Cleveland Clinic
Robert J. Tomsich Pathology & Laboratory Medicine Institute

Technical Update • April 2015

The Robert J. Tomsich Pathology and Laboratory Medicine Institute (RT-PLMI) 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 or days performed. For your convenience, tests are listed alphabetically.

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.

Summary of Changes by Test Name		Name Change	New Test	Test Discontinued	Special Information	Specimen Requirement	Component Change	Methodology	Reference Range	Days Performed/Reported	Stability
3	Aldosterone					■					
3	Aldosterone/Renin Activity Ratio					■					
10	Allergen, False Ragweed IgE		■								
3	Allergen, Respiratory Region 8						■		■		
10	Allergen, Seafood Panel		■								
3	Allergen, Whey IgG										■
4	Alpha-1-Antitrypsin					■					
13	Alpha-1-Antitrypsin Quantitation and Phenotyping			■							
4	Anti-Streptolysin O					■					
13	Aspergillus Antibody, CF			■							
13	Aspergillus Antibody, (CF/ID)			■							
11	Aspergillus Antibody (CF reflex to ID)		■								
13	Aspergillus Antibody, ID			■							
4	Aspergillus galactomannan BAL									■	■
4	Aspergillus galactomannan Serum									■	■
4	Beta-2 Transferrin					■					
13	Blastomyces Antibody, CF			■							
13	Blastomyces Antibody, (CF/ID)			■							
11	Blastomyces Antibody (CF reflex to ID)		■								
13	Blastomyces Antibody, ID			■							
4	Calculi (Stone) Analysis									■	
4	Ceruloplasmin					■					

	Summary of Changes by Test Name	Name Change	New Test	Test Discontinued	Special Information	Specimen Requirement	Component Change	Methodology	Reference Range	Days Performed/Reported	Stability
13	Coccidiodes Antibody, CF			■							
13	Coccidiodes Antibody, (CF/ID)			■							
11	Coccidiodes Antibody (CF reflex to ID)		■								
13	Coccidiodes Antibody, ID			■							
4, 5	Estrogen, Serum Fractionated					■			■	■	■
5	Fatty Acid Oxidation Probe Assay, Fibroblast Culture				■					■	
5	Fecal Lactoferrin	■									
5	First Trimester Screening, First Screen				■						
13	FISH for BCR/ABL			■							
13	Fungal Antibodies, CF			■							
13	Fungal Antibodies, (CF/ID)			■							
11	Galactose-alpha-1,3-galactose IgE		■								
6	Glomerular Basement Membrane IgG				■	■		■	■	■	■
6	Herpes Simplex by PCR				■	■		■		■	■
13	Histoplasma Antibodies, CF			■							
13	Histoplasma Antibodies, CF/ID			■							
11	Histoplasma Antibody (CF reflex to ID)		■								
13	Histoplasma Antibodies, ID			■							
6	HIV 1/2 Combo (Antigen/Antibody)				■						
6	Hypercoagulation Diagnostic Interpretive Panel				■						
6	Integrated Screen, First Trimester Screen				■						
6	Integrated Screen, Second Trimester Screen				■						
13	Lactoferrin, Fecal			■							
7	Leflunomide as Metabolite				■	■				■	
12	Levamisole		■								
7	Lupus Anticoagulant Diagnostic Interpretive Panel				■						
7	Meconium Drug Screen 5				■			■			
7	NMO/Aquaporin-4 IgG Cell Binding Assay, CSF				■			■			
13	Organic Acids, Neonate Urine			■							
7	Organic Acids Urine, Quant				■						
8	Paraneoplastic Autoantibody Evaluation, CSF				■	■	■	■		■	■
8	Pipecolic Acid, Serum				■						
9	Platelet Aggregation				■						
9	Prostate Cancer Biomarker									■	
9	Sequential Screen, First Trimester (SQSEQL1)				■						
9	Sequential Screen, Second Trimester (SQSEQL2)				■						
9	Serotonin, Whole Blood				■						
9	Stratify JCV Antibody and Index with Reflex to Inhibition Assay									■	
9	Torch Antibodies, IgG & IgM					■		■	■	■	■
9	TSH Binding Inhibition									■	

	Summary of Changes by Test Name	Name Change	New Test	Test Discontinued	Special Information	Specimen Requirement	Component Change	Methodology	Reference Range	Days Performed/Reported	Stability
10	von Willebrand Diagnostic Interpretive Panel					■					
12	von Willebrand Diagnostic Interpretive Panel (Limited)		■								

Test Changes

Test Name	Change	Effective Date
Aldosterone	**Special Information: If specimen is collected in upright position, patient should be seated or standing for at least 30 minutes prior to collection. If specimen is collected in supine position, patient should be in supine position for at least 30 minutes prior to collection.**	3/5/2015
Aldosterone/Renin Activity Ratio	**Special Information: If specimen is collected in upright position, patient should be seated or standing for at least 30 minutes prior to collection. If specimen is collected in supine position, patient should be in supine position for at least 30 minutes prior to collection.**	3/5/2015
Allergen, Respiratory Region 8	**Includes:** Box Elder Tree (Maple Tree) Elm Tree Short Ragweed (Common ragweed) Cat Epithelium and dander Aspergillus Fumigatus Mountain cedar (mountain juniper) Dermatophagoides Farinae Pigweed Timothy Grass White ash tree Sycamore tree Pecan tree Mucor Racemosus Oak tree Alternaria alternata Cockroach Marsh Elder Dog Dander Hormodendrum Cottonwood Tree Russian Thistle Bermuda Grass Penicillium Notatum Walnut Tree Mouse Epithelium White Mulberry Tree Dermatophagoides Pteronyssinus **Birch Tree** **Reference Range:** **Birch Tree: < 0.35 kU/L** **Birch Tree Class: 0** **All other ranges are unchanged**	6/2/2015
Allergen, Whey IgG	**Stability:** Ambient: **After separation from cells, 48 hours** Refrigerated: **After separation from cells, 2 weeks** Frozen: **After separation from cells,** 1 year	6/2/2015

Test Changes (Cont.)

Test Name	Change	Effective Date
Alpha-1-Antitrypsin	**Effective date:** Do to circumstances beyond our control the Alpha-1-Antitrypsin assay will not change on 4/6/2015 as previously announced. We apologize for any inconvenience this may have caused.	To be determined
Anti-Streptolysin O	**Effective date:** Do to circumstances beyond our control the Anti-Streptolysin O assay will not change on 4/6/2015 as previously announced. We apologize for any inconvenience this may have caused.	To be determined
Aspergillus galactomannan BAL	**Days Performed: Tuesday, Friday** **Reported: 1–5** days **Stability:** Ambient: **48 hours** Refrigerated: **5** days Frozen: **5 months**	6/2/2015
Aspergillus galactomannan Serum	**Days Performed: Tuesday, Friday** **Reported: 1–5** days **Stability:** Ambient: **48 hours** Refrigerated: **5** days Frozen: **7 months**	6/2/2015
Beta-2 Transferrin	**Special Information: Direct collections may be done with a pipette, syringe, test tube, or microcollection device. If submitting a syringe, remove needle. Add cap to end of syringe.** Beta-2 transferrin is also found in aqueous humor and in serum of patients with rare metabolic glycoprotein disorders or genetic variants of transferrin. **A cotton swab may be used if direct collection is not feasible. Place swab in a small, sealed container. Do not add any additional fluid to the swab.**	4/1/2015
Calculi (Stone) Analysis	**Days Performed:** Monday–Friday **Reported:** 1–5 days	5/5/2015
Ceruloplasmin	**Effective date:** Do to circumstances beyond our control the Ceruloplasmin assay will not change on 4/6/2015 as previously announced. We apologize for any inconvenience this may have caused.	To be determined
Estrogen, Serum Fractionated *(continued on page 5)*	**Specimen Requirement:** 0.5 mL serum - serum separator tube; Minimum: 0.3 mL *OR* 0.5 mL plasma - lavender top EDTA tube; Minimum: 0.3 mL *OR* 0.5 mL plasma - sodium or lithium heparin green top tube; Minimum: 0.3 mL *OR* 0.5 mL serum - red top tube; Minimum: 0.3 mL **Reference Range:** ESTRADIOL: Female: Tanner Stage I: < 56 pg/mL Tanner Stage II: 2-133 pg/mL Tanner Stage III: 12-277 pg/mL Tanner **Stage IV and V**: 2-259 pg/mL 7-9 years: < 36 pg/mL 10-12 years: 1-87 pg/mL 13-15 years: 9-249 pg/mL 16-17 years: 2-266 pg/mL 18-99 years: Premenopausal: Early Follicular 30-100 pg/mL 18-99 years: Premenopausal: Late Follicular 100-400 pg/mL 18-99 years: Premenopausal: Luteal 50-150 pg/mL 18-99 years: Postmenopausal: 2-21 pg/mL Male: Tanner Stage I: < 8 pg/mL Tanner Stage II: < 10 pg/mL Tanner Stage III: 1-35 pg/mL Tanner **Stage IV and V**: 3-35 pg/mL 7-9 years: < 7 pg/mL 10-12 years: < 11 pg/mL 13-15 years: 1-36 pg/mL 16-17 years: 3-34 pg/mL 18-99 years: 10-42 pg/mL	6/16/2015

Test Changes (Cont.)

Test Name	Order Code	Change	Effective Date
Estrogen, Serum Fractionated (continued)		ESTRONE: Female: Tanner Stage I: < 27 pg/mL Tanner Stage II: 1-39 pg/mL Tanner Stage III: 8-117 pg/mL Tanner **Stage IV and V:** 4-109 pg/mL 7-9 years: < 20 pg/mL 10-12 years: 1-40 pg/mL 13-15 years: 8-105 pg/mL 16-17 years: 4-133 pg/mL 18-99 years: Premenopausal: Early Follicular < 150 pg/mL 18-99 years: Premenopausal: Late Follicular 100-250 pg/mL 18-99 years: Premenopausal: Luteal 0-200 pg/mL 18-99 years: Postmenopausal: 3-32 pg/mL Male: Tanner Stage I: < 7 pg/mL Tanner Stage II: < 11 pg/mL Tanner Stage III: 1-31 pg/mL Tanner **Stage IV and V:** 2-30 pg/mL 7-9 years: < 7 pg/mL 10-12 years: < 11 pg/mL 13-15 years: 1-30 pg/mL 16-17 years: 1-32 pg/mL 18-99 years: 9-36 pg/mL ESTROGENS, TOTAL: Female: Tanner Stage I: 1-86 pg/mL Tanner Stage II: 3-169 pg/mL Tanner Stage III: 23-351 pg/mL Tanner **Stage IV and V:** 8-341 pg/mL 7-9 years: 1-48 pg/mL 10-12 years: 2-116 pg/mL 13-15 years: 15-333 pg/mL 16-17 years: 6-354 pg/mL 18-99 years: Premenopausal: Early Follicular 30-250 pg/mL 18-99 years: Premenopausal: Late Follicular 200-650 pg/mL 18-99 years: Premenopausal: Luteal 50-350 pg/mL 18-99 years: Postmenopausal: 5-52 pg/mL Male: Tanner Stage I: 1-11 pg/mL Tanner Stage II: 1-19 pg/mL Tanner Stage III: 3-61 pg/mL Tanner **Stage IV and V:** 4-62 pg/mL 7-9 years: < 10 pg/mL 10-12 years: 1-19 pg/mL 13-15 years: 3-62 pg/mL 16-17 years: 4-64 pg/mL 18-99 years: 19-69 pg/mL **Days Performed: Tuesday, Thursday, Saturday** **Reported: 4–6** days **Stability:** Ambient: After separation from cells: **4 days** Refrigerated: After separation from cells: 1 week Frozen: After separation from cells: 1 month	
Fatty Acid Oxidation Probe Assay, Fibroblast Culture		**Days Performed:** Varies **Reported: 16–72** days **Special Information:** Specimen received in formalin or fixative preservative is not acceptable. **Patients residing in New York state require informed consent.**	4/23/2015
Fecal Lactoferrin		**Test Name:** Previously Fecal Leukocyte Detection by EIA	6/2/2015
First Trimester Screening, First Screen		**Special Information:** Due to circumstances beyond our control, the First Trimester Screening, First Screen changes did not happen on 3/3/2015 as previously announced. We apologize for any inconvenience this may have caused.	4/28/2015

Test Changes (Cont.)

Test Name	Order Code	Change	Effective Date
Glomerular Basement Membrane IgG		**Specimen Requirement:** **1 mL** serum - serum separator tube; Minimum: **0.5 mL** **Stability:** Ambient: **8 hours** Refrigerated: **1 week** Frozen: **1 month** **Methodology: Enzyme Immunoassay (EIA)** **Reference Range: 0 - 99 years:** **Negative: 0–20 U/mL** **Weak Positive: 21–30 U/mL** **Moderate Strong Positive: > 30 U/mL** **Days Performed: Monday, Wednesday, Friday** **Reported: 4–6** days **Special Information: This test is designed for the in-vitro measurement of specific IgG auto-antibodies against the glomerular basement membrane (GBM). It is intended to be an aid in the diagnosis of Goodpasture's Syndrome. Some patients with other renal diseases may exhibit positive results. Glomerular Basement Membrane antibodies are not found in normal healthy individuals.**	6/16/2015
Herpes Simplex by PCR		**Specimen Requirement: 1 mL serum - serum separator tube;** Minimum: 0.5 mL; Deliver to **the laboratory within 3 hours of collection** *OR* **Swab in Viral Transport Media** *OR* **1 g tissue in Viral Transport Media** *OR* **1 mL** plasma - EDTA lavender top tube; Minimum: 0.5 mL; **Deliver to the laboratory within 3 hours of collection** **Stability:** **Ambient: 2** days **Refrigerated: 1 week** **Frozen: 1 week** **Methodology: Strand Displacement Amplification (SDA)** **Days Performed: Monday - Saturday** **Reported: 3–5 days** **Special Information: Please order Herpes Simplex Virus by PCR, CSF for CSF samples. Testing on serum or plasma is recommended for immunocompromised or newborn patients only.**	6/16/2015
HIV 1/2 Combo (Antigen/Antibody)		**Special Information:** If results are inconsistent with an individual's clinical presentation or risk profile for HIV infection, a repeat specimen is suggested. A repeat specimen is also recommended for any individual identified reactive for the first time. When the HIV-1/2 Antigen/ Antibody Combo Screen is repeatedly reactive, **the Multispot differentiation assay is automatically performed at an additional charge. Patients who are screen positive and Multispot negative must be tested with HIV RNA test to rule out an acute infection.**	3/31/2015
Hypercoagulation Diagnostic Interpretive Panel		**Special Information:** Patient Preparation: Discontinue Coumadin therapy for 7 days, heparin therapy for 2 days and thrombolytic therapy for 7 days prior to test, if possible. Submit a Coagulation Consultation Patient History Sheet. 3.2% sodium citrate is the preferred anticoagulant recommended by NCCLS. If tests are abnormal in the panel, the following tests may be ordered and billed: PTT Incubated Mixing Add On (85730, 85732 x2), Dilute Russell Viper Venom (85613), Platelet Neutralization (85597), Factor V Leiden (81241), MTHFR by PCR (81291), Thrombin Time (85670), Reptilase (85635), Fibrinogen Antigen (85385), Prot C Immunologic (85302), Prot S Immunologic (85306), Heparin fXa Inhibition (85520), and/or **Anti-Xa Inhibitor Assay. Sample MUST be accompanied be a completed Clinical History Form for Hemostasis and Thrombosis Evaluation. This form is available on the Cleveland Clinic Laboratories Test Directory website or through Client Services at 444-5755.**	6/2/2015
Integrated Screen, First Trimester Screen		**Special Information:** Due to circumstances beyond our control, the Integrated Screen, First Trimester Screen did not go live on 3/3/2015 as previously announced. We apologize for any inconvenience this may have caused.	4/28/2015
Integrated Screen, Second Trimester Screen		**Special Information:** Due to circumstances beyond our control, the Integrated Screen, Second Trimester Screen did not go live on 3/3/2015 as previously announced. We apologize for any inconvenience this may have caused.	4/28/2015

Test Changes (Cont.)

Test Name	Test Information	Effective Date
Leflunomide as Metabolite	**Specimen Requirement:** 1 mL serum - red top tube; Minimum: 0.3 mL; Do not use serum separator tubes; **Draw blood no sooner than 12 hours (trough) after last dose; Deliver to the Send Out Laboratory ASAP** **Days Performed: Monday, Wednesday, Friday** **Reported:** 3–6 days **Special Information:** Leflunomide is a prodrug: rapid and complete metabolism converts Leflunomide to its active metabolite, teriflunomide (also called A77 1726), which acts by inhibiting pyrimidine synthesis. Teriflunomide has a very long half-life, on average >2 weeks. Enhanced elimination of the drug may be required in patients who are or who wish to become pregnant, or who are experiencing toxicity; teriflunomide can persist up to 2 years after ceasing therapy unless elimination is accelerated. This can be accomplished through use of activated charcoal or a bile acid sequestrant such as cholestyramine, reducing the half-life of teriflunomide to approximately 1 day, Serum concentrations <0.020 mcg/mL (<20 ng/mL) on 2 independent tests at least 2 weeks apart, are preferred for patients anticipating pregnancy to minimize the potential risk of teratogenesis associated with the drug. **CAUTION: Leflunomide toxicity does not appear to correlate with teriflunomide concentrations, thus this assay is unlikely to aid in evaluation of potential adverse drug reactions.**	4/9/2015
Lupus Anticoagulant Diagnostic Interpretive Panel	**Special Information:** 3.2% sodium citrate is the preferred anticoagulant recommended by NCCLS. Patient preparation: Discontinue heparin therapy for 2 days prior to collection. If tests are abnormal, the following tests may be ordered and billed: Factor II (85210), Factor V (85220), Factor X (85260), Factor VIII (85247), Von Willebrand Factor Antigen (85246), Ristocetin Co-factor (85245), Factor IX Assay (85250), Factor XI Assay (85270), Factor XII Assay (85280), Heparin fXa inhibition (85520), Fibrinogen, **Anti-Xa Inhibitor Assay** and/or Bethesda Assay. **Sample MUST be accompanied by a completed Clinical History Form for Hemostasis and Thrombosis Evaluation. This form is available on the Cleveland Clinic Laboratories Test Directory website or through Client Services at 444-5755.**	6/2/2015
Meconium Drug Screen 5	**Methodology: Chromatography with Mass Spectrometry** **Clinical Information:** The specimen is screened by immunoassay at the following threshold concentrations: Amphetamines: **100** ng/gm Barbiturates: **100** ng/gm Cocaine and Metabolites: **50** ng/gm Opiates: **50** ng/gm Cannabinoids: **25** ng/gm Positive results are confirmed by **Chromatography with Mass Spectrometry** to limit of detection at no additional charge.	6/4/2015
NMO/Aquaporin-4 IgG Cell Binding Assay, CSF	**Methodology: Cell Binding assay by IFA** **Special Information: This is a reflex test from Paraneoplastic Autoantibody Evaluation in CSF and will be performed at an additional cost, if indicated. It is also orderable alone.** CAUTION: A negative result does not exclude a diagnosis of neuromyelitis optica spectrum disorder (NMOSD). Serum is generally more sensitive than cerebrospinal fluid for detection of neuromyelitis optica (NMO)/aquaporin-4(AQ4)-IgG {NMO-IgG/AQ4-igG}.	6/2/2015
Organic Acids Urine, Quant	**Special Information: This testing is now available for all age groups, including neonates.**	4/2/2015

Test Changes (Cont.)

Test Name	Test Information	Effective Date
Paraneoplastic Autoantibody Evaluation, CSF	**Includes:** Anti-Neuronal Nuclear Abs Types 1, 2, 3 Purkinje Cell Cytoplasmic Ab Types 1, 2, Tr Anti-Glial Nuclear Ab Type 1 Amphiphysin Ab CRMP-5-IgG **NMO/Aquaporin4 - IgG CBA, if indicated** CRMP-5-IgG Western Blot, if indicated GAD65 Ab, RIA, if indicated VGKC-complex Ab **IPA**, if indicated Amphiphysin Western Blot, if indicated **NMDA-R Ab, CBA, if indicated** **NMDA-R Ab Titer, if indicated** **AMP-A Ab CBA, if indicated** **AMPA-R Ab Titer, if indicated** **GABA-B-R Ab CBA, if indicated** **GABA-B-R titer, if indicated** **Specimen Requirement:** 4 mL cerebrospinal fluid - sterile container; **Minimum: 2 mL** **Stability:** Ambient: 72 hours Refrigerated: **28 days** Frozen: **28 days** **Methodology:** Cell Binding assay (CBA), if indicated Indirect Immunofluorescence Assay (IFA) **Radioimmunoassay (RIA)** Western Blot (WB), if indicated **Immunoprecipitation Assay (IPA), if indicated** **Special Information:** Reflex algorithm: If indirect immunofluorescence assay (IFA) (ANN1C, ANN2C, ANN3C, PCA1C, PCA2C, PCTRC, AMPHC, CRMC, AGN1C) is indeterminate, then Paraneoplastic autoantibody Western blot is performed at an additional charge. **If IFA pattern suggest NMO/AQP4-IgG, then NMO/AQP4-IgG CBA is performed at an additional charge.** If client requests, or if IFA patterns suggest CRMP-5-IgG, then CRMP-5-IgG Western blot is performed at an additional charge. If IFA patterns suggest GAD65 antibody, then GAD65 antibody radioimmunoassay is performed at an additional charge. If IFA patterns suggest neuronal voltage-gated potassium channel-complex autoantibody, then VGKC-complex antibody **IPA** is performed at an additional charge. **If IFA patterns suggest Amphiphysin antibody, then Amphiphysin Western blot is performed at an additional charge.** **If IFA pattern suggest NMDA-R, then NMDA-R antibody CBA and/or NMDA-R titer is performed at an additional charge.** **If IFA pattern suggest AMPA-R, then AMPA-R antibody CBA and/or AMPA-R titer is performed at an additional charge.** **If IFA pattern suggest GABA-B-R, then GABA-B-R antibody CBA and/or GABA-B-R titer is performed at an additional charge.** **Clinical Information: Antibodies directed at onconeural proteins shared by neurons, glia, muscle, and certain cancers are valuable serological markers of a patient's immune response to cancer. They are not found in healthy subjects, and are usually accompanied by subacute neurological symptoms and signs. Several autoantibodies have a syndromic association, but no autoantibody predicts a specific neurological syndrome. Conversely, a positive autoantibody profile has 80% - 90% predictive value for a specific cancer. It is not uncommon for more than one Paraneoplastic autoantibody to be detected, each predictive of the same cancer. CAUTION: Patients with a history of tobacco use or other lung cancer risk, or if thymoma is suspected, a Paraneoplastic autoantibody in serum is also recommended.** **Days Performed:** Monday–Friday **Reported: 4–9** days	6/2/2015
Pipecolic Acid, Serum	**Special Information:** Patients living in New York state must submit a signed informed consent form. Useful for the differential diagnosis between disorders of peroxisomal biogenesis and disorders with loss of a single peroxisomal function. Elevated levels are seen in disorders of peroxisomal biogenesis; normal levels are seen in disorders with loss of a single peroxisomal function. Abnormal results may reflect either prematurity or nongenetic liver and/or renal disease. **CAUTION: Newborns with disorders of peroxisomal biogenesis often have normal levels of Pipecolic acid which increase with age.**	4/1/2015

Test Changes (Cont.)

Test Name	Test Information	Effective Date
Platelet Aggregation	**Special Information:** 3.2% sodium citrate is the preferred anticoagulant recommended by CLSI. Test will not be performed if platelet count is less than 100,000/μL. Patient preparation: discontinue aspirin, phenylbutazone, phenothiazines, thienopyridines and glycoprotein IIb/IIIa inhibitors (if ordered to study intrinsic platelet dysfunction) and antihistamines for seven days prior to test. **Sample MUST be accompanied by a completed Clinical History Form for Hemostasis and Thrombosis Evaluation. This form is available on the Cleveland Clinic Laboratories Test Directory website or through Client Services at 444-5755.**	6/2/2015
Prostate Cancer Biomarker	**Days Performed:** 2 days per week **Reported: 4–7** days	3/4/2015
Sequential Screen, First Trimester (SQSEQL1)	**Effective date:** Do to circumstances beyond our control the new Sequential Screen, First Trimester (SQSEQL1) test will not go-live on 3/31/15 as previously announced. We apologize for any inconvenience this may have caused.	4/28/2015
Sequential Screen, Second Trimester (SQSEQL2)	**Effective date:** Do to circumstances beyond our control the new Sequential Screen, Second Trimester (SQSEQL2) test will not go-live on 3/31/15 as previously announced. We apologize for any inconvenience this may have caused.	4/28/2015
Serotonin, Whole Blood	**Special Information:** In general, serotonin containing foods **(avocados, bananas, plums, walnuts, pineapple, eggplant, plantain, tomatoes, hickory nuts, kiwi, dates, grapefruit, cantaloupe, and honeydew melon)** do not interfere significantly. Note: Medications which may affect serotonin concentrations include reserpine, methyldopa, MAO inhibitors, lithium and morphine. **Metastasizing midgut carcinoid tumors usually produce blood or serum 5-hydroxytryptamine (5-HT) concentrations >1,000 ng/mL. However, elevations >400 ng/mL are suggestive of carcinoid tumors as the cause of carcinoid syndrome-like symptoms.**	4/9/2015
Stratify JCV Antibody and Index with Reflex to Inhibition Assay	**Days Performed:** Monday–Friday **Reported: 2–6** days	4/30/2015
Torch Antibodies, IgG & IgM	**Specimen Requirement:** **2 mL** serum - serum separator tube; Minimum: **2 mL** **Stability:** Ambient: **Undetermined** Refrigerated: 1 week Frozen: 1 month **Methodology:** Enzyme Immunoassay (EIA) Enzyme-Linked Immunosorbent Assay (ELISA) **Immunochemiluminometric Assay (ICMA)** **Chemiluminescence Immunoassay (CLIA)** **Reference Range:** Toxoplasma IgG: **Negative** Toxoplasma IgM: **Negative** Rubella IgG: **Presumed Immune: ≥ 10 IU/mL** **Equivocal: 5 - 9 IU/mL** **Presumed Non-Immune: < 5 IU/mL** Rubella IgM: **Negative** CMV IgG: **Negative** CMV IgM: **Negative** HSV 1 IgG Type Specific: **Negative** HSV 2 IgG Type Specific: **Negative** HSV non-type Specific IgM: **Negative** **Days Performed: Monday–Saturday** **Reported: 3–4** days	6/16/2015
TSH Binding Inhibition	**Days Performed:** Monday, **Thursday** **Reported: 1–6** days	3/26/2015

Test Changes (Cont.)

Test Name	Test Information	Effective Date
von Willebrand Diagnostic Interpretive Panel	**Special Information:** If platelet function testing is required, the specimen must arrive in the testing lab less than 4 hours post collection and before 2:00 PM. Von Willebrand panels collected after the established cut-off time will still be performed; however, the platelet function portion of the panel cannot be performed because the platelet viability is impaired four hours post collection. The portions of the von Willebrand panel which can still be performed are the PT, INR, APTT, von Willebrand factor antigen, Factor VIII, Ristocetin co-factor , Collagen binding assay and von Willebrand factor multimers (if indicated). If test results in panel are abnormal additional tests may be ordered and billed. Do not draw this test on weekends. **Sample MUST be accompanied by a completed Clinical History Form for Hemostasis and Thrombosis Evaluation. If test results in panel are abnormal, additional testing may be ordered and billed. This form is available on the Cleveland Clinic Laboratories Test Directory website or through Client Services at 444-5755.**	6/2/2015

New Tests

Test Name	Test Information	Effective Date
Allergen, False Ragweed IgE	**Specimen Requirement:** 0.1 mL serum–serum separator tube; Minimum: 0.1 mL *OR* 0.1 mL plasma–lithium heparin PST; Minimum: 0.1 mL *OR* 0.1 serum–red top tube; Minimum 0.1 mL **Stability:** Ambient: 48 hours Refrigerated: 7 days Frozen: 1 year **Methodology:** Fluorescence Immunoassay by ImmunoCAP **Reference Range:** < 0.35 kU/L, Class: 0 **Days Performed:** Sunday–Saturday **Reported:** 1–3 days	6/2/2015
Allergen, Seafood Panel	**Includes:** Codfish, Crab Lobster, Shrimp Tuna, Oyster Scallop, Blue Mussel **Specimen Requirements:** 0.8 mL serum–serum separator tube; Minimum: 0.8 mL *OR* 0.8 mL plasma–lithium heparin green top tube; Minimum: 0.8 mL *OR* 0.8 mL serum–red top tube; Minimum: 0.8 mL **Stability:** Ambient: 48 hours Refrigerated: 7 days Frozen: 1 year **Methodology:** Fluorescent Enzyme Immunoassay (FEIA) by ImmunoCAP **Reference Range:** < 0.35 kU/L **Clinical Information:** Specific evaluation of allergic reactions; 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 **Days Performed:** Sunday–Saturday **Reported:** 1–2 days	6/2/2015

New Tests (Cont.)

Test Name	Test Information	Effective Date
Aspergillus Antibody (CF reflex to ID)	**Specimen Requirement:** 1.5 mL serum–serum separator tube; Minimum: 1 mL **Stability:** Ambient: 12 hours Refrigerated: 48 hours Frozen: -80° C: Indefinitely, no freeze thaw cycles **Methodology:** Complement Fixation (CF) **Reference Range:** < 1:8 **Special Information:** Any CF result not < 1:8 will automatically reflex to Aspergillus Antibody ID at an additional cost. **Days Performed:** Monday, Wednesday **Reported:** 2–7 days	6/16/2015
Blastomyces Antibody (CF reflex to ID)	**Specimen Requirement:** 1.5 mL serum–serum separator tube; Minimum: 1 mL **Stability:** Ambient: 12 hours Refrigerated: 72 hours Frozen: Indefinitely at -80° C with no freeze thaw cycles **Methodology:** Complement Fixation (CF) **Reference Range:** Negative < 1:8 **Special Information:** Any CF result not < 1:8, will reflex to Blastomyces Antibody ID at an additional cost. **Days Performed:** Monday, Wednesday **Reported:** 2–7 days	6/16/2015
Coccidiodes Antibody (CF reflex to ID)	**Specimen Requirement:** 1.5 mL serum–serum separator tube; Minimum: 1 mL **Stability:** Ambient: 12 hours Refrigerated: 72 hours Frozen: Indefinitely at -80° C with no freeze/thaw cycles **Methodology:** Complement Fixation (CF) **Reference Range:** Negative < 1:2 **Special Information:** Any CF result which is not < 1:2 will automatically reflex to Coccidiodes Antibody ID at an additional cost. **Days Performed:** Monday, Wednesday **Reported:** 2–7 days	6/16/2015
Galactose-alpha-1,3-galactose IgE	**Specimen Requirement:** 1 mL serum–serum separator tube; Minimum: 0.5 mL **Stability:** Ambient: 4 weeks Refrigerated: 4 weeks Frozen: 1 year **Methodology:** Immunoassay (IA) **Reference Range:** < 0.35 kU/L **Days Performed:** Monday–Friday **Reported:** 2–3 days	6/9/2015
Histoplasma Antibody (CF reflex to ID)	**Includes:** Histoplasma Mycelial Antibody CF Histoplasma Yeast Antibody CF **Specimen Requirement:** 1.5 mL serum–serum separator tube; Minimum: 1 mL **Stability:** Ambient: 12 hours Refrigerated: 72 hours Frozen: Indefinitely at -80° C with no freeze/thaw cycles **Methodology:** Complement Fixation (CF) **Reference Range:** Histoplasma Mycelial Ab: Negative < 1:8 Histoplasma Yeast Ab: Negative < 1:8 **Special Information:** Any result which is not < 1:8 will automatically reflex to Histoplasma Antibody ID at an additional cost. **Days Performed:** Monday, Wednesday **Reported:** 2–7 days	6/16/2015

New Tests (Cont.)

Test Name	Test Information	Effective Date
Levamisole	**Specimen Requirement:** 1 mL serum–red top tube; Minimum: 0.4 mL *OR* 1 mL plasma–EDTA lavender top tube; Minimum: 0.4 mL **Stability:** Ambient: 2 days Refrigerated: 30 days Frozen: 12 months **Methodology:** High Performance Liquid Chromatography–Tandem Mass Spectrometry (LC-MS/MS) **Days Performed:** Thursday **Reported:** 4–11 days	6/2/2015
von Willebrand Diagnostic Interpretive Panel (Limited)	**Includes:** Prothrombin Time (PT) APTT Ristocetin Cofactor Collagen Binding Assay (CBA) Factor VIII assay (FVIII) von Willebrand Factor Antigen (VWF) CBA/VWF Ratio Ristocetin Cofactor/VWF Ratio FVIII/VWF Ratio von Willebrand Multimer **Specimen Requirement:** 6 mL plasma–sodium citrate light blue top tube; Minimum: 3 mL **Special Information:** Sample MUST be accompanied by a completed Clinical History Form for Hemostasis and Thrombosis Evaluation. This form is available on the Cleveland Clinic Laboratories Test Directory website or through Client Services at 444-5755. If test results in panel are abnormal, additional testing may be ordered and billed. **Methodology:** Aggregation Clotting Assay Enzyme-Linked Immunosorbent Assay (ELISA) Latex Immunoassay (LIA) **Reference Range:** Prothrombin Time: Refer to individual component APTT: Refer to individual component Ristocetin Cofactor: Refer to individual component Collagen Binding Assay (CBA): Refer to individual component Factor VIII assay: Refer to individual component von Willebrand Factor Antigen (VWF): Refer to individual component CBA/VWF Ratio: > 0.6 Ristocetin Cofactor/VWF Ratio: > 0.5 FVIII/VWF Ratio: > 0.5 von Willebrand Multimer: Refer to individual component **Days Performed:** Monday–Friday **Reported:** 10 days	6/2/2015

Discontinued Tests

Test Name	Test Information	Effective Date
Alpha-1-Antitrypsin Quantitation and Phenotyping	This test will no longer be available. Suggest ordering Alpha 1 Anti-trypsin Serum Level and SERPINA1 Targeted Genotyping	6/23/2015
Aspergillus Antibody, CF	This test will no longer be available. Suggest ordering Aspergillus Antibody (CF reflex to ID)	6/16/2015
Aspergillus Antibody, (CF/ID)	This test will no longer be available. Suggest ordering Aspergillus Antibody (CF reflex to ID)	6/16/2015
Aspergillus Antibody, ID	This test will no longer be available. Suggest ordering Aspergillus Antibody (CF reflex to ID)	6/16/2015
Blastomyces Antibody, CF	This test will no longer be available. Suggest ordering Blastomyces Antibody (CF reflex to ID)	6/16/2015
Blastomyces Antibody, (CF/ID)	This test will no longer be available. Suggest ordering Blastomyces Antibody (CF reflex to ID)	6/16/2015
Blastomyces Antibody, ID	This test will no longer be available. Suggest ordering Blastomyces Antibody (CF reflex to ID)	6/16/2015
Coccidiodes Antibody, CF	This test will no longer be available. Suggest ordering Coccidiodes Antibody (CF reflex to ID)	6/16/2015
Coccidiodes Antibody, (CF/ID)	This test will no longer be available. Suggest ordering Coccidiodes Antibody (CF reflex to ID)	6/16/2015
Coccidiodes Antibody, ID	This test will no longer be available. Suggest ordering Coccidiodes Antibody (CF reflex to ID)	6/16/2015
FISH for BCR/ABL	This test will no longer be available. Suggest ordering BCR-ABL Qualitative Multiplex RT-PCR	4/28/2015
Fungal Antibodies, CF	This test will no longer be available. Suggest ordering Aspergillosis Antibodies, CF and/or Blastomyces Antibody, CF and/or Coccidiodes Antibody, CF and/or Histoplasma Antibody, CF	6/16/2015
Fungal Antibodies, (CF/ID)	This test will no longer be available. Suggest ordering Aspergillosis Antibodies, CF/ID and/or Blastomyces Antibody, CF/ID and/or Coccidiodes Antibody, CF/ID and/or Histoplasma Antibody, CF/ID	6/16/2015
Histoplasma Antibodies, CF	This test will no long be available. Suggest ordering Histoplasma Antibodies (CF reflex to ID)	6/16/2015
Histoplasma Antibodies, CF/ID	This test will no long be available. Suggest ordering Histoplasma Antibodies (CF reflex to ID)	6/16/2015
Histoplasma Antibodies, ID	This test will no long be available. Suggest ordering Histoplasma Antibodies (CF reflex to ID)	6/16/2015
Lactoferrin, Fecal	This test will no longer be available. Suggest ordering Fecal Lactoferrin	6/2/2015
Organic Acids, Neonate Urine	This test will no longer be available. Suggest ordering Organic Acids Urine, Quantitative	6/9/2015