Cleveland Clinic

Cleveland Clinic Laboratories

Technical Update • January 2017

Cleveland Clinic Laboratories is dedicated to keeping you updated and informed about recent testing changes. That's why we are happy to provide this technical update on a monthly basis.

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

If you wish to compare the new information with previous test information, refer to the Test Directory, which can be accessed at clevelandcliniclabs.com.

Deleted tests and new tests are listed separately. 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	Billing Code	Name Change	New Test	Test Discontinued	Special Information	Specimen Requirement	Component Change(s)	Methodology	Reference Range	Days Performed/Reported	Stability	CPT	Fee
3, 4	AFB Culture & Stain						■	■	■	■					
4	Anaerobe Culture						■	■				■			
14	Bird Fanciers Precipitin Panel I				■										
14	Chromosome Analysis with Reflex MDS FISH				■										
5	C Telopeptide, Beta Cross Linked						■	■			■		■		
5	Cytomegalovirus Antiviral Drug Resistance						■	■				■			
6	DHEA-S							■			■		■		
6	Estradiol-17 B						■	■			■		■		
7	Estrone							■							
7	FISH for ALK (2p23) Translocation													■	
7	FISH for IGH Translocations													■	
7	Fluconazole						■	■			■	■	■		
16	Fructose, Quantitative, Semen					■									
7	Gastrin										■				
7	Glucose						■						■		
8	Glucose, CSF						■				■				
8	Her-2-Neu Serum						■	■			■	■	■		
8	Herpes Simplex by PCR							■							
9	High Sensitivity C-Reactive Protein			■			■	■			■		■		
9	IgE										■				
14	Isavuconazole				■										
9, 16	Itraconazole						■	■	■		■	■	■		■

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10	Kappa, Free, Serum										■				
10	Kappa/Lambda, Free, Serum										■				
10	Lorazepam							■				■	■		
10	Lung Cancer Hot Spot Panel v2 NGS 2 gene							■							
10	Lymphocyte Transformation Test						■								
15	MET Gene Analysis				■										
10	Myoglobin, Urine												■		
10	N Glycan and Transferrin for CDG													■	
11, 16	Posaconazole			■			■	■			■	■	■		■
11	Progesterone						■	■			■		■		
16	PRO-PredictR TPMT					■									
12	Protein, CSF										■				
12	PTH Related Peptide						■	■				■			
12	Testosterone						■				■		■		
15, 16	TPMT Genotyping Assay				■										
12	Tryptase										■				
13, 16	Voriconazole						■	■			■	■	■		■

Test Changes

Test Name	Order Code	Billing Code	Change	Effective Date
AFB Culture & Stain	AFC	77907	**For Interfaced Clients Only: Test build may need to be modified** **Includes:** AFB Stain AFB Culture **PCR Results: (PCRRES)** **Special Information:** Test will include both a culture for AFB plus acid fast stain performed directly from the clinical specimen. Swabs are unacceptable and will be rejected. **Culture of > 5 mL specimen improves recovery of mycobacteria.** For AFB stain-positive **sputum samples, PCR for detection of M tuberculosis and rifampin resistance (rpoB) will be performed automatically. PCR for M tuberculosis vs. non-tuberculous mycobacteria may be performed if AFB stain is positive from fresh tissue and other sample types if there is clinical indication. Mycobacteria grown in culture will be identified to species.** Susceptibility testing will be performed for all M tuberculosis and for other species upon request. Additional charges **for PCR, identification, and susceptibility testing will** apply. **Specimen Requirement:** 10 mL bronchial aspirate in a sterile container; Larger volumes improve recovery; Refrigeration is preferred if transport is delayed longer than 2–4 hours; Ambient *OR* 10 mL tracheal aspirate in a sterile container; Larger volumes improve recovery; Refrigeration is preferred if transport is delayed longer than 2–4 hours; Ambient *OR* Tissue (unspecified) in a sterile container; Add a small amount of sterile saline or sterile water to keep tissue moist; Send separate portions to Cleveland Clinic Laboratories; Separate the portion of the surgical specimen submitted for AFB Culture using sterile technique; Refrigeration is preferred if transport is delayed longer than 2–4 hours; Ambient *OR* 5 mL sputum in a sterile container; Specimen may be induced or expectorated; A minimum of three early morning sputum specimens collected on separate days is recommended; Specimens must be collected at least 8 hours apart; Plan collection of these specimens to ensure they reach the laboratory before 12:00 noon EST; Refrigeration is preferred if transport is delayed longer than 2–4 hours; Refrigerated *OR* 10 mL body fluid in a sterile container; Refrigeration is preferred if transport is delayed longer than 2–4 hours; Ambient *OR* Surgical aspirate (unspecified) in a sterile container; Larger volumes improve recovery; Swabs are unacceptable; Refrigeration is preferred if transport is delayed longer than 2–4 hours; Ambient *OR* Skin (unspecified) in a sterile container; Skin scraping in sterile petri dish or sterile container with blade used to obtain specimen; Refrigerated *OR* 5 mL gastric aspirate in a sterile container; Patient must be fasting; Transport to laboratory for receipt within 4 hours of collection; For increased sensitivity, collect specimens on 3 consecutive days; Refrigerated *OR* 5 mL random urine in a sterile container; Submit entire first morning void in sterile container; For increased sensitivity, collect specimens on 3 consecutive days; Twenty-four hour collections are unacceptable; Patient Preparation: Usual preparation for clean-catch mid-void urine collection; Refrigeration is preferred if transport is delayed longer than 2–4 hours; Ambient *OR* **5 mL** cerebrospinal fluid (CSF) in a sterile container; Culture yield is increased with larger specimen volumes; Refrigeration is preferred if transport is delayed longer than 2–4 hours; Ambient *OR* 1 g stool in a sterile container; Refrigeration is preferred if transport is delayed longer than 2–4 hours; Ambient *(continued on page 4)*	3/1/17

Test Changes (Cont.)

Test Name	Order Code	Billing Code	Change	Effective Date
AFB Culture & Stain *(continued from page 3)*			**Methodology:** Culture **Polymerase Chain Reaction (PCR)** Probe and Pyrosequencing for Identification Stain	
Anaerobe Culture	ANACUL	89789	**Special Information:** Aerobic culture and gram stain requires a separate order (e.g., WCUL, TISCUL, BFCUL, CSFCUL). Submit tissue or aspirates. Swabs are suboptimal and will be rejected, **unless collected using the eSwab collection and transport system.** Transport tissue specimens in a BBL Port-A-Cul Jar. A sterile container may be used for tissue if transported to the microbiology lab immediately (add drops of sterile saline to keep small pieces of tissue moist). Fluid collections should be aspirated through disinfected tissue or skin. Transport fluid specimens in a **Copan eSwab collection and transport system or a Remel anaerobic transport medium**. Anaerobic cultures are routinely held 5 days. Incubation will be extended to 10 days if order includes a request to rule out Actinomyces spp. or Propionibacterium acnes. Susceptibility testing is performed on pure culture isolates of anaerobic bacteria or by request. **Clinical Information:** Specimens from mucosal surfaces which have anaerobic bacteria as normal flora should not be submitted for anaerobic culture. These specimens will routinely be rejected: throat or nasopharyngeal swabs, oral surface swabs, sputum, tracheal aspirates, bronchial washings, voided or catheterized urine, gastric and small bowel contents, feces, rectal swabs, cervical or vaginal swabs. **Only swabs collected with eSwab collection and transport system are acceptable for anaerobic culture.** **Specimen Requirement:** 0.5–10 mL body fluid in an anaerobic vial; Minimum: 0.5 mL; **Anaerobic transport medium (Remel); Acceptable alternate collection device: eSwab collection and transport system (Copan). Collection with eSwab is acceptable if fluid or tissue cannot be collected;** Ambient *OR* Biopsy (unspecified) specimen in an anaerobic vial; The preferred container type is an Anaerobic Jar (BBL Port-A-Cul Jar); Ambient *OR* Surgical tissue (unspecified) in an anaerobic vial; The preferred container type is an Anaerobic Jar (BBL Port-A-Cul Jar); Ambient **Days Performed: Monday–Friday** **Reported:** 5–10 days	3/14/17

Test Changes (Cont.)

Test Name	Order Code	Billing Code	Change	Effective Date
C Telopeptide, Beta Cross Linked	CTELO	84398	**Special Information: Patient preparation: Fasting. Draw specimen before 10 a.m. Twelve hours before this blood test, do not take multivitamins or dietary supplements containing biotin or vitamin B7 that are commonly found in hair, skin and nail supplements and multivitamins. Grossly hemolyzed specimens will be rejected.** **Clinical Information: Useful as an aid in monitoring antiresorptive therapies (e.g., bisphosphonates and hormone replacement therapy) in postmenopausal women treated for osteoporosis and individuals diagnosed with osteopenia. An adjunct in the diagnosis of medical conditions associated with increased bone turnover.** **Specimen Requirement:** 1 mL serum from a **red top tube with no additive;** Minimum: 0.4 mL; Collect before 10 a.m.; Patient should be fasting; **Centrifuge and aliquot into plastic vial;** Frozen *OR* 1 mL serum from a **serum separator (gold) tube;** Minimum: 0.4 mL; Collect before 10 a.m.; Patient should be fasting; **Centrifuge and aliquot into plastic vial;** Frozen **Stability:** Ambient: Unacceptable Refrigerated: 72 hours Frozen: **90** days **Reference Range:** Male 0–17 Years: Not established 18–30 Years: **120–946 pg/mL** 31–50 Years: 93–630 pg/mL 51–70 Years: 35–836 pg/mL 71–99 Years: Not established Female 0–17 Years: Not established Premenopausal: 25–573 pg/mL Postmenopausal: 104–1008 pg/mL	1/17/17
Cytomegalovirus Antiviral Drug Resistance	CYTOSQ	89289	**Special Information: Rejection criteria: Samples containing heparin; unspun PPT tube; received at room temperature. Avoid repeated freezing and thawing of specimen. If blood is collected in a PPT tube, centrifuge preferably within 2 hours of collection, but it is not necessary to transfer the plasma to aliquot tubes.** **Clinical Information:** Treatment of CMV diseases includes three licensed drugs: ganciclovir, foscarnet and cidofovir. All three drugs inhibit the viral DNA polymerase through various mechanisms. Over time, as CMV makes copies of itself, the virus can change its structure. These changes may make CMV resistant to the effects of antiviral drugs. Therefore, it is important to detect resistance as quickly and accurately as possible for proper management of CMV infection. **Specimen Requirement:** 1 mL plasma in an EDTA **white top plasma preparation tube (PPT);** Minimum: 0.3 mL; **Centrifuge** within 2 hours of collection and freeze; Frozen *OR* 1 mL bronchoalveolar lavage (BAL) specimen in a sterile container; Minimum: 0.3 mL; Frozen *OR* 1 mL cerebrospinal fluid (CSF) in a sterile container; Minimum: 0.3 mL; Frozen *OR* 1 mL plasma from an EDTA **lavender top tube;** Minimum: 0.3 mL; Separate plasma from cells within 2 hours of collection; **Transfer into sterile, plastic screw-capped aliquot tube** and freeze; Frozen **Days Performed: Monday,** Wednesday **Reported:** 5–**14** days	3/1/17

Test Changes (Cont.)

Test Name	Order Code	Billing Code	Change	Effective Date
DHEA-S	DHEAS	75410	**Specimen Requirement:** 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** *OR* 1 mL serum from a serum separator (gold) tube; Minimum: **0.5 mL; Centrifuge and refrigerate** **Stability:** Ambient: **Unacceptable** Refrigerated: 2 days Frozen: 2 months **Reference Range:** **0–6 Days: 108.0–607.0 µg/dL** **7–29 Days: 31.6–431.0 µg/dL** **30–364 Days: < 125.0 µg/dL** **1–4 Years: < 19.5 µg/dL** **5–9 Years: < 85.3 µg/dL** Female **10**–14 Years: **33.9–280.0 µg/dL** 15–**19** Years: **65.1–368.0 µg/dL** **20–24** Years: **148.0–407.0 µg/dL** **25–34** Years: **98.8–340.0 µg/dL** **35–44** Years: **60.9–337.0 µg/dL** **45–54** Years: **35.4–256.0 µg/dL** **55–64** Years: **18.9–205.0 µg/dL** **65–74** Years: **< 247.0 µg/dL** **75**–99 Years: **12.0–154.0 µg/dL** Male **10**–14 Years: **24.4–247.0 µg/dL** 15–**19** Years: **70.2–492.0 µg/dL** **20–24** Years: **211.0–492.0 µg/dL** **25–34** Years: **160.0–449.0 µg/dL** **35–44** Years: **88.9–427.0 µg/dL** **45–54** Years: **44.3–331.0 µg/dL** **55–64** Years: **51.7–295.0 µg/dL** **65–74** Years: **33.6–249.0 µg/dL** **75**–99 Years: **16.2–123.0 µg/dL**	2/15/17
Estradiol-17 B	E2	83233	**Clinical Information:** Differential diagnosis of amenorrhea; monitoring ovulation induction; gynecomastia; precocious puberty in females. **Female Estradiol interpretive guidelines: Menstrual cycle Estradiol reference ranges: Follicular: < 234 pg/mL; Ovulation: 41 to 398 pg/mL; Luteal: < 342 pg/mL; Pregnancy Estradiol reference ranges vary by gestational period: First trimester: 154 to 3243 pg/mL; Second trimester: 1561 to 21280 pg/mL; Third trimester: 8285 to > 30000 pg/mL; Post-menopausal Estradiol: < 41 pg/mL. Reference: 1. Estradiol – E2(Estradiol III) [package insert V 3.0 English]. Roche Diagnostics, Indianapolis, IN; June 2016** **Clinical Limitation: This test is not suitable for patients receiving treatment with the drug Fulvestrant (Faslodex). The drug causes an interference leading to falsely elevated estradiol results.** **Specimen Requirement:** 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** *OR* 1 mL serum from a serum separator (gold) tube; Minimum: 0.5 mL; **Centrifuge and refrigerate** **Stability:** Ambient: **24** hours Refrigerated: 2 days Frozen: 6 months **Reference Range:** Female: **See Clinical Information** Male: **< 38 pg/mL**	2/28/17

Test Changes (Cont.)

Test Name	Order Code	Billing Code	Change	Effective Date
Estrone	EST	75641	**Specimen Requirement:** 0.5 mL serum from a serum separator (gold) tube; Minimum: 0.3 mL; Centrifuge and aliquot serum within 24 hours of collection; **Refrigerated** *OR* 0.5 mL serum from a red top tube with no additive; Minimum: 0.3 mL; **Refrigerated**	Effective immediately
FISH for ALK (2p23) Translocation	ALKFSH	84330	**CPT: 88377 x 1**	2/1/17
FISH for IGH Translocations		84364	**CPT: 88377 x 1**	2/1/17
Fluconazole	FLUC	80344	**Clinical Information: Therapeutic, prophylactic, and toxic ranges are not well established.** **Specimen Requirement: 0.5 mL** serum from a red top tube with no additive; Minimum: **0.2 mL;** Do not use serum separator tubes; **Refrigerated** *OR* **0.5 mL** plasma from a lithium heparin green top tube; Minimum: **0.2 mL; Do not use plasma separator tubes; Refrigerated** **Stability:** Ambient: **After separation from cells: 15 days** Refrigerated: **After separation from cells: 15 days** Frozen: **After separation from cells: 60 days** **Reference Range: Therapeutic, prophylactic, and toxic ranges are not well established.** **Days Performed: 3 days per week** **Reported: 1–4** days	3/7/17
Gastrin	GAST	82941	**Reference Range:** Fasting: **< 115.0 pg/mL**	1/17/17
Glucose	GLU	82947	**Clinical Information: The American Diabetes Association (ADA) provides guidance for cutoff values for fasting glucose and random glucose. The ADA defines fasting as no caloric intake for at least 8 hours. Fasting plasma glucose results between 100 to 125 mg/dL indicate increased risk for diabetes (prediabetes). Fasting plasma glucose results greater than or equal to 126 mg/dL meet the criteria for diagnosis of diabetes. In the absence of unequivocal hyperglycemia, results should be confirmed by repeat testing. In a patient with classic symptoms of hyperglycemia or hyperglycemic crisis, random plasma glucose results greater than or equal to 200 mg/dL meet the criteria for diagnosis of diabetes. Reference: Standards of Medical Care in Diabetes 2016; American Diabetes Association. Diabetes Care. 2016;39(Suppl 1).** For patient population 0-17 years of age: Reference ranges for this patient's age group have not been established. These reference ranges reflect verified or established ranges for the adult population. Interpret these ranges with caution using the clinical context and additional reference resources. **Stability:** Ambient: 8 hours Lithium heparin plasma (light green) or **24 hours** fluoride plasma (gray) Refrigerated: 3 days **Lithium heparin plasma (light green) removed from cells or 24 hours fluoride plasma (gray)** Frozen: Unacceptable	1/11/17

Test Changes (Cont.)

Test Name	Order Code	Billing Code	Change	Effective Date
Glucose, CSF	CGLUC	77605	**Clinical Information:** Evaluation of CSF, diagnosis of meningitis. **Lumbar CSF glucose values of healthy patients are approximately 60% of the plasma values and must always be compared with a concurrently measured plasma value for adequate clinical interpretation. References:** **1. Glucose HK (GLUC3) [package insert V 12.0 English]. Roche Diagnostics, Indianapolis, IN; May 2016.** **2. Tumani, H., Hegen, H. (2015). Chapter 7: Glucose and Lactate. F. Deisenhammer et al. (eds.), Cerebrospinal Fluid in Clinical Neurology. Switzerland: Springer International Publishing.** **Reference Range:** **0–17 Years: 60–80 mg/dL** **18–99 Years: 40–70 mg/dL**	1/25/17
Her-2-Neu Serum	HER2S	81391	**Special Information: This test is New York State approved. Grossly hemolyzed specimens will be rejected.** **Clinical Information: Clinical Reference: 1. Fehm T, Malmonis P, Weitz S, Teramoto Y, Katalinic A, Jager W. Influence of circulating c-erb-2 serum protein on response to adjuvant chemotherapy in node-positive breast cancer patients. Breast Cancer Res Treat. 1997; 43(1):87-95. 2. Molina R, Jo J, Fiella X, et al., c-erb-2 oncoprotein in the sera and tissue of patients with breast cancer: Utility in prognosis. Anti-cancer Research 1996 Jul-Aug; 16(4B) 2295-2300.** **Specimen Requirement:** 1 mL serum from a **red top tube with no additive;** Minimum: **0.2 mL; Immediately centrifuge, aliquot into plastic screw-capped vial and freeze; Frozen** *OR* 1 mL serum from a **serum separator (gold) tube;** Minimum: **0.2 mL; Immediately centrifuge, aliquot into plastic screw-capped vial and freeze; Frozen** **Stability:** Ambient: **Unacceptable** Refrigerated: **Unacceptable** Frozen: **Sample must be frozen** **Reference Range: 0.0–15.0 ng/mL** **Days Performed: Tuesday, Friday** **Reported: 6–10** days	Effective immediately
Herpes Simplex by PCR	HSPCR	79044	**Specimen Requirement:** 1 mL serum from a serum separator (gold) tube; Minimum: 0.5 mL; Separate serum from the cells within six hours of collection and transfer to a sterile polypropylene tube; **Frozen** *OR* 1 g tissue in Viral Transport Media; **Frozen** *OR* 1 mL plasma from an EDTA lavender top tube; Minimum: 0.5 mL; Separate plasma from the cells within six hours of collection and transfer to a sterile polypropylene tube; **Frozen** *OR* Swab(s) in Viral Transport Media; **Frozen**	Effective immediately

Test Changes (Cont.)

Test Name	Order Code	Billing Code	Change	Effective Date
High Sensitivity C-Reactive Protein	HSCRP	81384	**Test Name:** Previously CRP, High Sensitive **Clinical Information:** Assessment of cardiovascular event risk. **hsCRP < 1.0 mg/L, relative risk is low; hsCRP 1.0-3.0 mg/L, relative risk is average; hsCRP > 3.0 mg/L, relative risk is high; Reference: Pearson TA, Mensah GA, Alexander RW, et al. Markers of Inflammation and Cardiovascular Disease. Application to Clinical and Public Health Practice. A Statement for Healthcare Professionals From the Centers for Disease Control and Prevention and the American Heart Association. Circulation 2003;107:499-511.** **Specimen Requirement:** 1 mL plasma from a lithium heparin (light green) plasma separator tube (PST); Minimum: **0.4 mL; Submit in original tube or aliquot specimen into CCL aliquot tube; Centrifuge and refrigerate** *OR* 1 mL serum from a serum separator (gold) tube; Minimum: **0.4 mL; Centrifuge and refrigerate** **Stability:** Ambient: 11 days Refrigerated: 2 months Frozen: 3 years **Reference Range: See Clinical Information** **0–99 Years: < 3.1 mg/L**	2/16/17
IgE	IGE	82785	**Reference Range:** **0–6 Weeks: Not established** **6–12 Weeks: < 6.6 kU/L** **3–6** Months: **< 10.2 kU/L** **6–9** Months: **< 16.6 kU/L** **9–12** Months: **< 22.6 kU/L** 1–2 Years: **< 29.2 kU/L** 2–3 Years: **< 51.7 kU/L** 3–4 Years: **< 72 kU/L** 4–5 Years: **< 90 kU/L** 5–6 Years: **< 108 kU/L** 6–7 Years: **< 126 kU/L** 7–8 Years: **< 142 kU/L** 8–9 Years: **< 160 kU/L** 9–10 Years: **< 176 kU/L** **10–11 Years: < 192 kU/L** 11–99 Years: < 114 kU/L	1/17/17
Itraconazole	ITRAC	81269	**For Interfaced Clients Only: Test build may need to be modified** **Includes:** Itraconazole Hydroxyitraconazole **Total Itraconazole** **Clinical Information: Ranges are based off the Total Itraconazole trough levels: Therapeutic: > 1.0 µg/mL; Prophylaxis: > 0.5 µg/mL; Toxic: > 4.9 µg/mL (Toxic values will not be called).** **Specimen Requirement: 0.5 mL** serum from a red top tube with no additive; Minimum: 0.2 mL; Do not use serum separator tubes; Refrigerated ***OR* 0.5 mL plasma from a lithium heparin green top tube;** Minimum: 0.2 mL; **Do not use plasma separator tubes; Refrigerated** **Stability:** Ambient: **After separation from cells: 15 days** Refrigerated: **After separation from cells: 15 days** Frozen: **After separation from cells: 60 days** **Reference Range:** **Total Itraconazole** **0–99 Years: 0.6–4.9 µg/mL** **Days Performed: 3 days per week** **Reported: 1**–4 days	3/6/17

Test Changes (Cont.)

Test Name	Order Code	Billing Code	Change	Effective Date
Kappa, Free, Serum	FKAPPS	82697	**Reference Range: 3.30–19.40 mg/L**	1/17/17
Kappa/Lambda, Free, Serum	KLFRS	82696	**Reference Range:** Kappa, Free, Serum: **3.30–19.40 mg/L** Lambda, Free, Serum: 5.7–26.3 mg/L Kappa/Lambda Ratio: **0.26–1.65**	1/17/17
Lorazepam	LORAZE	76671	**Specimen Requirement:** 2 mL serum from a red top tube with no additive; Minimum: **0.6 mL;** Do not use serum separator tubes; **Centrifuge and aliquot into plastic screw-capped vial;** Refrigerated *OR* 2 mL plasma from a sodium heparin green top tube; Minimum: **0.6 mL;** Do not use plasma separator tubes; **Centrifuge and aliquot into plastic screw-capped vial;** Refrigerated **Stability:** Ambient: 72 hours Refrigerated: **7 days** Frozen: **180 days** **Days Performed: Monday**–Sunday **Reported:** 6–**11** days	2/28/17
Lung Cancer Hot Spot Panel v2 NGS 2 gene		90479	**Specimen Requirement:** 3-5 mL fine needle aspirate (FNA) in CytoLyt solution; FNA specimens are preserved in CytoLyt solution and should be stored at 4 °C until DNA extraction can be performed; Transport to lab at ambient temperature is acceptable; **Provide the percentage of tumor cells present;** Ambient *OR* 10 mm square formalin-fixed paraffin-embedded (FFPE) tissue block; FFPE tissue 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; **Provide the percentage of tumor cells present;** Ambient ***OR* 10 mm square formalin-fixed paraffin-embedded cell block; FFPE tissue slides; Transport and store 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; Provide the percentage of tumor cells present; Ambient**	2/28/17
Lymphocyte Transformation Test	LTT	43001	**Special Information:** The lab provides the antigen Candida albicans. **For optimum performance of test, specimens should be sent only Monday through Thursday by 4:00 pm EST. Specimen may be cancelled if they arrive in lab 24 hours after draw. Please call lab to set up order. If shipping specimen, make sure it is in an ambient mailer and marked as 'critical specimen.'**	1/18/17
Myoglobin, Urine	UMYO	83875	**Stability:** Ambient: **pH 8-9: 1 hour** Refrigerated: **pH 8-9: 72 hours** Frozen: **pH 8-9: 1 month**	Effective immediately
N Glycan and Transferrin for CDG	NCDG	88374	**CPT:** 82373 **x 1,** 83789 x 1, 84375 x 1	Effective immediately

Test Changes (Cont.)

Test Name	Order Code	Billing Code	Change	Effective Date
Posaconazole	POSACN	88031	**Test Name:** Previously Posaconazole, Serum **Clinical Information: Therapeutic: > 0.9 μg/mL; Prophylaxis: > 0.6 μg/mL; Toxic: > 3.9 μg/mL (Toxic values will not be called). Ranges are based on trough levels.** **Specimen Requirement: 0.5 mL** serum from a red top tube with no additive; Minimum: **0.2 mL;** Do not use serum separator tubes; **Refrigerated** *OR* 1 mL plasma from a lithium heparin green top tube; Minimum: **0.2 mL; Do not use plasma separator tubes; Refrigerated** **Stability:** Ambient: **After separation from cells: 15 days** Refrigerated: **After separation from cells: 15 days** Frozen: **After separation from cells: 60 days** **Reference Range:** **0–99 Years: 0.7–3.9 μg/mL** **Days Performed: 3 days per week** **Reported: 1–4** days	3/7/17
Progesterone	PROG	84144	**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 > 60.0 ng/mL; Third trimester: 58.7 to > 60.0 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.** **Specimen Requirement:** 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** *OR* 1 mL serum from a serum separator (gold) tube; Minimum: 0.5 mL; **Centrifuge and refrigerate** **Stability:** Ambient: **1 day** Refrigerated: 5 days Frozen: 6 months **Reference Range:** Female **0–3 Days: < 1.4 ng/mL** **4–364 Days: < 1.4 ng/mL** **1–9 Years: < 0.4 ng/mL** **10–14 Years: < 0.9 ng/mL** **15–17 Years: 0.2–10.3 ng/mL** **18–99 Years: See Clinical Information** Male **0–29 Days: < 0.7 ng/mL** **30–364 Days: < 0.7 ng/mL** **1–9 Years: < 0.4 ng/mL** **10–14 Years: < 0.9 ng/mL** **15–17 Years: < 0.6 ng/mL** **18–99 Years: < 0.6 ng/mL**	2/9/17

Test Changes (Cont.)

Test Name	Order Code	Billing Code	Change	Effective Date
Protein, CSF	CPROT	34222	**Reference Range:** **91–364 Days:** 15–45 mg/dL **1–99 Years:** 15–45 mg/dL **Male** **0–14 Days: 15–100 mg/dL** **15–30 Days: 15–96 mg/dL** **31–90 Days: 15–48 mg/dL** **Female** **0–14 Days: 15–153 mg/dL** **15–30 Days: 15–100 mg/dL** **31–90 Days: 15–93 mg/dL**	1/25/17
PTH Related Peptide	PTHPEP	77085	**Special Information:** CRITICAL FROZEN: Non-frozen specimens are unacceptable. **Patient must be fasting.** **Clinical Information: Diagnostic work-up of patients with suspected** hypercalcemia of malignancy. **Diagnostic work-up of patients with hypercalcemia of unknown origin.** **Specimen Requirement:** 0.7 mL plasma from an EDTA lavender top tube; Minimum: **0.25 mL;** Patient **preparation:** Fasting; Collect in pre-chilled EDTA lavender-top tube and place on ice after collection; Centrifuge ASAP in a refrigerated centrifuge or refrigerated centrifuge cups; Centrifuge, aliquot and freeze ASAP **Days Performed:** Monday–**Friday** **Reported:** 3–**6** days	Effective immediately
Testosterone	TESTO	84403	**Clinical Information: Adult Males: A testosterone level in the 193-320 ng/dL range with associated clinical symptoms is considered low and may indicate hypogonadism (from NEJM 2010 363:123-135). Results > 320 ng/dL are considered normal. Pediatric Patients: Reference ranges were not locally established for pediatric patients. The normal values are based on the following source: Kulasingam V, Jung BP, Blasutig IM, et al. Pediatric reference intervals for 28 chemistries and immunoassays on the Roche cobas® 6000 analyzer—A CALIPER pilot study. Clinical Biochemistry. 2010;43:1045-1050.** **Stability:** Ambient: **5 days** Refrigerated: **14** days Frozen: 6 months Reference Range: Male **0–364 Days: < 12 ng/dL** **1–5 Years: < 12 ng/dL** **6–10** Years: **< 25 ng/dL** **11–15** Years: **< 830 ng/dL** **16–17** Years: **102–1010 ng/dL** 18–99 Years: 193–824 ng/dL Female **0–364 Days: < 21 ng/dL** **1–5 Years: < 12 ng/dL** **6–10** Years: < 25 ng/dL **11–17** Years: < 79 ng/dL 18–99 Years: **< 40 ng/dL**	2/14/17
Tryptase	TRYPT	80411	**Reference Range: < 11.0 µg/L**	1/17/17

Test Changes (Cont.)

Test Name	Order Code	Billing Code	Change	Effective Date
Voriconazole	VORCON	84568	**Clinical Information: Therapeutic: > 0.9 µg/mL; Prophylaxis: > 0.9 µg/mL; Toxic: > 5.9 µg/mL (Toxic values will not be called). Ranges are based on trough levels.** **Specimen Requirement: 0.5 mL** serum from a red top tube with no additive; Minimum: **0.2 mL;** Do not use serum separator tubes; **Refrigerated** *OR* **0.5 mL** plasma from a lithium heparin green top tube; Minimum: **0.2 mL; Do not use plasma separator tubes; Refrigerated** **Stability:** Ambient: After separation from cells: **15** days Refrigerated: After separation from cells: **15** days Frozen: After separation from cells: **60 days** **Reference Range:** 0–99 Years: 1.0–**5.9 µg/mL** **Days Performed: 3 days per week** **Reported: 1–4** days	3/7/17

New Tests

Test Name	Order Code	Billing Code	Change	Effective Date
Bird Fanciers Precipitin Panel I	BFPP1		**Effective Date:** Due to circumstances beyond our control, the Bird Fanciers Precipitin Panel I will not go live on 11/30/16 as previously announced. We apologize for any inconvenience this may have caused.	1/24/17
Chromosome Analysis with Reflex MDS FISH	CHRMDS		**Special Information:** If the chromosome results are suboptimal or no growth, MDS FISH will be added at an additional charge. **Specimen Requirement:** 2-3 mL bone marrow in a sodium heparin green top tube; If aliquoting is necessary, sterile aliquot tubes must be used; Ambient *OR* 2-3 mL bone marrow in an EDTA lavender top tube; If aliquoting is necessary, sterile aliquot tubes must be used; Ambient **Stability:** Ambient: 48 hours Refrigerated: Not preferred Frozen: Unacceptable **Methodology:** Culture Karyotyping Microscopy **Days Performed:** Sunday–Saturday **Reported:** 7–21 days **CPT:** 88237 x 1, 88262 x 1, 88291 x 1	1/26/17
Isavuconazole	ISACON		**Clinical Information:** Therapeutic, prophylactic, and toxic ranges are not well established. **Specimen Requirement:** 0.5 mL serum from a red top tube with no additive; Minimum: 0.2 mL; Do not use serum separator tubes; Refrigerated *OR* 0.5 mL plasma from a lithium heparin green top tube; Minimum: 0.2 mL; Do not use plasma separator tubes; Refrigerated **Stability:** Ambient: After separation from cells: 15 days Refrigerated: After separation from cells: 15 days Frozen: After separation from cells: 60 days **Methodology:** High Performance Liquid Chromatography/Tandem Mass Spectrometry (LC/MS/MS) **Reference Range:** Therapeutic, prophylactic, and toxic ranges are not well established. **Days Performed:** 3 days per week **Reported:** 1–4 days **CPT:** 80299 x 1 **Price:** $88.00 (non-discountable)	3/7/17

New Tests (Cont.)

Test Name	Order Code	Billing Code	Change	Effective Date
MET Gene Analysis			**Interpretive Data:** Tumors harboring MET exon 14 skipping mutations have increased sensitivity to MET inhibitors. **Specimen Requirement:** 10 mm square formalin-fixed paraffin-embedded (FFPE) tissue block; Formalin-fixed paraffin-embedded tissue slides; Transport and store slides at ambient temperature; 10 sections FFPE tissue on charged, unbaked slides plus one H&E stained section with best tumor area circled by a pathologist; Provide the percentage of tumor cells present; Ambient *OR* 3-5 mL fine needle aspirate (FNA) in CytoLyt solution; FNA specimens are preserved in CytoLyt solution and should be stored at 4 °C until DNA extraction can be performed; Transport to lab at ambient temperature is acceptable; Provide the percentage of tumor cells present *OR 10 mm square formalin-fixed paraffin-embedded cell block; Cell block specimens; Formalin-fixed paraffin-embedded tissue slides; Transport and store slides at ambient temperature; 10 sections FFPE tissue on charged, unbaked slides plus one H&E stained section with best tumor area circled by a pathologist; Provide the percentage of tumor cells present; Ambient **Stability:** Ambient: Indefinitely for FFPE slides; FFPE slides and FNA can be transported at ambient temperature Refrigerated: 2 weeks for FNA samples Frozen: Unacceptable **Methodology:** Next Gen Sequencing **Days Performed:** Bi-weekly **CPT:** 81479 x 1, G0452 x 1 **Price:** $458.00 (non-discountable)	2/28/17
TPMT Genotyping Assay	TPMTGN		**Special Information:** Disclaimer: The performance characteristics of this LDT were established at the Molecular Pathology Section of the Pathology and Laboratory Medicine Institute at the Cleveland Clinic. The Food and Drug Administration (FDA) of the USA has not approved this test nor is it required for clinical use. **Clinical Limitation:** The TPMT genotyping assay detects only TPMT*2, TPMT*3A, TPMT*3B, and TPMT*3C variants. This assay does not interrogate other TPMT variants, and therefore their genotype-phenotype associations to thiopurine drugs are not indicated. This genotyping test will not distinguish *1/*3A heterozygous from the rare *3B/*3C genotype, which can only be identified with a test for TPMT enzyme activity. **Clinical Reference:** Relling MV et al. Clinical Pharmacogenetics Implementation Consortium Guidelines for Thiopurine Methyltransferase Genotype and Thiopurine Dosing. Clin Pharmacol Ther. 2013 update. 93:324-325. **Clinical Information:** TPMT genotyping test is used for identifying patients at risk for myelosuppression with the standard dosage of thiopurine drugs, and for adjusting the drug dosage or to select alternate drug therapy. Reference Range for the test is TPMT*1/TPMT*1. No variants detected is an indication of homozygous wild type (two *1 functional alleles), which is associated with normal TPMT enzyme activity. Patients with two functional *1 alleles are predicted to have normal (high or extensive) TPMT enzyme activity. Patients with one functional allele (*1) and one nonfunctional allele (*2, *3A, *3B, or *3C) are predicted to have intermediate TPMT enzyme activity. These patients are at risk for severe myelosuppression or drug toxicity, and may require only a lower than standard dosage of thiopurine drugs. *(continued on page 16)*	2/28/17

New Tests (Cont.)

Test Name	Order Code	Billing Code	Change	Effective Date
TPMT Genotyping Assay *(continued from page 15)*			Patients with two nonfunctional alleles (*2, *3A, *3B, or *3C) are predicted to have deficient (no or low) TPMT enzyme activity. These patients are at a greater risk (almost 100%) of experiencing myelosuppression, who may require even a reduced dosage of thiopurine drugs than patients with one nonfunctional allele and should be considered for an alternate drug therapy. **Recommended Usage:** For identifying patients at risk for myelosuppression with the standard dosage of thiopurine drugs, and for adjusting the drug dosage or to consider alternate drug therapy. **Interpretive Data:** Reference Range for this test is TPMT*1/TPMT*1, which is associated with normal TPMT enzyme activity. **Specimen Requirement:** 4 mL peripheral blood in an EDTA lavender top tube; Specimen is stable at ambient conditions up to 72 hours; Refrigerate after 72 hours for up to 2 weeks; Ambient **Stability:** Ambient: Ambient specimen is acceptable up to 72 hours after collection. Refrigerated: Refrigerated specimen is acceptable up to 2 weeks after collection. Frozen: Frozen specimen is unacceptable. **Methodology:** Fluorescence Monitoring Real-Time Polymerase Chain Reaction (RT-PCR) **CPT:** 81401 x 1	

Fee Reductions

Test Name	Order Code	Billing Code	List Fee	CPT Code	Effective Date
Itraconazole	ITRAC	81269	$88.00 (non-discountable)	80299	3/6/17
Posaconazole	POSACN	88031	$88.00 (non-discountable)	80299	3/7/17
Voriconazole	VORCON	84568	$88.00 (non-discountable)	80299	3/7/17

Discontinued Tests

Test Name	Order Code	Billing Code	Test Information	Effective Date
Fructose, Quantitative, Semen	SMQNFR	82758	This test will no longer be available.	Effective immediately
PRO-PredictR TPMT	PPTMPT	81267	This test will no longer be available. Suggest ordering TPMT Genotyping Assay (TPMTGN).	2/28/17