



LABORATORY UPDATE

www.DLOLab.com

Routine Testing

New Tests

- Bacterial Pneumonia Panel 3
- Gastrointestinal Panel 4
- Infectious Disease Panel 5
- Respiratory Infections Panel 6
- Staphylococcus Differentiation Panel..... 7
- Viral Respiratory Panel..... 8

Test Changes

- Urine Drug Screen 10
- C-Peptide - Update reporting of patient results to 2 decimal places..... 9
- HIV 1 RNA, Quantitative Real Time PCR – Update specimen stability and reference range..... 9

Quest Diagnostics Nichols Institute (San Juan Capistrano, Chantilly, and Valencia) and Focus Diagnostics, Inc.

New Test Offerings

- CMV Antigenemia Assay 10
- Malaria Blood Parasites 10
- JAK2 V617F Mutation, Quantitative..... 11
- Colorectal Cancer Mutation Panel (KRAS, PIK3CA, BRAF, NRAS)..... 12
- Serotonin Release Assay (SRA), Fondaparinux 13
- Serotonin Release Assay (SRA), LMWH..... 13
- Meningoencephalitis Comprehensive Panel (CSF) (to include West Nile Virus) 14

The CPT Codes provided in this document are based on AMA guidelines and are for informational purposes only. CPT coding is the sole responsibility of the billing party. Please direct any questions regarding coding to the payor being billed. Any Profile/panel component may be ordered separately. Reflex tests are performed at an additional charge.

Test Changes

- Acetylcholinesterase - Update specimen volume.15
- Alpha-Fetoprotein, AF w/Reflex to ACHe/Fetal Hgb - Update specimen volume.15
- BRAF Mutation Analysis - Update reference range.....15
- EGFR Pathway (KRAS with reflex to NRAS, BRAF) - Update reference range and always message for NRAS and KRAS components.15
- KRAS Mutation Analysis - Update reference range and always message.15
- NRAS Mutation Analysis - Update reference range and always message.15
- PIK3CA Mutation Analysis - Update reference range.15
- CYP2C19 Genotyping - Update test name and CPT coding.
Remove component - CYP2D6 Genotype.....15
- Lung Cancer Mutation Panel (EGFR, KRAS, ALK) - Update preferred specimen type and CPU interface mapping. Remove result codes.....16
- Serotonin Release Assay, Unfractionated Heparin - Update test name, test code, result codes, reference range, add new reporting analytes.....16
- *Echinococcus* Antibody (IgG) - Update reference range and always message.....16
- *Entamoeba histolytica* IgG, ELISA - Update reference range and always message.16
- Trichinella IgG Antibody, ELISA - Update transport temperature, stability, reference range and always message.16
- CA 125, CSF - Update performing site.....16
- CellSearch® Circulating Tumor Cells - Update specimen volume and collection instruction.....17

DLO is pleased to inform you of the following new and updated laboratory testing information:

Routine Testing

New Tests

Bacterial Pneumonia Panel	
Includes: <i>Acinetobacter baumannii</i> , <i>Bordetella pertussis</i> , <i>Chlamydomphila pneumoniae</i> , <i>Haemophilus influenzae</i> , <i>Klebsiella pneumoniae</i> , <i>Legionella pneumophila</i> , <i>MRSA - Methicillin Resistant Staphylococcus aureus</i> , <i>Mycoplasma pneumoniae</i> , <i>Neisseria meningitidis</i> , <i>Pseudomonas aeruginosa</i> , <i>Staphylococcus aureus</i> , <i>Streptococcus pneumoniae</i> and <i>Streptococcus pyogenes (Group A)</i> . Antibiotic Resistances: Aminoglycoside Resistance, Cephalosporin Resistance (Staphylococcal), Erythromycin/Clindamycin Resistance, Methicillin Resistance (Staphylococcal) and Tetracycline Resistance.	
Clinical Significance:	Target enriched multiplex molecular panel testing for the DNA of multiple bacterial and viral pathogens.
Effective Date:	Now Available
Test Code:	95052
CPT Code(s):	87798 (x7), 87486, 87541, 87641, 87581, 87640, 87651, 87798
Specimen Requirements:	<p><u>Nasal/Nasopharyngeal:</u> Starplex swab kit containing a standard flocced swab and a blue top transport tube. After collection place swab in transport tube with .75ml transport fluid, swirl swab 5 times in transport fluid, raise swab 1 inch from fluid and roll against the side of the tube to press any remaining liquid out of the swab. Discard swab. Send inoculated transport tube to lab.</p> <p><u>Nasopharyngeal wash/Bronchial Aspirate:</u> Add 4 ml of nasopharyngeal wash or bronchial aspirate to tube containing .75ml transport fluid. Total volume will register as 5 on the transport tube.</p> <p><u>Sputum:</u> Collect in plain container put the swab tip in the sputum specimen and move it around in a mixing motion to expose the swab to as much sputum as possible. Discard swab. Send inoculated transport tube to lab.</p>
Transport Temperature:	Room Temperature
Specimen Stability:	Room Temperature: 5 DAYS Refrigerated: Unacceptable Frozen: Unacceptable
Reference Ranges:	Not Detected
Methodology:	TEM-PCR
Rejection Criteria:	<ul style="list-style-type: none"> - Swabs/Containers used from collection kits other than the Starplex kit - Specimens received at temperature other than room temperature - Specimens exceeding 5 days
Performing Site:	Diatherix Laboratories

Gastrointestinal Panel

Includes: *Clostridium difficile*, *Clostridium difficile Toxin B Gene*, *Campylobacter jejuni*, *Escherichia coli* Strain 0157, *Listeria monocytogenes*, *Salmonella enterica*, *Shigella flexneri*, *Shigella sonnei*, *Staphylococcus aureus*, *Vibrio cholerae* and *Vibrio parahaemolyticus*.

Clinical Significance:	Rapid target enriched multiplex molecular testing for the presence of common gastrointestinal pathogens.
Effective Date:	Now Available
Test Code:	95045
CPT Code(s):	87798 (x9), 87493, 87640
Specimen Requirements:	<u>Stool</u> : Using a Starplex swab kit containing a standard flocced swab and a blue top transport tube provided by DLO, swab the stool specimen in a mixing motion to expose the swab to as much stool as possible. Place swab in blue top transport tube and roll the swab 5 times in the .75ml transport media. Discard the swab. Send the inoculated transport tube to DLO.
Transport Temperature:	Room Temperature
Specimen Stability:	Room Temperature: 5 DAYS Refrigerated: Unacceptable Frozen: Unacceptable
Reference Ranges:	Not Detected
Methodology:	TEM-PCR
Rejection Criteria:	<ul style="list-style-type: none">- Swabs/Containers used from collection kits other than the Starplex kit- Specimens received at temperature other than room temperature- Specimens exceeding 5 days
Performing Site:	Diatherix Laboratories

Infectious Disease Panel

Includes: *Acinetobacter baumannii*, *Klebsiella pneumoniae*, *Enterobacter aerogenes*, *Proteus mirabilis*, *Enterobacter cloacae*, *Pseudomonas aeruginosa*, *Enterococcus faecalis*, *Serratia marcescens*, *Enterococcus faecium*, *Stenotrophomonas maltophilia*, *Escherichia coli*, *Streptococcus pyogenes* (Group A), MRSA - Methicillin Resistant *Staphylococcus aureus*, *Staphylococcus aureus*, Panton-Valentine leukocidin (PVL) Gene, Methicillin resistant Coagulase Negative *Staphylococcus*, Coagulase Negative *Staphylococcus* and *Staphylococcus epidermidis*, Antibiotic Resistances: Aminoglycoside Resistance, Cephalosporin Resistance (Staphylococcal), Erythromycin/Clindamycin Resistance, Methicillin Resistance (Staphylococcal), Tetracycline Resistance and Vancomycin Resistance.

Clinical Significance:	Target enriched multiplex molecular panel testing for the DNA of multiple bacterial and viral pathogens.
Effective Date:	Now Available
Test Code:	95048
CPT Code(s):	87798 (x13), 87651, 87640, 87641, 87500
Specimen Requirements:	<p><u>Wound/Infection source:</u> Starplex swab kit containing a standard flocced swab and a blue top transport tube. Clean wound with sterile saline and gauze removing ointments. Rub the swab on the area and place transport tube with .75ml transport fluid. Twirl swab 5 times in transport fluid, raise swab 1 inch from fluid and roll against the side of the tube to press any remaining liquid out of the swab. Discard swab. Send inoculated transport tube to lab.</p> <p><u>Synovial fluid or Positive Blood Culture:</u> 4 ml placed in a Starplex swab transport tube containing .75ml of transport fluid total volume will register as 5 on the transport tube.</p>
Transport Temperature:	Room Temperature
Specimen Stability:	Room Temperature: 5 DAYS Refrigerated: Unacceptable Frozen: Unacceptable
Reference Ranges:	Not Detected
Methodology:	TEM-PCR
Rejection Criteria:	<ul style="list-style-type: none"> - Swabs/Containers used from collection kits other than the Starplex kit - Specimens received other than room temperature - Specimens exceeding 5 days
Performing Site:	Diatherix Laboratories

Respiratory Infections Panel

Includes: *Adenovirus Types 3,4,7,21, Coxsackievirus/Echovirus, Human metapneumovirus, Influenza A - Human influenza, **Influenza A - H1N1-09, Influenza B, Parainfluenza Types 1,2,3,4, Respiratory Syncytial Virus A, Respiratory Syncytial Virus B, Rhinoviruses, Acinetobacter baumannii, Bordetella pertussis, Chlamydophila pneumoniae, Haemophilus influenzae, Klebsiella pneumoniae, Legionella pneumophila, MRSA – Methicillin Resistant Staphylococcus aureus, Mycoplasma pneumoniae, Neisseria meningitidis, Pseudomonas aeruginosa, Staphylococcus aureus, Streptococcus pneumoniae, Streptococcus pyogenes (Group A), Antibiotic Resistances: Aminoglycosides Resistance, Cephalosporin Resistance (Staphylococcal), Erythromycin/Clindamycin Resistance, Methicillin Resistance (Staphylococcal) and Tetracycline Resistance.*

Clinical Significance:	Target enriched multiplex molecular panel testing for DNA of multiple bacterial and viral pathogens including H1N1.
Effective Date:	Now Available
Test Code:	95049
CPT Code(s):	87798 (x13), 87486, 87541, 87641, 87581, 87640, 87651, 87999, 87498, 87502, 87503
Specimen Requirements:	<p><u>Nasal/Nasopharyngeal:</u> Starplex swab kit containing a standard flocked swab and a blue top transport tube. After collection place swab in transport tube with .75ml transport fluid, twirl swab 5 times in transport fluid, raise swab 1 inch from fluid and roll against the side of the tube to press any remaining liquid out of the swab. Discard swab. Send inoculated transport tube to lab.</p> <p><u>Nasopharyngeal wash/Bronchial Aspirate:</u> Add 4 ml of nasopharyngeal wash or bronchial aspirate to tube containing .75ml transport fluid. Total volume will register as 5 on the transport tube.</p> <p><u>Sputum:</u> Collect in plain container put the swab tip in the sputum specimen and move it around in a mixing motion to expose the swab to as much sputum as possible. Discard swab. Send inoculated transport tube to lab.</p>
Transport Temperature:	Room Temperature
Specimen Stability:	Room Temperature: 5 DAYS Refrigerated: Unacceptable Frozen: Unacceptable
Reference Ranges:	Not Detected
Methodology:	TEM-PCR
Rejection Criteria:	<ul style="list-style-type: none"> - Swabs/Containers used from collection kits other than the Starplex kit - Specimens received at temperature other than room temperature - Specimens exceeding 5 days
Additional Information:	<p>**The Diatherix Laboratories H1N1-09 Test is a multiplex RT-PCR panel intended for the in vitro qualitative detection of the 2009 H1N1 influenza A viral RNA in nasopharyngeal swabs, nasal swabs, throat swabs, nasal aspirates, and nasopharyngeal aspirates from human patients with signs and symptoms of respiratory infection in conjunction with clinical and epidemiological risk factors. The Diatherix H1N1-09 Influenza Test is the only test within the Viral Respiratory Panel authorized by the FDA under the Emergency Use Authorization. Authorization is only for the detection of 2009 H1N1 influenza virus and not for seasonal influenza A, B.</p>
Performing Site:	Diatherix Laboratories

Staphylococcus Differentiation Panel

Includes: MRSA - Methicillin Resistant Staphylococcus aureus, Staphylococcus aureus, Panton-Valentine Leukocidin (PVL) Gene, Methicillin Resistant Coagulase Negative Staphylococcus, Coagulase Negative Staphylococcus, Staphylococcus epidermidis. Antibiotic Resistances: Aminoglycoside Resistance, Cephalosporin Resistance, Erythromycin/Clindamycin Resistance, Methicillin Resistance, and Tetracycline Resistance.

Clinical Significance:	Target enriched multiplex molecular panel testing of staph species including MRSA with antibiotic resistance.
Effective Date:	Now Available
Test Code:	95047
CPT Code(s):	87640, 87641, 87798 (x2), 87500
Specimen Requirements:	<p><u>Wound/Infection source:</u> Starplex swab kit containing a standard flocced swab and a blue top transport tube. Clean wound with sterile saline and gauze removing ointments. Rub the swab on the area and place transport tube with .75ml transport fluid. Twirl swab 5 times in transport fluid, raise swab 1 inch from fluid and roll against the side of the tube to press any remaining liquid out of the swab. Discard swab. Send inoculated transport tube to lab.</p> <p><u>Synovial fluid or Positive Blood Culture:</u> 4 ml placed in a Starplex swab transport tube containing .75ml of transport fluid total volume will register as 5 on the transport tube.</p> <p><u>Nasal/Nasopharyngeal:</u> Starplex swab kit containing a standard flocced swab and a blue top transport tube. After collection place swab in transport tube with .75ml transport fluid, twirl swab 5 times in transport fluid, raise swab 1 inch from fluid and roll against the side of the tube to press any remaining liquid out of the swab. Discard swab. Send inoculated transport tube to lab.</p>
Transport Temperature:	Room Temperature
Specimen Stability:	Room Temperature: 5 DAYS Refrigerated: Unacceptable Frozen: Unacceptable
Reference Ranges:	Not Detected
Methodology:	TEM-PCR
Rejection Criteria:	<ul style="list-style-type: none"> - Swabs/Containers used from collection kits other than the Starplex kit - Specimens received at temperature other than room temperature - Specimens exceeding 5 days
Performing Site:	Diatherix Laboratories

Viral Respiratory Panel

Includes: Adenovirus Types 3,4,7,21, Coxsackievirus/Echovirus, Human metapneumovirus, Influenza A - Human influenza, **Influenza A - H1N1-09, Influenza B, Parainfluenza Types 1,2,3,4,, Respiratory Syncytial Virus A, Respiratory Syncytial Virus B and Rhinoviruses.

Clinical Significance:	Target enriched multiplex molecular panel testing for the presence of multiple viral pathogens including H1N1.
Effective Date:	Now Available
Test Code:	58753
CPT Code(s):	87798 (x6), 87498, 87502, 87503
Specimen Requirements:	<p><u>Nasal/Nasopharyngeal:</u> Starplex swab kit containing a standard flocked swab and a blue top transport tube. After collection place swab in transport tube with .75ml transport fluid, twirl swab 5 times in transport fluid, raise swab 1 inch from fluid and roll against the side of the tube to press any remaining liquid out of the swab. Discard swab. Send inoculated transport tube to lab.</p> <p><u>Nasopharyngeal wash:</u> Add 4 ml of nasopharyngeal wash to tube containing .75ml transport fluid. Total volume will register as 5 on the transport tube.</p>
Transport Temperature:	Room Temperature
Specimen Stability:	Room Temperature: 5 DAYS Refrigerated: Unacceptable Frozen: Unacceptable
Reference Ranges:	Not Detected
Methodology:	TEM-PCR
Rejection Criteria:	<ul style="list-style-type: none"> - Swabs/Containers used from collection kits other than the Starplex kit - Specimens received at temperature other than room temperature - Specimens exceeding 5 days
Additional Information:	<p>**The Diatherix Laboratories H1N1-09 Test is a multiplex RT-PCR panel intended for the in vitro qualitative detection of the 2009 H1N1 influenza A viral RNA in nasopharyngeal swabs, nasal swabs, throat swabs, nasal aspirates, and nasopharyngeal aspirates from human patients with signs and symptoms of respiratory infection in conjunction with clinical and epidemiological risk factors. The Diatherix H1N1-09 Influenza Test is the only test within the Viral Respiratory Panel authorized by the FDA under the Emergency Use Authorization. Authorization is only for the detection of 2009 H1N1 influenza virus and not for seasonal influenza A, B.</p>
Performing Site:	Diatherix Laboratories

Test Changes

The following test changes will be effective on the dates indicated below. **Please note that only the fields listed in bold type are being changed.** Additional information, regarding the change, will be provided where applicable.

Urine Drug Screen	
Effective Date:	Immediately
Test Code:	59084
Specimen Requirements:	5 mL Random Urine (No Preservatives)
Rejection Criteria:	Received Room Temperature
Transport Temperature:	Refrigerated
Specimen Stability:	Room Temperature: Unacceptable Refrigerated: 7 days Frozen: 2 weeks
Additional Information:	Update specimen stability and reject criteria.

C-Peptide	
Effective Date:	March 7, 2011
Test Code:	372
Reference Range:	0.80-3.10 ng/mL
Additional Information:	Update reporting of patient results to 2 decimal places. These changes apply to the following series codes: 15448 – C-Peptide response to glucose, 9 specimens; 15843 – C-Peptide response to glucose, 2 specimens; 15844 – C-Peptide response to glucose, 3 specimens; 15845 – C-Peptide response to glucose, 4 specimens; 15846 – C-Peptide response to glucose, 6 specimens; 15847 – C-Peptide response to glucose, 7 specimens; 15848 – C-Peptide response to glucose, 8 specimens; 31345 – C-Peptide response to glucose, 5 specimens

HIV 1 RNA, Quantitative Real Time PCR		
Effective Date:	March 7, 2011	
Test Code:	40085	
Specimen Stability: EDTA Plasma	Room temperature: 24 hours Refrigerated: 6 days Frozen: 42 days	
Reference Ranges:	copies/mL: <20 copies/mL	Log copies/mL: <1.30 Log copies/mL

Quest Diagnostics Nichols Institute (San Juan Capistrano, Chantilly, and Valencia) and Focus Diagnostics, Inc.

New Test Offerings

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

CMV Antigenemia Assay	
Effective Date:	Immediately
Former Test Code:	59319
Former Test Name:	CMV Antigenemia
Test Code:	17461
CPT Code(s):	87271
Specimen Requirements:	10 mL whole blood collected in an EDTA (Lavender-Top) tube. Instructions: Do not centrifuge whole blood specimens. Whole blood specimen must be received in the testing department within 72 hours of collection.
Rejection Criteria:	Received Room Temperature; Received Frozen
Transport Temperature:	Refrigerated
Specimen Stability:	Room Temperature: Unacceptable Refrigerated: 72 hours Frozen: Unacceptable
Reference Ranges:	Zero CMV-infected cells observed
Methodology:	Direct Immunofluorescence Assay
Additional Information:	Please coordinate with your local DLO laboratory regarding timing requirements for this assay. This test, previously performed at DLO, will now be performed at Nichols Institute Chantilly.

Malaria Blood Parasites	
Effective Date:	Immediately
Test Code:	831
CPT Code(s):	87207
Specimen Requirements:	2-3 air-dried blood smears (1 thick and 1-2 thin) and a whole blood EDTA (lavender-top) tube
Rejection Criteria:	Hemolysis; Clotted
Transport Temperature:	Room Temperature
Stability:	Slides: Room Temperature: 30 days Whole Blood: Room Temperature: 48 hours
Methodology:	Microscopic Evaluation One negative observation cannot rule out blood parasites. <i>Babesia</i> and other blood parasites are noted and reported.
Additional Information:	This test, previously performed at DLO, will now be performed at Quest Diagnostics-Dallas.

JAK2 V617F Mutation, Quantitative			
Clinical Significance:	Detection of JAK2 mutation is important for diagnosis and monitoring of chronic myeloproliferative neoplasms. This cell-based pyrosequencing assay determines the percentage of mutated allele compared to unmutated allele, down to 1% sensitivity and is available for use on blood, bone marrow or formalin-fixed paraffin-embedded tissue blocks, including bone marrow biopsies.		
Effective Date:	January 20, 2011		
Test Code:	18950		
CPT Code:	83891, 83898, 83894, 83904, 83912		
Specimen Requirements:	Formalin-fixed, paraffin-embedded tissue in IHC specimen transport kit --or-- 3 mL EDTA (lavender-top tube) whole blood or bone marrow aspirate *Pathology report required for paraffin blocks/slides and tissue submissions.		
Rejection Criteria:	Grossly hemolyzed specimens are unacceptable.		
Transport Temperature:	Room temperature		
Specimen Stability:		Paraffin block	Whole blood or Bone marrow
	Room temperature:	Indefinitely	72 hours
	Refrigerated:	Indefinitely	72 hours
	Frozen:	Unacceptable	Unacceptable
Reference Ranges:	Accompanies report		
Methodology:	Polymerase Chain Reaction-Pyrosequencing		
Assay Category:	Laboratory Developed Test		
Performing Site:	Quest Diagnostics Nichols Institute, Chantilly		

Colorectal Cancer Mutation Panel (KRAS, PIK3CA, BRAF, NRAS)

*Includes: KRAS Mutation Analysis * PIK3CA Mutation Analysis * BRAF Mutation Analysis
NRAS Mutation Analysis

Clinical Significance:	This panel detecting tumor-associated somatic mutations in 4 different oncogenes can predict response to EGFR-targeted immunotherapy in patients with metastatic colorectal cancer. Tumors with mutations in KRAS, NRAS, BRAF and PI3KCA (exons 9 and 20) are associated with inferior response to anti-EGFR immunotherapy, and variably associated with more aggressive clinical behavior compared to unmutated cases.
Effective Date:	March 14, 2011
Test Code:	18902
CPT Code(s):	83891, 83898 (x2), 83892 (x2), 83909 (x4), 83904 (x4), 83912, 83898 (x3), 83904 (x3), 83907, 83909 (x3), 83912; 83898 (x3), 83894 (x3), 83892 (x3), 83909 (x6), 83904 (x3), 83912, 83898 (x2), 83892 (x2), 83909 (x4), 83904 (x4), 83912
Specimen Requirements:	Formalin fixed, paraffin embedded tissue block
Transport Temperature:	Room temperature
Specimen Stability:	Room temperature and Refrigerated: Indefinite Frozen: Do Not Freeze
Reference Ranges:	KRAS Mutation Analysis: Not Detected PIK3CA Mutation Analysis: Not Detected BRAF Mutation Analysis: Not Detected NRAS Mutation Analysis: Not Detected
Methodology:	Polymerase Chain Reaction, Sequencing
Assay Category:	Laboratory Developed Test
Performing Site:	Quest Diagnostics Nichols Institute, San Juan Capistrano

Serotonin Release Assay (SRA), Fondaparinux	
Clinical Significance:	Fondaparinux-SRA assay may be useful for in-vitro investigation of suspected fondaparinux-induced thrombocytopenia and/or thrombocytopenia with thrombosis syndrome (HIT/HITT).
Effective Date:	February 14, 2011
Test Code:	16285
CPT Code(s):	86022
Specimen Requirements:	1 mL serum
Transport Temperature:	Frozen
Specimen Stability:	Room temperature: 24 hours Refrigerated: 48 hours Frozen: 6 months
Reference Ranges:	Fondaparinux SRA Result: Negative Low Dose, 0.5 mcg/mL: % release Low Dose, 1.0 mcg/mL: % release High Dose, 100 mcg/mL: % release Interpretation accompanies report
Methodology:	Radiobinding 14C Serotonin Radiolabel
Assay Category:	Laboratory Developed Test
Performing Site:	Quest Diagnostics Nichols Institute

Serotonin Release Assay (SRA), LMWH	
Clinical Significance:	Low molecular weight heparin serotonin release assay (LMWH-SRA) may be useful for in-vitro investigation of LMWH-induced thrombocytopenia and/or thrombocytopenia with thrombosis syndrome (HIT/HITT).
Effective Date:	February 14, 2011
Test Code:	16284
CPT Code(s):	86022
Specimen Requirements:	1 mL serum
Transport Temperature:	Frozen
Specimen Stability:	Room temperature: 24 hours Refrigerated: 48 hours Frozen: 6 months
Reference Ranges:	LMWH SRA Result: Negative LMWH Low Dose, 0.1 U/mL: % release LMWH Low Dose, 1.0 U/mL: % release LMWH High Dose, 50 U/mL: % release Interpretation accompanies report
Methodology:	Radiobinding 14C Serotonin Radiolabel
Assay Category:	Laboratory Developed Test
Performing Site:	This test is currently available at Quest Diagnostics Nichols Institute, Chantilly and will also be available at Quest Diagnostics Nichols Institute, San Juan Capistrano.

Meningoencephalitis Comprehensive Panel (CSF)

Includes: Adenovirus Antibody, CSF; California Encephalitis Virus Antibody Panel, IFA (CSF); Coxsackie A Antibodies, CSF; Coxsackie B (1-6) Antibodies, CSF; Eastern Equine Encephalitis Virus Antibody, IFA (CSF); West Nile Virus Antibody Panel, ELISA (CSF); Echovirus Antibodies, CSF; Herpes Simplex Virus (HSV) 1/2 IgM Antibody, IFA (CSF); Herpes Simplex Virus 1/2 (IgG Type-Specific Antibodies, CSF; Influenza Type A and B Antibodies, CSF; Lymphocytic Choriomeningitis (LCM) Virus Ab, IFA (CSF); Measles (Rubeola) IgG and IgM Antibody Panel, IFA (CSF); Mumps Antibody Panel, IFA (CSF); St. Louis Encephalitis Virus Antibody, IFA (CSF); Varicella-Zoster Virus Antibody, CSF; Western Equine Encephalitis IgG & IgM Ab Pnl, IFA (CSF); Cytomegalovirus (CMV) IgG Antibody, ELISA (CSF); Cytomegalovirus (CMV) IgM Antibody, ELISA (CSF);

Effective Date:	March 21, 2011
Test Code:	18957
CPT Code(s):	86651 (x2), 86652 (x2), 86653 (x2), 86654 (x2), 86727 (x2), 86695 (x2), 86696 (x2), 86603, 86710 (x2), 86765 (x2), 86735 (x2), 86787, 86658 (x17), 86644, 86645, 86788, 86798
Specimen Requirements:	4 mL CSF
Transport Temperature:	Refrigerated
Specimen Stability:	Room temperature: Unacceptable Refrigerated: 7 days Frozen: 30 days
Reference Ranges:	See individual tests
Methodology:	See individual tests
Assay Category:	See individual tests
Performing Site:	Focus Diagnostics, Inc

Test Changes

The following test changes will be effective on the dates indicated below. Please note that only the fields listed in bold type are being changed; former test names and test codes have been italicized. Additional information, regarding the change, will be provided where applicable.

Acetylcholinesterase	
Effective Date:	March 14, 2011
Test Code:	4929
Specimen Requirements:	1.5 mL amniotic fluid (sterile, leak-proof container) (0.5 mL minimum)
Performing Site:	Quest Diagnostics Nichols Institute
Additional Information:	Update specimen volume.

Alpha-Fetoprotein, AF w/Reflex to AChE/Fetal Hgb	
Effective Date:	March 14, 2011
Test Code:	232
Specimen Requirements:	3 mL amniotic fluid (sterile, leak-proof container) (1.5 mL minimum)
Performing Site:	Quest Diagnostics Nichols Institute
Additional Information:	Update specimen volume.

16767-BRAF Mutation Analysis 16819-EGFR Pathway (KRAS with reflex to NRAS, BRAF) 16510 -KRAS Mutation Analysis 16818-NRAS Mutation Analysis 16897-PIK3CA Mutation Analysis	
Effective Date:	March 14, 2011
Reference Range:	Not Detected
Performing Site:	Quest Diagnostics Nichols Institute
Additional Information:	Update reference range.

CYP2C19 Genotyping	
Effective Date:	March 14, 2011
<i>Former Test Name:</i>	<i>Plavix® P450 Genotype</i>
Test Code:	16605
CPT Code:	83891, 83892, 83896 (x2), 83900, 83912
Performing Site:	Quest Diagnostics Nichols Institute, Chantilly
Additional Information:	Update test name and CPT coding. Remove component 90000009 - CYP2D6 Genotype.

Lung Cancer Mutation Panel (EGFR, KRAS, ALK)	
Effective Date:	March 14, 2011
Test Code:	16461
Specimen Requirements:	Formalin fixed paraffin embedded tissue block is preferred specimen for all components in this panel.
Performing Site:	Quest Diagnostics Nichols Institute, San Juan Capistrano
Additional Information:	Update preferred specimen type. Update CPU interface mapping. Remove result codes 86006583 and 86004530 Mutation Type, Level.

Serotonin Release Assay, Unfractionated Heparin			
Effective Date:	March 14, 2011		
<i>Former Test Name:</i>	<i>Serotonin Release Assay (SRA)</i>		
Test Code:	14627		
Reference Range:	UFH SRA Result:	Negative	
	UFH Low Dose, 0.1 IU/mL:		% release
	UFH Low Dose, 0.5 IU/mL:		% release
	UFH High Dose, 100 IU/mL:		% release
	Interpretation accompanies report		
Performing Site:	Quest Diagnostics Nichols Institute		
Additional Information:	Update test name, reference range, add new reporting analytes. Please note: this test is included in the following group codes: 14874 - Heparin-Induced Thrombocytopenia Panel 15334 - Heparin Induced Platelet Antibody, Reflex to SRA		

<i>Echinococcus</i> Antibody (IgG)	
Effective Date:	March 14, 2011
Test Code:	34169
Reference Range:	Negative
Performing Site:	Focus Diagnostics, Inc.
Additional Information:	Update reference range and always message.

<i>Entamoeba histolytica</i> IgG, ELISA	
Effective Date:	March 14, 2011
Test Code:	34278
Reference Range:	Negative
Performing Site:	Focus Diagnostics, Inc.
Additional Information:	Update reference range and always message.

<i>Trichinella</i> IgG Antibody, ELISA	
Effective Date:	March 14, 2011
Test Code:	34321
Transport Temperature:	Room temperature
Specimen Stability:	Room temperature: 7 days Refrigerated: 14 days Frozen: 30 days
Reference Range:	Negative
Performing Site:	Focus Diagnostics, Inc.
Additional Information:	Update transport temperature, stability, reference range and always message.

CA 125, CSF	
Effective Date:	March 28, 2011
Test Code:	17416
Performing Site:	Quest Diagnostics Nichols Institute, San Juan Capistrano, that previously performed this test, will now send to Quest Diagnostics Nichols Institute, Chantilly.
Additional Information:	Update performing site.

16011-CellSearch® Circulating Tumor Cells, Breast
16811-CellSearch® Circulating Tumor Cells, Colon
16812-CellSearch® Circulating Tumor Cells, Prostate

Effective Date:	March 28, 2011
Specimen Requirements:	<p>10 ml (x2) whole blood in CellSave™ Preservative Tube (minimum 10 ml [x2])</p> <p>1. Draw at least one CellSave (TM) 10 mL tube. It is highly recommended that 2 10 mL tubes be drawn due to the possibility of a repeat due to carry over or system malfunction.</p> <p>2. Collect blood aseptically by venipuncture or from a venous port into a CellSave™ Preservative Tube only. Circulating tumor cells (CTC) are fragile and require preservation for accurate analysis.</p> <p>3. Fill the tube until blood flow stops to ensure the correct ratio of sample to anticoagulant and preservative. Immediately mix by gently inverting the tube eight times. Tube inversion prevents clotting. Inadequate or delayed mixing may result in inaccurate test results.</p> <p>4. Process samples within 96 hours of collection.</p> <p>5. Blood samples may be stored or transported in CellSave™ Preservative Tubes for up to 96 hours at room temperature (15 to 30C) prior to processing. Draw date and time must be provided with the whole blood specimen. Draw samples prior to intravenous therapy. After initiation of therapy, blood can be drawn at the first follow-up visit, which is usually 3-4 weeks after initiation of therapy. If the patient is on doxorubicin therapy, allow at least 7 days following administration of a dose of therapy before blood draw.</p>
Performing Site:	Quest Diagnostics Nichols Institute
Additional Information:	Update specimen volume and collection instruction.