

7/22/2013 - 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 #
<u>90814</u>		Thyroid Cancer Monitoring	7/18/2013	1
<u>90814</u>		Thyroid Cancer Monitoring	8/26/2013	1
<u>S51345</u>		21-Hydroxylase Antibody	9/30/2013	2

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 that only the information that is changing appears in this update. Former test names and test codes have been italicized.

Thyroid Cancer Monitoring	
Effective Date	7/18/2013
Test Code	90814
Reference Range	Thyroglobulin Ab, ECL: < or = 20 IU/mL Thyroglobulin, Second Gen: <0.05 ng/mL Thyroglobulin, LC/MS/MS: Adults: <0.4 ng/mL
Performing Site	Quest Diagnostics Nichols Institute, San Juan Capistrano
Additional Information	If Thyroglobulin Ab, ECL result is < or = 20 then Thyroglobulin, Second Generation (Beckman Coulter) will be performed at an additional charge (CPT: 84432). If Thyroglobulin Ab, ECL result is > 20, then Thyroglobulin, LC/MS/MS will be performed at an additional charge (CPT: 84432). Change in reflex cut-off due to recent publication (Thyroid 2011; 21:813) and additional information gathered at Quest Diagnostics Nichols Institute.

Thyroid Cancer Monitoring	
Effective Date	8/26/2013
Test Code	90814
Specimen Requirements	2.3 mL serum
Reference Range	Thyroglobulin Antibody: < or = 1 IU/mL Thyroglobulin, Second Gen: <0.05 ng/mL Thyroglobulin, LC/MS/MS: Adults <0.4 ng/mL
Always Message	90814 Thyroglobulin Antibody: This Thyroglobulin antibody test was performed using the Beckman Coulter Immunoenzymatic method . Values obtained from different assay methods cannot be used interchangeably. Thyroglobulin antibody levels, regardless of value, should not be interpreted as absolute evidence of the presence or absence of disease. As of 08/26/2013, the TgAb test is conducted using the Beckman Coulter Dxl platform--the original platform used for thyroid cancer screening. The Roche Modular Analytics E170 Electrochemiluminescent

	method was substituted during a period when the Beckman Coulter reagents were unavailable.															
Methodology	90814 Thyroglobulin Antibody: Immunoenzymatic															
Performing Site	Quest Diagnostics Nichols Institute, San Juan Capistrano															
CPU Mappings	<table border="1"> <tr> <td colspan="3">90814 Thyroglobulin Antibody</td> </tr> <tr> <td>Result Code</td> <td>Result Name</td> <td>Unit of Measure</td> </tr> <tr> <td>86008054</td> <td>Thyroglobulin Antibody</td> <td>IU/mL</td> </tr> <tr> <td colspan="3"><i>TR 90814-2Thyroglobulin, Second Generation (Beckman Coulter)</i></td> </tr> <tr> <td colspan="3"><i>TR 90814-3Thyroglobulin, LC/MS/MS</i></td> </tr> </table>	90814 Thyroglobulin Antibody			Result Code	Result Name	Unit of Measure	86008054	Thyroglobulin Antibody	IU/mL	<i>TR 90814-2Thyroglobulin, Second Generation (Beckman Coulter)</i>			<i>TR 90814-3Thyroglobulin, LC/MS/MS</i>		
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Additional Information	If Thyroglobulin Ab is > 1 IU/mL then Tg by LCMSMS (CPT: 84432) will be performed at an additional charge. If Thyroglobulin Ab is < or = 1 IU/mL, then Tg 2nd Gen (CPT: 84432) is tested on the Beckman Coulter Dxl at an additional charge.															

21-Hydroxylase Antibody	
Effective Date	9/30/2013
Test Code	S51345
Always Message	<p>Patient with indeterminate result may benefit from serial testing to confirm positivity.</p> <p>Remove the following 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.</p>
Assay Category	FDA Approved/Cleared
Performing Site	Quest Diagnostics Nichols Institute, San Juan Capistrano