

July 2012 - Monthly Update, Quest Diagnostics Nichols Institute, Valencia

Revision Message!

In the June Laboratory Update, we announced two new tests: 91029 Vitamin B3 and 91030 Vitamin B5 (Pantothenic Acid). Please note the following CPT Code corrections to these two new tests available 8/13/2012:

91029 Vitamin B3: CPT Code: 84591

91030 Vitamin B5 (Pantothenic Acid): CPT Codes: 84591

Also, please note that as announced previously, effective July 10, test code 16558 Vitamin D, 1,25-Dihydroxy, LC/MS/MS will be available and performed by Quest Diagnostics Institute, Valencia. Please note that our current referral test code S51661 will be discontinued on the same date.

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 #
11175	Alpha-Globin Common Mutation Analysis	8/7/2012	2
11174	Alpha-Globin Common Mutation Analysis [NY]	8/7/2012	3
91065	BCR-ABL1 Gene Rearrangement, Quantitative PCR	8/7/2012	4
10458	Cystic Fibrosis Screen	8/7/2012	5
16539	JAK2 V617F Mutation, QL w/Reflex to Exons 12 and 13 Leumeta®	8/7/2012	6
16175	JAK2 V617F Mutation, Quantitative, Plasma-Based, Leumeta®	8/7/2012	8

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 #
4914		Amitriptyline	8/6/2012	9
4962		Clomipramine	8/6/2012	9
4918		Clonazepam	8/6/2012	10
4964		Clozapine	8/6/2012	11
4922		Desipramine	8/6/2012	11
4924		Doxepin	8/6/2012	11
4950		Fluoxetine	8/6/2012	12
3364		Gabapentin	8/6/2012	12
4932		Imipramine	8/6/2012	13
4930		Nortriptyline	8/6/2012	13
4154		Tricyclic Antidepressants (TCA) Confirm Serum Extended	8/6/2012	14
4157		Tricyclic Antidepressants (TCA) Confirmation Serum	8/6/2012	14
4661		Cardiolipin Antibody (IgA)	8/7/2012	15
4662		Cardiolipin Antibody (IgG)	8/7/2012	15
4663		Cardiolipin Antibody (IgM)	8/7/2012	16

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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 #
16536	5392	JAK2 Exons 12 and 13 Mutations, Qualitative, Leumeta®	8/7/2012	16
16538	5396	JAK2 V617F, QL, w/rfl to Exons 12,13 and MPL W515, S505	8/7/2012	17
18947		Pain Management, CYP450 2D6/2C19 Geno, Qual [NY]	8/7/2012	19
18946		Pain Management, CYP450 2D6/2C19 Geno, Qualitative	8/7/2012	19

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 #
5270	AccuType® Metformin	8/7/2012	20
5220	Alpha-Thalassemia GenotypR™	8/7/2012	20
4565	AmpliChip™ CYP450 2D6 & 2C19 GenotypR™	8/7/2012	20
5342	BCR/ABL UltraQuant® Major 210 KD Transcript Bone Marrow	8/7/2012	20
5352	BCR/ABL UltraQuant® Major 210 KD Transcript Whole Blood	8/7/2012	20
5344	BCR/ABL UltraQuant® Minor 190 KD Transcript Bone Marrow	8/7/2012	20
5354	BCR/ABL UltraQuant® Minor 190 KD Transcript Whole Blood	8/7/2012	21
5859	Chromosomes X-Y Aneuploidy DetectR™	8/7/2012	21
5432	Cystic Fibrosis 23 Mutation Analysis	8/7/2012	21
5434	Cystic Fibrosis 23 Mutation Analysis, Fetus w/Reflex MCC	8/7/2012	21
5388	FcGammaRIIa & FcGammaRIIIa Mutation Analysis	8/7/2012	21
5394	JAK2 V617F Mutation, Qual PCR, Plasma w/Rfx Exons 12, 13	8/7/2012	22
5395	JAK2 V617F Mutation, Qual, PCR	8/7/2012	22
5398	MPL W515 & MPL S505 Mutation Analysis, Qualitative, Plasma	8/7/2012	22
4555	Thrombotic Risk AssessR™ for Obstetric Complications	8/7/2012	22
5384	UGT1A1 (Camptosar/Irinotecan) GenotypR™	8/7/2012	22

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 #
	SureSwab(TM) Assays	22

New Test Offerings

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

Alpha-Globin Common Mutation Analysis	
Message	Suggested replacement for discontinued test code 5220 Alpha-Thalassemia GenotypR™

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Clinical Significance	Alpha Thalassemia is a common hereditary trait and disease among individuals of Asian heritage. Disease ranges in severity from mild abnormalities of erythrocytic indices to severe anemia. Genetic counseling may be advised for some patients.				
Effective Date	8/7/2012				
Test Code	11175				
CPT Codes	83891, 83894, 83900, 83901 (x5), 83912				
Specimen Requirements	Preferred Specimen: 5 (3) mL Whole Blood collected in an EDTA (lavender-top) tube Alternate Specimen(s): Whole Blood in EDTA (royal blue-top) tube Sodium Heparin (green-top) tube Lithium Heparin (green-top) tube ACD-B (yellow-top) tube ACD-A (yellow-top) tube				
Transport Temperature	Room temperature				
Specimen Stability	Room temperature: 7 days Refrigerated: 7 days Frozen: Unacceptable				
Set-up/Analytic Time	Set up: Mon; Report available: 6 days				
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. 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. For assistance with the interpretation of those 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. 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	<table border="1"> <thead> <tr> <th>Result Code</th> <th>Result Name</th> </tr> </thead> <tbody> <tr> <td>85995944</td> <td>Alpha-Globin CommonMutat</td> </tr> </tbody> </table>	Result Code	Result Name	85995944	Alpha-Globin CommonMutat
Result Code	Result Name				
85995944	Alpha-Globin CommonMutat				
Additional Information	For New York patient testing, use test code 11174.				

Alpha-Globin Common Mutation Analysis [NY]	
Message	Suggested NY replacement for discontinued test code 5220 Alpha-Thalassemia GenotypR™
Clinical Significance	Alpha Thalassemia is a common hereditary trait and disease among individuals of Asian heritage. Disease ranges in severity from mild abnormalities of erythrocytic indices to severe anemia. Genetic counseling may be advised for some patients.
Effective Date	8/7/2012
Test Code	11174

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CPT Codes	83891, 83894, 83900, 83901 (x5), 83912				
Specimen Requirements	Preferred Specimen: 5 (3) mL Whole Blood collected in an EDTA (lavender-top) tube Alternate Specimen(s): Whole Blood in EDTA (royal blue-top) tube Sodium Heparin (green-top) tube Lithium Heparin (green-top) tube ACD-B (yellow-top) tube ACD-A (yellow-top) tube				
Transport Temperature	Room temperature				
Specimen Stability	Room temperature: 7 days Refrigerated: 7 days Frozen: Unacceptable				
Set-up/Analytic Time	Set up: Mon; Report available: 6 days				
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. 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. For assistance with the interpretation of those 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. 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	<table border="1"> <thead> <tr> <th>Result Code</th> <th>Result Name</th> </tr> </thead> <tbody> <tr> <td>85999222</td> <td>Alpha-Globin CommonMutat</td> </tr> </tbody> </table>	Result Code	Result Name	85999222	Alpha-Globin CommonMutat
Result Code	Result Name				
85999222	Alpha-Globin CommonMutat				
Additional Information	For non-New York patient testing, use test code 11175.				

BCR-ABL1 Gene Rearrangement, Quantitative PCR	
Message	Includes: BCR-ABL1/ABL1, P190 BCR-ABL1, P210 BCR-ABL1 <i>Suggested replacement for discontinued test code 5352 BCR/ABL UltraQuant® Major 210 KD Transcript Whole Blood, 5352SR BCR/ABL UltraQuant® Major 210 KD Transcript Whole Blood w/ Serial Reporting and 5344 BCR/ABL UltraQuant® Minor 190 KD Transcript Bone Marrow</i>
Clinical Significance	This reverse-transcription PCR-based assay detects the BCR-ABL1 transcript produced by the t(9;22) chromosomal translocation associated with chronic myelogenous leukemia (CML) and a subset of lymphoblastic leukemias. For the P190 transcript associated with the minor t(9;22) breakpoint in lymphoblastic leukemia, BCR-ABL1 transcript levels are expressed as a percent ratio of BCR-ABL1 to the normalizing ABL1 transcript. For the P210 transcript associated with CML, quantitation is further adjusted to the international scale (IS) to allow comparison with other IS-compliant BCR-ABL1 assays. Optimal therapy in CML is associated with transcript levels below the major molecular response (MMR) milestone indicated by a BCR-ABL1/ABL1 % (IS) below 0.1.
Effective Date	8/7/2012
Test Code	91065
CPT Codes	83891, 83902, 83898, 83896, 83912

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Specimen Requirements	6 mL whole blood collected in EDTA (lavender-top) tube Alternate: 3 mL bone marrow																					
Instructions	Collect 6 mL of whole blood or 3 mL bone marrow in an EDTA (lavender-top) tube. Whole blood or bone marrow is shipped at room temperature or refrigerated. Do not freeze whole blood or bone marrow. After collection of the sample, draw date and time, as well as sample type, must be written on the tube and included as requested information. Ship sample immediately due to short stability of 72 hours. If the stability of the sample cannot be determined, delay in result or cancellation of test may occur. Clotted specimens are unacceptable. Do not reject.																					
Transport Temperature	Room temperature																					
Specimen Stability	Room temperature: 72 hours Refrigerated: 72 hours Frozen: Unacceptable																					
Set-up/Analytic Time	Set up: Mon-Sat; Report available: 3-4 days																					
Reference Range	<table border="1"> <tr> <td>BCR-ABL1/ABL1 %: 0.000 BCR-ABL1/ABL1 % (IS): 0.000 Interpretation: Accompanies report</td> </tr> </table>		BCR-ABL1/ABL1 %: 0.000 BCR-ABL1/ABL1 % (IS): 0.000 Interpretation: Accompanies report																			
BCR-ABL1/ABL1 %: 0.000 BCR-ABL1/ABL1 % (IS): 0.000 Interpretation: Accompanies report																						
Methodology	Quantitative Real-Time Polymerase Chain Reaction																					
Performing Site	Quest Diagnostics Nichols Institute, San Juan Capistrano																					
CPU Mappings	<table border="1"> <thead> <tr> <th>Result Code</th> <th>Result Name</th> </tr> </thead> <tbody> <tr> <td>86008600</td> <td>Prior Result: AOE</td> </tr> <tr> <td>86007404</td> <td>Specimen Source: AOE</td> </tr> <tr> <td>86008603</td> <td>BCR-ABL1/ABL1 %</td> </tr> <tr> <td>86008604</td> <td>BCR-ABL1/ABL1 % (IS)</td> </tr> <tr> <td>86008605</td> <td>Interpretation</td> </tr> <tr> <td>91065-2</td> <td>Reflex P190 BCR-ABL1</td> </tr> <tr> <td>86008601</td> <td>P190 BCR-ABL1</td> </tr> <tr> <td>91065-3</td> <td>Reflex P210 BCR-ABL1</td> </tr> <tr> <td>86008602</td> <td>P210 BCR-ABL1</td> </tr> </tbody> </table>		Result Code	Result Name	86008600	Prior Result: AOE	86007404	Specimen Source: AOE	86008603	BCR-ABL1/ABL1 %	86008604	BCR-ABL1/ABL1 % (IS)	86008605	Interpretation	91065-2	Reflex P190 BCR-ABL1	86008601	P190 BCR-ABL1	91065-3	Reflex P210 BCR-ABL1	86008602	P210 BCR-ABL1
Result Code	Result Name																					
86008600	Prior Result: AOE																					
86007404	Specimen Source: AOE																					
86008603	BCR-ABL1/ABL1 %																					
86008604	BCR-ABL1/ABL1 % (IS)																					
86008605	Interpretation																					
91065-2	Reflex P190 BCR-ABL1																					
86008601	P190 BCR-ABL1																					
91065-3	Reflex P210 BCR-ABL1																					
86008602	P210 BCR-ABL1																					
Additional Information	<ul style="list-style-type: none"> ● If P190 transcript expression was previously documented, only P190 BCR-ABL1 will be added (CPT codes: 83898; 83896). ● If P210 transcript expression was previously documented, only P210 BCR-ABL1 will be added (CPT codes: 83898; 83896). ● If no prior positive is documented P190 BCR-ABL1 and P210 BCR-ABL1 will be added (CPT codes: 83898(x2); 83896 (x2)). 																					

Cystic Fibrosis Screen	
Message	Suggested replacement test code for discontinued test 5432 Cystic Fibrosis 23 Mutation Analysis and 5432FH Cystic Fibrosis 23 Mutation Analysis w/Family History
Clinical Significance	General screen for carrier status and assessment of CF risk. This test will identify approximately 90% of Cystic Fibrosis (CF) mutations in the Caucasian population, and 97% in the Ashkenazi Jewish population.
Effective Date	8/7/2012

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Test Code	10458															
CPT Codes	83891, 83900, 83901 (x13), 83909, 83912, 83914 (x32)															
Specimen Requirements	<p>Preferred Specimens: 4 (3) mL Whole Blood collected in EDTA (lavender-top) tube</p> <p>Alternate Specimens: Whole Blood collected in ACD solution B (yellow-top) tube Sodium Heparin (green-top) tube EDTA (royal blue-top) tube Lithium Heparin (green-top) tube ACD solution A (yellow-top) tube 2 mL saliva in Oragene DNA self-collection kit</p>															
Instructions	<p>Please indicate the ethnicity of the patient. Whole blood: Normal phlebotomy procedure. Specimen stability is crucial. Store and ship ambient immediately. Do not freeze.</p> <p>Saliva: Rinse mouth, spit into collection tube until liquid phase reaches mark, seal with cap, replace funnel with small cap. See package insert. Store and ship ambient. Do not freeze. The oragene reagent is released from the cap. The reagent stabilizes/releases DNA from saliva. For Genetic Testing, original tube required. Aliquots for other testing from original tube are permitted, if performed without cross contamination of samples and using sterile techniques. Rinse mouth prior to spitting.</p>															
Transport Temperature	Room temperature															
Specimen Stability	<p>Whole Blood: Room temperature: 8 days Refrigerated: 8 days Frozen: Unacceptable</p> <p>Saliva: Room temperature: 14 days Refrigerated: 14 days Frozen: Call Lab</p>															
Set-up/Analytic Time	Set up: Daily; Report available: 4-5 days															
Reference Range	See Laboratory Report															
Always Message	The performance characteristics of this assay 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 Oligonucleotide Ligation Assay															
Performing Site	Quest Diagnostics Nichols Institute, San Juan Capistrano															
CPU Mappings	<table border="1"> <thead> <tr> <th>Result Code</th> <th>Result Name</th> </tr> </thead> <tbody> <tr> <td>86003354</td> <td>Ethnicity: AOE</td> </tr> <tr> <td>85998603</td> <td>CF Result</td> </tr> <tr> <td>85998604</td> <td>Interpretation</td> </tr> <tr> <td>85998605</td> <td>Mutations/Polymorphisms</td> </tr> <tr> <td>85998606</td> <td>Method</td> </tr> <tr> <td>85998607</td> <td>Reviewer</td> </tr> </tbody> </table>		Result Code	Result Name	86003354	Ethnicity: AOE	85998603	CF Result	85998604	Interpretation	85998605	Mutations/Polymorphisms	85998606	Method	85998607	Reviewer
Result Code	Result Name															
86003354	Ethnicity: AOE															
85998603	CF Result															
85998604	Interpretation															
85998605	Mutations/Polymorphisms															
85998606	Method															
85998607	Reviewer															

JAK2 V617F Mutation, QL w/Reflex to Exons 12 and 13 Leumeta®

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Message	Suggested replacement for discontinued test code 5394 JAK2 V617F Mutation, Qual PCR, Plasma w/Rfx Exons 12, 13
Clinical Significance	Myeloproliferative disorders (MPDs) are clonal hematopoietic stem cell malignancies characterized by excessive production of blood cells by hematopoietic precursors. In addition to thrombotic and hemorrhagic complications, leukemic transformation can occur. The main members of MPD are Polycythemia Vera (PV), Essential Thrombocythemia (ET) and Idiopathic Myelofibrosis (MF). The molecular pathogenesis of most MPDs is unknown. This V617F mutation leads to constitutive tyrosine phosphorylation activity that promotes cytokine activity and induces erythrocytosis. The V617F mutation in JAK2 is a dominant gain-of function mutation that contributes to the expansion of the myeloproliferative disorder clone. JAK2 exon 12 mutations define a distinctive myeloproliferative syndrome.
Effective Date	8/7/2012
Test Code	16539
CPT Codes	83891, 83902, 83898, 83904, 83912
Specimen Requirements	Preferred Specimen: 6 (4) mL Whole Blood collected in an EDTA (lavender-top) tube Alternate Specimen: 3 (2) mL Bone Marrow collected in an EDTA (lavender-top) tube
Reject Criteria	Frozen whole blood and bone marrow
Instructions	Submission of whole blood (preferred): Follow standard whole blood collection procedure. Collect 3-5 mL whole blood samples in EDTA tube. Blood samples are shipped at room temperature or 4 degrees C. Do not freeze whole blood. Record the draw time and date on the tube. Ship immediately to maintain sample stability.
Transport Temperature	Refrigerated
Specimen Stability	Room temperature: 72 hours Refrigerated: 72 hours Frozen: Unacceptable
Set-up/Analytic Time	Set up: Mon-Sat; Report available: 2-3 days
Reference Range	Not detected
Always Message	<p>The V617F mutation was found in >80% of the patients with polycythemia vera (PV), 30-50% of patients with either essential thrombocythemia (ET) or myelofibrosis (MF) according to recent publications. The mutation is not detected in normal individuals. JAK2 exon 12 mutations define a distinctive myeloproliferative syndrome in patients without the V617F mutation.</p> <p>*On reflex: JAK2 exon 12 mutations define a distinctive myeloproliferative syndrome without the V617F mutation. Patients with JAK2 exon 12 mutation presented with an isolated erythrocytosis and distinctive bone marrow morphology or had reduced serum erythropoietin levels. JAK2 exon 12 mutations are rare when compared with V617F mutation, and it is always heterozygous according to publications.</p> <p>This is a PCR/sequencing assay.</p> <p>Our studies demonstrate that plasma-based testing for JAK2 provides significantly higher sensitivity and better determination of heterozygous Vs homozygous/hemizygous. Effective immediately our preferred sample type for K2 testing is plasma rather than cells. We recommend submitting whole blood for testing and plasma will be tested first; if quantity is inadequate cells will be tested.</p> <p>1. Ma W. et al. Hemizygous/homozygous and heterozygous JAK2 mutation detected in plasma of patients with myeloproliferative diseases: correlation with clinical behavior. 2006. Br J Haematol. 134(3):341-3.</p> <p>2. Ma et al. Higher detection rate of JAK2 mutation using plasma. Blood. 2008 Apr 1;111(7):3906-7.</p> <p>This test is performed pursuant to a license agreement with Roche Molecular Systems, Inc.</p> <p>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.</p>

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Methodology	Polymerase Chain Reaction, if reflexed Sequencing													
Performing Site	Quest Diagnostics Nichols Institute, San Juan Capistrano													
CPU Mappings	<table border="1"> <thead> <tr> <th>Result Code</th> <th>Result Name</th> </tr> </thead> <tbody> <tr> <td>20142</td> <td>Sample Type: AOE</td> </tr> <tr> <td>16539</td> <td>JAK2 V617F</td> </tr> <tr> <td>16539-2</td> <td>Reflex JAK2 Exons 12 and 13 Mutations, Qualitative, Leumeta(TM)</td> </tr> <tr> <td>16536</td> <td>JAK2 exon 12 Mutations</td> </tr> <tr> <td>31191</td> <td>JAK2 exon 13 Mutations</td> </tr> </tbody> </table>		Result Code	Result Name	20142	Sample Type: AOE	16539	JAK2 V617F	16539-2	Reflex JAK2 Exons 12 and 13 Mutations, Qualitative, Leumeta(TM)	16536	JAK2 exon 12 Mutations	31191	JAK2 exon 13 Mutations
Result Code	Result Name													
20142	Sample Type: AOE													
16539	JAK2 V617F													
16539-2	Reflex JAK2 Exons 12 and 13 Mutations, Qualitative, Leumeta(TM)													
16536	JAK2 exon 12 Mutations													
31191	JAK2 exon 13 Mutations													

JAK2 V617F Mutation, Quantitative, Plasma-Based, Leumeta®	
Message	Suggested replacement for discontinued test code 5395 JAK2 V617F Mutation, Qual, PCR
Clinical Significance	The Jak2 tyrosine kinase (V617F) was detected in most patients (>80%) with polycythemia vera (PV), 30-50% of patients with either essential thrombocythemia (ET) or myelofibrosis. The Quantitative measurement of V617F may be useful for assessing the correlation of tumor load/phenotype; monitoring/predicting the progression or responses of the disease when MPD patients are under therapy.
Effective Date	8/7/2012
Test Code	16175
CPT Codes	83891, 83896, 83898, 83904 (x2), 83912
Specimen Requirements	Preferred Specimen: 5 (4) mL Whole Blood collected in an EDTA (lavender-top) tube Alternate Specimen: Sodium Heparin (green-top) tube
Instructions	Follow standard whole blood collection procedure. Collect 5 mL whole blood samples in an EDTA tube. Blood samples are shipped at room temperature or 4° C. Do not freeze whole blood. Record the draw time and date on the tube. Ship immediately to maintain sample stability.
Transport Temperature	Room temperature
Specimen Stability	Room temperature: 72 hours Refrigerated: 72 hours Frozen: Do Not Freeze
Set-up/Analytic Time	Set up: Monday; Report available: 7 days
Reference Range	Interpretation: Negative
Always Message	The V617F mutation was found in >80% of the patients with polycythemia vera (PV), 30-50% of patients with either essential thrombocythemia (ET) or myelofibrosis (MF) according to recent publications. The mutation is not detected in normal individuals. This is a PCR/sequencing assay. The sensitivity of the assay is 10% mutant allele in the background of normal allele. This test is performed pursuant to a license agreement with Roche Molecular Systems, Inc. This test was developed and its performance characteristics have been determined by Quest Diagnostics. Performance characteristics refer to the analytical performance of the test.
Methodology	Polymerase Chain Reaction Sequencing

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Performing Site	Quest Diagnostics Nichols Institute, San Juan Capistrano	
CPU Mappings	Result Code	Result Name
	86004937	JAK2 Mutation,QN,Leumeta
	86004938	Interpretation

Test Changes

Amitriptyline		
Clinical Significance	The tricyclics are used to treat depression. Nortriptyline is an active metabolite of Amitriptyline. Therapeutic drug levels are monitored to assist the physician assessing therapeutic response and avoid toxicity.	
Effective Date	8/6/2012	
Former Test Name	<i>Amitriptyline and Nortriptyline</i>	
Test Code	4914	
Specimen Requirements	3.0 (1.5) mL serum collected in red-top (no gel) tube ACD not acceptable Alternates: Serum collected in a No additive (royal blue-top) Plasma collected in a: EDTA (lavender-top), EDTA (royal blue-top), sodium heparin (green-top), lithium heparin (green-top), or sodium heparin lead-free (tan-top) tube	
Reject Criteria	Gross Hemolysis, Gel Barrier/Serum, Separator tubes	
Instructions	Collect at steady-state trough concentration. Specimen should be collected >12 hrs after dose. Do not use gel barrier/serum separator tubes. Sodium or Lithium heparin tubes are acceptable.	
Specimen Stability	Room Temperature: 5 days Refrigerated 7 days Frozen: Not established	
Units Of Measure	mcg/L	
Always Message	Remove Always Message: Amitriptyline + Nortriptyline therapeutic range is 100-250 ng/mL	
CPU Mappings	Result Code	Result Name
	37061	Amitriptyline
	80047100	Nortriptyline
	37063	Total

Clomipramine	
Clinical Significance	Clomipramine and its active metabolite, norclomipramine are antidepressant drugs. Therapeutic drug monitoring is useful to optimize dose and avoid toxicity.
Effective Date	8/6/2012
Former Test Name	<i>Clomipramine & Desmethylclomipramine</i>

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Test Code	4962				
Specimen Requirements	3 mL (1.5) serum collected in a red-top tube (no gel) ACD is not acceptable Alternates: Serum collected in a no additive (royal blue-top) Plasma collected in a: EDTA (lavender-top), EDTA (royal blue-top), sodium heparin (green-top), lithium heparin (green-top), or sodium heparin lead-free (tan-top) tube				
Reject Criteria	Gross hemolysis, Gel barrier tube				
Instructions	Collect at steady state trough concentration. Specimen should be collected >12 hours after dose. Do not use gel barrier/serum separator tubes. ACD plasma is unacceptable.				
Transport Temperature	Refrigerated				
Specimen Stability	Room Temperature: 8 hours Refrigerated: 5 days Frozen: 30 days				
Reference Range	Clomipramine: 50-250 mcg/L Desmethyloclopramine: 150-350 mcg/L Total: 200-600 mcg/L				
Units Of Measure	mcg/L				
Always Message	Remove always message: Desired Clomipramine (Anafranil) concentration for the treatment of chronic pain: 20 - 85 ng/mL				
CPU Mappings	<table border="1"> <thead> <tr> <th>Add: Result Code</th> <th>Result Name</th> </tr> </thead> <tbody> <tr> <td>80048700</td> <td>Total</td> </tr> </tbody> </table>	Add: Result Code	Result Name	80048700	Total
Add: Result Code	Result Name				
80048700	Total				

Clonazepam	
Clinical Significance	Clonazepam is a benzodiazepine used as a tranquilizer. Clonazepam is used in treating patients with seizures and reducing tardive dyskinesia. Therapeutic drug monitoring is useful to avoid toxicity.
Effective Date	8/6/2012
Test Code	4918
Specimen Requirements	Alternates: Plasma: EDTA (lavender-top) EDTA (royal blue-top) Sodium heparin (green-top) Lithium heparin (green-top)
Reject Criteria	Gel barrier tube/Serum Separator tubes
Instructions	Collect at trough concentration, i.e., immediately before the administration of the next dose. Do not use gel barrier/Serum Separator tubes.
Transport Temperature	Frozen
Specimen Stability	Room Temperature: 24 hours Refrigerated: 72 hours Frozen: 14 days
Set-up/Analytic Time	Report available: 1 day
Units Of Measure	mcg/L
Always Message	Remove always message: Potentially toxic: >70 ng/mL

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Tests Affected	Test Codes:	Name:
	4090	Benzodiazepines Serum
	RLH	Rfx Benzodiazepines Serum

Clozapine							
Clinical Significance	Clozapine is an atypical antipsychotic agent. Norclozapine has minimal therapeutic activity.						
Effective Date	8/6/2012						
Former Test Name	<i>Clozapine & Norclozapine</i>						
Test Code	4964						
Reject Criteria	Gel barrier/Serum Separator tubes: Gross Hemolysis						
Transport Temperature	Refrigerated						
Specimen Stability	Room temperature: 24 hours Refrigerated: 5 days Frozen: 30 days						
Units Of Measure	mcg/L						
Always Message	The therapeutic response begins to appear at 100 mcg/L. Refractory schizophrenia appears to require a therapeutic concentration of at least 350 mcg/L (trough, at steady state). Toxic range: Greater than 1000 mcg/L						
CPU Mappings	<table border="1"> <thead> <tr> <th>Result Code</th> <th>Result Name</th> </tr> </thead> <tbody> <tr> <td>200630</td> <td>Norclozapine</td> </tr> <tr> <td>37230</td> <td>Clozepine</td> </tr> </tbody> </table>	Result Code	Result Name	200630	Norclozapine	37230	Clozepine
Result Code	Result Name						
200630	Norclozapine						
37230	Clozepine						

Desipramine	
Clinical Significance	Desipramine is a tricyclic antidepressant. Therapeutic drug levels are monitored to assist the physician assessing therapeutic response and avoid toxicity.
Effective Date	8/6/2012
Test Code	4922
Specimen Requirements	3.0 (1.5) mL serum collected in red-top (no gel) tube Add Alternate: Heparin (green-top) ACD not acceptable
Reject Criteria	Gel barrier/Serum Separator tubes;Gross hemolysis
Instructions	Collect at steady-state trough concentration. Specimen should be collected >12 hrs after dose. Do not use gel barrier/Serum Separator tubes. Oxalate/Fluoride tube is unacceptable
Specimen Stability	Room temperature: 5 days Refrigerated: 5 days Frozen: 30 days
Set-up/Analytic Time	Report Available: 1 day
Reference Range	50 - 300 mcg/L
Units Of Measure	mcg/L

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Doxepin									
Clinical Significance	Doxepin is a tricyclic antidepressant. Therapeutic drug levels are monitored to assist the physician assessing therapeutic response and avoid toxicity.								
Effective Date	8/6/2012								
<i>Former Test Name</i>	<i>Doxepin & Nordoxepin</i>								
Test Code	4924								
Specimen Requirements	3.0 (1.5) mL serum collected in red-top (no gel) tube								
Reject Criteria	Gel barrier/Serum Separator tubes; Gross hemolysis								
Instructions	Collect at steady-state trough concentration. Specimen should be collected >12 hrs after dose. Do not use gel barrier/Serum Separator tubes. ACD tube is unacceptable								
Transport Temperature	Room temperature								
Specimen Stability	Room temperature: 5 days Refrigerated: 7 days Frozen: 30 days								
Set-up/Analytic Time	Report available: 1 day								
Units Of Measure	mcg/L								
CPU Mappings	<table border="1"> <thead> <tr> <th>Result Code</th> <th>Result Name</th> </tr> </thead> <tbody> <tr> <td>37086</td> <td>Doxepin</td> </tr> <tr> <td>37087</td> <td>Nordoxepin</td> </tr> <tr> <td>37088</td> <td>Total</td> </tr> </tbody> </table>	Result Code	Result Name	37086	Doxepin	37087	Nordoxepin	37088	Total
Result Code	Result Name								
37086	Doxepin								
37087	Nordoxepin								
37088	Total								

Fluoxetine					
Clinical Significance	Fluoxetine is an antidepressant drug that is also used in the treatment of bulimia nervosa and obsessive-compulsive disorder. Therapeutic drug monitoring is useful to optimize dose and avoid toxicity.				
Effective Date	8/6/2012				
<i>Former Test Name</i>	<i>Fluoxetine & Norfluoxetine</i>				
Test Code	4950				
Reject Criteria	Gross hemolysis; gel barrier/Serum Separator tubes				
Instructions	Collect at steady-state trough concentration. Specimen should be collected >12 hours after dose. Do not use gel barrier/Serum Separator tubes. ACD plasma is unacceptable				
Transport Temperature	Refrigerated				
Specimen Stability	Room temperature: 48 hours Refrigerated: 5 days Frozen: 30 days				
Set-up/Analytic Time	Report available: 2 days				
Units Of Measure	mcg/L				
CPU Mappings	<table border="1"> <thead> <tr> <th>Result Code</th> <th>Result Name</th> </tr> </thead> <tbody> <tr> <td>37196</td> <td>Norfluoxetine</td> </tr> </tbody> </table>	Result Code	Result Name	37196	Norfluoxetine
Result Code	Result Name				
37196	Norfluoxetine				

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37195	Fluoxetine
37197	Total

Gabapentin

Clinical Significance	Gabapentin is an anticonvulsant drug commonly used as adjunctive therapy to treat partial seizures. Therapeutic drug monitoring is useful to optimize dose and avoid toxicity.
Effective Date	8/6/2012
Test Code	3364
Specimen Requirements	1.0 (0.5) mL serum collected in red-top (no gel) tube
Reject Criteria	Gross hemolysis; gel barrier/Serum Separator tubes
Instructions	Draw sample two hours after last dose. Do not use gel barrier/ Serum Separator tubes. Separate serum or plasma from red cells as soon as possible; pipette or pour into plastic transport tubes.
Set-up/Analytic Time	Report available: 1 day

Imipramine

Clinical Significance	Imipramine is a tricyclic antidepressant drug used to treat depression. Therapeutic drug monitoring is used to optimize dose and avoid toxicity.								
Effective Date	8/6/2012								
Former Test Name	<i>Imipramine & Desipramine</i>								
Test Code	4932								
Specimen Requirements	3.0 (1.5) mL serum collected in red-top tube (no gel) ACD is not acceptable								
Reject Criteria	Gross hemolysis; gel barrier/Serum Separator tubes.								
Instructions	Collect at steady state trough concentration. Specimen should be collected > 12 hours after dose. Do not use gel barrier/Serum Separator tubes. ACD plasma is unacceptable								
Transport Temperature	Room temperature								
Specimen Stability	Room temperature: 5 days Refrigerated: 5 days Frozen: 30 days								
Set-up/Analytic Time	Report available: 2 days								
Reference Range	Total: 150 -250 mcg/L								
Units Of Measure	mcg/L								
CPU Mappings	<table border="1"> <thead> <tr> <th>Result Code</th> <th>Result Name</th> </tr> </thead> <tbody> <tr> <td>37106</td> <td>Imipramine</td> </tr> <tr> <td>37107</td> <td>Desipramine</td> </tr> <tr> <td>37108</td> <td>Total</td> </tr> </tbody> </table>	Result Code	Result Name	37106	Imipramine	37107	Desipramine	37108	Total
Result Code	Result Name								
37106	Imipramine								
37107	Desipramine								
37108	Total								

Nortriptyline

Clinical Significance	Nortriptyline is a tricyclic antidepressant. Therapeutic drug levels are monitored to assist the physician assessing therapeutic response and to avoid toxicity.
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Effective Date	8/6/2012
Test Code	4930
Specimen Requirements	3.0 (1.5) mL serum collected in red-top (no gel) tube ACD tube is unacceptable New Alternates: Sodium heparin (green-top) Lithium heparin (green-top) Sodium heparin lead-free (tan-top)
Reject Criteria	Gel barrier/Serum Separator tubes; Gross hemolysis
Instructions	Collect at steady-state trough concentration. Specimen should be collected > 12 hrs after dose. Do not use gel barrier/Serum Separator tubes. ACD tube is unacceptable
Transport Temperature	Room temperature
Specimen Stability	Room temperature: 5 days Refrigerated: 7 days Frozen: 30 days
Set-up/Analytic Time	Report available: 1 day
Units Of Measure	mcg/L

Tricyclic Antidepressants (TCA) Confirm Serum Extended							
Effective Date	8/6/2012						
Test Code	4154						
Specimen Requirements	3.0 (2.0) mL serum collected in red-top (no gel) tube ACD not acceptable Alternates: Serum collected in a No additive (royal blue-top) Plasma collected in a: EDTA (lavender-top), EDTA (royal blue-top), sodium heparin (green-top), lithium heparin (greentop), or sodium heparin lead-free (tan-top) tube						
Reject Criteria	Gross Hemolysis, Gel Barrier/Serum, Separator tubes						
Specimen Stability	Room Temperature: 5 days Refrigerated 7 days Frozen: Not established						
Reference Range	<table border="1"> <tr> <td>Desipramine</td> <td>50 - 300 mcg/L</td> </tr> <tr> <td>Clomipramine</td> <td>50-250 mcg/L</td> </tr> <tr> <td>Desmethylclomipramine</td> <td>150-350 mcg/L</td> </tr> </table>	Desipramine	50 - 300 mcg/L	Clomipramine	50-250 mcg/L	Desmethylclomipramine	150-350 mcg/L
Desipramine	50 - 300 mcg/L						
Clomipramine	50-250 mcg/L						
Desmethylclomipramine	150-350 mcg/L						
Units Of Measure	mcg/L						
Always Message	Remove always message: Desired Clomipramine (Anafranil) concentration for the treatment of chronic pain: 20 - 85 ng/mL						

Tricyclic Antidepressants (TCA) Confirmation Serum	
Effective Date	8/6/2012
Test Code	4157
Specimen Requirements	3.0 (2.0) mL serum collected in red-top (no gel) tube ACD not acceptable Alternates:

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	Serum collected in a No additive (royal blue-top) Plasma collected in a: EDTA (lavender-top), EDTA (royal blue-top), sodium heparin (green-top), lithium heparin (greentop), or sodium heparin lead-free (tan-top) tube		
Reject Criteria	Gross Hemolysis, Gel Barrier/Serum, Separator tubes		
Specimen Stability	Room Temperature: 5 days Refrigerated 7 days Frozen: Not established		
Reference Range	<table border="1"> <tr> <td>Desipramine</td> <td>50 - 300 mcg/L</td> </tr> </table>	Desipramine	50 - 300 mcg/L
Desipramine	50 - 300 mcg/L		
Units Of Measure	mcg/L		

Cardiolipin Antibody (IgA)																
Effective Date	8/7/2012															
Test Code	4661															
Reference Range	<table border="1"> <thead> <tr> <th>Value</th> <th>Units</th> <th>Interpretation</th> </tr> </thead> <tbody> <tr> <td>< =11</td> <td>APL</td> <td>Negative</td> </tr> <tr> <td>12 – 20</td> <td>APL</td> <td>Indeterminate</td> </tr> <tr> <td>21 - 80</td> <td>APL</td> <td>Low to Medium Positive</td> </tr> <tr> <td>> 80</td> <td>APL</td> <td>High Positive</td> </tr> </tbody> </table>	Value	Units	Interpretation	< =11	APL	Negative	12 – 20	APL	Indeterminate	21 - 80	APL	Low to Medium Positive	> 80	APL	High Positive
Value	Units	Interpretation														
< =11	APL	Negative														
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21 - 80	APL	Low to Medium Positive														
> 80	APL	High Positive														
Tests Affected	<table border="1"> <thead> <tr> <th>Test Codes:</th> <th>Name:</th> </tr> </thead> <tbody> <tr> <td>7352</td> <td>Cardiolipin Antibodies (IgG, IgA, IgM) [7352]</td> </tr> <tr> <td>9759</td> <td>Antiphospholipid Antibody Panel [9759]</td> </tr> <tr> <td>9762</td> <td>Lupus Anticoagulant and Cardiolipin Ab Panel with Reflexes</td> </tr> <tr> <td>1080S</td> <td>Antiphospholipid Syndrome Evaluation without LA</td> </tr> <tr> <td>1776</td> <td>Antiphospholipid Evaluation</td> </tr> </tbody> </table>	Test Codes:	Name:	7352	Cardiolipin Antibodies (IgG, IgA, IgM) [7352]	9759	Antiphospholipid Antibody Panel [9759]	9762	Lupus Anticoagulant and Cardiolipin Ab Panel with Reflexes	1080S	Antiphospholipid Syndrome Evaluation without LA	1776	Antiphospholipid Evaluation			
Test Codes:	Name:															
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Cardiolipin Antibody (IgG)																
Effective Date	8/7/2012															
Test Code	4662															
Reference Range	<table border="1"> <thead> <tr> <th>Value</th> <th>Units</th> <th>Interpretation</th> </tr> </thead> <tbody> <tr> <td>< =14</td> <td>GPL</td> <td>Negative</td> </tr> <tr> <td>15 – 20</td> <td>GPL</td> <td>Indeterminate</td> </tr> <tr> <td>21 - 80</td> <td>GPL</td> <td>Low to Medium Positive</td> </tr> <tr> <td>> 80</td> <td>GPL</td> <td>High Positive</td> </tr> </tbody> </table>	Value	Units	Interpretation	< =14	GPL	Negative	15 – 20	GPL	Indeterminate	21 - 80	GPL	Low to Medium Positive	> 80	GPL	High Positive
Value	Units	Interpretation														
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15 – 20	GPL	Indeterminate														
21 - 80	GPL	Low to Medium Positive														
> 80	GPL	High Positive														
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Test Codes:	Name:															

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	7352	Cardiolipin Antibodies (IgG, IgA, IgM) [7352]
	36333	Cardiolipin Antibodies (IgG, IgM) [36333]
	9759	Antiphospholipid Antibody Panel [9759]
	9762	Lupus Anticoagulant and Cardiolipin Ab Panel with Reflexes
	1776	Antiphospholipid Evaluation
	1080S	Antiphospholipid Syndrome Evaluation without LA

Cardiolipin Antibody (IgM)																	
Effective Date	8/7/2012																
Test Code	4663																
Reference Range	<table border="1"> <thead> <tr> <th>Value</th> <th>Units</th> <th>Interpretation</th> </tr> </thead> <tbody> <tr> <td>< =12</td> <td>MPL</td> <td>Negative</td> </tr> <tr> <td>13 – 20</td> <td>MPL</td> <td>Indeterminate</td> </tr> <tr> <td>21 - 80</td> <td>MPL</td> <td>Low to Medium Positive</td> </tr> <tr> <td>> 80</td> <td>MPL</td> <td>High Positive</td> </tr> </tbody> </table>		Value	Units	Interpretation	< =12	MPL	Negative	13 – 20	MPL	Indeterminate	21 - 80	MPL	Low to Medium Positive	> 80	MPL	High Positive
Value	Units	Interpretation															
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Redirects

JAK2 Exons 12 and 13 Mutations, Qualitative, Leumeta®	
Clinical Significance	Myeloproliferative disorders (MPDs) are clonal hematopoietic stem cell malignancies characterized by excessive production of blood cells by hematopoietic precursors. In addition to thrombotic and hemorrhagic complications, leukemic transformation can occur. The main members of MPD are Polycythemia Vera (PV), Essential Thrombocythemia (ET) and Idiopathic Myelofibrosis (MF). The molecular pathogenesis of most MPDs is unknown. This V617F mutation leads to constitutive tyrosine phosphorylation activity that promotes cytokine activity and induces erythrocytosis. The V617F mutation in JAK2 is a dominant-gain of function mutation that contributes to the expansion of the myeloproliferative disorder clone. JAK2 exon 12 mutations define a distinctive myeloproliferative syndrome.
Effective Date	8/7/2012
Former Test Name	JAK2 Exons 12 & 13 Mutation, Qualitative, Plasma

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Former Test Code	5392									
Test Code	16536									
Specimen Requirements	<p>Preferred Specimen: 6 (4) mL whole blood collected in an EDTA (lavender-top) tube</p> <p>Alternate Specimen: 3 (2) mL bone marrow collected in an EDTA (lavender-top) tube</p>									
Reject Criteria	Frozen whole blood and bone marrow									
Instructions	<p>Submission of whole blood (preferred): Follow standard whole blood collection procedure. Collect 3-5 mL whole blood samples in an EDTA tube. Blood samples are shipped at room temperature or 4° C. Do not freeze whole blood. Record the draw time and date on the tube. Ship immediately to maintain sample stability.</p>									
Transport Temperature	Refrigerated									
Specimen Stability	<p>Room temperature: 72 hours Refrigerated: 72 hours Frozen: Unacceptable -70 Degrees: Unacceptable</p>									
Set-up/Analytic Time	Set up Mon-Fri ; Report available: 3-5 days									
Reference Range	<table border="1"> <tr> <td>JAK2 exon 12 Mutations</td> <td>Not detected</td> </tr> <tr> <td>JAK2 exon 13 Mutations</td> <td>Not detected</td> </tr> </table>		JAK2 exon 12 Mutations	Not detected	JAK2 exon 13 Mutations	Not detected				
JAK2 exon 12 Mutations	Not detected									
JAK2 exon 13 Mutations	Not detected									
Always Message	<p>JAK2 exon 12 mutations define a distinctive myeloproliferative syndrome without the V617F mutation. Patients with JAK2 exon 12 mutation presented with an isolated erythrocytosis and distinctive bone marrow morphology or had reduced serum erythropoietin levels. JAK2 exon 12 mutations are rare when compared with V617F mutation, and it is always heterozygous according to publications.</p> <p>This is a PCR/sequencing assay.</p> <p>Our studies demonstrate that plasma-based testing for JAK2 provides significantly higher sensitivity and better determination of heterozygous Vs homozygous/hemizygous. Effective immediately our preferred sample type for JAK2 testing is plasma rather than cells. We recommend submitting whole blood for testing and plasma will be tested first; if quantity is inadequate cells will be tested.</p> <p>1. Ma W. et al. Hemizygous/homozygous and heterozygous JAK2 mutation detected in plasma of patients with myeloproliferative diseases: correlation with clinical behavior. 2006. Br J Haematol. 134(3):341-3.</p> <p>2. Ma et al. Higher detection rate of JAK2 mutation using plasma. Blood. 2008 Apr 1;111(7):3906-7.</p> <p>This test is performed pursuant to a license agreement with Roche Molecular Systems, Inc.</p> <p>This test was developed and its performance characteristics have been determined by Quest Diagnostics. Performance characteristics refer to the analytical performance of the test.</p>									
Methodology	Polymerase Chain Reaction Sequencing									
Performing Site	Quest Diagnostics Nichols Institute, San Juan Capistrano									
CPU Mappings	<table border="1"> <thead> <tr> <th>Analyte Code</th> <th>Result Name</th> </tr> </thead> <tbody> <tr> <td>20142</td> <td>SAMPLE TYPE: AOE</td> </tr> <tr> <td>16536</td> <td>JAK2 exon 12 Mutations</td> </tr> <tr> <td>31191</td> <td>JAK2 exon 13 Mutations</td> </tr> </tbody> </table>		Analyte Code	Result Name	20142	SAMPLE TYPE: AOE	16536	JAK2 exon 12 Mutations	31191	JAK2 exon 13 Mutations
Analyte Code	Result Name									
20142	SAMPLE TYPE: AOE									
16536	JAK2 exon 12 Mutations									
31191	JAK2 exon 13 Mutations									

JAK2 V617F, QL, w/rfl to Exons 12,13 and MPL W515, S505	
Clinical Significance	Diagnose polycythemia vera (PV), essential thrombocythemia (ET), and idiopathic myelofibrosis (MF)
Effective Date	8/7/2012
Former Test Name	JAK2 V617F Mutation QI, w/Rfx Exons 12, 13 & MPL W515, S505
Former Test Code	5396
Test Code	16538
Specimen Requirements	Preferred Specimen: 6 (4) mL Whole Blood collected in an EDTA (lavender-top) tube Alternate Specimen: 3 (2) mL Bone Marrow collected in an EDTA (lavender-top) tube
Reject Criteria	Frozen whole blood and bone marrow
Instructions	Submission of whole blood (Preferred): Follow standard whole blood collection procedure. Collect 5-6 mL whole blood samples in an EDTA tube. Blood samples are shipped at RT or 4 degrees C. Do not freeze whole blood. Record the draw time and date on the tube. Ship immediately to maintain sample stability.
Transport Temperature	Refrigerated
Specimen Stability	Room temperature: 72 hours Refrigerated: 72 hours Frozen: Unacceptable
Reference Range	Not Detected
Always Message	<p>The V617F mutation was found in >80% of the patients with polycythemia vera(PV), 30-50% of patients with either essential thrombocythemia (ET) or myelofibrosis (MF) according to recent publications. The mutation is not detected in normal individuals. JAK2 exon 12 mutations define a distinctive myeloproliferative syndrome in patients without the V617F mutation.</p> <p>Reflex 16538-2 JAK2 exon 12 mutations define a distinctive myeloproliferative syndrome without the V617F mutation. Patients with JAK2 exon 12 mutation presented with an isolated erythrocytosis and distinctive bone marrow morphology or had reduced serum erythropoietin levels. JAK2 exon 12 mutations are rare when compared with V617F mutation, and it is always heterozygous according to publications.</p> <p>This is a PCR/sequencing assay.</p> <p>Our studies demonstrate that plasma-based testing for JAK2 provides significantly higher sensitivity and better determination of heterozygous Vs homozygous/hemizygous. Effective immediately our preferred sample type for JAK2 testing is plasma rather than cells. We recommend submitting whole blood for testing and plasma will be tested first; if quantity is inadequate cells will be tested.</p> <p>1. Ma W. et al. Hemizygous/homozygous and heterozygous JAK2 mutation detected in plasma of patients with myeloproliferative diseases: correlation with clinical behavior. 2006. Br J Haematol. 134(3):341-3.</p> <p>2. Ma et al. Higher detection rate of JAK2 mutation using plasma. Blood. 2008 Apr 1;111(7):3906-7.</p> <p>This test is performed pursuant to a license agreement with Roche Molecular Systems, Inc.</p> <p>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.</p> <p>Reflex 16538-3 MPL W515 mutations are present in patients with idiopathic myelofibrosis or essential thrombocythemia at a frequency of approximately 5% and 1%, respectively. The S505 mutation is usually detected in patients with familial essential thrombocythemia.</p>

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	<p>The MPL W515 and S505 mutations are not detected in normal individuals.</p> <p>This assay detects only mutations that are within the amplicons generated. Sequence changes that are in the PCR primer sites will not be detected. Degraded RNA sample will cause PCR failure and uninterpretable results.</p> <p>This PCR/sequencing assay can detect 10% of mutant cells in the background of wildtype cells.</p> <p>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.</p>																		
Methodology	Polymerase Chain Reaction Sequencing																		
Performing Site	Quest Diagnostics Nichols Institute, San Juan Capistrano																		
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Result Code	Result Name																		
20142	Sample Type: AOE																		
16539	JAK2 V617F																		
16538-2	Reflex JAK2 Exons 12 and 13 Mutations, QI, Leumeta™																		
16536	JAK2 exon 12 Mutations																		
31191	JAK2 exon 13 Mutations																		
16538-3	Reflex MPL W515 & MPL S505 Mut. Analysis, QI, Leumeta™																		
31195	MPL W515 Mutation																		
31196	MPL S505 Mutation																		

Pain Management, CYP450 2D6/2C19 Geno, Qual [NY]															
Effective Date	8/7/2012														
Test Code	18947														
Performing Site	Quest Diagnostics Nichols Institute, San Juan Capistrano														
CPU Mappings	<table border="1"> <thead> <tr> <th>Result Code</th> <th>Result Name</th> </tr> </thead> <tbody> <tr> <td>86006794</td> <td>Result</td> </tr> <tr> <td>86008125</td> <td>CYP2C19 Genotype</td> </tr> <tr> <td>86008126</td> <td>CYP2D6 Genotype</td> </tr> <tr> <td>86006795</td> <td>Interpretation</td> </tr> <tr> <td>86008127</td> <td>Drug Information</td> </tr> <tr> <td>86006796</td> <td>Laboratory Director</td> </tr> </tbody> </table>	Result Code	Result Name	86006794	Result	86008125	CYP2C19 Genotype	86008126	CYP2D6 Genotype	86006795	Interpretation	86008127	Drug Information	86006796	Laboratory Director
Result Code	Result Name														
86006794	Result														
86008125	CYP2C19 Genotype														
86008126	CYP2D6 Genotype														
86006795	Interpretation														
86008127	Drug Information														
86006796	Laboratory Director														

Pain Management, CYP450 2D6/2C19 Geno, Qualitative	
Effective Date	8/7/2012
Test Code	18946
Performing Site	Quest Diagnostics Nichols Institute, San Juan Capistrano

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CPU Mappings	Result Code	Result Name
	86006794	Result
	86008125	CYP2C19 Genotype
	86008126	CYP2D6 Genotype
	86006795	Interpretation
	86008127	Drug Information
	86006796	Laboratory Director

Discontinued Tests

AccuType® Metformin	
Message	Test discontinued due to low volume. There is no replacement available.
Effective Date	8/7/2012
Test Code	5270

Alpha-Thalassemia GenotypR™	
Message	Suggested replacement test code 11175 Alpha-Globin Common Mutation Analysis
Effective Date	8/7/2012
Test Code	5220

AmpliChip™ CYP450 2D6 & 2C19 GenotypR™	
Message	Test discontinued due to low volume. There is no replacement available.
Effective Date	8/7/2012
Test Code	4565

BCR/ABL UltraQuant® Major 210 KD Transcript Bone Marrow					
Message	Test discontinued due to low volume. There is no replacement available.				
Effective Date	8/7/2012				
Test Code	5342				
Tests Affected	<table border="1"> <tr> <td>Test Codes:</td> <td>Name:</td> </tr> <tr> <td>5342SR</td> <td>BCR/ABL ULTRAQUANT MAJOR 210 KD TRANSCRIPT BM, W/SER REP</td> </tr> </table>	Test Codes:	Name:	5342SR	BCR/ABL ULTRAQUANT MAJOR 210 KD TRANSCRIPT BM, W/SER REP
Test Codes:	Name:				
5342SR	BCR/ABL ULTRAQUANT MAJOR 210 KD TRANSCRIPT BM, W/SER REP				

BCR/ABL UltraQuant® Major 210 KD Transcript Whole Blood	
Message	Suggested replacement test code 91065 BCR-ABL1 Gene Rearrangement, Quantitative PCR
Effective Date	8/7/2012

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Test Code	5352					
Tests Affected	<table border="1"> <tr> <td>Test Codes:</td> <td>Name:</td> </tr> <tr> <td>5352SR</td> <td>BCR/ABL UltraQuant® Major 210 KD Transcript Whole Blood w/ Serial Reporting</td> </tr> </table>		Test Codes:	Name:	5352SR	BCR/ABL UltraQuant® Major 210 KD Transcript Whole Blood w/ Serial Reporting
Test Codes:	Name:					
5352SR	BCR/ABL UltraQuant® Major 210 KD Transcript Whole Blood w/ Serial Reporting					

BCR/ABL UltraQuant® Minor 190 KD Transcript Bone Marrow						
Message	Suggested replacement test code 91065 BCR-ABL1 Gene Rearrangement, Quantitative PCR					
Effective Date	8/7/2012					
Test Code	5344					
Tests Affected	<table border="1"> <tr> <td>Test Codes:</td> <td>Name:</td> </tr> <tr> <td>5344SR</td> <td>BCR/ABL UltraQuant® Minor 190 KD Transcript Bone Marrow w/ Serial Reporting</td> </tr> </table>		Test Codes:	Name:	5344SR	BCR/ABL UltraQuant® Minor 190 KD Transcript Bone Marrow w/ Serial Reporting
Test Codes:	Name:					
5344SR	BCR/ABL UltraQuant® Minor 190 KD Transcript Bone Marrow w/ Serial Reporting					

BCR/ABL UltraQuant® Minor 190 KD Transcript Whole Blood						
Message	Test discontinued due to low volume. There is no replacement available.					
Effective Date	8/7/2012					
Test Code	5354					
Tests Affected	<table border="1"> <tr> <td>Test Codes:</td> <td>Name:</td> </tr> <tr> <td>5354SR</td> <td>BCR/ABL UltraQuant® Minor 190 KD Transcript Whole Blood w/ Serial Reporting</td> </tr> </table>		Test Codes:	Name:	5354SR	BCR/ABL UltraQuant® Minor 190 KD Transcript Whole Blood w/ Serial Reporting
Test Codes:	Name:					
5354SR	BCR/ABL UltraQuant® Minor 190 KD Transcript Whole Blood w/ Serial Reporting					

Chromosomes X-Y Aneuploidy DetectR™						
Message	Test discontinued due to low volume. There is no replacement available.					
Effective Date	8/7/2012					
Test Code	5859					
Tests Affected	<table border="1"> <tr> <td>Test Codes:</td> <td>Name:</td> </tr> <tr> <td>5859BK</td> <td>CHROMOSOMES X & Y ANEUPLOIDY DETECTR-PARAFFIN BLOCK [PCR]</td> </tr> </table>		Test Codes:	Name:	5859BK	CHROMOSOMES X & Y ANEUPLOIDY DETECTR-PARAFFIN BLOCK [PCR]
Test Codes:	Name:					
5859BK	CHROMOSOMES X & Y ANEUPLOIDY DETECTR-PARAFFIN BLOCK [PCR]					

Cystic Fibrosis 23 Mutation Analysis						
Message	Suggested replacement code 10458 Cystic Fibrosis Screen					
Effective Date	8/7/2012					
Test Code	5432					
Tests Affected	<table border="1"> <tr> <td>Test Codes:</td> <td>Name:</td> </tr> <tr> <td>5432FH</td> <td>Cystic Fibrosis 23 Mutation Analysis w/Family History</td> </tr> </table>		Test Codes:	Name:	5432FH	Cystic Fibrosis 23 Mutation Analysis w/Family History
Test Codes:	Name:					
5432FH	Cystic Fibrosis 23 Mutation Analysis w/Family History					

Cystic Fibrosis 23 Mutation Analysis, Fetus w/Reflex MCC		
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Message	Test discontinued due to low volume. There is no replacement available.
Effective Date	8/7/2012
Test Code	5434

FcGammaRIIIa & FcGammaRIIIa Mutation Analysis	
Message	Test discontinued due to low volume. There is no replacement available.
Effective Date	8/7/2012
Test Code	5388

JAK2 V617F Mutation, Qual PCR, Plasma w/Rfx Exons 12, 13	
Message	Suggested replacement test code 16539 JAK2 V617F Mutation, Qualitative PCR, Leumeta(R) with Reflex to Exons12,13
Effective Date	8/7/2012
Test Code	5394

JAK2 V617F Mutation, Qual, PCR	
Message	Suggested replacement test code 16175 JAK2 V617F Mutation, Quantitative, Plasma-Based, Leumeta®
Effective Date	8/7/2012
Test Code	5395

MPL W515 & MPL S505 Mutation Analysis, Qualitative, Plasma	
Message	Test discontinued due to low volume. There is no replacement available.
Effective Date	8/7/2012
Test Code	5398

Thrombotic Risk AssessR™ for Obstetric Complications	
Message	Test discontinued due to low volume. There is no replacement available.
Effective Date	8/7/2012
Test Code	4555

UGT1A1 (Camptosar/Irinotecan) GenotypR™	
Message	Test discontinued due to low volume. There is no replacement available.
Effective Date	8/7/2012
Test Code	5384

New York Update

SureSwab(TM) Assays	
Message	The following tests are now available for New York patient testing at Quest Diagnostics Nichols Institute, Valencia: <ul style="list-style-type: none"> ● 16495 SureSwab(TM), Candida albicans DNA (16495)

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	<ul style="list-style-type: none">● 16494 SureSwab(TM), Candidiasis, PCR (16494)● 16898 SureSwab(TM), Bacterial Vaginosis DNA, Quantitative RT-PCR● 15509 SureSwab(TM), Bacterial Vaginosis/vaginitis● 17333 SureSwab(TM), Vaginosis/Vaginitis Plus - (17333)● 16491 SureSwab(TM), Vaginosis, CT/NG
Effective Date	6/11/2012