SPECIALTY LABORATORIES
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Test Updates

December 25, 2010

Dear Colleague:

Please review the following specific test listings for important information about new assay availability and test revisions. Each upcoming change also provides an effective date to assist in the prioritization of any changes necessary to your own ordering systems. If you are not also receiving this information via email, please contact our Client Relations team at 1-800-421-4449 to be added to our electronic mailing list.

As a reminder, *Specialty* will be changing its name on January 25, 2011. Nothing changes for you from a service perspective. You may have noted that we have begun transitioning the way that we answer calls, however most of the changes will take several months to implement. According to federal regulation, we will change to the Quest Diagnostics Nichols Institute name on all patient data documentation, including laboratory reports, on the effective date in January.

In 2011 we will continue our focus on providing better turnaround times for our time sensitive assays. The TAT for the Triple and Quad Marker will be changing from three to two days. In order for the decreased TAT to be evident to your clients it is imperative that the patient information be provided at the time of order since this information is critical to the finalization of the results. If the information is not provided, the TAT will be delayed while Specialty contacts you to ascertain the information. We appreciate your assistance in proactively providing the demographic requirements for these assays.

We are pleased to inform you that a number of our tests are now New York approved. Serum tests include Clonazpem [4918], Cocaine Metabolites [4118], Flurazepam (Dalmane®) [4920], Lorazepam [4087], Triazolam [4089], Temazepam [4088], Oxazepam [4934], Nordiazepam [4928], Midazolam [4085], Chlordiazepoxide [4916], Leflunomide Metabolite [4191], and Benzodiazepines Screen [4090]. In addition, Nicotine & Cotinine [4190 & 4190U respectively] performed on serum and urine are New York approved for testing.

The American Medical Association (AMA) has made CPT code changes in the 2011 edition of the AMA Current Procedural Terminology (CPT) coding manual. Specialty Laboratories will be implementing these changes effective January 1, 2011. Overall, the changes for 2011 affect the way we bill some of our tests. We have posted the chart listing the tests affected and the appropriate CPT code changes on our website for ease of reference.

We thank you for choosing *Specialty* and look forward to your continued support. For additional information, please visit our Web site at *www.specialtylabs.com* or contact Client Relations at 800-421-4449.

Respectfully Yours,

Basel Kashlan

Basel Kashlan, MD, FCAP
Laboratory Director

New Tests (*Specialty*):

1712 Phosphatidylserine IgG Autoabs (Available January 31)

Component	Method	Reference Range/Units
Phosphatydilserine IgG	**EIA**	**<11.0 GPS U/mL**

Specimen/Stability	Serum 2.0 (0.6) mL: Refrigerated 7 days, Frozen 2 months
Schedule	Sunday, Tuesday - Saturday
Report	Same day
CPT Code	86148
Regulatory Status	FDA Approved

1713 Phosphatidylserine IgM Autoabs (Available January 31)

Component	Method	Reference Range/Units
Phosphatydilserine IgM	**EIA**	**<25.0 MPS U/mL**

Specimen/Stability	Serum 2.0 (0.6) mL: Refrigerated 7 days, Frozen 2 months
Schedule	Sunday, Tuesday - Saturday
Report	Same day
CPT Code	86148
Regulatory Status	FDA Approved

1714 Phosphatidylserine IgA Autoabs (Available January 31)

Component	Method	Reference Range/Units
Phosphatydilserine IgA	**EIA**	**<20.0 APS U/mL**

Specimen/Stability	Serum 2.0 (0.6) mL: Refrigerated 7 days, Frozen 2 months
Schedule	Sunday, Tuesday - Saturday
Report	Same day
CPT Code	86148
Regulatory Status	FDA Approved

4085U Midazolam, Urine (Available January 31)

Component	Method	Reference Range/Units
Midazolam Urine	**LC-MS-MS**	**<100 ng/mL**

Specimen/Stability	Urine 6.0 (4.0) mL: Refrigerated 14 days, Frozen 14 days
Collection Instructions	Collect random urine in a urine collection cup. No preservative is needed. Ship refrigerated or frozen. Specimens contaminated with blood (RBC 3+) will be rejected.
Schedule	Tuesday, Thursday, Saturday
Report	Within 2 days
CPT Code	80154
Regulatory Status	Laboratory Developed Test
Always Statement	Limit of quantitation: Midazolam 100 ng/mL

New Tests (*Specialty*): (cont'd)

4087U Lorazepam, Urine (Available January 31)

Component	Method	Reference Range/Units
Lorazepam Urine	**LC-MS-MS**	**<100 ng/mL**

Specimen/Stability	Urine 6.0 (4.0) mL: Refrigerated 14 days, Frozen 14 days
Collection Instructions	Collect random urine in a urine collection cup. No preservative is needed. Ship refrigerated or frozen. Specimens contaminated with blood (RBC 3+) will be rejected.
Schedule	Tuesday, Thursday, Saturday
Report	Within 2 days
CPT Code	80154
Regulatory Status	Laboratory Developed Test
Always Statement	Limit of quantitation: Lorazepam 100 ng/mL

4691U Pain Management Heroin Metabolite Screen w/Confirm, Urine (Available January 31)

Component	Method	Cut-off/Units
Heroin Metabolite	**EIA**	**Negative**
6 Acetylmorphine	**LC-MS-MS**	**10 ng/mL**

Specimen/Stability	Urine 20 (7) mL: Ambient 7 days, Refrigerated 14 days, Frozen 30 days
Collection Instructions	Collect 20 mL of random urine. Ship ambient.
Schedule	Tuesday - Saturday
Report	Next day
CPT Code	80101
Regulatory Status	FDA Approved
Note	Limit of screen quantitation: 10 ng/mL. Confirmation testing will automatically be performed on all Positive screen results for an additional charge (add CPT code 83925).

8947NY *Borrelia burgdorferi* IgG Abs w/Reflex IB + Bands [NY] (Available January 31)

Component	Method	Reference Range/Units
***B. burgdorferi* IgG Abs**	**EIA**	**<0.80 Index**

Specimen/Stability	Serum 2.0 (1.0): Ambient 7 days, Refrigerated 14 days, Frozen 2 months
Schedule	Sunday, Tuesday - Saturday
Report	Same day
CPT Code	86618
Regulatory Status	FDA Approved
Always Statement	REFERENCE RANGE for *B. burgdorferi* IgG Abs: Less than 0.80 Index . . . Negative 0.80 - 1.19 Index . . . . . Equivocal Greater than 1.19 Index . . Positive
Note	If positive, *B. burgdorferi* IgG immunoblot panel (New York criteria), code 7712BNY, is performed for An additional fee (add CPT code 86617).
Clinical Utility	Aid in the diagnosis of infection with the Lyme disease agent.

New Tests (*Specialty*): (cont'd)

8948NY *Borrelia burgdorferi* IgM Abs w/Reflex IB + Bands [NY] (Available January 31)

Component	Method	Reference Range/Units
***B. burgdorferi* IgM Abs**	**EIA**	**<0.80 Index**

Specimen/Stability	Serum 2.0 (1.0): Ambient 7 days, Refrigerated 14 days, Frozen 2 months
Schedule	Sunday, Tuesday - Saturday
Report	Same day
CPT Code	86618
Regulatory Status	FDA Approved
Always Statement	REFERENCE RANGE for *B. burgdorferi* IgM Abs: Less than 0.80 Index . . . Negative 0.80 - 1.19 Index . . . . . Equivocal Greater than 1.19 Index . . Positive
Note	If positive, *B. burgdorferi* IgM immunoblot panel (New York criteria), code 7714BNY, is performed for an additional fee (add CPT code 86617).
Clinical Utility	Aid in the diagnosis of infection with the Lyme disease agent.

7712BNY *Borrelia burgdorferi* IgG IB + Bands [NY] (Available January 31)

Component	Method	Reference Range
***B. burgdorferi* IgG Abs**	**IB**	**Negative**
p18	**IB**	
p23	**IB**	
p28	**IB**	
p30	**IB**	
p39	**IB**	
p41	**IB**	
p45	**IB**	
p58	**IB**	
p66	**IB**	
p93	**IB**	

Specimen/Stability	Serum 1.0 (0.5): Ambient 7 days, Refrigerated 14 days, Frozen 2 months
Schedule	Monday - Saturday
Report	Same day
CPT Code	86617
Regulatory Status	FDA Approved
Always Statement	INTERPRETIVE CRITERIA: POSITIVE: Lyme IgG IB is considered as POSITIVE by the New York State Dept. of Health if any FIVE of the following bands are Present: 18, 23, 28, 30, 39, 41, 45, 58, 66 or 93 kd INDETERMINATE: New York State Dept. of Health considers the test results as INDETERMINATE if ONE to FOUR bands are Present. NEGATIVE: No bands present.$^{N}{}_{U}{}^{N}{}_{U}$
Note	Sera from individuals, with other pathogenic spirochetal diseases such as syphilis, yaws, pinta, leptospirosis, relapsing fever and periodontal disease, may give false positive results. Individuals with connective tissue autoimmune diseases such as rheumatoid arthritis and systemic lupus erythromatosis, and individuals with anti-nuclear antibody may also give false positive results. Individuals with other bacterial and viral infections such as Rocky Mountain Spotted Fever, Epstein-Barr Virus, and Cytomegalovirus may also have antibodies which cross-react with *B. burgdorferi*.
Clinical Utility	There are multiple criteria for interpreting Lyme immunoblots. The "New York State" criterion provides an indeterminate interpretation in addition to a positive and negative interpretation. For interpretation of an IgG positive blot, at least 5 of 10 IgG bands (18, 23, 28, 30, 39, 41, 45, 58, 66 or 93 kDa) must be present. An indeterminate IgG blot is interpreted by the presence of 1 to 4 IgG bands (18, 23, 28, 30, 39, 41, 45, 58, 66 or 93 kDa). Positive, indeterminate and negative results are reported.

New Tests (*Specialty*): (cont'd)

7714BNY ***Borrelia burgdorferi*** **IgM IB + Bands [NY]** **(Available January 31)**

Component	Method	Reference Range
B. burgdorferi **IgM Abs**	**IB**	**Negative**
p23	**IB**	
p39	**IB**	
p41	**IB**	

Specimen/Stability	Serum 1.0 (0.5): Ambient 7 days, Refrigerated 14 days, Frozen 2 months
Schedule	Monday - Saturday
Report	Same day
CPT Code	86617
Regulatory Status	FDA Approved
Always Statement	INTERPRETIVE CRITERIA: POSITIVE: Lyme IgM IB is considered as POSITIVE by the New York State Dept. of Health if any TWO of the following bands are Present: 23, 39 or 41 kd. INDETERMINATE: New York State Dept. of Health considers the test results as INDETERMINATE if ONE band is Present. NEGATIVE: No bands present. Caution must be used in supporting a diagnosis of *B. burgdorferi* infection when sera are immunoblot IgM positive and immunoblot IgG negative after the initial 4 week period from onset. Because the likelihood of a false-positive test result is high for these individuals, a positive IgM test alone is not recommended for use in determining active disease in persons with illness longer than one month duration.
Note	Sera from individuals, with other pathogenic spirochetal diseases such as syphilis, yaws, pinta, leptospirosis, relapsing fever and periodontal disease, may give false positive results. Individuals with connective tissue autoimmune diseases such as rheumatoid arthritis and systemic lupus erythromatosis, and individuals with anti-nuclear antibody may also give false positive results. Individuals with other bacterial and viral infections such as Rocky Mountain Spotted Fever, Epstein-Barr Virus, and Cytomegalovirus may also have antibodies which cross-react with *B. burgdorferi*.
Clinical Utility	There are multiple criteria for interpreting Lyme immunoblots. The "New York State" criterion provides an indeterminate interpretation in addition to a positive and negative interpretation. For interpretation of an IgM positive blot, at least 2 of 3 IgM bands (23, 39 or 41 kDa) must be present. An indeterminate IgM blot is interpreted by the presence of only 1 of 3 IgM bands (23, 39 or 41 kDa). Positive, indeterminate and negative results are reported.

New Tests (*Specialty*): (cont'd)

2523 Influenza Virus, Type A Detection [DFA] (Available January 31)

Component	Method	Reference Range
Specimen Source		
Influenza A Antigen	**DFA**	**Not detected**

Specimen/Stability	Smear/Slides 4 (2): Ambient 48 hours, Refrigerated 72 hours, Frozen 7 days
Alt Specimen	Culturette/Swab: Ambient 24 hours, Refrigerated 72 hours, Frozen 7 days M4 Transport Media/Swab: Ambient 24 hours, Refrigerated 72 hours, Frozen 7 days Sterile Container/Tube: Ambient 24 hours, Refrigerated 72 hours, Frozen 7 days Swab Viral Transport: Ambient 24 hours, Refrigerated 72 hours, Frozen 7 days Viral Transport Media: Ambient 24 hours, Refrigerated 72 hours, Frozen 7 days
Collection Instructions	1. Source of specimen is required, please include on requisition. 2. Specimens should be collected early in the acute phase of infection. The chance of viral recovery is best during the first 3 days after onset and is greatly reduced beyond 5 days with many viruses. 3. Submit 2 acetone-fixed slides or specimens in viral transport media. These specimens are from respiratory sources such as nasal swab or washings. 4. Unacceptable specimens: Wooden swabs, dry swabs and calcium alginate. 5. Specimens received more than 72 hours from time of draw must be frozen at -70C (not -20C) or on dry ice. Do not freeze at -20 C. Virus loses infectivity. 6. Ship specimens on cold pack or on dry ice. 7. M4 transport media (M4) and dacron-tipped swabs with plastic or fine-wire shafts available for use with M4 are provided. 8. Ship specimens on cold pack or on dry ice.
Schedule	Sunday - Saturday
Report	Same day
CPT Code	87276
Regulatory Status	FDA Approved
Always Statement	For negative influenza antigen results, cell culture should be considered to confirm the results or to identify other viruses producing similar clinical symptoms.
Note	Tests available for other respiratory viruses are #2425 Respiratory Infection Evaluation, Viral and #2503 Viral Culture, Respiratory.
Clinical Utility	Aid in the diagnosis of influenza A viruses which can cause highly contagious respiratory diseases and typically results in epidemics.

New Tests (*Specialty*): (cont'd)

2524 Influenza Virus, Type B Detection [DFA] (Available January 31)

Component	Method	Reference Range
Specimen Source		
Influenza B Antigen	**DFA**	**Not detected**

Specimen/Stability	Smear/Slides 4 (2): Ambient 48 hours, Refrigerated 72 hours, Frozen 7 days
Alt Specimen	Culturette/Swab: Ambient 24 hours, Refrigerated 72 hours, Frozen 7 days M4 Transport Media/Swab: Ambient 24 hours, Refrigerated 72 hours, Frozen 7 days Sterile Container/Tube: Ambient 24 hours, Refrigerated 72 hours, Frozen 7 days Swab Viral Transport: Ambient 24 hours, Refrigerated 72 hours, Frozen 7 days Viral Transport Media: Ambient 24 hours, Refrigerated 72 hours, Frozen 7 days
Collection Instructions	1. Source of specimen is required, please include on requisition. 2. Specimens should be collected early in the acute phase of infection. The chance of viral recovery is best during the first 3 days after onset and is greatly reduced beyond 5 days with many viruses. 3. Submit 2 acetone-fixed slides or specimens in viral transport media. These specimens are from respiratory sources such as nasal swab or washings. 4. Unacceptable specimens: Wooden swabs, dry swabs and calcium alginate. 5. Specimens received more than 72 hours from time of draw must be frozen at -70C (not -20C) or on dry ice. Do not freeze at -20 C. Virus loses infectivity. 6. Ship specimens on cold pack or on dry ice. 7. M4 transport media (M4) and dacron-tipped swabs with plastic or fine-wire shafts available for use with M4 are provided. 8. Ship specimens on cold pack or on dry ice.
Schedule	Sunday - Saturday
Report	Same day
CPT Code	87275
Regulatory Status	FDA Approved
Always Statement	For negative influenza antigen results, cell culture should be considered to confirm the results or to identify other viruses producing similar clinical symptoms.
Note	Tests available for other respiratory viruses are #2425 Respiratory Infection Evaluation, Viral and #2503 Viral Culture, Respiratory.
Clinical Utility	Aid in the diagnosis of influenza B viruses which can cause highly contagious respiratory diseases and typically results in epidemics.

Test Changes:

1081 **Antiphospholipid Syndrome EvaluatR™**

Effective	Immediately
Specimen/Stability #1	Plasma Citrated 2.0 (1.0) mL: Frozen 14 days
Specimen/Stability #2	Serum 2.0 (1.0) mL: Refrigerated 7 days, Frozen 2 months **Note: Increased frozen serum stability.**

1083 **Beta-2-Glycoprotein I (Beta-2-GPI) IgG, IgM & IgA Autoabs**

Effective	Immediately
Specimen/Stability	Serum 1.0 (0.6) mL: Ambient 14 days, Refrigerated 28 days, Frozen 2 months **Note: Increased frozen stability.**
Also Affected	DOS Codes 1182, 1183, 1184

1100 **ANA w/International Units & Pattern**

Effective	Immediately
CPT Code	86039 **(NEW)**
Also Affected	DOS Codes 1000, 1004, 1006, 1010, 1100C, 1118, 1121, 1122, 1126, 1127, 1726, 1862, 1866, 1868, 5906, 5908

5038 **FLT3 & NPM1 GenotypR™**

Effective	Immediately
Specimen/Stability	Whole Blood EDTA 5.0 (3.0) mL: Ambient 7 days, Refrigerated 7 days, Frozen 7 days Whole Blood ACD 5.0 (3.0) mL: Ambient 7 days, Refrigerated 7 days, Frozen 7 days Whole Blood Heparin 5.0 (3.0) mL: Ambient 7 days, Refrigerated 7 days, Frozen 7 days Bone Marrow EDTA 1.5 (0.5) mL: Ambient 7 days, Refrigerated 7 days, Frozen 7 days Bone Marrow ACD 1.5 (0.5) mL: Ambient 7 days, Refrigerated 7 days, Frozen 7 days Bone Marrow Heparin 1.5 (0.5) mL: Ambient 7 days, Refrigerated 7 days, Frozen 7 days Cell Pellet: Ambient 6 months **Note: Frozen specimens now accepted.**

1915 **Lupus Anticoagulant: Hexagonal Phase**

Effective	January 1
CPT Code	85598 **(NEW)**
Also Affected	DOS Codes 1910, 5962, 5976

1033 **Glutamic Acid Decarboxylase (GAD) Autoabs**

Effective	February 8
Reference Range	<1.1 U/mL **(NEW)**
Also Affected	DOS Code 1032

1325 **Glomerular Filtration Rate (GFR), Estimated**

Effective	February 8
Always Statement	The National Kidney Foundation defines the stages of CKD based on the GFR:

Stage	Description	GFR[ml/min/1.73m2]
1	Kidney damage with normal or increased GFR	>=90
2	Kidney damage with mildly decreased GFR	60-89
3	Moderately decreased GFR	30-59
4	Severely decreased GFR	15-29
5	Kidney failure	<15(or dialysis)

Source:

1. National Kidney Foundation. K/DOQI Clinical Practice Guidelines for Chronic Kidney Disease: Evaluation, Classification and Stratification. Am J Kidney Dis 39:S1-S262, 2002 (suppl 1)
2. Levey AS, Stevens LA, Schmid CH, Zhang YL, et al. A new equation to estimate glomerular filtration rate. Ann Intern Med 2009; 150:604-12.

Test Changes: (cont'd)

1760 Kappa/Lambda Light Chains, Free w/Ratio, Serum

Effective	February 8
Component	Kappa Free Light Chain
Reference Range	3.3 – 19.9 mg/L (same)
Component	Lambda Free Light Chain
Reference Range	5.7 – 26.3 mg/L (same)
Component	Kappa/Lambda Ratio
Reference Range	0.26 – 1.65 **(NEW)**
Always Statement	Interpretation: In serum, kappa/lambda ratio of whole immunoglobulin molecules is 2:1, whereas the kappa/lambda ratio of free light chains is 1:1.5. The latter is attributed to the occurrence of lambda light chains as dimers whose serum 1/2-life is approximately 3 times longer than that of monomeric kappa light chains. Excess production of kappa or lambda light chains alters the kappa/lambda ratio. Alterations that fall outside the normal range are attributed to the presence of monoclonal light chains. Monoclonal light chains are found in serum of patients with multiple myeloma, the light chain variant of MM, Waldenstrom's macroglobulinemia, mu-heavy chain disease, primary amyloidosis, light chain deposition disease, monoclonal gammopathy of undetermined significance, and lymphoproliferative disease such as B-CLL. Measurement of free light chain concentration in serum is useful for diagnosis, prognosis, monitoring disease activity and following response to therapy of these disorders. Chronic infection and chronic inflammatory diseases, as well as renal insufficiency, may be accompanied by a diffuse increase in both kappa and lambda free chains, but kappa/lambda ratio remains within normal limits. The serum concentration of free light chains increases with age over 60 years; light chains may reach 50 mg/L in those 70-80 yrs of age; in these cases the kappa/lambda ratio still remains within normal limits. Physicians, who are accustomed to the identification of clonal protein by electrophoretic means, may order immunofixation in addition to free light chain immunoassay. In rare instances, immunofixation may identify monoclonal light chain protein in the absence of abnormalities in the quantitative light chain immunoassay. Katzman JA et al., Serum reference intervals and diagnostic ranges for free kappa and free lambda immunoglobulin light chains: Relative sensitivity for detection of monoclonal light chains. Clin Chem 2002, 48:1437-1444.
Also Affected	DOS Code 1762

1821 Human Papillomavirus High Risk DetectR™

Effective	February 8
Specimen/Stability	Brush Qiagen (Digene) Medium 1.0 (1.0) mL: Ambient 14 days, Refrigerated 21 days, Frozen 3 months
Alt Specimen	ThinPrep Vial 8.0 (4.0) mL: Ambient 3 months, Refrigerated 3 months SurePath Vial 3.0 (2.0) mL: Ambient 30 days, Refrigerated 30 days Tissue: Frozen 2 months **Note: AutoCyte PREP Tubes are no longer accepted. Increased ambient and decreased refrigerated stability for SurePath Vials.**
Also affected	DOS Codes 1820, 1822, 1824

3244 Testosterone, Total

Effective	February 8
Always Statement	In hypogonadal males, Testosterone, Total, LC/MS/MS is the recommended assay. This test code (15983) must be collected in a red-top tube with no gel. The Endocrine Society recommends obtaining at least two morning (8-10 a.m.) samples on different days when screening for hypogonadism. Aging Men with clinically significant hypogonadal symptoms and testosterone values repeatedly in the range of 200-300 ng/dL or less may benefit from testosterone treatment after adequate risk and benefits counseling.
Also Affected	DOS Codes 2017, 2023, 2025, 3188, 3248, 3916, 3917

Test Changes: (cont'd)

4882UR Chromium Random Urine

Effective	February 8
Component	Chromium Random Urine **(ADD)**
Reference Range	<2.0 mcg/L
Component	Chromium/Creatinine Ratio **(NEW NAME)**
Reference Range	<5.0 mcg/g creat (same)

4900P Amikacin, Peak & Trough

Effective	February 8
Specimen/Stability #1	Serum Peak 1.0 (0.5) mL: Ambient 5 days, Refrigerated 7 days Plasma Heparin Peak 1.0 (0.5) mL: Ambient 5 days, Refrigerated 7 days Plasma EDTA Peak 1.0 (0.5) mL: Ambient 5 days, Refrigerated 7 days
Specimen/Stability #2	Serum Trough 1.0 (0.5) mL: Ambient 5 days, Refrigerated 7 days Plasma Heparin Trough 1.0 (0.5) mL: Ambient 5 days, Refrigerated 7 days Plasma EDTA Trough 1.0 (0.5) mL: Ambient 5 days, Refrigerated 7 days **Note: Plasma Heparin and EDTA specimens are now accepted; ambient specimens are now accepted; frozen specimens are no longer accepted.**
Collection Instructions	Collect peak at end of 60 minute IV infusion, or 30 minutes after end of 30 minute infusion, or 60 minutes after IM dose. Collect trough immediately prior to next dose. Serum separator tubes are not acceptable. Moderate to grossly lipemic specimens will be rejected. Transport room temperature.
Methodology	Immunoassay **(NEW)**
Reference Range	Peak: 20.0-25.0 mg/L **(NEW UNITS)** Trough: 1.0-8.0 mg/L **(NEW UNITS)**
Always Statement	Peak concentration: 20.0-25.0 mg/L$^{N}_{U}$(collected 30-60 min after injection) Trough concentration: 1.0- 4.0 mg/L (for less severe infection) 4.0- 8.0 mg/L (for more severe infection)
Also Affected	DOS Codes 4700P, 4700P

4900 Amikacin

Effective	February 8
Specimen/Stability	Serum 1.0 (0.5) mL: Ambient 5 days, Refrigerated 7 days Plasma Heparin 1.0 (0.5) mL: Ambient 5 days, Refrigerated 7 days Plasma EDTA 1.0 (0.5) mL: Ambient 5 days, Refrigerated 7 days **Note: Plasma Heparin and EDTA specimens are now accepted; ambient specimens are now accepted; frozen specimens are no longer accepted.**
Collection Instructions	Collect peak at end of 60 minute IV infusion, or 30 minutes after end of 30 minute infusion, or 60 minutes after IM dose. Collect trough immediately prior to next dose. Serum separator tubes are not acceptable. Moderate to grossly lipemic specimens will be rejected. Transport room temperature.
Methodology	Immunoassay **(NEW)**
Always Statement	Peak concentration: 20.0-25.0 mg/L$^{N}_{U}$(collected 30-60 min after injection) **(NEW UNITS)** Trough concentration: 1.0- 4.0 mg/L (for less severe infection) **(NEW UNITS)** 4.0- 8.0 mg/L (for more severe infection) **(NEW UNITS)**

8766 Varicella-Zoster Virus Antibody (IgM)

Effective	February 8
Specimen/Stability	Serum 1.0 (0.5) mL: Ambient 7 days, Refrigerated 14 days, Frozen 30 days **Note: Decreased frozen stability.**

Test Changes: (cont'd)

1305UR Protein, Total & Creatinine Urine Random w/Ratio

Effective	February 15
Specimen/Stability	Urine 10 (2) mL: Ambient 4 days, Refrigerated 5 days, Frozen 28 days **Note: Increased refrigerated and decreased frozen stability.**
Collection Instructions	10 mL urine form a well-mixed random collection; no preservative. Transport at room temperature.
Component	Protein, Total Urine Random
Reference Range	Male: 5-25 mg/dL **(NEW)** Female: 5-24 mg/dL **(NEW)**
Component	Creatinine Urine Random
Reference Range	no change
Component	Protein/Creatinine Ratio
Reference Range	Male: 22-128 mg/g creat **(NEW)** Female: 21-161 mg/g creat **(NEW)**

1320U Creatinine 24Hr Urine

Effective	February 15
Specimen/Stability	Urine 24 hour 10 (2) mL: Ambient 7 days, Refrigerated 7 days, Frozen 28 days Urine Acetic Acid 10 (2) mL: Ambient 7 days, Refrigerated 7 days, Frozen 28 days Urine Boric Acid 10 (2) mL: Ambient 7 days, Refrigerated 7 days, Frozen 28 days Urine Transport Tube 10 (2) mL: Ambient 7 days, Refrigerated 7 days, Frozen 28 days **Note: Decreased refrigerated and frozen stability.**

1320UR Creatinine Urine Random

Effective	February 15
Specimen/Stability	Urine 10 (2) mL: Ambient 7 days, Refrigerated 7 days, Frozen 28 days Urine Transport Tube 10 (2) mL: Ambient 7 days, Refrigerated 7 days, Frozen 28 days **Note: Decreased refrigerated and frozen stability.**

1322 Creatinine Clearance

Effective	February 15
Specimen/Stability #1	Serum 1.0 (0.5) mL: Ambient 7 days, Refrigerated 7 days, Frozen 28 days Plasma Haparin 1.0 (0.5) mL: Ambient 7 days, Refrigerated 7 days, Frozen 28 days
Specimen/Stability #1	Urine 10 (2) mL: Ambient 7 days, Refrigerated 7 days, Frozen 28 days **Note: Decreased refrigerated and frozen urine stability.**

1324U Protein, Total 24Hr Urine

Effective	February 15
Specimen/Stability	Urine 24 hour 10 (2) mL: Ambient 4 days, Refrigerated 5 days, Frozen 28 days **Note: Decreased ambient, refrigerated and frozen stability.**
Collection Instructions	Do not include first morning specimen in 24-hour collections. Collect all subsequent voidings. The last sample collected should be the first specimen voided the following morning at the same time as the previous morning's first voiding or at the end of the collection period. Refrigerate during collection. Do not preserve. Total volume should be indicated on the requisition if collected overnight or during 24 hours. Transport at room temperature.
Reference Range	< 150 mg/24 hr **(NEW)**
Also Affected	DOS Codes 1584U, 1595U (Reference ranges only)

1324UR Protein, Total Urine Random

Effective	February 15
Specimen/Stability	Urine 10 (2) mL: Ambient 4 days, Refrigerated 5 days, Frozen 28 days **Note: Decreased ambient and refrigerated stability.**
Collection Instructions	Pour a well-mixed aliquot of specimen into a clean leak-proof container. Collect without preservative. Transport at room temperature.
Reference Range	Male: 5-25 mg/dL **(NEW)** Female: 5-24 mg/dL **(NEW)**
Also Affected	DOS Codes 1580U, 1584U, 1584UR, 1595U (Reference ranges only)

Test Changes: (cont'd)

1324C Protein, Total CSF

Effective	February 15
Specimen/Stability	CSF 1.0 (0.5) mL: Refrigerated 7 days, Frozen 6 months **Note: Ambient specimens are no longer accepted; increased refrigerated and frozen stability.**
Collection Instructions	Grossly hemolyzed specimens will be rejected. Transport refrigerated.
Reference Range	< 29 Days: 15-100 mg/dL **(NEW)** 29 Days – 60 Year: 15- 45 mg/dL (same) > 60 Year: 15- 60 mg/dL **(NEW**)
Also Affected	DOS Codes 1580C, 1584C (Reference ranges only)

1328U Protein, Total w/Creatinine 12-Hour Urine

Effective	February 15
Specimen/Stability	Urine 12 hour 10 (2) mL: Ambient 4 days, Refrigerated 5 days, Frozen 28 days Urine Transport Tube 10 (2) mL: Ambient 4 days, Refrigerated 5 days, Frozen 28 days **Note: Decreased ambient, refrigerated and frozen stability.**
Collection Instructions	10 mL 12-Hour Urine Instructions: 10 ml aliquot from a well-mixed, 12-hour urine collection, no preservatives. Record 12-hour urine volume on test request form and urine vial. Transport at room temperature.

3441U Microalbumin 24Hr Urine

Effective	February 15
Specimen/Stability	Urine 24 hour 10 (2) mL: Ambient 7 days, Refrigerated 14 days, Frozen 1 year **Note: Frozen specimens now accepted; increased ambient stability.**
Collection Instructions	Submit 10 mL aliquot from a well-mixed 24-hour urine, submitted in a plastic, leakproof container. Do not use preservatives. Record 24-hour urine volume on test request form and urine container. Transport at room temperature.
Methodology	Turbidimetric **(New)**
Component	Microalbumin, 24 Hour Urine **(ADD)**
Reference Range	< 30 mg/24 hr **(NEW)**
Component	Microalbumin, 24 Hour Urine **(NEW NAME)**
Reference Range	< 20 mcg/min **(NEW)**
Component	Microalbumin Urine, ug/mL **(REMOVE)**
Component	Creatinine Urine (no change)

3441UR Microalbumin Urine Random

Effective	February 15
Name	Microalbumin, Random Urine (w/Creatinine) **(NEW)**
Specimen/Stability	Urine 10 (2) mL: Ambient 7 days, Refrigerated 7 days, Frozen 28 days Urine Transport Tube 10 (2) mL: Ambient 7 days, Refrigerated 7 days, Frozen 28 days **Note: Frozen specimens now accepted; increased ambient and decreased refrigerated stability.**
Collection Instructions	10 mL aliquot from unpreserved urine, random submitted in a plastic leak-proof container. Transport at room temperature.
Methodology	Turbidimetric **(New)**
Component	Microalbumin Urine
Reference Range	**(REMOVE)**
Component	Microalbumin/Creatinine Ratio
Reference Range	< 30 mcg/mg **(NEW UNITS)**
Component	Creatinine Urine (no change)

Test Changes: (cont'd)

4332U Oxalate 24Hr Urine

Effective	February 15
Name	Oxalic Acid, 24-Hour Urine **(NEW)**
Specimen/Stability	Urine Preserved (6N HCl) 24 hour 10 (2) mL: Ambient 6 days, Refrigerated 7 days, Frozen 4 months **Note: Increased frozen stability; decreased ambient stability.**
Collection Instructions	Patient should refrain from taking excessive amounts of Ascorbic Acid or Oxalate-rich foods (i.e., spinach, coffee, tea, chocolate, rhubarb) for at least 48 hours before the collection period. Collect urine with 25 mL 6N HCl to maintain a pH below 3. Specify 24 hr urine volume on the requisition. Transport at room temperature.
Reference Range	3.6-38.0 mg/24 hr **(NEW)**
Also Affected	DOS Code 4168 (Reference ranges only)

4332UR Oxalate Urine Random

Effective	February 15
Name	Oxalic Acid, Random Urine **(NEW)**
Specimen/Stability	Urine Preserved (6N HCl) 10 (2) mL: Ambient 6 days, Refrigerated 7 days, Frozen 4 months Urine Transport Tube 10 (2) mL: Ambient 13 days, Refrigerated 13 days, Frozen 28 days **Note: Increased frozen stability; decreased ambient stability.**
Collection Instructions	Patient should refrain from taking excessive amounts of Ascorbic Acid or Oxalate-rich foods (i.e., spinach, coffee, tea, chocolate, rhubarb) for at least 48 hours before the collection period. Collect urine with 25 mL 6N HCl to maintain a pH below 3. Transport at room temperature.

4333U Uric Acid 24Hr Urine

Effective	February 15
Specimen/Stability	Urine 24 hour 10 (2) mL: Ambient 13 days, Refrigerated 13 days, Frozen 28 days Urinalysis Transport Tube 10 (2) mL: Ambient 13 days, Refrigerated 13 days, Frozen 28 days **Note: Increased ambient stability; decreased refrigerated and frozen stability.**
Collection Instructions	Do not acidify the urine. Please aliquot for uric acid testing prior to addition of any acid for those tests requiring preservative. Do not include first morning specimen; collect all subsequent voidings. The last sample collected should be the first morning specimen voided the following morning at the same time as the previous morning's first voiding. Specify total volume and duration of collection on container and test requisition. Transport at room temperature.
Reference Range	Male: 120-820 mg/24 hr **(NEW)** Female: 65-630 mg/24 hr **(NEW)**
Also Affected	DOS Code 4168 (Reference ranges only)

4333UR Uric Acid Urine Random

Effective	February 15
Specimen/Stability	Urine 10 (2) mL: Ambient 13 days, Refrigerated 13 days, Frozen 28 days Urinalysis Transport Tube 10 (2) mL: Ambient 13 days, Refrigerated 13 days, Frozen 28 days **Note: Increased ambient stability; decreased refrigerated and frozen stability.**
Collection Instructions	10 mL urine aliquot from a random urine collection. No preservatives. Instructions: Collect urine without preservative. Do not acidify the specimen. Transport at room temperature is preferred; transport refrigerated (cold packs) or frozen is acceptable.
Always Statement	Reference ranges are not available for random collections.

Test Changes: (cont'd)

4836U Calcium 24Hr Urine

Effective	February 15
Specimen/Stability	Urine Preserved (6N HCl) 24 hour 10 (2) mL: Ambient 5 days, Refrigerated 5 weeks, Frozen 6 months Urine 24 hour 10 (2) mL: Ambient 5 days, Refrigerated 5 weeks, Frozen 6 months Urinalysis Transport Tube 10 (2) mL: Ambient 5 days, Refrigerated 5 weeks, Frozen 6 months **Note: Increased refrigerated and frozen stability; decreased ambient stability.**
Collection Instructions	24 hour urine: Do not include first morning specimen in 24-hour collection. Collect all subsequent voidings. The last sample collected should be the first specimen voided the following morning at the same time as the previous morning's first voiding. Collect urine with 25 mL of 6N HCL to maintain a pH below 3. It is acceptable to add preservative after collection if urine is refrigerated during collection. Adjust pH to <3. Record the total volume of urine on the requisition. Transport at room temperature.
Methodology	Spectrophotometry **(NEW)**
Reference Range	Male: 55-300 mg/24 hr **(NEW)** Female: 35-250 mg/24 hr **(NEW)**
Always Statement	Low Calcium Diet: Males: 55-200 mg/24 hr Females: 35-200 mg/24 hr
Also Affected	DOS Code 4168 (Reference ranges only)

4836UR Calcium Urine Random

Effective	February 15
Specimen/Stability	Urine Preserved (6N HCl) 10 (2) mL: Ambient 5 days, Refrigerated 5 weeks, Frozen 6 months Urine 10 (2) mL: Ambient 5 days, Refrigerated 5 weeks, Frozen 6 months Urinalysis Transport Tube 10 (2) mL: Ambient 5 days, Refrigerated 5 weeks, Frozen 6 months **Note: Increased refrigerated and frozen stability; decreased ambient stability.**
Collection Instructions	Collect 10 mL random urine in a plastic, screw-capped container and adjust pH to < 3.0 with 6N HCl (Minimum: 2 mL). Aliquot urine specimens and send at room temperature to the laboratory.
Methodology	Spectrophotometry **(NEW)**
Always Statement	Reference ranges are not available for random collections.

4866U Magnesium 24Hr Urine

Effective	February 15
Reference Range	24-255 mg/24 hr **(NEW)**
Also Affected	DOS Codes 4168

5304U Chloride with Creatinine, 24-Hour Urine

Effective	February 15
Specimen/Stability	Urine 24 hour 10 (2) mL: Ambient 7 days, Refrigerated 7 days, Frozen 28 days Urine Acetic Acid 10 (2) mL: Ambient 7 days, Refrigerated 7 days, Frozen 28 days Urine Boric Acid 10 (2) mL: Ambient 7 days, Refrigerated 7 days, Frozen 28 days Urinalysis Transport Tube 10 (2) mL: Ambient 7 days, Refrigerated 7 days, Frozen 28 days **Note: Decreased refrigerated and frozen stability.**

5304UR Chloride with Creatinine, Random Urine

Effective	February 15
Specimen/Stability	Urine 10 (2) mL: Ambient 7 days, Refrigerated 7 days, Frozen 28 days Urinalysis Transport Tube 10 (2) mL: Ambient 7 days, Refrigerated 7 days, Frozen 28 days **Note: Decreased refrigerated and frozen stability.**

Test Changes: (cont'd)

5307U Sodium with Creatinine, 24-Hour Urine

Effective	February 15
Specimen/Stability	Urine 24 hour 10 (2) mL: Ambient 7 days, Refrigerated 7 days, Frozen 28 days Urine Acetic Acid 10 (2) mL: Ambient 7 days, Refrigerated 7 days, Frozen 28 days Urine Boric Acid 10 (2) mL: Ambient 7 days, Refrigerated 7 days, Frozen 28 days Urinalysis Transport Tube 10 (2) mL: Ambient 7 days, Refrigerated 7 days, Frozen 28 days **Note: Decreased refrigerated and frozen stability.**

5307UR Sodium with Creatinine, Random Urine

Effective	February 15
Specimen/Stability	Urine 10 (2) mL: Ambient 7 days, Refrigerated 7 days, Frozen 28 days Urinalysis Transport Tube 10 (2) mL: Ambient 7 days, Refrigerated 7 days, Frozen 28 days **Note: Decreased refrigerated and frozen stability.**

5308U Phosphorus 24Hr Urine

Effective	February 15
Specimen/Stability	Urine Preserved (6N HCl) 24 hour 10 (2) mL: Ambient 6 months, Refrigerated 6 months, Frozen 6 months Urine 24 hour 10 (2) mL: Ambient 48 hours, Refrigerated 7 days, Frozen 28 days Urinalysis Transport Tube 10 (2) mL: Ambient 6 months, Refrigerated 6 months, Frozen 6 months **Note: Increased ambient, refrigerated and frozen stability if preserved.**
Collection Instructions	Collect urine with 25 mL of 6N HCL to maintain a pH below 3. Do not include first morning specimen; collect all subsequent voidings. The last sample collected should be the first morning specimen voided the following morning at the same time as the previous morning's first voiding. Specify 24-hour total volume on container and test requisition. Transport at room temperature.
Reference Range	Male: 360-1600 mg/24 hr **(NEW)** Female: 170-1200 mg/24 hr **(NEW)**
Also Affected	DOS Code 4168 (Reference ranges only)

5308UR Phosphorus Urine Random

Effective	February 15
Specimen/Stability	Urine Preserved (6N HCl) 10 (2) mL: Ambient 6 months, Refrigerated 6 months, Frozen 6 months Urine 10 (2) mL: Ambient 48 hours, Refrigerated 7 days, Frozen 28 days Urinalysis Transport Tube 10 (2) mL: Ambient 6 months, Refrigerated 6 months, Frozen 6 months **Note: Increased ambient, refrigerated and frozen stability if preserved.**
Collection Instructions	Random urine: 10 mL random urine, adjust pH to < 3.0 with 6N HCL before aliquoting for phosphate testing. Transport at room temperature. Unpreserved urine: Keep urine refrigerated during and after collection and send frozen. Transport at room temperature.
Always Statement	Reference ranges are not available for random collections.

5312U Potassium with Creatinine, 24-Hour Urine

Effective	February 15
Specimen/Stability	Urine 24 hour 10 (2) mL: Ambient 7 days, Refrigerated 7 days, Frozen 28 days Urine Acetic Acid 10 (2) mL: Ambient 7 days, Refrigerated 7 days, Frozen 28 days Urine Boric Acid 10 (2) mL: Ambient 7 days, Refrigerated 7 days, Frozen 28 days Urinalysis Transport Tube 10 (2) mL: Ambient 7 days, Refrigerated 7 days, Frozen 28 days **Note: Decreased refrigerated and frozen stability.**

Test Changes: (cont'd)

5312UR **Potassium with Creatinine, Random Urine**

Effective	February 15
Specimen/Stability	Urine 10 (2) mL: Ambient 7 days, Refrigerated 7 days, Frozen 28 days Urinalysis Transport Tube 10 (2) mL: Ambient 7 days, Refrigerated 7 days, Frozen 28 days **Note: Decreased refrigerated and frozen stability.**

The CPT Codes provided are based on AMA Guidelines and are for informational purposes only. CPT Coding is the sole responsibility of the billing party. Please direct any questions regarding CPT Coding to the payer being billed.

New Referral Tests:

The following tests are now available from Quest Diagnostics and may be referred through Specialty Laboratories.

S52249N-METANEPHRINES (RANDOM) (14961X) (NY)
Test performed at Quest Diagnostics, San Juan Capistrano

S52251N-VANILLYLMADELIC ACID, RANDOM URINE [1710][NY]
Test performed at Quest Diagnostics, San Juan Capistrano

S52268-FISH, DUPLICATION 22Q11.2 [16672X]
Test performed at Quest Diagnostics, San Juan Capistrano

S52308-B-CELL GENE REARRANGEMENT, QUANT. PCR, CELL-BASED [16005X]
Test performed at Quest Diagnostics, San Juan Capistrano

S52309-VON WILLEBRAND FACTOR COLLAGEN BINDING ASSAY [10924X]
Test performed at Quest Diagnostics, San Juan Capistrano

S52312-CAH PANEL 6B (COMPREHENSIVE SCREEN) [10299X]
Test performed at Quest Diagnostics, San Juan Capistrano

S52314-MUMPS VIRUS RNA, QUAL R-T PCR [49930]
Test performed at Focus Diagnostics

S52315-CHLAMYDIA TRACHOMATIS/PSITTACI CULTURE [81025]
Test performed at Focus Diagnostics

S52316-ANTIMICROBIAL SUSCEPTIBILITY, AFB, IMIPENEM [51200]
Test performed at Focus Diagnostics

S52317-ANTIMICROBIAL SUSCEPTIBILITY - DORIPENEM [51330]
Test performed at Focus Diagnostics

S52318-ANTIMICROBIAL SUSCEPTIBILITY - CARBENICILLIN [51330]
Test performed at Focus Diagnostics

S52319-ANTIMICROBIAL SUSCEPTIBILITY - GENTAMICIN [51330]
Test performed at Focus Diagnostics

S52320-ANTIMICROBIAL SUSCEPTIBILITY - CEFAZOLIN [51330]
Test performed at Focus Diagnostics

S52321-ANTIMICROBIAL SUSCEPTIBILITY - CEFEPIME [51330]
Test performed at Focus Diagnostics

S52322-SHIGELLA SEROTYPING [52185]
Test performed at Focus Diagnostics

S52323-MYCOPLASMA PNEUMONIAE ANTIBODY, CF (SERUM) [40730]
Test performed at Focus Diagnostics

S52324-ANTIMICROBIAL SUSCEPT. AFB, MOXIFLOXACIN [51200]
Test performed at Focus Diagnostics

New Referral Tests: (cont'd)

S52325-ANTIMICROBIAL SUCEPTIBILITY, AFB, TIGECYCLINE [51200]
Test performed at Focus Diagnostics

S52326-CHIKUNGUNYA VIRUS RNA, QUAL RT-PCR [45606]
Test performed at Focus Diagnostics

S52328-ANTIMICROBIAL SUSCEPTIBILITY - CEPHALEXIN [51330]
Test performed at Focus Diagnostics

S52329-TOXOPLASMA GONDII IGG AVIDITY (AVIDX(TM)), ELISA [40927]
Test performed at Focus Diagnostics

S52330-ANTIMICROBIAL SUSC, AEROBIC BACTERIA, CUSTOM MIC (2) [51340]
Test performed at Focus Diagnostics

S52332-ANTIMICROBIAL LEVEL, RIFABUTIN, HPLC [51949]
Test performed at Focus Diagnostics

S52333-CYTOMEGALOVIRUS (CMV) DNA, QUANT RT PCR [45050]
Test performed at Focus Diagnostics

S52334-TOXOPLASMA GONDII DNA, QUANT RT PCR [45600]
Test performed at Focus Diagnostics

S52335-CHIKUNGUNYA ANTIBODIES WITH REFLEX(ES) TO TITER [40680]
Test performed at Focus Diagnostics

S52336-TREPONEMA PALLIDUM DNA, QUAL RT PCR [47020]
Test performed at Focus Diagnostics

S52337-MAG ANTIBODY, DUAL ELISA (SERUM) [21004][NY]
Test performed at Focus Diagnostics

S52338-ANTIFUNGAL SUSCEPT., MOLD, CUSTOM (2) MIC PANEL [53620]
Test performed at Focus Diagnostics

S52340-ANTIMICROBIAL SUSC, AEROBIC BACTERIA, CUSTOM MIC (3) [51350]
Test performed at Focus Diagnostics

S52341-ANTIMICROBIAL SUSC, AEROBIC BACTERIA, CUSTOM MIC (4) [51360]
Test performed at Focus Diagnostics

S52342-CHLAMYDIA GROUP ANTIBODY SCREEN, IFA (SERUM) [40265]
Test performed at Focus Diagnostics

S52343-BORRELIA BURGDORFERI IGG & IGM AB PANEL, IFA SER [40677]
Test performed at Focus Diagnostics

S52344-BARTONELLA ANTIBODY PANEL, IFA (CSF) [6020]
Test performed at Focus Diagnostics

S52345-ASPERGILLUS ANTIBODY PANEL, CF AND ID (SERUM) [2305]
Test performed at Focus Diagnostics

New Referral Tests: (cont'd)

S52346-HISTOPLASMA ANTIBODY PANEL CF, ID AND ELISA [4490]
Test performed at Focus Diagnostics

S52347-INFLUENZA A VIRUS H1/H3 SUBTYPING BY REAL-TIME RT-PCR[42690]
Test performed at Focus Diagnostics

Please call client relations at 800-421-4449 or visit our website at www.specialtylabs.com for ordering information.

Discontinued Tests:

Effective Immediately:

S48545-Paroxysmal Nocturnal Hemoglobin Profile [95864]
Recommended replacement: S52351-PNH WITH FLAER [16433]
Test performed at Quest Diagnostics, San Juan Capistrano

S52042-CD55 and CD59 Expression, Red Cells & Gran. [19835X]
Recommended replacement: S52351-PNH with FLAER [16433]
Test performed at Quest Diagnostics, San Juan Capistrano

S51445-Prazepam (39776R)
No replacement

Effective January 15:

4984 – Hemoglobin Variant Screen w/Reflex Electrophoresis
Recommended replacement: 4983 – Hemoglobinopathy Evaluation
Test performed at Specialty Laboratories

Effective January 25:

5382 – Cytochrome P450 2C19 (Clopidogrel) GenotypR™
Recommended replacement: S52048 - AccuType™CP, Clopidgrel CYP2C19 Genotype [16924]
Test performed at Quest Diagnostics Nichols Institute, San Juan Capistrano

Effective January 31

S48335-MIDAZOLAM URINE [3057U]
Recommended replacement: 4085U Midazolam, Urine
Test performed at Specialty Laboratories

S49504-LORAZEPAM URINE [2535]
Rcommended replacement: 4087U Lorazepam, Urine
Test performed at Specialty Laboratories