

5/24/2013 - 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 #
3138		Anti-Mullerian Hormone AssessR™	5/29/2013	1

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.

Anti-Mullerian Hormone AssessR™																											
Message	<b>**This test is pending approval for NY patient testing.</b>																										
Effective Date	5/29/2013																										
Test Code	3138																										
Reject Criteria	Gross hemolysis, icteric, and lipemic																										
Specimen Stability	Room temperature: Unacceptable Refrigerated: 5 days Frozen: 30 days																										
Always Message	<p><b>REFERENCE RANGES for AMH/MIS:</b></p> <table border="1"> <thead> <tr> <th>Age</th> <th>Expected range (ng/mL)</th> </tr> </thead> <tbody> <tr> <td colspan="2">-----</td> </tr> <tr> <td><b>Female:</b> &lt;14 yrs</td> <td>0.49-3.15</td> </tr> <tr> <td>14-19 yrs</td> <td>1.28-16.37</td> </tr> <tr> <td>20-29 yrs</td> <td>0.76-11.34</td> </tr> <tr> <td>30-39 yrs</td> <td>&lt;9.24</td> </tr> <tr> <td>40-49 yrs</td> <td>&lt;4.50</td> </tr> <tr> <td>&gt;49 yrs</td> <td>&lt;0.45</td> </tr> <tr> <td><b>Male:</b> &lt;1 yr</td> <td>37.20-345.67</td> </tr> <tr> <td>1-6 yrs</td> <td>59.54-320.65</td> </tr> <tr> <td>7-11 yrs</td> <td>40.99-203.67</td> </tr> <tr> <td>12-17 yrs</td> <td>&lt;128.29</td> </tr> <tr> <td>&gt;17 yrs</td> <td>1.15-15.23</td> </tr> </tbody> </table> <p>This test(s) was developed and its performance characteristics have been determined by Quest Diagnostics Nichols Institute, Valencia, CA. Performance characteristics refer to the analytical performance of the test.</p>	Age	Expected range (ng/mL)	-----		<b>Female:</b> <14 yrs	0.49-3.15	14-19 yrs	1.28-16.37	20-29 yrs	0.76-11.34	30-39 yrs	<9.24	40-49 yrs	<4.50	>49 yrs	<0.45	<b>Male:</b> <1 yr	37.20-345.67	1-6 yrs	59.54-320.65	7-11 yrs	40.99-203.67	12-17 yrs	<128.29	>17 yrs	1.15-15.23
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Methodology	Chemiluminescence																										
Assay Category	Laboratory Developed Test																										
Performing Site	Quest Diagnostics Nichols Institute, Valencia																										