

6/12/2014 - 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>92208</u>	3a-Androstenediol Glucuronide, ELISA	7/21/2014	2

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 #
<u>S51746</u>		<i>Helicobacter pylori</i> , Urea Breath Test	6/23/2014	2
<u>14577</u>	A51540	Bacterial Vaginosis/Vaginitis Panel	7/14/2014	3
<u>8401</u>		HIV-1 DNA, Qualitative PCR	7/14/2014	3
<u>34286</u>	7745	<i>Pneumocystis jirovecii</i> (<i>P. carinii</i>), DFA	7/14/2014	4

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 #
<u>S51864</u>	17 Ketosteroids, Fractionated, Urine	7/21/2014	5
<u>S51355</u>	3a-Androstenediol Glucuronide (3-Alpha Diol G)	7/21/2014	5
<u>S51344</u>	Cortisol Binding Globulin (Transcortin)	7/21/2014	5
<u>S51384</u>	DHEA (Dehydroepiandrosterone), Urine	7/21/2014	5
<u>S51460</u>	Pregnanetriol, Urine	7/21/2014	5
<u>S49986</u>	Testosterone, Urine	7/21/2014	5
<u>S51411</u>	Tetrahydroaldosterone, Urine	7/21/2014	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	Page #
<u>S49825</u>	Vitamin B2 (Riboflavin), Plasma	6

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 #
<u>A52601</u>		Raji Cell Immune Complex Assay	6/12/2014	6
<u>S49558</u>		NeoCerebellar Degeneration Paraneo w/Recombx	6/16/2014	6

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

6/12/2014 - Immediate Action, Quest Diagnostics Nichols Institute, Valencia

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

3a-Androstenediol Glucuronide, ELISA											
Message	**This test is not available for New York patient testing.**										
Clinical Significance	Marker for disorders of peripheral androgen formation and action, such as in hirsutism and acne.										
Effective Date	7/21/2014										
Test Code	92208										
CPT Codes	82154										
Specimen Requirements	Preferred: 0.5 mL (0.25 mL minimum) serum Acceptable: 0.5 mL (0.25 mL minimum) plasma collected in an EDTA (lavender-top) tube										
Reject Criteria	Hemolysis; lipemia, ictericia, received room temperature										
Transport Temperature	Refrigerated										
Specimen Stability	Room temperature: 24 hours Refrigerated: 14 days Frozen: 60 days										
Set-up/Analytic Time	Set up: Tues; Report available: Sun										
Reference Range	<table border="1"> <thead> <tr> <th></th> <th>Males (ng/dL)</th> <th>Females (ng/dL)</th> </tr> </thead> <tbody> <tr> <td>< 18 years:</td> <td>No Range Established for this Age Group</td> <td>No Range Established for this Age Group</td> </tr> <tr> <td>> or = 18 years:</td> <td>251-1503</td> <td>38-576</td> </tr> </tbody> </table>			Males (ng/dL)	Females (ng/dL)	< 18 years:	No Range Established for this Age Group	No Range Established for this Age Group	> or = 18 years:	251-1503	38-576
	Males (ng/dL)	Females (ng/dL)									
< 18 years:	No Range Established for this Age Group	No Range Established for this Age Group									
> or = 18 years:	251-1503	38-576									
Always Message	This test was performed using a kit that has not been approved or cleared by the FDA. The analytical performance characteristics of this test have been determined by Quest Diagnostics Nichols Institute, San Juan Capistrano. This test should not be used for diagnosis without confirmation by other medically established means.										
Methodology	Enzyme-linked immunosorbent assay (ELISA)										
Assay Category	Research Use Only										
Performing Site	Quest Diagnostics Nichols Institute, San Juan Capistrano										
CPU Mappings	<table border="1"> <thead> <tr> <th>Result Code</th> <th>Result Name</th> <th>Unit of Measure</th> </tr> </thead> <tbody> <tr> <td>86010897</td> <td>3a Androstenediol-G</td> <td>ng/dL</td> </tr> </tbody> </table>		Result Code	Result Name	Unit of Measure	86010897	3a Androstenediol-G	ng/dL			
Result Code	Result Name	Unit of Measure									
86010897	3a Androstenediol-G	ng/dL									

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.

<i>Helicobacter pylori</i>, Urea Breath Test	
Effective Date	6/23/2014

Former Test Name	<i>Helicobacter pylori</i> Urea Breath Test (UBiT-®)					
Test Code	S51746					
Reject Criteria	Reject specimen types other than BreathTek™ UBT bags. Reject specimens from patients <3 years old.					
Instructions	<p>Patient should fast one hour before collection of baseline breath sample. Pranactin®-Citric contains a small amount of aspartame sweetener. Test may not be suitable for patients with phenylketonuria whose dietary phenylalanine should be restricted.</p> <p>The test can only be performed on specimens from patients greater than 3 years old.</p> <p>For patients 3-17 years of age: gender, height, weight, and age, must be provided on the pediatric UHR card included in the BreathTek™ UBT Collection Kit.</p> <p>Human breath: paired breath samples (pre and post) collected in BreathTek™ UBT Collection Kit bags and must be submitted together. Follow instructions provided with kit.</p>					
Always Message	Antimicrobials, proton pump inhibitors, and bismuth preparations are known to suppress <i>H. pylori</i>, and ingestion of these prior to <i>H. pylori</i> diagnostic testing may lead to false negative results. If clinically indicated, the test may be repeated on a new specimen obtained two weeks after discontinuing treatment.					
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>80009812</td> <td>H.pylori,Urea Breath Test</td> </tr> </tbody> </table>		Result Code	Result Name	80009812	H.pylori,Urea Breath Test
Result Code	Result Name					
80009812	H.pylori,Urea Breath Test					

Bacterial Vaginosis/Vaginitis Panel										
Effective Date	7/14/2014									
Former Test Code	A51540									
Test Code	14577									
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	<table border="1"> <thead> <tr> <th>Result Code</th> <th>Result Name</th> </tr> </thead> <tbody> <tr> <td>85999061</td> <td>Candida species</td> </tr> <tr> <td>85999062</td> <td>Trichomonas vaginalis</td> </tr> <tr> <td>85999063</td> <td>Gardnerella vaginalis</td> </tr> </tbody> </table>		Result Code	Result Name	85999061	Candida species	85999062	Trichomonas vaginalis	85999063	Gardnerella vaginalis
Result Code	Result Name									
85999061	Candida species									
85999062	Trichomonas vaginalis									
85999063	Gardnerella vaginalis									
Tests Affected	<table border="1"> <thead> <tr> <th>Test Codes:</th> <th>Name:</th> </tr> </thead> <tbody> <tr> <td>A52078</td> <td>ALT-BACTERIAL VAGINOSIS/VAGINITIS PANEL [14577X]</td> </tr> </tbody> </table>		Test Codes:	Name:	A52078	ALT-BACTERIAL VAGINOSIS/VAGINITIS PANEL [14577X]				
Test Codes:	Name:									
A52078	ALT-BACTERIAL VAGINOSIS/VAGINITIS PANEL [14577X]									

HIV-1 DNA, Qualitative PCR	
Message	**This test is now available for New York patient testing.**
Effective Date	7/14/2014
Test Code	8401

Performing Site	This test previously performed at Focus Diagnostics, Inc. will now be performed at Quest Diagnostics Nichols Institute, Chantilly.		
CPU Mappings	Result Code	Type	Result Name
	86003134		HIV-1 DNA, Qual, PCR
	85997830	Prompt-Result (no return)	If Required by Your State
	80004900	Prompt-Result (no return)	Patient address
	80004901	Prompt-Result (no return)	Patient city
	80004902	Prompt-Result (no return)	Patient state
	80004903	Prompt-Result (no return)	Patient zip
	80003400	Prompt-Result (no return)	Patient race
	85997836	Prompt-Result (no return)	Patient Hispanic (Y/N)
	85997837	Prompt-Result (no return)	Requesting physician
	85997838	Prompt-Result (no return)	Physician address
	85997839	Prompt-Result (no return)	Physician city
	85997840	Prompt-Result (no return)	Physician state
	85997841	Prompt-Result (no return)	Physician zip
	85997842	Prompt-Result (no return)	Physician phone
	85997843	Prompt-Result (no return)	Social Security Number

<i>Pneumocystis jirovecii</i> (P. carinii), DFA			
Clinical Significance	<i>Pneumocystis carinii</i> , now considered a fungus, is an opportunistic infection seen especially in patients infected with HIV and on immunosuppressive therapy, e.g., post-transplantation. <i>Pneumocystis carinii</i> causes pneumonia.		
Effective Date	7/14/2014		
Former Test Name	<i>Pneumocystis jirovecii</i> (carinii), DFA		
Former Test Code	7745		
Test Code	34286		
CPT Codes	87015, 87281		
Specimen Requirements	Preferred: 3 mL (2 mL minimum) bronchial lavage/wash, sputum, bronchial alveolar lavage collected in a sterile, leak-proof container Acceptable: Bronchial brushings collected on 2 acetone fixed slides		
Reject Criteria	Broken slides; slides fixed in formalin; slides fixed in ethanol; unfixed slides		
Instructions	Keep refrigerated. All client prepared slides must be fixed in acetone for 10 minutes prior to drying. Client prepared slides made from tissue require Director approval. Slides must be shipped in plastic or cardboard slide transport devices.		
Specimen Stability	<table border="1"> <tr> <td>Bronchial lavage/wash, sputum, bronchial alveolar lavage:</td> <td>Room temperature: Unacceptable Refrigerated: 7 days</td> </tr> </table>	Bronchial lavage/wash, sputum, bronchial alveolar lavage:	Room temperature: Unacceptable Refrigerated: 7 days
Bronchial lavage/wash, sputum, bronchial alveolar lavage:	Room temperature: Unacceptable Refrigerated: 7 days		

		Frozen: Unacceptable									
	Slides:	Room temperature and Refrigerated: 7 days Frozen: 30 days									
Set-up/Analytic Time	Set up: Mon-Sat; Report available: 1-2 days										
Reference Range	Not detected										
Methodology	Direct Immunofluorescence Assay										
Performing Site	Quest Diagnostics Nichols Institute, Valencia										
CPU Mappings	<table border="1"> <thead> <tr> <th>Result Code</th> <th>Type</th> <th>Result Name</th> </tr> </thead> <tbody> <tr> <td>86007404</td> <td>Prompt-Result</td> <td>Specimen Source:</td> </tr> <tr> <td>85992437</td> <td></td> <td>P.jirovecii (P.carinii)DFA</td> </tr> </tbody> </table>		Result Code	Type	Result Name	86007404	Prompt-Result	Specimen Source:	85992437		P.jirovecii (P.carinii)DFA
Result Code	Type	Result Name									
86007404	Prompt-Result	Specimen Source:									
85992437		P.jirovecii (P.carinii)DFA									
Additional Information	Pricing Message: Negotiated pricing on 7745 - Pneumocystis jiroveci (carinii), DFA will be applied to code 34286.										

Discontinued Tests

17 Ketosteroids, Fractionated, Urine	
Effective Date	7/21/2014
Test Code	S51864
Additional Information	An alternative test is available through Genova Diagnostics. Please contact Genova Diagnostics directly for more information about the alternative test panels.

3a-Androstenediol Glucuronide (3-Alpha Diol G)	
Effective Date	7/21/2014
Test Code	S51355
Additional Information	The recommended alternative is test code 92208- 3a-Androstenediol Glucuronide, ELISA in the New Test Offering section.

Cortisol Binding Globulin (Transcortin)	
Effective Date	7/21/2014
Test Code	S51344
Additional Information	The recommended alternative is test code [S52588] -Corticosteroid Binding Globulin (CBG).

DHEA (Dehydroepiandrosterone), Urine	
Effective Date	7/21/2014
Test Code	S51384
Additional Information	An alternative test is available through Genova Diagnostics. Please contact Genova Diagnostics directly for more information about the alternative test panels.

6/12/2014 - Immediate Action, Quest Diagnostics Nichols Institute, Valencia

Pregnanetriol, Urine	
Effective Date	7/21/2014
Test Code	S51460
Additional Information	An alternative test is available through Genova Diagnostics. Please contact Genova Diagnostics directly for more information about the alternative test panels.

Testosterone, Urine	
Effective Date	7/21/2014
Test Code	S49986
Additional Information	An alternative test is available through Genova Diagnostics. Please contact Genova Diagnostics directly for more information about the alternative test panels.

Tetrahydroaldosterone, Urine	
Effective Date	7/21/2014
Test Code	S51411
Additional Information	An alternative test is available through Genova Diagnostics. Please contact Genova Diagnostics directly for more information about the alternative test panels.

New York Patient Testing Update

Vitamin B2 (Riboflavin), Plasma	
Message	**This test is <i>now available</i> for New York patient testing.**
Test Code	S49825

Test Send Out (Referrals)

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**.

Raji Cell Immune Complex Assay	
Effective Date	6/12/2014
Test Code	A52601
Reference Range	<=83

NeoCerebellar Degeneration Paraneo w/Recombx		
Effective Date	6/16/2014	
Test Code	S49558	
CPU Mappings	Result Code	Result Name

	108432	Interpretation
	108433	Comments
	108426	Recombx Hu
	108544	Zic4
	113854	GAD65
	108430	Ri
	108427	Ma 1
	108428	Ma 2
	108431	CV2
	108429	Yo
	112699	Amphiphysin
Additional Information	Update report format.	