Cleveland Clinic

Cleveland Clinic Laboratories

Technical Update • November 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 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	Methodology	Reference Range	Days Performed/Reported	CPT	Fee
3	11-Deoxycorticosterone Quantitative, Serum/Plasma											■		
8, 13	ADAMTS13 Antibody				■	■								
8	Adulterants Survey, Urine				■									
3, 13	Aldolase							■				■		■
3	Allergy Food Panel IgG							■				■		
3	Amphetamine Confirmation, Serum								■			■		
3	Amphetamine Confirmation, Urine						■	■		■		■		
3	Arsenic, Blood						■							
3	Arsenic, Fractionated Urine						■							
4	Arsenic, Urine 24 Hour						■							
9	Barbiturates Confirmation, Urine				■									
4	CD4 Absolute Count								■					
4	Chlamydia Amplification, Genital			■			■	■						
9	Chlamydia Amplification, Urine				■									
10	Chromosomal Microarray Analysis, HR and SNP Screen (Comprehensive)				■									
10	COL3A1 Deletion/Duplication Analysis				■									
4	Complement, Alternate Pathway (AH50), Functional							■		■	■			
4	Cryofibrinogen						■	■						
4	Cryoglobulin, Qualitative with Reflex to IgG, IgA, IgM							■						
10	DNA Content, Cell Cycle Analysis, Hydatidiform Mole				■									
4	DNA Content, Cell Cycle Analysis, Ploidy and S-Phase								■					
4	DNA Damage											■		
4	Entamoeba Histolytica Antigen											■		
4	Febrile Antibodies							■		■				
13	Fentanyl and Metabolite, Urine													■

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	Methodology	Reference Range	Days Performed/Reported	CPT	Fee
4	Fibrinogen Antigen							■						
4	Fibrinogen Panel							■						
4	Gabitril										■			
5	Gamma-Hydroxybutyric Acid, Serum						■	■		■			■	
5	GC Amplification, Genital			■			■	■						
11	GC Amplification, Urine				■									
5	GC/Chlamydia Amplification, Genital			■			■	■						
11	GC/Chlamydia Amplification, Urine				■									
5	Giardia Antigen, Stool, EIA											■		
5	Glyburide							■						
5	Guanidinoacetic Acid, Urine						■				■			
5	Heavy Metals with Cadmium, Urine						■							
5	Heavy Metals, Urine						■							
12, 13	Hepatitis C Genotype				■	■								
6	Hepatitis C RNA by PCR						■	■		■				
6	Hepatitis D Virus RNA, PCR											■		
12	HIV Types 1 and 2 Ab Differentiation by Multispot				■									
6	HLA-A, B, and C							■	■			■		
6	IDH1 and IDH2 Mutation Analysis, Exon 4								■					
6	Immunodeficiency (CDC) Panel								■					
6	Immunodeficiency Basic Panel								■					
6	Influenza A H1N1 (2009) RT-PCR											■		
6	Ketamine Confirmation, Urine						■							
6	Mercury, Blood						■							
6	Mercury, Urine 24 Hour						■							
6	Mitochondrial DNA Deletion Analysis											■		
6	Mitochondrial DNA/Nuclear DNA Ratio											■		
6	MPL Mutation Analysis			■				■		■		■		
6	Mycoplasma Culture, Non Urogenital							■						
13	Natural Killer Cells, Functional				■									
7	Opiates Confirmation, Quantitative Serum/Plasma											■		
13	Oxycodone Confirmation, Urine				■									
13	Oxycodone Screen, Urine					■								
7	Pancreatic Elastase, Fecal						■	■				■		
7	Paroxetine										■			
7	Pneumococcal IgG Antibodies, 23 Serotypes											■		
7	Procainamide/NAPA						■							
7	PRO-PredictoR TPMT											■		
7	Pyridoxal 5-Phosphate, CSF											■		
7	Rabies Antibody							■						
13	Reticulin Antibody IgG with Reflex to Titer					■								
7	Reverse T3											■		
7	Rufinamide						■							
7	Streptozyme											■		

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	Methodology	Reference Range	Days Performed/Reported	CPT	Fee
7	Total Antioxidant Capacity											■		
7	Toxoplasma PCR											■		
7	Urticaria-Induced Basophil Activation						■							
8	Widal Panel						■					■		

Test Changes

Test Name	Order Code	Billing Code	Change	Effective Date
11-Deoxycorticosterone Quantitative, Serum/ Plasma	11DCOR	89747	**Reference Range:** Premature Gestation Time 29-33 Weeks: **Not Established** Premature Gestation Time 34-36 Weeks: **28-78 ng/dL**	10/6/2014
Aldolase	ALD	82085	**Specimen Requirements:** **Alternate: 1.0 mL Plasma - sodium heparin PST (Light Green); Refrigerated.** Avoid hemolysis. Allow specimen to clot completely at room temperature. **Reported: 1-2** Days	12/9/2014
Allergy Food Panel IgG	FPIGG	90087	**Reported:** 2-**4** Days **Transport Temperature: Ambient** **Stability:** Ambient: **7** Days	12/4/2014
Amphetamine Confirmation, Serum	AMPCQ	88679	**Component: Includes: Amphetamine, Methamphetamine, Methylenedioxyamphetamine, Methylenedioxymethamphetamine, Methylenedioxymethamphetamine, Methylenedioxyethylamphetamine** **Reported:** 2-**9** Days **Days Performed: Monday**	10/14/2014 10/3/2014
Amphetamine Confirmation, Urine	UAMPC	83603	**Specimen Requirment: 10.0 mL** Urine, random - clean container (**2.5 mL** minimum); Refrigerated. **Special Information: For medical purposes only; not valid for forensic use.** **Methodology: High Performance Liquid Chromatography/Tandem Mass Spectrometry (LC-MS/MS)** **Days Performed: 4** Days **Reported: 2-5** Days **Stability:** Frozen: **14** Days Refrigerated: **14** Days Ambient: **3** Days	12/10/2014
Arsenic, Blood	ASB	82175	**Special Instructions: HEAVY METALS FORM REQUIRED.** Forms are available by calling Client Services at 800.628.6816 or 216.444.5755.	12/4/2014
Arsenic, Fractionated Urine	UASFR	88171	**Clincal Information: The ACGIH Biological Exposure Index for the sum of inorganic and methylated species of arsenic is 35 µg/L. Inorganic species of arsenic are most toxic. Methylated species arise primarily from metabolism of inorganic species but may also come from dietary sources and are of moderate toxic potential. The organic species of arsenic are considered nontoxic and arise primarily from food. The sum of the inorganic, methylated, and organic species of arsenic may be lower than the total arsenic concentration due to the presence of unidentified organic species of arsenic.**	10/3/2014

Test Changes (cont.)

Test Name	Order Code	Billing Code	Change	Effective Date
Arsenic, Urine 24 Hr	UARSND	30120	**Special Instructions: HEAVY METALS FORM REQUIRED.** Forms are available by calling Client Services at 800.628.6816 or 216.444.5755.	11/27/2014
CD4 Absolute Count	CD4ABS	27	**Component: Interpretation component removed** (percent and absolute numbers still reported).	12/2/2014
Chlamydia Amplification, **Genital**	CT	79809	**Specimen Requirements: Swab in APTIMA™ transport media (M4 and ThinPrep PreservCyt™)** **Special Information: Rejection criteria: swab not received in correct transport media. If urethral or urine specimen, the patient should not have urinated within one hour of collection. For endocervical specimens, remove excess mucus using cleaning swab and then insert blue shaft swab into the endocervical canal and rotate for 10-30 seconds. For urethral specimens, insert the blue shaft swab 2-4 cm into the urethra and rotate for 2-3 seconds. When collecting vaginal specimens, insert the swab about 2 inches and rotate for 10-30 seconds against the vaginal wall. Immediately place swab in the transport tube. Carefully break swab shaft at score line against side of tube and discard top portion of shaft. Transport specimens at 2-30 degrees C.** **Primary Name:** Chlamydia Amplificaton, **Genital**	12/16/2014
Complement, Alternate Pathway (AH50), Functional	COMAP	88533	**Methodology: Enzyme-Linked Immunosorbent Assay (ELISA)** **Reference Range: > or = 46** (% normal) **Stability:** Frozen: **14** Days	10/6/2014
Cryofibrinogen	CRYOFI	82585	**Specimen Requirements:** 3.0 mL Plasma - sodium citrate (Light Blue - 1.0 mL minimum); Ambient. Whole blood must be drawn in a PRE-WARMED (37 degrees C) syringe and kept at 37 degrees C. Immediately after collection, transfer blood to two PRE-WARMED (37 degrees C) sodium citrate light blue top tubes. Keep at 37 degrees C until separated from cells. **Fasting specimen required.** **Special Information:** 3.2% sodium citrate is the preferred anticoagulant recommended by NCCLS. Unacceptable conditions: Frozen, refrigerated samples, or heparinized blood. Fasting sample is **required**.	10/6/2014
Cryoglobulin, Qualitative with Reflex to IgG, IgA, IgM	CRYQL	89356	**Specimen Requirements:** 3.0 mL Serum - no additive (Red - 1.0 mL minimum); Ambient. Collect in PRE-WARMED red top tube. Maintain tube at 37 degrees until clotting is complete (up to 1 hour). Separate serum from cells ASAP. **Fasting specimen is required.**	10/7/2014
DNA Content, Cell Cycle Analysis, Ploidy and S-Phase	DNAMIS	88088	**Component: Test build may need to be modified.**	10/14/2014
DNA Damage	TUNEL	84387	**Reported: 21** Days	10/7/2014
Entamoeba Histolytica Antigen	ENTEIA	89508	**Reported: 3-4** Days	10/7/2014
Febrile Antibodies	FEBAB	84353	**Methodology: Immunoblot (IB)** **Stability:** Ambient: **48 Hours** Frozen: **1 Year**	10/6/2014
Fibrinogen Antigen	FIBRAG	76560	**Specimen Requirements:** 2.0 mL Plasma - sodium citrate (Light Blue); Frozen. **Critical frozen. Separate specimens must be submitted when multiple tests are ordered.** **Stability:** Refrigerated: **Unacceptable**	11/17/2014
Fibrinogen Panel	FIBPN	89297	**Specimen Requirements:** 2.0 mL Plasma - sodium citrate (Light Blue); Frozen. **Critical Frozen.** Please collect a clearing (discard) tube before the sodium citrate light blue top tube. Centrifuge the sodium citrate tube and immediately remove the top 2/3 of the plasma and freeze. **Separate specimens must be submitted when multiple tests are ordered.** **Stability:** Refrigerated: **Unacceptable**	11/17/2014
Gabitril	GABIT	80319	**Reference Range:** Trough: **20-200** ng/mL	10/6/2014

Test Changes (cont.)

Test Name	Order Code	Billing Code	Change	Effective Date
Gamma-Hydroxybutyric Acid, Serum	GHBSER	82415	**Specimen Requirements:** 5.0 mL Plasma - sodium heparin (Green - 1.2 mL minimum); Refrigerated. Do not use plasma separator tubes. **Methodology: Liquid Chromatography-Tandem Mass Spectrometry (LC-MS/MS)** **Clinical Information: Reporting limit: 5.0 ug/mL.** **CPT: 80101x1** **Stability:** Frozen: **180** Days Refrigerated: **7** Days	10/16/2014
GC Amplification, **Genital**	GC	79810	**Specimen Requirements: Swab in APTIMA™ transport media (M4 and ThinPrep PreservCyt™).** **Special Information:** Rejection criteria: **Swab not received in correct transport media.** For endocervical specimens, remove excess mucus using cleaning swab and then insert blue shaft swab into the endocervical canal and rotate for 10-30 seconds. For urethral specimens, insert the blue shaft swab 2-4 cm into the urethra and rotate for 2-3 seconds. When collecting vaginal specimens, insert the swab about 2 inches and rotate for 10-30 seconds against the vaginal wall. Immediately place swab in the transport tube. Carefully break swab shaft at score line against side of tube and discard top portion of shaft. Transport specimens at 2-30 degrees C. **Primary Name:** GC Amplification, **Genital**	12/16/2014
GC/Chlamydia Amplification, **Genital**	GCCT	79830	**Specimen Requirements: Swab in APTIMA™ transport media (M4 and ThinPrep PreserveCyt solution™).** **Special Information:** Rejection criteria: **Swab not received in correct transport media.** If urethral specimen, the patient should not have urinated within one hour of collection. For endocervical specimens, remove excess mucus using cleaning swab and then insert blue shaft swab into the endocervical canal and rotate for 10-30 seconds. For urethral specimens, insert the blue shaft swab 2-4 cm into the urethra and rotate for 2-3 seconds. When collecting vaginal specimens, insert the swab about 2 inches and rotate for 10-30 seconds against the vaginal wall. Immediately place swab in the transport tube. Carefully break swab shaft at score line against side of tube and discard top portion of shaft. Transport specimens at 2-30 degrees C. **Primary Name:** GC/Chlamydia Amplification, **Genital**	12/16/2014
Giardia Antigen, Stool, EIA	GIAEIA	89735	**Reported: 3-4** Days	10/6/2014
Glyburide	GLYBUR	80351	**Specimen Requirements:** **Alternate** - 3.0 mL Plasma - **potassium oxalate/sodium flouride (Gray)**; Refrigerated. **Stability:** Frozen: **1 Month** Ambient: **1 Month**	10/7/2014
Guanidinoacetic Acid, Urine	UGUANI	82928	**Reference Range**: 4-12 Years: **0.01-0.7** **Clinical Information: X-linked creatine transporter deficiency: Typically > 1.5**	10/9/2014
Heavy Metals with Cadmium, Urine	UTXM4	88694	**Special Instructions: HEAVY METALS FORM REQUIRED.** Specimen MUST be collected in a plastic container. Transfer aliquot into a trace metal transport tube. Transport Tubes and Forms are available by calling Client Services at 800.628.6816 or 216.444.5755.	12/4/2014
Heavy Metals, Urine	UTXM3	88693	**Special Instructions: HEAVY METALS FORM REQUIRED.** Specimen MUST be collected in a plastic container. Transfer aliquot into a trace metal transport tube. Transport Tubes and Forms are available by calling Client Services at 800.628.6816 or 216.444.5755.	2/4/2014

Test Changes (cont.)

Test Name	Order Code	Billing Code	Change	Effective Date
Hepatitis C RNA by PCR	HCQPCR	79132	**Specimen Requirement:** 3.0 mL Plasma - EDTA PPT (White); Refrigerated. **Centrifuge within 24 hours of collection. Do not aliquot. Transport refrigerated or frozen within the storage period described. (Ambient is unacceptable, Refrigerated - 3 days, Frozen - 6 weeks). Specimens collected in heparin cannot be used.** **Methodology: Polymerase Chain Reaction (PCR), Quantitative** **Clinical Information: The assay is intended for use as an aid in the management of HCV infected individuals undergoing anti-viral therapy, and results are to be interpreted within the context of all relevant clinical and laboratory findings.**	11/18/2014
Hepatitis D Virus RNA, PCR	HDPCR	88551	**Days Performed: Tuesday, Thursday, Saturday**	11/20/2014
HLA-A, B, and C	HLAABC	82817	**Specimen Requirement:** **Alternate - 14.0 mL** Whole blood - ACD A or B (Yellow); Ambient. **14.0 mL** Whole blood - EDTA (Lavender); Ambient. **Days Performed: Monday-Friday** **Component: Test build may need to be modified.**	10/9/2014
IDH1 and IDH2 Mutation Analysis, Exon 4	IDH12	88044	**Component: IDHSRC (IDH 1 and 2 Source)**	11/20/2014
Immunodeficiency (CDC) Panel	IMMDEF	25	**Component: Interpretation component removed** (percent, absolute numbers and 4/8 ratio still reported).	12/2/2014
Immunodeficiency Basic Panel	HIVFCM	35	**Component: Interpretation component removed** (percent, absolute numbers and 4/8 ratio still reported).	12/2/2014
Influenza A H1N1 (2009) RT-PCR	H1N1	87594	**Days Performed: Monday, Wednesday, Friday**	11/20/2014
Ketamine Confirmation, Urine	UKETA	87791	**Special Information: If adulterant testing is desired, please order UADULT, Adulterants Survey, Urine, as a separate orderable test performed at an additional charge.**	10/9/2014
Mercury, Blood	MERC2	79631	**Special Instructions: HEAVY METALS FORM REQUIRED.** Transport in original collection tube. Forms are available by calling Client Services at 800.628.6816 or 216.444.5755.	12/4/2014
Mercury, Urine 24 Hour	UMERC3	79632	**Special Instructions: HEAVY METALS FORM REQUIRED.** Specimen MUST be collected in a plastic container. Transfer aliquot into a trace metal transport tube. Transport Tubes and Forms are available by calling Client Services at 800.628.6816 or 216.444.5755**.**	12/4/2014
Mitochondrial DNA Deletion Analysis	DNADEL	88557	**Reported: 15-17** Days	12/18/2014
Mitochondrial DNA/ Nuclear DNA Ratio	MTRAT	88563	**Reported: 15-17** Days	12/18/2014
MPL **Mutation** Analysis	MPL	87657	**Specimen Requirements: 4.0 mL** Whole blood - EDTA (Lavender - **1.0 mL** minimum); Refrigerated. **Alternate -** **2.0 mL** Bone marrow - EDTA (Lavender - **1.0 mL** minimum); Refrigerated. **1 Bone marrow formalin-fixed, paraffin-embedded block. FFPE bone marrow** clot section. **Methodology: Sequencing** **Days Performed: 1** Day **Reported: 7-14** Days **Primary Name:** MPL **Mutation** Analysis	11/17/2014
Mycoplasma Culture, Non Urogenital	UMPLAS	88455	**Specimen Requirements:** Specimens must be submitted in M4 or Universal Transport Media (UTM). **Sterile containers without media are no longer acceptable**.	9/30/2014

Test Changes (cont.)

Test Name	Order Code	Billing Code	Change	Effective Date
Opiates Confirmation, Quantitative Serum/ Plasma	OPISEC	80193	**Days Performed: Monday, Wednesday, Friday**	10/7/2014
Pancreatic Elastase, Fecal	PANCEF	83044	**Special Information:** When ordering Pancreatic Elastase along with Fecal Fat Qualitative (FFAT), please submit two separate specimens. Pancreatic Elastase needs to be sent frozen and Fecal Fat Qualitative should be sent refrigerated. **Interruption of enzyme substitution therapy is recommended in order to avoid the possibility of cross-reaction with porcine enzymes.** **Days Performed: Sunday, Tuesday-Friday** **Stability:** Ambient: **5** Days Refrigerated: **7** Days	10/7/2014
Paroxetine	PAROX	83602	**Reference Range: 30-120 ng/mL**	10/6/2014
Pneumococcal IgG Antibodies, 23 Serotypes	PNE23	89757	**Days Performed:** Tuesday, **Friday** **Reported:** 2-**6** Days	10/6/2014
Procainamide/NAPA	PROC	84142	**Clinical Information: The commonly expected therapeutic range for the sum of NAPA and Procainamide is 5-30 ug/mL. However, the concentration of NAPA is dependent on many factors, including; time of last procainamide dose, mode of administration, concomitant drug therapy, sample condition, time of sample collection and individual variations in absorption, biotransformation, distribution and excretion. Therapeutic ranges are provided only as a guide for interpretation along with other clinical symptoms and patient history.**	11/17/2014
PRO-PredictoR TPMT	PPTMPT	81267	**Reported: 4-8** Days	12/11/2014
Pyridoxal 5-Phosphate, CSF	P5PCSF	87765	**Reported: 15-17** Days	12/18/2014
Rabies Antibody	Rabies	50154	**Specimen Requirements:** **Alternate** - 0.5 mL **Plasma - sodium heparin (Green - 0.1 mL minimum)**; Refrigerated. Separate **plasma** from cells ASAP. 0.5 mL **Plasma - EDTA (Lavender - 0.1 mL minimum)**; Refrigerated. Separate **plasma** from cells ASAP. 0.5 mL **Plasma - ACD A (Yellow - 0.1 mL minimum)**; Refrigerated. Separate **plasma** from cells ASAP. 0.5 mL **Plasma - sodium citrate (Lt. Blue - 0.1 mL minimum)**; Refrigerated. Separate **plasma** from cells ASAP.	11/17/2014
Reverse T3	T3REV	75064	**Reported: 2-5** Days	12/4/2014
Rufinamide	RUFIN	88110	**Clincal Information:** Useful for Therapeutic Drug Monitoring. Maintenance therapy with 45 mg/kg (approximately 1600 mg) daily rufinamide resulted in plasma concentrations ranging from 5,000 - 48,000 ng/mL (n=74). **Reporting Limit: 2500 ng/mL.**	10/2/2014
Streptozyme	STRPTO	79194	**Days Performed: Monday, Wednesday, Friday**	11/17/2014
Total Antioxidant Capacity	TAC	83810	**Reported: 21-28** Days	10/7/2014
Toxoplasma PCR	TXPCR	81737	**Days Performed: Monday, Wednesday, Friday**	11/20/2014
Urticaria-Induced Basophil Activation	UTBAS	90197	**Clinical Information: Reference Interval: 32 percent or less. A value of 33 percent or greater suggests the presence of basophil stimulating antibodies (or other serum factors).** 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 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.	11/17/2014

Test Changes (cont.)

Test Name	Order Code	Billing Code	Change	Effective Date
Widal Panel	SALM	75690	**Special Information: This assay detects antibodies directed against 5 *Salmonella typhi* and *paratyphi antigens*: O Type D, O Type Vi, H Type A, H Type B, or H Type D.** **Clinical Information: May be used to determine past exposure to *S. typhi* (eg, infection or vaccination) and *S. paratyphi*. This test cannot be used to confirm acute salmonellosis. If systemic symptoms of acute salmonellosis are present, the preferred tests are Stool Culture and *E. coli* Shiga-like Toxin by EIA and Blood Culture if typhoid fever is suspected.** **Days Performed: Tuesday, Thursday, Saturday** **Reported: 3-6 Days**	9/26/2014 11/17/2014

New Tests

Test Name	Order Code	Billing Code	Test Information	Effective Date
ADAMTS13 Antibody	**ABADM**	**90219**	**Specimen Requirements: 2.0 mL Plasma - sodium citrate (Light Blue); Frozen.** **Methodology: Enzyme Immunoassay (EIA)** **Clinical Information: Thrombotic thrombocytopenia purpura (TTP) is a life-threatening hematological condition characterized by low platelet count, microvascular thrombi, red cell fragmentation, CNS and renal complications. Severe deficiency of ADAMTS13 activity, either because of a congenital or an acquired etiology, has been shown to be a major cause of TTP. ADAMTS13 (a disintegrin and metalloproteinase with a thrombospondin type 1 motif, member 13) is also known as von Willebrand Factor (VWF) cleaving protease (VWFCP). It is a zinc-containing metalloproteinase that cleaves ultra large VWF multimers (ULVWF) at the Tyr(1605)-Met(1606) bond located in the A2 region of VWF. The ULVWF, if not cleaved, has the ability to bind platelets and trigger intravascular platelet aggregation and lead to thrombus formation. Anti-ADAMTS13 antibodies have been isolated in a number of TTP patients and are closely associated with idiopathic TTP. Most of these ADAMTS13 autoantibodies have inhibitory function of the ADAMTS13 enzymatic activity and thus can be measured by the ADAMTS13 inhibitor test (mixing study). However, the ADAMTS13 antibody test may detect some additional non-inhibitory antibodies. The ADAMTS13 antibody test, when used as a panel with the ADAMTS13 activity and inhibitor tests, should further help to characterize the disease and aid clinicians in the differential diagnosis of TTP and guide treatment selection.** **Days Performed: Monday-Friday** **Reported: 2-4 Days** **CPT: 83520x1, 85390x1** **Price: $500.00**	**11/6/2014**
Adulterants Survey, Urine	**UADULT**	**90353**	**Specimen Requirements: 20.0 mL Urine, random - clean container (0.4 mL minimum - submitting less than 20 mL will compromise the ability to perform all necessary testing.); Refrigerated.** **Special Information: Assess the possible adulteration of a urine specimen submitted for drug of abuse testing, as well as for providing the urine creatinine for "creatinine normalization."** **Methodology: Spectrophotometry (S)** **Clinical Information: Specimen adulteration is the manipulation of a sample that may cause falsely negative test results for the presence of drugs of abuse. Common adulterants that may affect testing are water, soap, bleach, vinegar, oxidants, and salt. The adulteration testing includes assessment of creatinine concentration, pH, urine specific gravity, presence or absence of an oxidant, and presence or absence of nitrite.** **Days Performed: Sunday-Saturday** **Reported: 2-3 Days** **CPT: 81005x1** **Price: $60.00**	**12/18/2014**

New Tests (cont.)

Test Name	Order Code	Billing Code	Test Information	Effective Date
Barbiturates Confirmation, Urine	UBARBC	90310	Specimen Requirements: 5.0 mL Urine, random in a clean container (3.0 mL minimum); Refrigerated. For confirmation purposes only. Special Information: This test can only be added to a drug screen which has been performed and confirmation is indicated. Follow chain of custody procedure when appropriate. Methodology: Gas Chromatography Mass Spectrometry (GC/MS) Clinical Information: To confirm screen. Days Performed: Sunday-Saturday Reported: 1-3 Days CPT: 80102x1 Price: $70.00	11/13/2014
Chlamydia Amplification, Urine	UCT	90364	Specimen Requirements: 2.0 mL Urine, first-catch in an APTIMA™ urine specimen collection kit. Notes: First-catch urine is the optimal specimen for screening asymptomatic men; urine may also be used for testing symptomatic patients of either gender. Patients providing urine specimens should not have urinated within one hour of collection. Transfer 2 mL of urine into the APTIMA™ urine specimen transport tube using a sterile, disposable pipette. The correct volume of urine has been added when the fluid level is between the black fill lines on the APTIMA™ urine specimen transport tube. Do not overfill or underfill the APTIMA™ urine transport tube. Alternate - 20.0 mL Urine, in a first-catch sterile container (no preservatives). Notes: First-catch urine is the optimal specimen for screening asymptomatic men; urine may also be used for testing symptomatic patients of either gender. Patients providing urine specimens should not have urinated within one hour of collection. Unpreserved urine must be transported to the lab within 24 hours. Special Information: Rejection criteria: unpreserved urine received more than 24 hours after collection; overfilled or underfilled urine APTIMA™ tube; If urethral or urine specimen, the patient should not have urinated within one hour of collection. Collect the first-catch urine (approximately 20 mL of initial urine stream; collection of larger volumes of urine will reduce test sensitivity). Within 24 hours of collection, transfer 2 mL of urine into the APTIMA™ urine transport tube so the fluid level is BETWEEN the black lines on label. Transport specimens at 2-30 degrees C. Methodology: Target Amplification Nucleic Acid Probe, Qualitative Clinical Information: Because the predictive value of a test correlates with disease prevalence, positive results in low prevalence populations should be interpreted carefully with the understanding that the likelihood of a false positive may be higher than a true positive. In most cases, a test of cure is not recommended because a positive result may indicate persistent, but nonviable nucleic acids. Repeat testing to ensure cure is recommended for pregnant women, but should not be performed until 3 weeks after treatment. In cases of suspected sexual assault or therapy failure, culture is recommended. Days Performed: Monday-Friday Reported: 6 Days CPT: 87491x1 Price: $79.00	12/16/14

New Tests (cont.)

Test Name	Order Code	Billing Code	Test Information	Effective Date
Chromosomal Microarray Analysis, HR and SNP Screen (Comprehensive)	HRSNPC	90344	Specimen Requirements: 5.0 mL Whole blood - EDTA and sodium heparin (Lavender and Green - 3.0 mL minimum); Ambient. THIS ASSAY REQUIRES MULTIPLE TUBE TYPES. Alternate - Extracted DNA - EDTA (Lavender); Ambient. 15 ug extracted DNA at a concentration of 1 ug/uL is required. Methodology: Chromosomal Microarray Analysis Clinical Information: Chromosomal Microarray Analysis - Comprehensive (CMA-Comprehensive) combines both CMA-HR and CMA-SNP into one array. The new 400k custom designed CMA-Comprehensive microarray (v10.1) now targets over 4,200 genes at the exon level. In addition to exon level copy number, this array also includes 60,000 probes used for SNP analysis for the detection of uniparental disomy (UPD) and absence of heterozygosity (AOH). Days Performed: Upon Receipt Reported: 15-16 Days CPT: 81229x1 Price: $1,895.00	12/18/2014
COL3A1 Deletion/ Duplicaton Analysis	COL3DD	90354	Specimen Requirements: 7.0 mL Whole blood - EDTA (Lavender - 5.0 mL minimum); Ambient. Collect Monday-Thursday only. Alternate - Extracted DNA - EDTA (Lavender); Ambient. 150 uL extracted DNA at a concentration of 200 ng/uL is required. Special Information: Refrigerated sample if not shipped the same day. Methodology: Comparative Genomic Hybridization (CGH) Days Performed: Upon Receipt Reported: 28-35 Days CPT: 81228x1 Price: $1,150.00	12/4/2014
DNA Content, Cell Cycle Analysis, Hydatidiform Mole	DNAHYD	90342	Specimen Requirements: Paraffin block; Refrigerated. Paraffin-embedded tissue block with Hydatidiform mole. If no normal tissue is included in the block, please supply a control tissue block to be processed in parallel. Include H&E stained slide and surgical pathology report. Special Information: Flow Cytometry can be used to distinguish between partial and complete hydatidiform moles. Partial moles are usually triploid while complete moles are diploid or tetraploid. Of the 35 cases of histologically apparent partial moles, no complication occurred in those that were triploid. However, 20 percent of those that were diploid had complications (persistence, metastasis). Methodology: Flow Cytometry (FC) Clinical Information: A thin section of each tissue submitted is stained with H&E. The DNA content is classified as diploid, triploid, tetraploid or aneuploid. The DNA index is the ratio of the DNA content of abnormal cells compared to normal cells. Days Performed: Sunday, Tuesday Reported: 5-11 Days CPT: 88182x1 Price: $160.00	12/18/2014

New Tests (cont.)

Test Name	Order Code	Billing Code	Test Information	Effective Date
GC Amplification, Urine	UGC	90365	Specimen Requirements: 2.0 mL Urine, first-catch APTIMA™ urine specimen collection kit. Notes: First-catch urine is the optimal specimen for screening asymptomatic men; urine may also be used for testing symptomatic patients of either sex. Patients providing urine specimens should not have urinated within one hour of collection. Alternate - 20.0 mL Urine, first-catch in a sterile container. Special Information: Rejection criteria: unpreserved urine received more than 24 hours after collection; overfilled or underfilled urine APTIMA™ tube. Urine specimen, the patient should not have urinated within one hour of collection. Collect the first-catch urine (approximately 20 mL of initial urine stream; collection of larger volumes of urine will reduce test sensitivity). Within 24 hours of collection, transfer 2 mL of urine into the APTIMA™ urine transport tube so the fluid level is BETWEEN the black lines on label. Transport specimens at 2-30 degrees C. Methodology: Target Amplification Nucleic Acid Probe, Qualitative Clinical Information: Because the predictive value of a test correlates with disease prevalence, positive results in low prevalence populations should be interpreted carefully with the understanding that the likelihood of a false positive may be higher than a true positive. In most cases, a test of cure is not recommended because a positive result may indicate persistent, but nonviable nucleic acids. Repeat testing to ensure cure is recommended for pregnant women, but should not be performed until 3 weeks after treatment. In cases of suspected sexual assault or therapy failure, culture is recommended. Days Performed: Monday-Friday Reported: 6 Days CPT: 87591x1, 87491x1 Price: $79.00	12/16/2014
GC/Chlamydia Amplification, Urine	UGCCT	90366	Specimen Requirements: 2.0 mL Urine, first-catch APTIMA™ urine specimen collection kit. First-catch urine is the optimal specimen for screening asymptomatic men; urine may also be used for testing symptomatic patients of either sex. Patients providing urine specimens should not have urinated within one hour of collection. Transfer 2 mL of urine into the APTIMA™ urine specimen transport tube using a sterile, disposable pipette. The correct volume of urine has been added when the fluid level is between the black fill lines on the APTIMA™ urine specimen transport tube. Do not overfill or underfill the APTIMA™ urine transport tube. Alternate - 20.0 mL Urine, first-catch sterile container (no preservatives). First-catch urine is the optimal specimen for screening asymptomatic men; urine may also be used for testing symptomatic patients of either sex. Patients providing urine specimens should not have urinated within one hour of collection. Unpreserved urine must be transported to the lab within 24 hours. Special Information: Rejection criteria: unpreserved urine received more than 24 hours after collection; overfilled or underfilled urine APTIMA™ tube. Methodology: Target Amplification Nucleic Acid Probe, Qualitative Clinical Information: Because the predictive value of a test correlates with disease prevalence, positive results in low prevalence populations should be interpreted carefully with the understanding that the likelihood of a false positive may be higher than a true positive. In most cases, a test of cure is not recommended because a positive result may indicate persistent, but nonviable nucleic acids. Repeat testing to ensure cure is recommended for pregnant women, but should not be performed until 3 weeks after treatment. In cases of suspected sexual assault or therapy failure, culture is recommended. Days Performed: Monday-Friday Reported: 6 Days CPT: 87491x1, 87591x1 Price: $158.00	12/16/2014

New Tests (cont.)

Test Name	Order Code	Billing Code	Test Information	Effective Date
Hepatitis C Genotype	HEPGEN	81511	Specimen Requirement: 3.0 mL Plasma - EDTA PPT (White - 1.0 mL minimum); Refrigerated. Centrifuge PPT tube within 24 hours of collection. Do not aliquot. Alternate - 3.0 mL Serum - SST (Gold - 1.0 mL minimum); Refrigerated. Centrifuge SST tube within 24 hours of collection. Do not aliquot. 3.0 mL Plasma - EDTA (Lavender - 1.0 mL minimum); Refrigerated. Separate plasma from whole blood within 24 hours of collection by centrifugation at 800-1600 x g for 20 minutes at room temperature. Transfer plasma to a sterile, polypropylene screw-cap tube. Special Information: A quantitative HCV PCR (HCQPCR) must be performed within 4 weeks prior to HCV Genotype order. The viral load of the HCV must be greater than 1000 IU/ml for the genotype to be performed. Viral loads below 1000 IU/ml will be rejected. Specimens collected in heparin will be rejected. Methodology: Reverse Transcription/Polymerase Chain Reaction (RT/PCR), Electrochemical Detection Clinical Information: This assay is designed for the genotyping of Hepatitis C virus in human serum and plasma. This test allows the genotyping of the 6 major HCV types and their most common subtypes. Therapy based on the HCV viral genotype has proven to be cost effective when managing patients with chronic Hepatitis C. Days Performed: 1 Day a week Reported: 14 Days CPT: 87902x1 Price: $415.00	11/4/2014
HIV Types 1 and 2 Ab Differentiation by Multispot	HIV12M	90367	Specimen Requirements: 1.0 mL Serum - no additive SST (Gold - 0.5 mL minimum); Refrigerated. Alternate - 0.5 mL Plasma - EDTA (Lavender); Refrigerated. Special Information: For use only when patient has a repeatedly reactive third or fourth generation HIV screen test result. This test is for use as the antibody differentiation test in the specific multi-test algorithm proposed by the Centers for Disease Control and Prevention (CDC) and adopted by Clinical and Laboratory Standards Institute (CLSI). It is not to be ordered as a rapid screen test and cannot be used as a supplemental test if the initial screen test was a rapid test. This test discriminates between HIV-1 and HIV-2 antibodies. Results for each type are reported. A recommendation to order further testing on a separate specimen for HIV-1 Nucleic Acid will be made for certain results. Methodology: Qualitative Immunoassay Clinical Information: AIDS is caused by 2 known types of HIV. HIV type 1 (HIV-1) is found in patients with AIDS, AIDS-related complex, and asymptomatic infected individuals at high risk for AIDS. The virus is transmitted by sexual contact, by exposure to infected blood or blood products, or from an infected mother to her fetus or infant. HIV type 2 (HIV-2) infection is endemic only in West Africa, and it has been identified in individuals who have had sexual relations with individuals from that geographic region. HIV-2 is similar to HIV-1 in viral morphology, overall genomic structure, and its ability to cause AIDS. Antibodies against HIV-1 and HIV-2 are usually not detectable until 6 to 12 weeks following exposure and are almost always detectable by 12 months. They may fall to undetectable levels (ie, seroreversion) in the terminal stage of AIDS when the patient's immune system is severely depressed. Routine serologic screening of patients at risk for HIV-1 or HIV-2 infection usually begins with a HIV-1/2 antigen and/or antibody screening test, which may be performed by various FDA-approved assay methods, including rapid HIV antibody tests, enzyme immunoassays, chemiluminescent immunoassays. In testing algorithms that begin with these methods, supplemental or confirmatory testing should be requested only for specimens that are repeatedly reactive by these methods according to assay manufacturers' instructions for use. Days Performed: Monday-Friday Reported: 1-2 Days CPT: 86701x1, 86689x1 Price: $185.00	12/2/2014

New Tests (cont.)

Test Name	Order Code	Billing Code	Test Information	Effective Date
Natural Killer Cells, Functional	**NKFUNC**	**90322**	**Specimen Requirement: 10.0 mL Whole blood - sodium heparin (Green - 5.0 mL minimum); Ambient. Specimen must be received in the send out laboratory on the day of collection, Monday - Thursday only. DO NOT collect the day before or after a major holiday.** **Special Information: Normal diet, fasting preferred to avoid lipemia** **Methodology: Flow Cytometry (FC)** **Clinical Information: Natural killer cells (NK cells) are a subset of non-B, non-T peripheral blood lymphocytes that appear to play a crucial role in the human innate immune response. The function of NK cells is important for the clearance of tumor cells, for the removal of immunoglobulin-bound antigens, and for the control of viral infections. NK function has been reported to be decreased in certain individuals, including those with primary immunodeficiencies, those with late-stage human immunodeficiency virus infections, and pregnant women.** **Days Performed: Tuesday-Saturday** **Reported: 3-6 Days** **CPT: 88184x1, 88185x2** **Price: $100.00**	**11/20/2014**
Oxycodone Confirmation, Urine	**UOXYCC**	**82615**	**Specimen Requirements: 10.0 mL Urine, random - clean container (2.5 mL minimum); Refrigerated.** **Methodology: Liquid Chromatography-Tandem Mass Spectrometry (LC-MS/MS)** **Clinical Information: For medical purposes only; not valid for forensic use.** **Days Performed: 4 Days per week** **Reported: 2-5 Days** **CPT: 83925** **Price: $89.00**	**12/10/2014**

Fee Reductions

Test Name	Order Code	Billing Code	List Fee	CPT Codes	Effective Date
Aldolase	ALD	82085	$25.00	82085x1	12/9/2014
Fentanyl and Metabolite, Urine	UFENT	82344	$100.00	80299x1	1/1/2015

Discontinued Tests

Test Name	Order Code	Billing Code	Test Information	Effective Date
ADAMTS13 Antibody	ADMAB	87677	Test Discontinued. Replaced by ABADM.	11/6/2014
Hepatitis C Genotype	HEPCGE	80799	Test Discontinued. Replaced by HEPGEN.	11/4/2014
Oxycodone Screen, Urine	OXYCOD	82615	Test Discontinued. Replaced by UOXYCC.	12/10/2014
Reticulin Antibody IgG with Reflex to Titer	RETIGG	89775	Test Discontinued. Recommended replacement is ENDIGG.	10/4/2014