December 2014 - Monthly Update, Quest Diagnostics Nichols Institute, Valencia

NEW TESTS Please Note: Not all test codes assigned to each assay are listed in the table of contents. Please refer to the complete listing on the page numbers indicated.			
Test Code	**Test Name**	**Effective Date**	**Page #**
92447	**Hepatitis C Viral RNA NS5a Drug Resistance**	11/17/2014	3
92204	**Hepatitis C Viral RNA NS5b Drug Resistance**	11/17/2014	3

TEST CHANGES Please Note: Not all test codes assigned to each assay are listed in the table of contents. Please refer to the complete listing on the page numbers indicated.				
Test Code	**Former Test Code**	**Test Name**	**Effective Date**	**Page #**
31789	3334	**Homocysteine**	1/12/2015	4
		Homocysteine change in Custom Panels	1/12/2015	5
17656		Methicillin Resistant *Staphylococcus aureus*, PCR	1/12/2015	5
661		Myoglobin, Urine	1/12/2015	6
91768		*Streptococcus* Group B DNA, PCR with Broth Enrichment	1/12/2015	6
91770		*Streptococcus* Group B DNA, PCR with Broth Enrichment and Reflex to Susceptibility	1/12/2015	6
91258		Zolpidem, Quantitation, Urine	1/12/2015	6

DISCONTINUED TESTS Please Note: Not all test codes assigned to each assay are listed in the table of contents. Please refer to the complete listing on the page numbers indicated.			
Test Code	**Test Name**	**Effective Date**	**Page #**
	Influenza Virus Type A and B Discontinued Tests	12/29/2014	7
29273	HIV-1 RNA, Quantitative, bDNA	1/12/2015	7
36362	Homocysteine, Nutritional and Congenital	1/12/2015	7
A52261	Methylmalonic Acid	1/12/2015	7

NY UPDATE Please Note: Not all test codes assigned to each assay are listed in the table of contents. Please refer to the complete listing on the page numbers indicated.		
Test Code	**Test Name**	**Page #**
S52079	**CEA, Pancreatic Cyst Fluid (NY)**	8
S52313	**Fibroblast Growth Factor 23 (FGF23) (NY)**	8

SEND OUTS Please Note: Not all test codes assigned to each assay are listed in the table of contents. Please refer to the complete listing on the page numbers indicated.				
Test Code	**Former Test Code**	**Test Name**	**Effective Date**	**Page #**
91594		Diuretics Screen, Urine	1/5/2015	8
91905		**Androsterone, Serum**	1/12/2015	8

S44740		Androsterone, Serum	1/12/2015	9
91930		**Carcinoembryonic Antigen (CEA), Pancreatic Cyst Fluid**	1/12/2015	9
91931		**FGF-23 (Fibroblast Growth Factor 23)**	1/12/2015	9
92572		**Xpansion Interpreter®**	1/19/2015	10

Announcements

AMA CPT® changes for 2015

Effective 01/01/2015, the AMA is implementing a significant number of changes to CPT coding. Quest Diagnostics recommends that you refer to our website as a resource for comprehensive information regarding this change.

http://www.questdiagnostics.com/home/physicians/cpt-icd.html

Toxicology Changes

The Centers for Medicare & Medicaid Services (CMS) is recommending to delay pricing for these codes at this time, until further information and education is obtained.

In order to alleviate ambiguity regarding reporting drug procedures, a number of significant changes have been made within the Pathology and Laboratory section. The revisions allow for additional specificity in differentiating the materials being tested.

Instead of differentiating testing procedures based on qualitative or quantitative methodology, the new reporting mechanism differentiates procedures according to whether they are: (1) presumptive (used to identify possible use or non-use of a drug or drug class), (2) definitive (qualitative or quantitative methods that identify possible drug use or non-use and identify the specific drugs and associated metabolites), or (3) Therapeutic Drug Assays (quantitative procedures performed to monitor clinical response to a known, prescribed medication). The updated reporting mechanism has been designed to address the following: (1) ability to be easily modified for future changes and technological advances, (2) identification of updated clinical settings, and (3) identification of "sources" for specimen(s).

The new section in the AMA book includes the addition of guidelines, parentheticals, and tables that are used to direct reporting within the 2 new subsections. The codes included within these subsections identify drug procedures according to the purpose of the procedure and type of patient results obtained.

The Presumptive Drug Class Screening section includes Guidelines for the Presumptive Drug Class Screening section, Drug Class List A (which itemizes commonly assayed drugs within the listing), and Drug Class List B (which itemizes assays that require more resources than Class A). This section also includes guidelines that explain the intended use for the listing and the codes. Five new codes have been developed to identify presumptive testing with introductory guidelines explaining the intent for use of these codes.

Definitive Drug Testing includes fifty-nine new definitive drug testing codes. The codes are arranged by drug classes. Refer to the Definitive Drug Classes Listing table for drugs and metabolites included in each definitive drug class.

Molecular Pathology Changes

Advances in DNA sequencing technology, commonly referred to as next generation sequencing (NGS) or massively parallel sequencing (MPS) are allowing the human genome to be analyzed in complex and diverse ways.

Applications of this technology have resulted in new clinical diagnostic procedures that are having a significant impact on the practice of medicine.

In response to the changes in clinical practice and the need to provide a reporting mechanism for NGS or MPS procedures, the CPT code set has been expanded to include a new subsection for reporting these analyses, "Genomic Sequencing Procedures (GSPs) and other Molecular Multianalyte Assays." This new subsection includes introductory guidelines which describe some of the characteristics of GSPs and other Molecular Multianalyte Assays including their unique features, functions and applications. The new subsection includes 21 new codes.

Microbiology Changes

Along with several other changes, codes 87623, 87624, 87625 have been added to report human papilloma virus (HPV) genotyping to differentiate high and low risk HPV types. HPV genotyping is used in conjunction with or as follow-up to an abnormal cytology report. The existing HPV codes

87620, 87621 and 87622 have been deleted and replaced with genotyping codes that describe the specific types tested.

Surgical Pathology Changes

Immunocytochemistry and immunohistochemistry CPT codes have undergone additional changes for 2015.

The histomorphometry codes 88360, 88361 for reporting detection of protein receptors for diagnosing the development of tumor(s) and cancer have been revised.

The in situ hybridization codes 88365, 88367, 88368 have been revised and expanded into three separate families of codes that identify; 1) the initial single probe stain procedure (88365, 88367, 88368), 2) each additional single probe stain procedure (88364, 88373, 88369), and 3) each multiplex probe stain procedure (88366, 88374, 88377).

Quest Diagnostics will make every effort to assist our clients with the transition to the 2015 AMA CPT coding being used for our test offerings.

New Test Offerings

The following tests will be available through Quest Diagnostics on the dates indicated below.

<table>
<tr><th colspan="2">Hepatitis C Viral RNA NS5a Drug Resistance</th></tr>
<tr><td>Clinical Significance</td><td>For detection of mutations in the NS5a gene associated with resistance to NS5a inhibitors (example: daclatasvir, ledipasvir and ombitasvir inhibitors of HCV NS5a).</td></tr>
<tr><td>Effective Date</td><td>11/17/2014</td></tr>
<tr><td>Test Code</td><td>92447</td></tr>
<tr><td>CPT Codes</td><td>87902</td></tr>
<tr><td>Specimen Requirements</td><td>Preferred:
2 mL (0.6 mL minimum) plasma collected in an EDTA (lavender-top) tube

Acceptable:
Plasma collected in a PPT potassium EDTA (white-top) tube or serum</td></tr>
<tr><td>Reject Criteria</td><td>Specimens collected using heparin as anticoagulant; gross hemolysis; grossly lipemic</td></tr>
<tr><td>Instructions</td><td>Collect blood in sterile tubes containing EDTA anticoagulant (lavender-top) or PPT (white-top) tube. Separate plasma from the cells by centrifugation within 24 hours after collection, transfer the plasma to a separate plastic screw-cap vial and ship frozen.</td></tr>
<tr><td>Transport Temperature</td><td>Frozen</td></tr>
<tr><td>Specimen Stability</td><td>Room temperature: 72 hours
Refrigerated: 14 days
Frozen: 42 days</td></tr>
<tr><td>Set-up/Analytic Time</td><td>Set up: Tues; Report available: 4-11 days</td></tr>
<tr><td>Reference Range</td><td><table>
<tr><td>HCV NS5a Subtype:</td><td>Not detected</td></tr>
<tr><td>Daclatasvir Resistance:</td><td>Not predicted</td></tr>
<tr><td>Ledipasvir Resistance:</td><td>Not predicted</td></tr>
<tr><td>Ombitasvir Resistance:</td><td>Not predicted</td></tr>
</table></td></tr>
<tr><td>Methodology</td><td>Polymerase Chain Reaction; Sequencing</td></tr>
<tr><td>Performing Site</td><td>Focus Diagnostics, Inc.</td></tr>
</table>

Interface Mapping	

Result Code	Result Name
86011275	HCV NS5a Subtype
86011276	Daclatasvir Resistance
86011277	Ledipasvir Resistance
86011726	Ombitasvir Resistance

Hepatitis C Viral RNA NS5b Drug Resistance	
Clinical Significance	**For detection of mutations in the NS5b gene associated with resistance to nucleotide analog NS5b polymerase inhibitors (example: sofosbuvir, a nucleotide analog inhibitor of HCV NS5b polymerase).**
Effective Date	**11/17/2014**
Test Code	**92204**
CPT Codes	**87902**
Specimen Requirements	**Preferred:** **2 mL (0.6 mL minimum) plasma collected in an EDTA (lavender-top) tube** **Acceptable:** **Plasma collected in a PPT potassium EDTA (white-top) tube or serum**
Reject Criteria	**Specimens collected using heparin as anticoagulant; gross hemolysis; grossly lipemic**
Instructions	**Collect blood in sterile tubes containing EDTA anticoagulant (lavender-top) or PPT (white-top) tube. Separate plasma from the cells by centrifugation within 24 hours after collection, transfer the plasma to separate plastic screw-cap vial and ship frozen.**
Transport Temperature	**Frozen**
Specimen Stability	**Room temperature: 72 hours** **Refrigerated: 14 days** **Frozen: 42 days**
Set-up/Analytic Time	**Set up: Tues; Report available: 4-11 days**
Reference Range	

HCV NS5b Subtype:	**Not detected**
Sofosbuvir Resistance:	**Not predicted**

Methodology	**Polymerase Chain Reaction; Sequencing**
Performing Site	**Focus Diagnostics, Inc.**
Interface Mapping	

Result Code	Result Name
86010892	HCV NS5b Subtype
86010893	Sofosbuvir Resistance

Test Changes

The following test changes will be effective on the dates indicated below. **Please note information that is changing appears in bold text in this update.** *Former test names and test codes have been italicized*.

<table>
<tr><th colspan="2">Homocysteine</th></tr>
<tr><td>Clinical Significance</td><td>An elevated concentration of Homocysteine is an independent risk factor for cardiovascular disease. When used in conjunction with Methylmalonic Acid (MMA), these tests are useful to diagnose and monitor Vitamin B12 (cobalamin) and folic acid deficiency and are often useful in evaluating macrocytosis (an elevated MCV, an erythrocytic index).</td></tr>
<tr><td>Effective Date</td><td>1/12/2015</td></tr>
<tr><td>Former Test Name</td><td>Homocysteine (Cardiovascular)</td></tr>
<tr><td>Former Test Code</td><td>3334</td></tr>
<tr><td>Test Code</td><td>31789</td></tr>
<tr><td>Reject Criteria</td><td>Gross hemolysis; unseparated serum or plasma; whole blood specimens; grossly lipemic</td></tr>
<tr><td>Transport Temperature</td><td>Room temperature</td></tr>
<tr><td>Methodology</td><td>Enzymatic</td></tr>
<tr><td>Performing Site</td><td>Quest Diagnostics Nichols Institute, Valencia</td></tr>
<tr><td>Interface Mapping</td><td>
<table>
<tr><th>Result Code</th><th>Result Name</th></tr>
<tr><td>50131900</td><td>Homocysteine</td></tr>
</table>
</td></tr>
<tr><td>Pricing Message</td><td>Negotiated pricing on 3334 will be applied to code 31789.</td></tr>
<tr><td>Tests Affected</td><td>
<table>
<tr><th>Test Codes:</th><th>Name:</th></tr>
<tr><td>4994</td><td>Megaloblastic Anemia Assessr</td></tr>
<tr><td>1537</td><td>Treatable Ischemia Predictr</td></tr>
</table>
</td></tr>
</table>

<table>
<tr><th colspan="2">Homocysteine change in Custom Panels</th></tr>
<tr><td>Clinical Significance</td><td>An elevated concentration of Homocysteine is an independent risk factor for cardiovascular disease. When used in conjunction with Methylmalonic Acid (MMA), these tests are useful to diagnose and monitor Vitamin B12 (cobalamin) and folic acid deficiency and are often useful in evaluating macrocytosis (an elevated MCV, an erythrocytic index).</td></tr>
<tr><td>Effective Date</td><td>1/12/2015</td></tr>
<tr><td>Former Test Name</td><td>Homocysteine (Cardiovascular)</td></tr>
<tr><td>Methodology</td><td>Enzymatic</td></tr>
<tr><td>Performing Site</td><td>Quest Diagnostics Nichols Institute, San Juan Capistrano</td></tr>
<tr><td>Interface Mapping</td><td>
<table>
<tr><th>Result Code</th><th>Result Name</th></tr>
<tr><td>50131900</td><td>Homocysteine</td></tr>
</table>
</td></tr>
<tr><td>Tests Affected</td><td>
<table>
<tr><th>Test Codes:</th><th>Name:</th></tr>
<tr><td>P39991G</td><td>Custom Beverly Hypercoagulation Panel</td></tr>
<tr><td>P38164H</td><td>Custom Carson Venous Thrombosis Panel</td></tr>
<tr><td>P6271H</td><td>Custom Regional VWCA Thrombophilia Panel</td></tr>
</table>
</td></tr>
</table>

Methicillin Resistant *Staphylococcus aureus*, PCR	
Effective Date	**1/12/2015**
Test Code	17656
Specimen Requirements	Preferred: Nasal **double** swab (Liquid Amies Collection Tube) Acceptable: Nasal swab collected in **Gel Amies w/out charcoal, or Liquid Stuarts, or Cepheid Collection Device**
Instructions	Swab must be inserted into nostril up to 2.5 cm (1 inch) from edge of the nare and rolled 5 times. Repeat using same swab in the other nostril. **Return swab to its container.** **Nasal swab collected in: BBL™ Culture Swab™ Liquid Amies, Double Swab or Copan Venturi Transystem™ Liquid Amies, Double Swab.**
Specimen Stability	**Room temperature: 24 hours** Refrigerated: 5 days Frozen: Unacceptable
Performing Site	Focus Diagnostics, Inc.

Myoglobin, Urine	
Effective Date	**1/12/2015**
Test Code	661
Reject Criteria	Received in a non-Myoglobin transport tube; specimen received past stability; pH <8.0; **more than 4 mL urine in Myoglobin transport tube; received room temperature; timed urine**
Instructions	**Add exactly 4 mL random urine** to a Myoglobin transport tube within one hour of collection. Freeze and ship frozen. (Transport tube, product # 170764, is available through Client Supply) **Exactly 4 mL of urine in the Myoglobin transport tube is required to achieve the required pH of >8.0. More than 4 mL of urine will lower the pH outside acceptable range.**
Specimen Stability	Room temperature: Unacceptable Refrigerated and **Frozen: 72 hours**
Performing Site	Quest Diagnostics Nichols Institute, Valencia

***Streptococcus* Group B DNA, PCR with Broth Enrichment**		
Effective Date	**1/12/2015**	
Test Code	91768	
Specimen Stability	Amies Transport Medium:	**Room temperature: 24 hours** Refrigerated: 48 hours Frozen: Unacceptable
	LIM Broth Tube:	Room temperature: Unacceptable **Refrigerated: 72 hours** Frozen: Unacceptable
Performing Site	Focus Diagnostics, Inc.	

***Streptococcus* Group B DNA, PCR with Broth Enrichment and Reflex to Susceptibility**

Effective Date	**1/12/2015**
Test Code	91770
Specimen Stability	Amies Transport Medium: **Room temperature: 24 hours** Refrigerated: 48 hours Frozen: Unacceptable LIM Broth Tube: Room temperature: Unacceptable **Refrigerated: 72 hours** Frozen: Unacceptable
Performing Site	Focus Diagnostics, Inc.

Zolpidem, Quantitation, Urine	
Effective Date	**1/12/2015**
Test Code	91258
Reference Range	**Zolpidem** <5 ng/mL **Zolpidem Metabolite** **<5 ng/mL**
Performing Site	Quest Diagnostics Nichols Institute, Chantilly
Interface Mapping	**Result Code** / **Result Name** 86008832 / **Zolpidem** **86011300** / **Zolpidem Metabolite**

Discontinued Tests

Influenza Virus Type A and B Discontinued Tests	
Effective Date	**12/29/2014**
Additional Information	Reagents are no longer available. There is no recommended alternative.
Tests Affected	**Test Codes:** / **Name:** P6970M / Custom Terrebonne Adult Respiratory Panel 8516 / Influenza Type A and B Antibodies (IgG,IgM,IgA) 8517 / Influenza Virus A IgG ABS 8520 / Influenza Virus B IgG ABS 8519 / Influenza Virus Type A (IgG,IgM) 8518 / Influenza Virus Type A Antibody (IgM) 8523 / Influenza Virus Type B Antibody (IgG,IgM) 8522 / Influenza Virus Type B Antibody (IgM)

HIV-1 RNA, Quantitative, bDNA	
Effective Date	**1/12/2015**
Test Code	29273
Additional Information	The recommended alternative is test code 40085 - HIV-1 RNA, Quantitative, Real-Time PCR.
Pricing Message	Due to the suggested replacement negotiated fees will not be copied.

Homocysteine, Nutritional and Congenital	
Effective Date	**1/12/2015**
Test Code	36362
Additional Information	**Please note:** Orders for 36362- Homocysteine, Nutritional and Congenital will automatically be replaced with test code 31789- Homocysteine.
Pricing Message	Negotiated fees for codes 36362 and 31789 will be reviewed and adjusted if applicable.

Methylmalonic Acid	
Effective Date	**1/12/2015**
Test Code	A52261
Additional Information	The recommended alternative is test code 3496- Methylmalonic Acid

New York Patient Testing Update

CEA, Pancreatic Cyst Fluid (NY)	
Message	*****This test is only available for New York patient testing. For non-New York patient testing please refer to test code 91930- Carcinoembryonic Antigen (CEA), Pancreatic Cyst Fluid.*****
Effective Date	**1/12/2015**
Test Code	S52079

Fibroblast Growth Factor 23 (FGF23) (NY)	
Message	*****This test is only available for New York patient testing. For non-New York patient testing please refer to test code 91931- FGF 23 (Fibroblast Growth Factor 23).*****
Effective Date	**1/12/2015**
Test Code	S52313

Test Send Outs (Referrals)

Diuretics Screen, Urine	
Effective Date	**1/5/2015**
Test Code	91594

Specimen Stability	**Room temperature: 48 hours** **Refrigerated** and Frozen: **28 days**
Set-up/Analytic Time	Set up: **Thurs**; Report available: 2 days

Androsterone, Serum	
Message	*****This test is not available for New York patient testing*****
Clinical Significance	**Androsterone is one of the androgens, produced both from adrenals and gonads. Androsterone can be reversibly converted to 3 alpha androstenediol. An elevated level of androsterone has cholesterol lowering effect. High levels of androsterone are frequently seen in female patients with acne with or without hirsutism. Hirsute females without acne show normal levels of androsterone. Elevated levels of androsterone are shown in hyperthyroid patients. Lower levels of androsterone are seen in patients with myxedema and in cancer patients.**
Effective Date	**1/12/2015**
Test Code	**91905**
CPT Codes	**82160**
Specimen Requirements	**3 mL (1 mL minimum) frozen serum**
Reject Criteria	**Received room temperature**
Instructions	**Patient Preparation:** **Fasting specimen is preferred. Patients should avoid any hormonal medications for 2 days.**
Transport Temperature	**Frozen**
Specimen Stability	**Room temperature: 6 hours** **Refrigerated: 48 hours** **Frozen: 6 months**
Set-up/Analytic Time	**Set up: Wed; Report available: 2-7 days**
Reference Range	**20-80 ng/dL**
Methodology	**Extraction and Enzyme Linked Immunosorbent Immunoassay**
Interface Mapping	**Result Code**: **86010169**; **Result Name**: **Androsterone, Serum**

Androsterone, Serum	
Effective Date	**1/12/2015**
Test Code	S44740
Additional Information	This test will be discontinued. The recommended alternative is 91905-Androsterone, Serum

Carcinoembryonic Antigen (CEA), Pancreatic Cyst Fluid	
Message	*****This test is not available for New York patient testing. For New York patient testing, please refer to test code S52079-CEA, Pancreatic Cyst Fluid (NY). *****
Effective Date	**1/12/2015**
Test Code	**91930**
CPT Codes	**82378**

Specimen Requirements	**1 mL (0.3 mL minimum) fluid collected in a sterile leak-proof container**
Reject Criteria	**Received room temperature; gross hemolysis; turbid samples**
Transport Temperature	**Frozen**
Specimen Stability	**Room temperature: 6 hours** **Refrigerated: 7 days** **Frozen: 30 days**
Set-up/Analytic Time	**Set up: Tues, Fri; Report available: 1-4 days**
Reference Range	**0-5 ng/mL**
Always Message	**This test was performed using FDA approved reagents. The analytical performance characteristics of this test for fluids (Pancreatic cyst) have been determined by Pan Laboratories, Irvine, CA. This test should not be the sole basis for diagnosis. Test result should be correlated with other medically established means (e.g) imaging, cytology.**
Methodology	**Immunochemiluminometric Assay (ICMA)**
Interface Mapping	

Result Code	Result Name	Unit of Measure
86010163	CEA,Pancreatic Cyst Fluid	ng/mL

FGF-23 (Fibroblast Growth Factor 23)	
Message	****This test is not available for New York patient testing. For New York patient testing, please refer to test code S52313- Fibroblast Growth Factor 23 (FGF23) (NY).*****
Effective Date	**1/12/2015**
Test Code	**91931**
CPT Codes	**83520**
Specimen Requirements	**1 mL (0.3 mL minimum) plasma collected in an EDTA (lavender-top) tube**
Reject Criteria	**Received room temperature**
Instructions	**Fasting specimen is preferred**
Transport Temperature	**Frozen**
Specimen Stability	**Room temperature: Unacceptable** **Refrigerated: 6 hours** **Frozen: 90 days**
Set-up/Analytic Time	**Set up: Mon; Report available: 1-3 days**
Reference Range	

Adults	**< 180**	**RU/mL**
Children (1 month to 17 years)	**<230**	**RU/mL**
Infants	**> 900**	**RU/mL**

Always Message	**This test was performed using a Research Use Only (RUO) kit that has not been cleared or approved by the FDA. The analytical performance characteristics of this test has been determined by Pan Laboratories, Irvine, CA. This test should not be used for diagnosis without confirmation by other medically established means.**
Methodology	**Enzyme Linked Immunosorbent Immunoassay**
Interface Mapping	

Result Code	Result Name	Unit of Measure

	86010161	**FGF 23**	**RU/mL**

Xpansion Interpreter®	
Effective Date	**1/19/2015**
Test Code	**92572**
CPT Codes	**81243**
Specimen Requirements	**3 mL whole blood collected in an EDTA (lavender-top) tube**
Reject Criteria	**Incorrect sample type; broken sample container; incomplete sample labeling; insufficient sample; male samples; female samples that have fewer than 45 repeats or more than 90 repeats**
Transport Temperature	**Refrigerated**
Specimen Stability	**Room temperature: 72 hours** **Refrigerated: 14 days** **Frozen: Unacceptable**
Set-up/Analytic Time	**9-11 business days after the patient's sample is received**
Methodology	**Polymerase Chain Reaction**
Interface Mapping	

Result Code	**Type**	**Result Name**
86011727	**Prompt-Result (no return)**	**Previous Fragile X Result**
86011728	**Prompt-Result (no return)**	**Family History of Fragile X**
86011540		**Result**