

1/14/2013 - 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>3982</u>		Inhibin B	1/15/2013	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 fields listed in bold type are being changed; former test names and test codes have been italicized. Additional information, regarding the change, will be provided where applicable.

Inhibin B																									
Message	This assay is traceable to WHO standards and no baseline values will be necessary as values correlate well with the previous Inhibin B assay.																								
Effective Date	1/15/2013																								
Test Code	3982																								
CPT Codes	82397																								
Specimen Stability	Room temperature: 72 hours Refrigerated: 7 days Frozen: 28 days																								
Reference Range	<table border="1"> <tr> <td>(Age):</td> <td>Male</td> <td>Female</td> </tr> <tr> <td>5-9.9 years</td> <td>21 - 166 pg/mL</td> <td>< or = 18 pg/mL</td> </tr> <tr> <td>10-13.9 years</td> <td>41 - 328 pg/mL</td> <td>< or = 86 pg/mL</td> </tr> <tr> <td>14-17.9 years</td> <td>54 - 295 pg/mL</td> <td>< or = 123 pg/mL</td> </tr> <tr> <td>> or = 18 years:</td> <td>47 - 308 pg/mL</td> <td></td> </tr> <tr> <td colspan="3">Females:</td> </tr> <tr> <td>Pre-menopausal:</td> <td colspan="2"><153 pg/mL</td> </tr> <tr> <td>Post-menopausal:</td> <td colspan="2"><10 pg/mL</td> </tr> </table>	(Age):	Male	Female	5-9.9 years	21 - 166 pg/mL	< or = 18 pg/mL	10-13.9 years	41 - 328 pg/mL	< or = 86 pg/mL	14-17.9 years	54 - 295 pg/mL	< or = 123 pg/mL	> or = 18 years:	47 - 308 pg/mL		Females:			Pre-menopausal:	<153 pg/mL		Post-menopausal:	<10 pg/mL	
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Always Message	<p>Values obtained from different assay methods cannot be used interchangeably. Inhibin B levels, regardless of value, should not be interpreted as absolute evidence of the presence or absence of disease.</p> <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>																								
Methodology	Chemiluminescence																								
Assay Category	Laboratory Developed Assay																								
Performing Site	Quest Diagnostics Nichols Institute, Valencia																								
Tests Affected	<table border="1"> <thead> <tr> <th>Test Codes:</th> <th>Name:</th> </tr> </thead> <tbody> <tr> <td>34445</td> <td>Inhibin B</td> </tr> <tr> <td>CCOVB</td> <td>CCOVB Inhibin B</td> </tr> </tbody> </table>	Test Codes:	Name:	34445	Inhibin B	CCOVB	CCOVB Inhibin B																		
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