October 2012 - Monthly Update, Quest Diagnostics Nichols Institute, Valencia

Important Message!
In order to more explicitly define the limited role for food-allergen specific IgG antibody testing to promote appropriate utilization, we will be changing the report Always Message appended to each request for a test including a food-allergen specific IgG. The revised Always Message will read as follows:

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 Quest Diagnostics Nichols Institute, Valencia, CA. This test, and any food-specific allergen IgG result, should not be used for the diagnosis of allergic or atopic disease states (except for sensitivity to milk in neonates and gluten sensitivity). The use of food-specific allergen IgG results should be restricted to the assessment of response to therapeutic interventions.

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 #
90348	**Pain Management Profile 5 with Confirmation, Urine**	8/13/2012	3
90318	**Pain Management Profile 5 with Confirmation, without medMATCH, Urine**	8/13/2012	7
90347	**Pain Management Profile 5 without Confirmation, Urine**	8/13/2012	9
90321	**Pain Mgmt, Syn Stimulants Qn, W/medMATCH, U**	10/23/2012	10
90322	**Pain Mgmt, Syn Stimulants, Qn, U**	10/23/2012	11
16160	**AccuType® Warfarin**	10/30/2012	11
91126	**Chromosome Analysis, Tissue with Reflex to Microarray, ClariSure® Oligo-SNP**	10/30/2012	13
91283	**FISH, MET Amplification**	10/30/2012	14
35079	**Hereditary Hemochromatosis DNA Mutation Analysis**	10/30/2012	14
91278	**MDMA/MDA Screen with Confirmation, Urine**	11/5/2012	16
17161	**MDMA/MDA, Quantitative, Urine**	11/5/2012	16
38994	**Beta-2-Microglobulin, Random Urine with Creatinine**	11/19/2012	17
90376	***Aspergillus* Antigen, EIA, BAL**	11/26/2012	18

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 #
4458		Plasminogen Activity	9/4/2012	27
10596		HIV-1 RNA, Quantitative bDNA with Reflex to HIV-1 Genotype	11/5/2012	27
34471		HIV-1 RNA, Quantitative PCR w/Reflex to Genotype	11/5/2012	27
3121		CA 125	11/6/2012	28
5301C		Glucose, CSF	11/6/2012	28
S50989		Glucose, Synovial Fluid	11/6/2012	28
3352		HDL Cholesterol	11/6/2012	28
3454		Lipid Panel	11/6/2012	29
1324C		Protein, Total, CSF	11/6/2012	29
S52443		Aspirin Resistance (11-Dehydrothromboxane B2)	11/12/2012	29
S52553		Heparin Anti-Xa (Low Molecular Weight Heparin)	11/12/2012	29

S51587		Interleukin-6, Highly Sensitive ELISA	11/13/2012	29
3924		Testosterone, Free, Bioavailable and Total, LC/MS/MS	11/13/2012	29
3231		Testosterone, Total and Free and Sex Hormone Binding Globulin	11/13/2012	30
S50507		Vascular Endothelial Growth Factor (VEGF), ELISA	11/13/2012	30
4944	3143U	**Beta-2-Microglobulin, Random Urine**	11/19/2012	30
1530		**C1 Esterase Inhibitor, Protein**	11/19/2012	30
10124	1536	**Cardio CRP®**	11/19/2012	31
1516		Ceruloplasmin	11/19/2012	31
1517		Haptoglobin	11/19/2012	32
4988		**Myoglobin, Serum**	11/19/2012	32
4988UR		**Myoglobin, Urine**	11/19/2012	32
1549		Prealbumin	11/19/2012	33
1519		Transferrin	11/19/2012	33
S50346		**Hantavirus Antibodies (IgG, IgM) with Reflex to Confirmation**	11/26/2012	33

REDIRECTS
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 #
15340	1515	**Alpha-1-Antitrypsin (AAT) Mutation Analysis, Genotype**	10/30/2012	18
15538	5383	**Dihydropyrimidine Dehydrogenase (DPD) Gene Mutation Analysis**	10/30/2012	20
17900	1966	**Factor V (Leiden) Mutation Analysis**	10/30/2012	21
17911	4562	**Methylenetetrahydrofolate Reductase (MTHFR), DNA Mutation Analysis**	10/30/2012	22
11368	5375	**Plasminogen Activator Inhibitor-1 (PAI-1) 4G/5G**	10/30/2012	23
17909	5371	**Prothrombin (Factor II) 20210G>A Mutation Analysis**	10/30/2012	24
37742	5353	**Thiopurine S-Methyltransferase (TPMT) Genotype**	10/30/2012	25
17401	S51443	**C-Reactive Protein, High Sensitivity, CSF**	11/19/2012	26
14950	S51556	***Aspergillus* Antigen, EIA, Serum**	11/26/2012	27

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 #
1518	Alpha-1-Antitrypsin Deficiency Fetal Study w/reflex to MCC	10/30/2012	34
1515S	Alpha-1-Antitrypsin GenotypR™ - Saliva	10/30/2012	34
5383S	DPD 5-FU GenotypR™ - Saliva	10/30/2012	34
5371S	Factor II (Prothrombin) GenotypR™ - Saliva	10/30/2012	35
1966S	Factor V [Leiden] GenotypR™ - Saliva	10/30/2012	35
5369	Hemochromatosis GenotypR™	10/30/2012	35

5369S	Hemochromatosis GenotypR™ - Saliva	10/30/2012	35
4562S	MTHFR C677T/A1298C GenotypR™ Saliva	10/30/2012	35
5375S	Plasminogen Activator Inhibitor (PAI-1) GenotypR™ - Saliva	10/30/2012	35
5353S	TPMT GenotypR™ - Saliva	10/30/2012	35
5353SNY	TPMT GenotypR™ - Saliva [NY]	10/30/2012	36
5055S	Warfarin Sensitivity DetectR™ (VKORC1 and CYP 2C9) - Saliva	10/30/2012	36
5055	Warfarin Sensitivity DetectR™ (VKORC1 and CYP2C9)	10/30/2012	36
S51312	Corticotropin Releasing Hormone	11/5/2012	36
S51367	MDMA and Metabolite, Random Urine [17161X]	11/5/2012	36
2042	HE4 & CA 125	11/6/2012	36
S51684	FISH, Subtelomere Screen	11/12/2012	36
S51725	*Brucella* Antibodies (IgG, IgM) CSF	11/26/2012	36
S51520	Sars Coronavirus RNA, Qualitative RT-PCR	11/26/2012	37

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 #**
S41005		Calcium - Total, RBCs [0938R]	10/29/2012	37

New Test Offerings

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

Pain Management Profile 5 with Confirmation, Urine	
Clinical Significance	**This panel can be used to monitor patients currently prescribed pain medication for compliance to their drug therapy and to evaluate the possibility of illicit drug use.**
Effective Date	**8/13/2012**
Test Code	**90348**
CPT Codes	**80101 (x8) (HCPCS: G0434), 84311, 83986, 82570**
Specimen Requirements	**30 mL urine collected in a Clinical Drug Test Transport Vial**
Reject Criteria	**Preserved samples**
Transport Temperature	**Room temperature**
Specimen Stability	**Room temperature: 5 days** **Refrigerated: 7 days** **Frozen: 30 days**
Set-up/Analytic Time	**Set up: Mon-Sat; Report available: 1-2 days**
Reference Range	**Creatinine** — **> or = 20.0 mg/dL** **Specific Gravity** — **> or = 1.003** **pH** — **4.5-9.0** **Oxidant** — **<200 mcg/mL** **Amphetamines** — **<500 ng/mL**

Amphetamine	**<250 ng/mL**
Methamphetamine	**<250 ng/mL**
Barbiturates	**<300 ng/mL**
Amobarbital	**<100 ng/mL**
Butalbital	**<100 ng/mL**
Pentobarbital	**<100 ng/mL**
Phenobarbital	**<100 ng/mL**
Secobarbital	**<100 ng/mL**
Benzodiazepines	**<100 ng/mL**
Alphahydroxyalprazolam	**<50 ng/mL**
Alphahydroxytriazolam	**<50 ng/mL**
Lorazepam	**<50 ng/mL**
Midazolam	**<50 ng/mL**
Nordiazepam	**<50 ng/mL**
Oxazepam	**<50 ng/mL**
Marijuana Metabolite	**<20 ng/mL**
Marijuana Metabolite	**<5 ng/mL**
Cocaine Metabolite	**<150 ng/mL**
Benzoylecgonine	**<100 ng/mL**
Methadone	**<150 ng/mL**
EDDP	**<100 ng/mL**
Methadone	**<100 ng/mL**
Opiates	**<100 ng/mL**
Codeine	**<50 ng/mL**
Morphine	**<50 ng/mL**
Hydrocodone	**<50 ng/mL**
Hydromorphone	**<50 ng/mL**
Oxycodone	**<100 ng/mL**
Oxycodone	**<50 ng/mL**
Oxymorphone	**<50 ng/mL**

Methodology	**Screen: Immunoassay** **Confirm: Mass Spectrometry**
Performing Site	**Quest Diagnostics Nichols Institute, Valencia**

CPU Mappings

Result Code	Type	Result Name
82090100	**AOE**	**Prescribed Drug 1**

82090110	AOE	Prescribed Drug 2
82090120	AOE	Prescribed Drug 3
82090130	AOE	Prescribed Drug 4
82090140	AOE	Prescribed Drug 5
84002730		Creatinine
84002710		Specific Gravity
84002720		pH
84002740		Oxidant
84003615		Abnormal Spec. Validity:
82090191		Report Comments
82000000		Amphetamines
82000001		medMATCH Amphetamines
82000010		Amphetamine
82000011		medMATCH Amphetamine
82000020		Methamphetamine
82000021		medMATCH Methamphetamine
82000030		Barbiturates
82000031		medMATCH Barbiturates
82000040		Amobarbital
82000041		medMATCH Amobarbital
82000050		Butalbital
82000051		medMATCH Butalbital
82000060		Pentobarbital
82000061		medMATCH Pentobarbital
82000070		Phenobarbital
82000071		medMATCH Phenobarbital
82000080		Secobarbital
82000081		medMATCH Secobarbital
82000090		Benzodiazepines
82000091		medMATCH Benzodiazepines
82000130		Alphahydroxyalprazolam
82000131		medMATCH aOH alprazolam
82000150		Alphahydroxytriazolam
82000151		medMATCH aOH triazolam
82000120		Lorazepam
82000121		medMATCH Lorazepam

82000140		Midazolam
82000141		medMATCH Midazolam
82000100		Nordiazepam
82000101		medMATCH Nordiazepam
82000110		Oxazepam
82000111		medMATCH Oxazepam
82000158		Temazepam
82000159		medMATCH Temazepam
82000160		Marijuana Metabolite
82000161		medMATCH Marijuana Metabolite
82000170		Marijuana Metabolite
82000171		medMATCH Marijuana Metabolite
82000180		Cocaine Metabolite
82000181		medMATCH Cocaine Metabolite
82000190		Benzoylecgonine
82000191		medMATCH Benzoylecgonine
82000200		Methadone
82000201		medMATCH Methadone
82000210		EDDP
82000211		medMATCH EDDP
82000220		Methadone
82000221		medMATCH Methadone
82000230		Opiates
82000231		medMATCH Opiates
82000240		Codeine
82000241		medMATCH Codeine
82000250		Morphine
82000251		medMATCH Morphine
82000260		Hydrocodone
82000261		medMATCH Hydrocodone
82000270		Hydromorphone
82000271		medMATCH Hydromorphone
82000280		Oxycodone
82000281		medMATCH Oxycodone
82000290		Oxycodone
82000291		medMATCH Oxycodone

	82000300		**Oxymorphone**
	82000301		**medMATCH Oxymorphone**
Additional Information	All positive screens will have a quantitative confirmation performed at an additional charge. CPT coding varies by drugs confirmed. **medMATCH comments are:** • **present when drug test results may be the result of metabolism of one or more drugs or when results are inconsistent with prescribed medication(s) listed.** • **may be blank when drug results are consistent with prescribed medication(s) listed.**		

Pain Management Profile 5 with Confirmation, without medMATCH, Urine	
Clinical Significance	**This panel can be used to monitor patients currently prescribed pain medication for compliance to their drug therapy and to evaluate the possibility of illicit drug use.**
Effective Date	**8/13/2012**
Test Code	**90318**
CPT Codes	**80101 (x8) (HCPCS: G0434), 84311, 83986, 82570**
Specimen Requirements	**30 mL urine collected in a Clinical Drug Test Transport Vial**
Reject Criteria	**Preserved samples**
Transport Temperature	**Room temperature**
Specimen Stability	**Room temperature: 5 days** **Refrigerated: 7 days** **Frozen: 30 days**
Set-up/Analytic Time	**Set up: Mon-Sat; Report available: 1-2 days**
Reference Range	**Creatinine**: **> or = 20.0 mg/dL** **Specific Gravity**: **> or = 1.003** **pH: 4.5-9.0** **Oxidant**: **<200 mcg/mL** **Abnormal Specimen Validity Test:** **Report Comments**: **Amphetamines: <500 ng/mL** **Amphetamine: <250 ng/mL** **Methamphetamine**: **<250 ng/mL** **Barbiturates: <300 ng/mL** **Amobarbital: <100 ng/mL** **Butalbital: <100 ng/mL** **Pentobarbital**: **<100 ng/mL** **Phenobarbital: <100 ng/mL** **Secobarbital: <100 ng/mL** **Benzodiazepines**: **<100 ng/mL** **Alphahydroxyalprazolam**: **<50 ng/mL** **Alphahydroxytriazolam: <50 ng/mL** **Lorazepam: <50 ng/mL** **Midazolam: <50 ng/mL** **Nordiazepam: <50 ng/mL** **Oxazepam: <50 ng/mL** **Temazepam: <50 ng/mL** **Marijuana Metabolite**: **<20 ng/mL** **Marijuana Metabolite: <5 ng/mL** **Cocaine Metabolite: <150 ng/mL** **Benzoylecgonine: <100 ng/mL** **Methadone: <150 ng/mL** **EDDP: <100 ng/mL** **Methadone**: **<100 ng/mL** **Opiates: <100 ng/mL**

	Codeine: <50 ng/mL **Morphine: <50 ng/mL** **Hydrocodone**: **<50 ng/mL** **Hydromorphone**: **<50 ng/mL** **Oxycodone: <100 ng/mL** **Oxycodone: <50 ng/mL** **Oxymorphone: <50 ng/mL**
Methodology	**Screen: Immunoassay** **Confirm: Mass Spectrometry**
Performing Site	**Quest Diagnostics Nichols Institute, Valencia**
CPU Mappings	

Result Code	Result Name
84002730	Creatinine
84002710	Specific Gravity
84002720	pH
84002740	Oxidant
84003615	Abnormal Spec. Validity:
82090191	Report Comments
82000000	Amphetamines
82000010	Amphetamine
82000020	Methamphetamine
82000030	Barbiturates
82000040	Amobarbital
82000050	Butalbital
82000060	Pentobarbital
82000070	Phenobarbital
82000080	Secobarbital
82000090	Benzodiazepines
82000130	Alphahydroxyalprazolam
82000150	Alphahydroxytriazolam
82000120	Lorazepam
82000140	Midazolam
82000100	Nordiazepam
82000110	Oxazepam
82000158	Temazepam
82000160	Marijuana Metabolite
82000170	Marijuana Metabolite
82000180	Cocaine Metabolite
82000190	Benzoylecgonine
82000200	Methadone

82000210	EDDP
82000220	Methadone
82000230	Opiates
82000240	Codeine
82000250	Morphine
82000260	Hydrocodone
82000270	Hydromorphone
82000280	Oxycodone
82000290	Oxycodone
82000300	Oxymorphone

Additional Information	**All positive screens will have a quantitative confirmation performed at an additional charge. CPT coding varies by drugs confirmed.**

Pain Management Profile 5 without Confirmation, Urine	
Clinical Significance	**This panel can be used to monitor patients currently prescribed pain medication for compliance to their drug therapy and to evaluate the possibility of illicit drug use.**
Effective Date	**8/13/2012**
Test Code	**90347**
CPT Codes	**80101 (x8) (HCPCS: G0434), 84311, 83986, 82570**
Specimen Requirements	**30 mL urine collected in a Clinical Drug Test Transport Vial**
Reject Criteria	**Preserved samples**
Transport Temperature	**Room temperature**
Specimen Stability	**Room temperature: 5 days** **Refrigerated: 7 days** **Frozen: 30 days**
Set-up/Analytic Time	**Set up: Mon-Sat; Report available: 1-2 days**
Reference Range	**Creatinine: > or = 20.0 mg/dL** **Specific Gravity: > or = 1.003** **pH: 4.5-9.0** **Oxidant: <200 mcg/mL** **Abnormal Specimen Validity Test:** **Report Comments:** **Amphetamines: <500 ng/mL** **Barbiturates: <300 ng/mL** **Benzodiazepines: <100 ng/mL** **Marijuana Metabolite: <20 ng/mL** **Cocaine Metabolite: <150 ng/mL** **Methadone: <150 ng/mL** **Opiates: <100 ng/mL** **Oxycodone: <100 ng/mL**
Methodology	**Screen: Immunoassay**
Performing Site	**Quest Diagnostics Nichols Institute, Valencia**

CPU Mappings

Result Code	Result Name
84002730	Creatinine
84002710	Specific Gravity

84002720	pH
84002740	Oxidant
84003615	Abnormal Spec. Validity:
82090191	Report Comments
82000000	Amphetamines
82000030	Barbiturates
82000090	Benzodiazepines
82000160	Marijuana Metabolite
82000180	Cocaine Metabolite
82000200	Methadone
82000230	Opiates
82000280	Oxycodone

Additional Information	**Please read this important message:** **This drug screen is for medical use only. The results are presumptive; based only on screening methods, and they have not been confirmed by a second independent chemical method. These results should be used only by physicians to render diagnosis or treatment, or to monitor progress of medical conditions.**

Pain Mgmt, Syn Stimulants Qn, W/medMATCH, U	
Clinical Significance	**This test is utilized to detect the use of the compounds known as Bath Salts including mephedrone, MDPV, methylone, and butylone.**
Effective Date	**10/23/2012**
Test Code	**90321**
CPT Codes	**83789**
Specimen Requirements	**7.0 mL (3.0 mL) Random urine**
Reject Criteria	**Preserved Samples**
Transport Temperature	**Room temperature**
Specimen Stability	**Room temperature: 5 days** **Refrigerated: 14 days** **Frozen: 30 days**
Set-up/Analytic Time	**Set up: Tues, Thurs, Sat; Report available: 3-4 days**
Reference Range	**Mephedrone <50 ng/mL** **Methylone <50 ng/mL** **MDPV <50 ng/mL** **Butylone <50 ng/mL**
Always Message	**medMATCH comments are:** **- present when drug test results may be the result of metabolism of one or more drugs or when results are inconsistent with prescribed medication(s) listed.** **- may be blank when drug results are consistent with prescribed medication(s) listed.**
Methodology	**Liquid Chromatography Mass Spectrometry**
Performing Site	**Quest Diagnostics Nichols Institute, Valencia**

CPU Mappings

Result Code	Type	Result Name
82090100	AOE	Prescribed Drug 1
82090110	AOE	Prescribed Drug 2
82090120	AOE	Prescribed Drug 3
82090130	AOE	Prescribed Drug 4
82090140	AOE	Prescribed Drug 5
82090191		Report Comments
86008797		MDPV
86008801		medMATCH MDPV
86008798		Mephedrone
86008802		medMATCH Mephedrone
86008799		Methylone
86008803		medMATCH Methylone
86008800		Butylone
86008804		medMATCH Butylone

Pain Mgmt, Syn Stimulants, Qn, U

Clinical Significance	**This test is utilized to detect the use of the compounds known as Bath Salts including mephedrone, MDPV, methylone, and butylone.**
Effective Date	**10/23/2012**
Test Code	**90322**
CPT Codes	**83789**
Specimen Requirements	**7.0 mL (3.0 mL) Random urine**
Reject Criteria	**Preserved Samples**
Transport Temperature	**Room temperature**
Specimen Stability	**Room temperature: 5 days** **Refrigerated: 14 days** **Frozen: 30 days**
Set-up/Analytic Time	**Set up: Tues, Thurs, Sat; Report available: 3-4 days**
Reference Range	**Mephedrone <50 ng/mL** **MDPV <50 ng/mL** **Methylone <50 ng/mL** **Butylone <50 ng/mL**
Methodology	**Liquid Chromatography Mass Spectrometry**
Performing Site	**Quest Diagnostics Nichols Institute, Valencia**

CPU Mappings

Result Code	Result Name
82090191	Report Comments
86008797	MDPV
86008798	Mephedrone

86008799	**Methylone**
86008800	**Butylone**

AccuType® Warfarin	
Message	Suggested replacement for discontinued test 5055 Warfarin Sensitivity DetectR™ (VKORC1 and CYP2C9)
Clinical Significance	**Warfarin (Coumadin®) therapy is associated with significant complications because of its narrow therapeutic index and large interpatient dosage variation necessary to achieve an optimal therapeutic response. This variation is due to both genetic and environmental factors. A promoter variant (-1639 G>A) of the Vitamin K epoxide complex subunit 1 (VCR) accounts for 25%-44% of this variability and variants of the cytochrome P enzyme C (SPCA) account for 10%-15% of this variability. Identification of these warfarin sensitive variants of the VKORC1 and the CYP2C9 genes may allow a more individualized therapy and reduced risk of bleeding complications.**
Effective Date	**10/30/2012**
Test Code	**16160**
CPT Codes	**83891, 83896 (x5), 83900, 83901 (x4), 83909, 83912 or 81355, 81227*** ***The 2012 AMA CPT codebook contains Tier 1 and Tier 2 Molecular Pathology Procedures as well as Molecular Pathology Procedures to be coded by procedure rather than analyte. Please direct any questions regarding coding to the payor being billed.**
Specimen Requirements	**5 mL (3 mL) whole blood collected in an EDTA (lavender-top) tube or ACD solution A (yellow-top)** **Alternatives:** **Whole blood: Sodium heparin (royal blue-top), Sodium heparin (green-top), ACD solution B (yellow-top) , Lithium heparin (green-top), Saliva: 2 mL in Oragene DNA self-collection kit**
Transport Temperature	**Room temperature**
Specimen Stability	**Whole blood** **Room temperature: 8 Days** **Refrigerated: 8 Days** **Frozen: Unacceptable** **Saliva** **Room temperature: 14 Days** **Refrigerated: 14 Days** **Frozen: Unacceptable**
Set-up/Analytic Time	**Set up: Mon, Weds, Fri; Report available: 6 days**
Reference Range	**See Laboratory Report**
Always Message	**CYP2C9 and VKORC1:** **Warfarin (coumadin) therapy is associated with significant complications because of its narrow therapeutic index, and the large inter-patient variation in dosage required for an optimal therapeutic response. This variation is due to both genetic and environmental factors. Genetic factors include reduced activity variants of the Vitamin K Epoxide Reductase Complex subunit 1 (VKORC1) and Cytochrome P450 2C9 (CYP2C9) genes, which account for approximately 25%-44% and 10%-15% of the variability respectively. Identification of these VKORC1 and CYP2C9 variants could allow a more individualized course of therapy, and reduce the risk of bleeding complications.** **This assay detects the c.-1639G>A variant in the VKORC1 promoter, which leads African-Americans, and 90%-95% of Asians, carry at least one copy of the c.1639G>A allele.** **This assay also detects the four most common, CYP2C9 poor metabolizer variants (CYP2C9*2 (R144C), CYP2C9*3 (I359L), CYP2C9*5 (D360E) and CYP2C9*6 (818delA)). The wild-type allele of the CYP2C9 gene is designated CYP2C9*1. Approximately 33% of Caucasians, 3%-13% of Africans, and 2%-8% of Asians are positive for at least one of these CYP2C9 poor metabolizer variants.** **The VKORC1 and CYP2C9 gene variants described above are detected by polymerase chain reaction amplification of the appropriate regions of the VKORC1 (promoter region) and CYP2C9 (exons 3, 5, and 7) genes, allelic discrimination using a single nucleotide primer extension reaction, and detection of**

	fluorescent extension products on an automated DNA sequencer. **DNA-based testing is highly accurate, but rare false negative/false positive results may occur. Please contact the laboratory if you have questions about these test results. Since genetic variation and other problems can affect the accuracy of direct mutation testing, test results should always be interpreted in light of clinical and familial data.** **For assistance with the interpretation of these results, please contact your local Quest Diagnostics genetic counselor or call 1-866-GENEINFO (436-3463).** **This test was performed pursuant to a license agreement with Orchid Biosciences, Inc.** **This test was developed and its performance characteristics have been determined by Quest Diagnostics Nichols Institute, San Juan Capistrano. Performance characteristics refer to the analytical performance of the test.**
Methodology	**Single Nucleotide Primer Extension**
Assay Category	**Laboratory Developed Test**
Performing Site	**Quest Diagnostics Nichols Institute, San Juan Capistrano**
CPU Mappings	**Result Code** / **Result Name** **16160** / **CYP2C9 and VKORC1**
Additional Information	**Limitations:** **Variations in two genes (VKORC1 and CYP2C9) are particularly important in warfarin metabolism. VKORC1 may explain 30% of the variability in drug response between patients and changes in CYP2C9 may explain 10% of the dose variation. While significant portion of the dose variability can be accounted for by genetic factors, this testing will not determine all factors associated with dose variability.**

Chromosome Analysis, Tissue with Reflex to Microarray, ClariSure® Oligo-SNP	
Clinical Significance	**Women with recurrent spontaneous abortions are referred, along with their spouses, for genetic counseling and further studies. Approximately half of these abortions have cytogenetic abnormalities yet traditional cytogenetic preparations of products of conception have >20% failure rate. The chromosomal microarray analysis (CMA), a DNA-based analysis, rarely has assay failures and is more sensitive in the detection of abnormalities. This makes chromosomal microarray testing an excellent tool in the study of Products of Conception (POC).**
Effective Date	**10/30/2012**
Test Code	**91126**
CPT Codes	**88233, 88262**
Specimen Requirements	**2 x 3 mm fresh (unfixed) tissue** **Tissue sample minimum 2x3 mm in culture medium with antibiotics or in a sterile container with Hanks', Ringer's or saline solution. Refrigerated (DO NOT FREEZE).** **Specimen viability decreases during transit. Send specimen to testing lab for viability determination. Do not reject.**
Transport Temperature	**Refrigerated**
Specimen Stability	**See instructions**
Set-up/Analytic Time	**Set up: daily; Chromosome reports 14 days;** **Micro-array 10 days if needed**
Reference Range	**Accompanies report**
Methodology	**Culture, Microscopy, Karyotype (Reflexed: Oligo-SNP Array)**
Performing Site	**Quest Diagnostics Nichols Institute, San Juan Capistrano**
CPU Mappings	**Result Code** / **Type** / **Result Name** **85985470** / **Chromosome, Tissue**

	86007537	**AOE**	**Clinical Indication:**
	86007538	**AOE**	**Referring Physician:**
	86007468	**AOE**	**Physician's Phone Number:**
	86007469	**AOE**	**Client Accession #:**
	86007539	**AOE**	**Patient ID:**
	Reflex 91126-2 Reflex Chromosomal Microarray, POC, ClariSure(R) Oligo-SNP		
	Result Code	**Result Name**	
	86008377	**ClariSure OligoSNP, POC**	
Additional Information	**If Chromosome Analysis result is "Tissue has no growth", then Chromosomal Microarray, POC, ClariSure® Oligo-SNP will be performed at an additional charge (CPT code(s): 88386, 83891, 83892, 83898).**		

FISH, MET Amplification	
Clinical Significance	**The proto-oncogene MET (c-Met) product is the hepatocyte growth factor receptor and encodes tyrosine-kinase activity. Over-expression of MET has been observed in variety of neoplasms such as kidney, lung, head and neck, ovary, breast, thyroid, brain, stomach, pancreas and colon. MET gene amplification, detected by FISH, has been associated with an unfavorable prognosis in non-small cell lung cancer (NSCLC) and resistance to EGFR inhibitors.**
Effective Date	**10/30/2012**
Test Code	**91283**
CPT Codes	**88271 (x2), 88275**
Specimen Requirements	**Formalin fixed paraffin embedded tissue block** **Acceptable samples:** • **Bone marrow 1-3 mL in transport medium or sodium heparin (green-top) tube.** • **Whole blood 3-5 mL in sodium heparin (green-top) tube.** • **Tumor biopsy in tissue culture media.** • **4 charged/+slides from formalin fixed paraffin embedded tissue.** **Specimen MUST be fixed in 10% neutral buffered formalin. Fixation between 6 and 48 hours is recommended. Pathology report must accompany paraffin block or slides. Information required in this report include: Physician identification, specimen identifiers (case and block number), specimen site and type, tissue processing used (routine or microwave), type of fixative, time and duration of fixation, pathological diagnosis. Ship at room temperature. Do not freeze.** **Specimen viability decreases during transit. Send specimen to testing lab for viability determination. Do not reject**
Transport Temperature	**Room temperature**
Specimen Stability	**See Instructions**
Set-up/Analytic Time	**Set up: daily ; Report available: 7 days**
Reference Range	**Accompanies report**
Methodology	**Fluorescence In Situ Hybridization**
Performing Site	**Quest Diagnostics Nichols Institute, San Juan Capistrano**
CPU Mappings	

Result Code	**Type**	**Result Name**
86008845		**FISH, MET Amplification**
85997860	**AOE**	**Specimen Type/Source/Vol**
86007537	**AOE**	**Clinical Indication**

86007538	**AOE**	**Referring Physician**
85997863	**AOE**	**Referring Physician Phone**
85997864	**AOE**	**Client/Phone #**
86007469	**AOE**	**Client Accession #**
86007539	**AOE**	**Patient ID**

Hereditary Hemochromatosis DNA Mutation Analysis	
Message	Suggested replacement for discontinued test 5369 Hemochromatosis GenotypR™
Clinical Significance	**Hereditary Hemochromatosis is an autosomal recessive disease that results in an abnormal build-up of iron in the body. The C282Y and H63D are among the most common mutations in patients with hereditary hemochromatosis. Penetrance of the mutations (phenotypic disease), including by individuals with compound heterozygous mutations, is variable.**
Effective Date	**10/30/2012**
Test Code	**35079**
CPT Codes	**83891, 83892 (x2), 83900, 83909, 83912 or 81256*** ***The 2012 AMA CPT codebook contains Tier 1 and Tier 2 Molecular Pathology Procedures as well as Molecular Pathology Procedures to be coded by procedure rather than analyte. Please direct any questions regarding coding to the payor being billed.**
Specimen Requirements	**5 mL (3 mL) whole blood collected in an EDTA (lavender-top) tube** **Alternatives:** **EDTA (royal blue-top), sodium heparin (green-top) or ACD solution B (yellow-top) tube**
Reject Criteria	**Received frozen**
Transport Temperature	**Room temperature**
Specimen Stability	**Room temperature: 8 days** **Refrigerated: 8 days** **Frozen: Unacceptable**
Set-up/Analytic Time	**Set up: Mon-Sun; Report available: 5-7 days**
Reference Range	**See Laboratory Report**
Always Message	**DNA Mutation Analysis:** **Hereditary hemochromatosis (HH) is an autosomal recessive disorder of iron metabolism that results in iron overload and potential organ failure. It is one of the most common genetic disorders in individuals of European-Caucasian ancestry, with an estimated carrier frequency of 10%. HH is caused by mutations in the HFE gene. Most individuals with HH (60%-90%) are homozygous for the C282Y mutation. A smaller percentage of affected individuals are either compound heterozygous for the C282Y and H63D mutations (3%-8%), or homozygous for the H63D mutation (approximately 1%).** **This assay detects the two mutations in the HFE gene, C282Y (NM-000410.2:c.845G>A) and H63D (NM-000410.2: c.187C>G), that are commonly associated with HH. The mutations are detected by multiplex-polymerase chain reaction (PCR) amplification, followed by digestion of the amplification products with the restriction enzymes RsaI and NlaIII, for the detection of the C282Y and H63D mutations respectively. Fluorescent-labeled restriction fragments are detected by capillary electrophoresis.** **This assay does not detect other mutations in the HFE gene that can cause HH. Since genetic variation and other factors can affect the accuracy of direct mutation testing, these results should be interpreted in light of clinical and familial data.** **For assistance with the interpretation of these results, please contact your local Quest Diagnostics genetic counselor or call 1-866-GENEINFO (436-3463).** **This test was developed and its performance characteristics have been determined by Quest Diagnostics Nichols Institute, San Juan Capistrano. Performance characteristics refer to the analytical performance of**

	the test. **http://education.questdiagnostics.com/faq/hemochromatos**
Methodology	**Fluorescent Restriction Fragment Length Polymorphism, Polymerase Chain Reaction (PCR)**
Assay Category	**Laboratory Developed Test**
Performing Site	**Quest Diagnostics Nichols Institute, San Juan Capistrano**
CPU Mappings	**Result Code**: **85987560**; **Result Name**: **DNA Mutation Analysis**
Additional Information	**Limitations:** **Expression of C282Y/C282Y homozygosity is variable. Some individuals who fail to meet the diagnostic criteria for hemochromatosis are homozygous for the gene. If these mutations are not found by the testing procedure, it does not mean that the risk of carrying or developing HH is not present. It simply means that these specific mutations have not been found, although other mutations may be present. It is also possible that such a patient may have secondary hemochromatosis, due to nongenetic causes, that would not be detected by this test.**

MDMA/MDA Screen with Confirmation, Urine	
Clinical Significance	**This test is designed to detect the use of the stimulant/ hallucinogen methylenedioxymethamphetamine (MDMA, XTC, Ecstasy) and its metabolite methylenedioxyamphetamine (MDA).**
Effective Date	**11/5/2012**
Test Code	**91278**
CPT Codes	**80101**
Specimen Requirements	**20 mL random urine in a plastic leak proof container**
Transport Temperature	**Room temperature**
Specimen Stability	**Room temperature and Refrigerated: 14 days** **Frozen: 30 days**
Set-up/Analytic Time	**Set up: Tue-Sat; Report available: 3 days**
Reference Range	**Negative** **Cut-Off: 500 ng/mL**
Methodology	**Immunoassay**
Performing Site	**Quest Diagnostics Nichols Institute, Valencia**
CPU Mappings	**Result Code**: **86008842**; **Result Name**: **MDMA Screen**
Additional Information	**If Screen is positive, confirmation will be performed at an additional charge (CPT code(s): 82145).**

MDMA/MDA, Quantitative, Urine	
Clinical Significance	This test is designed to detect the use of the stimulant/ hallucinogen methylenedioxymethamphetamine (MDMA, XTC, Ecstasy) and its metabolite methylenedioxyamphetamine (MDA).
Effective Date	**11/5/2012**
Test Code	**17161**
CPT Codes	**82145**
Specimen Requirements	**20 mL random urine in a plastic leak proof container, no preservatives**

Reject Criteria	**Preserved urine**
Transport Temperature	**Refrigerated**
Specimen Stability	**Room temperature and Refrigerated: 14 days** **Frozen: 30 days**
Set-up/Analytic Time	**Set up: Tues, Thurs, Sat; Report available: 3 days**
Reference Range	**MDA: <200 ng/mL** **MDMA: <200 ng/mL** **MDEA: <200 ng/mL**
Methodology	**Mass Spectrometry**
Performing Site	**Quest Diagnostics Nichols Institute, Valencia**
CPU Mappings	

Result Code	Result Name
85996774	MDA
85996775	MDMA
85996776	MDEA

Beta-2-Microglobulin, Random Urine with Creatinine	
Clinical Significance	**Urinary Beta-2-Microglobulin is used as an indicator of renal impairment.**
Effective Date	**11/19/2012**
Test Code	**38994**
CPT Codes	**82232, 82570**
Specimen Requirements	**1 mL random urine in a plastic screw cap vial.** **Patient should void bladder, then drink at least 500 mL of water. A urine sample should be collected within 1 hour and pH adjusted to pH 6-8 with 1M NaOH. Beta-2-Microglobulin is unstable in acidic urine (less than pH 6).**
Instructions	**Beta-2-Microglobulin is unstable in acidic urine (less than pH 6)**
Transport Temperature	**Refrigerated (cold packs)**
Specimen Stability	**Room temperature: 8 hours** **Refrigerated: 7 days** **Frozen: 28 days**
Set-up/Analytic Time	**Set up: Mon-Sat; Report available: 1-3 days**
Reference Range	

B2 Microglobulin/Creatinine Ratio	**≤132 mcg/g creat**
Creatinine, Random Urine:	
0-6 months	**2-32 mg/dL**
7-11 months	**2-36 mg/dL**
1-2 years	**2-128 mg/dL**
3-8 years	**2-149 mg/dL**
9-12 years	**2-183 mg/dL**
>12 years	
Male:	**20-370 mg/dL**

	Female: **20-320 mg/dL**
Units Of Measure	**B2 Microglobulin/Creatinine Ratio mcg/g creat** **Creatinine, Random Urine: mg/dL**
Methodology	**Fixed Rate Time Nephelometry**
Performing Site	**Quest Diagnostics Nichols Institute, Valencia**
CPU Mappings	**Result Code** / **Result Name** **45030600** / **B2 Microglobulin/g Creat** **25026500** / **Creatinine, Random Urine**

***Aspergillus* Antigen, EIA, BAL**	
Clinical Significance	**Invasive pulmonary aspergillosis has become one of the most common fungal pulmonary diseases in certain immunocompromised patients. Medical interventions that predispose patients to invasive aspergillosis include treatment with immunosuppressive drugs, radiation, and high doses of corticosteroids, among others.**
Effective Date	**11/26/2012**
Test Code	**90376**
CPT Codes	**87305**
Specimen Requirements	**2 mL bronchoalveolar lavage in a sterile leak proof container**
Transport Temperature	**Frozen**
Specimen Stability	**Room temperature: Unacceptable** **Refrigerated: 5 days unopened** **Frozen: 5 months**
Set-up/Analytic Time	**Set up: Tues, Fri; Report available: 1-4 days**
Reference Range	**<0.50, Not Detected**
Always Message	**REFERENCE RANGE: <0.5, NOT DETECTED** **A negative result does not exclude invasive aspergillosis. Follow-up testing may be indicated for high-risk patients.**
Methodology	**Immunoassay**
Performing Site	**Focus Diagnostics, Inc.**
CPU Mappings	**Result Code** / **Result Name** **86008876** / **Index Value** **86007511** / **Aspergillus Ag, EIA, BAL**

Redirects

Alpha-1-Antitrypsin (AAT) Mutation Analysis, Genotype	
Clinical Significance	**Individuals who carry two copies (homozygous) for the Z allele are at a higher risk to develop liver disease and emphysema.**
Effective Date	**10/30/2012**

Former Test Name	*Alpha-1-Antitrypsin GenotypR™*
Former Test Code	*1515*
Test Code	**15340**
CPT Codes	83891, 83892 (x2), 83900, 83909, 83912 or 81332* *The 2012 AMA CPT codebook contains Tier 1 and Tier 2 Molecular Pathology Procedures as well as Molecular Pathology Procedures to be coded by procedure rather than analyte. Please direct any questions regarding coding to the payor being billed.
Specimen Requirements	5 mL **(2 mL)** whole blood collected in an EDTA (lavender-top) tube Alternatives: Set up: Mon, Wed, Fri; Report available: 4-5 days Whole blood collected in EDTA (royal blue-top), Sodium heparin (green-top), Lithium heparin (green-top), ACD solution B (yellow-top) or ACD solution A (yellow-top), Extracted DNA
Transport Temperature	Room temperature
Specimen Stability	**Room temperature: 8 days** **Refrigerated: 8 days** **Frozen: Unacceptable**
Set-up/Analytic Time	**Set up: Mon, Wed, Fri; Report available: 4-5 days**
Reference Range	See Laboratory Report
Always Message	**A-1 Antitrypsin Mutation:** **Alpha-1-antitrypsin deficiency is a relatively common autosomal recessive condition. The two most common deficiency alleles in the alpha-1-antitrypsin gene (protease inhibitor locus, PI) are designated PI*Z and PI*S, and the normal allele is designated PI*M. The PI*Z/PI*Z, PI*S/PI*Z, and PI*S/PI*S genotypes associated with decreased serum PI levels that are equivalent to approximately 10-20%, 35-40%, and 50-60% of normal, respectively. The PI*Z/PI*Z and PI*S/PI*Z genotypes are reported to be associated with an increased risk of liver disease in childhood, and chronic obstructive pulmonary disease (COPD) and emphysema in adult life. The PI*M/PI*Z, and PI*M/PI*S genotypes are also associated with decreased serum PI levels but these levels, and the PI levels associated with the PI*S/PI*S genotype, are apparently adequate to protect the lungs in the vast majority of individuals. Individuals with the PI*M/PI*Z genotype may have decreased pulmonary function, and may be at increased risk for COPD, especially if they smoke.** **It should be noted that serum alpha-1-antitrypsin levels can be induced by a wide variety of conditions that include pregnancy, infection, numerous inflammatory conditions, cancer, and liver disease. Levels of alpha-1-antitrypsin may be reduced by other conditions. Therefore, immunological and functional determinations of serum alpha-1-antitrypsin levels may not correlate with the individual's PI genotype.** **The PI*Z, PI*S, and PI*M alleles are detected by multiplex polymerase chain reaction (PCR) amplification of specific regions of the PI gene, followed by restriction enzyme digestion and capillary electrophoresis. This assay does not test for the presence of other mutations within the alpha-1-antitrypsin gene or non-genetic causes of alpha-1-antitrypsin deficiency. Since genetic variation and other factors can affect the accuracy of direct mutation testing, these results should be interpreted in light of clinical and familial data.** **This test was developed and its performance characteristics have been determined by Quest Diagnostics Nichols Institute, San Juan Capistrano.**
Methodology	**Fluorescent Restriction Fragment Length Polymorphism**
Assay Category	Laboratory Developed Test
Performing Site	**Quest Diagnostics Nichols Institute, San Juan Capistrano**
CPU Mappings	**Result Code** / **Type** / **Result Name** **3837** / / **A-1 Antitrypsin Mutation**

	26870	**AOE**	**Clinical Indication**
	21238	**AOE**	**Referring Physician**
	26760	**AOE**	**Physician's Phone Number**

Additional Information	**Limitations:** **Rare alleles (other than S and Z types) are not tested for by this assay.**

Dihydropyrimidine Dehydrogenase (DPD) Gene Mutation Analysis	
Clinical Significance	**Partial or complete deficiency of DPD activity has been associated with an increased risk for severe adverse reactions when treated with pyrimidine-based chemotherapeutic agents, such as 5-fluorouracil (5-FU). The test can also be used to confirm the clinical diagnosis of dihydropyrimidine dehydrogenase (DPD) deficiency in affected patients and for the detection of the IVS14+1G>A mutation in asymptomatic carriers.**
Effective Date	**10/30/2012**
Former Test Name	*DPD 5-FU GenotypR™*
Former Test Code	*5383*
Test Code	**15538**
CPT Codes	**83891, 83892 (x3), 83898, 83909, 83912, 83914 or 81400*** ***The 2012 AMA CPT codebook contains Tier 1 and Tier 2 Molecular Pathology Procedures as well as Molecular Pathology Procedures to be coded by procedure rather than analyte. Please direct any questions regarding coding to the payor being billed.**
Specimen Requirements	5 mL (3 mL) whole blood collected in EDTA (lavender-top) or ACD solution B (yellow-top) tube Alternatives: ACD solution A (yellow-top) ,Lithium heparin (green-top) , Sodium heparin (green-top)
Transport Temperature	Room temperature
Specimen Stability	**Room temperature: 8 days** **Refrigerated: 8 days** **Frozen: Do Not Freeze**
Set-up/Analytic Time	**Set up: Mon, Thurs: Report available: 5-6 days**
Reference Range	See Laboratory Report
Always Message	**DPD Gene Mutation:** **Dihydropyrimidine dehydrogenase (DPD) is the rate-limiting enzyme in the pathway for the degradation of the pyrimidine bases, uracil and thymine. DPD also catalyzes the detoxification of pyrimidine-based chemotherapeutic agents (e.g. 5-fluorouracil (5-FU) and capecitabine). Decreased DPD activity is associated with severe myelosuppression or even lethal toxicity, in patients treated with standard doses of 5-FU. DPD deficiency is associated with congenital thymine-uraciluria, an autosomal recessive condition characterized by convulsive disorders, microcephaly, and mental retardation. The IVS14+1G>A mutation in the splice-donor site of intron 14 of the DPD gene (located on chromosome 1) accounts for approximately 50% of DPD deficiency alleles.** **The IVS14+1G>A mutation is detected by polymerase chain reaction (PCR) amplification of a portion of the DPD gene, followed by a single nucleotide primer extension reaction using fluorescent dideoxynucleotides, and detection of the fluorescent reaction products using an automated, capillary DNA sequencer. Since genetic variation and other problems can affect the accuracy of the direct mutation testing, these results should always be interpreted in light of clinical and familial data. For assistance with the interpretation of these results, please contact your local Quest Diagnostics genetic counselor or call 1-866-GENEINFO (436-3463).** **This test is performed pursuant to a license agreement with Orchid Biosciences Inc.** **This test was developed and its performance characteristics have been determined by Quest Diagnostics Nichols Institute, San Juan Capistrano. Performance characteristics refer to the analytical performance of the test.**

Methodology	**Polymerase Chain Reaction (PCR), Single Nucleotide Primer Extension**
Assay Category	Laboratory Developed Test
Performing Site	**Quest Diagnostics Nichols Institute, San Juan Capistrano**
CPU Mappings	**Result Code** / **Type** / **Result Name** **3446** / / **DPD Gene Mutation** **26811** / **AOE** / **Referring Physician:** **26812** / **AOE** / **Physician's Phone Number:**
Additional Information	**Limitations:** **The test identifies the IVS14+1G>A mutation, which accounts for approximately 50% of DPD deficiency alleles. Individuals with one copy of the IVS14+1G>A mutation are predicted to have significant side effects when treated with standard doses of 5-FU and caution should be taken when treating with any pyrimidine based therapy. This test does not detect other variations or mutations in the DPD gene which may impair 5-FU or pyrimidine based therapy metabolism and detoxification, nor does it examine other genetic or non-genetic modifiers of DPD metabolism.**

Factor V (Leiden) Mutation Analysis	
Clinical Significance	**Factor V (Leiden) Mutation is a point mutation that causes resistance of Factor V protein degradation by activated protein C (APC). This mutation is associated with increased risk of venous thrombosis.**
Effective Date	**10/30/2012**
Former Test Name	*Factor V [Leiden] GenotypR™*
Former Test Code	*1966*
Test Code	**17900**
CPT Codes	**83891, 83898, 83909, 83912, 83914 or 81241*** ***The 2012 AMA CPT codebook contains Tier 1 and Tier 2 Molecular Pathology Procedures as well as Molecular Pathology Procedures to be coded by procedure rather than analyte. Please direct any questions regarding coding to the payor being billed.**
Specimen Requirements	5 mL (3 mL) whole blood collected in an EDTA (lavender-top) tube Alternatives: Whole blood collected in: EDTA (royal blue-top), sodium heparin (green-top), ACD solution A or B (yellow-top), or lithium heparin (green-top), Extracted DNA
Transport Temperature	Room temperature
Specimen Stability	**Room temperature: 8 days** **Refrigerated: 8 days** **Frozen: Unacceptable**
Set-up/Analytic Time	**Set up: Mon-Sun; Report available: in 5 days**
Reference Range	See Laboratory Report
Always Message	**This test was developed and its performance characteristics have been determined by Quest Diagnostics Nichols Institute, San Juan Capistrano.** **It has not been cleared or approved by the U.S. Food and Drug Administration. The FDA has determined that such clearance or approval is not necessary. Performance characteristics refer to the analytical performance of the test.**
Methodology	**Fluorescent Microspheres, Oligonucleotide Ligation Assay, Polymerase Chain Reaction (PCR)**
Assay Category	ASR Class I

Performing Site	**Quest Diagnostics Nichols Institute, San Juan Capistrano**
CPU Mappings	**Result Code** / **Result Name** **5062** — **Mutation Analysis** **29246** — **Shared Assay Components**

Methylenetetrahydrofolate Reductase (MTHFR), DNA Mutation Analysis	
Clinical Significance	**The Methylenetetrahydrofolate Reductase (MTHFR) enzyme plays a major role in homocysteine metabolism and contains several known polymorphisms, of which the most common is C677T. This mutation is reported to reduce MTHFR activity, resulting in hyperhomocysteinemia. This condition is a risk factor for cardiovascular disease, increased risk for arterial and venous thrombosis, and an increased risk for obstetrical complications, e.g., preeclampsia, abruptio placentae, fetal growth retardation, and stillbirth.**
Effective Date	**10/30/2012**
Former Test Name	*MTHFR C677T/A1298C GenotypR™*
Former Test Code	*4562*
Test Code	**17911**
CPT Codes	**83891, 83900, 83909, 83912, 83914 (x2) or 81291*** ***The 2012 AMA CPT codebook contains Tier 1 and Tier 2 Molecular Pathology Procedures as well as Molecular Pathology Procedures to be coded by procedure rather than analyte. Please direct any questions regarding coding to the payor being billed.**
Specimen Requirements	5 mL (3 mL) whole blood collected in an EDTA (lavender-top) tube Alternatives: Whole blood collected in: EDTA (royal blue-top), sodium heparin (green-top), ACD-A (yellow-top), ACD-B (yellow-top) or lithium heparin (green-top) tube, **Amniotic fluid, Amniocyte culture, Dissected chorionic villus (CVS)**
Instructions	**Whole blood (preferred):** Normal phlebotomy procedure. Specimen stability is crucial. Store and ship room temperature immediately. **Do not freeze.** For prenatal diagnosis with a fetal specimen: 1) parents must be documented carriers of one of the mutations tested; 2) maternal blood or DNA must be available; 3) contact the laboratory genetic counselor before submission. **Amniotic fluid (acceptable):** Normal collection procedure. Specimen stability is crucial. Store and ship room temperature immediately. **Do not refrigerate or freeze.** **Amniocyte culture (acceptable):** Sterile T25 flask, filled with culture medium. Specimen stability is crucial. Store and ship room temperature immediately. **Do not refrigerate or freeze.** **Dissected chorionic villus (CVS) biopsy (acceptable):** 10-20 mg dissected chorionic villi collected in sterile tube filled with sterile culture media. Specimen stability is crucial. Store and ship room temperature immediately. **Do not refrigerate or freeze.**
Transport Temperature	Room temperature
Specimen Stability	**Room temperature: 8 days** **Refrigerated: 8 days** **Frozen: Unacceptable**
Set-up/Analytic Time	**Set up: Mon-Sun; Report available: 6-7 days**
Reference Range	See Laboratory Report
Always Message	**This test was developed and its performance characteristics have been determined by Quest Diagnostics Nichols Institute, San Juan Capistrano. It has not been cleared or approved by the U.S. Food and Drug Administration. The FDA has determined that such clearance or approval is not necessary. Performance characteristics refer to the analytical performance of the test.**

Methodology	**Fluorescent Microspheres, Oligonucleotide Ligation Assay, Polymerase Chain Reaction (PCR)**
Assay Category	ASR Class I
Performing Site	**Quest Diagnostics Nichols Institute, San Juan Capistrano**
CPU Mappings	**Result Code**: **22327** — **Result Name**: **DNA Mutation Analysis**
Additional Information	**Limitations:** **The purpose of this test is to determine if you have two, one, or no copies of either of two mutations in the MTHFR gene, C677T and A1298C.**

Plasminogen Activator Inhibitor-1 (PAI-1) 4G/5G	
Clinical Significance	**The 4G allele of a recently described common guanine insertion/deletion polymorphism (4G/5G) in the PAI-1 gene promoter region is associated with higher plasma plasminogen activator inhibitor (PAI-1) activity. When PAI-1 is high, fibrinolytic activity is depressed, and there is increased risk for arterial and venous thrombosis. PAI-1 is also a significant risk factor for coronary artery disease, myocardial infarction and recurrent spontaneous abortion.**
Effective Date	**10/30/2012**
Former Test Name	*Plasminogen Activator Inhibitor (PAI-1) GenotypR™*
Former Test Code	*5375*
Test Code	**11368**
CPT Codes	**83891, 83900, 83909, 83912 or 81400*** ***The 2012 AMA CPT codebook contains Tier 1 and Tier 2 Molecular Pathology Procedures as well as Molecular Pathology Procedures to be coded by procedure rather than analyte. Please direct any questions regarding coding to the payor being billed.**
Specimen Requirements	5 mL (3 mL) whole blood collected in EDTA (lavender-top) tube Alternatives: Whole blood collected in ACD solution B (yellow-top), EDTA (royal blue-top), sodium heparin (green-top), lithium heparin (green-top) or ACD solution A (yellow-top) tube , **100 ng Extracted DNA (Reference ranges do not apply), Bone marrow or Fresh (unfixed) tissue or Tissue biopsy**
Transport Temperature	Room temperature
Specimen Stability	**Room temperature: 8 days** **Refrigerated: 8 days** **Frozen: Unacceptable**
Set-up/Analytic Time	**Set up: Weds, Sat; Report available: 5 days**
Reference Range	See Laboratory Report
Always Message	**PAI-1 4G/5G Polymorphism: NEGATIVE** **The 4G variant (AF386492.2:g.837del) in the promoter of the PAI-1 (SERPINE 1) gene is associated with an increase in the level of PAI-1 in plasma, relative to that associated with the normal 5G variant. Increased plasma PAI-1 activity may increase the risk for venous thrombosis and myocardial infarction, especially in the presence of other thrombophilic risk factors.** **METHODOLOGY: The 4G/5G variants in the promoter of the PAI-1 gene are detected by Fluorescent PCR amplification and capillary electrophoresis of the products. Since genetic variation and other factors can affect the accuracy of direct mutation testing, these results should be interpreted in light of clinical and familial data.** **For assistance with the interpretation of these results, please contact your local Quest Diagnostics genetic counselor or call 1-866-GENEINFO (436-3463).**

	This test was developed and its performance characteristics have been determined by Quest Diagnostics Nichols Institute, San Juan Capistrano. Performance characteristics refer to the analytical performance of the test.
Methodology	**Polymerase Chain Reaction (PCR), Single Nucleotide Primer Extension**
Assay Category	Laboratory Developed Test
Performing Site	**Quest Diagnostics Nichols Institute, San Juan Capistrano**
CPU Mappings	**Result Code: 85996835 — Result Name: PAI-1 4G/5G Polymorphism**

Prothrombin (Factor II) 20210G>A Mutation Analysis	
Clinical Significance	**Factor II Mutation (G20210A) is one of the most common causes of venous thrombosis. 2.3% of the general population is heterozygous in contrast with 6.2% of patients with venous thrombosis and 18% with familial venous thrombosis. Other risk factors compound the risk for venous thrombosis.**
Effective Date	**10/30/2012**
Former Test Name	*Factor II (Prothrombin) GenotypR™*
Former Test Code	*5371*
Test Code	**17909**
CPT Codes	**83891, 83898, 83909, 83912, 83914 or 81240*** ***The 2012 AMA CPT codebook contains Tier 1 and Tier 2 Molecular Pathology Procedures as well as Molecular Pathology Procedures to be coded by procedure rather than analyte. Please direct any questions regarding coding to the payor being billed.**
Specimen Requirements	5 mL (3 mL) whole blood collected in EDTA (lavender-top) tub Alternatives: Whole blood collected in EDTA (royal blue-top), sodium heparin (green-top), ACD solution A (yellow-top), ACD solution B (yellow-top) **or** lithium heparin (green-top), **100 ng Extracted DNA**
Transport Temperature	Room temperature
Specimen Stability	**Room temperature: 8 days** **Refrigerated: 8 days** **Frozen: Unacceptable**
Set-up/Analytic Time	**Set up: Mon-Sun; Report available: 6 days**
Reference Range	See Laboratory Report
Always Message	**This test was developed and its performance characteristics have been determined by Quest Diagnostics Nichols Institute, San Juan Capistrano.** **It has not been cleared or approved by the U.S. Food and Drug Administration. The FDA has determined that such clearance or approval is not necessary. Performance characteristics refer to the analytical performance of the test.**
Methodology	**Polymerase Chain Reaction (PCR), Oligonucleotide Ligation Assay, Fluorescent Microspheres**
Assay Category	**ASR Class I**
Performing Site	**Quest Diagnostics Nichols Institute, San Juan Capistrano**
CPU Mappings	**Result Code: 5661 — Result Name: Prothrombin Gene Analysis** **Result Code: 29248 — Result Name: Shared Assay Components**

Additional Information	**Limitations: If this mutation is not found by the testing procedure, it does not mean that the risk of carrying or developing deep vein thrombosis is not present. It simply means that this specific mutation has not been found, although other mutations may be present. It is also possible that such a patient may have secondary deep vein thrombosis due to non-genetic causes that would not be detected by this test. A person with one copy of the mutation has an approximate 3-fold increase in risk for venous thrombosis. The increase in risk for a person with two copies of the mutation is not known.**

Thiopurine S-Methyltransferase (TPMT) Genotype	
Clinical Significance	**This test detects common deficiency variants in the TPMT gene and therefore identifies individuals who are at risk of developing serious adverse effects when administered thiopurine drugs.**
Effective Date	**10/30/2012**
Former Test Name	*TPMT GenotypR™*
Former Test Code	*5353*
Test Code	**37742**
CPT Codes	**83890, 83892 (x2), 83896 (x4), 83900, 83912 or 81401*** ***The 2012 AMA CPT codebook contains Tier 1 and Tier 2 Molecular Pathology Procedures as well as Molecular Pathology Procedures to be coded by procedure rather than analyte. Please direct any questions regarding coding to the payor being billed.**
Transport Temperature	Room temperature
Specimen Stability	**Room temperature: 8 days** **Refrigerated: 8 days** **Frozen: Unacceptable**
Set-up/Analytic Time	**Set up: Mon, Thurs; Report available: 5-6 days**
Reference Range	See Laboratory Report
Always Message	**TPMT Genotype:** **Thiopurine S-methyltranferase (TPMT) is an enzyme involved in the metabolism of drugs such as azathioprine and 6- mercaptopurine. Deficiency of TPMT activity is caused by mutations in the TPMT gene on chromosome 6. This test detects the wild type (TPMT*1) and the four most common deficiency variants [TPMT*2 (238G>C in exon 5), TPMT*3A (460G>A in exon 7 and 719A>G in exon 10), TPMT*3B (460G>A) and TPMT*3C (719A>G in exon 10)]. Approximately 10% of the African-American and Caucasian populations carry one of these four deficiency alleles.** **The mutations are detected by multiplex amplification of exons 5, 7, and 10 of the TPMT gene by polymerase chain reaction (PCR), followed by single-nucleotide primer extension reactions. The biotinylated extension products are then hybridized on microspheres and detected by the identity of the microspheres as well as the reporter fluorescence. DNA-based testing is highly accurate, but rare false negative/ false positive results may occur. Please contact the laboratory if you have questions about these results.** **Since genetic variation and other problems can affect the accuracy of direct mutation testing, the results should always be interpreted in light of clinical and familial data.** **This test was developed and its performance characteristics have been determined by Quest Diagnostics Nichols Institute, San Juan Capistrano. Performance characteristics refer to the analytical performance of the test.**
Methodology	**Polymerase Chain Reaction (PCR), Single Nucleotide Primer Extension**
Assay Category	Laboratory Developed Test
Performing Site	**Quest Diagnostics Nichols Institute, San Juan Capistrano**
CPU Mappings	

Result Code	Type	Result Name
4232		TPMT Genotype
24715	AOE	Ethnicity

	27773 AOE Clinical Indication 27774 AOE Referring Physician 27775 AOE Physician's Phone Number
Additional Information	**Limitations:** **This test detects 95% of the mutations in the TPMT gene and thus not all intermediate or slow metabolizers will be identified.**

C-Reactive Protein, High Sensitivity, CSF	
Effective Date	**11/19/2012**
Former Test Name	*C-reactive Protein (CRP), Highly Sensitive, CSF [17401X]*
Former Test Code	*S51443*
Test Code	**17401**
Set-up/Analytic Time	**Set up: Mon-Fri; Report available: next day**
Reference Range	**< or = 0.3 mg/L**
Performing Site	**This test previously performed at Quest Diagnostics Nichols Institute, San Juan Capistrano will now be performed at Quest Diagnostics Nichols Institute, Chantilly**
CPU Mappings	**Result Code** / **Result Name** **86001101** / **CRP, Highly Sensitive,CSF**

***Aspergillus* Antigen, EIA, Serum**	
Effective Date	**11/26/2012**
Former Test Name	*Aspergillus Antigen [14950Z]*
Former Test Code	*S51556*
Test Code	**14950**
Transport Temperature	**Frozen: < or = -70°C dry ice**
Specimen Stability	**Room temperature: Unacceptable** **Refrigerated: 5 days** **Frozen -70°C: 5 months**
Reference Range	**<0.50 Not Detected**
Performing Site	**Quest Diagnostics Nichols Institute, Valencia currently sends the test to Chantilly and will redirect the test to Focus, beginning 11/26/12.**
CPU Mappings	**Result Code** / **Result Name** **86008879** / **Index Value** **86002336** / **Aspergillus AG, EIA, Ser**

Test Changes

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

Plasminogen Activity	
Effective Date	**9/4/2012**
Test Code	4458
Set-up/Analytic Time	**Set up: Wed; Report available: Fri**

HIV-1 RNA, Quantitative bDNA with Reflex to HIV-1 Genotype	
Effective Date	**11/5/2012**
Test Code	10596
CPU Mappings	

Result Code	**Result Name**
70043600	**HIV-1 RNA, QN BDNA (V3.0)**
70011110	**HIV-1 RNA, QN BDNA (V3.0)**
Reflex: 10596-2 Reflex HIV-1 Genotype	
Result Code	**Result Name**
86007864	**HIV-1 Genotype**

HIV-1 RNA, Quantitative PCR w/Reflex to Genotype	
Effective Date	**11/5/2012**
Test Code	34471
Reject Criteria	Specimen collected using heparin as anticoagulant; Leaking, uncapped or broken containers.; Frozen plasma received in PPT
CPU Mappings	

Result Code	**Result Name**
70011130	**HIV-1 RNA, QN PCR**
70011135	**HIV-1 RNA, QN PCR**
Reflex 34471-2 Reflex HIV-1 Genotype	
Result Code	**Result Name**
86007864	**HIV-1 Genotype**

CA 125	
Effective Date	**11/6/2012**
Test Code	3121
Reference Range	**< 21 (Change to reporting in whole numbers)**
Tests Affected	

Test Codes:	**Name:**
3121SR	CA 125 w/Serial Reporting

Glucose, CSF	
Effective Date	**11/6/2012**
Test Code	5301C
Transport Temperature	**Frozen**
Specimen Stability	**Room temperature: Unacceptable**

	Refrigerated: 14 days **Frozen: 28 days**
Methodology	**Spectrophotometry**

Glucose, Synovial Fluid	
Effective Date	**11/6/2012**
Test Code	S50989
Reference Range	**Report message: Synovial fluid glucose values are equivalent to plasma values if obtained from a fasting patient. The difference between the plasma glucose and synovial fluid glucose value should be <10 mg/dL.**

HDL Cholesterol	
Effective Date	**11/6/2012**
Former Test Name	*Cholesterol, HDL*
Test Code	3352
Specimen Requirements	**Replace with: Patient preparation: If an HDL measurement is to be performed along with Triglycerides, the patient should be fasting 9-12 hours prior to collection.**
Reject Criteria	Anticoagulants other than heparin
Transport Temperature	Room temperature
Specimen Stability	Room temperature: 48 hours Refrigerated: 7 days **Frozen: 15 days**
Tests Affected	**Test Codes:** / **Name:** 91247 — Lipid Panel, Non-Fasting w/o Triglycerides 3454 — Lipid Panel

Lipid Panel	
Effective Date	**11/6/2012**
Test Code	3454
Reference Range	All reference ranges remain the same except non-HDL Cholesterol: **<20 yrs : <120 mg/dL** > or = 20 yrs: Target for non-HDL cholesterol is 30 mg/dL higher than LDL cholesterol target.
Tests Affected	**Test Codes:** / **Name:** 91247 — Lipid Panel, Non-Fasting w/o Triglycerides

Protein, Total, CSF	
Effective Date	**11/6/2012**
Test Code	1324C
Transport Temperature	Refrigerated
Specimen Stability	**Room temperature: 7 days** Refrigerated: 7 days **Frozen: 28 days**
Methodology	**Spectrophotometry**

Aspirin Resistance (11-Dehydrothromboxane B2)	
Effective Date	**11/12/2012**
Test Code	S52443
Reject Criteria	**Excessive sediment, blood, insoluble materials.**
Instructions	Recommend using BD C&S Vacutainer tube for collection. If urine is not collected in this tube, it must be poured off into this tube within 4 hours of collection. **It is not recommended to test individuals suffering from urinary tract infections, severe liver disease, or end stage renal disease.**

Heparin Anti-Xa (Low Molecular Weight Heparin)	
Effective Date	**11/12/2012**
Test Code	S52553
Units Of Measure	**IU/mL**

Interleukin-6, Highly Sensitive ELISA	
Effective Date	**11/13/2012**
Test Code	S51587
Specimen Requirements	1 mL plasma collected in EDTA (lavender-top) tube
Reject Criteria	Received room temperature; received refrigerated; **serum separator tube; Gross or moderate hemolysis; lipemia; icteric samples are unacceptable**

Testosterone, Free, Bioavailable and Total, LC/MS/MS	
Effective Date	**11/13/2012**
Test Code	3924
Specimen Requirements	**Sodium heparin plasma is no longer acceptable**
Specimen Stability	**Frozen: 60 days**
Set-up/Analytic Time	**Set up: Sun-Sat; Report available: 1-3 days**
Tests Affected	**Test Codes:** 14966X — **Name:** Testosterone, Free, Bioavailable and Total, LC/MS/MS

Testosterone, Total and Free and Sex Hormone Binding Globulin	
Effective Date	**11/13/2012**
Test Code	3231
Specimen Requirements	**Plasma no longer acceptable.**

Vascular Endothelial Growth Factor (VEGF), ELISA	
Effective Date	**11/13/2012**
Test Code	S50507
Reject Criteria	Received room temperature; received refrigerated; **gross hemolysis; gross lipemia; grossly icteric**

Beta-2-Microglobulin, Random Urine	
Effective Date	**11/19/2012**
Former Test Name	*Beta-2-Microglobulin Urine*
Former Test Code	*3143U*

Test Code	4944
Specimen Requirements	**1 mL random urine (0.5 mL min)** in a plastic screw cap vial. Patient should void bladder, then drink at least 500 mL of water. A urine sample should be collected within 1 hour and pH adjusted to pH 6-8 with 1M NaOH. **Beta-2-Microglobulin is unstable in acidic urine (less than pH 6).**
Reject Criteria	Received room temperature
Transport Temperature	**Frozen**
Specimen Stability	**Room temperature: 8 hours** **Frozen: 1 year**
Set-up/Analytic Time	Set up: Mon-Sat; Report available: 1-3 days
CPU Mappings	**Result Code** / **Result Name** **45030400** / **B2 Microglobulin, Urine**
Tests Affected	**Test Codes:** / **Name:** 4500I / Cadmium Exposure Panel OSHA - Whole Blood & Urine Random 4500URI / Cadmium Exposure Panel OSHA - Urine Random

C1 Esterase Inhibitor, Protein	
Clinical Significance	**The C1 esterase inhibitor protein is a normal constituent of serum which functions as a serine proteinase inhibitor of the serpin family. The C1 esterase inhibitor inhibits the complement proteases C1r and C1s, as well as the proteases Kallikrein, factor XIa, XIIa and plasmin of the blood clotting system. The concentration of C1 esterase inhibitor protein is reduced to 10-30% of normal in patients with angioedema secondary to C1 esterase inhibitor deficiency (85% of patients with hereditary angioedema (HAE)); in 15% of patients with HAE, the concentrations of the inhibitor protein is normal but function is markedly reduced.**
Effective Date	**11/19/2012**
Former Test Name	*Complement C1 Esterase Inhibitor*
Test Code	1530
Transport Temperature	**Room temperature**
Specimen Stability	**Room temperature: 7 days** **Refrigerated: 8 days** **Frozen: 1 year**
Set-up/Analytic Time	**Set up: Mon- Sat; Report available: 1-2 days**
Reference Range	**21-39 mg/dL**
CPU Mappings	**Result Code** / **Result Name** 11210 / **C1 Inhibitor, Protein**
Tests Affected	**Test Codes:** / **Name:** 1529 / Angioedema Evaluation

Cardio CRP®	
Clinical Significance	**Useful in predicting risk of cardiovascular disease.**
Effective Date	**11/19/2012**

Former Test Name	*Cardio CRP*
Former Test Code	*1536*
Test Code	**10124**
Reject Criteria	**Gross hemolysis, gross lipemia**
CPU Mappings	**Result Code**: **45203715** — **Result Name**: **Cardio CRP(R)**

Ceruloplasmin

Clinical Significance	**Decreased levels of ceruloplasmin are found in Wilson's disease, fulminant liver failure, intestinal malabsorption, renal failure resulting in proteinuria chronic active hepatitis and malnutrition. Elevated levels are found in primary biliary cirrhosis, pregnancy (first trimester), oral contraceptive use and in acute inflammatory conditions since ceruloplasmin is an acute phase reactant.**
Effective Date	**11/19/2012**
Test Code	1516
Transport Temperature	**Room temperature**
Specimen Stability	Room temperature; 7 days **Refrigerated: 60 days** **Frozen: 90 days**
Reference Range	**Adults: Males: 18-36 mg/dL** **Females: 18-53 mg/dL**

Pediatrics:	**Males (mg/dL)**	**Females (mg/dL)**
0-30 Days	**8-25**	**3-28**
31 Days-11 Month	**15-48**	**15-43**
1-3 Years	**25-56**	**29-54**
4-6 Years	**29-56**	**26-54**
7-9 Years	**25-52**	**23-48**
10-12 Years	**21-51**	**21-48**
13-15 Years	**20-50**	**21-46**
16-18 Years	**20-45**	**22-50**

The pediatric ranges are derived from the following criteria:

Soldin SJ, Hicks JM, Baily J et al Pediatric reference ranges for Beta-2-Microglobulin and ceruloplasmin. Clin. Chem 1997; 43:S1999

Pediatric Reference Ranges, 2nd.,SF Soldin,et al. editors. AACC Press, Washington, DC 1997.

Haptoglobin

Clinical Significance	**Decreased haptoglobin is found in hemolytic disease, hepatocellular disease and infectious mononucleosis. Increased haptoglobin is found in inflammatory disease in the presence of tissue necrosis and in general acute inflammatory conditions.**
Effective Date	**11/19/2012**
Test Code	1517
Reject Criteria	**Gross hemolysis, Hyperlipemic**
Instructions	**CSF is an unacceptable sample type for this test. Overnight fasting is preferred.**
Set-up/Analytic Time	**Set Up: Mon-Sat; report available: 1-2 days**

Myoglobin, Serum	
Clinical Significance	**Assessment of skeletal muscle breakdown (rhabdomyolysis).**
Effective Date	**11/19/2012**
Former Test Name	*Myoglobin*
Test Code	4988
Specimen Requirements	**Plasma no longer acceptable**
Transport Temperature	**Room temperature**
Specimen Stability	**Room temperature: 7 Days** **Refrigerated: 14 Days** **Frozen: 35 Days**
Set-up/Analytic Time	**Set up: Mon-Sat; Report available: 1-2 days**
Reference Range	**Adult Male: < or = 50** **Adult Female: < or = 30**
Units Of Measure	**UOM=mcg/L**
Methodology	**Nephelometry**
CPU Mappings	**Result Code** / **Result Name** **55188800** / Myoglobin, Serum

Myoglobin, Urine	
Clinical Significance	**The breakdown of skeletal muscle (rhabdomyolysis) releases myoglobin. Very high concentrations of myoglobin may increase the risk of acute renal failure.**
Effective Date	**11/19/2012**
Former Test Name	*Myoglobin Urine Random*
Test Code	4988UR
Specimen Requirements	**3 mL (0.5 mL)** random urine
Reject Criteria	**Received room temperature**
Instructions	**Removal of existing instructions.**
Transport Temperature	**Frozen**
Specimen Stability	Room temperature: Unacceptable **Refrigerated: 48 Hours** **Frozen: 30 Day**
Set-up/Analytic Time	**Set up: Mon-Sat; Report available: 1-3 days**
Reference Range	**<28 mcg/L**
Units Of Measure	**mcg/L**
Methodology	**Fixed Rate Time Nephelometry**
CPU Mappings	**Result Code** / **Result Name** **85986220** / Myoglobin, Urine

Prealbumin	
Clinical Significance	**Prealbumin is decreased in protein-calorie malnutrition, liver disease, and acute inflammation. It may be**

	used as an indicator of nutritional requirements and response to therapy during total parenteral nutrition and as a biochemical marker of nutritional adequacy in premature infants.
Effective Date	**11/19/2012**
Test Code	1549
Reject Criteria	**Gross hemolysis, gross lipemia**
Transport Temperature	Room temperature
Specimen Stability	Room temperature: 7 days Refrigerated: 14 days **Frozen: 4 months**
Reference Range	**0-5 Days: 6-21 mg/dL** **6 Days-11 months: Not Established** **1-5 Years: 14-30 mg/dL** **6-9 Years: 15-33 mg/dL** **10-13 Years: 20-36 mg/dL** **14-17 Years: 22-45 mg/dL** **Adults Males: 21-43 mg/dL** **Adult Females: 17-34 mg/dL**

Transferrin	
Clinical Significance	**Transferrin is a direct measure of the Iron Binding Capacity. Transferrin is thus useful in assessing iron balance. Iron deficiency and overload are often evaluated with complementary laboratory tests.**
Effective Date	**11/19/2012**
Test Code	1519
Specimen Requirements	Avoid hemolysis. **Fasting for at least 12 hours is required.**
Specimen Stability	Room temperature: 7 days Refrigerated: 14 days **Frozen: 90 days**

Hantavirus Antibodies (IgG, IgM) with Reflex to Confirmation	
Effective Date	**11/26/2012**
Former Test Name	*Hantavirus IgG, IgM [41244]*
Test Code	S50346
Specimen Stability	**Room temperature: 5 days**
Reference Range	**<2.00**
Always Message	**REFERENCE RANGE: <2.00** **INTERPRETIVE CRITERIA:** **<2.00 Antibody not detected** **> or = 2.00 Antibody detected** Two major groups of hantaviruses are recognized based on clinical presentation. The first group includes Sin Nombre Virus (SNV), which causes hantavirus pulmonary syndrome, a severe and sometimes fatal form of acute respiratory distress. A second group of hantaviruses (including Seoul, Hantaan, Dobrava, and Puumala) causes hemorrhagic fever with renal syndrome, a condition not typically seen in the United States. Sera are initially screened for IgG and IgM antibodies recognizing the nucleocapsid protein common to all hantaviruses. All screen IgM positive samples are then tested for SNV-specific IgM; any screen IgM positive samples that are also screen IgG positive are tested for SNV-specific IgG, as well as SNV-specific IgM. Samples that are screen IgG positive but screen IgM negative are not subjected to SNV-specific IgG testing, since the lack of IgM rules out acute SNV infection. A positive screening result but a negative SNV-specific antibody result may indicate either reactivity to a hantavirus other than SNV or false positive reactivity. A small number of SNV IgM positive (but screen IgG negative) samples represent false positive reactivity associated with acute cytomegalovirus or Epstein Barr virus infection.

	This test was developed and its performance characteristics have been determined by Focus Diagnostics. Performance characteristics refer to the analytical performance of the test.
CPU Mappings	**Result Code** / **Result Name** 105625 / Hantavirus IgG 105626 / Hantavirus IgM
Additional Information	If result code Hantavirus IgG is **>=2.00** and Hantavirus IgM is **>=2.00** then Sin Nombre Virus IgG Confirmation, IBL is performed at an additional charge (CPT 86790). If Hantavirus IgM is **>=2.00** Sin Nombre Virus IgM Confirmation, ELISA will be performed at an additional charge (CPT 86790)

Discontinued Tests

Alpha-1-Antitrypsin Deficiency Fetal Study w/reflex to MCC	
Message	This test is being discontinued due to low volume.
Effective Date	**10/30/2012**
Test Code	1518
Additional Information	There is no recommended alternative

Alpha-1-Antitrypsin GenotypR™ - Saliva	
Message	This test is being discontinued due to low volume.
Effective Date	**10/30/2012**
Test Code	1515S
Additional Information	There is no recommended alternative

DPD 5-FU GenotypR™ - Saliva	
Message	This test is being discontinued due to low volume.
Effective Date	**10/30/2012**
Test Code	5383S
Additional Information	There is no recommended alternative

Factor II (Prothrombin) GenotypR™ - Saliva	
Message	This test is being discontinued due to low volume.
Effective Date	**10/30/2012**
Test Code	5371S
Additional Information	There is no recommended alternative

Factor V [Leiden] GenotypR™ - Saliva	
Message	This test is being discontinued due to low volume.
Effective Date	**10/30/2012**
Test Code	1966S
Additional Information	There is no recommended alternative

Hemochromatosis GenotypR™	
Message	Refer to replacement test 35079 in New Offerings section.
Effective Date	**10/30/2012**
Test Code	5369
Additional Information	This test will be discontinued and referred to 35079 Hereditary Hemochromatosis DNA Mutation Analysis.

Hemochromatosis GenotypR™ - Saliva	
Message	This test is being discontinued due to low volume.
Effective Date	**10/30/2012**
Test Code	5369S
Additional Information	There is no recommended alternative

MTHFR C677T/A1298C GenotypR™ Saliva	
Message	This test is being discontinued due to low volume.
Effective Date	**10/30/2012**
Test Code	4562S
Additional Information	There is no recommended alternative

Plasminogen Activator Inhibitor (PAI-1) GenotypR™ - Saliva	
Message	This test is being discontinued due to low volume.
Effective Date	**10/30/2012**
Test Code	5375S
Additional Information	There is no recommended alternative

TPMT GenotypR™ - Saliva	
Message	This test is being discontinued due to low volume.
Effective Date	**10/30/2012**
Test Code	5353S
Additional Information	There is no recommended alternative.

TPMT GenotypR™ - Saliva [NY]	
Message	This test is being discontinued due to low volume.
Effective Date	**10/30/2012**
Test Code	5353SNY
Additional Information	There is no recommended alternative

Warfarin Sensitivity DetectR™ (VKORC1 and CYP 2C9) - Saliva	
Message	Refer to suggested replacement 16160 AccuType(R) Warfarin in New Offerings section.
Effective Date	**10/30/2012**
Test Code	5055S
Additional Information	This test will be discontinued and referred to 16160 AccuType(R) Warfarin

Warfarin Sensitivity DetectR™ (VKORC1 and CYP2C9)	
Message	Refer to suggested replacement test 16160 AccuType(R) Warfarin in New Offerings section.
Effective Date	**10/30/2012**
Test Code	5055
Additional Information	This test will be discontinued and referred to 16160 AccuType® Warfarin

Corticotropin Releasing Hormone	
Effective Date	**11/5/2012**
Test Code	S51312
Additional Information	There is no recommended alternative.

MDMA and Metabolite, Random Urine [17161X]	
Message	Refer to test code 17161 in New Test Offerings. Now performed at Quest Diagnostics Nichols Institute, Valencia.
Effective Date	**11/5/2012**
Test Code	S51367

HE4 & CA 125	
Effective Date	**11/6/2012**
Test Code	2042
Additional Information	Please order tests individually using test codes 2040 HE4, Ovarian Cancer Monitoring and 3121 CA 125.

FISH, Subtelomere Screen	
Effective Date	**11/12/2012**
Test Code	S51684
Additional Information	The recommended alternative is S52307 Chromosomal Microarray, Postnatal, ClariSure® Oligo-SNP

***Brucella* Antibodies (IgG, IgM) CSF**	
Effective Date	**11/26/2012**
Test Code	S51725
Additional Information	The recommended alternative is 91068 *Brucella* Antibodies (IgG, IgM) EIA, with Reflex to Agglutination

Sars Coronavirus RNA, Qualitative RT-PCR	
Effective Date	**11/26/2012**
Test Code	S51520
Additional Information	There is no recommended alternative

Test Sendouts

Due to these assays being performed by outside vendors, we are unable to use our normal method of communication. Some of the changes listed in this document may be effective in less than 30 days. Please note the individual effective dates below, as these changes may require **IMMEDIATE ACTION.**

Calcium - Total, RBCs [0938R]	
Clinical Significance	**Exposure Monitoring/Investigation; Not for clinical diagnostic purposes.**

Effective Date	**10/29/2012**
Test Code	S41005
Specimen Requirements	**2 mL (0.7) RBCs**
Reject Criteria	**Received Room Temperature. Lavender top tube (EDTA).**
Specimen Stability	**Refrigerated: 30 day(s)** **Frozen:(-20 °C): 30 day(s)**
Set-up/Analytic Time	**Set up: Mon, Wed, Fri; Report available: 1-4 days**
Methodology	**ICP/OES**
Performing Site	National Medical Services