

Technical Update • August 2014

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 demographics, 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	Reference Range	Methodology	Days Performed/Reported
4	ALGN Food Alpha-Gal											
4	Allergen, Food Panel IgG											
2	Allergen, Chick Pea IgG											
4	Allergen, Tree Aspen IgG											
4	Aminolevulinic Acid Dehydratase (ALAD), Whole Blood											
5	BCR-ABL Qualitative Multiplex RT-PCR											
2	C1 Esterase Inhibitor											
2	C1 Esterase Inhibitor Functional											
2	Carbohydrate Deficient Transferrin, Pediatric											
2	Chlorpromazine, Quantitative											
2	Coenzyme Q10											
2	Copper											
2	Copper/Zinc											
5	Diffuse Large B-cell Lymphoma Molecular Subtyping											
5	Eosinophil Cationic Protein											
5	Estradiol; Males, Children, or Postmenopausal Females by Tandem Mass Spectrometry											
2	Histoplasma Ag, Urine											
7	HIV-1 Antibody EIA											
2	HIV-2 DNA PCR											
2	Human Erythrocyte Antigen											
3	Hydroxyprogesterone											
3	Insulin Like Growth Factor Binding Protein 2											
3	KIT Asp816Val Mutation Analysis											
5	Lyme Reflex Panel CSF											

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6	Meconium Drug Screen 9										
3	Mycoplasma Cult Non Urogenital										
3	Nicotine and Cotinine, Serum										
3	Oxcarbamazepine										
3	PRO-PredictR TPMT										
3	Prostate Cancer Biomarker										
3	RHCE Variant Antigen										
3	RHD Variant Antigen										
6	Urticaria-Induced Basophil Activation										
6	Urticaria-Inducing Activity										
7	Valproic Acid, Free and Total										
3	Voriconazole										
3	Zinc										

Test Changes

Test Name	Order Code	Billing Code	Change	Effective Date
Allergen, Chick Pea IgG	CPEA	84031	***Test build may need to be modified to remove PEAIGE from battery***	7/24/2014
C1 Esterase Inhibitor	C1EST	40005	Specimen Requirement: 1mL of serum from an serum separator tube (gold). Remove serum from cells within 2 hours of collection *CRITICAL FROZEN* Separate specimens must be submitted when multiple tests are ordered.	7/22/2014
C1 Esterase Inhibitor Functional	C1EFUN	75459	Specimen Requirement: 1 mL serum Remove serum from cells ASAP or within 2 hours of collection and freeze. *CRITICAL FROZEN* Separate specimens must be submitted when multiple tests are ordered.	7/22/2014
Carbohydrate Deficient Transferrin, Pediatric	CDTRAP	87674	Minimum Specimen Requirement: 0.05 mL serum	7/14/2014
Chlorpromazine, Quantitative	CLORPR	75523	Days Performed: Wednesday, Saturday	7/3/2014
Coenzyme Q10	COEQ10	81932	Specimen Requirement: Stability: Ambient: Unacceptable, Refrigerated: 8 hours, Frozen: 72 hours	7/3/2014
Copper	Copper	82525	Specimen Requirement: Serum (navy) no longer acceptable as alternate specimen	9/3/2014
Copper/Zinc	CUZN	47	Specimen Requirement: Serum (navy) no longer acceptable as alternate specimen	9/3/2014
Histoplasma Ag, Urine	UHISTO	79421	Reference Range: 0 - 99 years < 0.4 ng/mL	8/4/2014
HIV-2 DNA PCR	HIV2PC	81872	Specimen Requirement: Minimum 0.4 mL Stability: Ambient: 6 days, Refrigerated: 6 days Days Reported: 2 - 3 days	7/17/2014
Human Erythrocyte Antigen	HEA	87880	Specimen Requirement: Stability: Refrigerated: 14 days, Frozen: Unacceptable	7/1/2014

Test Changes (cont.)

Test Name	Order Code	Billing Code	Change	Effective Date
Hydroxyprogesterone	HPROG	83498	Reference Range: Females: 1 - 18 years: Pediatric reference range: Pre-pubertal <80 ng/dL < 1year 30 - 160 ng/dL 18 - 99 years: Follicular 10 - 80 ng/dL Luteal 90 - 300 ng/dL Tanner Stage Age Range 1 <9.0 <83 2 9 - 14 11 - 98 3 10 - 15 11 - 155 4/5 11 - 18 18 - 265 Males: 0 - 18 years: Pediatric reference range: Pre-pubertal <80 ng/dL 18 - 99 years 40 - 180 ng/dL Tanner Stage Age Range 1 <10 <91 2 10 - 14 <116 3 11 - 15 10 - 138 4/5 12 - 17 24 - 180	7/1/2014
Insulin Like Growth Factor Binding Protein 2	IGFBP2	79461	Specimen Requirements: 1 mL serum from a RED tube. Fasting is preferred.	7/3/2014
KIT Asp816Val Mutation Analysis	KITMST	84159	Minimum Specimen Requirement: 1 mL Bone marrow	5/29/2014
Mycoplasma Cult Non Urogenital	UMPLAS	88455	Days Reported: 4 - 9 days	7/14/2014
Nicotine and Cotinine, Serum	NICOT	76556	Clinical Information: Active tobacco product user: Nicotine concentration: 30 ng/mL - 50 ng/mL; Cotinine concentration: 200 ng/mL - 800 ng/mL. Passive exposure to tobacco: Nicotine concentration: < 2 ng/mL; Cotinine concentration: < 8 ng/mL. Unexposed non-tobacco user or Abstinent user for > 2 weeks: Nicotine concentration: < 2 ng/mL; Cotinine concentration: < 2 ng/mL.	8/31/2014
Oxcarbamazepine	OXCARB	81702	Specimen Requirement: 2 mL plasma from a Sodium or Lithium heparin (Green) tube. Alternate: 2 mL serum Stability: Ambient: 24 hours, Refrigerated: 1 week, Frozen: 1 month	9/2/2014
PRO-PredictR TPMT	PPTMPT	81267	*** Test build may need to be modified*** Additional component included.	9/30/2014
Prostate Cancer Biomarker	PCA3	87736	Specimen Requirements: Collect 2.5 mL urine using the following guidelines: 1) Perform attentive digital rectal exam (DRE) by applying firm pressure from the base to apex and from the lateral to midline of prostate. Three strokes per lobe. Firm pressure is enough pressure to depress the surface approximately 1 cm. 2) Collect first 20 - 30 mL of urine in a clean urine collection cup immediately following the DRE. 3) Immediately pipette 2.5 mL of urine into Progenisa collection tube. 4) The correct volume of urine has been added when the fluid level is between the black fill lines on the urine specimen transport tube label. 5) Replace tube lid and invert 5 times. Do not shake or vortex. 6) Place labeled Progenisa tube in a biohazard transport bag. 7) Complete Patient Information section of the requisition including: Patient name; Patient clinic number; Date of birth; Collection date, and Ordering physician. Place this form in the outside pouch of the biohazard bag. 8) Refrigerate specimen for pickup. For specimen collection kits, please contact Client Services at 216.445.5755. Stability: Ambient: 4 days, Refrigerated: 14 days, Frozen: 11 months	9/10/2014
RHCE Variant Antigen	RHCE	88772	Specimen Requirement: Stability: Frozen: Unacceptable, Refrigerated 14 days	7/1/2014
RHD Variant Antigen	RHD	88771	Specimen Requirement: Stability: Frozen: Unacceptable, Refrigerated 14 days	7/1/2014
Voriconazole	VORCON	84568	Days Performed: Tuesday, Thursday, Saturday Days Reported: 2 - 7 days	7/14/2014
Zinc	ZINC	84630	Specimen Requirement: Serum (navy) no longer acceptable as alternate specimen	9/3/2014

New Tests

Test Name	Order Code	Billing Code	Test Information	Effective Date
ALGN Food Alpha-Gal	GALIGE	90088	Specimen Requirement: 1 mL serum from a SST tube. Stability: Ambient: 1 month, Refrigerated: 1 month, Frozen: 1 month Methodology: Immunoassay Days Performed: Varies Reported: 4 - 6 days CPT: 86003	9/25/2014
Allergy Food Panel IgG	FPIGG	90087	Specimen Requirement: 1 mL serum from a SST tube. Minimum: 0.5 mL Serum Stability: Ambient: 2 weeks, Refrigerated: 2 weeks, Frozen: 30 days Methodology: Immunocap Includes: Corn, Egg White, Yeast (bakers, brewers) IgG, Barley (food), Beef IgG, Malt IgG, Casein IgG, Oat IgG, Chicken meat IgG, Cacao (chocolate) IgG, Orange IgG, Peanut IgG, Pork IgG, Lettuce IgG, Soybean IgG, Tomato IgG, Wheat IgG, Potato IgG, and Rye IgG. Days Performed: Sunday, Wednesday, Friday Reported: 3 - 4 days CPT: 86001	9/11/2014
Allergen, Tree Aspen IgE	ASPEN	90105	Specimen Requirement: 0.5 mL Serum from a SST tube. Hemolyzed, icteric or lipemic specimens will not be accepted. Stability: Ambient: 1 month, Refrigerated: 1 month, Frozen: 1 year Methodology: Quantitative Conventional RAST. Days Performed: Varies Reported: 5 - 8 days CPT: 86003	9/30/2014
Aminolevulinic Acid Dehydratase (ALAD), Whole Blood	ALADWB	90109	Clinical Information: Porphyrins are a group of inherited disorders resulting from enzyme defects in the heme biosynthetic pathway. Aminolevulinic acid (ALA) dehydratase (ALAD) deficiency porphyria (ADP) results from a deficiency of ALAD, which causes ALA accumulation with subsequent excretion in the urine. Urinary porphobilinogen (PBG) remains essentially normal, which rules out other forms of acute porphyria. ADP is an autosomal recessive, acute hepatic porphyria that produces neurologic symptoms similar to those seen in acute intermittent porphyria. Symptoms include acute abdominal pain, peripheral neuropathy, nausea, vomiting, constipation, and diarrhea. Respiratory impairment, seizures, and psychosis are possible during an acute period. ADP is extremely rare with only 7 cases described in the literature since 1979. Specimen Requirement: Whole blood Sodium heparin (Green). Place specimen on ice after draw. Patient should abstain from alcohol for 24 hours. Include a list of medications the patient is currently taking. Volume is full tube. Alternate: Whole blood EDTA (Lavender) or Lithium Heparin (Green). Place specimen on ice after draw Minimum: 3 mL Stability: Ambient: Unacceptable, Refrigerated: 4 days, Frozen: Unacceptable. Methodology: Enzymatic End Point Days Performed: Monday - Friday Reported: 4 - 5 days CPT: 82657	9/30/2014

New Tests (cont.)

Test Name	Order Code	Billing Code	Test Information	Effective Date
BCR-ABL Qualitative Multiplex RT-PCR	BCRQL	81479	Specimen Requirement: 10 mL Blood in an EDTA (Lavender) tube. Place specimen on ice after draw. Specimen must be delivered to testing lab by 2:00 PM on Fridays. Alternate: 5 mL Bone Marrow in an EDTA (Lavender) tube. Place specimen on ice after draw. Specimen must be delivered to testing lab by 2:00 PM on Fridays. Minimum: 5 mL Stability: Ambient: Unacceptable, Refrigerated: 48 hours, Frozen: Unacceptable Methodology: Reverse Transcription / Polymerase Chain Reaction, Capillary Electrophoresis Reference Range: n/a Days Performed: 1 day per week Reported: 8 - 11 days CPT: 81479	8/21/2014
Diffuse Large B-cell Lymphoma Molecular Subtyping	DLBCL	90090	Specimen Requirement: Paraffin block, formalin-fixed Methodology: Capillary Electrophoresis (CE) Reverse Transcription/ Polymerase Chain Reaction (RT/PCR) Days Performed: 1 day a week Reported: 10 - 14 days CPT: 81599	8/19/2014
Eosinophil Cationic Protein	EOSPRO	90093	Specimen Requirement: 1 mL serum from a SST tube. Minimum: 0.5 mL serum Stability: Ambient: 48 hours, Refrigerated: 1 week, Frozen: 2 weeks Methodology: Quantitative Fluorescent Enzyme Immunoassay Days Performed: Varies Reported: 7 - 16 days CPT: 83520	9/30/2014
Estradiol; Males, Children, or Postmenopausal Females by Tandem Mass Spectrometry	ESTMS	90094	Specimen Requirement: 0.5 mL serum from an SST tube. Alternate: 0.5 mL plasma from an EDTA (Lavender), sodium or lithium heparin (Green) Minimum: 0.3 mL serum or plasma Stability: After separation from cells: Ambient: 48 hours; Refrigerated: 1 week; Frozen: 1 months Methodology: Quantitative High Performance Liquid Chromatography-Tandem Mass Spectrometry Days Performed: Sunday - Saturday Reported: 3 - 6 days CPT: 82670	9/30/2014
Lyme Reflex Panel CSF	LYMCSF	90091	Specimen Requirement: 6 mL CSF in a sterile container Minimum: 2.5 mL CSF in a sterile container Stability: Ambient: 8 hours; Refrigerated: 2 weeks; Frozen: 1 year (avoid repeated freeze/thaw cycles) Methodology: Semi-Quantitative Enzyme-Linked Immunosorbent Assay/ Qualitative Western Blot Reference Range: 0.99 LIV or less: Negative - Antibody to <i>Borrelia burgdorferi</i> not detected. 1.00-1.20 LIV: Equivocal - Repeat testing in 10-14 days may be helpful. 1.21 LIV or greater: Positive - Probable presence of antibody to <i>Borrelia burgdorferi</i> detected. Reflex: <i>Borrelia burgdorferi</i> Antibody, IgG by Western Blot (CSF): Negative; <i>Borrelia burgdorferi</i> Antibody, IgM by Western Blot (CSF): Negative Days Performed: Sunday - Saturday Reported: 2 - 4 days CPT: 86618	9/25/2014

New Tests (cont.)

Test Name	Order Code	Billing Code	Test Information	Effective Date
Meconium Drug Screen 9	MECD59	90095	<p>Specimen Requirement: All available (4g preferred) meconium (blackish material) excreted until milk/formula based stool (yellow-green) appears. Minimum: 2g or 3/4 inch cube on each side Stability: Ambient: 1 week, Refrigerated: 3 months, Frozen 1 year</p> <p>Methodology: Qualitative Enzyme-Linked Immunosorbent Assay/Qualitative Gas Chromatography-Tandem Mass Spectrometry</p> <p>Reference Range: Negative Marijuana 30ng/g (Confirmation 5ng/g); Cocaine 30ng/g (Confirmation 20ng/g); Opiates 30ng/g (Confirmation 20ng/g); Phencyclidine 15ng/g (Confirmation 10ng/g); Amphetamines 30ng/g (Confirmation 20ng/g); Barbiturates 75ng/g (Confirmation 50ng/g); Methadone 40ng/g (Confirmation 10ng/g); Benzodiazepines 75ng/g (Confirmation 20ng/g); Propoxyphene 75ng/g (Confirmation 10ng/g)</p> <p>Days Performed: Sunday - Saturday</p> <p>Reported: 2 - 5 days</p> <p>CPT: 80101x9; if positive; add appropriate CPT codes(s): 82542; 82520; 83925; 83992; 82145;82205; 80154; 83840; 83925</p> <p>Special Information: If the specimen screens positive, then Confirmation/Quantitation by GC/MS and/or LC-MS/MS will be added to confirm result. Additional Charges Apply</p>	9/25/2014
Urticaria-Induced Basophil Activation	UTBAS	90080	<p>Specimen Requirement: 1 mL serum from no additive (Red) tube, Frozen, separate serum from sells within 2 hours of collection. Minimum: 0.5 mL serum Stability: Ambient: after separation from cells 30 minutes, Refrigerated: Unacceptable, Frozen: after separation from cells 1 year (avoid repeated freeze/thaw cycles).</p> <p>Methodology: Semi-Quantitative Flow Cytometry</p> <p>Days Performed: Monday, Friday</p> <p>Reported: 4 - 7 days</p> <p>CPT: 88184, 88185x2</p>	9/25/2014
Urticaria-Inducing Activity	UTACT	90019	<p>Specimen Requirement: 1 mL serum from a no additive (Red) tube, Critical Frozen. Separate serum from cells ASAP or within 2 hours of collection. Separate specimens must be submitted when multiple tests are ordered. Minimum: 0.5 mL serum Stability: Ambient: after separation from cells 30 minutes, Refrigerated: Unacceptable, Frozen: after separation from cells 1 year (avoid repeated freeze/thaw cycles).</p> <p>Special Information: Patients taking calcineurin inhibitors should stop their medications for 72 hours prior to draw. Patients on prednisone should be off medication for 2 weeks prior to draw.</p> <p>Clinical Information: Chronic urticaria (CU) is a common and complex dermatological condition that is suspected when patients experience persistent hives for over 6 weeks. No published evidence of an exogenous allergen as the cause of this disorder exists. About 45 percent of cases have autoantibodies directed against either basophil or mast cell-associated IgE or the high affinity IgE-Fc receptor (Fc epsilon R1 alpha). The presence of histamine releasing factors (including but not limited to IgE and Fc epsilon R1 alpha-specific autoantibodies) in the patient serum can be indirectly determined by evaluating basophil/mast cell activation status using histamine release assays, autologous serum-skin test, and flow cytometric measurement of the basophil and mast cell-specific marker CD203c. Serum from CU patients can activate donor basophils, which induces histamine release and CD203c upregulation.</p> <p>Methodology: Cell Culture, Enzyme-Linked Immunosorbent Assay (ELISA)</p> <p>Reference Range: <= 10</p> <p>Days Performed: Monday, Friday</p> <p>Reported: 4 - 7 days</p> <p>CPT: 86352</p>	8/5/2014

New Tests (cont.)

Test Name	Order Code	Billing Code	Test Information	Effective Date
Valproic Acid, Total and Free	VPAFT	34113	Specimen Requirement: 3 mL plasma from a Sodium or Lithium heparin (Green) tube Stability: Ambient: 1 day, Refrigerated: 1 week, Frozen: 1 month Methodology: Fluorescence Polarization Immunoassay (FPIA) Reference Range: Valproic Acid: Age 0 - 99: 50 - 100ug/mL; Urgent Range: >150; Valproic Acid, Free: Age 0 - 99: 4.0 - 50.0ng/mL; Urgent Range: > 75.0 Days Performed: Sunday - Saturday Reported: 1 - 2 days CPT: 80164x2	9/23/2014

Discontinued Tests

Test Name	Order Code	Billing Code	Test Information	Effective Date
HIV-1 Antibody EIA	HIV1AB	50136	This test will no longer be available.	7/31/2014