SPECIALTY LABORATORIES
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Test Updates

December 21, 2009

Dear Colleague:

Specialty Laboratories is pleased to announce the availability of **Fentanyl Screen Urine w/Reflex Confirmation [4175]** on February 5, adding to our growing list of tests in support of pain management programs. All positive Fentanyl screening results will be confirmed by Liquid Chromatography/Tandem Mass Spectrometry (LC/MS-MS) for an additional fee under CPT code 83925.

Please be sure to review the 2010 CPT code changes at the end of this client letter. An important change for Medicare is the **HCPCS Code G0430 – Drug screen, qualitative; multiple drug classes other than chromatographic method.** Each procedure is now **G0431 – Drug screen, qualitative; single drug class method**.

Specialty Laboratories encourages all clients and physicians to verify adequate HIV-1 RNA viral load prior to submission for drug resistance testing with our **HIV-1 GenotypR™ Plus [7480]** assay to avoid unnecessary delay or assay failure. This FDA-cleared assay generally requires a minimal HIV-1 RNA viral load of 1,000 copies/mL. While moderately successful at lower viral loads, significantly decreased or negative viral loads may result in assay failure, delay and incremental, but non-billable costs.

Since HIV-1 exists as a diverse population of strains (quasi-species), another adverse possibility exists when testing samples with low, but detectable, viral loads. A minor population may be selectively amplified and sequenced, generating a resistance result not consistent with the dominant strain. If HIV-1 RNA viral load testing is ordered at your laboratory simultaneously with *Specialty's* **HIV-1 GenotypR™ Plus [7480]**, shipment of the frozen specimen for genotyping should be delayed until adequate viral load is verified. The client may also refer to recent, but not concurrent, viral load data to determine whether the viral load is sufficient for sequencing. Please communicate these suggestions to your physicians ordering **HIV-1 GenotypR™ Plus [7480]**.

For clients not offering HIV-1 RNA viral load testing in their own lab, *Specialty* offers **HIV-1 RNA Quantitation [Real Time PCR] w/reflex to HIV-1 GenotypR™ PLUS [7482A]** and **HIV-1 RNA UltraQuant® [bDNA] w/reflex HIV-1 GenotypR™ PLUS (RTI+PI) [7482]**. Specimens with viral loads greater than or equal to 1,000 copies/mL will be automatically reflexed to the genotyping assay for an additional fee.

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,

Christopher Lockhart, M.D.
Laboratory Director

New Tests (*Specialty*):

4175 Fentanyl Screen Urine w/Reflex Confirmation (Available February 5)

This test is not approved for the testing of patient samples from New York State.

Component	Method	Reference Range/Units
Fentanyl Urine	**EIA**	**Negative**

Specimen/Stability	Urine 4.0 (2.0) mL: Ambient 14 days, Refrigerated 14 days, Frozen 14 days
Collection Instructions	Do not use any preservatives or additives.
Schedule	Wednesday
Report	Same day
CPT Code	80101
Regulatory Status	Research Use Only
Always Statement	Cut off: Index of 1.0 = 0.3 ng/mL used to derive the qualitative result of negative or positive. This test(s) was performed using a kit that has not been cleared or approved by the FDA. The analytical performance characteristics of this test have been determined by Specialty Laboratories. This test should not be used for diagnosis without confirmation by other medically established means.
Note	Cut off: Index of 1.0 = 0.3 ng/mL used to derive the qualitative result of negative or positive. All positive results will automatically reflex to Fentanyl & Norfentanyl Urine (test code 4302U) for confirmation for an additional fee (CPT code 83925). This test is not approved for the testing of patient samples from New York State.
Clinical Utility	Fentanyl is extensively used for anesthesia and analgesia. There are fentanyl transdermal patches available that are used in chronic pain management.

Test Changes:

1820 Human Papillomavirus DetectR™

Effective	January 26
Specimen/Stability	Brush Qiagen (Digene) Transport Medium 1.0 (1.0) mL: Ambient 14 days, Refrigerated 21 days, Frozen 3 months
Alt Specimen	AutoCyte PREP Tube 2.0 (1.0) mL: Ambient 28 days, Refrigerated 6 months Tissue: Frozen 2 months ThinPrep Vial 8.0 (4.0) mL: Ambient 21 days, Refrigerated 21 days SurePath Vial 3.0 (2.0) mL: Ambient 28 days, Refrigerated 6 months
Collection Instructions	Cervical brush specimens should be collected using the Qiagen (Digene) Specimen Collection Kit and transported in the Qiagen (Digene) Specimen Transport Medium. Specimens collected using a broom-type collection device and placed in Cytyc PreservCyt Solution for use in making ThinPrep Pap Test slides can be used for HPV testing. Specimens should be collected in the routine manner and the ThinPrep Test slides should be prepared according to the Cytyc instructions. There must be at least 4 mL of PreservCyt Solution remaining for the HPV test. PreservCyt Solution specimens may be held for up to 3 weeks at ambient temperature (do not freeze) following collection and prior to processing for HPV testing. Cervical biopsy specimens should be 2-5 mm in cross-section and must be placed in 1 mL of Qiagen (Digene) Specimen Transport Medium and shipped frozen. **Note: All references to "swab" should be changed to "brush".**
Also affected	DOS Codes 1822, 1824

1821 Human Papillomavirus High Risk DetectR™

Effective	January 26
Specimen/Stability	Brush Qiagen (Digene) Transport Medium 1.0 (1.0) mL: Ambient 14 days, Refrigerated 21 days, Frozen 3 months
Alt Specimen	AutoCyte PREP Tube 2.0 (1.0) mL: Ambient 28 days, Refrigerated 6 months Tissue: Frozen 2 months ThinPrep Vial 8.0 (4.0) mL: Ambient 21 days, Refrigerated 21 days SurePath Vial 3.0 (2.0) mL: Ambient 28 days, Refrigerated 6 months
Collection Instructions	Cervical brush specimens should be collected using the Qiagen (Digene) Specimen Collection Kit and transported in the Qiagen (Digene) Specimen Transport Medium. Specimens collected using a broom-type collection device and placed in Cytyc PreservCyt Solution for use in making ThinPrep Pap Test slides can be used for HPV testing. Specimens should be collected in the routine manner and the ThinPrep Test slides should be prepared according to the Cytyc instructions. There must be at least 4 mL of PreservCyt Solution remaining for the HPV test. PreservCyt Solution specimens may be held for up to 3 weeks at ambient temperature (do not freeze) following collection and prior to processing for HPV testing. If submitted ThinPrep sample volume is at least 2 mL, but less than the 4 mL required minimum volume, the test will be reported with a comment indicating the test was not performed, and an automatic replacement test code (QNS HPV High Risk) will be added. The test will then be referred to Nichols Institute, Chantilly for testing. Cervical biopsy specimens should be 2-5 mm in cross-section and must be placed in 1 mL of Qiagen (Digene) Specimen Transport Medium and shipped frozen. **Note: All references to "swab" should be changed to "brush".**

Test Changes: (cont'd)

1821R Human Papillomavirus High Risk DetectR™ Anal/Rectal

Effective	January 26
Specimen/Stability	Anal/Rectal Brush Qiagen (Digene) Transport 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 21 days, Refrigerated 21 days
Collection Instructions	Anal and rectal brush specimens should be collected using the Qiagen (Digene) Specimen Collection Kit and transported in the Qiagen (Digene) Specimen Transport Medium. Anal/rectal brush specimens collected in at least 4 mL of ThinPrep solution vials may be held for up to 2 weeks prior to shipping. Specimens collected on swabs or in other liquid cytology media (such as SurePath) will be rejected. **Note: All references to "swab" should be changed to "brush". SurePath Vial samples are no longer accepted.**
Always Statement	The performance characteristics of this assay(s) have been determined by Specialty Laboratories. Performance characteristics refer to the analytical performance of the test when used to test anal/rectal specimens in Qiagen (Digene) Transport Medium or ThinPrep vials.
Also affected	DOS Codes 1822R

3371 Cardiolipin IgG, IgM, & IgA Autoabs

Effective	January 26
Specimen/Stability	Serum 1.0 (0.6) mL: Refrigerated 48 hours, Frozen 2 months
Alt Specimen	Plasma EDTA 1.0 (0.6) mL: Refrigerated 48 hours, Frozen 2 months Plasma Heparin 1.0 (0.6) mL: Refrigerated 48 hours, Frozen 2 months **Note: Plasma EDTA and heparin specimens are now accepted.**
Also affected	DOS Codes 3372, 3373, 3374, 5963, 5976

4867UR Arsenic Urine Random

Effective	January 26	
Component	Arsenic Random Urine (same – no change)	
Component	Arsenic/Creatinine Ratio (same – no change)	
Component	Creatinine Random Urine **(ADD)**	
Methodology	Spectrophotometry	
Reference Range	0 – 6 months	2.0 – 32.0 mg/dL
	7 – 11 months	2.0 – 36.0 mg/dL
	1 – 2 years	2.0 – 128.0 mg/dL
	3 – 8 years	2.0 – 149.0 mg/dL
	9 – 12 years	2.0 – 183.0 mg/dL
	> 12 years	20.0 – 370.0 mg/dL
CPT Codes	82175, 82570	

Test Changes: (cont'd)

4868UR Cadmium Urine Random

Effective	January 26	
Component	Cadmium Random Urine (same – no change)	
Component	Cadmium/Creatinine Ratio (same – no change)	
Component	Creatinine Random Urine **(ADD)**	
Methodology	Spectrophotometry	
Reference Range	0 – 6 months	2.0 – 32.0 mg/dL
	7 – 11 months	2.0 – 36.0 mg/dL
	1 – 2 years	2.0 – 128.0 mg/dL
	3 – 8 years	2.0 – 149.0 mg/dL
	9 – 12 years	2.0 – 183.0 mg/dL
	> 12 years	20.0 – 370.0 mg/dL
CPT Codes	82570, 82300	

4872UR Manganese Urine Random

Effective	January 26	
Component	Manganese Random Urine (same – no change)	
Component	Manganese/Creatinine Ratio (same – no change)	
Component	Creatinine Random Urine **(ADD)**	
Methodology	Spectrophotometry	
Reference Range	0 – 6 months	2.0 – 32.0 mg/dL
	7 – 11 months	2.0 – 36.0 mg/dL
	1 – 2 years	2.0 – 128.0 mg/dL
	3 – 8 years	2.0 – 149.0 mg/dL
	9 – 12 years	2.0 – 183.0 mg/dL
	> 12 years	20.0 – 370.0 mg/dL
CPT Codes	82570, 83785	

7533 BNP EvaluatR™

Effective	January 26
Specimen/Stability	Plasma EDTA 0.5 (0.3) mL: Frozen 2 months
	Note: Plasma EDTA in PET Tube is no longer accepted.

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.

Discontinued Tests:

Effective Immediately:

S51563 **Bloom Syndrome DNA Mutation Analysis - Diagnostic [10224X]**
Recommended replacement: S51562 – Bloom Syndrome DNA Mutation Analysis [10224X]
Performed at Quest Diagnostics, San Juan Capistrano

S51564 **Bloom Syndrome DNA Mutation Analysis – Fetal Study [10224X]**
Recommended replacement: S51562 – Bloom Syndrome DNA Mutation Analysis [10224X]
Performed at Quest Diagnostics, San Juan Capistrano

S51565 ***Brucella* Antibody, IgG [0050334]**
Recommended replacement: S51666 – *Brucella* Antibodies (IgG, IgM) Serum [40010]
Performed at Focus Diagnostics

S51567 ***Brucella* Antibody, IgM [0050336]**
Recommended replacement: S51666 – *Brucella* Antibodies (IgG, IgM) Serum [40010]
Performed at Focus Diagnostics

S51569 **Canavan Disease Mutation Analysis – Diagnostic [31650X]**
Recommended replacement: S51568 – Canavan Disease Mutation Analysis [31650X]
Performed at Quest Diagnostics, San Juan Capistrano

S51570 **Canavan Disease Mutation Analysis – Fetal Study [31650X]**
Recommended replacement: S51568 – Canavan Disease Mutation Analysis [31650X]
Performed at Quest Diagnostics, San Juan Capistrano

S51575 **Familial Dysautonomia Mutation Analysis – Diagnostic [16040X]**
Recommended replacement: S51574 – Familial Dysautonomia Mutation Analysis [16040X]
Performed at Quest Diagnostics, San Juan Capistrano

S51576 **Familial Dysautonomia Mutation Analysis – Fetal Study [16040X]**
Recommended replacement: S51574 – Familial Dysautonomia Mutation Analysis [16040X]
Performed at Quest Diagnostics, San Juan Capistrano

S51578 **Fanconis Anemia DNA Mutation Analysis – Diagnostic [10221X]**
Recommended replacement: S51577 – Fanconis Anemia DNA Mutation Analysis [10221X]
Performed at Quest Diagnostics, San Juan Capistrano

S51579 **Fanconis Anemia DNA Mutation Analysis – Fetal Study [10221X]**
Recommended replacement: S51577 – Fanconis Anemia DNA Mutation Analysis [10221X]
Performed at Quest Diagnostics, San Juan Capistrano

S51582 **Gaucher Disease, DNA Mutation Analysis – Diagnostic [21503X]**
Recommended replacement: S51581 – Gaucher Disease, DNA Mutation Analysis [21503X]
Performed at Quest Diagnostics, San Juan Capistrano

S51583 **Gaucher Disease, DNA Mutation Analysis – Fetal Study [21503X]**
Recommended replacement: S51581 – Gaucher Disease, DNA Mutation Analysis [21503X]
Performed at Quest Diagnostics, San Juan Capistrano

Discontinued Tests: (cont'd)

Effective Immediately:

S51589 Mucolipidosis Type IV Mutation Analysis – Diagnostic [11192X]
Recommended replacement: S51588 – Mucolipidosis Type IV Mutation Analysis [11192X]
Performed at Quest Diagnostics, San Juan Capistrano

S51590 Mucolipidosis Type IV Mutation Analysis – Fetal Study [11192X]
Recommended replacement: S51588 – Mucolipidosis Type IV Mutation Analysis [11192X]
Performed at Quest Diagnostics, San Juan Capistrano

S51593 Niemann-Pick Disease Mutation Analysis – Diagnostic [10222X]
Recommended replacement: S51592 – Niemann-Pick Disease Mutation Analysis [10222X]
Performed at Quest Diagnostics, San Juan Capistrano

S51594 Niemann-Pick Disease Mutation Analysis – Fetal Study [10222X]
Recommended replacement: S51592 – Niemann-Pick Disease Mutation Analysis [10222X]
Performed at Quest Diagnostics, San Juan Capistrano

S51599 Tay-Sachs Disease Mutation Analysis – Diagnostic [21502X]
Recommended replacement: S51598 – Tay-Sachs Disease Mutation Analysis [21502X]
Performed at Quest Diagnostics, San Juan Capistrano

S51600 Tay-Sachs Disease Mutation Analysis – Fetal Study [21502X]
Recommended replacement: S51598 – Tay-Sachs Disease Mutation Analysis [21502X]
Performed at Quest Diagnostics, San Juan Capistrano

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December 2009

Subject: CPT Code changes for CPT 2010

Dear Valued Client:

The American Medical Association (AMA) has made CPT code changes in the 2010 edition of the AMA Current Procedural Terminology (CPT) coding manual.

Specialty Laboratories will be implementing these changes effective January 1, 2010. Overall, the changes for 2010 affect the way we bill some of our tests. The chart attached lists the tests affected and the appropriate CPT code changes.

***Important Medicare Change: HCPCS Code**

- **G0430 – Drug screen, qualitative; multiple drug classes other than chromatographic method, each procedure**

- **G0431 – Drug screen, qualitative; single drug class method (e.g., immunoassay, enzyme assay), each drug class**

Please do not hesitate to call your *Specialty* Sales Representative with any questions or concerns you may have regarding CPT code changes. Thank you very much for using *Specialty* for your laboratory testing needs.

Respectfully Yours,

Christopher Lockhart, M.D.
Laboratory Director

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 coding to the payor being billed.

AMA Changes in CPT Coding
Effective January 1, 2010

***Specialty* Test Name**	***Specialty* DOS Code**	**2009 CPT Codes**	**NEW CPT Codes Effective 1/1/2010**
Treponema pallidum IgM Abs [IFA]	2102	86781	**86780**
Treponema pallidum IgM Abs, FTA CSF	2102C	86781	**86780**
Treponema pallidum Total Abs [IFA]	2104	86781	**86780**
Treponema pallidum Total Abs [Blood Bank]	2104T	86781	**86780**
Treponema pallidum Total Abs [IFA] CSF	2104C	86781	**86780**
Treponema pallidum Antibodies (TP-PA)	9022	86781	**86780**
Reflex *Treponema pallidum* Total Antibodies [IFA]	Reflex of DOS Code 2365	86781	**86780**
Treponema pallidum Antibody, IFA (CSF) [63486]	S49738	86781	**86780**
Treponema pallidum IgG and IgM AB Panel Fetal [20493]	S49739	86781x2	**86780x2**
Procalcitonin, Serum [83169]	S51173	0194T	**84145**
AspirinWorks® [300353]	S50742	83520	**82570, 84431**
HE4, Ovarian Cancer Monitoring [16500X]	S51786	86316	**86305**

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