

10/8/2015 - 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 # |
| S52438 | | AQP4 (NMO-IgG) Autoantibody Test | 11/23/2015 | 1 |
| <i>38007</i> | | NAbFeron® (IFNB-1) Neutralizing Antibody Test | 11/23/2015 | 2 |
| <i>19215</i> | | Tysabri® Antibody Test | 11/23/2015 | 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 # |
| <i>92555</i> | BRCA2 Intron 12 Variant, Hispanic | 11/23/2015 | 3 |

| NY UPDATE | | |
|---|--|--------|
| 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 | Page # |
| S50903 | MVista® Blastomyces Quantitative Antigen EIA | 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.

| AQP4 (NMO-IgG) Autoantibody Test | | | |
|----------------------------------|---|---|------------------------|
| Effective Date | 11/23/2015 | | |
| Former Test Name | <i>Neuromyelitis Optica (NMO) AQP4 Autoantibody Test</i> | | |
| Test Code | S52438 | | |
| Specimen Stability | Room temperature | 72 hours | |
| | Refrigerated | 40 days | |
| | Frozen | 5 months | |
| Set-up/Analytic Time | Set up: Mon, Wed, Fri ; Report available: 5-7 days | | |
| Reference Range | Result Name | Reference Range | Unit Of Measure |
| | Technical Results | Negative <1.6 Borderline 1.6-3.0 Positive >3.0 | U/ml |

| | | |
|---------------------|--------------------------|--------------------|
| Performing Site | Athena Diagnostics, Inc. | |
| Interface Mapping | Result Code | Result Name |
| | 86008564 | Interpretation |
| | 86013832 | Technical Results |
| | 86008567 | Methods |
| | 86008568 | Comments |
| | 86008569 | References |
| Remove NMO Antibody | | |

| NAbFeron® (IFNB-1) Neutralizing Antibody Test | | |
|---|--|--------------------------|
| Effective Date | 11/23/2015 | |
| Test Code | 38007 | |
| Specimen Requirements | 2 mL serum Whole blood is no longer acceptable | |
| Specimen Stability | Room temperature | 72 hours |
| | Refrigerated | 28 days |
| | Frozen | 6 months |
| Set-up/Analytic Time | Set up: Tues; Report available: 14-21 days | |
| Performing Site | Athena Diagnostics, Inc. | |
| Interface Mapping | Result Code | Result Name |
| | 86011382 | Interpretation |
| | 86014287 | Technical Results |
| | 86011384 | Methods |
| | 86011385 | Comments |
| | 86011386 | References |
| Remove analyte 86000688 - NAB Titer | | |

| Tysabri® Antibody Test | | |
|------------------------|---|--------------------|
| Effective Date | 11/23/2015 | |
| Test Code | 19215 | |
| Specimen Requirements | 2 mL (0.5 mL minimum) serum | |
| Specimen Stability | Room temperature | 72 hours |
| | Refrigerated | 14 days |
| | Frozen | 6 months |
| Set-up/Analytic Time | Set up: Fri; Report available: 7-14 days | |
| Performing Site | Athena Diagnostics, Inc. | |
| Interface Mapping | Result Code | Result Name |
| | | |

| | | |
|---|-----------------|--------------------------|
| | 86011510 | Interpretation |
| | 86011394 | Technical Results |
| | 86011550 | Methods |
| | 86011511 | Comments |
| | 86011552 | References |
| Remove analytes 86011551-Background Information, and Tysabri Antibody Test | | |

Discontinued Test

| BRCA2 Intron 12 Variant, Hispanic | |
|--|---|
| Effective Date | 11/23/2015 |
| Test Code | 92555 |
| Additional Information | For assistance with a recommended alternative, please contact your local Quest Diagnostics genetic counselor or call 1-866-GENEINFO (1-866-436-3463). |

New York Patient Testing Update

| MVista® Blastomyces Quantitative Antigen EIA | |
|---|--|
| Message | **This test is not available for New York patient testing** |
| Effective Date | 10/8/2015 |
| Test Code | S50903 |