

3/27/2014 - 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>16039</u>		Mannose-binding Lectin (MBL)	3/27/2014	1

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>S50719</u>		14-3-3 Protein, CSF	3/31/2014	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.

Mannose-binding Lectin (MBL)	
Effective Date	3/27/2014
Test Code	16039
Reject Criteria	Received room temperature; received refrigerated; hemolysis; lipemia; heat treated; specimens containing visible particulate matter
Always Message	Mannan-binding lectin (MBL) is a serum collection (c-type lectin) and is considered an important component of the innate immune system. Clinical studies have used 50 or 100 ng/mL to define severe MBL deficiency. MBL is also known to activate the classical complement pathway through its binding to serine proteases MASP-2 and MASP-1. MBL deficiency has been associated with recurrent infections in children 6 months to 17 months of age, during the time when the adaptive immune system (IgG production) is not fully mature. 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.
Assay Category	Research Use Only
Performing Site	Quest Diagnostics Nichols Institute, San Juan Capistrano

Test Send Outs (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.

14-3-3 Protein, CSF	
Effective Date	3/31/2014

Test Code	S50719														
CPT Codes	83520														
Always Message	These tests were developed and their performance characteristics determined by the NPDPS. These tests have not been cleared or approved by the FDA. These assays should be used in conjunction with other clinical, pathological, and laboratory findings.														
Methodology	ELISA														
Assay Category	Laboratory Developed Assay														
CPU Mappings	<table border="1"> <tr> <td colspan="2">S50719- 14-3-3 Protein</td> </tr> <tr> <td>Result Code</td> <td>Result Name</td> </tr> <tr> <td>107060</td> <td>Result</td> </tr> <tr> <td>107737</td> <td>Comments</td> </tr> <tr> <td colspan="2"><i>This is a reflex. Please build this non-orderable unit code separately. A52602 – Reflex RT-QUIC</i></td> </tr> <tr> <td>Result Code</td> <td>Result Name</td> </tr> <tr> <td>113832</td> <td>Result</td> </tr> </table>	S50719- 14-3-3 Protein		Result Code	Result Name	107060	Result	107737	Comments	<i>This is a reflex. Please build this non-orderable unit code separately. A52602 – Reflex RT-QUIC</i>		Result Code	Result Name	113832	Result
S50719- 14-3-3 Protein															
Result Code	Result Name														
107060	Result														
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<i>This is a reflex. Please build this non-orderable unit code separately. A52602 – Reflex RT-QUIC</i>															
Result Code	Result Name														
113832	Result														
Additional Information	If 14-3-3 protein is positive or tau is >or= 500 pg/mL, then A52602 Reflex RT-QUIC will be performed at an additional charge (CPT: 87999).														