

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

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 #
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16142	Familial Mediterranean Fever Mutation Analysis (NY)	5/8/2012	3
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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.				
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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.			
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5044	B-Cell Gene Rearrangement DetectR™	5/8/2012	19
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1941	Factor II Activity	5/8/2012	20
1949	Factor IX Activity	5/8/2012	20
1943	Factor V Activity	5/8/2012	20

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1945	Factor VII Activity	5/8/2012	20
1951	Factor X Activity	5/8/2012	20
1953	Factor XI Activity	5/8/2012	20
1955	Factor XII Activity	5/8/2012	20
5290	Familial Mediterranean Fever (FMF) GenotypR™	5/8/2012	20
458	Fibrinolytic Degradation Product	5/8/2012	21
5032	KRAS Mutation Analysis	5/8/2012	21
5046	Microsatellite Instability (MSI) DetectR™	5/8/2012	21
5030	NRAS Mutation Analysis	5/8/2012	21
1492	Plasminogen Activity	5/8/2012	21
5034	RAS Mutation Analysis, Cell-based	5/8/2012	21
5042	T-Cell Gene Rearrangement DetectR™	5/8/2012	22

New Test Offerings

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

Familial Mediterranean Fever Mutation Analysis	
Message	Suggested replacement for discontinued test code 5290, Familial Mediterranean Fever (FMF) GenotypR™
Clinical Significance	1. To identify disease-causing mutations in individuals affected with Familial Mediterranean Fever. 2. To identify carriers in high risk ethnic groups or people with a positive family history. 3. Prenatal diagnosis of Familial Mediterranean Fever.
Effective Date	5/8/2012
Test Code	16141
CPT Codes	83891, 83900, 83892 (x2), 83901 (x2), 83909, 83912, 83914 (x11) or 81404* *The 2012 AMA CPT codebook contains Tier 1 and Tier 2 Molecular Pathology Procedures as well as Molecular Pathology Procedures to be coded by procedure rather than analyte. Please direct any questions regarding coding to the payor being billed.
Specimen Requirements	5 mL (3.0 mL) whole blood collected in EDTA (lavender-top) tube Whole blood collected in ACD solution A (yellow-top), ACD solution B (yellow-top), sodium heparin (green-top), lithium heparin (green-top) or EDTA (royal blue-top) tube Cultured cells from Amniotic fluid in T-25 Flask [x2], Cultured cells from CVS in T-25 Flask [x2], 20 mL (10 mL) Amniotic fluid in leak-proof 15 ml conical tube
Reject Criteria	Thawed Amniotic fluid, Whole blood received frozen.
Instructions	Whole blood: Normal phlebotomy procedure. Specimen stability is crucial. Store and ship room temperature immediately. Do not freeze. For prenatal diagnosis parental results must be available. Contact the laboratory genetic counselor before submission. Amniotic fluid: Normal collection procedure. Specimen stability is crucial. Store and ship room temperature immediately. Do not refrigerate or freeze. Amniocyte culture: Sterile T25 flask, filled with culture medium. Specimen stability is crucial. Store and ship room temperature. Do not refrigerate or freeze. Dissected chorionic villi (CVS) biopsy: 10-20 mg dissected CVS collected in a sterile tube filled with sterile culture medium. Specimen stability is crucial. Store and ship room temperature immediately. Do not refrigerate or freeze.
Transport Temperature	Room temperature
Specimen Stability	Whole blood Room temperature: 8 days Refrigerated: 8 days Frozen: Unacceptable Cultured cells from Amniotic fluid or CVS or Amniotic fluid

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	Room temperature: 48 hours Refrigerated: Unacceptable Frozen: Unacceptable				
Set-up/Analytic Time	Set up: Mon				
Reference Range	See laboratory report				
Always Message	<p>Familial Mediterranean Fever (FMF) is an autosomal recessive disorder characterized by recurrent episodes of fever and peritonitis with pain. FMF is most common in non-Ashkenazi Jewish, Armenian, Arab, and Turkish populations and has a carrier frequency as high as 1 in 3 to 1 in 7 in these populations. The carrier frequency of FMF in Ashkenazi-Jews is also high (up to 1 in 5) but FMF is not common in this population due to the predominance of a mutation for a mild form of FMF (E148Q). FMF is caused by mutations in the Familial Mediterranean Fever (MEFV) gene on chromosome 16p13 which encodes the protein pyrin. This assay analyzes 12 MEFV mutations that account for approximately 80%-90% of FMF mutations in Mediterranean populations (about 70% in the Arab population): p.E148Q (c.442 G>C), p.P369S (c.1105C>T), p.F479L (c.1437C>G), p.M680I (c.2040G>C or A), p.I692del (c.2074-2076del), p.M694V (c.2080A>G), p.M694I (c.2082G>A), O.K695R (c.2084A>G), p.V726A (c.2177T>C), p.A744S (c.2230G>T), and p.R761H (c.2282G>A).</p> <p>The 12 mutations listed above are detected by multiplex polymerase chain reaction (PCR) amplification of portions of exons 2, 3, 5 and 10 of the MEFV gene, single nucleotide primer extension, and detection of fluorescent primer extension products on an automated capillary DNA sequencer. DNA-based testing is highly accurate, but rare false negative/false positive results may occur.</p> <p>For assistance with the interpretation of these results, please contact your local Quest Diagnostics genetic counselor or call 1-866-GENEINFO (436-3463).</p> <p>This test is performed pursuant to a license agreement with Orchid Biosciences 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>				
Methodology	Polymerase Chain Reaction, Single nucleotide primer extension.				
Assay Category	Laboratory Developed Test				
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>16141</td> <td>Famil.Mediterranean Fever</td> </tr> </tbody> </table>	Result Code	Result Name	16141	Famil.Mediterranean Fever
Result Code	Result Name				
16141	Famil.Mediterranean Fever				
Additional Information	For New York patient testing, use test code 16142.				

Familial Mediterranean Fever Mutation Analysis (NY)	
Message	Suggested replacement for discontinued test code 5290, Familial Mediterranean Fever (FMF) GenotypR™ (New York patients only)
Clinical Significance	1. To identify disease-causing mutations in individuals affected with Familial Mediterranean Fever. 2. To identify carriers in high risk ethnic groups or people with a positive family history. 3. Prenatal diagnosis of Familial Mediterranean Fever.
Effective Date	5/8/2012
Test Code	16142
CPT Codes	83891, 83900, 83892 (x2), 83901 (x2), 83909, 83912, 83914 (x11) or 81404* *The 2012 AMA CPT codebook contains Tier 1 and Tier 2 Molecular Pathology Procedures as well as Molecular Pathology Procedures to be coded by procedure rather than analyte. Please direct any questions regarding coding to the payor being billed.
Specimen Requirements	5 mL (3.0 mL) whole blood collected in EDTA (lavender-top) tube Whole blood collected in ACD solution A (yellow-top), ACD solution B (yellow-top), sodium heparin (green-top), lithium heparin (green-top) or EDTA (royal blue-top) tube Cultured cells from Amniotic fluid in T-25 Flask [x2], Cultured cells from CVS in T-25 Flask [x2], 20 mL (10 mL) Amniotic fluid in leak-proof 15 ml conical tube
Reject Criteria	Thawed Amniotic fluid, Whole blood received frozen.

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Instructions	<p>Whole blood: Normal phlebotomy procedure. Specimen stability is crucial. Store and ship room temperature immediately. Do not freeze. For prenatal diagnosis parental results must be available. Contact the laboratory genetic counselor before submission.</p> <p>Amniotic fluid: Normal collection procedure. Specimen stability is crucial. Store and ship room temperature immediately. Do not refrigerate or freeze.</p> <p>Amniocyte culture: Sterile T25 flask, filled with culture medium. Specimen stability is crucial. Store and ship room temperature. Do not refrigerate or freeze.</p> <p>Dissected chorionic villi (CVS) biopsy: 10-20 mg dissected CVS collected in a sterile tube filled with sterile culture medium. Specimen stability is crucial. Store and ship room temperature immediately. Do not refrigerate or freeze.</p>				
Transport Temperature	Room temperature				
Specimen Stability	<p>Whole blood Room temperature: 8 days Refrigerated: 8 days Frozen: Unacceptable</p> <p>Cultured cells from Amniotic fluid or CVS or Amniotic fluid Room temperature: 48 hours Refrigerated: Unacceptable Frozen: Unacceptable</p>				
Set-up/Analytic Time	Set up: Mon				
Reference Range	See laboratory report				
Always Message	<p>Familial Mediterranean Fever (FMF) is an autosomal recessive disorder characterized by recurrent episodes of fever and peritonitis with pain. FMF is most common in non-Ashkenazi Jewish, Armenian, Arab, and Turkish populations and has a carrier frequency as high as 1 in 3 to 1 in 7 in these populations. The carrier frequency of FMF in Ashkenazi-Jews is also high (up to 1 in 5) but FMF is not common in this population due to the predominance of a mutation for a mild form of FMF (E148Q). FMF is caused by mutations in the Familial Mediterranean Fever (MEFV) gene on chromosome 16p13 which encodes the protein pyrin. This assay analyzes 12 MEFV mutations that account for approximately 80%-90% of FMF mutations in Mediterranean populations (about 70% in the Arab population): p.E148Q (c.442 G>C), p.P369S (c.1105C>T), p.F479L (c.1437C>G), p.M680I (c.2040G>C or A), p.I692del (c.2074-2076del), p.M694V (c.2080A>G), p.M694I (c.2082G>A), O.K695R (c.2084A>G), p.V726A (c.2177T>C), p.A744S (c.2230G>T), and p.R761H (c.2282G>A).</p> <p>The 12 mutations listed above are detected by multiplex polymerase chain reaction (PCR) amplification of portions of exons 2, 3, 5 and 10 of the MEFV gene, single nucleotide primer extension, and detection of fluorescent primer extension products on an automated capillary DNA sequencer. DNA-based testing is highly accurate, but rare false negative/false positive results may occur.</p> <p>For assistance with the interpretation of these results, please contact your local Quest Diagnostics genetic counselor or call 1-866-GENEINFO (436-3463).</p> <p>This test is performed pursuant to a license agreement with Orchid Biosciences 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>				
Methodology	Polymerase Chain Reaction, Single nucleotide primer extension.				
Assay Category	Laboratory Developed Test				
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>16142</td> <td>Famil.Mediterranean Fever</td> </tr> </tbody> </table>	Result Code	Result Name	16142	Famil.Mediterranean Fever
Result Code	Result Name				
16142	Famil.Mediterranean Fever				

Microsatellite Instability (MSI), HNPCC	
Message	Suggested replacement for discontinued test code 5046, Microsatellite Instability (MSI) DetectR™ and 5046BK, Microsatellite Instability (MSI) DetectR™ - Paraffin Block.
Effective Date	5/8/2012
Test Code	14989

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CPT Codes	83890 (x2), 83900 (x2), 83901 (x6), 83907, 83909 (x2), 83912 or 81301* *The 2012 AMA CPT codebook contains Tier 1 and Tier 2 Molecular Pathology Procedures as well as Molecular Pathology Procedures to be coded by procedure rather than analyte. Please direct any questions regarding coding to the payor being billed.				
Specimen Requirements	5.0 mL (2.0 mL) whole blood collected in an EDTA (lavender-top) tube and formalin-fixed, paraffin embedded tissue block Alternate: Whole blood collected in sodium heparin (green-top) or ACD solution B (yellow-top)				
Instructions	One formalin-fixed paraffin embedded tissue with representative tumor and one EDTA whole blood from the same patient must be submitted for testing. Both sample types are required for testing. Avoid hemolysis.				
Transport Temperature	Room temperature				
Specimen Stability	Whole blood Room temperature: 8 days Refrigerated: 8 days Frozen: Unacceptable Formalin fixed paraffin embedded tissue Frozen: Unacceptable				
Set-up/Analytic Time	Set up: Mon; Report available: 8 days				
Reference Range	See Laboratory Report				
Always Message	This panel is composed of the five Bethesda microsatellite markers which consist of two mononucleotide repeats (i.e. BAT26 and BAT25) and three dinucleotide repeats (i.e. D5S346, D2S123 and D17S250). This panel of markers is recommended for colorectal neoplasia only. The 5 MSI loci are amplified in a single multiplex fluorescent PCR reaction. The PCR products are then analyzed on an automated DNA sequencer with automated allele calling and quality scoring. A tumor is classified as microsatellite instability high (MSI-H) if two or more of the five markers show instability. A tumor is classified as microsatellite instability low (MSI-L) if only one of the five markers shows instability. A tumor is classified as microsatellite stable (MSS) if none of the five markers show instability. Germline mutation analysis for the mismatch repair genes (MLH1, MSH2 and MSH6) is recommended for individuals with MSI-H tumors. 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, Capillary Electrophoresis				
Assay Category	Laboratory Developed Test				
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>3328</td> <td>MSI, HNPCC</td> </tr> </tbody> </table>	Result Code	Result Name	3328	MSI, HNPCC
Result Code	Result Name				
3328	MSI, HNPCC				

Redirects

B-Cell Gene Rearrangement, Qualitative, PCR, Cell-based	
Message	Suggested replacement for discontinued test codes 5044, B-Cell Gene Rearrangement DetectR™ and 5044BK, B-Cell Gene Rearrangement DetectR® - Paraffin Block
Clinical Significance	Clinical use is to aid in the diagnosis of B-Cell malignancies, to determine lineage of leukemias and lymphomas for prognosis and treatment selection, and to detect minimal residual disease or recurrent disease.
Effective Date	5/8/2012
Former Test Name	B-Cell Gene Rearrangement DetectR™

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Former Test Code	5044					
Test Code	14868					
CPT Codes	83890, 83898 (x3), 83909 (x3), 83912 or 81261* *The 2012 AMA CPT codebook contains Tier 1 and Tier 2 Molecular Pathology Procedures as well as Molecular Pathology Procedures to be coded by procedure rather than analyte. Please direct any questions regarding coding to the payor being billed.					
Specimen Requirements	5 mL (1.0 mL) whole blood collected in an EDTA (lavender-top) tube Alternates: Whole blood collected in a EDTA (royal blue-top) tube, Paraffin embedded tissue, Bone marrow, Fixed tissue, Fresh (unfixed) tissue					
Instructions	Collect whole blood or bone marrow in an EDTA (lavender-top) tube ship refrigerated or room temperature. Stability of whole blood and bone marrow samples at room and refrigerated temperatures is 1 week. Paraffin blocks are to be shipped at room temperature. Stability for paraffin blocks is indefinite. For tissue samples, fresh frozen tissue is preferred and to be shipped frozen. Frozen tissue is stable for approximately 1 year at -70° C. Tissues in formalin fixative or RPMI are to be shipped at room temperature or refrigerated.					
Transport Temperature	Room temperature					
Specimen Stability	Whole blood or bone marrow: Room temperature: 7 days Refrigerated: 7 days Paraffin embedded tissue: Room temperature: Indefinite Fixed tissue or Fresh (unfixed) tissue: Room temperature: See instructions Refrigerated: See instructions					
Set-up/Analytic Time	Set up: Mon-Fri ; Report available: 4-5 days					
Reference Range	Negative					
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	Polymerase Chain Reaction (PCR)					
Assay Category	Laboratory Developed Test					
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>3382</td> <td>B-Cell Gene Rearrangement</td> </tr> </tbody> </table>		Result Code	Result Name	3382	B-Cell Gene Rearrangement
Result Code	Result Name					
3382	B-Cell Gene Rearrangement					
Tests Affected	<table border="1"> <thead> <tr> <th>Test Codes:</th> <th>Name:</th> </tr> </thead> <tbody> <tr> <td>5044BK</td> <td>B-Cell Gene Rearrangement DetectR® - Paraffin Block</td> </tr> </tbody> </table>		Test Codes:	Name:	5044BK	B-Cell Gene Rearrangement DetectR® - Paraffin Block
Test Codes:	Name:					
5044BK	B-Cell Gene Rearrangement DetectR® - Paraffin Block					

D-Dimer, Quantitative	
Message	Suggested replacement for discontinued test code 4202, D-Dimer, Quantitative
Clinical Significance	D-Dimer is one of the measurable byproducts of activation of the fibrinolytic system. Quantitation of D-Dimer assesses fibrinolytic activation and intravascular thrombosis. D-Dimer is of particular value in excluding the diagnosis of venous thromboembolism among patients at high risk.

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Effective Date	5/8/2012					
Former Test Name	D-Dimer, Quantitative					
Former Test Code	4202					
Test Code	8659					
CPT Codes	85379					
Specimen Requirements	1 mL (0.5 mL) plasma collected in 3.2% sodium citrate (lt. blue-top) tube					
Reject Criteria	Thawed specimen, Received room temperature, Received refrigerated, Gross hemolysis					
Instructions	<p>Platelet Poor Plasma: Centrifuge light blue-top tube 15 minutes at approx. 1500 g within 60 minutes of collection. Using a plastic pipette, remove plasma, taking care to avoid the WBC/platelet buffy layer and place into a plastic vial. Centrifuge a second time and transfer platelet-poor plasma into a new plastic vial. Plasma must be free of platelets (<10,000/mcl). Freeze immediately and ship on dry ice.</p>					
Transport Temperature	Frozen					
Specimen Stability	Room temperature: Unacceptable Refrigerated: Unacceptable Frozen: 30 days					
Set-up/Analytic Time	Set up: Mon-Sat ; Report available: 2-3 days					
Reference Range	<0.50 mcg/mL FEU					
Units Of Measure	mcg/mL FEU					
Methodology	Immunoturbidometric					
Assay Category	FDA Approved					
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>30031300</td> <td>D-Dimer</td> </tr> </tbody> </table>		Result Code	Result Name	30031300	D-Dimer
Result Code	Result Name					
30031300	D-Dimer					

Factor II Activity, Clotting	
Message	Suggested replacement for discontinued test code 1941, Factor II Activity.
Clinical Significance	This test is useful to evaluate a prolonged PT. Deficiency is associated with bleeding risk.
Effective Date	5/8/2012
Former Test Code	1941
Test Code	331
CPT Codes	85210
Specimen Requirements	1 mL (0.5 mL) plasma collected in a 3.2% Sodium Citrate (lt. blue-top)
Reject Criteria	Hemolysis, Received room temperature , Received refrigerated , Received thawed
Instructions	<p>Centrifuge light blue-top tube for 15 minutes at approximately 1500 g within 60 minutes of collection. Using a plastic pipette, remove plasma, taking care to avoid the WBC/platelet buffy layer and place into a plastic vial. Centrifuge a second time and transfer platelet-poor plasma into a new plastic vial. Plasma must be free of platelets (<10,000/mcL). Freeze immediately and ship on dry ice.</p>
Transport Temperature	Frozen
Specimen Stability	Room temperature: Unacceptable Refrigerated: Unacceptable

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	Frozen: 14 days -70 Degrees: 1 year				
Set-up/Analytic Time	Set up: Weds, Fri ; Report available: 2-4 days				
Reference Range	70-150 % normal				
Units Of Measure	%				
Methodology	Photometric Clot Detection				
Assay Category	FDA Approved				
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>30013700</td> <td>Factor II Activity</td> </tr> </tbody> </table>	Result Code	Result Name	30013700	Factor II Activity
Result Code	Result Name				
30013700	Factor II Activity				

Factor IX Activity, Clotting			
Message	Suggested replacement test for discontinued test code 1949, Factor IX Activity.		
Clinical Significance	This test is useful to evaluate a prolonged aPTT. The second most common form of hemophilia is caused by deficiency of factor IX. Hemophilia B is an x-linked disorder affecting between 1 in 25,000 to 30,000 males.		
Effective Date	5/8/2012		
<i>Former Test Name</i>	<i>Factor IX Activity</i>		
<i>Former Test Code</i>	<i>1949</i>		
Test Code	352		
CPT Codes	85250		
Specimen Requirements	1 mL (0.5 mL) plasma collected in 3.2% sodium citrate (lt. blue-top) tube		
Reject Criteria	Thawed specimen, Received room temperature, Received refrigerated, Hemolysis, Received thawed		
Instructions	Platelet-poor plasma: Centrifuge light blue-top tube for 15 minutes at approximately 1500 g within 60 minutes of collection. Using a plastic pipette, remove plasma, taking care to avoid the WBC/platelet buffy layer and place into a plastic vial. Centrifuge a second time and transfer platelet-poor plasma into a new plastic vial. Plasma must be free of platelets (<10,000/mcL). Freeze immediately and ship on dry ice.		
Transport Temperature	Frozen		
Specimen Stability	Room temperature: Unacceptable Refrigerated: Unacceptable Frozen -20° C: 14 days Frozen -70° C: 1 year		
Set-up/Analytic Time	Set up: Mon, Weds, Fri ; Report available: 2-3 days		
Reference Range	60-160 % normal		
Units Of Measure	%		
Methodology	Photometric Clot Detection		
Assay Category	FDA Approved		
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> </tbody> </table>	Result Code	Result Name
Result Code	Result Name		

	30017700	Factor IX Activity
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Factor V Activity, Clotting					
Message	Suggested replacement test for discontinued test code 1943, Factor V Activity.				
Clinical Significance	This test is useful to evaluate a prolonged PT. Deficiency is associated with bleeding risk.				
Effective Date	5/8/2012				
<i>Former Test Name</i>	<i>Factor V Activity</i>				
<i>Former Test Code</i>	<i>1943</i>				
Test Code	344				
CPT Codes	85220				
Specimen Requirements	1 mL plasma collected in 3.2% sodium citrate (lt. blue-top) tube.				
Reject Criteria	Thawed Plasma, Received room temperature, Received refrigerated, Hemolysis				
Instructions	Platelet-poor plasma: Centrifuge light blue-top tube for 15 minutes at approximately 1500 g within 60 minutes of collection. Using a plastic pipette, remove plasma, taking care to avoid the WBC/platelet buffy layer and place into a plastic vial. Centrifuge a second time and transfer platelet-poor plasma into a new plastic vial. Plasma must be free of platelets (<10,000/mcL). Freeze immediately and ship on dry ice.				
Transport Temperature	Frozen				
Specimen Stability	Room temperature: Unacceptable Refrigerated: Unacceptable Frozen: 14 days				
Set-up/Analytic Time	Set up: Sun, Mon, Tues ; Report available: 2-3 days				
Reference Range	65-150 % normal				
Units Of Measure	%				
Methodology	Photometric Clot Detection				
Assay Category	FDA Approved				
Performing Site	Quest Diagnostics Nichols Institute, San Juan Capistrano				
CPU Mappings	<table border="1" style="width: 100%;"> <thead> <tr> <th style="text-align: left;">Result Code</th> <th style="text-align: left;">Result Name</th> </tr> </thead> <tbody> <tr> <td>30014700</td> <td>Factor V Activity</td> </tr> </tbody> </table>	Result Code	Result Name	30014700	Factor V Activity
Result Code	Result Name				
30014700	Factor V Activity				

Factor VII Activity, Clotting	
Message	Suggested replacement test for discontinued test code 1945, Factor VII Activity.
Clinical Significance	This test is useful to evaluate a prolonged PT. Deficiency is associated with bleeding risk.
Effective Date	5/8/2012
<i>Former Test Name</i>	<i>Factor VII Activity</i>
<i>Former Test Code</i>	<i>1945</i>
Test Code	346
CPT Codes	85230
Specimen Requirements	1 mL plasma collected in 3.2% sodium citrate (lt. blue-top) tube.

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Reject Criteria	Hemolysis, Received room temperature, Received refrigerated, Thawed Plasma					
Instructions	Platelet-poor plasma: Centrifuge light blue-top tube for 15 minutes at approximately 1500 g within 60 minutes of collection. Using a plastic pipette, remove plasma, taking care to avoid the WBC/platelet buffy layer and place into a plastic vial. Centrifuge a second time and transfer platelet-poor plasma into a new plastic vial. Plasma must be free of platelets (<10,000/mcL). Freeze immediately and ship on dry ice. Note: Do not store specimen at 2-8 degrees C as the Factor VII in the sample may be activated at this temperature range.					
Transport Temperature	Frozen					
Specimen Stability	Room temperature: Unacceptable Refrigerated: Unacceptable Frozen: 14 days Frozen -70° C: 1 year					
Set-up/Analytic Time	Set up: Tues, Thurs, Sat ; Report available: 2-3 days					
Reference Range	60-150 % normal					
Units Of Measure	%					
Methodology	Photometric Clot Detection					
Assay Category	FDA Approved					
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>3405</td> <td>Factor VII Activity</td> </tr> </tbody> </table>		Result Code	Result Name	3405	Factor VII Activity
Result Code	Result Name					
3405	Factor VII Activity					

Factor X Activity, Clotting	
Message	Suggested replacement test for discontinued test code 1951, Factor X Activity.
Clinical Significance	This test is useful to evaluate a prolonged PT. Deficiency is associated with bleeding risk.
Effective Date	5/8/2012
<i>Former Test Name</i>	<i>Factor X Activity</i>
<i>Former Test Code</i>	<i>1951</i>
Test Code	359
CPT Codes	85260
Specimen Requirements	1 mL (0.5 mL) plasma collected in 3.2% sodium citrate (lt. blue-top) tube
Reject Criteria	Thawed specimen, Received room temperature, Received refrigerated, Hemolysis, Received thawed
Instructions	Platelet-poor plasma: Centrifuge light blue-top tube for 15 minutes at approximately 1500 g within 60 minutes of collection. Using a plastic pipette, remove plasma, taking care to avoid the WBC/platelet buffy layer and place into a plastic vial. Centrifuge a second time and transfer platelet-poor plasma into a new plastic vial. Plasma must be free of platelets (<10,000/mcL). Freeze immediately and ship on dry ice.
Transport Temperature	Frozen
Specimen Stability	Room temperature: Unacceptable Refrigerated: Unacceptable Frozen -20° C: 14 days Frozen -70° C: 1 year
Set-up/Analytic Time	Set up: Weds, Fri ; Report available: 2-4 days
Reference Range	70-150% normal

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Units Of Measure	%					
Methodology	Photometric Clot Detection					
Assay Category	FDA Approved					
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>3492</td> <td>Factor X Activity</td> </tr> </tbody> </table>		Result Code	Result Name	3492	Factor X Activity
Result Code	Result Name					
3492	Factor X Activity					

Factor XI Activity, Clotting					
Message	Suggested replacement for discontinued test code 1953, Factor XI Activity.				
Clinical Significance	This test is useful to evaluate a prolonged aPTT. Deficiency of Factor XI is most common among those with Ashkenazi Jewish heritage.				
Effective Date	5/8/2012				
Former Test Code	1953				
Test Code	360				
CPT Codes	85270				
Specimen Requirements	3 mL (0.5 mL) plasma collected in 3.2% sodium citrate (lt. blue-top) tube				
Reject Criteria	Hemolysis, Thawed plasma, Received room temperature, Received refrigerated, Received thawed				
Instructions	Platelet-poor plasma: Centrifuge light blue-top tube for 15 minutes at approximately 1500 g within 60 minutes of collection. Using a plastic pipette, remove plasma, taking care to avoid the WBC/platelet buffy layer and place into a plastic vial. Centrifuge a second time and transfer platelet-poor plasma into a new plastic vial. Plasma must be free of platelets (<10,000/mcL). Freeze immediately and ship on dry ice.				
Transport Temperature	Frozen				
Specimen Stability	Room temperature: Unacceptable Refrigerated: Unacceptable Frozen -20°C: 14 days Frozen -70° C: 1 year				
Set-up/Analytic Time	Set up: Tues, Thurs, Sat ; Report available: 2-3 days				
Reference Range	65-150 % normal				
Units Of Measure	%				
Methodology	Photometric Clot Detection				
Assay Category	FDA Approved				
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>30010700</td> <td>Factor XI Activity</td> </tr> </tbody> </table>	Result Code	Result Name	30010700	Factor XI Activity
Result Code	Result Name				
30010700	Factor XI Activity				

Factor XII Activity, Clotting	
Message	Suggested replacement test for discontinued test code 1955, Factor XII Activity.
Clinical Significance	This test is useful to evaluate a prolonged aPTT. Deficiency of Factor XII is not correlated with bleeding risk.

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Effective Date	5/8/2012				
<i>Former Test Name</i>	<i>Factor XII Activity</i>				
<i>Former Test Code</i>	1955				
Test Code	362				
CPT Codes	85280				
Specimen Requirements	1 mL (0.5 mL) plasma collected in 3.2% sodium citrate (lt. blue-top) tube				
Reject Criteria	Thawed specimen, Received room temperature, Received refrigerated, Hemolysis, Received thawed				
Instructions	Platelet-poor plasma: Centrifuge light blue-top tube for 15 minutes at approximately 1500 g within 60 minutes of collection. Using a plastic pipette, remove plasma, taking care to avoid the WBC/platelet buffy layer and place into a plastic vial. Centrifuge a second time and transfer platelet-poor plasma into a new plastic vial. Plasma must be free of platelets (<10,000/mcL). Freeze immediately and ship on dry ice.				
Transport Temperature	Frozen				
Specimen Stability	Room temperature: Unacceptable Refrigerated: Unacceptable Frozen -20° C: 14 days Frozen -70° C: 1 year				
Set-up/Analytic Time	Set up: Weds, Fri ; Report available: 2-4 days				
Reference Range	50-150% normal				
Units Of Measure	%				
Methodology	Photometric Clot Detection				
Assay Category	FDA Approved				
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>3092</td> <td>Factor XII Activity</td> </tr> </tbody> </table>	Result Code	Result Name	3092	Factor XII Activity
Result Code	Result Name				
3092	Factor XII Activity				

Fibrinogen Degradation Products (FDP)	
Message	Suggested replacement test for discontinued test code 4208, Fibrinolytic Degradation Product.
Clinical Significance	In disseminated intravascular coagulation (DIC), both thrombin and plasmin are generated. The breakdown products of fibrin clots and fibrinogen include D-Dimer and FDP. These analytes are also elevated when the coagulation and fibrinolytic systems are activated.
Effective Date	5/8/2012
<i>Former Test Name</i>	<i>Fibrinolytic Degradation Product</i>
<i>Former Test Code</i>	4208
Test Code	458
CPT Codes	85362
Specimen Requirements	1 mL (0.5 mL) plasma collected in 3.2% sodium citrate (lt. blue-top) tube
Reject Criteria	Clotted specimen
Specimen Stability	Room temperature: 8 hours Refrigerated: 48 hours Frozen: 30 days

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Set-up/Analytic Time	Set up: Thurs ; Report available: 2 days				
Reference Range	Less than 5 mcg/mL				
Units Of Measure	mcg/mL				
Methodology	Latex Agglutination				
Assay Category	FDA Approved				
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>3866</td> <td>FDP-Latex</td> </tr> </tbody> </table>	Result Code	Result Name	3866	FDP-Latex
Result Code	Result Name				
3866	FDP-Latex				

KRAS Mutation Analysis	
Message	Suggested replacement for discontinued test code 5032, KRAS Mutation Analysis.
Clinical Significance	Activating Ras mutations can be found in human malignancies with overall frequency of 15-20%. A high incidence of Ras gene mutations has been reported in 80-90% malignant tumors of the pancreas, 30-60% in colon rectal carcinomas, and in 18-30% of hematopoietic neoplasia of myeloid origin. Ras proteins were shown to influence proliferation, differentiation, transformation, and apoptosis by relaying mitogenic and growth signals into the cytoplasm and the nucleolus. Mutations leading to an amino acid substitution at positions 12,13 and 61 are the most common in naturally occurring neoplasms and are frequent in adenocarcinomas of the pancreas, colon, and certain types of hematological malignancies.
Effective Date	5/8/2012
Former Test Name	<i>KRAS Mutation Analysis</i>
Former Test Code	5032
Test Code	16510
CPT Codes	83891, 83898 (x2), 83892 (x2), 83909 (x2) , 83904 (x4), 83912
Specimen Requirements	Formalin fixed paraffin embedded tissue Alternates: 3 mL bone marrow (see collection instructions) collected in an EDTA (lavender-top) tube, 6 mL whole blood collected in an EDTA (lavender-top) tube
Reject Criteria	Gross hemolysis, Clotted and frozen whole blood/bone marrow samples
Instructions	Submission of formalin-fixed, paraffin-embedded tissue is the preferred sample type. Other sample types listed are acceptable for testing. For submission of paraffin block, another preferred specimen type, tissue source and block ID are required on the requisition form. A pathology report must be submitted. Whole Blood: Follow standard whole blood collection procedures. Collect 4-6 mLs whole blood in an EDTA tube. Record sample type, collection time and date onto tube and requisition form. Bone Marrow collection, the notation of sample type, collection time and date onto the tube and requisition form is required. Ship sample at refrigerated temperature or room temperature. Ship immediately to maintain stability.
Transport Temperature	Room temperature
Specimen Stability	Formalin fixed paraffin embedded tissue Room temperature: Indefinite Refrigerated: Indefinite Frozen: Do Not Freeze -70 Degrees: Do Not Freeze Bone Marrow (See Collection Instructions) or Whole blood Room temperature: 72 hours Refrigerated: 72 hours Frozen: Unacceptable -70 Degrees: Unacceptable

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Set-up/Analytic Time	Set up: Mon-Fri ; Report available: 4-5 days								
Reference Range	Not detected								
Always Message	<p>Activating KRAS (v-Ki-ras2 Kirsten rat sarcoma viral oncogene homolog) mutations can be found in 30-40% of colorectal cancer, 15-20% of lung cancer, and 60% of pancreatic cancer. Presence of KRAS mutation in colorectal cancer has been reported to render the tumor resistant to anti-EGFR therapy such as cetuximab.</p> <p>Nucleic acid was extracted from either paraffin embedded tissue, whole blood or bone marrow. For each sample, 2 PCR reactions were performed to detect mutations at exon 1 (codon 12 & 13) and exon 2 (codon 61) of the KRAS gene. The PCR products are then purified and sequenced in both forward and reverse directions. Sequencing data is analyzed and compared to a KRAS reference. The presence of the mutation(s) and its location(s) will be reported.</p> <p>For cases in which the tumor represents less than 10% of the analyzed tissue, this assay may not be able to detect mutations. However, we microdissect all tissues and selectively analyze the tumor cells in the provided specimen.</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								
Assay Category	Laboratory Developed Test								
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>86007404</td> <td>Specimen Source:</td> </tr> <tr> <td>86007405</td> <td>Paraffin Block Number:</td> </tr> <tr> <td>86003339</td> <td>KRAS Mutation Analysis</td> </tr> </tbody> </table>	Result Code	Result Name	86007404	Specimen Source:	86007405	Paraffin Block Number:	86003339	KRAS Mutation Analysis
Result Code	Result Name								
86007404	Specimen Source:								
86007405	Paraffin Block Number:								
86003339	KRAS Mutation Analysis								

NRAS Mutation Analysis	
Message	Suggested replacement for discontinued test code 5030, NRAS Mutation Analysis
Clinical Significance	N-RAS mutations have been described in 12% of leukemias, 18% of skin cancers, 18% of small intestine cancers, 3% of colon cancers, and 7% of thyroid cancer.
Effective Date	5/8/2012
Former Test Name	<i>NRAS Mutation Analysis</i>
Former Test Code	<i>5030</i>
Test Code	16818
CPT Codes	83891, 83892 (x2), 83898 (x2), 83904 (x4), 83909 (x2) , 83912 or 81404* *The 2012 AMA CPT codebook contains Tier 1 and Tier 2 Molecular Pathology Procedures as well as Molecular Pathology Procedures to be coded by procedure rather than analyte. Please direct any questions regarding coding to the payor being billed.
Specimen Requirements	Formalin fixed paraffin embedded tissue or 6 mL (4.0 mL) whole blood collected in an EDTA (lavender-top) tube. Alternate: 3 mL (1.0 mL) bone marrow aspirate collected in an EDTA (lavender-top) tube
Reject Criteria	Gross hemolysis, Clotted whole blood or bone marrow
Instructions	<p>Paraffin block is the preferred sample type. Sample source and block ID are required on the requisition form. A pathology report must be submitted.</p> <p>Whole Blood: Follow standard whole blood collection procedures. Collect 5-6 mLs whole blood in an EDTA tube. Record sample type, collection time and date onto tube and requisition form.</p> <p>Bone marrow collection, the notation of sample type, collection time and date onto the tube and requisition form is required. Ship sample at refrigerated temperature or room temperature. Ship immediately to maintain stability.</p>

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Transport Temperature	Tissue: Room temperature Whole blood and bone marrow: Refrigerated (cold packs)								
Specimen Stability	Tissue Room temperature: Indefinite Refrigerated: Indefinite Frozen: Do not freeze Whole blood and bone marrow Room temperature: 72 hours Refrigerated: 72 hours Frozen: Unacceptable								
Set-up/Analytic Time	Set up: Mon: Report available: 4 days								
Reference Range	Not Detected								
Always Message	Activating NRAS (neuroblastoma RAS viral (v-ras) oncogene homolog) mutations can be found in 3% of colorectal cancer, 1% of lung cancer, and 25% of small intestine cancer. Presence of NRAS mutation in colorectal cancer has been reported to render the tumor resistant to anti-EGFR therapy. Total nucleic acid was extracted from paraffin-embedded tissue. For each sample, 2 PCR reactions were performed to detect mutations at exon 1 (codon 12 & 13) and exon 2 (codon 61) of the NRAS gene. The PCR products are then purified and sequenced in both forward and reverse directions. Sequencing data is analyzed and compared to a NRAS reference. The presence of the mutation(s) and its location(s) will be reported. For cases in which the tumor represents less than 10% of the analyzed tissue, this assay may not be able to detect mutations. However, we microdissect all tissues and selectively analyze the tumor cells in the provided specimen. 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, Sequencing								
Assay Category	Laboratory Developed Test								
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>86007404</td> <td>Specimen Source:</td> </tr> <tr> <td>86007405</td> <td>Paraffin Block Number:</td> </tr> <tr> <td>86005840</td> <td>NRAS Mutation Analysis</td> </tr> </tbody> </table>	Result Code	Result Name	86007404	Specimen Source:	86007405	Paraffin Block Number:	86005840	NRAS Mutation Analysis
Result Code	Result Name								
86007404	Specimen Source:								
86007405	Paraffin Block Number:								
86005840	NRAS Mutation Analysis								

Plasminogen Activity	
Message	Suggested replacement for discontinued test code 1492, Plasminogen Activity.
Clinical Significance	The precursor of plasmin is plasminogen, plasmin lyses fibrin clots. Activity is increased in pregnancy and as an acute phase reactant. Rare hereditary deficiency of plasminogen predisposes to venous thrombosis. Low activity is associated with DIC, liver disease, and increased risk of thrombosis.
Effective Date	5/8/2012
<i>Former Test Name</i>	<i>Plasminogen Activity</i>
<i>Former Test Code</i>	<i>1492</i>
Test Code	4458
CPT Codes	85420
Specimen Requirements	2 mL (1.0 mL) plasma collected in 3.2% sodium citrate (lt. blue-top) tube

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Reject Criteria	Thawed specimen, Received room temperature, Received refrigerated, Hemolysis					
Instructions	Do not thaw. Hemolyzed specimens are not acceptable. Refer to Quest Diagnostics Nichols Institute Directory of Services under Specimen Collection section, Coagulation Testing for further information on specimen processing.					
Transport Temperature	Frozen					
Specimen Stability	Room temperature: Unacceptable Refrigerated: Unacceptable Frozen: 30 Days					
Set-up/Analytic Time	Set up: Weds, Fri ; Report available: 1 day					
Reference Range	65-176 %					
Units Of Measure	%					
Methodology	Chromogenic Substrate					
Assay Category	FDA Approved					
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>681</td> <td>Plasminogen Activity</td> </tr> </tbody> </table>		Result Code	Result Name	681	Plasminogen Activity
Result Code	Result Name					
681	Plasminogen Activity					

RAS Mutation Analysis, Cell-based	
Message	Suggested replacement for discontinued test code 5034, RAS Mutation Analysis, Cell-based.
Clinical Significance	Activating RAS mutations can be found in human malignancies with an overall frequency of 15-20%. A high incidence of RAS gene mutations has been reported in malignant tumors of the pancreas (80-90%, KRAS), in colorectal carcinomas (30-60%, KRAS), in non-melanoma skin cancer (30-50%, HRAS), in hematopoietic neoplasia of myeloid origin (18-30%, KRAS or NRAS).
Effective Date	5/8/2012
<i>Former Test Name</i>	<i>RAS Mutation Analysis, Cell-based</i>
<i>Former Test Code</i>	<i>5034</i>
Test Code	16128
CPT Codes	83891, 83898 (x3) ,83904 (x3), 83909 (x6), 83912
Specimen Requirements	5 mL (4.0 mL) peripheral blood collected in an EDTA (lavender-top) tube Alternate: Paraffin embedded tissue (IHC specimen transport kit) or 3 mL (2.0 mL) Bone marrow collected in an EDTA (lavender-top) tube
Reject Criteria	Gross hemolysis, Received frozen, Clotted
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° 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	Peripheral blood or Bone marrow Room temperature: 72 Hours Refrigerated: 72 Hours Frozen: Do Not Freeze Paraffin embedded tissue Room temperature: Fixed: Unlimited

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	Refrigerated: Fixed: Unlimited Frozen: Do Not Freeze												
Set-up/Analytic Time	Set up: Mon, Weds, Fri ; Report available: 4-5 days												
Reference Range	<table border="1"> <tr> <td>HRAS Mutation, Cell-based</td> <td>Negative</td> </tr> <tr> <td>KRAS Mutation, Cell-based</td> <td>Negative</td> </tr> <tr> <td>NRAS Mutation, Cell-based</td> <td>Negative</td> </tr> </table>	HRAS Mutation, Cell-based	Negative	KRAS Mutation, Cell-based	Negative	NRAS Mutation, Cell-based	Negative						
HRAS Mutation, Cell-based	Negative												
KRAS Mutation, Cell-based	Negative												
NRAS Mutation, Cell-based	Negative												
Always Message	<p>Nucleic acids were extracted from the patient's sample. For each sample, six PCR reactions were performed to detect mutations at exon 1 (codons 12 & 13) and exon 2 (codon 61) in the HRAS, KRAS, and NRAS genes. The PCR products were then purified and sequenced. Sequencing data are base-called by Sequencing Analysis software. Mutations, and their location in each of RAS genes, are reported above.</p> <p>This PCR/sequencing assay can detect 20% of the mutant alleles in a background of wild-type alleles.</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 (PCR), Sequencing												
Assay Category	Laboratory Developed Test												
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>86003417</td> <td>SAMPLE TYPE</td> </tr> <tr> <td>86003811</td> <td>BLOCK ID:</td> </tr> <tr> <td>86002045</td> <td>HRAS Mutation, Cell-based</td> </tr> <tr> <td>86002452</td> <td>KRAS Mutation, Cell-based</td> </tr> <tr> <td>86002453</td> <td>NRAS Mutation, Cell-based</td> </tr> </tbody> </table>	Result Code	Result Name	86003417	SAMPLE TYPE	86003811	BLOCK ID:	86002045	HRAS Mutation, Cell-based	86002452	KRAS Mutation, Cell-based	86002453	NRAS Mutation, Cell-based
Result Code	Result Name												
86003417	SAMPLE TYPE												
86003811	BLOCK ID:												
86002045	HRAS Mutation, Cell-based												
86002452	KRAS Mutation, Cell-based												
86002453	NRAS Mutation, Cell-based												

T-cell Receptor (TCR) Gene Rearrangement, Qualitative PCR, Cell-based	
Message	Suggested replacement for discontinued test codes 5042, T-Cell Gene Rearrangement DetectR™ and 5042BK. T-Cell Gene Rearrangement DetectR™ - Paraffin Block.
Clinical Significance	This assay is useful for establishing clonality of T-cell receptor gene rearrangement for the diagnosis of T-cell lymphoid neoplasms and identification of minimal residual disease or early recurrence in patients with previous diagnosis of T-cell neoplasm.
Effective Date	5/8/2012
Former Test Name	T-Cell Gene Rearrangement DetectR™
Former Test Code	5042
Test Code	15930
CPT Codes	83891, 83898 (x2) , 83909 , 83912
Specimen Requirements	<p>2.1 mL (1.0 mL) bone marrow collected in an EDTA (lavender-top) tube Alternates: 2.1 mL Bone marrow collected in sodium heparin (green-top) or ACD (yellow-top) tube or Fresh (unfixed) tissue or Frozen tissue or Fixed tissue or Formalin fixed, paraffin embedded tissue block or Tissue in neutral buffered formalin or 2.1 (1.0 mL) mL Whole blood collected in an EDTA (lavender-top) tube or Buffy coat or Tissue (biopsy)</p>

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Reject Criteria	Gross hemolysis, Clotted blood				
Instructions	After collection of the sample, draw date and time must be written onto the tube and included as requested information. Ship sample immediately. If the stability of the sample can not be determined, delay in result or cancellation of test may occur. Draw date and time is required to perform. For whole blood and bone marrow, collect sample in an EDTA tube. Note draw date and time. Ship refrigerated or room temperature. Stable for 7 days room temperature and 14 days refrigerated. Minimum and absolute minimum volumes apply to bone marrow samples. The preferred collection process for tissue is to collect sample into sterile container and store and ship frozen. Alternative process is to place fresh tissue samples in rpm media and ship refrigerated. Tissue samples in formalin only or embedded in paraffin blocks are acceptable and can be shipped at room temperature. Stability of tissue samples is approximately 1 year. Samples collected in rpm may be stable for only 1 month.				
Transport Temperature	Refrigerated (cold packs)				
Specimen Stability	Bone marrow or Whole blood Room temperature: 7 Days Refrigerated: 14 Days Frozen: Unacceptable Biopsy or Fresh (unfixed) tissue or Fixed tissue or Formalin fixed paraffin embedded tissue or Tissue in neutral buffered formalin or Buffy coat Room temperature: See Instructions Refrigerated: See Instructions Frozen: See Instructions				
Set-up/Analytic Time	Set up: 5 days a week ; Report available: 4-5 days				
Reference Range	Negative				
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	Polymerase Chain Reaction (PCR), Capillary Electrophoresis				
Assay Category	Laboratory Developed Test				
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>3683</td> <td>TCR Rearrange, QL, Cell</td> </tr> </tbody> </table>	Result Code	Result Name	3683	TCR Rearrange, QL, Cell
Result Code	Result Name				
3683	TCR Rearrange, QL, Cell				

Discontinued Tests

B-Cell & T-Cell Gene Rearrangement DetectR™					
Message	Suggested replacement test codes 14868 B-Cell Gene Rearrangement, Qualitative, PCR, Cell-based and 15930 T-cell Receptor (TCR) Gene Rearrangement, Qualitative PCR, Cell-based				
Effective Date	5/8/2012				
Test Code	5040				
Tests Affected	<table border="1"> <thead> <tr> <th>Test Codes:</th> <th>Name:</th> </tr> </thead> <tbody> <tr> <td>5040BK</td> <td>B-Cell & T-Cell Gene Rearrangement DetectR™ - Paraffin Block</td> </tr> </tbody> </table>	Test Codes:	Name:	5040BK	B-Cell & T-Cell Gene Rearrangement DetectR™ - Paraffin Block
Test Codes:	Name:				
5040BK	B-Cell & T-Cell Gene Rearrangement DetectR™ - Paraffin Block				
B-Cell Gene Rearrangement DetectR™					

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Message	Suggested replacement test code 14868, B-Cell Gene Rearrangement, Qualitative, PCR, Cell-based					
Effective Date	5/8/2012					
Test Code	5044					
Tests Affected	<table border="1"> <tr> <td>Test Codes:</td> <td>Name:</td> </tr> <tr> <td>5044BK</td> <td>B-Cell Gene Rearrangement DetectR® - Paraffin Block</td> </tr> </table>		Test Codes:	Name:	5044BK	B-Cell Gene Rearrangement DetectR® - Paraffin Block
Test Codes:	Name:					
5044BK	B-Cell Gene Rearrangement DetectR® - Paraffin Block					

D-Dimer Quantitative	
Message	Suggested replacement test code 8659, D-Dimer, Quantitative
Effective Date	5/8/2012
<i>Former Test Name</i>	<i>D-Dimer, Quantitative</i>
<i>Former Test Code</i>	<i>4202</i>
Test Code	8659

Factor II Activity	
Message	Suggested replacement test code 331, Factor II Activity, Clotting
Effective Date	5/8/2012
Test Code	1941

Factor IX Activity	
Message	Suggested replacement test code 352, Factor IX Activity, Clotting
Effective Date	5/8/2012
Test Code	1949

Factor V Activity	
Message	Suggested replacement test code 344 Factor V Activity, Clotting
Effective Date	5/8/2012
Test Code	1943

Factor VII Activity	
Message	Suggested replacement test code 346 Factor VII Activity, Clotting
Effective Date	5/8/2012
Test Code	1945

Factor X Activity	
Message	Suggested replacement test code 359, Factor IX Activity, Clotting
Effective Date	5/8/2012
Test Code	1951

Factor XI Activity	
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Message	Suggested replacement test code 360 Factor XI Activity, Clotting
Effective Date	5/8/2012
Test Code	1953

Factor XII Activity	
Message	Suggested replacement test code 362, Factor XII Activity, Clotting
Effective Date	5/8/2012
Test Code	1955

Familial Mediterranean Fever (FMF) GenotypR™	
Message	Suggested replacement test code 16141, Familial Mediterranean Fever Mutation Analysis
Effective Date	5/8/2012
Test Code	5290

Fibrinolytic Degradation Product	
Message	Suggested replacement test code 458, Fibrinogen Degradation Products (FDP)
Effective Date	5/8/2012
<i>Former Test Name</i>	<i>Fibrinolytic Degradation Product</i>
<i>Former Test Code</i>	<i>4208</i>
Test Code	458

KRAS Mutation Analysis	
Message	Suggested replacement test code 16510, KRAS Mutation Analysis
Effective Date	5/8/2012
Test Code	5032

Microsatellite Instability (MSI) DetectR™					
Message	Suggested replacement test code 14989, Microsatellite Instability (MSI), HNPCC				
Effective Date	5/8/2012				
Test Code	5046				
Tests Affected	<table border="1"> <tr> <td>Test Codes:</td> <td>Name:</td> </tr> <tr> <td>5046BK</td> <td>Microsatellite Instability (MSI) DetectR™ - Paraffin Block</td> </tr> </table>	Test Codes:	Name:	5046BK	Microsatellite Instability (MSI) DetectR™ - Paraffin Block
Test Codes:	Name:				
5046BK	Microsatellite Instability (MSI) DetectR™ - Paraffin Block				

NRAS Mutation Analysis	
Message	Suggested replacement test code 16818, NRAS Mutation Analysis
Effective Date	5/8/2012
Test Code	5030

Plasminogen Activity	
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Message	Suggested replacement test code 4458, Plasminogen Activity
Effective Date	5/8/2012
Test Code	1492

RAS Mutation Analysis, Cell-based	
Message	Suggested replacement test code 16128, RAS Mutation Analysis, Cell-based
Effective Date	5/8/2012
Test Code	5034

T-Cell Gene Rearrangement DetectR™					
Message	Suggested replacement test code 15930, T-cell Receptor (TCR) Gene Rearrangement, Qualitative PCR, Cell-based				
Effective Date	5/8/2012				
Test Code	5042				
Tests Affected	<table border="1"> <thead> <tr> <th>Test Codes:</th> <th>Name:</th> </tr> </thead> <tbody> <tr> <td>5042BK</td> <td>T-Cell Gene Rearrangement DetectR™ - Paraffin Block</td> </tr> </tbody> </table>	Test Codes:	Name:	5042BK	T-Cell Gene Rearrangement DetectR™ - Paraffin Block
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