

6/30/2014 - New Release, 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>S52335</u>	Chikungunya Antibodies with Reflex(es) to Titer	6/30/2014	1
<u>S52326</u>	Chikungunya Virus RNA, Qualitative Real-Time PCR	6/30/2014	2
<u>92392</u>	HPV Genotypes 16,18/45, SurePath® Vial	7/21/2014	2
<u>92203</u>	HPV mRNA E6/E7, SurePath® Vial	7/21/2014	3
<u>92211</u>	HPV mRNA E6/E7, SurePath® Vial with Reflex to HPV Genotype 16, 18/45	7/21/2014	3

## New Test Offerings

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

Chikungunya Antibodies with Reflex(es) to Titer							
Message	This test has been available since 2010. For those clients who have been ordering this test, no changes need to be made.						
Clinical Significance	Chikungunya virus is a mosquito-borne alphavirus associated with febrile illness in Africa, the Indian Ocean islands, India, Southeast Asia, and the Caribbean. Symptoms include severe arthralgia, rash, and headache. U.S. cases have been associated with international travel to countries with endemic Chikungunya virus.						
Effective Date	6/30/2014						
Test Code	S52335						
CPT Codes	86790 (x2)						
Specimen Requirements	0.5 mL (0.1 mL minimum) serum						
Transport Temperature	Room temperature						
Specimen Stability	Room temperature: 7 days Refrigerated: 14 days Frozen: 30 days						
Set-up/Analytic Time	Set up: Tues; Report available: 1-8 days						
Reference Range	Negative						
Always Message	This test 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						
Performing Site	Focus Diagnostics, Inc.						
CPU Mappings	<table border="1"> <thead> <tr> <th>Result Code</th> <th>Result Name</th> </tr> </thead> <tbody> <tr> <td>112954</td> <td>Chikungunya IgG Screen</td> </tr> <tr> <td>112955</td> <td>Chikungunya IgM Screen</td> </tr> </tbody> </table> <p><i>This is a reflex. Please build the unit code below separately.</i></p>	Result Code	Result Name	112954	Chikungunya IgG Screen	112955	Chikungunya IgM Screen
Result Code	Result Name						
112954	Chikungunya IgG Screen						
112955	Chikungunya IgM Screen						

	<b>Non-orderable Reflex A52608-Chikungunya IgG Titration</b>	
	Result Code	Result Name
	13328	Chikungunya IgG Titer
	<i>This is a reflex. Please build the unit code below separately.</i>	
	<b>Non-orderable Reflex A52609-Chikungunya IgM Titration</b>	
	Result Code	Result Name
	13329	Chikungunya IgM Titration
Additional Information	<p>If the IgG is positive, then Chikungunya IgG Titration will be performed at an additional charge (CPT code (s): 86790).</p> <p>If the IgM is positive, then Chikungunya IgM Titration will be performed at an additional charge (CPT code (s): 86790).</p>	

<b>Chikungunya Virus RNA, Qualitative Real-Time PCR</b>					
Message	<p><b>**This test is not available for New York patient testing**</b></p> <p>This test has been available since 2010. For those clients who have been ordering this test, no changes need to be made.</p>				
Clinical Significance	Chikungunya Virus is a mosquito-transmitted virus that is usually associated with acute epidemic polyarthralgia and fever. Detection of Chikungunya Virus by this assay is based upon the real-time amplification of viral genomic RNA sequences from total nucleic acid extraction of the specimen.				
Effective Date	6/30/2014				
Test Code	S52326				
CPT Codes	87798				
Specimen Requirements	0.7 mL (0.3 mL minimum) serum				
Transport Temperature	Frozen				
Specimen Stability	<p>Room temperature: 48 hours</p> <p>Refrigerated: 7 days</p> <p>Frozen: 30 days</p>				
Set-up/Analytic Time	Set up: Daily; Report available: 2 days				
Reference Range	Not detected				
Always Message	This test was developed and its performance characteristics have been determined by Focus Diagnostics, Inc. Performance characteristics refer to the analytical performance of the test. This test is pursuant to a license agreement with Roche Molecular Systems, Inc.				
Methodology	Real-Time Polymerase Chain Reaction				
Performing Site	Focus Diagnostics, Inc.				
CPU Mappings	<table border="1"> <tr> <td>Result Code</td> <td>Result Name</td> </tr> <tr> <td>112940</td> <td>Chikungunya Virus RNA, QL PCR</td> </tr> </table>	Result Code	Result Name	112940	Chikungunya Virus RNA, QL PCR
Result Code	Result Name				
112940	Chikungunya Virus RNA, QL PCR				

<b>HPV Genotypes 16,18/45, SurePath® Vial</b>	
Effective Date	7/21/2014
Test Code	92392

CPT Codes	87621 (x2)							
Specimen Requirements	SurePath® Collection Vial or Aptima® Transfer Tube with 0.5 ml SurePath® Fluid							
Instructions	<p>Transfer a 0.5 mL of SurePath® fluid into an Aptima® Transfer Tube (containing 2.9 mL STM) within 7 days of collection.</p> <p>Client labs performing cytology and testing departments: transfer 0.5ml of SurePath® solution into APTIMA® Specimen Transfer tube (green label).</p>							
Transport Temperature	Room temperature							
Specimen Stability	Room temperature and Refrigerated: 7 days							
Reference Range	Not detected							
Methodology	Transcription-Mediated Amplification							
Performing Site	Quest Diagnostics Nichols Institute, San Juan Capistrano							
CPU Mappings	<table border="1"> <thead> <tr> <th>Result Code</th> <th>Result Name</th> </tr> </thead> <tbody> <tr> <td>86011242</td> <td>HPV 16 RNA</td> </tr> <tr> <td>86011243</td> <td>HPV 18/45 RNA</td> </tr> </tbody> </table>		Result Code	Result Name	86011242	HPV 16 RNA	86011243	HPV 18/45 RNA
Result Code	Result Name							
86011242	HPV 16 RNA							
86011243	HPV 18/45 RNA							

HPV mRNA E6/E7, SurePath® Vial						
Effective Date	7/21/2014					
Test Code	92203					
CPT Codes	87621					
Specimen Requirements	SurePath® Collection Vial or Aptima® Transfer Tube with 0.5 ml SurePath® Fluid					
Instructions	<p>Transfer a 0.5 mL of SurePath® fluid into an Aptima® Transfer Tube (containing 2.9 mL STM) within 7 days of collection.</p> <p>Client labs performing cytology and testing departments: transfer 0.5ml of SurePath® solution into APTIMA® Specimen Transfer tube (green label).</p>					
Transport Temperature	Room temperature					
Specimen Stability	Room temperature and Refrigerated: 7 days					
Reference Range	Not detected					
Methodology	Transcription-Mediated Amplification					
Performing Site	Quest Diagnostics Nichols Institute, Valencia					
CPU Mappings	<table border="1"> <thead> <tr> <th>Result Code</th> <th>Result Name</th> </tr> </thead> <tbody> <tr> <td>86010891</td> <td>HPV mRNA E6/E7</td> </tr> </tbody> </table>		Result Code	Result Name	86010891	HPV mRNA E6/E7
Result Code	Result Name					
86010891	HPV mRNA E6/E7					

HPV mRNA E6/E7, SurePath® Vial with Reflex to HPV Genotype 16, 18/45		
Effective Date	7/21/2014	
Test Code	92211	

CPT Codes	87621														
Specimen Requirements	SurePath® Collection Vial or Aptima® Transfer Tube with 0.5 ml SurePath® Fluid.														
Instructions	Transfer a 0.5 mL of SurePath® fluid into an Aptima® Transfer Tube (containing 2.9 mL STM) within 7 days of collection.  Client labs performing cytology and testing departments: transfer 0.5ml of SurePath® solution into APTIMA® Specimen Transfer tube (green label).														
Transport Temperature	Room temperature														
Specimen Stability	Room temperature and Refrigerated: 7 days														
Reference Range	Not detected														
Methodology	Transcription-Mediated Amplification														
Performing Site	Quest Diagnostics Nichols Institute, San Juan Capistrano														
CPU Mappings	<table border="1"> <tr> <td colspan="2">92211-1 HPV mRNA E6/E7,SurePath</td> </tr> <tr> <td>Result Code</td> <td>Result Name</td> </tr> <tr> <td>86010891</td> <td>HPV mRNA E6/E7</td> </tr> <tr> <td colspan="2"><i>This test is a true reflex. Please build the unit code below separately. Non-orderable 92211-2 HPV Genotypes 16,18/45,SurePath</i></td> </tr> <tr> <td>Result code</td> <td>Result Name</td> </tr> <tr> <td>86011242</td> <td>HPV 16 RNA</td> </tr> <tr> <td>86011243</td> <td>HPV 18/45 RNA</td> </tr> </table>	92211-1 HPV mRNA E6/E7,SurePath		Result Code	Result Name	86010891	HPV mRNA E6/E7	<i>This test is a true reflex. Please build the unit code below separately. Non-orderable 92211-2 HPV Genotypes 16,18/45,SurePath</i>		Result code	Result Name	86011242	HPV 16 RNA	86011243	HPV 18/45 RNA
92211-1 HPV mRNA E6/E7,SurePath															
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86010891	HPV mRNA E6/E7														
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Result code	Result Name														
86011242	HPV 16 RNA														
86011243	HPV 18/45 RNA														
Additional Information	If the HPV mRNA E6/E7, SurePath® Vial is Detected, then HPV Genotypes 16,18/45, SurePath® Vial will be performed at an additional charge (CPT code(s): 87621 (x2)).														