

1/27/2015 - Immediate Action, Quest Diagnostics Nichols Institute, Valencia

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 #
8658	S51297	Alpha Subunit	1/26/2015	1
<u>17656</u>		Methicillin Resistant <i>Staphylococcus aureus</i> , PCR	1/27/2015	1
<u>91768</u>		Streptococcus Group B DNA, PCR with Broth Enrichment	2/2/2015	1
<u>91770</u>		Streptococcus Group B DNA, PCR with Broth Enrichment and Reflex to Susceptibility	2/2/2015	2

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 #
92895		Alpha-Subunit Pituitary Tumor Marker	2/2/2015	2
<u>S52155</u>		Insulin-Like Growth Factor II (IGF II)	2/2/2015	3

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.

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.

Alpha Subunit	
Message	**This test is not available for New York patient testing. For New York patient testing use test code 92895-Alpha-Subunit Pituitary Tumor Marker**
Effective Date	1/26/2015
Former Test Code	<i>S51297</i>
Test Code	8658
CPT Codes	82397
Methodology	Electrochemiluminescence Immunoassay
Performing Site	Quest Diagnostics Nichols Institute, San Juan Capistrano

Methicillin Resistant <i>Staphylococcus aureus</i> , PCR	
Message	**This test is not available for New York patient testing**
Effective Date	1/27/2015
Test Code	<i>17656</i>
Specimen Requirements	Preferred: Nasal double swab collected in Amies liquid collection tube

	Amies Agar Gel without charcoal is no longer acceptable
Performing Site	Focus Diagnostics, Inc.

Streptococcus Group B DNA, PCR with Broth Enrichment					
Effective Date	2/2/2015				
Test Code	91768				
Specimen Requirements	<p>Preferred: Vaginal/Rectal swab in Amies gel (blue-cap) transport medium or Amies liquid (red-cap) transport medium</p> <p>Acceptable: Vaginal/Rectal swab in Liquid Stuart transport medium or 2 mL LIM broth tube (pre-incubated)</p> <p>No other specimens are acceptable</p>				
Transport Temperature	Refrigerated				
Specimen Stability	<table border="1"> <tr> <td>Vaginal/Rectal swab:</td> <td>Room temperature: 24 hours Refrigerated: 6 days Frozen: Unacceptable</td> </tr> <tr> <td>LIM broth:</td> <td>Room temperature: Unacceptable Refrigerated: 72 hours Frozen: Unacceptable</td> </tr> </table>	Vaginal/Rectal swab:	Room temperature: 24 hours Refrigerated: 6 days Frozen: Unacceptable	LIM broth:	Room temperature: Unacceptable Refrigerated: 72 hours Frozen: Unacceptable
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LIM broth:	Room temperature: Unacceptable Refrigerated: 72 hours Frozen: Unacceptable				
Performing Site	Focus Diagnostics, Inc.				

Streptococcus Group B DNA, PCR with Broth Enrichment and Reflex to Susceptibility					
Effective Date	2/2/2015				
Test Code	91770				
Specimen Requirements	<p>Preferred: Vaginal/Rectal swab in Amies gel (blue-cap) transport medium or Amies liquid (red-cap) transport medium</p> <p>Acceptable: Vaginal/Rectal swab in Liquid Stuart transport medium or 2 mL LIM broth tube (pre-incubated)</p> <p>No other specimens are acceptable</p>				
Transport Temperature	Refrigerated				
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Vaginal/Rectal swab:	Room temperature: 24 hours Refrigerated: 6 days Frozen: Unacceptable				
LIM broth:	Room temperature: Unacceptable Refrigerated: 72 hours Frozen: Unacceptable				
Performing Site	Focus Diagnostics, Inc.				

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**.

Alpha-Subunit Pituitary Tumor Marker																				
Message	** This test is for New York patient testing only. For non-New York patient testing use test code 8658-Alpha Subunit**																			
Clinical Significance	Adjunct in the diagnosis of pituitary tumors. As part of the follow-up of treated pituitary tumor patients. Differential diagnosis of thyrotropin-secreting pituitary tumor versus thyroid hormone resistance. Differential diagnosis of constitutional delay of puberty versus hypogonadotropic hypogonadism.																			
Effective Date	2/2/2015																			
Test Code	92895																			
CPT Codes	83520																			
Specimen Requirements	1 mL (0.35 mL minimum) serum collected in an red-top tube (no gel)																			
Reject Criteria	Gross hemolysis, serum separator tube																			
Transport Temperature	Refrigerated																			
Specimen Stability	Room temperature: Unacceptable Refrigerated: 7 days Frozen: 90 days																			
Set-up/Analytic Time	Set up: Tues; Report available: 1-7 days																			
Reference Range	<table border="1"> <thead> <tr> <th>Pediatric</th> <th>ng/mL</th> </tr> </thead> <tbody> <tr> <td>< or = 5 days:</td> <td>< or = 50</td> </tr> <tr> <td>6 days - 12 weeks:</td> <td>< or = 10</td> </tr> <tr> <td>3 months - 17 years:</td> <td>< or = 1.2</td> </tr> <tr> <td>Tanner II-IV*</td> <td>< or = 1.2</td> </tr> <tr> <th>Adults</th> <th>ng/mL</th> </tr> <tr> <td>Males:</td> <td>< or = 0.5</td> </tr> <tr> <td>Premenopausal females:</td> <td>< or = 1.2</td> </tr> <tr> <td>Postmenopausal females:</td> <td>< or = 1.8</td> </tr> </tbody> </table> <p>*Puberty onset (transition from Tanner stage I to Tanner stage II) occurs for boys at a median age of 11.5 (+/-2) years and for girls at a median age of 10.5 (+/-2) years. There is evidence that it may occur up to 1 year earlier in obese girls and in African American girls. For boys, there is no proven relationship between puberty onset and body weight or ethnic origin. Progression through Tanner stages is variable. Tanner stage V (adult) should be reached by age 18.</p>		Pediatric	ng/mL	< or = 5 days:	< or = 50	6 days - 12 weeks:	< or = 10	3 months - 17 years:	< or = 1.2	Tanner II-IV*	< or = 1.2	Adults	ng/mL	Males:	< or = 0.5	Premenopausal females:	< or = 1.2	Postmenopausal females:	< or = 1.8
Pediatric	ng/mL																			
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Postmenopausal females:	< or = 1.8																			
Methodology	Immunochemiluminescent Assay (ICMA)																			
Assay Category	Investigative Use Only																			
Interface Mapping	<table border="1"> <thead> <tr> <th>Result Code</th> <th>Result Name</th> <th>Unit of Measure</th> </tr> </thead> <tbody> <tr> <td>86012731</td> <td>Alpha-Subunit Pituitary</td> <td>ng/mL</td> </tr> </tbody> </table>		Result Code	Result Name	Unit of Measure	86012731	Alpha-Subunit Pituitary	ng/mL												
Result Code	Result Name	Unit of Measure																		
86012731	Alpha-Subunit Pituitary	ng/mL																		

Insulin-Like Growth Factor II (IGF II)

1/27/2015 - Immediate Action, Quest Diagnostics Nichols Institute, Valencia

Effective Date	2/2/2015
Test Code	S52155
Specimen Requirements	0.5 mL (0.1 mL minimum) serum
Specimen Stability	Room temperature: 24 hours Refrigerated: 72 hours Frozen: 200 days
Set-up/Analytic Time	Set up: Tues; Report available: 3-10 days