptable **Methodology:** Hemolytic Assay **Days Performed:** Bi-weekly **Reported:** 15–16 days	9/12/23
TMA Complement Panel	TMAPAN	**Note:** Orders restricted to Nephrology and Hematology for inpatients and outpatients. **Special Information:** Performing Labs: Automated Chemistry (x45476), Client Services (x45755)–Vendor Children's Hosp of Cincinnati. Refer to individual tests: Complement C3 (C3COMP), Complement C4 (C4COMP), Complement Factor B (COMPFB), Complement Factor H Autoantibody (CMPFHA), Complement Factor H (COMPFH) and Complement Factor I (COMPFI). **Specimen Requirement:** Multiple specimen tubes must be collected for this panel. 2 mL plasma from lithium heparin plasma separator (Light Green) tube; Minimum 0.8 mL; Submitting the minimum volume will not allow for repeat testing or add-ons. Centrifuge and refrigerate. 2 mL plasma is for tests: Complement C3 (C3COMP) and Complement C4 (C4COMP). *AND* 4 mL serum from serum separator (Gold) tube; Minimum 1.0 mL; Submitting the minimum volume will not allow for repeat testing or add-ons. Frozen; 4 mL serum is for tests: Complement Factor B (COMPFB), Complement Factor H Autoantibody (CMPFHA), Complement Factor H (COMPFH), and Complement Factor I (COMPFI). Separate serum from cells ASAP or within 2 hours of collection. Transfer serum to standard aliquot tube and freeze. *OR* Multiple specimen tubes must be collected for this panel. 2 mL serum from *(continued on page 9)*	9/12/23

New Tests (Cont.)

Test Name	Order Code	Change	Effective Date
TMA Complement Panel *(continued from page 8)*		serum separator (Gold) tube; Minimum 0.8 mL; Submitting the minimum volume will not allow for repeat testing or add-ons. Centrifuge and refrigerate. 2 mL serum is for tests: Complement C3 (C3COMP) and Complement C4 (C4COMP). *AND* 4 mL serum from serum separator (Gold) tube; Minimum 1.0 mL; Submitting the minimum volume will not allow for repeat testing or add-ons. Frozen; 4 mL serum is for tests: Complement Factor B (COMPFB), Complement Factor H Autoantibody (CMPFHA), Complement Factor H (COMPFH), and Complement Factor I (COMPFI). Separate serum from cells ASAP or within 2 hours of collection. Transfer serum to standard aliquot tube and freeze. **Stability:** Ambient: After separation from cells: 2 mL aliquot for C3COMP/C4COMP: 48 hours; 4 mL aliquot for COMPFB/CMPFHA/COMPFH/COMPFI: Unacceptable Refrigerated: After separation from cells: 2 mL aliquot for C3COMP/C4COMP: 48 hours; 4 mL aliquot for COMPFB/CMPFHA/COMPFH/COMPFI: Unacceptable Frozen: After separation from cells: 2 mL aliquot for C3COMP/C4COMP: Unacceptable; 4 mL aliquot for COMPFB/CMPFHA/COMPFH/COMPFI: Acceptable **Methodology:** Enzyme-Linked Immunosorbent Assay (ELISA) Radial Immunodiffusion (RID) Turbidimetric Immunoassay (TUI) **Days Performed:** Varies **Reported:** 1–16 days	
UBA1 Mutation Testing for VEXAS Syndrome	VEXAS	**Special Information:** Requisition and Pathology report MUST accompany sample. Ship FedEx priority overnight Monday through Friday (mark Saturday delivery when shipping on Friday). **Clinical Information:** UBA1 mutation testing in recommended in patients with refractory autoimmune disorders and cytopenias of unknown etiology. UBA1 mutations are diagnostic of VEXAS syndrome in the appropriate clinicopathologic context. **Specimen Requirement:** 10 mL whole blood in EDTA (Lavender) tube; Minimum 5 mL; Requisition and Pathology report MUST accompany sample. *OR* 10 mL bone marrow in EDTA (Lavender) tube; Minimum 5 mL; Requisition and Pathology report MUST accompany sample. *OR* 10 mL whole blood in Acid Citric Dextrose (ACD) A or B (Yellow) tube; Minimum 5 mL; Requisition and Pathology report MUST accompany sample. *OR* 10 mL bone marrow in Acid Citric Dextrose (ACD) A or B (Yellow) tube; Minimum 5 mL; Requisition and Pathology report MUST accompany sample. *OR* One formalin fixed paraffin block; Requisition and Pathology report MUST accompany sample. *OR* 10 unstained slides; 4-5 microns. Requisition and Pathology report MUST accompany sample. *OR* Unspecified fresh tissue in RPMI; Requisition and Pathology report MUST accompany sample. *OR* Unspecified fresh tissue in saline; Requisition and Pathology report MUST accompany sample. *OR* Unspecified frozen tissue; Ship on dry ice. Requisition and Pathology report MUST accompany sample. *OR* 200 ng extracted DNA in sterile container; Minimum of 10 ng/μL. Requisition and Pathology report MUST accompany sample. **Stability:** Ambient: Fresh tissue: Acceptable Refrigerated: Whole blood, Bone marrow, Tissue block, Slides: 7 days Frozen: Frozen tissue: Acceptable **Methodology:** Next Generation DNA Sequencing **Days Performed:** Once per week **Reported:** 2–3 weeks	9/14/23

Fee Reductions

Test Name	Order Code	List Fee	CPT Code	Effective Date
Biotinidase Serum	BIOTIN	$90.00	82261	effective immediately