**Revision Message!**
**Please note: 8/6/13 communication revision to test codes 14868 B-cell Gene Rearrangement, Qualitative PCR, Cell-based and 15930 T-cell Receptor (TCR) Gene Rearrangement, Qualitative PCR, Cell-based, recommended alternatives in additional information.**

**NEW 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 # |
|---|---|---|---|
| **91711** | **Alpha-Globin Common Mutation Analysis, Fetus** | 8/12/2013 | 3 |
| **91709** | **Beta-Globin Complete™, Fetus** | 8/12/2013 | 3 |
| **91680** | **CAH (21-Hydroxylase Deficiency) Common Mutations, Fetal Cells** | 8/12/2013 | 5 |
| **91692** | **HIV-1 Genotype (RTI, PI, Integrase Inhibitors)** | 9/16/2013 | 6 |
| **91691** | **HIV-1 RNA, Quantitative Real-Time PCR with Reflex Genotype (RTI, PI, Integrase)** | 9/16/2013 | 7 |
| **91635** | **B-cell Clonality Panel (IGH, IGK), PCR** | 9/23/2013 | 8 |
| **90362** | **B-cell Receptor IGH Gene Rearrangement, PCR** | 9/23/2013 | 10 |
| **90363** | **B-cell Receptor IGK Gene Rearrangement, PCR** | 9/23/2013 | 11 |
| **91634** | **Lymphocyte Clonality Panel, PCR** | 9/23/2013 | 12 |
| **91445** | **T-cell Clonality Panel (TCRB, TCRG), PCR** | 9/23/2013 | 13 |
| **91446** | **T-cell Receptor (TCR) Beta Gene Rearrangement, PCR** | 9/23/2013 | 14 |
| **90509** | **T-cell Receptor (TCR) Gamma Gene Rearrangement, PCR** | 9/23/2013 | 15 |
| **90819** | **Thyroid FNA Cytomorphology Evaluation** | 9/23/2013 | 16 |
| **90818** | **Thyroid FNA Cytomorphology with Molecular Reflex** | 9/23/2013 | 17 |

**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 # |
|---|---|---|---|---|
| S51743 | | Bordetella pertussis/parapertussis DNA, Qual, RT PCR [45400] | 8/27/2013 | 18 |
| 35645 | | Hepatitis C Viral RNA, Quantitative, Real-Time PCR | 9/9/2013 | 18 |
| S51602 | | Voltage-Gated Calcium Channel (VGCC) Antibody Assay | 9/9/2013 | 19 |
| **38114** | F47G | **Garlic IgG** | 9/16/2013 | 20 |
| 414 | | Heparin Induced Platelet Antibody | 9/16/2013 | 20 |
| 15334 | | Heparin Induced Platelet Antibody with Reflex to SRA Unfractionated Heparin | 9/16/2013 | 20 |
| A52427 | | Heparin-Induced Thrombocytopenia Panel | 9/16/2013 | 21 |
| 36170 | | Testosterone, Free and Total, LC/MS/MS | 9/16/2013 | 21 |
| 34547 | F25G | **Tomato IgG** | 9/16/2013 | 22 |
| 38109 | F40G | **Tuna IgG** | 9/16/2013 | 22 |
| **10329** | F256G | **Walnut IgG** | 9/16/2013 | 22 |

| | | | | |
|---|---|---|---|---|
| 9436 | | Cytomegalovirus Antibodies (IgG, IgM) | 9/30/2013 | 23 |
| 9431 | | Cytomegalovirus Antibody (IgG) | 9/30/2013 | 23 |
| 9451 | | **Herpes Simplex Virus 1 (IgG), Type-Specific Antibody (HerpeSelect®)** | 9/30/2013 | 23 |
| 9461 | | **Herpes Simplex Virus 2 (IgG), Type-Specific Antibody (HerpeSelect®)** | 9/30/2013 | 24 |
| 9421 | | **Rubella Antibodies (IgG, IgM)** | 9/30/2013 | 25 |
| 2475 | | Rubella Antibody (IgM) | 9/30/2013 | 25 |
| 2263 | | **Toxoplasma Antibodies (IgG, IgM)** | 9/30/2013 | 25 |
| 9432 | | **Toxoplasma Antibody (IgG)** | 9/30/2013 | 25 |
| 7675 | | **Toxoplasma Antibody (IgM)** | 9/30/2013 | 26 |

**REDIRECTS**
**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 # |
|---|---|---|---|---|
| **35299** | S48659 | Quetiapine, Serum/Plasma | 9/16/2013 | 26 |

**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 # |
|---|---|---|---|
| 7577 | Hepatitis C Viral RNA, Quantitative, Real-Time PCR | 9/9/2013 | 27 |
| 10565 | Heptimax® HCV RNA | 9/9/2013 | 27 |
| 14868 | B-cell Gene Rearrangement, Qualitative PCR, Cell-based | 9/23/2013 | 27 |
| 15930 | T-cell Receptor (TCR) Gene Rearrangement, Qualitative PCR, Cell-based | 9/23/2013 | 27 |
| S52373 | CytomegaloviruS (CMV) Recent Infection Antibody Panel | 9/30/2013 | 27 |

**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 # |
|---|---|---|
| | New York Patient Testing Update | 28 |

**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 # |
|---|---|---|---|---|
| S44765 | | Atenolol, Serum/Plasma | 9/9/2013 | 28 |
| S48447 | | **Metoprolol, Serum/Plasma** | 9/9/2013 | 28 |
| S48605 | | Nadolol, Serum/Plasma | 9/9/2013 | 29 |
| S52295 | | Sotalol, Blood | 9/9/2013 | 29 |
| S44835 | | Sotalol, Serum/Plasma | 9/9/2013 | 29 |

| | | | | |
|---|---|---|---|---|
| S52297 | | Sotalol, Urine | 9/9/2013 | 29 |

## New Test Offerings

The following tests will be available through Quest Diagnostics on the dates indicated below.

| **Alpha-Globin Common Mutation Analysis, Fetus** | |
|---|---|
| Clinical Significance | Prenatal diagnosis of Alpha Thalassemia. |
| **Effective Date** | **8/12/2013** |
| Test Code | **91711** |
| CPT Codes | **81257** |
| Specimen Requirements | **Cultured cells from amniotic fluid or cultured cells from CVS collected in T-25 flask (X2)** |
| Reject Criteria | **Received refrigerated or frozen** |
| Instructions | **DO NOT HOLD OR CANCEL. SEND IMMEDIATELY TO TESTING LAB. Please call 866-GENE-INFO (866-436-3463) if there are questions about collection and transport. Sample will be stabilized upon receipt.<br>Cultured Cells (either Amniocyte culture or Chorionic villus (CVS) biopsy culture): Ship two 100% confluent T-25 flasks filled with growth media. Specimen stability is crucial. Store and ship the flasks at room temperature immediately. Do not refrigerate or freeze. Call lab for additional requirements for prenatal testing. Indicate source of cells: Amniotic Fluid (AF) or Chorionic Villus Sample (CVS). Please order test code 10262- Maternal Cell Contamination (MCC) Studies or 10477- Maternal Cell Contamination Study, STR Analysis (NY) with this test. A separate tube of maternal blood (EDTA) must be drawn in order to rule out maternal contamination of the fetal sample.** |
| Transport Temperature | **Room temperature** |
| Specimen Stability | **Room temperature: See Instructions<br>Refrigerated and Frozen: Unacceptable** |
| Set-up/Analytic Time | **Set up: Sun; Report available: 2-3 weeks following set-up.** |
| Reference Range | **Accompanies Report** |
| Always Message | **Alpha-globin is an essential component of the hemoglobin tetramer, starting from the early stages of embryonic development. Deletion mutations involving one or both of the two alpha-globin genes (alpha1 and alpha2, located on chromosome 16p13) lead to reduced production of alpha-globin chains, and are the major cause of alpha-thalassemia. Severity of the disease is dependent on the total copy number of functional alpha-globin genes remaining.<br><br>This assay detects the seven most common deletions (-alpha3.7, -alpha4.2, -alpha20.5, --SEA, --MED, -FIL, and --THAI) found in patients with alpha-thalassemia. This assay is performed by allele-specific PCR amplification of deletion mutation fragments, followed by agarose gel electrophoresis of the amplification products. It is not known what percentage of individuals with alpha-globin gene deletions will be detected by this test.<br><br>For assistance with the interpretation of those results, please contact your local Quest Diagnostics genetic counselor or call 1-866-GENEINFO (436-3463).<br><br>This test is performed pursuant to a license agreement with Roche Molecular Systems, Inc.<br><br>This test was developed and its performance characteristics have been determined by Quest Diagnostics Nichols Institute, San Juan Capistrano. Performance characteristics refer to the analytical performance of the test.** |
| Methodology | **Polymerase Chain Reaction** |
| Performing Site | **Quest Diagnostics Nichols Institute, San Juan Capistrano** |
| CPU Mappings | **Result Code** / **Result Name** |

| | |
|---|---|
| **86009868** | **Alpha-Globin Mutat,Fetus** |

| **Beta-Globin Complete™, Fetus** | |
|---|---|
| Clinical Significance | Prenatal diagnosis of beta-thalassemia. |
| **Effective Date** | **8/12/2013** |
| Test Code | **91709** |
| CPT Codes | **81404** |
| Specimen Requirements | **Cultured cells from amniotic fluid or cultured cells from CVS collected in T-25 flask (X2)** |
| Reject Criteria | **Received refrigerated or frozen** |
| Instructions | **DO NOT HOLD OR CANCEL. SEND IMMEDIATELY TO TESTING LAB. Please call 866-GENE-INFO (866-436-3463) if there are questions about collection and transport. Sample will be stabilized upon receipt.<br>Cultured Cells (either Amniocyte culture or Chorionic villus (CVS) biopsy culture): Ship two 100% confluent T-25 flasks filled with growth media. Specimen stability is crucial. Store and ship the flasks at room temperature immediately. Do not refrigerate or freeze. Call lab for additional requirements for prenatal testing. Indicate source of cells: Amniotic Fluid (AF) or Chorionic Villus Sample (CVS). Please order test code 10262- Maternal Cell Contamination (MCC) Studies or 10477- Maternal Cell Contamination Study, STR Analysis (NY) with this test. A separate tube of maternal blood (EDTA) must be drawn in order to rule out maternal contamination of the fetal sample.** |
| Transport Temperature | **Room temperature** |
| Specimen Stability | **Room temperature: See Instructions<br>Refrigerated and Frozen: Unacceptable** |
| Set-up/Analytic Time | **Set up: Mon, Thurs; Report available: 2 weeks following set-up** |
| Reference Range | **Accompanies Report** |
| Always Message | **Beta-globin and alpha-globin are components of the major adult hemoglobin, Hb A. Mutations in the beta-globin gene (HBB, on chromosome 11p15) can cause the synthesis of beta-globin structural variants that alter the oxygen-carrying or physical properties of hemoglobin or reduce its stability. Alternatively, mutations in the beta-globin gene can reduce the rate of synthesis of beta-globin chains and cause beta-thalassemia as the result of an imbalance in the amounts of alpha-and beta-globin synthesized. The genotype-phenotype correlations for beta globin mutations are complex. Depending on the nature of the mutations involved, individuals heterozygous for a beta-globin mutation may or may not be symptomatic while individuals with two mutant beta-globin genes are expected to be affected with a disease of variable severity (http://globin.cse.psu.edu/cgi-bin/hbvar/counter).<br><br>DNA analysis of the beta-globin gene was performed by nucleotide sequencing of the entire coding region, part of the second intron, splice junction sites and promoter region. Genomic DNA was amplified using the polymerase chain reaction (PCR), sequenced, and analyzed by automated, capillary electrophoresis. This analysis will theoretically identify greater than 99% of beta-globin mutations.<br><br>However, this assay cannot rule out the possibility of the heterozygous presence of a large deletion involving all or part of the beta-globin gene.<br>In addition, this assay cannot determine the effect of novel sequence changes in intronic regions on mRNA splicing and beta-globin protein synthesis. Neither can it detect fused or hybrid beta-globin genes or rule out the presence of a hemoglobinopathy involving other globin genes. Since genetic variation and other factors can affect the accuracy of direct mutation testing, the results of this testing should always be interpreted in light of clinical and familial data.<br><br>For assistance with the interpretation of these results, please contact your local Quest Diagnostics genetic counselor or call 1-866-GENEINFO (436-3463). This test is performed pursuant to a license agreement with Roche Molecular Systems, Inc.<br><br>This test was developed and its performance characteristics have been determined by Quest Diagnostics Nichols Institute, San Juan Capistrano. Performance characteristics refer to the analytical performance of the test.** |
| Methodology | **Polymerase Chain Reaction, DNA Sequencing** |

| | |
|---|---|
| Performing Site | **Quest Diagnostics Nichols Institute, San Juan Capistrano** |
| CPU Mappings | **Result Code** / **Result Name**<br>**86009867** / **BetaGlobin Complet,Fetus** |

| **CAH (21-Hydroxylase Deficiency) Common Mutations, Fetal Cells** | |
|---|---|
| Clinical Significance | Prenatal Diagnosis of CAH 21-OH Deficiency |
| **Effective Date** | **8/12/2013** |
| Test Code | **91680** |
| CPT Codes | **81402** |
| Specimen Requirements | **Cultured cells from amniotic fluid or cultured cells from CVS collected in T-25 flask (X2)** |
| Reject Criteria | **Received refrigerated or frozen** |
| Instructions | **DO NOT HOLD OR CANCEL. SEND IMMEDIATELY TO TESTING LAB. Please call 866-GENE-INFO (866-436-3463) if there are questions about collection and transport. Sample will be stabilized upon receipt.**<br>**Cultured Cells (either Amniocyte culture or Chorionic villus (CVS) biopsy culture): Ship two 100% confluent T-25 flasks filled with growth media. Specimen stability is crucial. Store and ship the flasks at room temperature immediately. Do not refrigerate or freeze. Call lab for additional requirements for prenatal testing. Indicate source of cells: Amniotic Fluid (AF) or Chorionic Villus Sample (CVS). Please order test code 10262- Maternal Cell Contamination (MCC) Studies or 10477- Maternal Cell Contamination Study, STR Analysis (NY) with this test. A separate tube of maternal blood (EDTA) must be drawn in order to rule out maternal contamination of the fetal sample.** |
| Transport Temperature | **Room temperature** |
| Specimen Stability | **Room temperature: See Instructions**<br>**Refrigerated and Frozen: Unacceptable** |
| Set-up/Analytic Time | **Set up: Tues; Report available: 1-2 weeks following set up** |
| Reference Range | **Accompanies Report** |
| Always Message | **Congenital Adrenal Hyperplasia (CAH) due to 21-hydroxylase deficiency is an autosomal recessive disorder caused by mutations or genetic rearrangements that disrupt both parental copies of the gene for 21-hydroxylase, CYP21A2. About 90% of mutant chromosomes carry one or more of 10 common mutations detected in this assay. The mutations are detected by a mini-sequencing analysis of four different PCR products that allow inspection of the 21-hydroxylase gene, its pseudogene, and various recombinant forms of those genes. Mutations tested include P30L, Intron 2 "g", G110del8nt, I172N, Exon 6 cluster I236N, V237E and M239K, V281L, F306+1nt, Q318X, R356W, and P453S and the patterns observed can be used to deduce deletions plus recombination events between CYP21A2 and its pseudogene. Given 90% sensitivity for mutation detection, one would expect that no mutations would be identified in 10% of heterozygous carriers of CAH. Similarly, 18% of those affected by CAH should have a detectable mutation on a single parental chromosome and 1% of those with CAH should not have a detectable mutation on either parental chromosome. Since genetic variation and other problems can affect the accuracy of direct mutation detection, test results should always be interpreted in light of clinical and family data.**<br><br>**CYP21A2 genotypes can be complex and analysis of first degree relatives may be required to fully understand the haplotype or pattern of markers on an individual chromosome. Family studies should always be completed in preparation for prenatal diagnosis and genetic counseling may be useful to interpret either individual or family results.**<br><br>**This test is performed pursuant to a license agreement with Roche Molecular Systems, Inc. and Orchid Biosciences Inc.**<br><br>**This test was developed and its performance characteristics have been determined by Quest Diagnostics Nichols Institute, San Juan Capistrano. Performance characteristics refer to the analytical performance of the test.** |

| | |
|---|---|
| Methodology | **Polymerase Chain Reaction, Electrophoresis, and Minisequencing** |
| Performing Site | **Quest Diagnostics Nichols Institute, San Juan Capistrano** |
| CPU Mappings | **Reporting Title: CAH COMMON MUTATION, FETAL**<br>**Result Code** / **Result Name**<br>**86009817** / **CYP21A2, Fetal** |

| **HIV-1 Genotype (RTI, PI, Integrase Inhibitors)** | |
|---|---|
| Clinical Significance | Identify drug resistance mutations in HIV-1 patients failing antiretroviral regimens containing RT, PR or Integrase inhibitors. Identify transmitted drug resistance mutations in the RT, PR or integrase genes in treatment-naive patients prior to initiation of antiretroviral therapy. |
| **Effective Date** | **9/16/2013** |
| Test Code | **91692** |
| CPT Codes | **87901, 87906** |
| Specimen Requirements | **4 mL (1.2 mL minimum) plasma collected in an EDTA (lavender-top) tube** |
| Reject Criteria | **Non-centrifuged PPT; frozen PPT (in situ); heparinized plasma; serum** |
| Instructions | **Collect blood in sterile tubes containing EDTA anticoagulant (lavender-top) or PPT (white-top) tube. Separate plasma from the cells by centrifugation within 24 hours after collection, transfer the plasma to a separate plastic screw-cap vial, and ship frozen.** |
| Transport Temperature | **Frozen** |
| Specimen Stability | **Room temperature: 24 hours**<br>**Refrigerated: 5 days**<br>**Frozen: 35 days** |
| Set-up/Analytic Time | **Set up: Mon-Sat; Report available: 7 days** |
| Always Message | **HIV-1 Genotype**<br>**The method used in this test is RT-PCR and sequencing of the HIV-1 polymerase gene.**<br><br>**The phrases "resistance predicted" and "probable or emerging resistance" refer to the application of the interpretive rules. The FDA has not reviewed all of the interpretive rules used by the laboratory to predict drug resistance. FDA may not currently recognize some of the HIV gene mutations reported as predictive of drug resistance, but the laboratory considers these mutations to be associated with resistance to anti-viral drugs based on current clinical or scientific studies. The test has been validated pursuant to CLIA regulations and is not considered investigational or for research use only. Treatment decisions should be made in consideration of all relevant clinical and laboratory findings and the prescribing information for the drugs.**<br><br>**This test was developed and its performance characteristics have been determined by Quest Diagnostics Nichols Institute, San Juan Capistrano. Performance characteristics refer to the analytical performance of the test.**<br><br>**HIV-1 Integrase Genotype**<br>**This test was developed and its performance characteristics have been determined by Quest Diagnostics Nichols Institute, San Juan Capistrano. Performance characteristics refer to the analytical performance of the test.**<br><br>**The method used in this test is RT-PCR and sequencing of the HIV-1 integrase gene. The phrases "resistance predicted" and "probable or emerging resistance" refer to the application of the interpretive rules. The FDA has not reviewed all of the interpretive rules used by the laboratory to predict drug resistance. FDA may not currently recognize some of the HIV gene mutations reported as predictive of drug resistance, but the laboratory considers these mutations to be associated with resistance to anti-viral drugs based on current clinical or scientific studies.** |

| | |
|---|---|
| | **The test has been validated pursuant to CLIA regulations and is not considered investigational or for research use only. Treatment decisions should be made in consideration of all relevant clinical and laboratory findings.** |
| Methodology | **Reverse Transcriptase Polymerase Chain Reaction and Sequencing** |
| Performing Site | **Quest Diagnostics Nichols Institute, San Juan Capistrano** |
| CPU Mappings | |

| **34949 HIV-1 Genotype** | | |
|---|---|---|
| **Result Code** | **Type** | **Result Name** |
| **86007864** | | **HIV-1 Genotype** |
| **16868-HIV-1 Integrase Genotype** | | |
| **Reporting Title: HIV-1 INTEGRASE GENOTYPE** | | |
| **Result Code** | **Type** | **Result Name** |
| **70000049** | **Prompt-Result** | **Value of Last Viral Load** |
| **70000048** | **Prompt-Result** | **Date Viral Load Collected** |
| **86004058** | | **Raltegravir Resistance** |
| **86008936** | | **Elvitegravir Resistance** |

| **HIV-1 RNA, Quantitative Real-Time PCR with Reflex Genotype (RTI, PI, Integrase)** | |
|---|---|
| Clinical Significance | Monitor viral load in HIV-1 patients undergoing antiretroviral therapy and automatically reflex to drug resistance testing for PR, RT and Integrase drugs in patients failing to achieve or maintain virologic suppression. |
| **Effective Date** | **9/16/2013** |
| Test Code | **91691** |
| CPT Codes | **87536** |
| Specimen Requirements | **7 mL (3.7 mL minimum) plasma collected in an EDTA (lavender-top) tube [x2]** |
| Reject Criteria | **Serum; non-centrifuged PPT; frozen PPT (in situ); heparinized plasma** |
| Instructions | **Collect blood in sterile tubes containing EDTA anticoagulant (lavender-top) or PPT (white-top) tube. Separate plasma from the cells by centrifugation within 24 hours after collection, transfer the plasma to a separate plastic screw-cap vial, and ship frozen.** |
| Transport Temperature | **Frozen** |
| Specimen Stability | **Room temperature: 24 hours**<br>**Refrigerated: 5 days**<br>**Frozen: 35 days** |
| Set-up/Analytic Time | **Set up: Mon-Sat; Report available: 10 days** |
| Reference Range | |

| **HIV-1 RNA, Quantitative, Real-Time PCR** | |
|---|---|
| **HIV-1 RNA, QN PCR:** | **<20 Copies/mL** |
| **HIV-1 RNA, QN PCR:** | **<1.30 Log copies/mL** |

| | |
|---|---|
| Always Message | **HIV-1 RNA, Quantitative, Real-Time PCR**<br>**This test was performed using the Cobas® AmpliPrep/Cobas® Taqman® HIV-1 test kit version 2.0 (Roche Molecular Systems, Inc.).** |

**HIV-1 Genotype**
**The method used in this test is RT-PCR and sequencing of the HIV-1 polymerase gene.**

**The phrases "resistance predicted" and "probable or emerging resistance" refer to the application of the interpretive rules. The FDA has not reviewed all of the interpretive rules used by the laboratory to predict drug resistance. FDA may not currently recognize some of the HIV gene mutations reported as predictive of drug resistance, but the laboratory considers these mutations to be associated with resistance to anti-viral drugs based on current clinical or scientific studies. The test has been validated pursuant to CLIA regulations and is not considered investigational or for research use only. Treatment decisions should be made in consideration of all relevant clinical and laboratory findings and the prescribing information for the drugs.**

**This test was developed and its performance characteristics have been determined by Quest Diagnostics Nichols Institute, San Juan Capistrano. Performance characteristics refer to the analytical performance of the test.**

**HIV-1 Integrase Genotype**
**This test was developed and its performance characteristics have been determined by Quest Diagnostics Nichols Institute, San Juan Capistrano. Performance characteristics refer to the analytical performance of the test.**

**The method used in this test is RT-PCR and sequencing of the HIV-1 integrase gene. The phrases "resistance predicted" and "probable or emerging resistance" refer to the application of the interpretive rules. The FDA has not reviewed all of the interpretive rules used by the laboratory to predict drug resistance. FDA may not currently recognize some of the HIV gene mutations reported as predictive of drug resistance, but the laboratory considers these mutations to be associated with resistance to anti-viral drugs based on current clinical or scientific studies.**

**The test has been validated pursuant to CLIA regulations and is not considered investigational or for research use only. Treatment decisions should be made in consideration of all relevant clinical and laboratory findings.**

Methodology

| | |
|---|---|
| **HIV-1 RNA, Quantitative, Real-Time PCR** | **Real-Time Polymerase Chain Reaction** |
| **HIV-1 Genotype** | **Reverse Transcriptase Polymerase Chain Reaction and DNA Sequencing** |
| **HIV-1 Integrase Genotype** | **Reverse Transcriptase Polymerase Chain Reaction and Sequencing** |

Performing Site

**Quest Diagnostics Nichols Institute, San Juan Capistrano**

CPU Mappings

| **91691-1-HIV-1 RNA, Quantitative, Real-Time PCR** | |
|---|---|
| **Reporting Title: HIV1 RNA, QUAN REAL TIME PCR** | |
| **Result Code** | **Result Name** |
| **70011130** | **HIV-1 RNA, QN PCR** |
| **70011135** | **HIV-1 RNA, QN PCR** |
| ***TR 91691-2-HIV-1 Genotype** | |
| **Result Code** | **Result Name** |
| **86007864** | **HIV-1 Genotype** |
| ***TR 91691-3-HIV-1 Integrase Genotype** | |
| **Reporting Title: HIV-1 INTEGRASE GENOTYPE** | |
| **Result Code** | **Result Name** |
| **86004058** | **Raltegravir Resistance** |

| | |
|---|---|
| | 86008936 \| Elvitegravir Resistance<br>***TR (True Reflexing) Flag**<br>***CPU interface clients: If you are set up to use our True Reflexing option, build the unit codes with the TR flag (indicated above) separately.*** |
| Additional Information | **If HIV-1 RNA, Quantitative, Real-Time PCR viral load is >400 copies mL, then the HIV-1 Genotype and HIV-1 Integrase Genotype are performed at an additional charge (CPT code(s): 87901 and 87906).** |

| **B-cell Clonality Panel (IGH, IGK), PCR** | |
|---|---|
| Message | ***Please note: Test includes pathologist interpretation*** |
| Clinical Significance | This assay, which interrogates the immunoglobulin kappa light chain gene (IGK) and the immunoglobulin heavy chain (IGH), by a PCR method based on the BIOMED-2 consensus, is useful for establishing clonality of B-cell lymphoid neoplasms. It can be used also for identification of minimal residual disease or early recurrence in patients with a previous diagnosis of a B-cell neoplasm. Testing for both IGH and IGK gene rearrangements is reported to detect up to 99% of B-cell malignancies, compared to 80-90% for IGH and 85-90% for IGK alone. |
| **Effective Date** | **9/23/2013** |
| Test Code | **91635** |
| CPT Codes | **81261, 81264, 84999 (HCPCS: G0452)** |
| Specimen Requirements | **5 mL (3 mL minimum) whole blood collected in an EDTA (lavender-top) tube or 1 mL (0.5 mL minimum) bone marrow aspirate in an EDTA (lavender-top) tube shipped refrigerated or room temperature.**<br><br>**Fixed tissues: 1 paraffin block (preferred) or 12 unstained sections on glass slides labeled with surgical case number (pathology report required, indicate if fixative is not formalin).**<br><br>**Fresh/unfixed tissue samples: Ship frozen on dry ice in tube labeled with specimen source and surgical case number; include preliminary path report. Frozen tissue is stable for approximately 1 year at -70° C.** |
| Instructions | **Collect whole blood or bone marrow in an EDTA (lavender-top) tube and ship refrigerated or room temperature. Stability of whole blood and bone marrow samples at room and refrigerated temperatures is 1 week.**<br><br>**Paraffin blocks are to be shipped at room temperature. Stability for paraffin blocks is indefinite.**<br><br>**For tissue samples, fresh frozen tissue is preferred and to be shipped frozen. Frozen tissue is stable for approximately 1 year at -70° C.**<br><br>**Tissues in formalin fixative or RPMI are to be shipped at room temperature or refrigerated.**<br><br>**Needle washings in alcohol based fixative (eg. CytoLyt) are acceptable. Please include pathology report for all fresh FNA, frozen tissue and FFPE cases (partial/preliminary reports OK).** |
| Transport Temperature | **Room temperature** |
| Specimen Stability | **Whole blood and Bone marrow**<br>**Room temperature and Refrigerated: 7 days**<br>**Frozen: Unacceptable** |
| Set-up/Analytic Time | **Set up: Mon, Wed; Report available: 5 days** |
| Reference Range | **Accompanies report** |
| Methodology | **Polymerase Chain Reaction, Fragment Analysis** |
| Performing Site | **Quest Diagnostics Nichols Institute, San Juan Capistrano** |
| CPU Mappings | **91635-1-B-cell Clonality Panel (IGH,IGK), PCR**<br>**Reporting Title: BCELL CLONALITY PANEL**<br>**Result Code \| Type \| Result Name** |

| | | |
|---|---|---|
| **86006921** | **Prompt-Result** | **Clinical Indication:** |
| **86007404** | **Prompt-Result** | **Specimen Source:** |
| **86007839** | **Prompt-Result** | **Block/Specimen ID:** |
| **86007471** | | **IGH Result** |
| **86007472** | | **IGK Result** |

| **91635-2-Pathologist Interpretation** | |
|---|---|
| **Result Code** | **Result Name** |
| **86009446** | **Pathologist Interpretation** |

| **B-cell Receptor IGH Gene Rearrangement, PCR** | |
|---|---|
| Message | ***Please note: Test includes pathologist interpretation*** |
| Clinical Significance | This assay, which interrogates the immunoglobulin heavy chain gene (IGH) by a PCR method based on the BIOMED-2 consensus, is useful for establishing clonality of B-cell lymphoid neoplasms and in the identification of minimal residual disease or early recurrence in patients with a previous diagnosis of a B-cell neoplasm. It can be used in association with the immunoglobulin kappa light chain (IGK test code 90363, or IGH/IGK combo test code 91635), since false-negative results can occur in up to 10-20% of B-cell malignancies when testing for IGH only. The highest rates of non-detectable IGH clonal rearrangements are in IGVH-mutated B-cell neoplasms such as follicular lymphoma and plasma cell neoplasms and in B-lymphoblastic leukemia/lymphoma due to absent or incomplete B-cell receptor rearrangements. |
| **Effective Date** | **9/23/2013** |
| Test Code | **90362** |
| CPT Codes | **81261, 84999 (HCPCS: G0452)** |
| Specimen Requirements | **5 mL (3 mL minimum) whole blood collected in an EDTA (lavender-top) tube or 1 mL (0.5 mL minimum) bone marrow aspirate in an EDTA (lavender-top) tube shipped refrigerated or room temperature.**<br><br>**Fixed tissues: 1 paraffin block (preferred) or 12 unstained sections on glass slides labeled with surgical case number (pathology report required, indicate if fixative is not formalin).**<br><br>**Fresh/unfixed tissue samples: Ship frozen on dry ice in tube labeled with specimen source and surgical case number; include preliminary path report. Frozen tissue is stable for approximately 1 year at -70° C.** |
| Instructions | **Collect whole blood or bone marrow in an EDTA (lavender-top) tube and ship refrigerated or room temperature. Stability of whole blood and bone marrow samples at room and refrigerated temperatures is 1 week.**<br><br>**Paraffin blocks are to be shipped at room temperature. Stability for paraffin blocks is indefinite.**<br><br>**For tissue samples, fresh frozen tissue is preferred and to be shipped frozen. Frozen tissue is stable for approximately 1 year at -70° C.**<br><br>**Tissues in formalin fixative or RPMI are to be shipped at room temperature or refrigerated.**<br><br>**Needle washings in alcohol based fixative (eg. CytoLyt) are acceptable. Please include pathology report for all fresh FAN, frozen tissue and FFPE cases (partial/preliminary reports OK).** |
| Transport Temperature | **Room temperature** |
| Specimen Stability | **Whole blood and Bone marrow**<br>**Room temperature and Refrigerated: 7 days**<br>**Frozen: Unacceptable** |
| Set-up/Analytic Time | **Set up: Mon, Wed; Report available: 5 days** |
| Reference Range | **Accompanies report** |

| | |
|---|---|
| Methodology | **Polymerase Chain Reaction, Fragment Analysis** |
| Performing Site | **Quest Diagnostics Nichols Institute, San Juan Capistrano** |
| CPU Mappings | **90362-1-B-cell Receptor IGH Gene Rearrangement** |
| | **Reporting Title: B CELL IGH REARRANGEMENT** |

| Result Code | Type | Result Name |
|---|---|---|
| 86006921 | Prompt-Result | Clinical Indication: |
| 86007404 | Prompt-Result | Specimen Source: |
| 86007839 | Prompt-Result | Block/Specimen ID: |
| 86007471 | | IGH Result |
| **90362-2-Pathologist Interpretation** | | |
| **Result Code** | **Result Name** | |
| 86009446 | Pathologist Interpretation | |

| **B-cell Receptor IGK Gene Rearrangement, PCR** | |
|---|---|
| Message | ***Please note: Test includes pathologist interpretation*** |
| Clinical Significance | This assay, which interrogates the immunoglobulin kappa light chain gene (IGK) by a PCR method based on the BIOMED-2 consensus, is useful for establishing clonality of B-cell lymphoid neoplasms and in the identification of minimal residual disease or early recurrence in patients with a previous diagnosis of a B-cell neoplasm. It can be used in association with the immunoglobulin heavy chain (IGH PCR assay test code 90362), since false-negative results can occur in up to 10-15% of B-cell malignancies when testing IGK only. |
| **Effective Date** | **9/23/2013** |
| Test Code | **90363** |
| CPT Codes | **81264, 84999 (HCPCS: G0452)** |
| Specimen Requirements | **5 mL (3 mL minimum) whole blood collected in an EDTA (lavender-top) tube or 1 mL (0.5 mL minimum) bone marrow aspirate in an EDTA (lavender-top) tube shipped refrigerated or room temperature.**<br><br>**Fixed tissues: 1 paraffin block (preferred) or 12 unstained sections on glass slides labeled with surgical case number (pathology report required, indicate if fixative is not formalin).**<br><br>**Fresh/unfixed tissue samples: Ship frozen on dry ice in tube labeled with specimen source and surgical case number; include preliminary path report. Frozen tissue is stable for approximately 1 year at -70° C.** |
| Instructions | **Collect whole blood or bone marrow in an EDTA (lavender-top) tube and ship refrigerated or room temperature. Stability of whole blood and bone marrow samples at room and refrigerated temperatures is 1 week.**<br><br>**Paraffin blocks are to be shipped at room temperature. Stability for paraffin blocks is indefinite.**<br><br>**For tissue samples, fresh frozen tissue is preferred and to be shipped frozen. Frozen tissue is stable for approximately 1 year at -70° C.**<br><br>**Tissues in formalin fixative or RPMI are to be shipped at room temperature or refrigerated.**<br><br>**Needle washings in alcohol based fixative (eg. CytoLyt) are acceptable. Please include pathology report for all fresh FNA, frozen tissue and FFPE cases (partial/preliminary reports OK).** |
| Transport Temperature | **Room temperature** |
| Specimen Stability | **Whole blood and Bone marrow** |

| | |
|---|---|
| | **Room temperature and Refrigerated: 7 days**<br>**Frozen: Unacceptable** |
| Set-up/Analytic Time | **Set up: Mon, Wed; Report available: 5 days** |
| Reference Range | **Accompanies report** |
| Methodology | **Polymerase Chain Reaction, Fragment Analysis** |
| Performing Site | **Quest Diagnostics Nichols Institute, San Juan Capistrano** |
| CPU Mappings | **90363-1-B-cell Receptor IGK Gene Rearrangement**<br>**Reporting Title: B CELL IGK REARRANGEMENT**<br>**Result Code** / **Type** / **Result Name**<br>**86006921** / **Prompt-Result** / **Clinical Indication:**<br>**86007404** / **Prompt-Result** / **Specimen Source:**<br>**86007839** / **Prompt-Result** / **Block/Specimen ID:**<br>**86007472** / / **IGK Result**<br>**90363-2-Pathologist Interpretation**<br>**Result Code** / **Result Name**<br>**86009446** / **Pathologist Interpretation** |

| **Lymphocyte Clonality Panel, PCR** | |
|---|---|
| Message | ***Please note: Test includes pathologist interpretation*** |
| Clinical Significance | This assay interrogates simultaneously the immunoglobulin kappa (IGK), the immunoglobulin heavy chain (IGH), the T-cell receptor beta (TCRB) and the T-cell receptor gamma (TCRG) genes by PCR methods based on the BIOMED-2 consensus. This combination assay will be most useful in diagnosing mixed B-cell and T-cell atypical infiltrates and for lineage identification in poorly differentiated or immature lymphoid malignancies. |
| **Effective Date** | **9/23/2013** |
| Test Code | **91634** |
| CPT Codes | **81261, 81264, 81342, 81340, 84999 (HCPCS: G0452)** |
| Specimen Requirements | **5 mL (3 mL minimum) whole blood collected in an EDTA (lavender-top) tube or 1 mL (0.5 mL minimum) bone marrow aspirate in an EDTA (lavender-top) tube shipped refrigerated or room temperature.**<br><br>**Fixed tissues: 1 paraffin block (preferred) or 12 unstained sections on glass slides labeled with surgical case number (pathology report required, indicate if fixative is not formalin).**<br><br>**Fresh/unfixed tissue samples: Ship frozen on dry ice in tube labeled with specimen source and surgical case number; include preliminary path report. Frozen tissue is stable for approximately 1 year at -70° C.** |
| Instructions | **Collect whole blood or bone marrow in an EDTA (lavender-top) tube and ship refrigerated or room temperature. Stability of whole blood and bone marrow samples at room and refrigerated temperatures is 1 week.**<br><br>**Paraffin blocks are to be shipped at room temperature. Stability for paraffin blocks is indefinite.**<br><br>**For tissue samples, fresh frozen tissue is preferred and to be shipped frozen. Frozen tissue is stable for approximately 1 year at -70° C.**<br><br>**Tissues in formalin fixative or RPMI are to be shipped at room temperature or refrigerated.**<br><br>**Needle washings in alcohol based fixative (eg. CytoLyt) are acceptable. Please include pathology report** |

| | |
|---|---|
| | **for all fresh FNA, frozen tissue and FFPE cases (partial/preliminary reports OK).** |
| Transport Temperature | **Room temperature** |
| Specimen Stability | **Whole blood and Bone marrow**<br>**Room temperature and Refrigerated: 7 days**<br>**Frozen: Unacceptable** |
| Set-up/Analytic Time | **Set up: Mon, Wed; Report available: 5 days** |
| Reference Range | **Accompanies report** |
| Methodology | **Polymerase Chain Reaction, Fragment Analysis** |
| Performing Site | **Quest Diagnostics Nichols Institute, San Juan Capistrano** |
| CPU Mappings | |

| **91634-1-Lymphocyte Clonality Panel, PCR** | | |
|---|---|---|
| **Reporting Title: BCELL TCELL CLONALITY PANEL** | | |
| **Result Code** | **Type** | **Result Name** |
| **86006921** | **Prompt-Result** | **Clinical Indication:** |
| **86007404** | **Prompt-Result** | **Specimen Source:** |
| **86007839** | **Prompt-Result** | **Block/Specimen ID:** |
| **86007471** | | **IGH Result** |
| **86007472** | | **IGK Result** |
| **86007874** | | **TCRG Result** |
| **86009119** | | **TCRB Result** |
| **91634-2-Pathologist Interpretation** | | |
| **Result Code** | **Result Name** | |
| **86009446** | **Pathologist Interpretation** | |

| **T-cell Clonality Panel (TCRB, TCRG), PCR** | |
|---|---|
| Message | ***Please note: Test includes pathologist interpretation*** |
| Clinical Significance | This test, which interrogates both the T-cell receptor beta (TCRB) locus and the T-cell receptor gamma (TCRG) locus by a PCR method based on the BIOMED-2 consensus, is useful in patients with suspected T-cell malignancies or to evaluate for residual disease after treatment. Several published studies have demonstrated that the combination of TCRB and TCRG PCR using the BIOMED-2 method can detect virtually all clonal T-cell populations. |
| **Effective Date** | **9/23/2013** |
| Test Code | **91445** |
| CPT Codes | **81342, 81340, 84999 (HCPCS: G0452)** |
| Specimen Requirements | **5 mL (3 mL minimum) whole blood collected in an EDTA (lavender-top) tube or 1 mL (0.5 mL minimum) bone marrow aspirate in an EDTA (lavender-top) tube shipped refrigerated or room temperature.**<br><br>**Fixed tissues: 1 paraffin block (preferred) or 12 unstained sections on glass slides labeled with surgical case number (pathology report required, indicate if fixative is not formalin).**<br><br>**Fresh/unfixed tissue samples: Ship frozen on dry ice in tube labeled with specimen source and surgical case number; include preliminary path report. Frozen tissue is stable for approximately 1 year at -70° C.** |
| Instructions | **Collect whole blood or bone marrow in an EDTA (lavender-top) tube and ship refrigerated or room** |

| | |
|---|---|
| | **temperature. Stability of whole blood and bone marrow samples at room and refrigerated temperatures is 1 week.**<br><br>**Paraffin blocks are to be shipped at room temperature. Stability for paraffin blocks is indefinite.**<br><br>**For tissue samples, fresh frozen tissue is preferred and to be shipped frozen. Frozen tissue is stable for approximately 1 year at -70° C.**<br><br>**Tissues in formalin fixative or RPMI are to be shipped at room temperature or refrigerated.**<br><br>**Needle washings in alcohol based fixative (eg. CytoLyt) are acceptable. Please include pathology report for all fresh FNA, frozen tissue and FFPE cases (partial/preliminary reports OK).** |
| Transport Temperature | **Room temperature** |
| Specimen Stability | **Whole blood and Bone marrow**<br>**Room temperature and Refrigerated: 7 days**<br>**Frozen: Unacceptable** |
| Set-up/Analytic Time | **Set up: Mon, Wed; Report available: 5 days** |
| Reference Range | **Accompanies report** |
| Methodology | **Polymerase Chain Reaction, Fragment Analysis** |
| Performing Site | **Quest Diagnostics Nichols Institute, San Juan Capistrano** |
| CPU Mappings | **91445-1-T-cell Clonality Panel (TCRG, TCRB), PCR**<br>**Reporting Title: TCELL CLONALITY PANEL**<br>**Result Code** / **Type** / **Result Name**<br>**86006921** / **Prompt-Result** / **Clinical Indication:**<br>**86007404** / **Prompt-Result** / **Specimen Source:**<br>**86007839** / **Prompt-Result** / **Block/Specimen ID:**<br>**86007874** / **TCRG Result**<br>**86009119** / **TCRB Result**<br>**91445-2-Pathologist Interpretation**<br>**Result Code** / **Result Name**<br>**86009446** / **Pathologist Interpretation** |

| **T-cell Receptor (TCR) Beta Gene Rearrangement, PCR** | |
|---|---|
| Message | ***Please note: Test includes pathologist interpretation*** |
| Clinical Significance | This assay which interrogates the T-cell receptor beta locus (TCRB) by a PCR method based on the BIOMED-2 consensus, is useful for establishing clonality of T-cell lymphoid neoplasms and identification of minimal residual disease or early recurrence in patients with a previous diagnosis of a T-cell neoplasm. It can be used in association with T-cell receptor (TCR) gamma PCR assay (Test code 90509), since false-negative results can occur in up to 5-10% of T-cell malignancies with TCRB PCR alone. |
| **Effective Date** | **9/23/2013** |
| Test Code | **91446** |
| CPT Codes | **81340, 84999 (HCPCS: G0452)** |
| Specimen Requirements | **5 mL (3 mL minimum) whole blood collected in an EDTA (lavender-top) tube or 1 mL (0.5 mL minimum) bone marrow aspirate in an EDTA (lavender-top) tube shipped refrigerated or room temperature.** |

| | |
|---|---|
| | **Fixed tissues: 1 paraffin block (preferred) or 12 unstained sections on glass slides labeled with surgical case number (pathology report required, indicate if fixative is not formalin).**<br><br>**Fresh/unfixed tissue samples: Ship frozen on dry ice in tube labeled with specimen source and surgical case number; include preliminary path report. Frozen tissue is stable for approximately 1 year at -70° C.** |
| Instructions | **Collect whole blood or bone marrow in an EDTA (lavender-top) tube and ship refrigerated or room temperature. Stability of whole blood and bone marrow samples at room and refrigerated temperatures is 1 week.**<br><br>**Paraffin blocks are to be shipped at room temperature. Stability for paraffin blocks is indefinite.**<br><br>**For tissue samples, fresh frozen tissue is preferred and to be shipped frozen. Frozen tissue is stable for approximately 1 year at -70° C.**<br><br>**Tissues in formalin fixative or RPMI are to be shipped at room temperature or refrigerated.**<br><br>**Needle washings in alcohol based fixative (eg. CytoLyt) are acceptable. Please include pathology report for all fresh FNA, frozen tissue and FFPE cases (partial/preliminary reports OK).** |
| Transport Temperature | **Room temperature** |
| Specimen Stability | **Whole blood and Bone marrow**<br>**Room temperature and Refrigerated: 7 days**<br>**Frozen: Unacceptable** |
| Set-up/Analytic Time | **Set up: Mon, Wed; Report available: 5 days** |
| Reference Range | **Accompanies report** |
| Methodology | **Polymerase Chain Reaction, Fragment Analysis** |
| Performing Site | **Quest Diagnostics Nichols Institute, San Juan Capistrano** |
| CPU Mappings | **91446-1-T-cell Receptor (TCR) Beta Gene Rearrangement, PCR**<br>**Reporting Title: T CELL BETA REARRANGEMENT**<br>**Result Code** / **Type** / **Result Name**<br>**86006921** / **Prompt-Result** / **Clinical Indication:**<br>**86007404** / **Prompt-Result** / **Specimen Source:**<br>**86007839** / **Prompt-Result** / **Block/Specimen ID:**<br>**86009119** / / **TCRB Result**<br>**91446-2-Pathologist Interpretation**<br>**Result Code** / **Result Name**<br>**86009446** / **Pathologist Interpretation** |

| **T-cell Receptor (TCR) Gamma Gene Rearrangement, PCR** | |
|---|---|
| Message | ***Please note: Test includes pathologist interpretation*** |
| Clinical Significance | This assay which interrogates the T-cell receptor gamma locus (TCRG) by a PCR method based on the BIOMED-2 consensus, is useful for establishing clonality of T-cell lymphoid neoplasms and identification of minimal residual disease or early recurrence in patients with a previous diagnosis of a T-cell neoplasm. It can be used in association with the T-cell receptor beta (TCRB) PCR assay (Test code 91446 or TCRG/TCRB combo test code 91445), since false-negative results can occur in up to 5-10% of T-cell malignancies when testing for TCRG PCR only. |
| **Effective Date** | **9/23/2013** |

| | |
|---|---|
| Test Code | **90509** |
| CPT Codes | **81342, 84999 (HCPCS: G0452)** |
| Specimen Requirements | **5 mL (3 mL minimum) whole blood collected in an EDTA (lavender-top) tube or 1 mL (0.5 mL minimum) bone marrow aspirate in an EDTA (lavender-top) tube shipped refrigerated or room temperature.**<br><br>**Fixed tissues: 1 paraffin block (preferred) or 12 unstained sections on glass slides labeled with surgical case number (pathology report required, indicate if fixative is not formalin).**<br><br>**Fresh/unfixed tissue samples: Ship frozen on dry ice in tube labeled with specimen source and surgical case number; include preliminary path report. Frozen tissue is stable for approximately 1 year at -70° C.** |
| Instructions | **Collect whole blood or bone marrow in an EDTA (lavender-top) tube and ship refrigerated or room temperature. Stability of whole blood and bone marrow samples at room and refrigerated temperatures is 1 week.**<br><br>**Paraffin blocks are to be shipped at room temperature. Stability for paraffin blocks is indefinite.**<br><br>**For tissue samples, fresh frozen tissue is preferred and to be shipped frozen. Frozen tissue is stable for approximately 1 year at -70° C.**<br><br>**Tissues in formalin fixative or RPMI are to be shipped at room temperature or refrigerated.**<br><br>**Needle washings in alcohol based fixative (eg. CytoLyt) are acceptable. Please include pathology report for all fresh FNA, frozen tissue and FFPA cases (partial/preliminary reports OK).** |
| Transport Temperature | **Room temperature** |
| Specimen Stability | **Whole blood and Bone marrow**<br>**Room temperature and Refrigerated: 7 days**<br>**Frozen: Unacceptable** |
| Set-up/Analytic Time | **Set up: Mon, Wed; Report available: 5 days** |
| Reference Range | **Accompanies report** |
| Methodology | **Polymerase Chain Reaction, Fragment Analysis** |
| Performing Site | **Quest Diagnostics Nichols Institute, San Juan Capistrano** |
| CPU Mappings | **90509-1-T-cell Receptor (TCR) Gamma Gene Rearrangement, PCR**<br>**Reporting Title: T CELL GAMMA REARRANGEMENT**<br>**Result Code / Type / Result Name**<br>**86006921 / Prompt-Result / Clinical Indication:**<br>**86007404 / Prompt-Result / Specimen Source:**<br>**86007839 / Prompt-Result / Block/Specimen ID:**<br>**86007874 / / TCRG Result**<br>**90509-2-Pathologist Interpretation**<br>**Result Code / Result Name**<br>**86009446 / Pathologist Interpretation** |

| **Thyroid FNA Cytomorphology Evaluation** | |
|---|---|
| Clinical Significance | Thyroid masses are evaluated by fine needle aspiration (FNA). This assay will provide cytologic evaluation and diagnosis of thyroid FNAs by a cytopathologist. |

| | |
|---|---|
| **Effective Date** | **9/23/2013** |
| Test Code | **90819** |
| CPT Codes | **88173** |
| Specimen Requirements | **Needle washings, in alcohol-based preservative (e.g. CytoLyt®), submitted in a plastic, leakproof container and 4 unstained, fixed or air-dried slides of needle washings, submitted in a slide holder.** |
| Reject Criteria | **Broken slides beyond repair; unlabeled container or slide; leakage of fluid during transport; mismatch between name of patient on slide and requisition** |
| Instructions | **Express a small portion of the FNA from needle directly onto glass slides and air dry or fix immediately by immersing in alcohol or by fixing with a commercially prepared cytology spray fixative. Label each slide with patient name, pathology sample ID and the number of needle pass (i.e. 1 for 1st, 2 for 2nd, etc). The needle should then be washed in a screw top vial of alcohol-based fixative (e.g. CytoLyt) and labeled with patient name, pathology sample ID and FNA location. FNAs from different locations (e.g. distinct nodules) should be collected individually on different slides and needle washings (e.g. A-left lobe, B-right lobe).** |
| Transport Temperature | **Room temperature** |
| Specimen Stability | **Room temperature and Refrigerated: 8 days**<br>**Frozen: Unacceptable** |
| Set-up/Analytic Time | **Set up: Mon-Fri; Report available: 2 days** |
| Reference Range | **Accompanies Report** |
| Always Message | **This test was developed and its performance characteristics have been determined by Quest Diagnostics Nichols Institute, San Juan Capistrano. Performance characteristics refer to the analytical performance of the test.** |
| Methodology | **Cytomorphology Review** |
| Performing Site | **Quest Diagnostics Nichols Institute, San Juan Capistrano** |
| CPU Mappings | |

| Result Code | Type | Result Name |
|---|---|---|
| **86007404** | **Prompt-Result** | **Specimen Source:** |
| **86007839** | **Prompt-Result** | **Block/Specimen ID:** |
| **86006921** | **Prompt-Result** | **Clinical Indication:** |
| **86008787** | **Prompt-Result** | **Ultrasound Findings** |
| **86005357** | **Prompt-Result** | **Collection Date** |
| **86008668** | | **Thyroid, FNA Evaluation** |

| **Thyroid FNA Cytomorphology with Molecular Reflex** | |
|---|---|
| Clinical Significance | Both benign and malignant thyroid neoplasms are associated with specific molecular alterations that can aid in diagnosis. Among thyroid tumors, BRAF V600E mutation (40-50% of cases) and RET over expression through juxtaposition to the PTC1 or PTC3 genes by chromosome fusion (5-40% of cases) are associated specifically with papillary thyroid cancer (PTC). Follicular thyroid carcinoma is specifically associated with PPARG-PAX8 gene fusions in 25-50% of cases. Other genetic lesions, such as NRAS, HRAS and KRAS mutations can serve as clonal markers for thyroid cancer but appear less specifically associated with morphologic findings. |
| **Effective Date** | **9/23/2013** |
| Test Code | **90818** |
| CPT Codes | **88173** |

<table>
<tr><td>Specimen Requirements</td><td>Needle washings, in alcohol-based preservative (e.g. CytoLyt®), submitted in a plastic, leakproof container and 4 unstained, fixed or air-dried slides of needle washings, submitted in a slide holder.</td></tr>
<tr><td>Reject Criteria</td><td>Broken slides beyond repair; unlabeled container or slide; leakage of fluid during transport; mismatch between name of patient on slide and requisition</td></tr>
<tr><td>Instructions</td><td>Express a small portion of the FNA from needle directly onto glass slides and air dry or fix immediately by immersing in alcohol or by fixing with a commercially prepared cytology spray fixative. Label each slide with patient name, pathology sample ID and the number of needle pass (i.e. 1 for 1st, 2 for 2nd, etc). The needle should then be washed in a screw top vial of alcohol-based fixative (e.g. CytoLyt) and labeled with patient name, pathology sample ID and FNA location. FNAs from different locations (e.g. distinct nodules) should be collected individually on different slides and needle washings (e.g. A-left lobe, B-right lobe).</td></tr>
<tr><td>Transport Temperature</td><td>Room temperature</td></tr>
<tr><td>Specimen Stability</td><td>Room temperature and Refrigerated: 8 days<br>Frozen: Unacceptable</td></tr>
<tr><td>Set-up/Analytic Time</td><td>Set up: Mon-Fri; Report available: 7 days</td></tr>
<tr><td>Reference Range</td><td>Accompanies Report</td></tr>
<tr><td>Always Message</td><td>Thyroid FNA Cytomorphology with Molecular Reflex:<br><br>This test was developed and its performance characteristics have been determined by Quest Diagnostics Nichols Institute, San Juan Capistrano. Performance characteristics refer to the analytical performance of the test.</td></tr>
<tr><td>Methodology</td><td>Cytomorphology Review and Polymerase Chain Reaction-based Molecular Testing</td></tr>
<tr><td>Performing Site</td><td>Quest Diagnostics Nichols Institute, San Juan Capistrano</td></tr>
<tr><td>CPU Mappings</td><td>
<table>
<tr><td colspan="3">90818-1 Thyroid FNA Cytomorphology with Molecular Reflex</td></tr>
<tr><td>Result Code</td><td>Type</td><td>Result Name</td></tr>
<tr><td>86007404</td><td>Prompt-Result</td><td>Specimen Source:</td></tr>
<tr><td>86007839</td><td>Prompt-Result</td><td>Block/Specimen ID:</td></tr>
<tr><td>86006921</td><td>Prompt-Result</td><td>Clinical Indication:</td></tr>
<tr><td>86008787</td><td>Prompt-Result</td><td>Ultrasound Findings</td></tr>
<tr><td>86005357</td><td>Prompt-Result</td><td>Collection Date</td></tr>
<tr><td>86008667</td><td></td><td>Thyroid,FNA rfl Molecular</td></tr>
<tr><td colspan="3">*TR 90818-2-Comprehensive Assessment</td></tr>
<tr><td>Result Code</td><td>Type</td><td>Result Name</td></tr>
<tr><td>86008405</td><td></td><td>Comprehensive Assessment</td></tr>
<tr><td colspan="3">*TR (True Reflex) Flag<br>CPU Interface clients: If you are set up to use our True Reflexing option, build the unit codes with the TR flag (indicated above) separately.</td></tr>
</table>
</td></tr>
<tr><td>Additional Information</td><td>If cytomorphology results belong to an indeterminate group it will be reflexed to molecular testing at an additional charge.</td></tr>
</table>

## 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*.

<table>
<tr><th colspan="2">Bordetella pertussis/parapertussis DNA, Qual, RT PCR [45400]</th></tr>
<tr><td>Effective Date</td><td>8/27/2013</td></tr>
<tr><td>Test Code</td><td>S51743</td></tr>
<tr><td>Performing Site</td><td>Focus Diagnostics</td></tr>
<tr><td>CPU Mappings</td><td>
<table>
<tr><th>Result Code</th><th>Type</th><th>Result Name</th></tr>
<tr><td>110118</td><td>AOE</td><td>Source</td></tr>
<tr><td>111258</td><td></td><td>B. Pertussis DNA</td></tr>
<tr><td>111259</td><td></td><td>B. Parapertussis DNA</td></tr>
</table>
</td></tr>
<tr><td>Additional Information</td><td>Adding Source analyte</td></tr>
</table>

<table>
<tr><th colspan="2">Hepatitis C Viral RNA, Quantitative, Real-Time PCR</th></tr>
<tr><td>Clinical Significance</td><td>Useful in monitoring response to therapy and/or disease progression. Reportable range is 15 to 100,000,000 IU/mL (1.18-8.00 log10 IU/mL)</td></tr>
<tr><td>Effective Date</td><td>9/9/2013</td></tr>
<tr><td>Test Code</td><td>35645</td></tr>
<tr><td>Specimen Requirements</td><td>Preferred:<br>3 mL (0.8 mL minimum) refrigerated plasma collected in two EDTA (lavender-top) tubes<br><br>Other acceptable:<br>Frozen or refrigerated plasma collected in two PPT EDTA (white-top) tubes. Separate plasma from whole blood within 24 hours of collection by centrifugation at 800 to 1600 x g for 20 minutes at room temperature. Transfer to a plastic screw-cap vial and freeze or refrigerate.<br><br>Serum collected in a serum separator tube or red top tube (no gel). Transfer to a plastic screw-cap vial and refrigerate.</td></tr>
<tr><td>Reject Criteria</td><td>Unspun PPT tube; unspun serum separator tube or red top tube</td></tr>
<tr><td>Instructions</td><td>Separate plasma from whole blood within 24 hours of collection by centrifugation at 800 to 1600 x g for 20 minutes at room temperature. Transfer plasma to a plastic screw-cap vial and refrigerate.</td></tr>
<tr><td>Transport Temperature</td><td>Refrigerated</td></tr>
<tr><td>Specimen Stability</td><td>Room temperature: 72 hours<br>Refrigerated: 14 days<br>Frozen: 42 days</td></tr>
<tr><td>Reference Range</td><td>HCV RNA, Quantitative Real Time PCR  <15 IU/mL<br>HCV RNA, Quantitative Real Time PCR  <1.18 Log IU/mL</td></tr>
<tr><td>Always Message</td><td>Please note: the guidelines for the use of new anti-HCV therapies (boceprevir and telaprevir) recommend using a test method that detects plasma viral nucleic acid levels as low as 10 IU/mL. This assay has a Limit of Detection of 10-13 IU/mL for genotype 1 and conforms to the recommendation. Quantitation of plasma HCV nucleic acid levels below 15 IU/mL (the Lower Limit of Quantitation for this test) may not be linear, and in this circumstance are reported as "<15 IU/mL HCV RNA Detected".<br><br>This test was performed using the COBAS(R)AmpliPrep/COBAS(R)TaqMan(R) HCV Test, v2.0 (Roche Molecular Systems, Inc).<br><br>For more information on this test, go to:</td></tr>
</table>

| | |
|---|---|
| | http://education.questdiagnostics.com/faq/HCV-RNA-PCR<br><br>The performance characteristics of this assay have been determined by Quest Diagnostics. Performance characteristics refer to the analytical performance of the test. |
| Performing Site | Quest Diagnostics Nichols Institute, Valencia |
| Tests Affected | **Test Codes:** / **Name:**<br>11348 – Hepatitis C Viral RNA Quantitative/Reflex to Genotyping<br>10051 – Hepatitis C Viral RNA, Quantitative Real-Time PCR<br>5906 – Hepatitis Autoimmune EvaluatR Plus<br>RJA – Reflex Hepatitis C Viral RNA, Quantitative, Real-Time PCR |

| **Voltage-Gated Calcium Channel (VGCC) Antibody Assay** | |
|---|---|
| **Effective Date** | **9/9/2013** |
| Test Code | S51602 |
| Specimen Stability | **Room temperature: 24 hours**<br>**Refrigerated: 7 days**<br>**Frozen: 35 days** |
| Reference Range | **<30 pmol/L** |
| Always Message | **Remove Always Message** |
| Assay Category | **FDA Approved/Cleared** |
| Performing Site | Quest Diagnostics Nichols Institute, San Juan Capistrano |

| **Garlic IgG** | |
|---|---|
| **Effective Date** | **9/16/2013** |
| *Former Test Name* | *Allergen – Garlic IgG* |
| *Former Test Code* | *F47G* |
| Test Code | **38114** |
| Methodology | **Immunoassay** |
| Performing Site | Quest Diagnostics Nichols Institute, Valencia |
| CPU Mappings | **Result Code** / **Result Name**<br>**86008238** / **Garlic IgG** |

| **Heparin Induced Platelet Antibody** | |
|---|---|
| **Effective Date** | **9/16/2013** |
| Test Code | 414 |
| Specimen Requirements | 1 mL serum **collected in a red-top tube (no gel)**<br><br>**Serum separator tubes are no longer acceptable.** |

| | |
|---|---|
| Instructions | **For serum: Centrifuge red top tube 15 minutes at approximately 1500g as soon as possible after clotting.** |
| Specimen Stability | **Refrigerated: Unacceptable**<br>**Frozen: 28 days**<br>**-70 degrees: 6 months** |
| Always Message | **OD Units** / **Results**<br>**< or = 0.300** / **Negative**<br>**>0.300 to < or = 0.500** / **Weak Positive**<br>**>0.500** / **Positive**<br><br>For more information on this test, go to:<br>http://education.questdiagnostics.com/faq/**FAQ06v1** |
| Performing Site | Quest Diagnostics Nichols Institute, San Juan Capistrano |

| **Heparin Induced Platelet Antibody with Reflex to SRA Unfractionated Heparin** | |
|---|---|
| Clinical Significance | **Diagnosis of Heparin Induced Thrombocytopenia is based on clinical criteria but serological confirmation is often necessary. The ELISA assay measures the Platelet Factor 4/Heparin Complex to IgG. When the ELISA test is positive, testing by Serotonin Release Assay (a platelet activation assay) is more predictive of thrombocytopenia and thrombosis.** |
| **Effective Date** | **9/16/2013** |
| Test Code | 15334 |
| Specimen Requirements | 1 mL serum **collected in a red-top tube (no gel) [x2]**<br><br>**Serum separator tubes are no longer acceptable** |
| Instructions | **Centrifuge red top tube 15 minutes at approximately 1500g as soon as possible after clotting.** |
| Specimen Stability | **Refrigerated: Unacceptable**<br>**Frozen: 28 days**<br>**-70 degrees: 6 months** |
| Always Message | **OD Units** / **Results**<br>**< or = 0.300** / **Negative**<br>**>0.300 to < or = 0.500** / **Weak Positive**<br>**>0.500** / **Positive**<br><br>For more information on this test, go to:<br>http://education.questdiagnostics.com/faq/**FAQ06v1** |
| Performing Site | Quest Diagnostics Nichols Institute, San Juan Capistrano |
| Additional Information | If the Heparin Induced Platelet Antibody result is a **weak positive or positive**, this test will reflex to the Serotonin Release Assay (SRA) at an additional charge (CPT code: 86022). |

| **Heparin-Induced Thrombocytopenia Panel** | |
|---|---|
| **Effective Date** | **9/16/2013** |
| Test Code | A52427 |
| Specimen Requirements | 1 mL serum **collected in a red-top tube (no gel) [x2]** |

| | |
|---|---|
| | **Serum separator tubes are no longer acceptable**. |
| Specimen Stability | **Refrigerated: Unacceptable**<br>**Frozen: 28 days**<br>**-70 degrees: 6 months** |
| Always Message | No change to 14627-Serotonin Release Assay, Unfractionated Heparin<br>**414 Heparin-Induced Platelet Antibody**<br>**OD Units** / **Results**<br>**< or = 0.300** / **Negative**<br>**>0.300 to < or = 0.500** / **Weak Positive**<br>**>0.500** / **Positive**<br>For more information on this test, go to:<br>http://education.questdiagnostics.com/faq**/FAQ06v1** |
| Performing Site | Quest Diagnostics Nichols Institute, San Juan Capistrano |

| **Testosterone, Free and Total, LC/MS/MS** | |
|---|---|
| **Effective Date** | **9/16/2013** |
| Test Code | 36170 |
| Reject Criteria | Samples received in serum separator tubes; **gross hemolysis; gross lipemia** |
| Performing Site | Quest Diagnostics Nichols Institute, Valencia |
| Tests Affected | **Test Codes:** / **Name:**<br>37073 / Testosterone, Total and Free, and Sex Hormone Binding Globulin |

| **Tomato IgG** | |
|---|---|
| **Effective Date** | **9/16/2013** |
| *Former Test Name* | *Allergen – Tomato IgG* |
| *Former Test Code* | *F25G* |
| Test Code | 34547 |
| Methodology | **Immunoassay** |
| Performing Site | Quest Diagnostics Nichols Institute, Valencia |
| CPU Mappings | **Result Code** / **Result Name**<br>**86008233** / **Tomato IgG** |

| **Tuna IgG** | |
|---|---|
| Revision Message! | **Please note: Former test name was corrected on 8/9/13** |

| | |
|---|---|
| **Effective Date** | **9/16/2013** |
| *Former Test Name* | *Allergen – Tuna IgG* |
| *Former Test Code* | *F40G* |
| Test Code | 38109 |
| Methodology | **Immunoassay** |
| Performing Site | Quest Diagnostics Nichols Institute, Valencia |
| CPU Mappings | **Result Code**: **86008236** — **Result Name**: **Tuna IgG** |

| **Walnut IgG** | |
|---|---|
| **Effective Date** | **9/16/2013** |
| *Former Test Name* | *Allergen – Walnut IgG* |
| *Former Test Code* | *F256G* |
| Test Code | **10329** |
| Methodology | **Immunoassay** |
| Performing Site | Quest Diagnostics Nichols Institute, Valencia |
| CPU Mappings | **Result Code**: **86008234** — **Result Name**: **Walnut IgG** |

| **Cytomegalovirus Antibodies (IgG, IgM)** | |
|---|---|
| **Effective Date** | **9/30/2013** |
| Test Code | 9436 |
| Specimen Requirements | 1 mL **(0.4 minimum)** serum |
| Reject Criteria | **Gross hemolysis; gross lipemia; plasma; cord blood** |
| Instructions | **Remove collection instruction** |
| Units Of Measure | **Cytomegalovirus (IgG)**: **Remove index value** |
| Always Message | **A positive result indicates that the patient has antibody to CMV. It does not differentiate between an active or past infection.** |
| Methodology | **Immunoassay** |
| Performing Site | Quest Diagnostics Nichols Institute, Valencia |

| **Cytomegalovirus Antibody (IgG)** | |
|---|---|
| **Effective Date** | **9/30/2013** |

| | |
|---|---|
| Test Code | 9431 |
| Reject Criteria | **Gross hemolysis; gross lipemia; plasma** |
| Instructions | **Remove collection instruction** |
| Reference Range | < or = 0.90 — Negative<br>0.91-1.09 — Equivocal<br>> or = 1.10 — Positive<br>**A positive result indicates that the patient has antibody to CMV. It does not differentiate between an active or past infection.** |
| Units Of Measure | **Remove index value** |
| Methodology | **Immunoassay** |
| Performing Site | Quest Diagnostics Nichols Institute, Valencia |
| Tests Affected | **Test Codes:** / **Name:**<br>9901 — Torch IgG & IgM Evaluation<br>9911 — Torch IgG Antibodies Evaluation Panel |

| **Herpes Simplex Virus 1 (IgG), Type-Specific Antibody (HerpeSelect®)** | |
|---|---|
| **Effective Date** | **9/30/2013** |
| *Former Test Name* | *Herpes Simplex Type 1 IgG Abs Serodex (Herpeselect)* |
| Test Code | 9451 |
| Specimen Requirements | **1 mL (0.2 mL minimum) serum** |
| Reject Criteria | **Plasma** |
| Specimen Stability | **Room temperature: 7 days**<br>**Refrigerated: 14 days**<br>**Frozen: 30 days** |
| Units Of Measure | **Remove index** |
| Always Message | **This assay utilizes recombinant type-specific antigens to differentiate HSV-1 from HSV-2 infections. A positive result cannot distinguish between recent and past infection. If recent HSV infection is suspected but the results are negative or equivocal, the assay should be repeated in 4-6 weeks. The performance characteristics of the assay have not been established for pediatric populations, immunocompromised patients, or neonatal screening.** |
| Methodology | **Immunoassay** |
| Performing Site | Quest Diagnostics Nichols Institute, Valencia |
| Tests Affected | **Test Codes:** / **Name:**<br>9496 — HSV ACCUDX: 1 & 2 IGG ABS [EIA] (HERPESELECT) & DNA [PCR]<br>8051 — HERPES SIMPLEX VIRUS TYPES 1 & 2 IGG (HERPESELECT) & IGM ABS<br>9446 — HERPES SIMPLEX VIRUS TYPES 1 & 2 IGG ABS (HERPESELECT)<br>9901 — TORCH IGG & IGM ABS EVALUATION |

| | |
|---|---|
| 9911 | TORCH IGG ABS EVALUATION |

| **Herpes Simplex Virus 2 (IgG), Type-Specific Antibody (HerpeSelect®)** | |
|---|---|
| **Effective Date** | **9/30/2013** |
| *Former Test Name* | *Herpes Simplex Virus Type 2 IgG Abs Serodx (Herpeselect)* |
| Test Code | 9461 |
| Specimen Requirements | **1 mL (0.2 mL minimum) serum** |
| Reject Criteria | **Gross hemolysis; gross lipemia; heat inactivated serum, plamsa** |
| Specimen Stability | **Room temperature: 7 days**<br>**Refrigerated: 14 days**<br>**Frozen: 30 days** |
| Units Of Measure | **Remove index** |
| Always Message | **This assay utilizes recombinant type-specific antigens to differentiate HSV-1 from HSV-2 infections. A positive result cannot distinguish between recent and past infection. If recent HSV infection is suspected but the results are negative or equivocal, the assay should be repeated in 4-6 weeks. The performance characteristics of the assay have not been established for pediatric populations, immunocompromised patients, or neonatal screening.** |
| Methodology | **Immunoassay** |
| Performing Site | Quest Diagnostics Nichols Institute, Valencia |
| Tests Affected | |

| **Test Codes:** | **Name:** |
|---|---|
| 9496 | HSV ACCUDX: 1 & 2 IGG ABS [EIA] (HERPESELECT) & DNA [PCR] |
| 8051 | HERPES SIMPLEX VIRUS TYPES 1 & 2 IGG (HERPESELECT) & IGM ABS |
| 9446 | HERPES SIMPLEX VIRUS TYPES 1 & 2 IGG ABS (HERPESELECT) |
| 9901 | TORCH IGG & IGM ABS EVALUATION |
| 9911 | TORCH IGG ABS EVALUATION |

| **Rubella Antibodies (IgG, IgM)** | |
|---|---|
| **Effective Date** | **9/30/2013** |
| *Former Test Name* | *RUBELLA IgG & IgM ABS* |
| Test Code | 9421 |
| Specimen Requirements | 1 mL **(0.7 minimum)** serum |
| Reject Criteria | **Gross hemolysis; gross lipemia; plasma; cord blood** |
| Transport Temperature | Room temperature |
| Specimen Stability | **Room temperature: 4 days**<br>**Refrigerate: 7 days**<br>**Frozen: 30 days** |
| Units Of Measure | **Rubella Antibody (IgM): Remove ratio** |
| Performing Site | Quest Diagnostics Nichols Institute, Valencia |

| **Rubella Antibody (IgM)** | |
|---|---|
| **Effective Date** | **9/30/2013** |
| Test Code | 2475 |
| Reject Criteria | Gross hemolysis; gross lipemia; **plasma; cord blood** |
| Units Of Measure | **Remove ratio** |
| Performing Site | Quest Diagnostics Nichols Institute, Valencia |
| Tests Affected | **Test Codes:** / **Name:**<br>9901 — Torch IgG & IgM Abs Evaluation<br>2231 — Torch IgM Abs Evaluation |

| **Toxoplasma Antibodies (IgG, IgM)** | |
|---|---|
| **Effective Date** | **9/30/2013** |
| *Former Test Name* | *Toxoplasma Gondii IgG & IgM Abs* |
| Test Code | 2263 |
| Reject Criteria | **Gross hemolysis; gross lipemia; plasma; cord blood** |
| Reference Range | **See individual assays** |
| Units Of Measure | **See individual assays** |
| Methodology | **Immunoassay** |
| Performing Site | Quest Diagnostics Nichols Institute, Valencia |

| **Toxoplasma Antibody (IgG)** | |
|---|---|
| **Effective Date** | **9/30/2013** |
| *Former Test Name* | *Toxoplasma gondii IgG Antibodies EIA* |
| Test Code | 9432 |
| Specimen Requirements | **1 mL (0.1 mL minimum) serum** |
| Reject Criteria | **Gross hemolysis; lipemia; plasma; cord blood** |
| Transport Temperature | **Room temperature** |
| Units Of Measure | **Remove index** |
| Always Message | **A positive result indicates infection with Toxoplasma gondii at some time, but does not differentiate between an active or past infection.** |
| Methodology | **Immunoassay** |
| Performing Site | Quest Diagnostics Nichols Institute, Valencia |
| Tests Affected | **Test Codes:** / **Name:**<br>9901 — Torch IgG & IgM Abs Evaluation |

| | |
|---|---|
| 9426 | TOXOPLASMA GONDII IGG ABS W/REFLEX IGM ABS |
| 9911 | Torch IgG Abs Evaluation |

| **Toxoplasma Antibody (IgM)** | |
|---|---|
| **Effective Date** | **9/30/2013** |
| *Former Test Name* | *Toxoplasma gondii IgM, Antibodies EIA* |
| Test Code | 7675 |
| Specimen Requirements | **1 mL (0.2 mL minimum) serum** |
| Reject Criteria | **Gross hemolysis; lipemia; cord blood** |
| Reference Range | **Negative**<br>**Remove reference range comment** |
| Units Of Measure | **Remove index** |
| Methodology | **Immunoassay** |
| Performing Site | Quest Diagnostics Nichols Institute, Valencia |
| Tests Affected | **Test Codes:** / **Name:**<br>9901 / TORCH IGG & IGM ABS EVALUATION<br>2231 / TORCH IGM ABS EVALUATION<br>RGA / Reflex Toxoplasma gondii IgM Abs EIA |

## Redirects

| **Quetiapine, Serum/Plasma** | |
|---|---|
| **Effective Date** | **9/16/2013** |
| *Former Test Code* | *S48659* |
| Test Code | **35299** |
| Specimen Requirements | 1 mL serum (0.4 mL minimum) collected in a red-top tube (no gel)<br>**Plasma collected in an EDTA (pink-top) tube is no longer acceptable**. |
| Instructions | **Collect as trough prior to next dose.** |
| Set-up/Analytic Time | **Set up: Mon, Wed, Fri; Report available: 2 days** |
| Reference Range | **100-1000 ng/mL** |
| Performing Site | **This test performed at NMS Labs will now be performed at Quest Diagnostics Nichols Institute, Chantilly.** |
| CPU Mappings | **Result Code** / **Result Name**<br>**86009961** / **Quetiapine** |

## Discontinued

| **Hepatitis C Viral RNA, Quantitative, Real-Time PCR** | |
|---|---|
| **Effective Date** | **9/9/2013** |
| Test Code | 7577 |
| Additional Information | The replacement is test code 35645 Hepatitis C Viral RNA, Quantitative, Real-Time PCR |

| **Heptimax® HCV RNA** | |
|---|---|
| **Effective Date** | **9/9/2013** |
| Test Code | 10565 |
| Additional Information | The recommended alternative is test code 35645 -Hepatitis C Viral RNA, Quantitative, Real-Time PCR |

| **B-cell Gene Rearrangement, Qualitative PCR, Cell-based** | |
|---|---|
| Revision Message! | **Please note: Recommended alternatives in the additional information was updated effective 8/6/13.** |
| **Effective Date** | **9/23/2013** |
| Test Code | 14868 |
| Additional Information | The recommended alternative are:<br>• 90362 -B-cell Receptor IGH Gene Rearrangement, PCR in the New Test Offering section<br>• **90363 -B-cell Receptor IGK Gene Rearrangement, PCR in the New Test Offering section** |

| **T-cell Receptor (TCR) Gene Rearrangement, Qualitative PCR, Cell-based** | |
|---|---|
| Revision Message! | **Please note: Recommended alternatives in the additional information was updated effective 8/6/13.** |
| **Effective Date** | **9/23/2013** |
| Test Code | 15930 |
| Additional Information | The recommended alternatives are:<br>• 90509-T-cell Receptor (TCR) Gamma Gene Rearrangement, PCR in the New Test Offering section<br>• **91446-T-cell Receptor (TCR) Beta Gene Rearrangement, PCR in the New Test Offering section** |

| **CytomegalovirusS (CMV) Recent Infection Antibody Panel** | |
|---|---|
| **Effective Date** | **9/30/2013** |
| Test Code | S52373 |
| Additional Information | The recommended alternatives are:<br>• 9431 Cytomegalovirus Antibody (IgG)<br>• 2486 Cytomegalovirus Antibody (IgM)<br>• S50904 Cytomegalovirus (CMV) IgG Avidity (AviDx), ELISA |

## New York Patient Testing Update

| **New York Patient Testing Update** | |
|---|---|
| Message | These tests are **now available** for New York patient testing. |
| **Effective Date** | **8/1/2013** |
| Tests Affected | |

| **Test Codes:** | **Name:** |
|---|---|
| S51317 | BK and JC Virus DNA, Qualitative Real-Time PCR |
| S52409 | JC Polyoma Virus DNA, Qualitative Real-Time PCR, CSF |
| S51744 | JC Polyoma Virus DNA, Qualitative Real-Time PCR, Plasma |
| S52408 | JC Polyoma Virus DNA, Qualitative Real-Time PCR, CSF, Urine |
| S52406 | JC Polyoma Virus DNA, Quantitative Real-Time PCR, CSF |
| S52407 | JC Polyoma Virus DNA, Quantitative Real-Time PCR, CSF, Urine |
| S51745 | JC Polyoma Virus DNA, Quantitative Real-Time PCR, Plasma |

## 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.**

| **Atenolol, Serum/Plasma** | |
|---|---|
| **Effective Date** | **9/9/2013** |
| Test Code | S44765 |
| Specimen Requirements | Preferred:<br>1 mL **(0.22 mL minimum)** serum collected in a red-top tube (no-gel)<br><br>**Acceptable:**<br>**Plasma collected in an EDTA (lavender-top) or EDTA (pink-top) tube** |
| Reject Criteria | Serum separator tube; Polymer gel separation tube<br><br>**Removed: Received room temperature** |
| Transport Temperature | **Room temperature** |
| Specimen Stability | **Room temperature: 7 days**<br>**Refrigerated and Frozen: 30 days** |

| **Metoprolol, Serum/Plasma** | |
|---|---|
| **Effective Date** | **9/9/2013** |
| *Former Test Name* | *Metoprolol* |
| Test Code | S48447 |

| | |
|---|---|
| Specimen Requirements | Preferred:<br>**1 mL (0.4 mL minimum)** serum collected in red-top tube (no-gel)<br><br>**Acceptable:**<br>**Plasma collected in an EDTA (lavender-top) or EDTA (pink-top) tube** |
| Specimen Stability | Room temperature: 14 days<br>**Refrigerated, and Frozen: 30 days** |

| **Nadolol, Serum/Plasma** | |
|---|---|
| **Effective Date** | **9/9/2013** |
| Test Code | S48605 |
| Specimen Requirements | Preferred:<br>**1 mL (0.4 mL minimum)** serum collected in red-top tube (no-gel)<br><br>**Acceptable:**<br>**Plasma collected in an EDTA (lavender-top) or EDTA (pink-top) tube** |
| Specimen Stability | **Room temperature, Refrigerated, and Frozen: 30 days** |

| **Sotalol, Blood** | |
|---|---|
| **Effective Date** | **9/9/2013** |
| Test Code | S52295 |
| Specimen Requirements | **1 mL (0.22 mL minimum)** whole blood collected in an EDTA (lavender-top) tube |
| Specimen Stability | **Room temperature, Refrigerated, and Frozen: 30 days** |

| **Sotalol, Serum/Plasma** | |
|---|---|
| **Effective Date** | **9/9/2013** |
| Test Code | S44835 |
| Specimen Requirements | Preferred:<br>1 mL **(0.22 mL minimum)** serum collected in a red-top tube (no-gel)<br><br>**Acceptable:**<br>**Plasma collected in an EDTA (lavender-top) or EDTA (pink-top) tube** |
| Instructions | **Promptly centrifuge and separate serum or plasma into a plastic, screw-cap, preservative-free vial using appropriate guidelines.** |
| Specimen Stability | Room temperature: 14 days<br>**Refrigerated and Frozen: 30 days** |

| **Sotalol, Urine** | |
|---|---|
| **Effective Date** | **9/9/2013** |
| Test Code | S52297 |
| Specimen Requirements | **1 mL (0.22 mL minimum)** random urine submitted in a plastic, leakproof, **preservative-free** container |
| Specimen Stability | **Room temperature, Refrigerated, and Frozen: 30 days** |