

12/10/2014 - Immediate Action, Quest Diagnostics Nichols Institute, Valencia

NEW TESTS			
Please Note: Not all test codes assigned to each assay are listed in the table of contents. Please refer to the complete listing on the page numbers indicated.			
Test Code	Test Name	Effective Date	Page #
<u>16924</u>	AccuType® CP, Clopidogrel CYP2C19 Genotype	12/15/2014	1
<u>16925</u>	AccuType® CP, Clopidogrel CYP2C19 Genotype (NY)	12/15/2014	2
<u>10490</u>	Cytochrome P450 2D6 Genotype	12/15/2014	2
<u>14589</u>	Cytochrome P450 2D6 Genotype (NY)	12/15/2014	3

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 #
	Arbovirus Testing Update	12/11/2014	3
<u>18946</u>	Pain Management, CYP450 2D6/2C19 Genotyping	12/15/2014	4
<u>18947</u>	Pain Management, CYP450 2D6/2C19 Genotyping (NY)	12/15/2014	5

NY UPDATE			
Please Note: Not all test codes assigned to each assay are listed in the table of contents. Please refer to the complete listing on the page numbers indicated.			
Test Code	Test Name	Effective Date	Page #
	HPV New York Patient Testing Update		5
	<i>Mycoplasma pneumoniae</i> CSF		5

Due to the background information related to these changes, we are unable to use our normal method of communication. These changes listed in this document are effective in less than 30 days. Please note the individual effective dates below, as some of these changes require IMMEDIATE ACTION.

## New Test Offerings

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

AccuType® CP, Clopidogrel CYP2C19 Genotype	
Message	<b>**This test is not approved for New York patient testing. For New York patient testing, use test code 16925-AccuType® CP, Clopidogrel CYP2C19 Genotype (NY).**</b>
Effective Date	12/15/2014
Test Code	16924
CPT Codes	81225
Specimen Requirements	4 mL (2 mL minimum) whole blood collected in an EDTA (lavender-top) tube
Instructions	Whole blood: Normal phlebotomy procedure. Specimen stability is crucial. Store and ship immediately. Saliva collection kits require patient to rinse mouth prior to spitting into Oragene collection kit. See Oragene product insert for further details.
Transport Temperature	Room temperature

Specimen Stability	Room temperature: 8 days Refrigerated: 30 days Frozen: 49 days					
Set-up/Analytic Time	Set up: Tues, Fri; Report available: 4-8 days					
Reference Range	Accompanies report					
Methodology	Polymerase Chain Reaction/Single Nucleotide Primer Extension					
Performing Site	Quest Diagnostics Nichols Institute, San Juan Capistrano					
Interface Mapping	<table border="1"> <thead> <tr> <th>Result Code</th> <th>Result Name</th> </tr> </thead> <tbody> <tr> <td>86004166</td> <td>Cytochrome P450 2C19</td> </tr> </tbody> </table>		Result Code	Result Name	86004166	Cytochrome P450 2C19
Result Code	Result Name					
86004166	Cytochrome P450 2C19					

AccuType® CP, Clopidogrel CYP2C19 Genotype (NY)						
Message	<b>**For non-New York patient testing, use test code 16924- AccuType® CP, Clopidogrel CYP2C19 Genotype .**</b>					
Effective Date	12/15/2014					
Test Code	16925					
CPT Codes	81225					
Specimen Requirements	4 mL (2 mL minimum) whole blood collected in an EDTA (lavender-top) tube					
Instructions	Whole blood: Normal phlebotomy procedure. Specimen stability is crucial. Store and ship immediately. Saliva collection kits require patient to rinse mouth prior to spitting into Oragene collection kit. See Oragene product insert for further details.					
Transport Temperature	Room temperature					
Specimen Stability	Room temperature: 8 days Refrigerated: 30 days Frozen: 49 days					
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Reference Range	Accompanies report					
Methodology	Polymerase Chain Reaction/Single Nucleotide Primer Extension					
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86004167	Cytochrome P450 2C19					

Cytochrome P450 2D6 Genotype		
Message	<b>**This test is not approved for New York patient testing. For New York patient testing, use test code 14589- Cytochrome P450 2D6 Genotype (NY).**</b>	
Clinical Significance	The CYP2D6 gene product is responsible for the metabolism of many major drug groups including many antidepressants, neuroleptics, and cardiovascular drugs. Cytochrome 450 2D6 Genotype detects eight alleles associated with the poor metabolizer phenotype (PM). Patients with duplication of the CYP2D6 gene are ultraextensive metabolizers (UEM). Approximately 5-10% of Caucasian individuals express PM phenotype and the same percentage the UEM phenotype.	
Effective Date	12/15/2014	

Test Code	10490					
CPT Codes	81226					
Specimen Requirements	5 mL (3 mL minimum) whole blood collected in an EDTA (lavender-top) tube					
Instructions	Specimen stability is crucial. Store and ship at room temperature immediately. Do not freeze.					
Transport Temperature	Room temperature					
Specimen Stability	Room temperature and Refrigerated: 8 days Frozen: Unacceptable					
Set-up/Analytic Time	Set up: Mon, Thurs; Report available: 6-10 days					
Reference Range	Accompanies report					
Methodology	PCR followed by a Single Nucleotide Primer Extension Reaction (SNP-IT)					
Performing Site	Quest Diagnostics Nichols Institute, San Juan Capistrano					
Interface Mapping	<table border="1"> <thead> <tr> <th>Result Code</th> <th>Result Name</th> </tr> </thead> <tbody> <tr> <td>85994482</td> <td>CYP2D6</td> </tr> </tbody> </table>		Result Code	Result Name	85994482	CYP2D6
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Cytochrome P450 2D6 Genotype (NY)						
Message	<b>**For New York patient testing, use test code 10490- Cytochrome P450 2D6 Genotype.**</b>					
Effective Date	12/15/2014					
Test Code	14589					
CPT Codes	81226					
Specimen Requirements	5 mL (3 mL minimum) whole blood collected in an EDTA (lavender-top) tube					
Instructions	Specimen stability is crucial. Store and ship at room temperature immediately. Do not freeze.					
Transport Temperature	Room temperature					
Specimen Stability	Room temperature and Refrigerated: 8 days Frozen: Unacceptable					
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Result Code	Result Name					
85998868	CYP2D6					

### Discontinued Tests

Arbovirus Testing Update	
Message	Dear client, The Arboviral reagents for the validated Arboviral antibody tests for both CSF/serum have been

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	<p>unavailable from the manufacturer for several months with no resolution in sight. Quest Diagnostics is working to bring up a new validated test in the future, however this may not be available for some time. We will be canceling all orders for Arboviral antibody testing at this point and inactivating the order codes. Panel codes will remain active and the Arboviral portions of the test will be canceled. Serum and CSF samples that have been held for Arbovirus antibody testing will be discarded on December 22, 2014. If you wish to have CSF specimens returned, please notify us. Testing for West Nile Virus antibodies will still be performed as those reagents have not been affected. We are sorry for this inconvenience and will notify you when we reactivate these test codes.</p>																																																											
<b>Effective Date</b>	12/11/2014																																																											
Additional Information	There is no recommended alternative.																																																											
Tests Affected	<table border="1"> <thead> <tr> <th data-bbox="508 611 735 657">Test Codes:</th> <th data-bbox="735 611 1510 657">Name:</th> </tr> </thead> <tbody> <tr><td>8290</td><td>Arbovirus IgG &amp; IgM Antibodies</td></tr> <tr><td>8290C</td><td>Arbovirus IgG &amp; IgM Antibodies CSF</td></tr> <tr><td>9521C</td><td>Arbovirus IgG Antibody Panel, IFA (CSF)</td></tr> <tr><td>9521</td><td>Arbovirus IgG Antibody, IFA</td></tr> <tr><td>8226C</td><td>Arbovirus IgM Antibody Panel, IFA (CSF)</td></tr> <tr><td>8226</td><td>Arbovirus IgM Antibody, IFA</td></tr> <tr><td>8120</td><td>California-La Crosse Encephalitis IgG &amp; IgM Abs</td></tr> <tr><td>8120C</td><td>California-La Crosse Encephalitis IgG &amp; IgM Abs CSF</td></tr> <tr><td>8926</td><td>California-La Crosse Encephalitis IgG Abs</td></tr> <tr><td>8926C</td><td>California-La Crosse Encephalitis IgG Abs CSF</td></tr> <tr><td>8176</td><td>California-La Crosse Encephalitis IgM Abs</td></tr> <tr><td>8176C</td><td>California-La Crosse Encephalitis IgM Abs CSF</td></tr> <tr><td>8936</td><td>Eastern Equine Encephalitis IgG</td></tr> <tr><td>8124</td><td>Eastern Equine Encephalitis IgG &amp; IgM Antibodies</td></tr> <tr><td>8124C</td><td>Eastern Equine Encephalitis IgG &amp; IgM Antibodies (CSF)</td></tr> <tr><td>8936C</td><td>Eastern Equine Encephalitis IgG(CSF)</td></tr> <tr><td>8181</td><td>Eastern Equine Encephalitis IgM AB, IFA</td></tr> <tr><td>8181C</td><td>Eastern Equine Encephalitis IgM Antibody, IFA (CSF)</td></tr> <tr><td>8122</td><td>St. Louis Encephalitis IgG &amp; IgM Abs</td></tr> <tr><td>8122C</td><td>St. Louis Encephalitis IgG &amp; IgM Abs CSF</td></tr> <tr><td>8921</td><td>St. Louis Encephalitis IgG IFA</td></tr> <tr><td>8921C</td><td>St. Louis Encephalitis IgG IFA (CSF)</td></tr> <tr><td>8186</td><td>St. Louis Encephalitis IgM IFA</td></tr> <tr><td>8186C</td><td>St. Louis Encephalitis IgM IFA (CSF)</td></tr> <tr><td>8931</td><td>Western Equine Encephalitis IgG</td></tr> <tr><td>8128C</td><td>Western Equine Encephalitis IgG &amp; IgM Abs (CSF)</td></tr> <tr><td>8128</td><td>Western Equine Encephalitis IgG &amp; IgM Antibodies</td></tr> <tr><td>8931C</td><td>Western Equine Encephalitis IgG Antibodies CSF</td></tr> </tbody> </table>		Test Codes:	Name:	8290	Arbovirus IgG & IgM Antibodies	8290C	Arbovirus IgG & IgM Antibodies CSF	9521C	Arbovirus IgG Antibody Panel, IFA (CSF)	9521	Arbovirus IgG Antibody, IFA	8226C	Arbovirus IgM Antibody Panel, IFA (CSF)	8226	Arbovirus IgM Antibody, IFA	8120	California-La Crosse Encephalitis IgG & IgM Abs	8120C	California-La Crosse Encephalitis IgG & IgM Abs CSF	8926	California-La Crosse Encephalitis IgG Abs	8926C	California-La Crosse Encephalitis IgG Abs CSF	8176	California-La Crosse Encephalitis IgM Abs	8176C	California-La Crosse Encephalitis IgM Abs CSF	8936	Eastern Equine Encephalitis IgG	8124	Eastern Equine Encephalitis IgG & IgM Antibodies	8124C	Eastern Equine Encephalitis IgG & IgM Antibodies (CSF)	8936C	Eastern Equine Encephalitis IgG(CSF)	8181	Eastern Equine Encephalitis IgM AB, IFA	8181C	Eastern Equine Encephalitis IgM Antibody, IFA (CSF)	8122	St. Louis Encephalitis IgG & IgM Abs	8122C	St. Louis Encephalitis IgG & IgM Abs CSF	8921	St. Louis Encephalitis IgG IFA	8921C	St. Louis Encephalitis IgG IFA (CSF)	8186	St. Louis Encephalitis IgM IFA	8186C	St. Louis Encephalitis IgM IFA (CSF)	8931	Western Equine Encephalitis IgG	8128C	Western Equine Encephalitis IgG & IgM Abs (CSF)	8128	Western Equine Encephalitis IgG & IgM Antibodies	8931C	Western Equine Encephalitis IgG Antibodies CSF
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	8191	Western Equine Encephalitis IgM
	8191C	Western Equine Encephalitis IgM (CSF)

Pain Management, CYP450 2D6/2C19 Genotyping	
Effective Date	12/15/2014
Test Code	18946
Additional Information	<p>Due to reagent issues, this test is being discontinued. The recommended alternatives are:</p> <ul style="list-style-type: none"> <li>  16924 - AccuType® CP, Clopidogrel CYP2C19 Genotype</li> <li>  10490 - Cytochrome P450 2D6 Genotype</li> </ul> <p>in the New Test Offering section.</p> <p>Due to the difference in methodology, the alleles detected are slightly different and the drugs are not listed.</p>
Pricing Message	Due to the suggested replacement, negotiated fees will not be copied.

Pain Management, CYP450 2D6/2C19 Genotyping (NY)	
Effective Date	12/15/2014
Test Code	18947
Additional Information	<p>Due to reagent issues, this test is being discontinued. The recommended alternatives are:</p> <ul style="list-style-type: none"> <li>  16925 - AccuType® CP, Clopidogrel CYP2C19 Genotype (NY)</li> <li>  14589 - Cytochrome P450 2D6 Genotype (NY)</li> </ul> <p>in the New Test Offering section.</p> <p>Due to the difference in methodology, the alleles detected are slightly different and the drugs are not listed.</p>
Pricing Message	Due to the suggested replacement, negotiated fees will not be copied.

**New York Patient Testing Update**

HPV New York Patient Testing Update															
Message	<b>**These tests are not available for New York patient testing at Focus Diagnostics, Inc.**</b>														
Effective Date	12/10/2014														
Tests Affected	<table border="1"> <thead> <tr> <th>Test Codes:</th> <th>Name:</th> </tr> </thead> <tbody> <tr> <td>19863</td> <td>HPV DNA, High Risk with Reflex to Genotypes 16,18</td> </tr> <tr> <td>19865</td> <td>HPV Genotypes 16 and 18</td> </tr> <tr> <td>91826</td> <td>HPV Genotypes 16, 18/45</td> </tr> <tr> <td>92392</td> <td>HPV Genotypes 16, 18/45, SurePath(TM) Vial</td> </tr> <tr> <td>90942</td> <td>HPV mRNA E6/E7 Reflex to Genotypes 16,18/45</td> </tr> <tr> <td>91932</td> <td>HPV mRNA E6/E7, Rectal</td> </tr> </tbody> </table>	Test Codes:	Name:	19863	HPV DNA, High Risk with Reflex to Genotypes 16,18	19865	HPV Genotypes 16 and 18	91826	HPV Genotypes 16, 18/45	92392	HPV Genotypes 16, 18/45, SurePath(TM) Vial	90942	HPV mRNA E6/E7 Reflex to Genotypes 16,18/45	91932	HPV mRNA E6/E7, Rectal
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91932	HPV mRNA E6/E7, Rectal														

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	92211	HPV mRNA E6/E7, SurePath(TM) with Reflex to HPV Genotypes 16, 18/45
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<b><i>Mycoplasma pneumoniae</i> CSF</b>							
Message	<b>**These tests are not available for New York patient testing at Focus Diagnostics, Inc.**</b>						
Effective Date	<b>12/10/2014</b>						
Tests Affected	<table border="1" style="width: 100%;"> <thead> <tr> <th style="width: 50%;">Test Codes:</th> <th style="width: 50%;">Name:</th> </tr> </thead> <tbody> <tr> <td>S50053</td> <td>Mycoplasma pneumoniae IgG Antibody, IFA (CSF)</td> </tr> <tr> <td>A50596; S51185</td> <td>Mycoplasma pneumoniae IgM Antibody, IFA (CSF)</td> </tr> </tbody> </table>	Test Codes:	Name:	S50053	Mycoplasma pneumoniae IgG Antibody, IFA (CSF)	A50596; S51185	Mycoplasma pneumoniae IgM Antibody, IFA (CSF)
	Test Codes:	Name:					
	S50053	Mycoplasma pneumoniae IgG Antibody, IFA (CSF)					
A50596; S51185	Mycoplasma pneumoniae IgM Antibody, IFA (CSF)						