

March 26, 2007

Dear Colleague:

We are pleased to announce ten new test offerings this month. In the area of women's health, the Vaginitis DNA DetectR™ offers clinicians next day DNA-based results to aid in the confirmation of *Gardnerella vaginalis*, *Candida albicans*, and *Trichomonas vaginalis*, which are often found in samples from patients with vaginitis/vaginosis. The detection of any 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.

In an effort to better serve clinicians and patients dealing with liver disease and cholestasis, Total Bile Acid (previously a sendout test) is now being performed at *Specialty*. Total Bile Acid is a well known bio-marker for diagnosis of liver diseases. Serum Total Bile Acids are elevated in patients with acute hepatitis, chronic hepatitis, liver sclerosis, and liver cancer. Total Bile Acids levels are found to be the most sensitive indicator for monitoring the effectiveness of interferon treatment of chronic hepatitis C patients. Moreover, Total Bile Acids tests are also widely used to screen pregnant women for the condition of obstetric cholestasis, a disease that is caused by elevated Total Bile Acids in the bloodstream of pregnant women. The symptoms of cholestasis include persistent itching in the third trimester of pregnancy and possible risks to the unborn baby including stillbirth, premature labor and bleeding.

To help doctors help patients who are trying to quit smoking, *Specialty* is proud to offer a test that measures nicotine metabolites in addition to nicotine. Simultaneous measurement of urinary nicotine, cotinine, trans-3'-hydroxycotinine, and their conjugates, which can account for >80% of the total nicotine dose, gives a better estimate of nicotine exposure and the extent of nicotine catabolism than the measurement of nicotine or a single nicotine metabolite. Serum nicotine and urinary/salivary cotinine are used to guide the dose of nicotine replacement therapy.

Chronic pain management is a delicate balance for clinicians and patients in today's society. In an effort to better gauge pain management regimens and identify possible abuse, *Specialty* now offers tandem mass spectroscopy testing for Fentanyl, Norfentanyl, and Meperidine (Demerol®, Mepergan®).

In oncology, the FISH-based assay UroVysion™ (test code 5842) for detecting urothelial carcinoma is now available. This assay is less invasive and more sensitive than cystoscopy with cytology when used for early detection or monitoring for disease recurrence. Urothelial carcinoma will recur within 2½ years in about 65% of patients with positive FISH results and negative urine cytology vs. 13% recurrence in FISH negative patients.

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



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Vice President and Laboratory Director

4939U Clonazepam and 7-Amino Clonazepam Urine (Available Immediately)

****Replaces S49203 Clonazepam & Metabolite Urine****

Component	Method	Reference Range/Units
Clonazepam	LC-MS-MS	<5.0 ng/mL
7-Amino Clonazepam	LC-MS-MS	<5.0 ng/mL

Specimen/Stability 2mL (1.0mL), Urine, Ambient – 3 days, Refrigerated – 2 weeks, Frozen – 2 weeks
 Clinical Utility For therapeutic drug monitoring of anticonvulsant drug. Peak concentrations are reached in 1-4 hours after oral administration. Elimination half-life is 30-40 hours.
 Schedule Tuesday, Thursday, Saturday
 Report Next day
 CPT Code 80154x2
 Note This panel includes Clonazepam and 7-Amino Clonazepam.

3217 Direct Renin (Available 04/03/07)

Component	Method	Reference Range/Units
Direct Renin	Chemiluminescent	6.6 - 39.9 mIU/mL

Specimen/Stability 2.0mL (1.0mL) Serum, Refrigerated – 3 days, Frozen – 5 days
 Clinical Utility The proteolytic enzyme renin (molecular weight: about 42 kDa) is mainly synthesized by the juxtaglomerular cells of the kidneys as prorenin and is stored in granules as prorenin or renin. It is released in response to physiological stimuli like decreased blood volume and blood pressure, and sodium depletion. Renin is secreted by kidneys in response to reduction in renal artery perfusion (intrarenal baroreceptor), reduction in distal tubular resorption of sodium ions (sodium leakage), hypokalaemia, or stimulation of β -adrenergic receptors. In addition, renin secretion is reduced (by negative feedback) in the presence of high plasma concentrations of angiotensin II.
 Schedule Monday, Wednesday, Friday
 Report Next day
 CPT Code 84244
 Note Frozen serum preferred.

4302 Fentanyl and Norfentanyl Confirmation Serum (Available 04/24/07)

****Replaces S50833 Fentanyl (Sublimaze) Serum****

Component	Method	Reference Range/Units
Fentanyl	LC-MS-MS	Cut off <0.1 ng/mL
Norfentanyl	LC-MS-MS	Cut off <0.1 ng/mL

Specimen/Stability 2.0mL (1.0mL) Serum, Ambient – 2 weeks, Refrigerated – 2 weeks, Frozen – 2 weeks
 Clinical Utility Fentanyl is extensively used for anesthesia and analgesia. There are fentanyl transdermal patches available that are used in chronic pain management.
 Schedule Wednesday, Friday
 Report Next day
 CPT Code 83925x2
 Note This panel includes Fentanyl and Norfentanyl.
 Collection Do not use serum separator tubes.

4302U Fentanyl and Norfentanyl Confirmation Urine (Available 04/24/07)

****Replaces S50832 Fentanyl (Sublimaze) Urine****

Component	Method	Reference Range/Units
Fentanyl	LC-MS-MS	Cut off <1.0 ng/mL
Norfentanyl	LC-MS-MS	Cut off <1.0 ng/mL

Specimen/Stability 4.0mL (2.0mL) Urine, Ambient – 2 weeks, Refrigerated – 2 weeks, Frozen – 2 weeks
 Clinical Utility Fentanyl is extensively used for anesthesia and analgesia. There are fentanyl transdermal patches available that are used in chronic pain management.
 Schedule Wednesday, Friday
 Report Next day
 CPT Code 83925x2
 Collection Do not use any preservatives or additives.

4300U Meperidine and Normeperidine Urine (Available 04/24/07)

****Replaces S43912 Meperidine and Normeperidine Urine****

<u>Component</u>	<u>Method</u>	<u>Reference Range/Units</u>
Meperidine	LC-MS-MS	Cut off <100 ng/mL
Normeperidine	LC-MS-MS	Cut off <100 ng/mL

Specimen/Stability 4.0mL (2.0mL) Urine, Ambient – 2 weeks, Refrigerated – 2 weeks, Frozen – 2 weeks
Clinical Utility Currently it is used for pre-anesthesia and the relief of moderate to severe pain, particularly in obstetrics and post-operative situations. Meperidine is available in tablets, syrups, and injectable forms under generic and brand name (Demerol®, Mepergan®, etc.).

Schedule Wednesday, Friday
Report Next day
CPT Code 83925x2
Collection Do not use any preservative or additive.

4190 Nicotine and Cotinine Serum (Available 04/24/07)

****Replaces S40445 Nicotine & Cotinine and S50087 Nicotine & Metabolite Screen Serum GC/MS Confirmation****

<u>Component</u>	<u>Method</u>	<u>Reference Range/Units</u>
Nicotine	LC-MS-MS	Unexposed/Non-Tobacco user <2 ng/mL
		Passive/Exposure <2 ng/mL
		Abstinent/Use >2 weeks <2 ng/mL
		Active Tobacco user 30-50 ng/mL
Cotinine	LC-MS-MS	Unexposed/Non-Tobacco user <2 ng/mL
		Passive/Exposure <8 ng/mL
		Abstinent/Use >2 weeks <2 ng/mL
		Active Tobacco user 200-800 ng/mL

Specimen/Stability 5.0mL (2.5mL) Serum, Ambient – 2 weeks, Refrigerated – 2 weeks, Frozen – 2 weeks
Clinical Utility Determination of nicotine metabolism/pharmacokinetics provides a useful tool for estimating uptake of nicotine and tobacco-related toxicants for understanding the pharmacologic effects of nicotine and nicotine addiction, and for optimizing nicotine dependency treatment. Metabolites of nicotine, such as cotinine, have been used as biomarkers of nicotine and tobacco smoke exposure.

Schedule Tuesday, Thursday
Report Next day
CPT Code 83887, 83789
Note This panel includes Nicotine and Cotinine.
Collection Do not use serum separator tubes.

****Replaces S46905 Nicotine & Metabolite****

Component	Method	Reference Range/Units
Nicotine	LC-MS-MS	Unexposed/Non-Tobacco user <2 ng/mL
		Passive/Exposure <20 ng/mL
		Abstinent/Use >2 weeks <30 ng/mL
		Active Tobacco user 1000-5000 ng/mL
Cotinine	LC-MS-MS	Unexposed/Non-Tobacco user <5 ng/mL
		Passive/Exposure <20 ng/mL
		Abstinent/Use >2 weeks <50 ng/mL
		Active Tobacco user 1000-8000 ng/mL
Nor nicotine	LC-MS-MS	Unexposed/Non-Tobacco user <2 ng/mL
		Passive/Exposure <2 ng/mL
		Abstinent/Use >2 weeks <2 ng/mL
		Active Tobacco user 30-900 ng/mL
Anabasine	LC-MS-MS	Unexposed/Non-Tobacco user <2 ng/mL
		Passive/Exposure <2 ng/mL
		Abstinent/Use >2 weeks <2 ng/mL
		Active Tobacco user 3-500 ng/mL

Specimen/Stability 10.0mL (5.0mL) Urine, Ambient – 2 weeks, Refrigerated – 2 weeks, Frozen – 2 weeks
 Clinical Utility Serum nicotine and urinary/saliva cotinine have been used to guide the dose of nicotine replacement therapy. Simultaneous measurement of urinary nicotine, cotinine, trans-3'-hydroxycotinine, and their conjugates can account for >80% of the total nicotine dose, thereby providing a better estimate of nicotine exposure and the extent of nicotine metabolism than the measurement of a single nicotine metabolite.

Schedule Tuesday, Thursday
 Report Next day
 CPT Code 83887, 83789
 Note This panel included Nicotine, Cotinine, Nor nicotine and Anabasine.
 Collection No additive or preservative is required.

6820 Total Bile Acid (Available 04/03/07)

****Replaces S49520 Bile Acids, Total Only****

Component	Method	Reference Range/Units
Bile acid	Spectrophotometric	0.9 – 9.0 µmol/L

Specimen/Stability 2.0mL (1.0mL) Serum, Ambient – 7 days, Refrigerated – 7 days, Frozen – 1 month
 Clinical Utility Elevated in acute hepatitis, chronic hepatitis, liver sclerosis, and liver cancer. Used to screen pregnant women for obstetric cholestasis. Symptoms of cholestasis include persistent itching in the third trimester of pregnancy and possible risks to the unborn baby including stillbirth, premature labor and bleeding. The frequency of obstetric cholestasis varies and is 1 in 100 pregnant European women vs. 1 in 10 pregnant South American women. Total bile acids levels are the most sensitive indicator for monitoring the effectiveness of interferon treatment of chronic hepatitis C patients.

Schedule Tuesday, Thursday, Saturday
 Report Next day
 CPT Code 82239

5841

UroVysion™

(Available 04/03/07)

****Replaces S50698 Urothelial Cancer (FISH) (UroVysion™) and S51155 UroVysion™ FISH****

Component	Method	Reference Range/Units
UroVysion™	FISH	By Report
Specimen/Stability	60.0mL (45.0mL), Urine Fixed in PreservCyt®, Refrigerated – 3 days	
Alternate Specimens	60.0mL (45.0mL), Fresh Urine, Refrigerated – 1 day	
Clinical Utility	Multi-probe FISH-based assay for the detection of recurrent bladder (urothelial) cancer and early stage bladder cancer. Less invasive and more sensitive than cystoscopy with cytology when used for early detection or monitoring for recurrence. Highly sensitive and specific for detection of high grade urothelial carcinoma. About ¼ of patients with negative or equivocal urine cytology results will have positive FISH results. Urothelial carcinoma will recur within 2 ½ years in about 65% of patients with positive FISH results and negative urine cytology vs. 13% recurrence in FISH negative patients.	
Schedule Report	Monday - Friday	
CPT Code	88367x4	
Note	Ambient and Frozen specimens are not acceptable.	
Collection	Specimen should be labeled with patient information: name, DOB, specimen source, and collection date. Collect optimum volume of 60ml urine in UroCyt™ collection container (blue cap). Add contents of PreservCyt® vial (white cap, 30ml) and tightly secure blue cap on specimen cup to prevent leakage (continue turning another 1/4 inch after you hear the audible click). Place cup and absorbent pads into biohazard bag and tightly seal bag. Specimen needs to be stored and transported at 2-8°C. (Note: For purposes of obtaining the greatest yield of diagnostic material, a second-morning clean catch voided urine specimen should be collected, if possible.)	

9645

Vaginitis DNA DetectR™

(Available Immediately)

Component	Method	Reference Range/Units
Gardnerella vaginalis DNA	PCR	Not detected
Candida albicans DNA	PCR	Not detected
Trichomonas vaginalis DNA	PCR	Not detected
Specimen/Stability	5.0mL (2.0mL), ThinPrep® Vial, Ambient – 21 days, Refrigerated – 21 days	
Alternate Specimens	5.0mL (2.0mL), Tripath SurePath® Vial, Ambient – 21 days, Refrigerated – 21 days	
Clinical Utility	The most common causes of vaginitis are bacterial vaginosis, vulvovaginal candidiasis, and trichomoniasis. This assay detects the presence of <i>Gardnerella vaginalis</i> , <i>Candida albicans</i> , and <i>Trichomonas vaginalis</i> often found in samples from patients with vaginitis/vaginosis. The detection of any of these organisms coupled with other clinical findings will aid the physician in the diagnosis of vaginitis/vaginosis.	
Schedule Report	Sunday - Saturday	
CPT Code	Next day	
Collection	87511, 87481, 87798	
	Cytologic specimens should be collected according to the instructions provided with the ThinPrep® or SurePath® kits for cervical samples.	