

May 09, 2007

Dear Colleague:

We are pleased to announce twenty-five new tests and test panels this month. In the area of women's health, *Gardnerella vaginalis* DNA DetectR™, *Trichomonas vaginalis* DNA DetectR™ and *Candida albicans* DNA DetectR™ offers clinicians next day DNA-based results to aid in the confirmation of *Gardnerella vaginalis*, *Trichomonas vaginalis* and *Candida albicans*, which are often found in samples from patients with vaginitis/vaginosis. The detection of either of these organisms coupled with other clinical findings will aid the physician in the diagnosis of vaginitis/vaginosis. A Technical bulletin is available for the Vaginitis DNA DetectR™ at www.specialtylabs.com in the related articles section for test code 9645.

ER/PR/KI-67/HER-2 by FISH/DNA Cell Cycle Analysis is introduced to provide a comprehensive breast marker panel for clients requesting HER-2/neu by FISH alone rather than as a reflex related to HER-2/neu immunohistochemistry results. We continue to offer a comprehensive menu of breast panels to serve a variety of client requests.

To better serve physicians treating patients with conditions associated with impaired renal function, Cystatin C is now available as an in-house assay at *Specialty*. This assay is used to detect renal deficiencies earlier than traditional methods and without the delays of 24HR collections. Since Cystatin C is not sensitive to age, body weight, nutritional status, or ethnicity and is formed at a constant rate and freely filtered by the healthy kidney, this protein is a good marker of renal function impairment, and is a more sensitive marker of early stage impairment than creatinine. Serum concentrations of Cystatin C are almost totally dependent on the glomerular filtration rate (GFR). A reduction in the GFR causes a rise in the concentration of Cystatin C. In most cases, kidney function has diminished by $\geq 50\%$ before serum creatinine levels exceed normal ranges, so earlier detection by Cystatin C gives physicians a greater window of opportunity for treatment before irreversible damage occurs.

To help physicians following patients with chronic myelogenous leukemia (CML) or acute lymphoblastic leukemia (ALL) *Specialty* is proud to offer BCR/ABL UltraQuant® Major 210KD Transcript with serial reporting and the BCR/ABL UltraQuant® Minor 190KD Transcript with serial reporting. BCR/ABL UltraQuant® Minor 190KD is for quantitative monitoring of minimal residual disease in Ph+ (ALL) and other disorders (e.g., AML or blast crisis of CML) with minor p190KD transcript, in bone marrow or whole blood. For confirming a diagnosis of CML, *Specialty* offers test code #5834 BCR/ABL Gene Rearrangement (Philadelphia chromosome) by FISH in addition to bone marrow karyotyping (test code #5800). BCR/ABL UltraQuant® Major 210KD Transcript is for quantitative monitoring of minimal residual disease in chronic myelogenous leukemia (CML) and other disorders (e.g. blast crisis of CML) with major p210KD transcript, in bone marrow and whole blood. For blast crisis of CML, both test codes #5342 and #5344 (for minor p190KD transcript) may be appropriate. For diagnosis of CML, *Specialty* offers test code #5834 BCR/ABL Gene Rearrangement (Philadelphia chromosome) by FISH, in addition to test code #5800 Cytogenetics, Hematologic and Neoplastic Disorders.

Protein electrophoresis (PEP) is now available with standardized reflexes to identify and quantify monoclonal proteins from serum, CSF, Urine, and 24HR Urine samples. All PEP tests include the monoclonal region scan with interpretation and several possible reflexes (for an additional fee) for confirmation. Because each sample type has a different test code please pay particular attention to the test code ordered and ensure that it matches the sample type you wish to submit.

Also included in this mailing is a list of recently added drugs of abuse screens with reflex additions as well as specific therapeutic levels for Triazolam (Halcion®), Temazepam (Restoril®), Nitrazepam (Mogadon®), Midazolam (Versed®), Lorazepam (Ativan®), and Acetaminophen. A comprehensive list of drugs of abuse and therapeutic drug tests will be available in the near future as a PDF document from our Web site below.

For additional information, please visit our Web site at www.specialtylabs.com or contact Client Relations at 800-421-4449.



Michael C. Dugan, M.D.
Vice President and Laboratory Director

EW WEBSITE SERVICE

It gives us great pleasure to announce the latest service enhancement from Specialty Laboratories. As one of our many initiatives to expand our services, our website (www.Specialtylabs.com) has been modified to allow clients to login and order supplies online. Simply create an account and enjoy quick and easy online supply ordering. Other added benefits to ordering supplies online are easy order expediting and delivery tracking information right at your fingertips. If you prefer to continue to phone or fax in your orders - our Client Relations Team is always there to assist you.

Signing up is easy! Simply follow the steps below:

1. Go to www.specialtylabs.com
2. Choose the Client Login link at the top of the page
3. Choose the "Request an Account" link
4. Fill-in your Account Profile information
5. Fill-in your User Name & Password
6. Choose the "Request Account" link
7. Your login request will be routed for password creation
8. Once created and authenticated, approximately 5 days, you are ready to begin ordering supplies online

Sign up now to take advantage of simple and easy online supplies ordering and all of the other great service enhancements that will be coming soon. Detailed instructions are available at our website.

4100 **Acetaminophen** (Available Immediately)
 ** Replaces S49697 Acetaminophen **

Component	Method	Reference Range/Units
Acetaminophen	FPIA	10-30 ug/mL

Specimen/Stability 0.5 (0.3) mL Serum, Ambient – 7 Days, Refrigerated – 7 Days, Frozen – 7 Days
 Clinical Utility Acetaminophen is one of several popular non-prescription pain relievers available to the public. It has analgesic and antipyretic effects like aspirin, but little of aspirin's anti-inflammatory properties. Serum levels are not typically monitored during therapeutic dosing (650-1000 mg), but because the drug is sold alone or in combination with other compounds in over two hundreds products, acetaminophen is frequently seen in overdose cases. Proper management of acetaminophen overdose requires early monitoring of the patient's serum levels, because toxic drug levels can cause hepatic necrosis, which is not clinically evident until twelve or more hours after ingestion; moreover, antidotes are available that can prevent liver damage, if they are administered early.

Schedule Sunday – Saturday
 Report Same day
 CPT Code 82003
 Note Toxic level: >300 ug/mL at 4 hours after ingestion or 50 ug/mL after 12 hours ingestion. Source: Textbook of Clinical Chemistry by Norbert W. Teitz.

4256U **Amphetamine/Methamphetamine Screen Urine** (Available 05/15/07)
 w/ Reflex to Confirmation

Component	Method	Reference Range/Units
Amphetamine/Methamphetamine	EMIT	Not Detected

Specimen/Stability 5 (3) mL Urine, Refrigerated – 7 Days, Frozen – 2 Months
 Clinical Utility Amphetamines are central nervous system stimulants that produce wakefulness, alertness, increased energy, reduced hunger. Amphetamines appear in urine within three hours after any type of administration.

Schedule Sunday – Saturday
 Report Same day
 CPT Code 80101
 Note Cut-off = 1000 ng/mL. If screen result is presumptive positive will reflex to Amphetamines Confirmation Urine (test code 4189U), for an additional fee.

5342SR **BCR/ABL UltraQuant™ Major 210KD Transcript Bone Marrow w/ SR** (Available 05/29/07)

Component	Method	Reference Range/Units
Major BCR/ABL (b2/a2 or b3/a2)	RT-PCR	Ratio

Interpretation

Specimen/Stability 2 (1) mL Bone Marrow EDTA, Refrigerated – 72 Hours
 Clinical Utility For quantitative monitoring of minimal residual disease in chronic myelogenous leukemia (CML) and other disorders (e.g. blast crisis of CML) with major p210KD transcript, in bone marrow. For blast crisis of CML, both test codes #5342 and #5344 (for minor p190KD transcript) may be appropriate. For diagnosis of CML, Specialty offers test code #5834 BCR/ABL Gene Rearrangement (Philadelphia chromosome) by FISH.

Schedule Tuesday, Thursday
 Report 3 days
 CPT Code 83891, 83896, 83898, 83902, 83912
 Note Serial reporting is not retroactive for samples tested prior to the effective date. Social Security Number must be provided.
 Collection Heparinized bone marrow or ACD bone marrow is not acceptable. Do not freeze. Specimens must be less than 3 days post-draw when received in the clinical laboratory. Sample should be REFRIGERATED after collection and shipped on cold pack by overnight courier to arrive at Specialty within 24 hours of collection. Specimens will be stabilized upon departmental receipt.

5352SR **BCR/ABL UltraQuant™ Major 210KD Transcript Whole Blood w/ SR** (Available 05/29/07)

Component	Method	Reference Range/Units
Major BCR/ABL (b2/a2 or b3/a2)	RT-PCR	Ratio

Interpretation

Specimen/Stability 8 (5) mL Whole Blood EDTA, Refrigerated – 72 Hours
 Clinical Utility For quantitative monitoring of minimal residual disease in chronic myelogenous leukemia (CML) and other disorders (e.g. blast crisis of CML) with major p210KD transcript, in whole blood. For blast crisis of CML, both test codes #5342 and #5344 (for minor p190KD transcript) may be appropriate. For diagnosis of CML, Specialty offers test code #5834 BCR/ABL Gene Rearrangement (Philadelphia chromosome) by FISH.

Schedule Tuesday, Thursday
 Report 3 days
 CPT Code 83891, 83896, 83898, 83902, 83912
 Note Serial reporting is not retroactive for samples tested prior to the effective date. Social Security Number must be provided.
 Collection Heparinized whole blood or ACD whole blood is not acceptable. Do not freeze. Sample should be REFRIGERATED after collection and shipped on cold pack by overnight courier to arrive at Specialty within 24 hours of collection. Specimens will be stabilized upon departmental receipt.

5344SR BCR/ABL UltraQuant™ Minor 190KD Transcript Bone Marrow w/ SR (Available 05/29/07)

Component	Method	Reference Range/Units
Minor BCR/ABL (e1/a2)	RT-PCR	Ratio

Interpretation

Specimen/Stability 2 (0.5) mL Bone Marrow EDTA, Refrigerated – 72 Hours
 Clinical Utility For quantitative monitoring of minimal residual disease in Ph+ acute lymphoblastic leukemia (ALL) and other disorders (e.g., AML or blast crisis of CML) with minor p190KD transcript, in bone marrow. For diagnosis of CML, Specialty offers test code #5834 BCR/ABL Gene Rearrangement (Philadelphia chromosome) by FISH.

Schedule Tuesday, Thursday
 Report 3 days
 CPT Code 83891, 83896, 83898, 83902, 83912
 Note Serial reporting is not retroactive for samples tested prior to the effective date. Social Security Number must be provided.
 Collection Do not freeze. Sample should be REFRIGERATED after collection and shipped on cold pack by overnight courier to arrive at Specialty within 24 hours of collection. Specimens will be stabilized upon departmental receipt.

5354SR BCR/ABL UltraQuant™ Minor 190KD Transcript Whole Blood w/ SR (Available 05/29/07)

Component	Method	Reference Range/Units
Minor BCR/ABL (e1/a2)	RT-PCR	Ratio

Interpretation

Specimen/Stability 8 (5) mL Whole Blood EDTA, Refrigerated – 72 Hours
 Clinical Utility For quantitative monitoring of minimal residual disease in Ph+ acute lymphoblastic leukemia (ALL) and other disorders (e.g., AML or blast crisis of CML) with minor p190KD transcript, in whole blood. For diagnosis of CML of Ph+ ALL, Specialty offers test code #5834 BCR/ABL Gene Rearrangement (Philadelphia chromosome) by FISH.

Schedule Tuesday, Thursday
 Report 3 days
 CPT Code 83891, 83896, 83898, 83902, 83912
 Note Serial reporting is not retroactive for samples tested prior to the effective date. Social Security Number must be provided.
 Collection Heparinized whole blood or ACD whole blood is not acceptable. Do not freeze. Sample should be REFRIGERATED after collection and shipped on cold pack by overnight courier to arrive at Specialty within 24 hours of collection. Specimens will be stabilized upon departmental receipt.

4107U Benzodiazepine Screen Urine w/ Reflex to Confirmation (Available 05/15/07)

Component	Method	Reference Range/Units
Benzodiazepine Urine	EMIT	Not Detected

Specimen/Stability 5 (3) mL Urine, Refrigerated – 7 Days, Frozen – 2 Months
 Clinical Utility Benzodiazepines are sedative-hypnotic drugs that are structurally similar and include widely used drugs such as chlordiazepoxide, diazepam, and oxazepam.

Schedule Sunday – Saturday
 Report Same day
 CPT Code 80101
 Note Cut-off = 300 ng/mL. If screen result is presumptive positive will reflex to Benzodiazepines Confirmation Urine (test code 4090U), for an additional fee.

9647 *Candida Albicans* DNA DetectR™ (Available Immediately)

Component	Method	Reference Range/Units
<i>Candida albicans</i> DNA	PCR	Not Detected

Specimen/Stability 5 (2) mL ThinPrep® Vial, Ambient – 21 Days, Refrigerated – 21 Days
 Alternate Specimen 5 (2) mL Tripath Surepath® Vial, Ambient – 21 Days, Refrigerated – 21 Days
 Clinical Utility One of the most common causes of vaginitis is vulvovaginal candidiasis. This assay detects the presence of *Candida albicans* often found in samples from these patients. The detection of this organism coupled with other clinical findings aids in the diagnosis of vaginitis.

Schedule Sunday – Saturday
 Report Next day
 CPT Code 87481
 Collection Cytologic specimens should be collected according to the instructions provided with the ThinPrep® or SurePath® kits for cervical samples.

4254U

Cannabinoids Screen Urine w/ Reflex to Confirmation

(Available 05/15/07)

Component	Method	Reference Range/Units
Cannabinoids Urine	EMIT	Not Detected

Specimen/Stability 1 (0.5) mL Urine, Refrigerated – 7 Days, Frozen – 2 Months
 Clinical Utility Marijuana is a mixture of dried leaves and flowering tops of the plant Cannabis sativa L. The agents that produce the hallucinogenic and other biological effects of marijuana are called cannabinoids.

Schedule Sunday – Saturday
 Report Same day
 CPT Code 80101
 Note Cut-off = 50 ng/mL. If screen result is presumptive positive will reflex to Cannabinoids Confirmation Urine (test code 4133U), for an additional fee.

4252U

Cocaine Metabolites Screen Urine w/ Reflex to Confirmation

(Available 05/15/07)

Component	Method	Reference Range/Units
Cocaine Metabolites Urine	EMIT	Not Detected

Specimen/Stability 5 (3) mL Urine, Refrigerated – 7 Days, Frozen – 2 Months
 Clinical Utility Cocaine is a central nervous system stimulant that is extracted from the coca plant. As a drug of abuse, cocaine is self-administered in a variety of ways, including inhalation and intravenous injection.

Schedule Sunday – Saturday
 Report Same day
 CPT Code 80101
 Note Cut-off = 300 ng/mL. If screen result is presumptive positive will reflex to Cocaine & Metabolites Confirmation Urine (test code 4170U), for an additional fee.

1139

Cystatin C

(Available 05/29/07)

** Replaces S50102 Cystatin C **

Component	Method	Reference Range/Units
Cystatin C	Nephelometry	0.53-0.95 mg/L

Specimen/Stability 1 (0.8) mL Serum, Ambient – 7 Days, Refrigerated – 7 Days, Frozen – 2 Months
 Alternative Specimen 1 (0.8) mL Plasma Heparin, Ambient – 7 Days, Refrigerated – 7 Days, Frozen – 2 Months
 Clinical Utility Cystatin C is a cysteine proteinase inhibitor. It is formed at a constant rate and freely filtered by the healthy kidney; this protein is a good marker of renal function. Serum concentrations of Cystatin C are almost totally dependent on the glomerular filtration rate (GFR). A reduction in the GFR causes a rise in the concentration of Cystatin C.

Schedule Tuesday, Thursday
 Report Same day
 CPT Code 83883
 Note Cystatin C has not been shown to be affected by factors such as muscle mass and nutrition, factors which have been demonstrated to affect creatinine values. In addition, a rise in creatinine does not become evident until the GFR has fallen by approximately 50%.

Collection Avoid repeated freeze-thaw cycles. Lipemic samples must be clarified by centrifugation prior to testing.

4129U

Drugs of Abuse Screen Urine w/ Reflex to Confirmation

(Available 05/15/07)

Component	Method	Reference Range/Units
Amphetamine/Methamphetamine	EMIT	Not detected
Cocaine Metabolites	EMIT	Not detected
Cannabinoids (THC)	EMIT	Not detected
Barbiturates	EMIT	Not detected
Benzodiazepines	EMIT	Not detected
Methadone	EMIT	Not detected
Opiates	EMIT	Not detected
Phencyclidine	EMIT	Not detected
Propoxyphene	EMIT	Not detected

Specimen/Stability	10 (5) mL Urine, Refrigerated – 7 Days, Frozen – 2 Months
Clinical Utility	Illicit drug use and abuse are widespread in society, and public awareness has been heightened as to their impact on public safety and on lost productivity in industry. Moreover, drug abuse during pregnancy is of concern, both medically and socially. Consequently, drug testing represents a significant activity for toxicology laboratories.
Schedule Report	Sunday – Saturday
CPT Code	Same day
Note	80101x9 Cut-offs: Amphetamines=1000 ng/mL; Barbiturates=200 ng/mL; Benzodiazepines=300 ng/mL; Cannabinoids=50 ng/mL; Cocaine Metabolites=300 ng/mL; Methadone=300 ng/mL; Opiates=300 ng/mL; Phencyclidine (PCP) =25 ng/mL; Propoxyphene=300 ng/mL. All Detected screen results will reflex to confirmation for an additional fee: Amphetamines Confirmation Urine (test code 4189U), Cocaine & Metabolites Confirmation Urine (test code 4170U), Cannabinoids Confirmation Urine (test code 4133U), Barbiturates Confirmation Urine (test code 4092U), Benzodiazepines Confirmation Urine (test code 4090U), Methadone Confirmation Urine (test code 4192U), Opiates Confirmation Urine (test code 4185UR), Phencyclidine (PCP) Confirmation Urine (test code 4183U), and Propoxyphene Confirmation Urine (test code 4094U).
Collection	After voided midstream collection is complete, mix the specimen and transfer a 10mL aliquot of urine to Specialty transfer tube with a screw cap closed tightly to avoid leakage. Transfer tubes are available from Specialty. Refrigerated specimen is preferred (store at 2-8 degrees C).

1810

ER/PR/KI-67/HER-2 by FISH/DNA Cell Cycle Analysis – Breast Ca

(Available Immediately)

Component	Method	Reference Range/Units
Specimen Source		See Report
Estrogen Receptor	IHC	%
ER Breast Interpretation		See Report
Progesterone Receptor	IHC	%
PR Breast Interpretation		See Report
KI67 (MIB-1)	IHC	%
KI67 (MIB-1) Breast Interpretation	IHC	See Report
DNA Index	FC	See Report
DNA Ploidy	FC	See Report
S-Phase	FC	%
S-Phase Interpretation	FC	See Report
HER-2/neu Gene Amplification	FISH	See Report

Specimen/Stability	Tissue Paraffin Block, Indefinite
Alternate Specimens	12 UNST Slides plus 5-6 50 um sections, Ambient – 12 Months, Refrigerated – 12 Months
Clinical Utility	ER and PR expression is associated with better prognosis in breast cancer patients. ER expression helps to identify patients likely to benefit from Neoadjuvant Tamoxifen Aromatase Inhibitors. For the detection of amplification of the HER-2/neu gene via FISH; results are intended as an adjunct to existing clinical and pathologic information currently used as prognostic factors in stage II, node-negative breast cancer patients. The test is further indicated as an aid to predict disease-free and overall survival in patients with stage II, node-positive breast cancer treated with adjuvant cyclophosphamide, doxorubicin and 5-fluorouracil (CAF) chemotherapy.
Schedule Report	Monday, Wednesday, Friday
CPT Code	3-5 days
Note	88360x3, 88367x2, 88182
Collection	Diagnostic code required for third party reimbursement. Please send copy of pathology report and other applicable test results. Formalin-fixed, paraffin-embedded tissue; Ambient/Refrigerated.

9646 *Gardnerella Vaginalis* DNA DetectR® (Available Immediately)

Component	Method	Reference Range/Units
<i>Gardnerella vaginalis</i> DNA	PCR	Not Detected
Specimen/Stability	5 (2) mL ThinPrep® Vial, Ambient – 21 Days, Refrigerated – 21 Days	
Alternate Specimen	5 (2) mL Tripath Surepath® Vial, Ambient – 21 Days, Refrigerated – 21 Days	
Clinical Utility	One of the most common causes of vaginitis is bacterial vaginosis (BV). This assay detects the presence of <i>Gardnerella vaginalis</i> often found in samples from patients exhibiting these symptoms. The detection of this organism coupled with other clinical findings aids in the diagnosis of BV.	
Schedule	Sunday – Saturday	
Report	Next day	
CPT Code	87511	
Collection	Cytologic specimens should be collected according to the instructions provided with the ThinPrep® or SurePath® kits for cervical samples.	

4087 **Lorazepam (Ativan)** (Available Immediately)

** Replaces S50848 Lorazepam (Ativan) **

Component	Method	Reference Range/Units
Lorazepam	LC-MS-MS	Therapeutic Range 50-240 ng/mL Potentially Toxic >500
Specimen/Stability	2 (1) mL Serum, Refrigerated – 5 Days, Frozen – 2 Weeks	
Clinical Utility	Lorazepam is used for the management of anxiety disorders, the short-term relief of the symptoms of anxiety or anxiety associated with depression. Lorazepam is rapidly and nearly completely absorbed after any mode of administration (oral, sublingual, intramuscular [i.m.], intravenous [i.v.]). Peak effects roughly coincide with peak serum levels, which occur several minutes after intravenous injections, 30 to 45 minutes after oral/sublingual administration, and up to 1 hour after intramuscular injections.	
Schedule	Tuesday, Thursday, Saturday	
Report	Next day	
CPT Code	80154	
Note	Do not use serum separator tubes.	

4085 **Midazolam (Versed®)** (Available Immediately)

** Replaces S43085 Midazolam (Versed®) **

Component	Method	Reference Range/Units
Midazolam	LC-MS-MS	Therapeutic Range 50-600 ng/mL Potentially Toxic >2000
Specimen/Stability	2 (1) mL Serum, Refrigerated – 5 Days, Frozen – 2 Weeks	
Clinical Utility	Midazolam is used to produce sleepiness or drowsiness and to relieve anxiety before surgery or certain procedures. It is also used to produce loss of consciousness before and during surgery. Midazolam is used sometimes in patients in intensive care units in hospitals to cause unconsciousness.	
Schedule	Tuesday, Thursday, Saturday	
Report	Next day	
CPT Code	80154	
Note	Do not use serum separator tubes.	

4086 **Nitrazepam (Mogadon®)** (Available Immediately)

** Replaces S48310 Nitrazepam **

Component	Method	Reference Range/Units
Nitrazepam	LC-MS-MS	Therapeutic Range 30-100 ng/mL Potentially Toxic >300
Specimen/Stability	2 (1) mL Serum, Refrigerated – 5 Days, Frozen – 2 Weeks	
Clinical Utility	Nitrazepam is a sedative used to treat insomnia. Nitrazepam is in the group of drugs known as benzodiazepines, a class of antidepressants, anti-panic agents, and muscle relaxants. Nitrazepam is usually used as a short term treatment for temporary insomnia, but if used daily, it will become ineffective in a few weeks. This medication has some anticonvulsant properties, but US prescribing guidelines are unavailable for this use.	
Schedule	Tuesday, Thursday, Saturday	
Report	Next day	
CPT Code	80154	
Note	Do not use serum separator tubes.	

4250U

Opiates Screen Urine w/ Reflex to Confirmation

(Available 05/15/07)

Component	Method	Reference Range/Units
Opiates Urine	EMIT	Not Detected
Specimen/Stability Clinical Utility	1 (0.5) mL Urine, Refrigerated – 7 Days, Frozen – 2 Months Opiates are a class of compounds that includes morphine, codeine, and heroin. Morphine and codeine are naturally occurring alkaloids that are found in opium, a substance exuded from the unripe seed pod of the opium poppy <i>Papaver somniferum</i> .	
Schedule Report CPT Code Note	Sunday – Saturday Same day 80101 Cut-off = 300 ng/mL. If screen result is presumptive positive will reflex to Opiates Confirmation Urine (test code 4185UR), for an additional fee.	

1584

Protein Electrophoresis (PEP) Serum Evaluation

(Available 05/15/07)

Component	Method	Reference Range/Units
Protein Total	S	>18Y g/dL Male = 6.4-8.4 Female = 6.4-8.4
Albumin	CE	3.40-5.10 g/dL
Alpha 1	CE	0.30-0.60 g/dL
Alpha 2	CE	0.60-1.10 g/dL
Beta	CE	0.60-1.10 g/dL
Gamma	CE	0.70-1.70 g/dL
A/G Ratio	CALC	1.00-1.80
Monoclonal Region Interpretation	CE	g/dL
Specimen/Stability Clinical Utility	3 (2) mL Serum, Refrigerated – 7 Days, Frozen – 2 Months Evaluate serum protein, nutritional status; work up liver disease, including chronic active hepatitis; useful in the evaluation of myeloma, macroglobulinemia of Waldenstrom, collagen diseases, and monoclonal gammopathies; evaluate inflammatory states; evaluate low back pain, arthritis, amyloidosis; evaluate lymphoma, leukemia, anemia.	
Schedule Report CPT Code Note	Tuesday – Sunday Next day 84155, 84165 If PEP Interpretation indicates possible monoclonal pattern, assay reflexes to Monoclonal Gammopathies (IFE) Serum (test code 3125), for an additional fee. If a monoclonal gammopathy is detected, assay will further reflex to IgA, IgG, and IgM Immunoglobulin Quantitation (test code 1045) and Myeloma EvaluatR™ (Serum Free Light Chain) (test code 1760), for an additional fee.	

1584C

Protein Electrophoresis (PEP) CSF Evaluation

(Available 05/15/07)

Component	Method	Reference Range/Units
Protein Total CSF	S	15-45 mg/dL
Pre-albumin	AE	2-7 %
Albumin	AE	57-76 %
Alpha 1	AE	1-7 %
Alpha 2	AE	3-13 %
Beta	AE	7-18 %
Gamma	AE	3-13 %
Monoclonal Region Monoclonal Region Interpretation	AE CALC	% mg/dL
Specimen/Stability Clinical Utility	3 (2) mL CSF, Refrigerated – 5 Days, Frozen – 1 Month Useful in the evaluation of meningitis, tuberculosis, brain abscess, meningovascular syphilis, CVA, neoplastic disease, multiple sclerosis, and other degenerative processes causing neurological disease.	
Schedule Report CPT Code Note	Tuesday–Saturday Next day 84157, 84166 If PEP Interpretation indicates possible monoclonal pattern, assay reflexes to Monoclonal Gammopathies (IFE) CSF (test code 3125C), for an additional fee. If a monoclonal gammopathy is detected, assay will further reflex to IgA, IgG, and IgM Immunoglobulin Quantitation CSF (test code 1045C) and Kappa Free Light Chain CSF (test code 1732C), for an additional fee.	

1584UR

Protein Electrophoresis (PEP) Urine Evaluation

(Available 05/15/07)

Component	Method	Reference Range/Units
Protein Total Urine	S	4-19 mg/dL
Albumin	AE	100 %
Alpha 1	AE	0 %
Alpha 2	AE	0 %
Beta	AE	0 %
Gamma	AE	0 %
Monoclonal Region	AE	%
Monoclonal Region Interpretation	CALC	mg/dL

Specimen/Stability
Clinical Utility

4 (2) mL Urine, Refrigerated – 5 Days, Frozen – 1 Month

Useful in the evaluation of myeloma, macroglobulinemia of Waldenstrom, lymphoma, amyloidosis; differentiate between normal renal function, glomerular proteinuria, and tubular proteinuria. Increased glomerular permeability leads to higher concentrations of large proteins in the glomerular filtrate. Diminished tubular reabsorption capacity results in a marked increase in urinary excretions of low molecular weight proteins.

Schedule
Report
CPT Code
Note

Tuesday–Saturday

Next day

84156, 84166

If PEP Interpretation indicates possible monoclonal pattern, assay reflexes to Monoclonal Gammopathies (IFE) Urine (test code 3125U), for an additional fee. If a monoclonal gammopathy is detected, assay will further reflex to IgA Urine Random (test code 1506UR), IgG Urine Random (test code 1505UR), and IgM Urine Random (test code 1508UR), and Kappa & Lambda Light Chain Urine Random (test code 1741UR), for an additional fee.

1584U

Protein Electrophoresis (PEP) 24hr Urine Evaluation

(Available 05/15/07)

Component	Method	Reference Range/Units
Protein Total 24hr Urine	CALC	<140 mg/24hr
Total Urine Volume		mL
Protein Total Urine	S	4-19 mg/dL
Albumin	AE	100 %
Alpha 1	AE	0 %
Alpha 2	AE	0 %
Beta	AE	0 %
Gamma	AE	0 %
Monoclonal Region	AE	%
Monoclonal Region Interpretation	CALC	mg/dL

Specimen/Stability
Clinical Utility

4 (2) mL Urine 24hr, Refrigerated – 5 Days, Frozen – 1 Month

Useful in the evaluation of myeloma, macroglobulinemia of Waldenstrom, lymphoma, amyloidosis; differentiate between normal renal function, glomerular proteinuria, and tubular proteinuria. Increased glomerular permeability leads to higher concentrations of large proteins in the glomerular filtrate. Diminished tubular reabsorption capacity results in a marked increase in urinary excretions of low molecular weight proteins.

Schedule
Report
CPT Code
Note

Tuesday–Saturday

Next day

84156, 84166

If PEP Interpretation indicates possible monoclonal pattern, assay reflexes to Monoclonal Gammopathies (IFE) Urine (test code 3125U), for an additional fee. If a monoclonal gammopathy is detected, assay will further reflex to IgA 24hr Urine (test code 1506U), IgG 24hr Urine (test code 1505U), and IgM 24hr Urine (test code 1508U), and Kappa & Lambda Light Chain, Quantitative 24hr Urine (test code 1741U), for an additional fee.

4088 **Temazepam (Restoril®)** (Available Immediately)

** Replaces S47635 Temazepam & Metabolite **

Component	Method	Reference Range/Units
Temazepam	LC-MS-MS	Therapeutic Range 50-1000 ng/mL Potentially Toxic >5000

Specimen/Stability 2 (1) mL Serum, Refrigerated – 5 Days, Frozen – 2 Weeks
 Clinical Utility Temazepam is one of several drugs in the class known as benzodiazepines. These drugs produce a variety of effects, but most cause some degree of drowsiness (sedation). Temazepam is used almost exclusively as a hypnotic, or drug given to help people fall asleep. It is nearly always taken just before bedtime.
 Schedule Tuesday, Thursday, Saturday
 Report Next day
 CPT Code 80154
 Note Do not use serum separator tubes.

4089 **Triazolam (Halcion®)** (Available Immediately)

** Replaces S42140 Triazolam **

Component	Method	Reference Range/Units
Triazolam	LC-MS-MS	Therapeutic Range 5-20 ng/mL Potentially Toxic >100

Specimen/Stability 2 (1) mL Serum, Refrigerated – 5 Days, Frozen – 2 Weeks
 Clinical Utility Triazolam is a powerful benzodiazepine. Triazolam is used to treat insomnia. It is prescribed in very low dosage. Triazolam is a benzodiazepine with a very short elimination half-life (about 3 hours).
 Schedule Tuesday, Thursday, Saturday
 Report Next day
 CPT Code 80154
 Note Do not use serum separator tubes.

9648 ***Trichomonas Vaginalis* DNA DetectR®** (Available Immediately)

Component	Method	Reference Range/Units
<i>Trichomonas vaginalis</i> DNA	PCR	Not Detected

Specimen/Stability 5 (2) mL ThinPrep® Vial, Ambient – 21 Days, Refrigerated – 21 Days
 Alternate Specimen 5 (2) mL Tripath Surepath® Vial, Ambient – 21 Days, Refrigerated – 21 Days
 Clinical Utility This assay detects the presence of *Trichomonas vaginalis* often found in samples from patients with vaginitis.
 Schedule Sunday – Saturday
 Report Next day
 CPT Code 87798
 Collection Cytologic specimens should be collected according to the instructions provided with the ThinPrep® or SurePath® kits for cervical samples.