Cleveland Clinic

Cleveland Clinic Laboratories

Technical Update • October 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	5-Hydroxyindoleacetic Acid, Urine Random							■		■				
2	ACTH Stimulation, 2 Time Points							■		■				
2	ACTH Stimulation, 3 Time Points									■				
3	Alcohols, Plasma		■			■	■	■		■	■	■		
10	Allergen, Bromelain IgE			■										
4, 13	Allergen, Cat Components IgE					■	■	■		■		■	■	■
4, 13	Allergen, Dog Components IgE					■	■	■		■		■	■	■
5, 13	Allergen, Pediatric RL							■				■	■	■
11	Allergen, Profilin, Birch IgE			■										
13	Angelman UBE3A Sequencing				■									
5	Beta HCG, Quantitative, Blood					■								
5	CMV by PCR, non-blood specimens										■			
5	Cortisol									■				
13	Cystic Fibrosis Pathogenic Variant Analysis													■
5	EBV by PCR Quant CSF										■			
5	Ehrlichia and Anaplasma Species by PCR										■			
5–6	Ethanol Confirmation, Plasma		■			■	■			■	■	■		
6, 13	Ethanol Confirmation, Urine		■			■	■		■	■	■	■		■
6	FISH for BIRC3/MALT1 Translocation												■	
6	Flow Cytometric Immunophenotyping for Lymphoma, Tissue					■							■	
6	Gamma-Hydroxybutyric Acid, Urine						■							

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11	Head and Neck Next Gen Sequencing			■										
6	HSV PCR, Miscellaneous Specimen Types										■			
7	IgG Synthesis, CSF (Tourtellotte and Index)									■				
7	IgM									■				
13	Iron, Urine 24 hrs				■									
7–8, 13	Isopropanol, Plasma		■			■	■		■	■	■	■		■
8	Lyme Western Blot					■						■		
8, 13	Methanol, Plasma		■			■	■		■	■	■	■		■
12	Next Generation Sequencing Hotspot Desmoid			■										
12	NTRK Next Gen Sequencing			■										
13	NTRK Plus Gene Fusion NGS Panel				■									
9	Phosphatidylethanol (PEth)					■				■				
9	Progesterone					■								
13	SCA17 DNA Test				■									
9	Vanillylmandelic Acid, Urine Random							■		■				
9	Varicella Zoster by PCR										■			
9	Vitamin B12						■					■		
10	Vitamin B12 w/reflex						■					■		

Test Changes

Test Name	Order Code	Change	Effective Date
5-Hydroxyindoleacetic Acid, Urine Random	UHIAR2	**For Interfaced Clients Only: Test build may need to be modified** **Includes:** 5HIAA Random **Urine, Creatinine** **Reference Range:** 5HIAA Random 2–10 Years: 0–12 mg/g crt 10–99 Years: 0–10 mg/g crt **Urine, Creatinine** **Male (18–99 Years): 46.8–314.5 mg/dL** **Female (18–99 Years): 42.2–237.9 mg/dL**	11/10/20
ACTH Stimulation, 2 Time Points	ACTHS2	**For Interfaced Clients Only: Test build may need to be modified** *(Note: Interpretation will be added.)* **Reference Range: See Comment**	11/10/20
ACTH Stimulation, 3 Time Points	ACTHST	**Reference Range: See Comment**	Effective immediately

Test Changes (Cont.)

Test Name	Order Code	Change	Effective Date
Alcohols, Plasma	ALCOS	**For Interfaced Clients Only: Test build may need to be modified** **Includes:** Methanol Isopropanol **Alcohol, Blood Confirmation** Acetone, Quant **Test Name:** Previously Alcohols **Note:** *Volatiles, Plasma will be added as an alias name.* **Special Information:** For medical purposes only; **not valid for forensic use. Do not use alcohol or other volatile disinfectants at the site of venipuncture. Aqueous Zephiran (benzalkonium chloride), aqueous Merthiolate (thimerosal), or povidone-iodine may be used.** **Clinical Information:** Use to identify ethanol, methanol, isopropanol, and/or acetone ingestion. **Reference ranges are based off of the assay's limit of quantitation (5 mg/dL). Ethanol: Therapy for methanol intoxication: 100–150 mg/dL. [American Academy of Clinical Toxicology Practice Guidelines on the Treatment of Methanol Poisoning. Clinical Toxicology, 2002, 40(4): 415–446.] Monitor exposure to ethanol. Elevated concentrations may cause disorientation, loss of motor functions, central nervous system (CNS) depression, vomiting, urine and feces incontinence, coma, and fatality. Toxic concentrations are dependent upon the usage history of the patient. Isopropanol and acetone: Monitor exposure to isopropanol. Elevated concentrations may cause nausea, dizziness, CNS depression and coma. Acetone is a metabolite of isopropanol. Acetone may also be detected during ketoacidosis. Methanol: Monitor exposure to methanol. Elevated concentrations may cause intoxication, metabolic acidosis, ocular toxicity, CNS depression and fatality if patients do not receive medical treatment.** **Specimen Requirement:** 2 mL plasma from a potassium oxalate/sodium fluoride (gray) tube; Minimum: **0.5 mL;** Separate plasma from cells as soon as possible; Transfer to standard CCL transport tube; Cap tube tightly **to minimize alcohol loss;** Do not draw plasma separator tubes; **Centrifuge, aliquot and refrigerate** *OR* 2 mL plasma from an EDTA (lavender) tube; Minimum: **0.5 mL;** Separate plasma from cells as soon as possible; Transfer to standard CCL transport tube; Cap tube tightly **to minimize alcohol loss;** Do not draw plasma separator tubes; **Centrifuge, aliquot and refrigerate** *OR* 2 mL plasma from a **lithium heparin (green)** tube; Minimum: **0.5 mL;** Separate plasma from cells as soon as possible; Transfer to standard CCL transport tube; Cap tube tightly **to minimize alcohol loss;** Do not draw plasma separator tubes; **Centrifuge, aliquot and refrigerate** *OR* 2 mL serum from a plain no additive (red) tube; Minimum: **0.5 mL;** Separate serum from cells as soon as possible; Transfer to standard CCL transport tube; Cap tube tightly **to minimize alcohol loss;** Do not draw serum separator tubes; **Centrifuge, aliquot and refrigerate** **Stability:** Ambient: After separation from cells in a tightly capped tube: **3 days** Refrigerated: After separation from cells in a tightly capped tube: **14 days** Frozen: After separation from cells **in a tightly capped tube: 14 days** **Reference Range:** Methanol **(0–99 Years): < 5 mg/dL** Isopropanol **(0–99 Years): < 5 mg/dL** **Alcohol, Blood Confirmation (0–99 Years): < 5 mg/dL** Acetone, Quant **(0–99 Years): < 5 mg/dL** **Days Performed:** Sunday–Saturday **Reported: 1 day**	11/17/20

Test Changes (Cont.)

Test Name	Order Code	Change	Effective Date
Allergen, Cat Components IgE	CATCP	**For Interfaced Clients Only: Test build may need to be modified** **Includes:** nFel d1 nFel d2 nFel d4 **nFel d7** **Note:** *nFel d7 will be added as an alias name.* **Specimen Requirement:** 0.8 mL serum from a serum separator (gold) tube; Minimum: **0.6 mL;** Submitting the minimum volume will not allow for repeat testing or add-ons; Required volume of 0.8 mL is preferred; An extra 50 µL will be required for each additional allergen ordered; Refrigerated *OR* 0.8 mL plasma from an EDTA (lavender) tube; Minimum: **0.6 mL;** Submitting the minimum volume will not allow for repeat testing or add-ons; Required volume of 0.8 mL is preferred; An extra 50 µL will be required for each additional allergen ordered; Refrigerated *OR* 0.8 mL plasma from a lithium heparin (light green) plasma separator tube (PST); Minimum: **0.6 mL;** Submitting the minimum volume will not allow for repeat testing or add-ons; Required volume of 0.8 mL is preferred; An extra 50 µL will be required for each additional allergen ordered; Refrigerated **Stability:** Ambient: 1 day Refrigerated: 7 days Frozen: **30** days **Reference Range:** nFel d1: < 0.35 kU/L nFel d2: < 0.35 kU/L nFel d4: < 0.35 kU/L **nFel d7: < 0.35 kU/L** **CPT:** 86008 **x 4**	11/10/20
Allergen, Dog Components IgE	DOGCP	**For Interfaced Clients Only: Test build may need to be modified** **Includes:** rCan f1 rCAN f2 rCAN f3 **rCAN f4** rCAN f5 **rCAN f6** **Note:** *rCAN f4 and rCAN f6 will be added as alias names.* **Specimen Requirement:** 0.8 mL serum from a serum separator (gold) tube; Minimum: **0.6 mL;** Submitting the minimum volume will not allow for repeat testing or add-ons; Required volume of 0.8 mL is preferred; An extra 50 µL will be required for each additional allergen ordered; Refrigerated *OR* 0.8 mL plasma from an EDTA (lavender) tube; Minimum: **0.6 mL;** Submitting the minimum volume will not allow for repeat testing or add-ons; Required volume of 0.8 mL is preferred; An extra 50 µL will be required for each additional allergen ordered; Refrigerated *OR* 0.8 mL plasma from a lithium heparin (light green) plasma separator tube (PST); Minimum: **0.6 mL;** Submitting the minimum volume will not allow for repeat testing or add-ons; Required volume of 0.8 mL is preferred; An extra 50 µL will be required for each additional allergen ordered; Refrigerated **Stability:** Ambient: 1 day Refrigerated: 7 days Frozen: **30** days **Reference Range:** rCan f1: < 0.35 kU/L rCAN f2: < 0.35 kU/L rCAN f3: < 0.35 kU/L **rCAN f4: < 0.35 kU/L** rCAN f5: < 0.35 kU/L **rCAN f6: < 0.35 kU/L** **CPT:** 86008 **x 6**	11/10/20

Test Changes (Cont.)

Test Name	Order Code	Change	Effective Date
Allergen, Pediatric RL	PEDMH	**For Interfaced Clients Only: Test build may need to be modified** **Includes:** Barley Codfish Corn Egg white Oat Peanut Rye Shrimp Soybean Tuna Wheat Whey *[Note: Allergen, Casein IgE and Allergen, Casein Class will be removed. Suggest ordering Allergen, Cow Milk Components IgE (MILKE) to obtain casein and other milk components]* **Stability:** Ambient: 1 day Refrigerated: 7 days Frozen: **30** days **CPT:** 86003 **x 12**	11/10/20
Beta HCG, Quantitative, Blood	HCGQT	**Clinical Information:** Early detection of pregnancy. HCG values 5 to 16 mU/mL may represent benign, pituitary **derived HCG in non-pregnant women over 40 years of age.** QUANTITATIVE HCG NORMAL RANGES [Weeks of Gestation (Weeks Since LMP)]: 3 Weeks (5.8–71.2 mU/mL); 4 Weeks (9.5–750 mU/mL); 5 Weeks (217–7138 mU/mL); 6 Weeks (158–31795 mU/mL); 7 Weeks (3697–163563 mU/mL); 8 Weeks (32065–149571 mU/mL); 9 Weeks (63803–151410 mU/mL); 10 Weeks (46509–186977 mU/mL); 12 Weeks (27832–210612 mU/mL). Referenced to 4th IS of NIBSC	10/20/20
CMV by PCR, non-blood specimens	CMVCSF	**Days Performed:** Sunday–Saturday **Reported: 3–6** days	Effective immediately
Cortisol	COR	**Reference Range: See Comment**	Effective immediately
EBV by PCR Quant CSF	EBVCSF	**Days Performed:** Sunday–Saturday **Reported: 3–7** days	Effective immediately
Ehrlichia and Anaplasma Species by PCR	EHRANA	**Days Performed:** Sunday–Saturday **Reported: 3–7** days	Effective immediately
Ethanol Confirmation, Plasma	BALCO	**Test Name:** Previously Alcohol, Blood Confirmation **Note:** *Alcohol confirmation, blood will be added as an alias name, and Ethanol Blood Confirmation will be removed.* **Special Information:** For medical purposes only. **Not valid for forensic use. Do not use alcohol or other volatile disinfectants at the site of venipuncture. Aqueous Zephiran (benzalkonium chloride), aqueous Merthiolate (thimerosal), or povidone-iodine may be used.** **Clinical Information: Reference range is based off of the assay's limit of quantitation (5 mg/dL).** Therapy for methanol intoxication: 100–**150 mg/dL. [American Academy of Clinical Toxicology Practice Guidelines on the Treatment of Methanol Poisoning. Clinical Toxicology, 2002, 40(4): 415-446.] Monitor exposure to ethanol. Elevated concentrations may cause disorientation, loss of motor functions, CNS depression, vomiting, urine and feces incontinence, coma, and fatality. Toxic concentrations are dependent upon the usage history of the patient.** **Specimen Requirement:** 2 mL plasma from a potassium oxalate/sodium fluoride (gray) tube; Minimum: 0.5 mL; Separate plasma from cells as soon as possible; Transfer to standard CCL transport tube; Cap tube tightly to minimize alcohol loss; Do not draw in plasma separator tubes; **Centrifuge, aliquot and refrigerate** *(continued on page 6)*	11/17/20

Test Changes (Cont.)

Test Name	Order Code	Change	Effective Date
Ethanol Confirmation, Plasma *(continued from page 5)*		*OR* 2 mL plasma from an EDTA (lavender) tube; Minimum: 0.5 mL; Separate plasma from cells as soon as possible; Transfer to standard CCL transport tube; Cap tube tightly to minimize alcohol loss; Do not draw in plasma separator tubes; **Centrifuge, aliquot and refrigerate** *OR* 2 mL plasma from a **lithium heparin (green)** tube; Minimum: 0.5 mL; Separate plasma from cells as soon as possible; Transfer to standard CCL transport tube; Cap tube tightly to minimize alcohol loss; Do not draw in plasma separator tubes; **Centrifuge, aliquot and refrigerate** *OR* 2 mL serum from a plain no additive (red) tube; Minimum: 0.5 mL; Separate serum from cells as soon as possible; Transfer to standard CCL transport tube; Cap tube tightly to minimize alcohol loss; Do not draw serum separator tubes; **Centrifuge, aliquot and refrigerate** **Stability:** Ambient: After separation from cells in a tightly capped tube: **3 days** Refrigerated: After separation from cells in a tightly capped tube: **14 days** Frozen: After separation from cells in a tightly capped tube: **14 days** **Reference Range:** 0–99 Years: **< 5 mg/dL** **Days Performed:** Sunday–Saturday **Reported: 1 day**	
Ethanol Confirmation, Urine	UETOHC	**Test Name:** Previously Alcohol Confirmation, Urine **Special Information: For medical purposes only; not valid for forensic use.** **Clinical Information: Reference range is based off of the assay's limit of quantitation (5 mg/dL).** **Specimen Requirement: 2 mL** random urine in a clean container (No preservatives); Minimum: **0.5 mL; Transfer to standard CCL transport tube; Cap tube tightly to minimize alcohol loss; Refrigerated** **Stability:** Ambient: **In a tightly capped tube: 3 days** Refrigerated: **In a tightly capped tube: 14 days** Frozen: **In a tightly capped tube: 14 days** **Methodology: Headspace** Gas Chromatography **Reference Range:** **0–99 Years**: **< 5 mg/dL** **Days Performed:** Sunday–Saturday **Reported: 1 day**	11/17/20
FISH for BIRC3/ MALT1 Translocation		**CPT: 88377 x 1**	12/9/20
Flow Cytometric Immunophenotyping for Lymphoma, Tissue	RLLYMP	**Special Information:** Flow Cytometry will be performed using the following antibodies: CD2, CD3, CD4, CD5, CD7, CD8, CD10, CD13, cd16/56, CD19, CD20, CD23, CD38, CD45, CD123, FMC7, KAPPA, LAMBDA **and CD200.** Based on review of the flow cytometry results, the following tests may be ordered and billed: Additional Flow Cytometry markers, Molecular and FISH assays **CPT:** 88184 x 1, 88185 **x 18,** 88189 x 1	10/6/20
Gamma-Hydroxybutyric Acid, Urine	GHBURN	**Specimen Requirement:** 10 mL random urine in a clean container; Minimum: **2 mL;** Refrigerated	11/10/20
HSV PCR, Miscellaneous Specimen Types	PCRHSV	**Days Performed:** Sunday–Saturday **Reported: 3–6** days	Effective immediately

Test Changes (Cont.)

Test Name	Order Code	Change	Effective Date
IgG Synthesis, CSF (Tourtellotte and Index)	TOURT	**Reference Range:** IgG, CSF: 1.0–3.0 mg/dL Albumin, CSF 3–47 Months: < 45 mg/dL 4–99 Years: 10–30 mg/dL IgG, Serum 0–11 Months: 232–1411 mg/dL 1–3 Years: 453–916 mg/dL 4–6 Years: 504–1465 mg/dL 7–9 Years: 572–1474 mg/dL 10–11 Years: 698–1560 mg/dL 12–13 Years: 759–1550 mg/dL 14–15 Years: 716–1711 mg/dL 16–19 Years: 549–1584 mg/dL 20–99 Years: 700–1600 mg/dL Albumin, Serum 0–4 Days: 2800–4400 mg/dL 5–364 Days: 3800–5400 mg/dL 1–14 Years: **3800–5400 mg/dL** 15–17 Years: 3200–4500 mg/dL 18–99 Years: 3900–4900 mg/dL IgG,CSF / Albumin,CSF Ratio: 0.06–0.17 IgG Synthesis, CSF (Tourtellotte): 0–3.0 mg/d IgG Index, CSF: 0–0.61	Effective immediately
IgM	IGM	**Reference Range:** 0–11 Months: < 145 mg/dL 1–3 Years: 19–146 mg/dL 4–6 Years: 24–210 mg/dL 7–9 Years: **31–208 mg/dL** 10–11 Years: 31–179 mg/dL 12–13 Years: 35–239 mg/dL 14–15 Years: 15–188 mg/dL 16–19 Years: 23–259 mg/dL 20–99 Years: 40–230 mg/dL	Effective immediately
Isopropanol, Plasma	ISOPRO	**Test Name:** Previously Isopropanol **Special Information:** For medical purposes only, **not valid for forensic use.** **Clinical Information: Reference intervals are based off of the assay's limit of quantitation (5 mg/dL).** Monitor exposure to isopropanol. **Elevated** concentrations may cause nausea, dizziness, central nervous system depression and coma. **Acetone is a metabolite of isopropanol. Acetone may also be detected during ketoacidosis.** **Note:** *2-propanol will be added as an alias name.* **Specimen Requirement: 2 mL** plasma from a potassium oxalate/sodium fluoride (gray) tube; Minimum: 0.5 mL; Separate plasma from cells as soon as possible; Transfer to standard CCL transport tube; Cap tube tightly to minimize alcohol loss; Do not draw in plasma separator tubes; **Centrifuge, aliquot and refrigerate** *OR* **2 mL** plasma from an **EDTA (lavender)** tube; Minimum: 0.5 mL; Separate plasma from cells as soon as possible; Transfer to standard CCL transport tube; Cap tube tightly to minimize alcohol loss; Do not draw in plasma separator tubes; **Centrifuge, aliquot and refrigerate** *OR* **2 mL** plasma from a **lithium heparin (green)** tube; Minimum: 0.5 mL; Separate plasma from cells as soon as possible; Transfer to standard CCL transport tube; Cap tube tightly to minimize alcohol loss; Do not draw in plasma separator tubes; **Centrifuge, aliquot and refrigerate** *OR* **2 mL** serum from a plain no additive (red) tube; Minimum: 0.5 mL; Separate serum from cells as soon as possible; Transfer to standard CCL transport tube; Cap tube tightly to minimize alcohol loss; Do not draw in serum separator tubes; **Centrifuge, aliquot and refrigerate** **Stability:** Ambient: After separation from cells in a tightly capped tube: **3 days** Refrigerated: After separation from cells in a tightly capped tube: **14 days** Frozen: After separation from cells in a tightly capped tube: **14 days** *(continued on page 8)*	11/17/20

Test Changes (Cont.)

Test Name	Order Code	Change	Effective Date
Isopropanol, Plasma *(continued from page 7)*		**Methodology: Headspace** Gas Chromatography **Reference Range:** Isopropanol **(0–99 Years): < 5 mg/dL** Acetone, Quant **(0–99 Years): < 5 mg/dL** **Days Performed:** Sunday–Saturday **Reported: 1 day**	
Lyme Western Blot	LYMEWB	**Clinical Information: Lyme western blot (immunoblot) is used as an aid in diagnosis of Lyme disease only where Lyme antibody screen test is positive. Lyme IgM results should only be used within 30 days after onset of compatible early Lyme disease signs and symptoms. The sensitivity of the test is affected by the stage of the disease (most sensitive in late Lyme disease, such as Lyme arthritis) and by early antibiotic treatment. Clinical and epidemiological correlation is required for final interpretation.** **Stability:** Ambient: 48 hours Refrigerated: **14** days Frozen: 15 days–for long term storage, store at minus 70 °C; Avoid multiple freeze thaw cycles	10/6/20
Methanol, Plasma	METHOL	**Test Name:** Previously Methanol **Note:** *Methyl Alcohol will be removed as an alias name.* **Special Information:** For medical purposes only; **not valid for forensic use.** **Clinical Information: Reference interval is based off of the assay's limit of quantitation (5 mg/dL).** Monitor exposure to methanol. **Elevated** concentrations may cause intoxication, metabolic acidosis, ocular toxicity, central nervous system (CNS) depression and fatality if patients do not receive medical treatment. **Specimen Requirement: 2 mL** plasma from a potassium oxalate/sodium fluoride (gray) tube; Minimum: 0.5 mL; Separate plasma from cells as soon as possible; Transfer to standard CCL transport tube; Cap tube tightly to minimize alcohol loss; Do not draw in plasma separator tubes; **Centrifuge, aliquot and refrigerate** *OR* **2 mL** plasma from an EDTA (lavender) tube; Minimum: 0.5 mL; Separate plasma from cells as soon as possible; Transfer to standard CCL transport tube; Cap tube tightly to minimize alcohol loss; Do not draw in plasma separator tubes; **Centrifuge, aliquot and refrigerate** *OR* 3 mL plasma from a lithium heparin (green) tube; Minimum: 0.5 mL; Separate plasma from cells as soon as possible; Transfer to standard CCL transport tube; Cap tube tightly to minimize alcohol loss; Do not draw in plasma separator tubes; **Centrifuge, aliquot and refrigerate** *OR* **2 mL** serum from a plain no additive (red) tube; Minimum: 0.5 mL; Separate serum from cells as soon as possible; Transfer to standard CCL transport tube; Cap tube tightly to minimize alcohol loss; Do not draw in serum separator tubes; **Centrifuge, aliquot and refrigerate** **Stability:** Ambient: After separation from cells in tightly capped tube: **3 days** Refrigerated: After separation from cells in tightly capped tube: **14 days** Frozen: After separation from cells in tightly capped tube: **14 days** **Methodology: Headspace** Gas Chromatography **Reference Range:** **0–99 Years: < 5 mg/dL** **Days Performed:** Sunday–Saturday **Reported: 1 day**	11/17/20

Test Changes (Cont.)

Test Name	Order Code	Change	Effective Date
Phosphatidylethanol (PEth)	PETH	**Clinical Information:** PEth is a group of phospholipids formed in the presence of ethanol, phospholipase D and phosphatidylcholine. PEth is known to be a direct alcohol biomarker. The predominant PEth homologues are PEth 16:0/18:1 (POPEth) and PEth 16:0/18:2 (PLPEth), which account for 37–46% and 26–28% of the total PEth homologues, respectively. PEth is incorporated into the phospholipid membrane of red blood cells and has a general half–life of 4 – 10 days and a window of detection of 2 – 4 weeks. However, the window of detection is longer in individuals who chronically or excessively consume alcohol. Serial monitoring of PEth may be helpful in monitoring alcohol abstinence over time. PEth results should be interpreted in the context of the patient's clinical and behavioral history. Patients with advanced liver disease may have falsely elevated PEth concentrations (Nguyen VL et al 2018, Alcoholism Clinical & Experimental Research). **Reference Range: Refer to report**	Effective immediately
Progesterone	PROG	**Clinical Information:** Fertility diagnosis for detection of ovulation and assessment of the luteal phase. Female reference ranges/interpretive guidelines: Menstrual cycle Progesterone reference ranges: Follicular: < 1.0 ng/mL; Ovulation: < 12.1 ng/mL; Luteal: 1.8 to 23.9 ng/mL; Pregnancy Progesterone reference ranges vary by gestational period: First trimester: 11.0 to 44.3 ng/mL; Second trimester: 25.4 to **83.3 ng/mL;** Third trimester: 58.7 to **214 ng/mL;** Post-menopausal Progesterone: < 0.5 ng/mL Reference: 1. Progesterone (Progesterone III) [package insert V 1.0 English]. Roche Diagnostics, Indianapolis, IN; October 2015. Pediatric references: Reference ranges were not locally established for pediatric patients. The normal values are based on the following source: CALIPER Pediatric Reference Intervals. www.sickkids.ca/caliperproject/index.html. The Hospital for Sick Children (SickKids). 1999-2016: Toronto, Canada. Accessed on November 15, 2016. For females ages 0 to 3 days and males ages 0 to 29 days: Reference ranges for female patients under 4 days old and male patients under 30 days old have not been established. Cutoffs are based on normal values for infants up to one year of age. Source: CALIPER Pediatric Reference Intervals. www.sickkids.ca/caliperproject/index.html. The Hospital for Sick Children (SickKids). 1999-2016: Toronto, Canada. Accessed on November 15, 2016.	10/1/20
Vanillylmandelic Acid, Urine Random	UVMAR	**For Interfaced Clients Only: Test build may need to be modified** **Includes:** Vanilmandelic Acid, Urine **Urine, Creatinine** **Reference Range:** Vanilmandelic Acid, Urine **0–11 Months: 0.0–27.0 mg/g crt** **12–23 Months: 0.0–18.0 mg/g crt** **2–4 Years: 0.0–13.0 mg/g crt** **5–9 Years: 0.0–8.5 mg/g crt** **10–14 Years: 0.0–7.0 mg/g crt** 15–99 Years: **0.0–6.0 mg/g crt** **Urine, Creatinine** **Male (18–99 Years): 46.8–314.5 mg/dL** **Female (18–99 Years): 42.2–237.9 mg/dL**	11/10/20
Varicella Zoster by PCR	VZPCR	**Days Performed:** Sunday–Saturday **Reported: 3–6** days	Effective immediately
Vitamin B12	B12	**Specimen Requirement:** 1 mL serum from a serum separator (gold) tube; Minimum: 0.5 mL; Submit in original tube or aliquot into CCL aliquot tube; Centrifuge and refrigerate *OR* 1 mL **plasma from a lithium heparin (light green) plasma separator tube (PST);** Minimum: 0.5 mL; Submit in original tube or aliquot into CCL aliquot tube; Centrifuge and refrigerate **Stability:** Ambient: 24 hours Refrigerated: 24 hours Frozen: **56 days**	11/12/20

Test Changes (Cont.)

Test Name	Order Code	Change	Effective Date
Vitamin B12 w/reflex	B12RFX	**Specimen Requirement:** 3 mL serum from a serum separator (gold) tube; Minimum: 2 mL; Place specimen on ice after draw; Centrifuge and separate serum from cells less than one hour after collection; If collected in a non-gel separator tube, centrifuge and transfer serum to a CCL tube and refrigerate; Refrigerated *OR* 3 mL **plasma from a lithium heparin (light green) plasma separator tube (PST);** Minimum: 2 mL; Place specimen on ice after draw; Centrifuge and separate plasma from cells less than one hour after collection; If collected in a non-gel separator tube, centrifuge and transfer plasma to a CCL tube and refrigerate; Refrigerated **Stability:** Ambient: 24 hours Refrigerated: 24 hours Frozen: **56 days**	11/12/20

New Tests

Test Name	Order Code	Change	Effective Date
Allergen, Bromelain IgE	BROMLN	**Clinical Limitation:** MUXF3 CCD, Bromelain is highly cross-reactive with pollens, plant foods, and venoms and is associated with the lowest risk of systemic reaction. **Specimen Requirement:** 0.5 mL serum from a serum separator (gold) tube; Minimum: 0.3 mL; Submitting the minimum volume will not allow for additional testing or add-ons; Required volume of 0.5 mL is preferred; An extra 50 µL will be required for each additional allergen ordered; Refrigerated *OR* 0.5 mL plasma from a lithium heparin (light green) plasma separator tube (PST); Minimum: 0.3 mL; Submitting the minimum volume will not allow for additional testing or add-ons; Required volume of 0.5 mL is preferred; An extra 50 µL will be required for each additional allergen ordered; Refrigerated *OR* 0.5 mL plasma from an EDTA (lavender) tube; Minimum: 0.3 mL; Submitting the minimum volume will not allow for additional testing or add-ons; Required volume of 0.5 mL is preferred; An extra 50 µL will be required for each additional allergen ordered; Refrigerated **Stability:** Ambient: 1 day Refrigerated: 7 days Frozen: 30 days **Methodology:** Quantitative ImmunoCAP Fluorescent Enzyme Immunoassay **Reference Range:** < 0.35 kU/L **Days Performed:** Sunday–Saturday **Reported:** 1–2 days **CPT:** 86008 x 1 **Price:** $33.00 (non-discountable)	10/13/20

New Tests (Cont.)

Test Name	Order Code	Change	Effective Date
Allergen, Profilin, Birch IgE	PROFLN	**Clinical Information:** rBet v2 Profilin is cross-reactive with pollens and is associated with the lowest risk of systemic reaction. **Specimen Requirement:** 0.5 mL serum from a serum separator (gold) tube; Minimum: 0.3 mL; Submitting the minimum volume will not allow for additional testing or add-ons; Required volume of 0.5 mL is preferred; An extra 50 µL will be required for each additional allergen ordered; Refrigerated *OR* 0.5 mL plasma from an EDTA (lavender) tube; Minimum: 0.3 mL; Submitting the minimum volume will not allow for additional testing or add-ons; Required volume of 0.5 mL is preferred; An extra 50 µL will be required for each additional allergen ordered; Refrigerated *OR* 0.5 mL plasma from a lithium heparin (light green) plasma separator tube (PST); Minimum: 0.3 mL; Submitting the minimum volume will not allow for additional testing or add-ons; Required volume of 0.5 mL is preferred; An extra 50 µL will be required for each additional allergen ordered; Refrigerated **Stability:** Ambient: 1 day Refrigerated: 7 days Frozen: 30 days **Methodology:** Quantitative ImmunoCAP Fluorescent Enzyme Immunoassay **Reference Range:** < 0.35 kU/L **Days Performed:** Sunday–Saturday **Reported:** 1–2 days **CPT:** 86008 x 1 **Price:** $55.00 (non-discountable)	10/13/20
Head and Neck Next Gen Sequencing	HDNK	**Special Information:** The following genes are interrogated: ALK, BRAF, CAMTA1, CRTC1, ETV6, EWSR1, FOS, FOSB, FOXO1, FUS, GLI1, HMGA2, MAML2, MKL2, MYB, NCOA1, NR4A3, NTRK1, NTRK2, NTRK3, NUTM1, PAX3, PAX7, PLAG1, PRKD1, RET, SS18, STAT6, TFE3, AND YAP1 **Specimen Requirement:** 10 mm square formalin-fixed paraffin block; Formalin-fixed paraffin-embedded tissue (FFPET) slides; Transport and store slides at ambient temperature; 10 unstained sections FFPE tissue on charged, unbaked slides plus one H&E stained section with best tumor area circled by a pathologist; Ambient **Stability:** Ambient: Indefinitely for FFPET slides; FFPET slides are transported at ambient temperature Refrigerated: Not acceptable Frozen: Not acceptable **Methodology:** Next Gen Sequencing **Days Performed:** Once per week **Reported:** 14 days **CPT:** 81445 x 1 **Price:** $1694.00 (non-discountable)	11/3/20

New Tests (Cont.)

Test Name	Order Code	Change	Effective Date
Next Generation Sequencing Hotspot Desmoid	DESMHS	**Special Information:** The following genes are interrogated: APC and CTNNB1 **Specimen Requirement:** 10 mm square formalin-fixed paraffin block; Formalin-fixed paraffin-embedded tissue (FFPET) slides; Transport and store slides at ambient temperature; 10 unstained sections FFPE tissue on charged, unbaked slides plus one H&E stained section with best tumor area circled by a pathologist; Ambient *OR* 3–5 mL fine needle aspirate (FNA) in CytoLyt solution; Liquid based cytology specimens are preserved in CytoLyt solution and should be stored at 4 °C until DNA extraction can be performed; Transport to Cleveland Clinic Laboratories at ambient temperature is acceptable; Ambient **Stability:** Ambient: Indefinitely for FFPET slides; FFPET slides and FNA can be transported at ambient temperature Refrigerated: 2 weeks for liquid-based cytology specimens Frozen: Not acceptable **Methodology:** Next Generation DNA Sequencing **Days Performed:** 3 days per week **Reported:** 14 days **CPT:** 81479 x 1 **Price:** $973.00 (non-discountable)	11/3/20
NTRK Next Gen Sequencing	NTRK	**Special Information:** The following genes are interrogated: NTRK1, NTRK2, and NTRK3 **Specimen Requirement:** 10 mm square formalin-fixed paraffin block; Formalin-fixed paraffin-embedded tissue (FFPET) slides; Transport and store slides at ambient temperature; 10 unstained sections FFPE tissue on charged, unbaked slides plus one H&E section with best tumor area circled by a pathologist; Ambient **Stability:** Ambient: Indefinitely for FFPET slides; FFPET slides are transported at ambient temperature Refrigerated: Not acceptable Frozen: Not acceptable **Methodology:** Next Gen Sequencing **Days Performed:** Once per week **Reported:** 14 days **CPT:** 81479 x 1 **Price:** $1330.00 (non-discountable)	11/3/20

Fee Increases

Test Name	Order Code	List Fee	CPT Code	Effective Date
Allergen, Cat Components IgE	CATCP	$132.00 (non-discountable)	86008 x 4	11/10/20
Allergen, Dog Components IgE	DOGCP	$198.00 (non-discountable)	86008 x 6	11/10/20
Cystic Fibrosis Pathogenic Variant Analysis	CFMDX	$575.00	81220	10/5/20
Ethanol Confirmation, Urine	UETOHC	$85.00	80320 (G0480, if appropriate)	11/17/20

Fee Reductions

Test Name	Order Code	List Fee	CPT Code	Effective Date
Allergen, Pediatric RL	PEDMH	$396.00	86003 x 12	11/10/20
Isopropanol, Plasma	ISOPRO	$85.00	80320 (G0480, if appropriate)	11/17/20
Methanol, Plasma	METHOL	$85.00	80320 (G0480, if appropriate)	11/17/20

Discontinued Tests

Test Name	Order Code	Test Information	Effective Date
Angelman UBE3A Sequencing	UBE3A	This test will no longer be available.	11/10/20
Iron, Urine 24 hrs	UFE	This test will no longer be available.	11/10/20
NTRK Plus Gene Fusion NGS Panel		This test will no longer be available. Suggest ordering NTRK Next Gen Sequencing (NTRK)	11/3/20
SCA17 DNA Test	SCA17	This test will no longer be available.	11/10/20