



LABORATORY UPDATE

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Routine Testing

New Tests

- Prolactin, Dilution Study 3

Test Changes

- Lead, Blood - Update reference range for ages 6 years and under 4
- HCV RNA, Quantitative Real Time PCR – Update reportable range, submission requirements and assay category 5
- Prothrombin Time – INR – Update reference range..... 5
- Troponin I. 6

Quest Diagnostics Nichols Institute (San Juan Capistrano and Chantilly), Focus Diagnostics, Inc. and Specialty Laboratories

New Tests

- Vitamin D, 1,25-Dihydroxy, LC/MS/MS 7
- Vitamin D, 25-Hydroxy and 1, 25-Dihydroxy, LC/MS/MS..... 8
- *Borrelia burgdorferi* Antibody Index for CNS Infection 8
- Calprotectin, Stool 9
- CellSearch® Circulating Tumor Cells, Colon10
- CellSearch® Circulating Tumor Cells, Prostate11
- HLA-A29 DNA Typing.....12
- HLA-B51 DNA Typing12
- Chromosome Analysis, Neonatal Blood.....13
- FISH, HES/Leukemia, 4q12 Rearrangement (FIP1L1-PDGFR).....13

The CPT Codes provided in this document are based on AMA guidelines and are for informational purposes only. CPT coding is the sole responsibility of the billing party. Please direct any questions regarding coding to the payor being billed. Any Profile/panel component may be ordered separately. Reflex tests are performed at an additional charge.

Test Changes

- GlycoMark® - Update reference range14
- CellSearch® Circulating Tumor Cells, Breast - Update test name, result code and name, and stability.15
- FISH, DiGeorge, Velocardiofacial (VCFS) - Update specimen requirements.15
- Methicillin Resistant *Staphylococcus aureus*, PCR -- Update specimen requirements.....16
- Organic Acids - Update collection instructions.....16
- Thyroglobulin, Fine Needle Aspirate – Update reference range.16

Discontinued Tests

- Vitamin D, 1-, 25-Dihydroxy.....17
- Vitamin D Panel.....17
- Lyme Disease Antibody, Total, EIA with Reflex to CSF Ratio.....17

Additional Information:	<p>Prolactin dilution studies are done to determine if there is a high-dose hook effect (i.e. a non-linear assay response due to a very high concentration of prolactin). This is reported to occur at prolactin concentrations at or above 30,000 ng/mL.</p> <p>Prolactin Dilution Study is not recommended for identifying macroprolactin – use test order code 16122 to test for presence of macroprolactin (performed at Quest Diagnostics Nichols Institute).</p>
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Blood Lead Test Changes

In 1991, the Centers for Disease Control (CDC) defined the blood lead level (BLL) that should prompt public health actions as 10 mcg/dL. In the Nov 2, 2007 MMWR, the CDC published “Interpreting and Managing Blood Lead Levels <10 mcg/dL in Children and Reducing Childhood Exposures to Lead: Recommendations of CDC’s Advisory Committee on Childhood Lead Poisoning Prevention”. The CDC public health action threshold of 10 mcg/dL has not changed. However, research conducted since 1991 has strengthened the evidence that children’s physical and mental development can be affected at blood lead levels < 10 mcg/dL. Blood lead levels in the range 5-9 mcg/dL have been associated with adverse health effects in children aged 6 years and younger.

Lead, Blood	
Clinical Significance:	Children are especially susceptible to neurologic damage from lead and acute neurologic toxicity may develop without previous symptoms.
Effective Date:	August 31, 2009
Test Code:	599
Reference Ranges:	Birth to 6 years: < 5 mcg/dL > 6 years: < 10 mcg/dL
Additional Information:	Update reference range for ages 6 years and under

Test Changes

HCV RNA, Quantitative Real Time PCR	
Clinical Significance:	Useful in monitoring therapy and disease progression.
Effective Date:	September 14, 2009
Test Code:	35645
Specimen Requirements:	3 mL plasma collected in two EDTA Lavender-top tubes. Separate plasma from whole blood within 6 hours of collection by centrifugation at 800 to 1600 x g for 20 minutes at room temperature (minimum volume 1.1mL)
Transport Temperature:	Frozen
Specimen Stability:	Room Temperature- Unacceptable Refrigerated- 3 days (separated plasma) Frozen- 6 weeks at -18°C or lower (separated plasma)
Reference Ranges:	< 43 IU/mL <1.63 LogIU/mL
Methodology:	Real Time PCR
Assay Category:	FDA Approved/Cleared
Additional Information	Reportable range 43 IU/mL to 69,000,000 IU/mL Update reportable range, submission requirements and assay category.

Prothrombin Time - INR									
Clinical Significance:	Screening test for abnormalities of coagulation factors that are involved in the extrinsic pathway. Also used to monitor effects of Warfarin anticoagulants and to study patients with hereditary and acquired clotting disorders.								
Effective Date:	August 3, 2009								
Test Code:	8847								
Reference Ranges:	<table border="1"> <thead> <tr> <th colspan="2">INR:</th> </tr> </thead> <tbody> <tr> <td>Reference Range</td> <td>0.9-1.1</td> </tr> <tr> <td>Moderate-intensity Warfarin Therapy</td> <td>2.0-3.0</td> </tr> <tr> <td>Higher-intensity Warfarin Therapy</td> <td>3.0-4.0</td> </tr> </tbody> </table>	INR:		Reference Range	0.9-1.1	Moderate-intensity Warfarin Therapy	2.0-3.0	Higher-intensity Warfarin Therapy	3.0-4.0
INR:									
Reference Range	0.9-1.1								
Moderate-intensity Warfarin Therapy	2.0-3.0								
Higher-intensity Warfarin Therapy	3.0-4.0								
Additional Information:	INR results >1.1 will flag as abnormal Update reference range.								

Troponin I	
Clinical Significance:	Troponin I is part of a protein complex, which regulates the contraction of striated muscle. In acute coronary syndromes (ACS), it can be detected in blood at 4-8 hours following the onset of chest pain, reaches a peak concentration at 12-16 hours, and remains elevated for 5-9 days. Troponin I has been used as a reliable marker in the diagnosis of perioperative myocardial infarction in patients undergoing cardiac surgery.
Effective Date:	September 21, 2009
Former Test Code:	34693
New Test Code:	59039
CPT Code(s):	84484
Specimen Requirements:	1 mL Heparin Plasma is the preferred specimen. Separate from cells within 2 hours. Please note: Serum is an acceptable specimen type. However, it is not recommended for 2 sample types to be used interchangeably.
Specimen Stability:	Room temperature: 2 hours Refrigerated: 24 Hours Frozen: 6 months
Reference Range	Adult: < or = 0.04 ng/mL The following message will be applied to all Troponin I reports: “In accord with published recommendations, serial testing of Troponin I at intervals of 2 to 4 hours for up to 12 to 24 hours is suggested in order to corroborate a single Troponin I result. An elevated troponin alone is not sufficient to make the diagnosis of MI.”
Additional Information:	Update test code, acceptable specimen types, stability and reference range.

**QUEST DIAGNOSTICS NICHOLS INSTITUTE, (San Juan Capistrano & Chantilly),
Focus Diagnostics, Inc. and Specialty Laboratories**

New Tests

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

Vitamin D, 1,25 Dihydroxy, LC/MS/MS	
Clinical Significance:	This test is used to measure the bio-active form of Vitamin D. This test is also used in the differential diagnosis of hypocalcemia and to monitor patients with renal osteodystrophy or chronic renal failure.
Effective Date:	September 14, 2009
Test Code:	16558
CPT Code:	82652
Specimen Requirements:	2 mL serum (1.1 mL minimum) Collect blood in a non-gel barrier red-top tube. Allow blood to clot (30 minutes) at room temperature, 18°C to 25°C. Centrifuge and separate the serum from the cells. Note: If sample is submitted with less than 1.1 mL and needs to be repeated, the sample will be canceled with the comment "TNP-Initial testing necessitated a repeat, but there was insufficient sample to perform repeat".
Transport Temperature:	Room temperature
Specimen Stability:	Room temperature, Refrigerated, and Frozen: 28 days
Reference Ranges:	Vitamin D, 1,25 (OH)₂Total, LC/MS/MS: 1-9 years: 31-87 pg/mL 10-13 years: 30-83 pg/mL 14-17 years: 19-83 pg/mL Adults: 18-72 pg/mL
Methodology:	Liquid Chromatography Tandem Mass Spectrometry
Assay Category:	Laboratory Developed Test
Performing Site:	Quest Diagnostics Nichols Institute

Vitamin D, 25 Hydroxy and 1, 25-Dihydroxy, LC/MS/MS	
Clinical Significance:	Vitamin D originating from dietary and endogenous sources is converted to 25-hydroxyvitamin D in the liver, and subsequently to 1, 25-dihydroxyvitamin D in the kidney. Measurement of both the 1, 25-Dihydroxy and 25-Hydroxy forms provide insights into a variety of medical conditions such as Vitamin D status in renal failure, differential diagnosis of primary, secondary and tertiary hyperparathyroidism. Differential diagnosis of hypercalcemia and type I and II inherited rickets.
Effective Date:	September 14, 2009
Test Code:	16761
CPT Code:	82306, 82652
Specimen Requirements:	2 mL serum Collect blood in a non-gel barrier red-top tube. Allow blood to clot (30 minutes) at room temperature, 18°C to 25°C. Centrifuge and separate the serum from the cells. Note: If sample is submitted with less than 1.2 mL and needs to be repeated, the sample will be canceled with the comment "TNP-Initial testing necessitated a repeat, but there was insufficient sample to perform repeat".
Transport Temperature:	Room temperature
Specimen Stability:	Room temperature, Refrigerated, and Frozen: 21 days
Reference Ranges:	Accompanies report
Methodology:	Liquid Chromatography Tandem Mass Spectrometry
Assay Category:	Laboratory Developed Test
Performing Site:	Quest Diagnostics Nichols Institute, San Juan Capistrano

<i>Borrelia burgdorferi</i> Antibody Index for CNS Infection									
Clinical Significance:	The <i>Borrelia burgdorferi</i> Antibody Index is used as an aid in the diagnosis of neuroborreliosis. An increased <i>B. burgdorferi</i> Antibody Index (>1.2), accompanied by a Control Antibody Index of less than 1.0 and an Albumin ratio of less than 0.0078 is strong evidence for intrathecal synthesis of organism-specific antibody, and thus CNS involvement by <i>B. burgdorferi</i> . Elevation of either the control antibody index, the Albumin Ratio, or both may indicate leakage of antibody across the blood-brain barrier, which may falsely elevate the <i>B. burgdorferi</i> Antibody Index.								
Effective Date:	September 21, 2009								
Test Code:	34194								
CPT Code:	82040, 82784(X2), 86618(X4), 82042								
Specimen Requirements:	2 mL CSF in sterile leak-proof container AND 2 mL serum								
Transport Temperature:	Refrigerated								
Specimen Stability:	Room temperature: Unacceptable Refrigerated: 14 days Frozen: 30 days								
Reference Ranges:	<table border="1"> <tr> <td><i>Borrelia burgdorferi</i> Ab:</td> <td>< or = 1.0 Negative 1.1-1.2 Equivocal > or =1.3 Positive</td> </tr> <tr> <td>Control Ab Index:</td> <td>< or = 1.0</td> </tr> <tr> <td>Albumin Ratio:</td> <td>< 0.0078</td> </tr> <tr> <td>Interpretation:</td> <td>With report</td> </tr> </table>	<i>Borrelia burgdorferi</i> Ab:	< or = 1.0 Negative 1.1-1.2 Equivocal > or =1.3 Positive	Control Ab Index:	< or = 1.0	Albumin Ratio:	< 0.0078	Interpretation:	With report
<i>Borrelia burgdorferi</i> Ab:	< or = 1.0 Negative 1.1-1.2 Equivocal > or =1.3 Positive								
Control Ab Index:	< or = 1.0								
Albumin Ratio:	< 0.0078								
Interpretation:	With report								
Methodology:	Immunoassay, Nephelometry								
Assay Category:	Laboratory Developed Test								
Performing Site:	Focus Diagnostics, Inc.								

Calprotectin, Stool	
Clinical Significance:	Used to diagnose inflammatory bowel disease (IBD), including Crohn's disease and ulcerative colitis, or to differentiate IBD from irritable bowel syndrome (IBS).
Effective Date:	September 21, 2009
Test Code:	16796
CPT Code(s):	83993
Specimen Requirements:	1 g stool, unpreserved in sterile leak-proof container Collect undiluted feces in clean, dry sterile leak proof container. Do not add fixative or preservative.
Transport Temperature:	Frozen
Specimen Stability:	Room temperature and Refrigerated: 11 days Frozen: 1 year
Reference Ranges:	< OR = 162.9 mcg/g
Methodology:	Immunoassay
Assay Category:	FDA Approved/Cleared
Performing Site:	Quest Diagnostics Nichols Institute, San Juan Capistrano

CellSearch® Circulating Tumor Cells, Colon																
Clinical Significance:	This test can detect the presence of circulating tumor cells (CTC) in the peripheral blood of patients with metastatic breast cancer, colorectal or prostate cancer in patients. A count of 5 CTC or more in breast and prostate cancers and 3 CTC or more in colon cancer in 7.5 mL of blood is predictive of shorter progression free survival and overall survival. Physicians can draw samples prior to a new line of therapy for baseline prediction. Physicians can also draw samples at the first follow-up visit for evaluating response to therapy. The Veridex CellSearch® System is the only semi-automated system designed to standardize and optimize the measurement of CTC in peripheral blood, this test is also the only FDA approved kit for CTC detection.															
Effective Date:	September 21, 2009															
Test Code:	16811															
CPT Code(s):	88346 (x2); 88361															
Specimen Requirements:	<p>10 ml whole blood in CellSave™ Preservative Tube</p> <ol style="list-style-type: none"> 1. Draw one tube per patient. 2. Collect blood aseptically by venipuncture or from a venous port into a CellSave™ Preservative Tube only. Circulating tumor cells (CTC) are fragile and require preservation for accurate analysis. 3. Fill the tube until blood flow stops to ensure the correct ratio of sample to anticoagulant and preservative. Immediately mix by gently inverting the tube eight times. Tube inversion prevents clotting. Inadequate or delayed mixing may result in inaccurate test results. 4. Process samples within 96 hours of collection. 5. Blood samples may be stored or transported in CellSave™ Preservative Tubes for up to 96 hours at room temperature (15 to 30C) prior to processing. Draw date and time must be provided with the whole blood specimen. Draw samples prior to intravenous therapy. After initiation of therapy, blood can be drawn at the first follow-up visit, which is usually 3-4 weeks after initiation of therapy. If the patients on doxorubicin therapy, allow at least 7 days following administration of a dose of therapy before blood draw. 															
Transport Temperature:	Room temperature															
Specimen Stability:	Room temperature: 4 days Refrigerated or Frozen: Unacceptable															
Reference Ranges:	<p>The CellSearch® Circulating Tumor Cell Kit "is intended for the enumeration of circulating tumor cells (CTC) of epithelial origin in whole blood." The assay has been reported to predict progression-free survival (PFS) and overall survival (OS) in patients treated for colorectal cancer.</p> <p>CTC counts ≥ 3 for metastatic colorectal cancer have been reported to predict shorter PFS and OS. The table lists median PFS and OS based on CTC counts at baseline and 1st follow up.</p> <table border="1"> <thead> <tr> <th>Number of CTC</th> <th>PFS (months)</th> <th>OS (months)</th> </tr> </thead> <tbody> <tr> <td>At all time points < 3</td> <td>8.1</td> <td>18.6</td> </tr> <tr> <td>Baseline < 3; at last draw ≥ 3</td> <td>4.3</td> <td>7.1</td> </tr> <tr> <td>Baseline ≥ 3; at last draw < 3</td> <td>7.2</td> <td>11.7</td> </tr> <tr> <td>At all time points ≥ 3</td> <td>2.2</td> <td>3.9</td> </tr> </tbody> </table>	Number of CTC	PFS (months)	OS (months)	At all time points < 3	8.1	18.6	Baseline < 3 ; at last draw ≥ 3	4.3	7.1	Baseline ≥ 3 ; at last draw < 3	7.2	11.7	At all time points ≥ 3	2.2	3.9
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Baseline ≥ 3 ; at last draw < 3	7.2	11.7														
At all time points ≥ 3	2.2	3.9														
Methodology:	Veridex CellSearch®															
Assay Category:	FDA Approved/Cleared															
Performing Site:	Quest Diagnostics Nichols Institute															

CellSearch® Circulating Tumor Cells, Prostate																
Effective Date:	September 21, 2009															
Test Code:	16812															
CPT Code(s):	88346 (x2); 88361															
Specimen Requirements:	<p>10 ml whole blood in CellSave™ Preservative Tube</p> <ol style="list-style-type: none"> 1. Draw one tube per patient. 2. Collect blood aseptically by venipuncture or from a venous port into a CellSave™ Preservative Tube only. Circulating tumor cells (CTC) are fragile and require preservation for accurate analysis. 3. Fill the tube until blood flow stops to ensure the correct ratio of sample to anticoagulant and preservative. Immediately mix by gently inverting the tube eight times. Tube inversion prevents clotting. Inadequate or delayed mixing may result in inaccurate test results. 4. Process samples within 96 hours of collection. 5. Blood samples may be stored or transported in CellSave™ Preservative Tubes for up to 96 hours at room temperature (15 to 30C) prior to processing. Draw date and time must be provided with the whole blood specimen. Draw samples prior to intravenous therapy. After initiation of therapy, blood can be drawn at the first follow-up visit, which is usually 3-4 weeks after initiation of therapy. If the patients on doxorubicin therapy, allow at least 7 days following administration of a dose of therapy before blood draw. 															
Transport Temperature:	Room temperature															
Specimen Stability:	Room temperature: 4 days Refrigerated or Frozen: Unacceptable															
Reference Ranges:	<p>The CellSearch® Circulating Tumor Cell Kit "is intended for the enumeration of circulating tumor cells (CTC) of epithelial origin in whole blood." The assay has been reported to predict progression-free survival (PFS) and overall survival (OS) in patients treated for prostate cancer.</p> <p>CTC counts ≥ 5 for prostate cancer have been reported to predict shorter PFS and OS. The table lists median PFS and OS based on CTC counts at baseline and 1st follow up.</p> <table border="1"> <thead> <tr> <th>Number of CTC</th> <th>PFS (months)</th> <th>OS (months)</th> </tr> </thead> <tbody> <tr> <td>At all time points < 5</td> <td>6.5</td> <td>> 26</td> </tr> <tr> <td>Baseline < 5; at last draw ≥ 5</td> <td>4.2</td> <td>9.3</td> </tr> <tr> <td>Baseline ≥ 5; at last draw < 5</td> <td>7.3</td> <td>21.3</td> </tr> <tr> <td>At all time points ≥ 5</td> <td>2.5</td> <td>6.8</td> </tr> </tbody> </table>	Number of CTC	PFS (months)	OS (months)	At all time points < 5	6.5	> 26	Baseline < 5; at last draw ≥ 5	4.2	9.3	Baseline ≥ 5; at last draw < 5	7.3	21.3	At all time points ≥ 5	2.5	6.8
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Baseline < 5; at last draw ≥ 5	4.2	9.3														
Baseline ≥ 5; at last draw < 5	7.3	21.3														
At all time points ≥ 5	2.5	6.8														
Methodology:	Veridex CellSearch®															
Assay Category:	FDA Approved/Cleared															
Performing Site:	Quest Diagnostics Nichols Institute															

HLA-A29 DNA Typing	
Clinical Significance:	Birdshot retinochoroidopathy (BSCR) is a rare posterior uveitis characterized by distinctive, multiple, hypopigmented choroidal and retinal lesions. More than 97% of BSCR patients carry HLA-A29. The frequency of HLA-A29 in the general US population is 8%. Together with clinical manifestations, HLA-29 typing is used for diagnosis of BSCR.
Effective Date:	September 21, 2009
Test Code:	16773
CPT Code:	83891, 83896 (x30), 83900, 83912
Specimen Requirements:	10 mL ACD -A, -B (yellow-top tube) whole blood
Transport Temperature:	Room temperature
Specimen Stability:	Room temperature and Refrigerated: 7 days Frozen: Unacceptable
Reference Ranges:	Interpretive report
Methodology:	Polymerase Chain Reaction followed by Sequence Specific Oligonucleotide Probes
Assay Category:	FDA Approved/Cleared
Performing Site:	Quest Diagnostics Nichols Institute, Chantilly

HLA-B51 DNA Typing	
Clinical Significance:	Behcet's Disease (BD) is a chronic inflammatory disease characterized by oral aphthous ulcers, genital ulcers, and skin lesions. Between 50 to 80% BD patients are HLA-B51 positive. The frequency of HLA-B51 in the general US population is 7%.
Effective Date:	September 21, 2009
Test Code:	16775
CPT Code:	83891, 83896 (x30), 83900, 83912
Specimen Requirements:	10 mL ACD -A, -B (yellow-top tube) whole blood
Transport Temperature:	Room temperature
Specimen Stability:	Room temperature and Refrigerated: 7 days Frozen: Unacceptable
Reference Ranges:	Interpretive report
Methodology:	Polymerase Chain Reaction followed by Sequence Specific Oligonucleotide Probes
Assay Category:	FDA Approved/Cleared
Performing Site:	Quest Diagnostics Nichols Institute, Chantilly

Chromosome Analysis, Neonatal Blood	
Clinical Significance:	A specific chromosome analysis test code to rule out chromosomal abnormalities in neonates. Rapid cytogenetics results in these patients elicit timely clinical decisions.
Effective Date:	August 17, 2009
Test Code:	16843
CPT Code(s):	88230, 88262, 88291
Specimen Requirements:	3 mL peripheral blood in sodium heparin (green-top) tube Other vacutainer tubes containing sodium heparin are acceptable. See Genetics specimen collection section for detailed specimen instructions. SPECIMEN VIABILITY DECREASES DURING TRANSIT. SEND SPECIMEN TO TESTING LAB FOR VIABILITY DETERMINATION. DO NOT REJECT.
Transport Temperature:	Room temperature
Specimen Stability:	Room Temperature and Refrigerated: See Instructions Frozen Unacceptable
Reference Ranges:	Per report
Methodology:	Chromosome Analysis
Assay Category:	Laboratory Developed Test
Performing Site:	Quest Diagnostics Nichols Institute

FISH, HES/Leukemia, 4q12 Rearrangement (FIP1L1-PDGFR)	
Clinical Significance:	FIP1L1-PDGFR fusion (rearrangement of 4q12; interstitial deletion of CHIC2 region) is observed in diverse eosinophilia-associated hematologic disorders. The cases with FIP1L1-PDGFRa fusion show an excellent response to the tyrosine kinase inhibitor imatinib mesylate (Metzgeroth et al, 2007)
Effective Date:	July 6, 2009
Test Code:	16837
CPT Code(s):	88271 (x3), 88275, 88291
Specimen Requirements:	3 mL bone marrow in transport media Bone marrow: 1-3 mL in transport medium (preferred) or sodium heparin tube or whole blood in sodium heparin Green, dark/ royal blue or tan top tubes are acceptable containers for this test. Ship at room temperature. Do not freeze. SPECIMEN VIABILITY DECREASES DURING TRANSIT. SEND SPECIMEN TO TESTING LAB FOR VIABILITY DETERMINATION. DO NOT REJECT.
Transport Temperature:	Room temperature
Specimen Stability:	Room Temperature and refrigerated: See instructions
Reference Ranges:	Per report
Methodology:	Fluorescence In Situ Hybridization
Assay Category:	ASR Class 1
Performing Site:	Quest Diagnostics Nichols Institute

Test Changes

The following test changes will be effective on the dates indicated below. Please note that only the fields listed in bold type are being changed; former test names and test codes have been italicized. Additional information, regarding the change, will be provided where applicable.

Effective September 8, 2009 plasma will no longer be an acceptable specimen type for the test codes listed below:

Test Code:	Test Name:
16031	ABL Kinase Domain Mutation in CML, Plasma
19782	ABL T315I Mutation in CML, Leumeta®
16119	B Cell Gene Rearrangement, QL PCR, Leumeta®
16118	B Cell Gene Rearrangement, QN PCR, Leumeta®
16169	B Cell, Patient specific Monitoring, Plasma based
17853	BCR/ABL Rearrangement, QN PCR, Leumeta®
17702	IgVH Mutation, Plasma
19960	c kit Mutation Analysis, Plasma based, Leumeta®
17690	bcl 2/JH t(14,18), Plasma
16536	JAK2 Exons 12 and 13 Mutations, QL, Leumeta®
16175	JAK2 Mutation (V617F) QN, Plasma, Leumeta®
16538	JAK2 V617F, QL, w/rfl Exons 12,13 and MPL W515, S505
16539	JAK2 V617F, QL, Leumeta® w/Refl Exons12 and 13
16510	KRAS Mutation Analysis
17679	bcl 1/JH t(11,14), Plasma
16184	MPL W515 and MPL S505 Mutation , QL, Leumeta®
16159	NPM (Exon 12) Mutation Analysis, Leumeta®
16515	P53 Mutation Analysis, Plasma based, Leumeta®
70182	PML/RARA t(15,17), QN RT PCR, Leumeta®
16127	RAS Mutation Analysis, Plasma based Leumeta®
17862	TCR Gene Rearrangement, QL PCR, Leumeta®
17861	TCR Gene Rearrangement, QN PCR, Leumeta®

GlycoMark®			
Clinical Significance:	The test is indicated for the intermediate term monitoring of glycemic control in people with diabetes.		
Effective Date:	September 14, 2009		
Test Code:	19599		
Reference Ranges:	0-1 years:	No Range Established	
	2-17 years:	Males:	15.0-38.0 mcg/mL
		Females:	11.2-35.7 mcg/mL
> or = 18 years:	Males:	7.3 – 36.6 mcg/mL	
	Females:	7.5 – 28.4 mcg/mL	
Always Message:	GlycoMark® reference ranges apply to persons without diabetes. In people with diabetes under good to moderate glycemic control (hemoglobin A1c levels 8% or less), GlycoMark® levels less than 8 mcg/mL suggest significant glycemic variability, most likely due to post meal blood glucose levels increasing above 180 mg/dL.		
Additional Information:	Update reference ranges and always message. Please note this test is included in the following group codes: 16715-Hemoglobin A1c w/Reflex to GlycoMark®		
DLO	Page 14 of 17		August 2009

CellSearch® Circulating Tumor Cells, Breast																		
Effective Date:	September 21, 2009																	
<i>Former Test Name:</i>	<i>CellSearch(R) Circulating Tumor Cells</i>																	
Test Code:	16011																	
Specimen Stability:	Room temperature: 4 days Refrigerated and Frozen: Unacceptable																	
Reference Range:	<p>The CellSearch® Circulating Tumor Cell Kit ".is intended for the enumeration of circulating tumor cells (CTC) of epithelial origin in whole blood." The assay has been reported to predict progression-free survival (PFS) and overall survival (OS) in patients treated for metastatic breast cancer.</p> <p>CTC counts ≥ 5 for metastatic breast cancer have been reported to predict shorter PFS and OS. The table lists median PFS and OS based on CTC counts at baseline and 1st follow up.</p> <table border="1"> <thead> <tr> <th>Number of CTC</th> <th>PFS (months)</th> <th>OS (months)</th> </tr> </thead> <tbody> <tr> <td>At all time points < 5</td> <td>7.2</td> <td>22.6</td> </tr> <tr> <td>Baseline < 5; at last draw ≥ 5</td> <td>5.9</td> <td>10.6</td> </tr> <tr> <td>Baseline ≥ 5; at last draw < 5</td> <td>6.1</td> <td>19.8</td> </tr> <tr> <td>At all time points ≥ 5</td> <td>1.8</td> <td>4.1</td> </tr> </tbody> </table>			Number of CTC	PFS (months)	OS (months)	At all time points < 5	7.2	22.6	Baseline < 5 ; at last draw ≥ 5	5.9	10.6	Baseline ≥ 5 ; at last draw < 5	6.1	19.8	At all time points ≥ 5	1.8	4.1
Number of CTC	PFS (months)	OS (months)																
At all time points < 5	7.2	22.6																
Baseline < 5 ; at last draw ≥ 5	5.9	10.6																
Baseline ≥ 5 ; at last draw < 5	6.1	19.8																
At all time points ≥ 5	1.8	4.1																
Methodology:	Veridex CellSearch®																	
Performing Site:	Quest Diagnostics Nichols Institute																	
Additional Information:	Update test name, result code and name, and stability.																	

FISH, DiGeorge, Velocardiofacial (VCFS)	
Clinical Significance:	This test is used to detect microdeletions of chromosome 22q11 associated with DiGeorge, Velocardiofacial (VCFS) syndrome using FISH (fluorescence in situ hybridization).
Effective Date:	September 28, 2009
Test Code:	14610
Specimen Requirements:	<p>5 mL sodium heparin (green-top) whole blood (preferred) Infants 2-3 mL in pediatric (3 mL) vacutainer. Other vacutainer tubes containing sodium heparin are acceptable.</p> <p>Acceptable specimens: 20 mL amniotic fluid in sterile, nontoxic centrifuge tubes. Room temperature. Do not freeze. Amniotic fluid kit and instructions available on request. OR 20 -40 mg Chorionic Villus Sampling in transport media, Hanks, or Ringer's solution in sterile, non-toxic, leak-proof container. Room temperature. Do not freeze. CVS transport kit available upon request.</p> <p>Primary or early passage monolayer of primary cultures, submitted in a T-25 flask filled with medium. Room temperature. Do not freeze.</p> <p>SPECIMEN VIABILITY DECREASES DURING TRANSIT. SEND SPECIMEN TO TESTING LAB FOR VIABILITY DETERMINATION. DO NOT REJECT.</p>
Performing Site:	Quest Diagnostics Nichols Institute
Additional Information:	Update specimen requirements.

Methicillin Resistant <i>Staph aureus</i>, PCR	
Clinical Significance:	This assay is used to detect the presence of methicillin-resistant <i>Staphylococcus aureus</i> (MRSA) DNA in a patient's nasal swab specimen. The use of real-time PCR to detect the presence of MRSA DNA in clinical specimens allows for rapid patient testing.
Effective Date:	September 28, 2009
Test Code:	17656
Specimen Requirements:	Nasal swab in Amies liquid collection tube Stuart's liquid collection tube or Copan Venturi Transystem™ Liquid Stuart are acceptable containers. Swab must be inserted into nostril up to 2.5 cm (1 inch) from edge of the nare and rolled 5 times. Repeat using same swab in the other nostril. Return swab to its container immediately and perform assay. Nasal Swab: Collect in BBL™ CultureSwab™ Liquid Amies, Single Swab (Cat. No. 220093) or Copan Venturi Transystem™ Liquid Amies - Single Swab (Cat. No. 140C) or BBL™ CultureSwab™ Liquid Stuart, Single Swab (Cat. No. 220099) or Copan Venturi Transystem™ Liquid Stuart - Single Swab (Cat. No. 141C).
Performing Site:	Quest Diagnostics Nichols Institute
Additional Information:	Update specimen requirements

38067-Organic Acids, Quantitative, Random Urine, Full Panel	
Clinical Significance:	Organic acidurias are a group of inborn errors of metabolism that may lead to acute life-threatening illness, developmental delays, and metabolic decompensation. Positive results may warrant confirmation by alternative specific methods.
Effective Date:	September 28, 2009
Specimen Requirements:	15 mL random urine (minimum 5 mL) Do not use preservatives. Do not thaw. Random urine. Avoid fecal contamination of urine. From one thoroughly mixed sterile collection container, divide into two sterile collections: (1) minimum 4 mL in sterile screw cap container AND (2) minimum 1 mL in sterile 12x75mm standard tube (to be used for Creatinine testing). Freeze immediately. Send both samples together
Performing Site:	Quest Diagnostics Nichols Institute, San Juan Capistrano
Additional Information:	Update collection instructions.

Thyroglobulin, Fine Needle Aspirate	
Clinical Significance:	Clinically enlarged cervical lymph nodes with a history of thyroid cancer are usually assessed by fine-needle aspiration biopsy (FNAB) followed by cytologic examination of the aspirate. Thyroglobulin (Tg) is frequently elevated in malignant FNAB needle wash specimens and its use may possibly augment or replace cytology.
Effective Date:	September 28, 2009
Test Code:	16559
Reference Ranges:	Thyroglobulin, FNA: <1.0 ng/mL
Performing Site:	Quest Diagnostics Nichols Institute, San Juan Capistrano
Additional Information:	Update reference range.

Discontinued Tests

Vitamin D, 1, 25-Dihydroxy	
Effective Date:	September 14, 2009
Test Code:	4729
Additional Information:	This test will be discontinued. The recommended alternative is test code 16558 - Vitamin D, 1, 25-Dihydroxy, LC/MS/MS.

Vitamin D Panel	
Effective Date:	September 14, 2009
Test Code:	5678
Additional Information:	This test will be discontinued. The recommended alternative is 16761 - Vitamin D, 25 Hydroxy and 1, 25 Dihydroxy, LC/MS/MS.

Lyme Disease Antibody, Total, EIA with Reflex to CSF Ratio	
Effective Date:	September 21, 2009
Test Code:	10534
Additional Information:	This test will be discontinued. The recommended alternative is 34194 - <i>Borrelia burgdorferi</i> Ab Index for CNS Infection performed at Focus Diagnostics, Inc.