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

Revision Message!
Please note: The announcement to withdraw test 18899- Cutaneous Direct Immunofluorescence on 12/15/14 and the recommended alternative was test 14508- Cutaneous Immunofluorescence Antibodies (IgG), Serum. This change is being retracted, 18899 will remain active.

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 #
92141	**Alcohol Metabolites, Quantitative, Urine**	11/3/2014	2
37581	**Multiple Sclerosis Panel 1**	12/15/2014	2
36565	**Mumps Virus Antibody (IgM)**	12/15/2014	4
973	**Urea Nitrogen, 24 Hour Urine without Creatinine**	12/15/2014	4

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 #
252		Arginine Vasopressin (AVP, Antidiuretic Hormone, ADH)	12/15/2014	5
S52398		DCP (Des-Gamma-Carboxy-Prothrombin)	12/15/2014	5
16529	S50108	Leptospira Antibody Screen with Reflex to Titer, IHA	12/15/2014	5
A50078		**NOTCH 3 DNA Sequencing Test**	12/15/2014	6
36637	4937	**Oxycarbazepine Metabolite**	12/15/2014	6

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 #
90379	S52169	**Glutathione**	12/15/2014	7

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 #
S50658	TA90 Monitor	12/8/2014	8
9711	Mumps IgG & IgM Abs	12/15/2014	8
9721	Mumps IgM Abs	12/15/2014	9
S51503	Urea Nitrogen, Urine 24 hr	12/15/2014	9

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 #

S50970		Buprenorphine and Metabolite - Free (Unconjugated) Screen, Serum/Plasma	12/1/2014	9
92021		Fluphenazine, Serum/Plasma	12/1/2014	9

New Test Offerings

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

Alcohol Metabolites, Quantitative, Urine	
Clinical Significance	**Ethylglucuronide (EtG) and Ethylsulfate (EtS) are metabolites of ethanol. While EtG has been used as a long-term biomarker in urine testing for more than 7 years, EtS has more recently been incorporated into testing programs. Scientific literature indicates that EtG may be detectable for up to 80 hours and that EtS may be detectable for 24 hours or more after ethanol ingestion - depending on cutoff, metabolism, and usage patterns. Under certain conditions, *in-vitro* (outside of the body, in the specimen container) formation of EtG may also occur when certain bacteria and ethanol or ethanol-producing bacteria are both present in a urine specimen. No published reports of *in-vitro* synthesis of EtS exist, however, even under the same conditions in which EtG may be synthesized *in-vitro*.** **EtS is typically present in urine at a lower concentration than EtG, although the ratio of EtG to EtS varies significantly between individual donors. In order to be reported positive for EtG, Quest Diagnostics' clinical reporting criteria require that EtS be present in a specimen at a minimum concentration of 100 ng/mL whenever EtG is present at a concentration greater than or equal to 500 ng/mL.** **As with EtG, the presence of EtS in a urine specimen does not establish the source of the ethanol containing product and the possibility of "incidental exposure" and post-collection specimen changes needs to be considered when interpreting results. EtG and EtS testing, as with any controlled substance testing, measure only the presence and concentration of EtG (or EtS) in a given urine specimen. Quest Diagnostics recommends clinical correlation and/or healthcare provider review when interpreting EtG and EtS results.**
Effective Date	**11/3/2014**
Test Code	**92141**
CPT Codes	**83789**
Specimen Requirements	**1 mL (0.5 mL minimum) urine collected in a plastic urine container**
Transport Temperature	**Room temperature**
Specimen Stability	**Room temperature and Refrigerated: 7 days** **Frozen: 30 days**
Set-up/Analytic Time	**Set up: Tues-Sat; Report available: 1-3 days**
Reference Range	**Ethyl Glucuronide** — **<500 ng/mL** **Ethyl Sulfate** — **<100 ng/mL**
Always Message	***These results are for medical treatment only*** ***Analysis was performed as non-forensic testing*** **For assistance with interpreting these drug results, please contact a Quest Diagnostics Toxicology Specialist: 1-877-40-RX TOX (1-877-407-9869), M-F 8am-6pm EST.**
Methodology	**Mass Spectrometry**
Performing Site	**Quest Diagnostics Nichols Institute, Valencia**
Interface Mapping	**Result Code** / **Result Name**

86010838	**Ethyl Glucuronide**
86010840	**Ethyl Sulfate**
82100625	**Please note:**

Multiple Sclerosis Panel 1	
Clinical Significance	**Patients with Multiple Sclerosis (MS) have multiple, scarred areas of the brain. Symptoms can initially be mild but typically lead to relapsing or progressive incapacitating neuromotor dysfunction.**
Effective Date	**12/15/2014**
Test Code	**37581**
CPT Codes	**83916; 82042; 82784; 82040; 82784**
Specimen Requirements	**2 mL (1 mL minimum) serum AND 3 mL (1.5 mL minimum) CSF collected in sterile screw cap container**
Instructions	**It is preferred that the collection date and time be the same for both CSF and serum; however, it is acceptable for them to be drawn within 48 hours of each other. NOTE: The client will be contacted when no serum is supplied to confirm the order. The IgG Synthesis requires both CSF and serum for testing, otherwise, this portion of the profile will be canceled. However, for Oligoclonal Banding test only, it is acceptable to send through CSF without serum, when client has indicated to "run with serum control". CSF must be crystal clear. (CSF collection tube #4 preferred)**
Specimen Stability	**Room temperature: 8 hours Refrigerated: 5 days Frozen: 14 days**
Reference Range	

Oligoclonal Bands, CSF	**No bands**	
Synthesis Rate IgG, CSF:	**-9.9 TO +3.3**	**mg/24 h**
IgG Index, CSF:	**< 0.66**	
Albumin, CSF:	**Adults: 8.0-42.0**	**mg/dL**
IgG, CSF:	**Adults: 0.8-7.7**	**mg/dL**
IgG, Serum:	**Cord Blood: 553-1360 1 Month: 213-765 2-5 Months: 170-595 6-9 Months: 187-765 10-12 Months: 247-910 1-3 Years: 533-1078 4-6 Years: 592-1723 7-9 Years: 673-1734 10-11 Years: 821-1835 12-13 Years: 893-1823 14-15 Years: 842-2013 >=16 Years: 694-1618**	**mg/dL**
Albumin, Serum:	**0-40 Years: 3.7-5.1 41-60 Years: 3.5-4.9 >60 Years: 3.2-4.6**	**g/dL**

Always Message	**Oligoclonal bands are present in the CSF of more than 85% of patients with clinically definite multiple sclerosis (MS). To distinguish between oligoclonal bands in the CSF due to a peripheral gammopathy and oligoclonal bands due to local production in the CNS, serum and CSF should be tested simultaneously. Oligoclonal bands can however be observed in a variety of other diseases, e.g., subacute sclerosing panencephalitis, inflammatory polyneuropathy, CNS lupus, and brain tumors and infarctions. The clinical significance of a numerical band count, determined by isoelectric focusing, has not been definitively defined. The data should be interpreted in conjunction with all pertinent clinical and laboratory data for this patient.**

	The IgG Synthesis rate, CSF and IgG index, CSF are two formulae for estimating the amount of IgG produced in the central nervous system. Evidence of increased synthesis of IgG provides support for the diagnosis of multiple sclerosis.
Methodology	**Isoelectric Focusing, Fixed Rate Time Nephelometry**
Performing Site	**Quest Diagnostics Nichols Institute, San Juan Capistrano**
Interface Mapping	

Result Code	Result Name	Unit of Measure
790	Oligoclonal Bands, CSF	
775	Synthesis Rate IgG, CSF	mg/24 h
9663	IgG Index, CSF	
782	Albumin, CSF	mg/dL
780	IgG, CSF	mg/dL
7563	IgG, Serum	mg/dL
25966	Albumin, Serum	g/dL

Mumps Virus Antibody (IgM)	
Clinical Significance	**Used in the diagnosis of acute mumps infection**
Effective Date	**12/15/2014**
Test Code	**36565**
CPT Codes	**86735**
Specimen Requirements	**1 mL (0.2 mL minimum) serum**
Reject Criteria	**Gross hemolysis; gross lipemia**
Transport Temperature	**Room temperature**
Specimen Stability	**Room temperature: 7 Days** **Refrigerated: 14 Days** **Frozen: 30 Days**
Set-up/Analytic Time	**Set up: Mon-Fri; Report available: 1-4 days**
Reference Range	**< 1:20**
Always Message	**Interpretive Criteria:** **<1:20 Antibody not detected** **> or = 1:20 Antibody detected** **The presence of IgM antibody to mumps typically indicates recent or current mumps infection; however, false positive results may occur due to antibody crossreactivity to parainfluenza virus.** **This assay was developed and its performance characteristics have been determined by Focus Diagnostics. 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	**Immunofluorescence Assay**
Performing Site	**Focus Diagnostics, Inc.**
Interface Mapping	

Result Code	Result Name

	70056200 — **Mumps Virus Antibody IgM**

Urea Nitrogen, 24 Hour Urine without Creatinine	
Clinical Significance	**About 80% of urinary nitrogen is in the form of urea which is the major end product of protein metabolism. Urea excreted in the urine is the primary method of nitrogen elimination; therefore, this test provides an approximate evaluation of nitrogen balance. Conditions associated with increased urine urea nitrogen are hyperthyroidism, high protein diets and post-operative states. Decreased levels are associated with convalescence, liver disease, toxemia and advanced renal disease.**
Effective Date	**12/15/2014**
Test Code	**973**
CPT Codes	**84540**
Specimen Requirements	**Preferred:** **10 mL (2 mL minimum) 24-hour urine, no preservative collected in a plastic leak-proof container** **Acceptable:** **24-hour urine preserved with 6N HCL to maintain a pH of <6.0**
Instructions	**10 mL urine aliquot from a well-mixed 24-hour collection. Do not include first morning specimen in 24-hour collection. Collect all subsequent voiding. The last sample collected should be the first specimen voided the following morning at the same time as the previous morning's first void. Record the total volume of urine and collection time on both the transport container and test requisition.** **Also acceptable: Urine preserved with 6N HCL to maintain a pH of <6.0.**
Specimen Stability	**Room temperature: 24 hours** **Refrigerated: 7 days** **Frozen: 15 months**
Set-up/Analytic Time	**Set up: Mon-Sat; Report available: 1-2 days**
Reference Range	**6-17 g/24 h**
Units Of Measure	**g/24 h**
Methodology	**Spectrophotometry**
Performing Site	**Quest Diagnostics Nichols Institute, Valencia**
Interface Mapping	**Result Code** / **Type** / **Result Name** / **Unit of Measure** **25023700** /	/ **Urea Nitrogen, 24 hr urine** / **g/24 h** **85993218** / **Prompt-Result** / **Total Volume** /

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.*

Arginine Vasopressin (AVP, Antidiuretic Hormone, ADH)	
Effective Date	**12/15/2014**
Test Code	252
Specimen Requirements	4 mL **(2.5 mL minimum)** plasma collected in an EDTA (lavender-top) tube

Performing Site	Quest Diagnostics Nichols Institute, San Juan Capistrano

DCP (Des-Gamma-Carboxy-Prothrombin)	
Effective Date	**12/15/2014**
Test Code	S52398
Reference Range	**<7.5** ng/mL
Performing Site	Quest Diagnostics Nichols Institute, San Juan Capistrano

Leptospira Antibody Screen with Reflex to Titer, IHA	
Effective Date	**12/15/2014**
Former Test Code	*S50108*
Test Code	**16529**
Specimen Requirements	**Preferred:** **0.5 mL (0.2 mL minimum)** serum **Acceptable:** **Plasma collected in a sodium heparin (green-top); EDTA (lavender-top); EDTA (royal blue-top); or PPT potassium EDTA (white-top) tube**
Specimen Stability	Room temperature: 7 days **Refrigerated: 14 days** **Frozen: 30 days**
Reference Range	**Leptospira Ab Screen: Negative** Leptospira Ab Titer: <1:50 **Interpretive Criteria:** **<1:50 Antibody not detected** **1:50 Equivocal; submission of a second specimen (collected 1-2 weeks after initial specimen) suggested if clinically warranted.** **> or = 1:100 Indicative of recent or current infection**
Units Of Measure	**Remove units of measure**
Always Message	**The IHA procedure detects genus-specific antibody only. In patients with leptospirosis, antibody is detectable by IHA within 1-2 weeks after onset of symptoms and peaks at 2-4 weeks. Titers generally reach values greater than 1:200 before decreasing, and then fall below the level of detectability within 9-12 months.**
Performing Site	Focus Diagnostics, Inc.
Interface Mapping	**Result Code** / **Result Name** **86003369** / **Leptospira Ab Screen** ***This is a true reflex. Please build the unit code below separately.*** ***Non-Orderable Reflex: 16529-2 Leptospira Antibody Titer, IHA (Serum)*** **Result Code** / **Result Name** **86003370** / **Leptospira Ab Titer**
Additional Information	**If screen is positive, then Leptospira Antibody Titer, IHA (Serum) will be performed at an additional charge (CPT code 86720).**

NOTCH 3 DNA Sequencing Test	
Effective Date	**12/15/2014**
Former Test Name	*Cadasil Evaluation*
Test Code	A50078
Instructions	**Ship within 24 hours.**
Methodology	**Polymerase Chain Reaction**, Next Generation Sequencing
Performing Site	Athena Diagnostics, Inc.
Interface Mapping	

Result Code	Result Name
86011684	**Interpretation**
86011685	**Technical Results**
86011686	**Methods**
86011687	**Comments**
86011688	**References**

Oxycarbazepine Metabolite	
Clinical Significance	**Oxcarbazepine (trileptal) is an anti-convulsant used for treating generalized tonic-clonic and partial seizures. It can be administered alone or as an adjunct to other anti-convulsants. Clinically significant effects of oxcarbazepine are observed when plasma levels of its active metabolite, 10-OH-carbazepine, are between 15 and 35 ug/mL. Toxic symptoms may occur when plasma levels exceed 35 ug/mL. The therapeutic mornitoring of oxcarbazepine and its active metabolite are important for achieving proper serum/plasma concentration to inhibit epileptic seizures and avoid adverse effects.The precise mechanism of the action by which oxcarbazepine and its active metabolite exert their antiseizure effect is unknown. However, in vitro electrophysiological studies indicate that they produce blockade of voltage-sensitive sodium channels, resulting in the stabilization of hyperexcited neural membranes, inhibition of repetitive neuronal firing, and diminution of propagation of synaptic impulses. These are important in prevention of seizure spread in the brain. In addition, the increased potassium conduction and calcium channel activities may contribute to the antiseizure treatment effects.After oral administration, oxcarbazepine is readily absorbed in the body, followed by rapid and almost complete metabolization to 10-OH-carbazepine, active metabolite. The half-life of oxcarbazepine is only 1 to 2.5 hours, while that of 10-OH-carbazepine is 11 to 15 hours. The protein binding of oxcarbazepine is about 67%, whereas that of the metabolite is about 38%. The clearance of oxcarbazepine and its active metabolite from the body is mainly through ketone reduction and O-site conjugation with glucuronic acid rather than oxidative processes via cytochrome P450 system. More than 95% of the treatment dosage is excreted by the kidneys. Fecal excretion only accounts for less than 4%.**
Effective Date	**12/15/2014**
Former Test Name	*Oxcarbazepine (Trileptal)*
Former Test Code	*4937*
Test Code	**36637**
CPT Codes	**80299**
Specimen Requirements	**Preferred:** **1 mL (0.25 mL minimum) serum collected in a no additive (red-top) tube** **Acceptable:** **1 mL (0.25 mL minimum) plasma collected in an EDTA (lavender-top) tube**
Reject Criteria	**Serum separator tubes**

Specimen Stability	**Room temperature: 72 Hours** **Refrigerated: 14 Days** Frozen: 60 Days
Reference Range	**8.0-35.0 mcg/mL**
Units Of Measure	**mcg/mL**
Methodology	**Liquid Chromatrography Tandem Mass Spectrometry (LC/MS/MS)**
Performing Site	Quest Diagnostics Nichols Institute, Valencia
Interface Mapping	**Result Code** / **Result Name** / **Unit of Measure** **85998764** / **10-Hydroxycarbazepine** / **mcg/mL**

Redirects

Glutathione	
Message	****This test is not available for New York patient testing****
Clinical Significance	**Glutathione is a tripeptide formed by a peptide linkage between the amine group of cysteine linked to glycine and the carboxyl group of the glutamate side-chain. It is an abundant cellular reducing agent, whose major biological function is mitigating oxidative damage to biological macromolecules. Glutathione is also important in the metabolism and excretion of xenobiotic compounds. Glutathione is consumed to maintain cells in a reduced condition. Consequently, glutathione levels in patient samples are expected to be diminished in disease states where oxygen reactive species are involved, such as rheumatoid arthritis and atherosclerosis. Low glutathione levels have been linked to reduced dopamine production in neurons, which suggests a relationship to dopamine based neurological disorders such as Parkinson's disease. High levels of glutathione have been linked to chemotherapy resistance in cancer treatments.**
Effective Date	**12/15/2014**
Former Test Name	*Glutathione (GSH)*
Former Test Code	*S52169*
Test Code	**90379**
CPT Codes	**82978**
Specimen Requirements	**10 mL (1 mL minimum) whole blood collected in ACD (yellow-top) tube**
Reject Criteria	**Hemolysis**
Instructions	**Send whole blood. Do not centrifuge.**
Transport Temperature	**Refrigerated**
Specimen Stability	**Room temperature: Not established** **Refrigerated: 21 days** **Frozen: Unacceptable**
Set-up/Analytic Time	**Set up: Fri; Report available: 3-11 days**
Reference Range	**544-1228 uM**
Always Message	**The performance characteristics of the listed assay was validated by Cambridge Biomedical Inc. The US FDA has not approved or cleared this test. The results of this assay can be used for clinical diagnosis without FDA approval. Cambridge Biomedical Inc. is a CLIA certified, CAP accredited laboratory for performing high complexity assays such as this one.** **Research use only not to be used for patient diagnostics.**

Methodology	**Kinetic**
Assay Category	**Research Use Only**
Performing Site	**This test previously performed at Genova Diagnostics will now be performed at Cambridge Biomedical Research Group**
Interface Mapping	**Result Code** / **Result Name** / **Unit of Measure** **86007516** / **Glutathione** / **uM**

Discontinued Tests

TA90 Monitor	
Effective Date	**12/8/2014**
Test Code	S50658
Additional Information	Reagents are no longer available. There is no recommended alternative.

Mumps IgG & IgM Abs	
Effective Date	**12/15/2014**
Test Code	9711
Additional Information	The recommended alternatives are: • 36565-Mumps Virus Antibody (IgM) performed at Focus Diagnostics, Inc. in the New Test Offering section • 9716-Mumps IgG Abs
Tests Affected	**Test Codes:** / **Name:** P44513P / Custom Duncan Mumps Titer- Employee

Mumps IgM Abs	
Effective Date	**12/15/2014**
Test Code	9721
Additional Information	The recommended alternative is test code 36565-Mumps Virus Antibody (IgM) performed at Focus Diagnostics, Inc. in the New Test Offering section.

Urea Nitrogen, Urine 24 hr	
Effective Date	**12/15/2014**
Test Code	S51503
Additional Information	The recommended alternative is test code 973- Urea Nitrogen, 24 hour Urine (w/o creatinine)

Test Send Out (Referrals)

Buprenorphine and Metabolite - Free (Unconjugated) Screen, Serum/Plasma	
Effective Date	**12/1/2014**
Test Code	S50970
Specimen Requirements	3 mL **(1.3 mL minimum)** serum collected in a red-top tube (no-gel)
Specimen Stability	**Room temperature, Refrigerated and Frozen: 29 days**
Set-up/Analytic Time	Set up: Mon, Wed, Fri; **Report available: 1 day**
Reference Range	**Buprenorphine/Metabolite - Maximum plasma buprenorphine concentrations in patients maintained on varying buprenorphine doses were:** **2 mg/day: 0.3 +/- 0.1 ng/mL** **16 mg/day: 6.3 +/- 0.9 ng/mL** **32 mg/day: 13 +/- 4.2 ng/mL**
Methodology	**Enzyme Linked Immunosorbent Assay**
Interface Mapping	**Result Code** / **Result Name** / **Unit of Measure** **86011633** / **Buprenorphine Metabolite** / ng/mL
Additional Information	**Remove Buprenorphine Free and Norbuprenorphine Free from report format**

Fluphenazine, Serum/Plasma	
Effective Date	**12/1/2014**
Test Code	92021
Specimen Stability	Room temperature: 24 hours **Refrigerated: 10 days** **Frozen: 90 days**