

November/December, 2004

Dear Colleague:

This is the last letter for 2004 prior to publication of the new 2005 Specialty Laboratories Directory of Services, scheduled for early January distribution. We want to thank you for your participation in the continuing improvements to our service. Your feedback is important to us and we are listening.

New Tests and Panels

New for December are tests for Cocaine and cocaine metabolite confirmation by tandem mass spectrometry. This menu includes Cocaethylene, which is a metabolic product of concurrent cocaine and ethyl alcohol consumption. Hydroxybenzoylecgonine is a cocaine metabolite mainly present in meconium. Both serum and urine tests are offered; however, serum levels are very transitory (1-5 hours) with most testing derived from urine samples where cocaine metabolites are detected up to several days after last use and longer in patients with chronic use. Also new are assays for Oxycodone (OxyContin, Percocet, Percodan), a semisynthetic opioid analgesic, and Oxymorphone, a metabolite of Oxycodone present typically in lower serum concentration. Therapeutic monitoring of Oxycodone use is aided by these assays; however, a therapeutic range for Oxymorphone is not established as it varies relative to Oxycodone concentration and metabolism.

We are also introducing EIA tests for Liver-Kidney-Microsome (LKM-1) IgG Autoantibodies and for Mitochondrial (M2) IgG Autoantibodies, seen primarily in Autoimmune Hepatitis, type 2 and in Primary Biliary Cirrhosis respectively.

CPT Coding Recommendations

As you are aware, the effective date for implementing CPT coding changes is January 1, 2005; there is no longer a grace period. The coding changes recommended for 2005 are appended to this letter. Note that this list also appears on our Website (www.specialtylabs.com).

Serum Separator Tube Update

In a memo dated October 29, 2004, Becton Dickinson announced:

BD has completed its clinical validations of adjusted BD Vacutainer® SST™ glass and Plus plastic and SST™ II blood collection tubes, and has initiated production of adjusted products. The adjusted products will resolve the previously communicated assay interferences. Once available, and until a new label design can be implemented, the adjusted products can be clearly recognized by the inclusion of an Alpha Character (A, B, C, D or E) at the end of the product lot number identification, for example: lot number 123456A. This Alpha Character lot number distinction will be clearly visible on all levels of packaging. Note that the lot numbers of the non-adjusted products are numeric only.

Thus, *Specialty* can once again accept specimens collected in the adjusted gel separator tubes for the assays listed below. The new tubes are available through Specialty Client Supply at 800-421-7110 ext. 6690 or via fax 661-799-5252. We do, however, continue to discourage use of SST tubes for shipping specimens, and serum separator tubes are unacceptable for assays used to determine therapeutic drug levels.

3224 Triiodothyronine (T3)	3507 Vitamin B12 EvaluatR™
3225 Triiodothyronine Free, Dialysis	3605 Pernicious Anemia EvaluatR™ with reflex
3072 Thyroid Panel, Hyperthyroidism	3134 CA 27.29
3226 Thyroxine (T4)	3134SR CA 27.29 with serial reporting
3230 Thyroxine, Free Index	2020 Follicle-Stimulating Hormone & Luteinizing Hormone Eval
3954 Thyroxine Free, Direct Dialysis	2016 Infertility: Endocrine Evaluation (Female)
3522 Folate	2017 Infertility: Endocrine Evaluation (Male)
3020 Vitamin B12 & Folate	2023 Polycystic Ovary Evaluation
3504 Vitamin B12 (Cyanocobalamin)	3174 Follicle-Stimulating Hormone

Care Plan Participation

Please note Specialty Laboratories is no longer a participating provider with the Northeast Managed Care plans 1199 SEIU National Benefit Fund or Fidelis Care of New York.

Requisitions

Specialty Laboratories will soon introduce a revised Oncology Requisition with some differences in test sequence. We plan to reprint a number of requisitions early in January 2005 to include our new address in Valencia, California; we do not anticipate significant changes in format or test sequence.

Homocysteine Testing

Specialty Laboratories is licensed to perform Homocysteine testing and each assay we perform results in a royalty payment. If you have any questions, please contact your *Specialty* representative or Client Services.

PTH Scattergraph

Test code #3942 "PTH ScatterGraph" is designed for adult patients. For patients less than 18 years of age, test code #3943 "PTH Intact including Total Calcium Only" can provide similar information for differential diagnosis.

Shipping Infectious Specimens

An infectious substance means a material known to contain or suspected of containing a pathogen. Human material containing a pathogen from risk group II or III can be shipped as a diagnostic specimen. Human material containing a pathogen from Risk Group IV must be shipped as an infectious substance. Cultures and stocks of an actively growing organism known to contain an infectious substance from Risk Group II, III or IV must be classified as an infectious substance. A list of assays with specimens that fit into this latter category that require special packaging is appended. Your personnel may identify additional testing that should have infectious substance packaging. A summary of risk groups can be found at www.absa.org/riskgroups.

For additional information, please contact Client Services at 800-421-4449.

A handwritten signature in black ink that reads "Michael C. Dugan MD". The signature is written in a cursive, flowing style.

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

Attachments:

- 2005 CPT Coding Change Recommendations
- Shipping Infectious Specimen List



New from *Specialty*

Effective December 14, 2004 or as noted

4170 Cocaine and Metabolites Confirmation, Serum

Component	Method	Reference Range	Units
Cocaine	LC/MS-MS	< 100	ng/mL
Benzoyllecgonine	LC/MS-MS	< 50	ng/mL
Hydroxybenzoyllecgonine	LC/MS-MS	< 100	ng/mL
Ecgonine Methylene	LC/MS-MS	< 50	ng/mL
Cocaethylene	LC/MS-MS	< 50	ng/mL

Peak concentration of cocaine after nasal administration of 100 mg is 200-400 mg.

Specimen/Stability

5 (2.5) mL Serum; Aliquot
Refrigerated – 3 Days, Frozen – 2 Months

Collection Notes

Do not use serum separator tubes.

Clinical Utility

Cocaine is metabolized mainly to benzoyllecgonine and ecgonine methylester. Cocaethylene is an indication of concurrent cocaine and alcohol consumption. Hydroxybenzoyllecgonine is a metabolite mainly present in meconium. Serum half-life of cocaine is 1-5 hours. Benzoyllecgonine appears in circulation 15-30 minutes after cocaine administration. Elimination half-life of benzoyllecgonine is 5-6 hours. Benzoyllecgonine will be detectable in urine after 2-3 hours and urine remains positive for 2-3 days (longer for chronic abusers) after cocaine use.

Schedule

Tuesday- Saturday

Turnaround Time

1-4 days

CPT Code

82520x5

Notes

This test is for clinical purposes only. Reference ranges indicate reporting limits.

4170U Cocaine and Metabolites Confirmation, Urine

Component	Method	Reference Range	Units
Cocaine	LC/MS-MS	< 150	ng/mL
Benzoyllecgonine	LC/MS-MS	< 150	ng/mL
Hydroxybenzoyllecgonine	LC/MS-MS	< 150	ng/mL
Ecgonine methylester	LC/MS-MS	< 150	ng/mL
Cocaethylene	LC/MS-MS	< 150	ng/mL

Specimen/Stability

10 (5) mL Urine; Sterile Container
Ambient – 5 Day(s), Refrigerated – 7 Day(s), Frozen – 2 Month(s)

Clinical Utility

Cocaine is metabolized mainly to benzoyllecgonine and ecgonine methylester. Cocaethylene is an indication of concurrent cocaine and alcohol consumption. Hydroxybenzoyllecgonine is a metabolite mainly present in meconium. Serum half-life of cocaine is 1-5 hours. Benzoyllecgonine appears in circulation 15-30 minutes after cocaine administration. Elimination half-life of benzoyllecgonine is 5-6 hours. Benzoyllecgonine will be detectable in urine after 2-3 hours and urine remains positive for 2-3 days (longer for chronic abusers) after cocaine use.

Schedule

Tuesday- Saturday

Turnaround Time

1-4 days

CPT Code

82520x5

Notes

This test is for clinical purposes only. Cutoff = 150 ng/mL.

4172 Cocaethylene Serum

Component	Method	Reference Range	Units
Cocaethylene	LC/MS-MS	< 50	ng/mL
Specimen/Stability	5 (2.5) mL Serum; Aliquot Refrigerated – 3 Day(s), Frozen – 2 Month(s)		
Collection Notes	Do not use serum separator tubes.		
Clinical Utility	Cocaine is metabolized mainly to benzoylecgonine and ecgonine methylester. Cocaethylene is an indication of concurrent cocaine and alcohol consumption.		
Schedule	Tuesday- Saturday		
Turnaround Time	1-4 days		
CPT Code	82520		
Notes	This test is for clinical purposes only.		

4172U Cocaethylene Urine

Component	Method	Reference Range	Units
Cocaethylene	LC/MS-MS	< 150	ng/mL
Specimen/Stability	10 (5) mL Urine; Sterile Ambient – 5 Day(s), Refrigerated – 7 Day(s), Frozen – 2 Month(s)		
Clinical Utility	Cocaine is metabolized mainly to benzoylecgonine and ecgonine methylester. Cocaethylene is an indication of concurrent cocaine and alcohol consumption.		
Schedule	Tuesday- Saturday		
Turnaround Time	1-4 days		
CPT Code	82520		
Notes	This test is for clinical purposes only.		

4171 Cocaine Metabolite – Benzoylecgonine, Serum

Component	Method	Reference Range	Units
Benzoylecgonine	LC/MS-MS	< 50	ng/mL
Specimen/Stability	10 (5) mL Serum; Aliquot Ambient – 5 Day(s), Refrigerated – 7 Day(s), Frozen – 2 Month(s)		
Collection Notes	Do not use serum separator tubes.		
Clinical Utility	Cocaine is metabolized mainly to benzoylecgonine and ecgonine methylester. Benzoylecgonine appears in circulation 15-30 minutes after cocaine administration. Elimination half-life of benzoylecgonine is 5-6 hours. Benzoylecgonine will be detectable in urine after 2-3 hours and urine remains positive for 2-3 days (longer for chronic abusers) after cocaine use.		
Schedule	Tuesday- Saturday		
Turnaround Time	1-4 days		
CPT Code	82520		
Notes	This test is for clinical purposes only.		

4171U Cocaine Metabolite – Benzoylecgonine, Urine

Component	Method	Reference Range	Units
Benzoylecgonine	LC/MS-MS	< 150	ng/mL
Specimen/Stability	10 (5) mL Urine; Sterile Ambient – 5 Day(s), Refrigerated – 7 Day(s), Frozen – 2 Month(s)		
Clinical Utility	Cocaine is metabolized mainly to benzoylecgonine and ecgonine methylester. Benzoylecgonine appears in circulation 15-30 minutes after cocaine administration. Elimination half-life of benzoylecgonine is 5-6 hours. Benzoylecgonine will be detectable in urine after 2-3 hours and urine remains positive for 2-3 days (longer for chronic abusers) after cocaine use.		
Schedule	Tuesday- Saturday		
Turnaround Time	1-4 days		
CPT Code	82520		
Notes	This test is for clinical purposes only.		

1112 Liver-Kidney-Microsome (LKM-1) IgG Autoantibodies

Component	Method	Reference Range	Units
LKM-1 IgG Autoantibodies	EIA	Negative: <= 20.0 Equivocal: 20.1-24.9 Positive: >= 25.0	Units Units Units
Specimen/Stability	1 (0.5) mL Serum; Aliquot Ambient – 7 Day(s), Refrigerated – 14 Day(s), Frozen – 2 Month(s)		
Clinical Utilities	LKM-1 IgG antibodies are typically found in Autoimmune Hepatitis Type 2. The major liver kidney microsome target antigen is cytochrome P450 2D6.		
Schedule	Monday		
Turnaround Time	3-8 days		
CPT Code	86376		
Notes	See also Autoimmune EvaluatR™ PLUS, #5906.		

1101 Mitochondrial (M2) IgG Autoantibodies

Component	Method	Reference Range	Units
AMA-M2 IgG Autoantibodies	EIA	Negative <1.0 Weak positive 1.0 – 1.3 Moderate to Strong Positive > 1.3	Units Units Units
Specimen/Stability	1 (0.5) mL Serum; Aliquot Ambient – 7 Day(s), Refrigerated – 14 Day(s), Frozen – 2 Month(s)		
Clinical Utilities	Anti-Mitochondrial antibodies (AMA) have been reported in greater than 90% of patients with Primary Biliary Cirrhosis (PBC). AMA are also occasionally found in patients with chronic active hepatitis, cryptogenic cirrhosis and in patients with clinical (but not biochemical) evidence of liver disease. The M2 type of AMA is strongly associated with PBC.		
Schedule	Monday		
Turnaround Time	3-8 days		
CPT Code	83520		

4176 Oxycodone and Metabolite, Serum

Component	Method	Reference Range	Units
Oxycodone	LC/MS-MS	10-100	ng/mL
Oxymorphone	LC/MS-MS	Therapeutic range is not established	
Specimen/Stability	5 (2.5) mL Serum; Aliquot Ambient – 5 Day(s), Refrigerated – 7 Day(s), Frozen – 2 Month(s)		
Collection Notes	Do not use serum separator tubes.		
Clinical Utility	For therapeutic drug monitoring of Oxycodone (OxyContin, Percocet, Percodan). Oxycodone is a semisynthetic opioid analgesic. Steady state concentration is reached in 24-36 hours after initiation of therapy. Elimination half-life of Oxycodone is 4.5 hours for controlled release and 3.2 hours for immediate release formulations. Peak plasma concentration after oral administration of single dose is 10, 20, 40, 80, 160 mg of OxyContin is 11, 21, 39, 99, 156 ng/mL, respectively. Oxymorphone is a minor but active metabolite of Oxycodone that is present at lower concentration in the circulation. Therapeutic concentrations for oxymorphone have not been established.		
Schedule	Tuesday- Saturday		
Turnaround Time	1-4 days		
CPT Code	83925x2		
Notes	This test is for clinical purposes only.		

4176U Oxycodone and Metabolite Urine

Component	Method	Reference Range	Units
Oxycodone	LC/MS-MS	< 100	ng/mL
Oxymorphone	LC/MS-MS	< 100	ng/mL
Specimen/Stability	10 (5) mL Urine; Sterile Refrigerated – 3 Day(s), Frozen – 2 Month(s)		
Clinical Utility	For therapeutic drug monitoring of Oxycodone (OxyContin, Percocet, Percodan). Oxycodone is a semisynthetic opioid analgesic. Elimination half-life of Oxycodone is 4.5 hours for controlled release and 3.2 hours for immediate release formulations. Oxymorphone is a minor but active metabolite of Oxycodone that is present at lower concentration in the circulation. Both of them are excreted primarily via the kidneys.		
Schedule	Tuesday- Saturday		
Turnaround Time	1-4 days		
CPT Code	83925x2		
Notes	This test is for clinical purposes only.		

Test Changes

Effective December 7, 2004 or as noted

<u>Test Code</u>	<u>Test Name</u>	<u>Specific Change</u>	<u>Also Affected</u>
1967	Factor VIII Inactivator	<u>Name</u> Factor VIII Inhibitor	
5908	Hepatitis Autoimmune EvaluatR™ <i>[effective 12-14-04]</i>	<u>Component</u> LKM-1 IgG (EIA) Mitochondrial IgG (EIA) Moderate to Strong Positive > 1.3 Units	5906 Hepatitis Autoimmune EvaluatR™ Plus 1002 Tissue Total Autoantibodies Screen (Mitochondrial changes only)
1140	Histone-DNA Complex (Chromatin) IgG Autoantibodies	<u>Name</u> Chromatin (Histone-DNA Complex) IgG Autoantibodies	
9926B	HIV-2 IgG Antibodies [IB] plus bands	<u>Alternate Specimen</u> 1 (0.2) mL Plasma ACD Ambient – 5 Day(s), Refrigerated – 14 Day(s), Frozen – 2 Month(s) 1 (0.2) mL Plasma Citrated Ambient – 5 Day(s), Refrigerated – 14 Day(s), Frozen – 2 Month(s) 1 (0.2) mL Plasma Heparinized Ambient – 5 Day(s), Refrigerated – 14 Day(s), Frozen – 2 Month(s) 1 (0.2) mL Plasma EDTA Ambient – 5 Day(s), Refrigerated – 14 Day(s), Frozen – 2 Month(s)	9926BNY HIV-2 IgG Antibodies [IB] plus bands New York
1506U	IgA 24 hour Urine	<u>Reference Range</u> < 1.2 mg/24hr	
1506UR	IgA Urine Random	<u>Reference Range</u> < 1.2 mg/dL	
3828	Interleukin-6	<u>Regulatory Status</u> RUO	
8781	Measles IgM Antibodies	<u>Reference Range</u> Negative: Less than 0.91 Equivocal: 0.91-1.09 Positive: Greater than 1.09	8771 Measles IgG & IgM Antibodies 2772 Meningoencephalomyelitis (MEM) Panel
3315U	Metanephrines, Fractionated Total 24 hour Urine	<u>Collection Instructions</u> If possible, patients should discontinue all drugs at least 1 week prior to collection. Medications that can interfere with the assay include: L-DOPA, Alpha-methyl dopa (Aldomet), Buspirone, Codeine, Isoetharine, Isoproterenol, Mandelamine, Metoclopramide, Acetaminophen (high concentrations only), Labetalol, Catecholamine-containing drugs, MAO inhibitors, diuretics and vasodilators. 24 Hour Collection Instructions: 1. Refrigerate during and after collection. 2. After collection, mix the specimen, measure the total volume and transfer a 10 mL aliquot to a clean, leakproof, screw-cap container. 3. Record the 24 hr total volume on the requisition form or shipping manifest. 4. Store and ship refrigerated. 5. Acid additive (hydrochloric, nitric or acetic acid) is acceptable, but not necessary if the specimen is refrigerated during collection and transportation.	
9620	NMP22® Bladder Tumor Marker	<u>Collection Instructions</u> Collect a single void of urine between midnight and noon. Stabilize sample immediately. Stabilized urine collected with the NMP22® Urine Collection Kit should be blue/green in color. Keep sample away from direct sunlight. Samples may be stored for up to 1 week refrigerated. For longer storage, freeze samples. Ship samples by overnight courier.	

<u>Test Code</u>	<u>Test Name</u>	<u>Specific Change</u>	<u>Also Affected</u>
3318U	Vanillylmandelic Acid 24 hour Urine	<u>Collection Instructions</u> If possible, patients should discontinue all drugs at least 1 week prior to collection. Medications that can interfere with the assay include: L-DOPA, Phenothiazines, Catecholamine-containing drugs, diuretics and vasodilators. The effect of drugs on Vanillylmandelic Acid result may not be predictable. 24 Hour Collection Instructions: 1. Refrigerate during and after collection. 2. After collection, mix the specimen, measure the total volume and transfer a 10 mL aliquot to a clean, leakproof, screw-cap container. 3. Record the 24 hr total volume on the requisition form or shipping manifest. 4. Store and ship refrigerated. 5. Acid additive (hydrochloric, nitric or acetic acid) is acceptable, but not necessary if the specimen is refrigerated during collection and transportation.	
3318UR	Vanillylmandelic Acid Urine Random	<u>Specimen Volume</u> 10 (6) mL Urine	

Discontinued Tests

Effective December 14, 2004 or as noted

The following test(s) are no longer routinely available from *Specialty*. Whenever possible, alternate tests are recommended. Please note that if a test is designated as a "replacement," contractual pricing will be copied from discontinued test to replacement test. Contractual pricing does not apply to alternate tests or sendout tests. Please contact Client Services or your Sales Representative if you have any questions.

Test Code	Test Name	Reason	Alternate or Replacement Tests
S48953	Chromatin IgG Autoantibody <i>[effective November 30, 2004]</i>	In-house test available.	1140 Chromatin (Histone-DNA Complex) IgG Autoabs
S44948	Cocaine and Metabolites Confirmation Urine	In-house test available.	4170U Cocaine and Metabolites Confirmation Urine
S44910	Cocaine and Metabolites, Serum/Plasma	In-house test available.	4170 Cocaine and Metabolites, Serum
S48847	Dihydrotestosterone Newborn <i>[effective November 30, 2004]</i>	In-house test available.	3245 Dihydrotestosterone
1666 1667 1670 1674 1679	Leukemia/Lymphoma Tissue/Body Fluid Eval Leukemia/Lymphoma Bone Marrow Evaluation Leukemia/Lymphoma Blood Evaluation Leukemia/Lymphoma Evaluation Blood Leukemia/Lymphoma Eval, Bone Marrow/Tissue	Standardized set up of 1680 panel for improved TAT and sample stability	1680 Leukemia/Lymphoma Evaluation Panel
1115	Liver-Kidney-Microsome Autoantibodies [IFA]	Replaced by EIA test	1112 Liver-Kidney Microsome IgG Autoabs [EIA]
1102	Mitochondrial Total Autoantibodies [IFA]	Replaced by EIA test	1101 Mitochondrial (M2) IgG Autoantibodies [EIA]
S42935	Oxycodone	In-house test available.	4176 Oxycodone and Metabolites Serum
S50394	Oxycodone and Metabolite Quant	In-house test available.	4176U Oxycodone and Metabolite Urine

**For additional information please call Client Services at 800-421-4449
or visit our Web site at www.specialtylabs.com**