

8/21/2014 - 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 # |
| 981 | 1615 | Complement Component C1q | 8/28/2014 | 1 |
| 19215 | S51258 | Tysabri® Antibody Test | 10/20/2014 | 2 |

| DISCONTINUED TESTS | | | |
|-----------------------------------------------------------------------------------------------------------------------------------------------------------------|-----------------------------------|----------------|--------|
| 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 | Test Name | Effective Date | Page # |
| S51634 | Hyaluronic Acid | 8/25/2014 | 2 |
| S51881 | Liver Fibrosis Panel (HepaScore®) | 8/25/2014 | 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 # |
| 92550 | | Hyaluronic Acid, Serum | 8/25/2014 | 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.

| Complement Component C1q | |
|--------------------------|---------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------|
| Clinical Significance | The complement system is critical to the inflammatory response. C1q concentrations may be decreased in patients with acquired angioedema, immune complex induced vasculitis, and concurrent low concentrations of C1 inhibitor, carcinoma, or lymphoma. |
| Effective Date | 8/28/2014 |
| Former Test Name | <i>Complement C1q</i> |
| Former Test Code | <i>1615</i> |
| Test Code | 981 |
| Specimen Requirements | Preferred: 1 mL (0.1 mL minimum) serum Acceptable: 1 mL (0.1 mL minimum) plasma collected in an EDTA (lavender-top) tube or a PPT Potassium EDTA (white top) tube |
| Reject Criteria | Gross hemolysis; grossly lipemic |
| Instructions | Separate serum within one hour of draw time and refrigerate. Can be drawn in gel barrier tube but needs to be separated within one hour from time drawn. |

| Specimen Stability | Room temperature: 4 days Refrigerated: 10 days Frozen: 29 days | | | | | | | | |
|----------------------|-------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------|-----------------|--|-------------|-------------|-----------------|----------|------------|-------|
| Set-up/Analytic Time | Set up: Mon, Wed; Report available: 4-9 days | | | | | | | | |
| Reference Range | 5.0-8.6 mg/dL | | | | | | | | |
| Methodology | Radial Immunodiffusion | | | | | | | | |
| Performing Site | This test previously performed at Quest Diagnostics Nichols Institute, Valencia will now be performed at Quest Diagnostics Nichols Institute, San Juan Capistrano. | | | | | | | | |
| CPU Mappings | <table border="1"> <thead> <tr> <th>Result Code</th> <th>Result Name</th> <th>Unit of Measure</th> </tr> </thead> <tbody> <tr> <td>85991683</td> <td>C1q, Serum</td> <td>mg/dL</td> </tr> </tbody> </table> | | | Result Code | Result Name | Unit of Measure | 85991683 | C1q, Serum | mg/dL |
| Result Code | Result Name | Unit of Measure | | | | | | | |
| 85991683 | C1q, Serum | mg/dL | | | | | | | |

| Tysabri® Antibody Test | | | | | | | | | |
|------------------------|----------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------|-------------|-------------|----------|----------------|----------|---------------------------|----------|----------|
| Clinical Significance | Detection of antibodies to Tysabri® (Natalizumab). | | | | | | | | |
| Effective Date | 10/20/2014 | | | | | | | | |
| Former Test Name | Tysabri Antibodies, ELISA | | | | | | | | |
| Former Test Code | S51258 | | | | | | | | |
| Test Code | 19215 | | | | | | | | |
| CPT Codes | 83516 | | | | | | | | |
| Specimen Requirements | 2 mL (2 mL minimum) serum | | | | | | | | |
| Instructions | Please label each specimen tube with two forms of patient identification. These forms of identification must also appear on the requisition form. | | | | | | | | |
| Transport Temperature | Refrigerated | | | | | | | | |
| Specimen Stability | Room temperature: 72 hours Refrigerated: 14 days Frozen: Unacceptable | | | | | | | | |
| Set-up/Analytic Time | Set up: Mon-Thurs; Report available: 7-14 days | | | | | | | | |
| Methodology | Enzyme Linked Immunosorbent Assay | | | | | | | | |
| Performing Site | This test previously performed at Focus Diagnostics, Inc. will now be performed at Athena Diagnostics, Inc. | | | | | | | | |
| CPU Mappings | <table border="1"> <thead> <tr> <th>Result Code</th> <th>Result Name</th> </tr> </thead> <tbody> <tr> <td>86011510</td> <td>Interpretation</td> </tr> <tr> <td>86011394</td> <td>Tysabri(R) Antibody Test:</td> </tr> <tr> <td>86011511</td> <td>Comments</td> </tr> </tbody> </table> | Result Code | Result Name | 86011510 | Interpretation | 86011394 | Tysabri(R) Antibody Test: | 86011511 | Comments |
| Result Code | Result Name | | | | | | | | |
| 86011510 | Interpretation | | | | | | | | |
| 86011394 | Tysabri(R) Antibody Test: | | | | | | | | |
| 86011511 | Comments | | | | | | | | |

Discontinued Tests

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|-----------------|
| Hyaluronic Acid |
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| | |
|------------------------|----------------------------------------------------------------------------------------------------------|
| Effective Date | 8/25/2014 |
| Test Code | S51634 |
| Additional Information | The recommended alternative is test code 92550- Hyaluronic Acid, Serum in Test Send Outs section. |

| Liver Fibrosis Panel (HepaScore®) | |
|------------------------------------------|------------------------------------------------------------------------------------|
| Effective Date | 8/25/2014 |
| Test Code | S51881 |
| Additional Information | The recommended alternative is test code S50584 -Hepatitis C Virus (HCV) FibroSURE |

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**.

| Hyaluronic Acid, Serum | | | | | | | |
|-------------------------------|--------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------|-----------------|-------------|-----------------|----------|------------------------|-------|
| Effective Date | 8/25/2014 | | | | | | |
| Test Code | 92550 | | | | | | |
| CPT Codes | 83520 | | | | | | |
| Specimen Requirements | <p>Preferred: 2 mL (0.5 mL minimum) serum</p> <p>Acceptable: 2 mL (0.5 mL minimum) plasma collected in sodium heparin (green-top) tube or lithium heparin (green-top) tube or EDTA (lavender-top) tube or EDTA K2 tube</p> | | | | | | |
| Reject Criteria | Specimens exposed to repeated freeze/thaw cycles | | | | | | |
| Instructions | Allow serum specimen to clot completely at room temperature. Separate serum or plasma from cells ASAP or within 2 hours of collection. Transfer 2 mL serum or plasma to an ARUP standard transport tube (min. 0.5 mL). | | | | | | |
| Transport Temperature | Refrigerated | | | | | | |
| Specimen Stability | <p>Room temperature: 24 hours Refrigerated: 14 days Frozen: 1 year</p> | | | | | | |
| Set-up/Analytic Time | Set up: Tues; Report available: 1-9 days | | | | | | |
| Reference Range | 0-54 ng/mL | | | | | | |
| Methodology | Enzyme Linked Immunosorbent Assay | | | | | | |
| CPU Mappings | <table border="1"> <thead> <tr> <th>Result Code</th> <th>Result Name</th> <th>Unit of Measure</th> </tr> </thead> <tbody> <tr> <td>86011358</td> <td>Hyaluronic Acid, Serum</td> <td>ng/mL</td> </tr> </tbody> </table> | Result Code | Result Name | Unit of Measure | 86011358 | Hyaluronic Acid, Serum | ng/mL |
| Result Code | Result Name | Unit of Measure | | | | | |
| 86011358 | Hyaluronic Acid, Serum | ng/mL | | | | | |