

## Technical Update • August 2017

Cleveland Clinic Laboratories is dedicated to keeping you updated and informed about recent testing changes. This Technical Update is provided on a monthly basis to notify you of any changes to the tests in our catalog.

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

To compare the new information with previous test information, refer to the online Test Directory at [clevelandcliniclabs.com](http://clevelandcliniclabs.com). Test information is updated in the online Test Directory on the Effective Date stated in the Technical Update. Please update your database as necessary.

For additional detail, contact Client Services at 216.444.5755 or 800.628.6816, or via email at [clientservices@ccf.org](mailto:clientservices@ccf.org).

Test Update Page #	Summary of Changes by Test Name	Name Change Order Code	New Test	Test Discontinued	Special Information	Specimen Requirement	Component Change(s)	Methodology	Reference Range	Days Performed/Reported	Stability	CPT	Fee
3	17-Hydroxyprogesterone, Urine												
3	50 gram, non-fasting, 1-hour, gestational glucose screen												
3	75 gram, fasting, 2-hour, non-gestational glucose tolerance												
3	75 gram, fasting, 5-hour, non-gestational glucose tolerance												
3	100 gram, fasting, 3-hour gestational glucose tolerance confirmation												
3	Alcohol, Blood Confirmation												
4	Alcohols												
19	Amniotic Bilirubin Scan												
19	Bupivacaine												
4	Candida albicans Abs, IgA, IgG, IgM												
4	CAR Autoantibody												
5	Cortisol, Saliva												
15	Cytochrome P450 2D6 (CYP2D6) Geno												
19	Cyto P450 2D6 Geno												
16	ERBB2 (HER2/neu) Gene Amplification by FISH, Gastric Tissue												
19	FISH for BK Virus												
19	Gastric Analysis												
16-17	Homocysteine, Total, Urine												
19	Homocystine, Urine Quantitative												

Test Update Page #	Summary of Changes by Test Name	Name Change Order Code	New Test	Test Discontinued	Special Information	Specimen Requirement	Component Change(s)	Methodology	Days Performed/Reported Reference Range	Stability	CPT	Fee
5	Hu Autoantibody											
5	Hypersensitivity Pneumonitis II											
6	Isopropanol											
19	Leucine Aminopeptidase (LAP), Serum											
6, 19	Lipid Associated Sialic Acid											
6-7	Manganese, Urine											
7	Methanol											
8	Multifocal Neuropathy Evaluation											
8	Neoenkephalitis Paraneoplastic Profile with Recombx											
8	Neopterin											
9	Neosensory Neuropathy Paraneoplastic Profile											
9-10	Nickel, Urine 24 Hour											
10	Pancreatic Elastase, Fecal											
10	Recombx CV2 Autoantibody Test											
10	Recombx MaTa Autoantibody Test											
17	Reticulin Antibodies, Serum											
19	Reticulin Antibody, IgA with reflex to Titer											
11	RI Autoantibody											
11	SensoriMotor Neuropathy Profile Complete											
12	Sensory Neuropathy Profile xp											
12	Thallium, Blood											
13	Thallium, Urine											
13	Toluene, Blood											
18	Toxicology Screen w/ confirmation, Urine											
13	Valproic Acid, Total and Free											
19	Xylose Absorption Test (Adult)											
19	Xylose Absorption Test, Child											
14	Yo Autoantibody											

# Test Changes

Test Name	Order Code	Change	Effective Date
17-Hydroxyprogesterone, Urine	U17OHP	<p><b>Special Information:</b> Patient should not be on any corticosteroid, ACTH, estrogen, or gonadotropin medications, if possible, for at least 48 hours prior to collection of specimen. Separate specimens must be submitted when multiple tests are ordered. No special preservatives required. Submit total volume. Note: Specimens from New York clients will be sent out to a New York DOH approved laboratory, if possible. This test is not New York DOH approved at any laboratory. An approved non-permitted laboratory (NPL) form must accompany specimen.</p> <p><b>Specimen Requirement:</b> 5 mL 24-hour urine (well-mixed) in a clean container; Minimum: 1 mL; Refrigerate during collection; Patient should not be on any corticosteroid, ACTH, estrogen, or gonadotropin medications, if possible, for at least 48 hours prior to start of urine collection; Transfer 5 mL aliquot to standard transport tube; Submit total volume; Transport on dry ice is preferred; Separate specimens must be submitted when multiple tests are ordered; Frozen</p> <p><b>Stability:</b>            Ambient: 1 hour            Refrigerated: 4 days            Frozen: 6 months</p> <p><b>Days Performed:</b> Varies</p> <p><b>Reported:</b> 7–10 days</p>	8/2/17
50 gram, non-fasting, 1-hour, gestational glucose screen	GLTGST	<p><b>Reference Range:</b>            Glucose Screen, Pregnancy: 74–134 mg/dL</p>	9/28/17
75 gram, fasting, 2-hour, non-gestational glucose tolerance	GTNG2	<p><b>Reference Range:</b>            Fasting: 74–99 mg/dL            1 Hour: See comment            2 Hour: 74–139 mg/dL</p>	9/28/17
75 gram, fasting, 5-hour, non-gestational glucose tolerance	GTNG5	<p><b>Reference Range:</b>            Fasting: 74–99 mg/dL            1 Hour: See comment            2 Hour: 74–139 mg/dL            3 Hour: See comment            4 Hour: See comment            5 Hour: See comment</p>	9/28/17
100 gram, fasting, 3-hour gestational glucose tolerance confirmation	GTGST3	<p><b>Reference Range:</b>            Glucose GST, Fasting: 74–94 mg/dL            Glucose GST, 1 Hr: 74–179 mg/dL            Glucose GST, 2 Hr: 74–154 mg/dL            Glucose GST, 3 Hr: 74–139 mg/dL</p>	9/28/17
Alcohol, Blood Confirmation	BALCO	<p><b>Special Information:</b> For medical purposes only. Timing of specimen collection: Dependent on time of exposure, test upon presentation to hospital. Cap tube tightly to minimize alcohol loss. Do NOT freeze whole blood. Unacceptable conditions: Whole blood, plasma separator tubes (PST), serum separator tubes (SST). This test is New York DOH approved.</p> <p><b>Specimen Requirement:</b> 2 mL serum from a red top tube with no additive; Minimum: 0.5 mL; Separate serum from cells ASAP or within 2 hours of collection; Transfer 2 mL serum to a standard transport tube; Cap tube tightly to minimize alcohol loss; Do NOT draw serum separator tubes (SST); Refrigerated</p> <p>*OR* 2 mL plasma from a sodium or lithium heparin green top tube; Minimum: 0.5 mL; Separate plasma from cells ASAP or within 2 hours of collection; Transfer 2 mL plasma to a standard transport tube; Cap tube tightly to minimize alcohol loss; Do NOT draw plasma separator tubes (PST); Refrigerated</p> <p>*OR* 2 mL plasma from a potassium oxalate/sodium fluoride (gray) tube; Minimum: 0.5 mL; Separate plasma from cells ASAP or within 2 hours of collection; Transfer 2 mL plasma to a standard transport tube; Cap tube tightly to minimize alcohol loss; Do NOT draw plasma separator tubes (PST); Refrigerated</p> <p>*OR* 2 mL plasma from an EDTA lavender top tube; Minimum: 0.5 mL; Separate plasma from cells ASAP or within 2 hours of collection; Transfer 2 mL plasma to a standard transport tube; Cap tube tightly to minimize alcohol loss; Do NOT draw plasma separator tubes (PST); Refrigerated</p> <p><b>Days Performed:</b> Sunday–Saturday</p> <p><b>Reported:</b> 2–4 days</p>	8/21/17

## Test Changes (Cont.)

Test Name	Order Code	Change	Effective Date
Alcohols	ALCOS	<p><b>Special Information: Patient Prep: For medical purposes only. Timing of specimen collection: Dependent on time of exposure, test upon presentation to hospital. Cap tube tightly to minimize alcohol loss. Unacceptable conditions: Whole blood, plasma separator tubes (PST), serum separator tubes (SST). This test is New York DOH approved.</b></p> <p><b>Clinical Information: Use to identify ethanol, methanol, isopropanol or acetone ingestion.</b></p> <p><b>Stability:</b>            Ambient: 1 week: After separation from cells (if tightly capped)            Refrigerated: 2 weeks: After separation from cells (if tightly capped)            Frozen: 1 month: After separation from cells</p> <p><b>Days Performed: Sunday–Saturday</b></p> <p><b>Reported: 2–4 days</b></p>	8/21/17
Candida albicans Abs, IgA, IgG, IgM	CNDAGM	<p><b>Special Information: Specimens from New York clients will be sent out to a New York DOH approved laboratory, if possible.</b></p> <p><b>Clinical Information: Limited clinical utility.</b></p> <p><b>Reference Range:</b>            Candida albicans Ab, IgA  <b>0.88 EV or less: Negative–No significant level of detectable Candida albicans antibody</b>  <b>0.89–0.99 EV: Equivocal: Questionable presence of antibodies; Repeat testing in 10-14 days may be helpful</b>  <b>1.00 EV or greater: Positive: Antibody to Candida albicans detected, which may indicate a current or past infection</b>            Candida albicans Ab, IgG  <b>0.88 EV or less: Negative–No significant level of detectable Candida albicans antibody</b>  <b>0.89–0.99 EV: Equivocal–Questionable presence of antibodies; Repeat testing in 10-14 days may be helpful</b>  <b>1.00 EV or greater: Positive–Antibody to Candida albicans detected, which may indicate a current or past infection</b>            Candida albicans Ab, IgM  <b>0.88 EV or less: Negative–No significant level of detectable Candida albicans antibody</b>  <b>0.89–0.99 EV: Equivocal–Questionable presence of antibodies; Repeat testing in 10-14 days may be helpful</b>  <b>1.00 EV or greater: Positive–Antibody to Candida albicans detected, which may indicate a current or past infection</b></p>	8/21/17
CAR Autoantibody	CARAB	<p><b>Special Information: Serum must be separated from cells within 48 hours of collection. Whole blood is not an acceptable specimen.</b></p> <p><b>Clinical Information: Anti-recoverin antibodies can be detected in patients with cancer-associated retinopathy (CAR).</b></p> <p><b>Specimen Requirement: 2 mL serum from a serum separator (gold) tube; Minimum: 0.5 mL; Serum must be separated from cells within 48 hours of collection; Refrigerated</b></p> <p><b>*OR* 2 mL serum from a red top tube with no additive; Minimum: 0.5 mL; Serum must be separated from cells within 48 hours of collection; Refrigerated</b></p> <p><b>*OR* 2 mL cerebrospinal fluid (CSF) in a sterile container; Minimum: 0.5 mL; Collect in sterile, leak-proof container; Refrigerated</b></p> <p><b>Stability:</b>            Ambient: <b>72 hours</b>            Refrigerated: <b>28 days</b>            Frozen: <b>28 days</b></p> <p><b>Methodology: Automated Nanoliter Scale Immunoassay</b></p> <p><b>Reference Range:</b>  <b>Serum: &lt; 1:50</b>  <b>CSF: &lt; 1:1</b></p> <p><b>Days Performed: Tuesday, Friday</b></p> <p><b>Reported: 4–6 days</b></p> <p><b>CPT: 83520 x 1</b></p>	8/28/17

## Test Changes (Cont.)

Test Name	Order Code	Change	Effective Date
Cortisol, Saliva	SCORT	<p><b>Special Information:</b> Collection instructions: 1. Do not brush teeth before collecting specimen. 2. Do not eat or drink for 15 minutes prior to specimen collection. 3. Collect specimen between 11 p.m. and midnight, and record collection time. 4. To use Salivette (preferred collection unit): a. Remove top cap of container to expose swab. b. Place swab directly into mouth by tipping container so that swab falls into mouth. Do not touch swab with fingers. c. Keep swab in mouth for approximately two minutes. Roll swab in mouth, do not chew swab. d. Place swab back into its container without touching, and replace the cap. e. Record collection time. Refrigerate. <b>If multiple specimens are collected, submit each vial under a separate order. This test is New York State approved.</b></p> <p><b>Clinical Information: Screening for Cushing syndrome. Diagnosis of Cushing syndrome in patients presenting with symptoms or signs suggestive of the disease.</b> CAUTION: Acute stress (including hospitalization and surgery), alcoholism, depression, and many drugs (e.g., exogenous glucocorticoids, anticonvulsants) can obliterate normal diurnal variation, affect response to suppression/stimulation tests and cause elevated cortisol levels. Cortisol levels may be increased in pregnancy and with exogenous estrogens.</p> <p><b>Specimen Requirement: 1.5 mL saliva in a SARSTEDT Salivette (T514) saliva collection kit; Minimum: 0.6 mL; Refer to Special Info for Salivette collection instructions; Do not brush teeth before collecting specimen; Do not eat or drink for 15 minutes prior to collection; Collect specimen between 11 p.m. and midnight (preferred time), and record collection date and time on container; Refrigerated</b></p> <p><b>Stability:</b>            Ambient: 1 week            Refrigerated: 1 week            Frozen: 60 days</p>	Effective immediately
Hu Autoantibody	ANTIHU	<p><b>Special Information: Serum must be separated from cells within 48 hours of collection.</b></p> <p><b>Clinical Information: Anti-Hu (ANNA1) antibody is found in 5–10% of patients with small cell carcinoma of the lung and is associated with paraneoplastic encephalomyelitis and sensory neuropathy. This semi-quantitative assay may be useful in monitoring therapeutic responses in select cases.</b></p> <p><b>Specimen Requirement: 2 mL serum from a red top tube with no additive; Minimum: 0.5 mL; Serum must be separated from cells within 48 hours of collection; Refrigerated</b></p> <p>*OR* 2 mL serum from a serum separator (gold) tube; Minimum: 0.5 mL; <b>Serum must be separated from cells within 48 hours of collection; Refrigerated</b></p> <p>*OR* 2 mL cerebrospinal fluid (CSF) in a sterile container; Minimum: 0.5 mL; <b>Collect in sterile, leak-proof container; Refrigerated</b></p> <p><b>Stability:</b>            Ambient: 72 hours            Refrigerated: 28 days            Frozen: 28 days</p> <p><b>Methodology: Automated Nanoliter Scale Immunoassay</b></p> <p><b>Reference Range:</b>            Serum: &lt; 1:100            CSF: &lt; 1:1</p> <p><b>Days Performed: Monday–Friday</b></p> <p><b>Reported: 4–6 days</b></p> <p><b>CPT: 83520 x 1</b></p>	8/28/17
Hypersensitivity Pneumonitis II	HYPNE2	<p><b>Specimen Requirement: 3 mL serum from a serum separator (gold) tube; Minimum: 2 mL; Refrigerated</b></p> <p>*OR* 3 mL serum from a red top tube with no additive; Minimum: 2 mL; Refrigerated</p> <p><b>Methodology:</b>            Double Diffusion (DD)            ImmunoCAP</p> <p><b>Days Performed: Sunday, Wednesday, Friday</b></p> <p><b>Reported: 8–9 days</b></p>	Effective immediately

## Test Changes (Cont.)

Test Name	Order Code	Change	Effective Date
Isopropanol	ISOPRO	<p><b>Special Information: Patient Prep:</b> For medical purposes only. <b>Timing of specimen collection: Dependent on time of exposure, test upon presentation to hospital. Do NOT freeze whole blood. Cap tube tightly to minimize alcohol loss. Unacceptable conditions: Whole blood, plasma separator tubes (PST), serum separator tubes (SST). This test is New York DOH approved.</b></p> <p><b>Clinical Information: Monitor exposure to isopropanol. Toxic concentrations may cause nausea, dizziness, central nervous system depression and coma.</b></p> <p><b>Specimen Requirement:</b> 3 mL serum from a red top tube with no additive; Minimum: 0.5 mL; <b>Separate</b> serum from cells <b>ASAP</b> or within 2 hours of collection; <b>Transfer 3 mL serum to a standard transport tube;</b> Cap tube tightly to minimize alcohol loss; <b>Do not draw serum separator tubes (SST);</b> Refrigerated</p> <p>*OR* 3 mL <b>plasma</b> from a potassium oxalate/sodium fluoride (gray) tube; Minimum: 0.5 mL; <b>Separate plasma from cells ASAP</b> or within 2 hours of collection; <b>Transfer 3 mL plasma to a standard transport tube; Cap tube tightly to minimize alcohol loss; Do not draw plasma separator tubes (PST);</b> Refrigerated</p> <p><b>Reference Range:</b>            Isopropanol                No therapeutic range; Assay detection limit: 5 mg/dL            Acetone                <b>No therapeutic range;</b> Assay detection limit: 5 mg/dL</p> <p><b>Days Performed:</b> Sunday–Saturday  <b>Reported:</b> 2–4 days</p>	8/21/17
Lipid Associated Sialic Acid	LIPSIA	<p><b>Special Information: If tube other than a gel-barrier tube is used, transfer separated serum or plasma to a plastic transport tube.</b></p> <p><b>Clinical Information: Lipid Associated Sialic Acid is a useful adjunct in the management of a variety of malignancies. It is generally used in conjunction with other tumor markers. Results for this test are for investigational purposes only by the assay's manufacturer. The performance characteristics of this product have not been established. Results should not be used as a diagnostic procedure without confirmation of the diagnosis by another medically established diagnostic product or procedure. Values obtained with different assay methods should not be used interchangeably in serial testing. It is recommended that only one assay method be used consistently to monitor each patient's course of therapy. This procedure does not provide serial monitoring; it is intended for one-time use only.</b></p> <p><b>Specimen Requirement: 2 mL</b> serum in a serum separator (gold) tube; Minimum: <b>0.1 mL; Ambient</b></p> <p>*OR* <b>2 mL</b> serum from a <b>red top tube with no additive;</b> Minimum: <b>0.1 mL;</b> <b>Separate serum from cells and transfer to a standard plastic aliquot tube; Ambient</b></p> <p>*OR* <b>2 mL plasma</b> from an <b>EDTA lavender top tube;</b> Minimum: <b>0.1 mL;</b> <b>Separate plasma from cells and transfer to a standard plastic aliquot tube; Ambient</b></p> <p><b>Stability:</b>            Ambient: <b>14 days</b>            Refrigerated: <b>14 days</b>            Frozen: <b>14 days; Stable for 3 freeze/thaw cycles</b></p> <p><b>Reference Range: &lt; 20 mg/dL</b></p> <p><b>Days Performed: Tuesday, Thursday</b>  <b>Reported: 2–4 days</b></p>	8/21/17
Manganese, Urine	UMANG	<p><b>Note:</b> <i>There is a clinically significant charting name change associated with this test.</i></p> <p><b>Includes:</b>            Creatinine mg/dL            Creatinine mg/day            Manganese, Urine–<b>per volume</b>            Manganese, Urine–<b>per 24h</b>            Manganese, Urine–<b>ratio to CRT</b></p> <p><i>(continued on page 7)</i></p>	8/21/17

## Test Changes (Cont.)

Test Name	Order Code	Change	Effective Date
Manganese, Urine <i>(continued from page 6)</i>		<p><b>Special Information:</b> Collection volume MUST be indicated. Diet, medication and nutritional supplements may introduce interfering substances. Patients should be encouraged to discontinue nutritional supplements, vitamins, minerals and nonessential over-the-counter medications (upon the advice of their physician). High concentrations of iodine may interfere with elemental testing. Abstinence from iodine-containing medications or contrast agents for at least one month prior to collecting specimens is recommended. ARUP studies indicate that refrigeration of urine alone, during and after collection, preserves specimens adequately, if tested within 14 days of collection. Urine collected within 48 hours after administration of a gadolinium (Gd) containing contrast media (may occur with MRI studies) and acid preserved samples are unacceptable. <b>Specimens contaminated with blood or fecal material and specimens transported in a non-trace element free transport tube (with the exception of the original device) are also unacceptable. This test is New York DOH approved.</b></p> <p><b>Clinical Information:</b> This assay provides limited utility in determining manganese exposure. Whole blood measurements are recommended for determining recent or active exposure.</p> <p><b>Specimen Requirement:</b> 8 mL 24-hour urine (well-mixed) in a clean container; Minimum: 1 mL; Refrigerate during collection; Collect in a plastic container; Aliquot into a trace metal free transport tube (ARUP #43116); <b>Record total volume and collection time interval on tube and requisition;</b> Refrigerated</p> <p>*OR* 8 mL random urine in a clean container; Minimum: 1 mL; Refrigerate during collection; Collect in a plastic container; Aliquot into a trace metal free transport tube (ARUP #43116); <b>Record total volume on tube and requisition;</b> Refrigerated</p> <p><b>Reference Range:</b>  Manganese, Urine—<b>ratio to CRT:</b> 0.0–0.9 µg/g crt  Manganese, Urine—<b>per volume:</b> 0.0–0.9 µg/L  Manganese, Urine—<b>per 24h:</b> 0.0–2.4 µg/d  Creatinine mg/day: Refer to report</p> <p><b>Days Performed:</b> Sunday–Saturday</p> <p><b>Reported:</b> 2–6 days</p>	
Methanol	METHOL	<p><b>Special Information: Patient Prep: For medical purposes only. Timing of specimen collection: Dependent on time of exposure, test upon presentation to hospital. Do NOT freeze whole blood. Cap tube tightly to minimize alcohol loss. Unacceptable conditions: Whole blood, plasma separator tubes (PST) and serum separator tubes (SST). This test is New York DOH approved.</b></p> <p><b>Clinical Information: Monitor exposure to methanol. Toxic concentrations may cause intoxication, metabolic acidosis, ocular toxicity, central nervous system (CNS) depression and fatality if patients do not receive medical treatment.</b></p> <p><b>Specimen Requirement:</b> 3 mL serum from a red top tube with no additive; Minimum: 0.5 mL; Do not use serum separator tubes (SST); Separate serum from cells <b>ASAP</b> or within 2 hours of collection; <b>Transfer 3 mL serum to a standard transport tube;</b> Cap tube tightly to minimize alcohol loss; Refrigerated</p> <p>*OR* 3 mL plasma from a sodium <b>or lithium heparin</b> green top tube; Minimum: 0.5 mL; Do not use plasma separator tubes (PST); Separate plasma from cells <b>ASAP</b> or within 2 hours of collection; <b>Transfer 3 mL plasma to a standard transport tube;</b> Cap tube tightly to minimize alcohol loss; Refrigerated</p> <p>*OR* 3 mL plasma from a potassium oxalate/sodium fluoride (gray) tube; Minimum: 0.5 mL; Do not use plasma separator tubes (PST); Separate plasma from cells <b>ASAP</b> or within 2 hours of collection; <b>Transfer 3 mL plasma to a standard transport tube;</b> Cap tube tightly to minimize alcohol loss; Refrigerated</p> <p>*OR* 3 mL plasma from an EDTA lavender top tube; Minimum: 0.5 mL; Do not use plasma separator tubes (PST); Separate plasma from cells <b>ASAP</b> or within 2 hours of collection; <b>Transfer 3 mL plasma to a standard transport tube;</b> Cap tube tightly to minimize alcohol loss; Refrigerated</p> <p><b>Days Performed:</b> Sunday–Saturday</p> <p><b>Reported:</b> 2–4 days</p>	8/21/17

## Test Changes (Cont.)

Test Name	Order Code	Change	Effective Date
Multifocal Neuropathy Evaluation	MULNEU	<p><b>Special Information:</b> Informed consent is required. Whole blood collected in a red top or serum separator tube (SST) is not acceptable. Hemolyzed, icteric or lipemic specimens will be rejected. Serum must be separated from cells within 48 hours of collection.</p> <p><b>Clinical Information:</b> For detection of a mutation in the gene causing HNPP. Detect presence of anti-GM1, anti-GD1a, anti-Asialo GM1, and anti-GD1b antibodies.</p> <p><b>Specimen Requirement:</b> 8 mL whole blood in an EDTA lavender top tube; Minimum: 6 mL; THIS ASSAY REQUIRES MULTIPLE SPECIMEN TYPES; Collect 2 EDTA lavender top tubes to ensure adequate specimen volume; Send to Cleveland Clinic Laboratories on the day of collection; Refrigerated</p> <p>*AND* 2 mL serum from a serum separator (gold) tube; Minimum: 0.5 mL; Serum must be separated from cells within 48 hours of collection; Must send refrigerated; Refrigerated</p> <p>*OR* 8 mL whole blood in an EDTA lavender top tube; Minimum: 6 mL; THIS ASSAY REQUIRES MULTIPLE SPECIMEN TYPES; Collect 2 EDTA lavender top tubes to ensure adequate specimen volume; Refrigerated</p> <p>*AND* 2 mL serum from a red top tube with no additive; Minimum: 0.5 mL; Serum must be separated from cells within 48 hours of collection; Must send refrigerated; Refrigerated</p> <p><b>Stability:</b>            Ambient: Whole blood: 10 days; Serum: 3 days            Refrigerated: Whole blood: 10 days; Serum: 21 days            Frozen: Whole blood: Unacceptable; Serum: 4 months</p> <p><b>Methodology:</b>            Enzyme-Linked Immunosorbent Assay (ELISA)            Multiplex Ligation-dependent Probe Amplification</p> <p><b>Reference Range:</b> Refer to report</p> <p><b>Days Performed:</b> Tuesday</p> <p><b>Reported:</b> 15–22 days</p> <p><b>CPT:</b> 81324 x 1, 83520 x 4</p>	8/28/17
Neoenkephalitis Paraneoplastic Profile with Recombx	CEPHAL	<p><b>Special Information:</b> Whole blood is not an acceptable specimen. Serum must be separated from cells within 48 hours of collection.</p> <p><b>Clinical Information:</b> Diseases tested for include Paraneoplastic Neurological Syndrome, Autoimmune Encephalitis, and Stiff Person Syndrome.</p> <p><b>Specimen Requirement:</b> 2 mL serum from a red top tube with no additive; Minimum: 0.5 mL; Serum must be separated from cells within 48 hours of collection; Refrigerated</p> <p>*OR* 2 mL serum from a serum separator (gold) tube; Minimum: 0.5 mL; Serum must be separated from cells within 48 hours of collection; Refrigerated</p> <p><b>Stability:</b>            Ambient: 72 hours            Refrigerated: 28 days            Frozen: 28 days</p> <p><b>Methodology:</b>            Automated Nanoliter Scale Immunoassay            Enzyme-Linked Immunosorbent Assay (ELISA)            Immunofluorescence            Radioimmunoassay (RIA)</p> <p><b>Reference Range:</b> Refer to report</p> <p><b>Days Performed:</b> Monday, Thursday</p> <p><b>Reported:</b> 8–11 days</p> <p><b>CPT:</b> 83519 x 1, 83520 x 4, 86255 x 3, 86341 x 1</p>	8/28/17
Neopterin	NEOPT	<p><b>Reference Range:</b>            Adults: &lt; 2.5 ng/mL</p>	9/27/17

## Test Changes (Cont.)

Test Name	Order Code	Change	Effective Date
Neosensory Neuropathy Paraneoplastic Profile	NEOSEN	<p><b>Special Information:</b> Serum must be separated from cells within 48 hours of collection. Whole blood is not an acceptable specimen.</p> <p><b>Clinical Information:</b> Diseases tested for include Paraneoplastic Neurological Syndrome and Stiff Person Syndrome.</p> <p><b>Specimen Requirement:</b> 2 mL serum from a red top tube with no additive; Minimum: 0.5 mL; Serum must be separated from cells within 48 hours of collection; Refrigerated</p> <p>*OR* 2 mL serum from a serum separator (gold) tube; Minimum: 0.5 mL; Serum must be separated from cells within 48 hours of collection; Refrigerated</p> <p>*OR* 2 mL cerebrospinal fluid (CSF) in a sterile container; Minimum: 0.5 mL; Collect in sterile, leak-proof container; Refrigerated</p> <p><b>Stability:</b>            Ambient: 72 hours            Refrigerated: 28 days            Frozen: 28 days</p> <p><b>Methodology:</b> Automated Nanoliter Scale Immunoassay</p> <p><b>Reference Range:</b> Refer to report</p> <p><b>Days Performed:</b> Monday–Friday</p> <p><b>Reported:</b> 4–6 days</p> <p><b>CPT:</b> 83520 x 3</p>	8/28/17
Nickel, Urine 24 Hour	UNI24	<p><b>Note:</b> There is a clinically significant charting name change associated with this test.</p> <p><b>Includes:</b>            Creatinine, Ur mg/dL            Creatinine, Ur mg/day            Nickel, Urine–per volume            Nickel, Urine–per 24h            Nickel, Urine–ratio to CRT</p> <p><b>Special Information:</b> Collection volume MUST be indicated. Diet, medication, and nutritional supplements may introduce interfering substances. Patients should be encouraged to discontinue nutritional supplements, vitamins, minerals, and nonessential over-the-counter medications (upon the advice of their physician). High concentrations of iodine may interfere with elemental testing. Abstinence from iodine-containing medications or contrast agents for at least one month prior to collecting specimens is recommended. ARUP studies indicate that refrigeration of urine alone, during and after collection, preserves specimens adequately, if tested within 14 days of collection. Urine collected within 48 hours after administration of a gadolinium (Gd) containing contrast media (may occur with MRI studies) and acid preserved samples are unacceptable. Specimens contaminated with blood or fecal material, and specimens transported in non-trace element free transport tubes (with the exception of the original device) are also unacceptable. This test is New York DOH approved.</p> <p><b>Clinical Information:</b> Measurement of nickel is not recommended in asymptomatic individuals or in individuals with a low likelihood of exposure. Elevations in nickel urine should be interpreted with caution in individuals with no exposure risks, and may indicate contamination of the specimen.</p> <p><b>Specimen Requirement:</b> 8 mL 24-hour urine (well-mixed) in a clean container; Minimum: 1 mL; Refrigerate during collection; Collect specimen in a plastic container; Aliquot into a trace metal-free transport tube (ARUP #43116); Record total volume and collection time interval on transport tube and requisition; Refrigerated</p> <p>*OR* 8 mL random urine in a clean container; Minimum: 1 mL; Refrigerate during collection; Collect specimen in a plastic container; Aliquot into a trace metal-free transport tube (ARUP #43116); Record total volume on transport tube and requisition; Refrigerated</p> <p><i>(continued on page 10)</i></p>	8/21/17

## Test Changes (Cont.)

Test Name	Order Code	Change	Effective Date
Nickel, Urine 24 Hour <i>(continued from page 9)</i>		<p><b>Reference Range:</b>            Nickel, Urine—<b>per volume: 0.0–10.4 µg/L</b>            Nickel, Urine—<b>per 24h: 0.0–14.9 µg/d</b>            Nickel, Urine—<b>ratio to CRT: 0.0–9.9 µg/g crt</b>            Creatinine, Urine mg/day: Refer to report</p> <p><b>Days Performed:</b> Sunday–Saturday  <b>Reported:</b> 2–9 days</p>	
Pancreatic Elastase, Fecal	PANCEF	<p><b>Special Information:</b> 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.  <b>Patient Preparation:</b> Interruption of enzyme substitution therapy recommended in order to avoid the possibility of cross-reaction with porcine enzymes. <b>Unacceptable conditions: Stool in media or preservative; Swabs. This test is New York DOH approved.</b></p> <p><b>Clinical Information: Screen for exocrine pancreatic insufficiency.</b>  <b>Normal: 201 µg/g or greater; Moderate to mild exocrine pancreatic insufficiency: 100–200 µg/g; Severe exocrine pancreatic insufficiency: 99 µg/g or less</b></p> <p><b>Specimen Requirement:</b> 5 g stool in a <b>clean container (No preservatives);</b> Minimum: 1 g; <b>Do not collect in media</b> or preservative; <b>Do not use swabs;</b> Frozen</p>	Effective immediately
Recombx CV2 Autoantibody Test	CV2	<p><b>Special Information:</b> Serum must be separated from <b>cells</b> within 48 hours of collection.</p> <p><b>Specimen Requirement:</b> 2 mL serum from a red top tube with no additive; Minimum: 0.5 mL; Serum must be separated from <b>cells</b> within 48 hours of collection; Refrigerated</p> <p>*OR* 2 mL serum from a serum separator (gold) tube; Minimum: 0.5 mL; Serum must be separated from <b>cells</b> within 48 hours of collection; Refrigerated</p> <p>*OR* 2 mL cerebrospinal fluid (CSF) in a sterile container; Minimum: 0.5 mL;  <b>Collect in sterile, leak-proof container;</b> Refrigerated</p> <p><b>Stability:</b>            Ambient: 72 hours            Refrigerated: 28 days            Frozen: <b>28 days</b></p> <p><b>Methodology: Automated Nanoliter Scale Immunoassay</b></p> <p><b>Reference Range:</b>  <b>Serum: &lt; 1:100</b>  <b>CSF: &lt; 1:1</b></p> <p><b>Days Performed:</b> Monday–Friday  <b>Reported:</b> 4–6 days  <b>CPT: 83520 x 1</b></p>	8/28/17
Recombx MaTa Autoantibody Test	MATA	<p><b>Special Information:</b> Serum must be separated from <b>cells</b> within 48 hours of collection.</p> <p><b>Specimen Requirement:</b> 2 mL serum from a red top tube with no additive; Minimum: 0.5 mL; Serum must be separated from <b>cells</b> within 48 hours of collection; Refrigerated</p> <p>*OR* 2 mL serum from a serum separator (gold) tube; Minimum: 0.5 mL; Serum must be separated from <b>cells</b> within 48 hours of collection; Refrigerated</p> <p>*OR* 2 mL cerebrospinal fluid (CSF) in a sterile container; Minimum: 0.5 mL;  <b>Collect in sterile, leak-proof container;</b> Refrigerated</p> <p><b>Stability:</b>            Ambient: 72 hours            Refrigerated: 28 days            Frozen: <b>28 days</b></p> <p><b>Methodology: Automated Nanoliter Scale Immunoassay</b></p> <p><b>Reference Range:</b>  <b>Serum: &lt; 1:100</b>  <b>CSF: &lt; 1:1</b></p> <p><b>Days Performed:</b> Monday–Friday  <b>Reported:</b> 4–6 days  <b>CPT: 83520 x 1</b></p>	8/28/17

## Test Changes (Cont.)

Test Name	Order Code	Change	Effective Date
RI Autoantibody	RIAUT	<p><b>Special Information:</b> Serum must be separated from cells within 48 hours of collection.</p> <p><b>Clinical Information:</b> Detection of anti-Ri antibodies using recombinant human antigens.</p> <p><b>Specimen Requirement:</b> 2 mL serum from a red top tube with no additive; Minimum: 0.5 mL; <b>Serum must be separated from cells within 48 hours of collection;</b> Refrigerated</p> <p>*OR* 2 mL serum from a serum separator (gold) tube; Minimum: 0.5 mL; <b>Serum must be separated from cells within 48 hours of collection;</b> Refrigerated</p> <p>*OR* 2 mL cerebrospinal fluid (CSF) in a sterile container; Minimum: 0.5 mL; <b>Collect in a sterile, leak-proof container;</b> Refrigerated</p> <p><b>Stability:</b>            Ambient: <b>72 hours</b>            Refrigerated: <b>28 days</b>            Frozen: <b>28 days</b></p> <p><b>Methodology:</b> Automated Nanoliter Scale Immunoassay</p> <p><b>Reference Range:</b>            Serum: &lt; 1:50            CSF: &lt; 1:1</p> <p><b>Days Performed:</b> Monday–Friday</p> <p><b>Reported:</b> 4–6 days</p> <p><b>CPT:</b> 83520 x 1</p>	8/28/17
SensoriMotor Neuropathy Profile Complete	SENMOT	<p><b>Special Information:</b> Serum must be separated from cells within 48 hours of collection. Hemolyzed, icteric or lipemic specimens will be rejected.</p> <p><b>Clinical Information:</b> Anti-MAG, anti-SGPG, anti-GM1, anti-GD1a, anti-GD1b, anti-asialo GM1, anti-sulfatide, anti-Hu, and IgM GALOP antibodies are found in patients with a peripheral neuropathy and mixed sensory and motor symptoms. This semi-quantitative assay may be useful in monitoring therapeutic responses in select cases. Includes Co-GM1 Autoantibody Test, Co-Asialo-GM1 Autoantibody Test, Co-GD1b Autoantibody Test, GD1a Autoantibody Test, GALOP Autoantibody Test, SGPG Autoantibody Test, MAG Autoantibody Test, Recomb<sup>®</sup> Hu Autoantibody Test, and Sulfatide Autoantibody Test.</p> <p><b>Specimen Requirement:</b> 2 mL serum from a serum separator (gold) tube; Minimum: 0.5 mL; <b>Serum must be separated from cells within 48 hours of collection;</b> Refrigerated</p> <p>*OR* 2 mL serum from a red top tube with no additive; Minimum: 0.5 mL; <b>Serum must be separated from cells within 48 hours of collection;</b> Refrigerated</p> <p><b>Stability:</b>            Ambient: <b>72 hours</b>            Refrigerated: <b>21 days</b>            Frozen: <b>28 days</b></p> <p><b>Methodology:</b>            Automated Nanoliter Scale Immunoassay            Enzyme-Linked Immunosorbent Assay (ELISA)            Western Blot (WB)</p> <p><b>Reference Range:</b> Refer to report</p> <p><b>Days Performed:</b> Monday, Wednesday</p> <p><b>Reported:</b> 8–11 days</p> <p><b>CPT:</b> 83520 x 11</p>	8/28/17

## Test Changes (Cont.)

Test Name	Order Code	Change	Effective Date
Sensory Neuropathy Profile xp	SENNRO	<p><b>Special Information:</b> Serum must be separated from cells within 48 hours of collection. Whole blood is not an acceptable specimen. Specimens that are hemolyzed, icteric or lipemic will be rejected.</p> <p><b>Specimen Requirement:</b> 2 mL serum from a red top tube with no additive; Minimum: 0.5 mL; <b>Serum must be separated from cells within 48 hours of collection;</b> Refrigerated</p> <p>*OR* 2 mL serum from a <b>serum separator (gold) tube;</b> Minimum: 0.5 mL; <b>Serum must be separated from cells within 48 hours of collection;</b> Refrigerated</p> <p><b>Stability:</b>            Ambient: 72 hours            Refrigerated: 21 days            Frozen: <b>28 days</b></p> <p><b>Methodology:</b>            Automated Nanoliter Scale Immunoassay            Enzyme-Linked Immunosorbent Assay (ELISA)            Western Blot (WB)</p> <p><b>Reference Range:</b> Refer to report</p> <p><b>Days Performed:</b> Monday, Wednesday</p> <p><b>Reported:</b> 8–11 days</p> <p><b>CPT:</b> 83520 x 7</p>	8/28/17
Thallium, Blood	THALL	<p><b>Special Information:</b> Diet, medication, and nutritional supplements may introduce interfering substances. Patients should be encouraged to discontinue nutritional supplements, vitamins, minerals, and non-essential over-the-counter medications (upon the advice of their physician). <b>This test is New York DOH approved.</b></p> <p><b>Unacceptable conditions:</b> Heparin anticoagulant, hemolyzed specimens</p> <p><b>Clinical Information:</b> Blood thallium levels reflect recent exposure as thallium has a biological half-life of approximately two to four days. Blood levels greater than 100 µg/L are considered toxic and greater than 300 µg/L indicate severe ingestion. After severe thallium poisonings, reported symptoms have varying times of onset and include gastroenteritis, multi-organ failure and neurologic injury. Peripheral neuropathy and alopecia are well-documented effects of acute and chronic exposure. Human health effects from low-level thallium exposure are unknown. Elevated results from noncertified trace element-free collection tubes may be due to contamination. Elevated concentrations of trace elements in blood should be confirmed with a second specimen collected in a tube designed for trace element determinations, such as a royal blue (K<sub>2</sub>EDTA) or (Na<sub>2</sub>EDTA) tube. If the specimen is drawn and stored in the appropriate container, the trace element values do not change with time.</p> <p><b>Specimen Requirement:</b> 7 mL whole blood in an EDTA royal blue top tube; Minimum: 0.5 mL; <b>Send blood in original collection tube;</b> Ambient</p> <p><b>Stability:</b>            Ambient: <b>Indefinitely</b>            Refrigerated: <b>Indefinitely</b>            Frozen: Unacceptable</p> <p><b>Days Performed:</b> Sunday–Saturday</p> <p><b>Reported:</b> 2–6 days</p>	8/21/17

## Test Changes (Cont.)

Test Name	Order Code	Change	Effective Date
Thallium, Urine	UTHAL	<p><b>Special Information:</b> Patient Prep: Diet, medication, and nutritional supplements may introduce interfering substances. Patients should be encouraged to discontinue nutritional supplements, vitamins, minerals, and non-essential over-the-counter medications (upon the advice of their physician). High concentrations of iodine may interfere with elemental testing. Abstinence from iodine-containing medications or contrast agents for at least one month prior to collecting specimens for elemental testing is recommended. <b>ARUP studies indicate that refrigeration of urine alone, during and after collection, preserves specimens adequately if tested within 14 days of collection. Record total volume and collection time interval on tube and requisition. This test is New York DOH approved.</b> Unacceptable Conditions: Urine collected within 48 hours after administration of a gadolinium (Gd) containing contrast media (may occur with MRI studies), acid preserved urine, <b>specimens contaminated with blood or fecal material, specimens transported in non-trace element-free transport tubes (with the exception of the original device)</b></p> <p><b>Clinical Information:</b> Urinary thallium levels may reflect recent or chronic exposure, and the presence of thallium in urine after acute exposure may persist for up to several weeks. Concentrations less than 5 µg/L are unlikely to cause adverse health effects while concentrations greater than 500 µg/L have been associated with clinical poisoning. After severe thallium poisoning, reported symptoms have varying times of onset and include gastroenteritis, multi-organ failure and neurologic injury. Peripheral neuropathy and alopecia are well-documented effects of acute and chronic exposure. Human health effects from low level thallium exposure are unknown.</p> <p><b>Specimen Requirement:</b> 8 mL 24-hour urine (well-mixed) in a metal-free clean container; Minimum: 1 mL; Refrigerate during collection; <b>Must collect specimen in plastic container; Transfer an 8 mL aliquot into a trace element-free transport tube (ARUP supply #43116); Record total volume and collection time interval on tube and requisition; Refrigerated</b></p> <p>*OR* 8 mL random urine in a metal-free clean container; Minimum: 1 mL; <b>Must collect specimen in plastic container; Transfer an 8 mL aliquot into a trace element-free transport tube (ARUP supply #43116); Record total volume on tube and requisition; Refrigerated</b></p> <p><b>Reference Range:</b>            Thallium, Urine per volume: <b>0.0–0.4 µg/L</b>            Thallium, Urine (24-hour): <b>0.0–0.4 µg/d</b>            Thallium, Urine ratio to creatinine: <b>0.0–0.4 µg/g crt</b>            Creatinine Urine per volume: Not established            Creatinine, per 24 hour            Female                3–8 Years: 140–700 mg/d                9–12 Years: 300–1300 mg/d                13–17 Years: 400–1600 mg/d                18–50 Years: 700–1600 mg/d                51–80 Years: 500–1400 mg/d                81–99 Years: 400–1300 mg/d            Male                3–8 Years: 140–700 mg/d                9–12 Years: 300–1300 mg/d                13–17 Years: 500–2300 mg/d                18–50 Years: 1000–2500 mg/d                51–80 Years: 800–2100 mg/d                81–99 Years: 600–2000 mg/d</p> <p><b>Days Performed: Sunday–Saturday</b>  <b>Reported: 2–6 days</b></p>	8/21/17
Toluene, Blood	TOLUEN	<p><b>Special Information:</b> Environmental/occupational exposure monitoring. Collect blood prior to the last shift of the work week. <b>Specimens received at room temperature will be rejected. This test is New York State approved.</b></p> <p><b>Clinical Information: Biological Exposure Index (ACGIH): 0.02 mcg Toluene/mL blood measured in a prior to last shift of work week specimen. Reporting limit 0.3 mcg/mL</b></p> <p><b>Specimen Requirement:</b> 2 mL whole blood in a potassium oxalate/sodium fluoride (gray) tube; Minimum: 0.7 mL; Refrigerated</p>	10/2/17
Valproic Acid, Total and Free	VPAFT2	<p><b>Specimen Requirement:</b> 3 mL plasma from a sodium or lithium heparin green top tube; <b>Collect immediately before next dose;</b> Refrigerated</p>	Effective immediately

## Test Changes (Cont.)

Test Name	Order Code	Change	Effective Date
Yo Autoantibody	ANTIYO	<p><b>Special Information:</b> Serum must be separated from cells within 48 hours of collection.</p> <p><b>Clinical Information:</b> Detection of anti-Yo antibodies using recombinant human antigens.</p> <p><b>Specimen Requirement:</b> 2 mL serum from a red top tube with no additive; Minimum: 0.5 mL; <b>Serum must be separated from cells within 48 hours of collection;</b> Refrigerated</p> <p>*OR* 2 mL serum from a serum separator (gold) tube; Minimum: 0.5 mL; <b>Serum must be separated from cells within 48 hours of collection;</b> Refrigerated</p> <p>*OR* 2 mL cerebrospinal fluid (CSF) in a sterile container; Minimum: 0.5 mL; <b>Collect in a sterile, leak-proof container;</b> Refrigerated</p> <p><b>Stability:</b>            Ambient: <b>72 hours</b>            Refrigerated: <b>28 days</b>            Frozen: <b>28 days</b></p> <p><b>Methodology:</b> Automated Nanoliter Scale Immunoassay</p> <p><b>Reference Range:</b>            Serum: &lt; 1:200            CSF: &lt; 1:1</p> <p><b>Days Performed:</b> Monday–Friday</p> <p><b>Reported:</b> 4–6 days</p> <p><b>CPT:</b> 83520 x 1</p>	8/28/17

# New Tests

Test Name	Order Code	Change	Effective Date
Cytochrome P450 2D6 (CYP2D6) Geno	2D6GEN	<p><b>Special Information:</b> Unacceptable conditions: Plasma or serum; Specimens collected in sodium heparin or lithium heparin</p> <p><b>Clinical Limitation:</b> Only the targeted CYP2D6 variants will be detected by this panel. Diagnostic errors can occur due to rare sequence variations. Risk of therapeutic failure or adverse reactions with CYP2D6 substrates may be affected by genetic and non-genetic factors that are not detected by this test. This result does not replace the need for therapeutic drug or clinical monitoring.</p> <p><b>Clinical Information:</b> Characteristics: The cytochrome P450 (CYP) isozyme 2D6 is involved in the metabolism of many drugs, such as antiestrogens (tamoxifen), alpha-blockers, analgesics, anticonvulsives, antidepressants, antidiabetics, antihypertensives, antipsychotics, antitussives, beta blockers, cardioactives, norepinephrine reuptake inhibitors, and stimulants. Variants of CYP2D6 will influence pharmacokinetics of CYP2D6 substrates and may predict non-standard dose requirements. Inheritance: Autosomal co-dominant. Cause: CYP2D6 gene variants and copy number result in increased, decreased or complete deficiency in enzyme activity. Variants Tested: (Variants are numbered according to M33388 sequence) Functional: *2 (2850C&gt;T), *2A (-1584C&gt;G; 2850C&gt;T). Decreased function: *9 (2613-5delAGA), *10 (100C&gt;T), *17 (1023C&gt;T; 2850C&gt;T), *29 (1659G&gt;A; 2850C&gt;T), *41 (2988G&gt;A; 2850C&gt;T). Non-functional: *3 (2549delA), *4 (100C&gt;T; 1846G&gt;A), *5 (gene deletion), *6 (1707delT), *7 (2935A&gt;C), *8 (1758G&gt;T; 2850C&gt;T), *12 (124G&gt;A; 2850C&gt;T), *14 (1758G&gt;A; 2850C&gt;T), *36 (a *10 carrying a CYP2D7-derived exon 9 conversion). Increased function: Duplicated functional alleles. Negative: No variants detected is predictive of *1 functional alleles and normal enzymatic activity. Allele frequencies: CYP2D6*2 or CYP2D6*2A: African-17.6%, Asian-21.2%, Caucasian-27.6%, Middle Eastern-21.7%, Oceanian-1.2%; CYP2D6*3: African-0.2%, Asian-0%, Caucasian-1.3%, Middle Eastern-0.1%, Oceanian-0.2%; CYP2D6*4: African-4.9%, Asian-4.6%, Caucasian-18.2%, Middle Eastern-7.8%, Oceanian-2.5%; CYP2D6*5: African-6.3%, Asian-4.3%, Caucasian-2.8%, Middle Eastern-2.3%, Oceanian-4.3%; CYP2D6*6: African-0.1%, Asian-0%, Caucasian-1.0%, Middle Eastern-0.6%, Oceanian-0%; CYP2D6*7: African-0%, Asian-0%, Caucasian-0.1%, Middle Eastern-0%, Oceanian-0%; CYP2D6*8: African-0%, Asian-0%, Caucasian-0%, Middle Eastern-0%, Oceanian-0%; CYP2D6*9: African-0.3%, Asian-0.5%, Caucasian-2.1%, Middle Eastern-0%, Oceanian-0%; CYP2D6*10: African-5.3%, Asian-30.2%, Caucasian-3.0%, Middle Eastern-3.5%, Oceanian-2.5%; CYP2D6*12: African-0%, Asian-0%, Caucasian-0%, Middle Eastern-0%, Oceanian-0%; CYP2D6*14: African-0.1%, Asian-0.4%, Caucasian-0%, Middle Eastern-0.2%, Oceanian-0%; CYP2D6*17: African-19.0%, Asian-0.1%, Caucasian-0.4%, Middle Eastern-1.6%, Oceanian-0.1%; CYP2D6*29: African-7.7%, Asian-0%, Caucasian-0.1%, Middle Eastern-0.8%, Oceanian-0%; CYP2D6*36: African-0.3%, Asian-0.7%, Caucasian-0%, Middle Eastern-0%, Oceanian-0%; CYP2D6*41: African-9.2%, Asian-4.9%, Caucasian-7.9%, Middle Eastern-19.9%, Oceanian-0.9%; CYP2D6xN (gene duplication): African-4.7%, Asian-1.6%, Caucasian-2.6%, Middle Eastern-7.1%, Oceanian-11.8%. Clinical Sensitivity: Drug-dependent. Analytical Sensitivity and Specificity: Greater than 99%</p> <p><b>Specimen Requirement:</b> 3 mL whole blood in an EDTA lavender top tube; Minimum: 1 mL; Refrigerated</p> <p>*OR* 3 mL whole blood in an ACD A or B (yellow) tube; Minimum: 1 mL; Refrigerated</p> <p>*OR* One saliva specimen in a Saliva Collection Device by Spectrum Solutions, LLC (SS-SAL-1, ARUP Supply #52535); Ambient</p> <p><b>Stability:</b> Ambient: 72 hours for whole blood; 2 weeks for saliva Refrigerated: 2 weeks for whole blood; Unacceptable for saliva Frozen: 1 month for whole blood; Unacceptable for saliva</p> <p><b>Methodology:</b> Polymerase Chain Reaction (PCR) Fluorescence Monitoring</p> <p><b>Reference Range:</b> Refer to report</p> <p><b>Days Performed:</b> Varies</p> <p><b>Reported:</b> 6–11 days</p> <p><b>CPT:</b> 81226 x 1</p> <p><b>Price:</b> \$459.00 (non-discountable)</p>	8/21/17

## New Tests (Con't)

Test Name	Order Code	Change	Effective Date
ERBB2 (HER2/neu) Gene Amplification by FISH, Gastric Tissue	HER2GT	<p><b>Special Information:</b> Include surgical pathology report with specimen. Preferred transport temperature is ambient. Refrigerated transport is also acceptable. Ship in cooled container during summer months. Equivocal cases will be reflexed to an alternate probe in an effort to resolve amplification status. Unacceptable conditions: Specimens fixed or processed in alternative fixatives (alcohol, Prefer) or heavy metal fixatives (B-4 or B-5). No tumor in tissue. Decalcified specimens. Tissue fixed for less than 6 hours or greater than 72 hours. This test is New York DOH approved.</p> <p><b>Clinical Information:</b> Aid in prediction of response to HER2-directed therapy in patients with gastric cancer.</p> <p><b>Specimen Requirement:</b> One formalin-fixed paraffin-embedded (FFPE) tissue block in a clean container; Collect tumor tissue; Formalin fix (10% neutral buffered formalin) and paraffin-embed tissue; Fixative duration: 6–72 hours; Protect paraffin block from excessive heat; Transport block in a tissue transport kit (ARUP supply #47808); Kit is recommended but not necessary; Include surgical pathology report; Ambient</p> <p>*OR* Five unstained FFPE slides in a clean container; Minimum: 2 slides; Collect tumor tissue; Formalin fix (10% neutral buffered formalin) and paraffin-embed tissue; Fixative duration: 6–72 hours; Protect paraffin block from excessive heat; Transport 5 unstained (4 micron thick sections) positively charged slides in a tissue transport kit (ARUP supply #47808); Kit is recommended but not necessary; Include surgical pathology report; Ambient</p> <p><b>Stability:</b>            Ambient: Indefinitely            Refrigerated: Indefinitely            Frozen: Unacceptable</p> <p><b>Methodology:</b> Fluorescent In-Situ Hybridization (FISH)</p> <p><b>Reference Range:</b> Refer to report</p> <p><b>Days Performed:</b> Monday–Friday</p> <p><b>Reported:</b> 4–8 days</p> <p><b>CPT:</b> 88377 x 1</p> <p><b>Price:</b> \$460.00 (non-discountable)</p>	8/3/17
Homocysteine, Total, Urine	UHCYS	<p><b>Special Information:</b> Specimens received at ambient temperature will be rejected. This test is New York DOH approved.</p> <p><b>Clinical Information:</b> To be used in conjunction with plasma amino acids and urine organic acids to aid in the biochemical screening for primary and secondary disorders of methionine metabolism. Homocysteine is an intermediary in the sulfur-amino acid metabolism pathways, linking the methionine cycle to the folate cycle. Inborn errors of metabolism that lead to homocysteinemia/-uria include cystathionine beta-synthase deficiency (homocystinuria) and various defects of methionine re-methylation. Homocysteine also was thought to be an independent predictor of cardiovascular disease (atherosclerosis, heart disease, thromboembolism), as early observational studies prior to 2000 linked homocysteine to cardiovascular risk and morbidity and mortality. However, following FDA-mandated folic acid supplementation in 1998, homocysteine concentrations decreased by approximately 10% without a similar change in cardiovascular or ischemic events. Currently, the use of homocysteine for assessment of cardiovascular risk is uncertain and controversial. Based on several meta-analyses, at present, homocysteine may be regarded as a weak risk factor for coronary heart disease, and there is a lack of direct causal relationship between hyperhomocysteinemia and cardiovascular disease. It is most likely an indicator of poor lifestyle and diet.</p> <p><b>Specimen Requirement:</b> 4 mL random urine in a clean container; Minimum: 2.25 mL; Void and discard the first-morning urine specimen following an overnight fast; Continue fasting, and collect the next random urine specimen; Refrigerated</p> <p><b>Stability:</b>            Ambient: Unacceptable            Refrigerated: 7 days            Frozen: 2 years</p> <p><i>(continued on page 17)</i></p>	8/21/17

## New Tests (Con't)

Test Name	Order Code	Change	Effective Date
Homocysteine, Total, Urine <i>(continued from page 16)</i>		<p><b>Methodology:</b> Liquid Chromatography-Tandem Mass Spectrometry (LC-MS/MS) Stable Isotope Dilution</p> <p><b>Reference Range:</b> Adults: 0–9 mcml/g creatinine</p> <p><b>Days Performed:</b> Monday–Saturday</p> <p><b>Reported:</b> 3–5 days</p> <p><b>CPT:</b> 83090 x 1</p> <p><b>Price:</b> \$317.00 (non-discountable)</p>	
Reticulin Antibodies, Serum	RTIABS	<p><b>Special Information:</b> If positive, results will be titered at no additional charge. Specimens that are grossly hemolyzed or grossly lipemic will be rejected. Specimens received at ambient temperature will be rejected. This test is New York DOH approved.</p> <p><b>Clinical Information:</b> Celiac disease (CD) is a genetically inherited autoimmune digestive disease and tends to occur in families of European descent. Family members of people with CD or dermatitis herpetiformis are at increased risk of CD. CD is characterized by a permanent intolerance to gluten. When gluten is ingested, the immune system triggers an isolated inflammatory response in the small intestinal mucosa. A lifetime gluten-free diet can completely stop the immune response. Once the patient is on a gluten-free diet, the small intestine begins to repair itself and the antibody levels decline and eventually disappear. However, reintroduction of gluten-containing products stimulates the immune response again. A significant reduction in morbidity and mortality occurs when patients adhere to the gluten-free diet. Patients with CD produce various autoantibodies, including endomysial (EMA), tissue transglutaminase (tTG), gliadin, and reticulin antibodies, as part of the immune response. IgA antibodies usually predominate although patients may also produce IgG autoantibodies. The levels of these antibodies decline following institution of a gluten-free diet. tTG is the primary autoantigen recognized by EMA antibodies in patients with CD and is currently considered the most useful first level screening test for CD. Reticulin antibodies are no longer considered useful in the diagnosis of CD because they lack the sensitivity and specificity of the EMA and tTG tests. Serological screening offers a minimally invasive option for rapid identification of those likely to have CD and to select those who should be subjected to biopsy. Markedly positive (serologically) individuals are highly likely to have CD and should undergo biopsy to confirm the diagnosis. Clinical Reference: 1. Murray JA: The widening spectrum of celiac disease. <i>Am J Clin Nutr</i> 1999;69:354-365 2. Lazzari R, Volta U, Bianchi FB, et al: R1 reticulin antibodies: markers of celiac disease in children on a normal diet and on gluten challenge. <i>J Pediatr Gastroenterol Nutr</i> 1984;3:516-522</p> <p><b>Specimen Requirement:</b> 0.5 mL serum from a serum separator (gold) tube; Minimum: 0.2 mL; Centrifuge and aliquot serum into standard transport tube; Refrigerated</p> <p>*OR* 0.5 mL serum from a red top tube with no additive; Minimum: 0.2 mL; Centrifuge and aliquot serum into standard transport tube; Refrigerated</p> <p><b>Stability:</b> Ambient: Unacceptable Refrigerated: 14 days Frozen: 14 days</p> <p><b>Methodology:</b> Indirect Immunofluorescence Assay (IFA)</p> <p><b>Reference Range:</b> Negative</p> <p><b>Days Performed:</b> Monday–Sunday</p> <p><b>Reported:</b> 3–4 days</p> <p><b>CPT:</b> 86255 x 1, (86256–Titer, if appropriate, no additional charge)</p> <p><b>Price:</b> \$40.00 (non-discountable)</p>	8/21/17

## New Tests (Con't)

Test Name	Order Code	Change	Effective Date
Toxicology Screen w/ confirmation, Urine	UTOXWC	<p><b>Includes:</b></p> <ul style="list-style-type: none"> <li>Amphetamines</li> <li>Barbiturates</li> <li>Benzodiazepines</li> <li>Cannabinoids</li> <li>Cocaine</li> <li>Ethanol</li> <li>Opiates</li> <li>Oxycodone</li> <li>Phencyclidine</li> </ul> <p><b>Special Information:</b> Urine sent for confirmation for all components not reported as negative.</p> <p><b>Specimen Requirement:</b> 5 mL random urine in a clean container; Minimum: 1.5 mL; Refrigerated</p> <p><b>Stability:</b></p> <ul style="list-style-type: none"> <li>Ambient: Unacceptable</li> <li>Refrigerated: 5 days at 2–8 °C</li> <li>Frozen: Unacceptable</li> </ul> <p><b>Methodology:</b> Fluorescence Polarization Immunoassay (FPIA)</p> <p><b>Reference Range:</b></p> <ul style="list-style-type: none"> <li>Amphetamines: Negative</li> <li>Barbiturates: Negative</li> <li>Benzodiazepines: Negative</li> <li>Cannabinoids: Negative</li> <li>Cocaine: Negative</li> <li>Ethanol: Negative</li> <li>Opiates: Negative</li> <li>Oxycodone: Negative</li> <li>Phencyclidine: Negative</li> </ul> <p><b>Days Performed:</b> 7 days per week</p> <p><b>Reported:</b> 8 hours</p> <p><b>CPT:</b> 80307 x 1</p> <p><b>Price:</b> \$78.00</p>	8/22/17

## Fee Increases

Test Name	Order Code	List Fee	CPT Code	Effective Date
Lipid Associated Sialic Acid	LIPSIA	\$124.00 (non-discountable)	84275	8/21/17

## Discontinued Tests

Test Name	Order Code	Test Information	Effective Date
Amniotic Bilirubin Scan	AMBILI	This test will no longer be available.	8/21/17
Bupivacaine	BUPIV	This test will no longer be available.	8/4/17
Cyto P450 2D6 Geno	2D6	This test will no longer be available. Suggest ordering Cytochrome P450 2D6 (CYP2D6) Geno (2D6GEN).	8/21/17
FISH for BK Virus		This test will no longer be available.	10/4/17
Gastric Analysis	GASTAN	This test will no longer be available.	8/21/17
Homocystine, Urine Quantitative	UHCY	This test will no longer be available. Suggest ordering Homocysteine, Total, Urine (UHCYS).	8/21/17
Leucine Aminopeptidase (LAP), Serum	LAPSER	This test will no longer be available.	8/21/17
Reticulin Antibody, IgA with reflex to Titer	RTICAB	This test will no longer be available. Suggest ordering Reticulin Antibodies, Serum (RTIABS).	8/21/17
Xylose Absorption Test (Adult)	XYLOSE	This test will no longer be available.	8/21/17
Xylose Absorption Test, Child	XYLPED	This test will no longer be available.	8/21/17