

September 2013 - Monthly Update, Quest Diagnostics Nichols Institute, Valencia

ANNOUNCEMENTS		
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 #
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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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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.				
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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.			
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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.				
Test Code	Former Test Code	Test Name	Effective Date	Page #
<u>S52276</u>		Prostate Cancer Gene 3 (PCA3)	9/24/2013	9
<u>S46515</u>		Bicarbonate, Urine	10/7/2013	10
<u>30540</u>	S43160	Bromide, Serum/Plasma	10/7/2013	10
<u>S43900</u>		Glutethimide, Serum/Plasma	10/7/2013	10
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## Announcement

**Recent discovery of rare falsely undetectable TSH variant**

In May 2013, Siemens (manufacturer of the ultra-sensitive TSH assay in use at Quest Diagnostics) issued a product safety notice (#10814911) to inform its customers that "a rare variant of TSH, identified in a small cluster of patients, is not detected" because "the monoclonal antibody used in the reagent fail(s) to detect the TSH molecule" in these individuals. In the notice, Siemens underscores the importance of "co-interpretation of TSH results in conjunction with thyroxine and T3, patient history, and clinical signs and symptoms." Please contact Quest Diagnostics Client Services if you would like a copy of the notice.

The following month, Siemens and Kaiser Permanente jointly presented their findings of "Falsely Undetectable TSH in Four Commonly Used Immunoassays: A Possible Novel Human TSH Variant" at the 2013 Endocrine Society meeting. In the abstract [published in Endocrine Reviews June 2013, Vol. 34 (03\_MeetingAbstracts): SAT-467], the authors write that "16 individuals (14 euthyroid and 2 hypothyroid), all but one of South Asian descent," "have been identified out of approximately two million Kaiser Permanente members in Northern California." The authors further advise that "health care providers should be aware that rare individuals may have falsely undetectable TSH results in some hyperselective TSH immunoassays." To read the entire abstract, go to [www.endojournals.org](http://www.endojournals.org) and enter "Falsely Undetectable TSH" in the search bar.

**Please note: Revision to the August Monthly Update**

<b>Quetiapine, Serum/Plasma</b>	
<b>Effective Date</b>	<b>9/16/2013</b>
Test Code	<b>35299</b>
Transport Temperature	<b>Room temperature</b>
Specimen Stability	<b>Room temperature, Refrigerated, and Frozen: 21 days</b>
Performing Site	Quest Diagnostics Nichols Institute, Chantilly

**New Test Offerings**

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

<b>Beta-lactamase Gene Detection, Enteric Bacteria</b>	
Clinical Significance	This beta-lactamase assessment gene panel is designed for the rapid molecular detection of a wide range of clinically important beta-lactamase genes in gram-negative bacteria. Beta-lactamase genes detected by this test include TEM, SHV and CTX-M Extended Spectrum beta-lactamase (ESBL) genes, AmpC beta-lactamase genes CMY II, DHA, FOX, CMY I/MOX, ACC, ACT/MIR, the Klebsiella pneumoniae Carbapenemase gene (KPC) and the New Delhi Metallo-beta-lactamase gene (NDM-1). The test detects the presence of the various genes and at the same time provides information on beta-lactamase resistant genes yielding extra information for outbreak management.
<b>Effective Date</b>	<b>9/9/2013</b>
Test Code	<b>91334</b>
CPT Codes	<b>87999</b>
Specimen Requirements	<b>Pure culture of gram-negative enteric bacillus only, submitted on appropriate culture medium, safely contained.</b>
Instructions	<b>Sample must be isolated bacteria. Primary specimens are unacceptable. Organism cannot be frozen.</b> <b>Client needs to include organism identification.</b>
Transport Temperature	<b>Room temperature or refrigerated</b>
Specimen Stability	<b>Room temperature and Refrigerated: 72 hours</b> <b>Frozen: Unacceptable</b>

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Set-up/Analytic Time	<b>Set up: Mon; Report available: 10 days</b>																																											
Reference Range	<b>Not detected</b>																																											
Always Message	<p><b>This test was performed using a kit that has not been cleared or approved by the FDA. The analytical performance characteristics of this test have been determined by Quest Diagnostics Nichols Institute, Chantilly, VA. This test should not be used for diagnosis without confirmation by other medically established means.</b></p> <p><b>For more information on this test, go to <a href="http://education.questdiagnostics.com/faq/FAQ100">http://education.questdiagnostics.com/faq/FAQ100</a></b></p>																																											
Methodology	<b>Microarray</b>																																											
Assay Category	<b>Research Use Only</b>																																											
Performing Site	Quest Diagnostics Nichols Institute, Chantilly																																											
CPU Mappings	<table border="1"> <thead> <tr> <th colspan="2">91334 Beta-lactamase Gene Detection,Enteric Bacteria</th> </tr> <tr> <th>Result Code</th> <th>Result Name</th> </tr> </thead> <tbody> <tr> <td>86009854</td> <td>Organism ID:</td> </tr> <tr> <td>86009837</td> <td>Kleb pneumo carbama. (KPC)</td> </tr> <tr> <td>86009838</td> <td>New Delhi Met.-BL (NDM-1)</td> </tr> <tr> <td>86009839</td> <td>AmpC Cephalosp. CMYII</td> </tr> <tr> <td>86009840</td> <td>AmpC Cephalosp. DHA</td> </tr> <tr> <td>86009841</td> <td>AmpC Cephalosp. FOX</td> </tr> <tr> <td>86009842</td> <td>AmpC Cephalosp. ACC</td> </tr> <tr> <td>86009843</td> <td>AmpC Cephalosp. ACT/MIR</td> </tr> <tr> <td>86009844</td> <td>AmpC Cephalo. CMYI/MOX</td> </tr> <tr> <td>86009845</td> <td>ESBL CTX-M1</td> </tr> <tr> <td>86009846</td> <td>ESBL CTX-M2</td> </tr> <tr> <td>86009847</td> <td>ESBL CTX-M8</td> </tr> <tr> <td>86009848</td> <td>ESBL CTX-M9</td> </tr> <tr> <td>86009849</td> <td>ESBL CTX-M25</td> </tr> <tr> <td>86009850</td> <td>ESBL SHV G238S/A</td> </tr> <tr> <td>86009863</td> <td>ESBL SHV E240K</td> </tr> <tr> <td>86009851</td> <td>ESBL TEM E104K</td> </tr> <tr> <td>86009852</td> <td>ESBL TEM R164S/H/C</td> </tr> <tr> <td>86009853</td> <td>ESBL TEM G238S</td> </tr> </tbody> </table>		91334 Beta-lactamase Gene Detection,Enteric Bacteria		Result Code	Result Name	86009854	Organism ID:	86009837	Kleb pneumo carbama. (KPC)	86009838	New Delhi Met.-BL (NDM-1)	86009839	AmpC Cephalosp. CMYII	86009840	AmpC Cephalosp. DHA	86009841	AmpC Cephalosp. FOX	86009842	AmpC Cephalosp. ACC	86009843	AmpC Cephalosp. ACT/MIR	86009844	AmpC Cephalo. CMYI/MOX	86009845	ESBL CTX-M1	86009846	ESBL CTX-M2	86009847	ESBL CTX-M8	86009848	ESBL CTX-M9	86009849	ESBL CTX-M25	86009850	ESBL SHV G238S/A	86009863	ESBL SHV E240K	86009851	ESBL TEM E104K	86009852	ESBL TEM R164S/H/C	86009853	ESBL TEM G238S
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HPV Genotypes 16,18/45	
Effective Date	10/7/2013
Test Code	91826
CPT Codes	87621 (x2)

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Specimen Requirements	<b>1 mL Liquid Cytology (PreservCyt®) Preservative (ThinPrep®)</b>							
Instructions	<b>Labs performing cytology: Aliquot PreservCyt® solution before or after performance of liquid based cytology testing. PreservCyt®: Transfer 1 mL of PreservCyt® solution into Aptima® Vaginal Collection tube (orange label) or Aptima® Specimen Transfer tube (green label). Ship to lab.</b>							
Transport Temperature	<b>Room temperature</b>							
Specimen Stability	<b>Room temperature and Refrigerated: 60 days Frozen: 2 years</b>							
Set-up/Analytic Time	<b>Set up: Mon, Wed, Fri; Report available: 3-6 days</b>							
Reference Range	<b>Not Detected</b>							
Always Message	<b>This test was performed using the APTIMA HPV 16, 18/45 genotype assay (Gen-Probe Inc.). The assay can differentiate HPV 16 from HPV 18 and/or HPV 45, but does not differentiate between HPV 18 and HPV 45.</b>							
Methodology	<b>Transcription- Mediated Amplification (TMA)</b>							
Performing Site	<b>In-house, Quest Diagnostics Nichols Institute, San Juan Capistrano</b>							
CPU Mappings	<table border="1"> <thead> <tr> <th>Result Code</th> <th>Result Name</th> </tr> </thead> <tbody> <tr> <td>86010019</td> <td>HPV 16 RNA</td> </tr> <tr> <td>86010020</td> <td>HPV 18/45 RNA</td> </tr> </tbody> </table>		Result Code	Result Name	86010019	HPV 16 RNA	86010020	HPV 18/45 RNA
Result Code	Result Name							
86010019	HPV 16 RNA							
86010020	HPV 18/45 RNA							
Additional Information	<b>This new offering will replace the reflex to 19865 HPV Genotypes 16 and 18 in codes listed in the Test or Panels Affected Section below.</b>							
Tests Affected	<table border="1"> <thead> <tr> <th>Test Codes:</th> <th>Name:</th> </tr> </thead> <tbody> <tr> <td>90942</td> <td>HPV mRNA E6/E7 Reflex HPV 16,18/45</td> </tr> </tbody> </table>		Test Codes:	Name:	90942	HPV mRNA E6/E7 Reflex HPV 16,18/45		
Test Codes:	Name:							
90942	HPV mRNA E6/E7 Reflex HPV 16,18/45							

<b>Platelet Antibody, Indirect (IgG), Flow Cytometry</b>	
Message	<b>**This test is not available for New York patient testing**</b>
Clinical Significance	Circulating antibodies to platelets have been associated with immune and drug-induced thrombocytopenia. Circulating platelet antibodies may play a role in platelet destruction. Platelet antibodies may consist of a single isotype (IgG, IgM or IgA) or any combination of isotypes.
Effective Date	<b>10/28/2013</b>
Test Code	<b>91805</b>
CPT Codes	<b>86022</b>
Specimen Requirements	<b>2 mL (1 mL minimum) serum</b>
Reject Criteria	<b>Hemolysis; lipemia; icterus</b>
Instructions	<b>Collect 5 mL whole blood in a serum separator tube (red-top) and separate serum before submitting</b>
Transport Temperature	<b>Room temperature</b>
Specimen Stability	<b>Room temperature: 7 days Refrigerated: 14 days Frozen: 30 days</b>
Set-up/Analytic Time	<b>Set up: Mon-Fri; Report available: 2-5 days</b>

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Reference Range	<b>Negative</b>					
Always Message	<p><b>Circulating antibodies to platelets, detected by Flow Cytometry, are found in the sera of patients with immune mediated disorders. Platelet antibodies have been associated with ITP and drug-induced thrombocytopenia.</b></p> <p><b>This test was developed and its performance characteristics have been determined by Quest Diagnostics Nichols Institute, San Juan Capistrano. It has not been cleared or approved by the U.S. Food and Drug Administration. The FDA has determined that such clearance or approval is not necessary. Performance characteristics refer to the analytical performance of the test.</b></p>					
Methodology	<b>Flow Cytometry</b>					
Performing Site	<b>Quest Diagnostics Nichols Institute, San Juan Capistrano</b>					
CPU Mappings	<table border="1"> <thead> <tr> <th>Result Code</th> <th>Result Name</th> </tr> </thead> <tbody> <tr> <td>85969500</td> <td>Platelet Ab,Indirect (IgG)</td> </tr> </tbody> </table>		Result Code	Result Name	85969500	Platelet Ab,Indirect (IgG)
Result Code	Result Name					
85969500	Platelet Ab,Indirect (IgG)					

<b>Platelet Antibody, Indirect (IgM)</b>					
Message	<b>**This test is not available for New York patient testing**</b>				
Clinical Significance	Circulating antibodies to platelets have been associated with immune and drug-induced thrombocytopenia. Circulating platelet antibodies may play a role in platelet destruction. Platelet antibodies may consist of a single isotype (IgG, IgM or IgA) or any combination of isotypes.				
<b>Effective Date</b>	<b>10/28/2013</b>				
Test Code	<b>91806</b>				
CPT Codes	<b>86022</b>				
Specimen Requirements	<b>2 mL (1 mL minimum) serum</b>				
Reject Criteria	<b>Hemolysis; lipemia; icterus</b>				
Instructions	<b>Collect 5 mL whole blood in a serum separator tube (red-top) and separate serum before submitting</b>				
Transport Temperature	<b>Room temperature</b>				
Specimen Stability	<b>Room temperature: 7 days Refrigerated: 14 days Frozen: 30 days</b>				
Set-up/Analytic Time	<b>Set up: Mon-Fri; Report available: 2-5 days</b>				
Reference Range	<b>Negative</b>				
Always Message	<p><b>Circulating antibodies to platelets, detected by Flow Cytometry, are found in the sera of patients with immune mediated disorders. Platelet antibodies have been associated with ITP and drug-induced thrombocytopenia.</b></p> <p><b>This test was developed and its performance characteristics have been determined by Quest Diagnostics Nichols Institute, San Juan Capistrano. It has not been cleared or approved by the U.S. Food and Drug Administration. The FDA has determined that such clearance or approval is not necessary. Performance characteristics refer to the analytical performance of the test.</b></p>				
Methodology	<b>Flow Cytometry</b>				
Performing Site	<b>Quest Diagnostics Nichols Institute, San Juan Capistrano</b>				
CPU Mappings	<table border="1"> <thead> <tr> <th>Result Code</th> <th>Result Name</th> </tr> </thead> <tbody> <tr> <td>85969510</td> <td>Platelet Ab,Indirect (IgM)</td> </tr> </tbody> </table>	Result Code	Result Name	85969510	Platelet Ab,Indirect (IgM)
Result Code	Result Name				
85969510	Platelet Ab,Indirect (IgM)				

**Test Changes**

The following test changes will be effective on the dates indicated below. **Please note that only the information that is changing appears in this update.** Former test names and test codes have been italicized.

<b><i>Chlamydia trachomatis/Neisseria gonorrhoeae</i> RNA, TMA</b>	
<b>Effective Date</b>	<b>10/7/2013</b>
<i>Former Test Name</i>	<i>SureSwab® Chlamydia trachomatis/Neisseria gonorrhoeae RNA, TMA</i>
<b>Test Code</b>	11363
<b>Specimen Requirements</b>	<p><b>1 mL liquid cytology (PreservCyt®) preservative (ThinPrep®) collected in APTIMA® Specimen Transfer tube (green label) or APTIMA® Vaginal Collection Kit (orange label) or APTIMA® Unisex Swab Specimen Collection Kit.</b></p> <p><b>0.5 mL of SurePath® preservative fluid collected in APTIMA® Specimen Transfer tube (green label) or APTIMA® Vaginal Collection Kit (orange label).</b></p> <p>Endocervical or urethral swabs in APTIMA® combo 2 assay unisex swab specimen collection kit.</p> <p>Vaginal swabs in the APTIMA® combo 2 assay vaginal swab collection kit.</p> <p>2 mL urine using APTIMA® urine specimen collection kit.</p>
<b>Instructions</b>	<p><b>Labs performing cytology: Aliquot PreservCyt® or SurePath® solution before performance of liquid based cytology testing.</b></p> <p><b>PreservCyt®: Transfer 1 mL of PreservCyt solution into APTIMA® Specimen Transfer tube (green label) or APTIMA® Vaginal Collection tube (orange label). Ship to lab.</b></p> <p><b>SurePath®: SurePath® fluid must be transferred to APTIMA® STM within 4 days of collection. Transfer 0.5 mL of SurePath® preservative fluid to APTIMA® Specimen Transfer tube (green label) or APTIMA® Vaginal Collection tube (orange label). Ship to lab.</b></p> <p>Endocervical or urethral swabs: Follow instructions in the APTIMA® Combo 2 assay unisex swab specimen collection kit. In females, to insure collection of cells infected with <i>C. trachomatis</i>, columnar epithelial cells lining the endocervix should be obtained. To that effect, excess mucus should be removed prior to sampling.</p> <p>Vaginal swabs: Follow instructions in the APTIMA® combo 2 assay vaginal swab collection kit.</p> <p>Urine: Patient should not have urinated within one hour prior to collection. Female patients should not cleanse the labial area prior to providing the specimen. Direct patient to provide a first-catch urine (a maximum of 20-30 mL of the initial urine stream) into a urine collection cup free of any preservatives. 2 mL of urine specimen must be transferred into the APTIMA® specimen transport within 24 hours of collection and before being assayed. Use tube provided in the urine specimen collection kit for urine specimens. The fluid (urine plus transport media) level in the urine transport tube must fall within the clear pane on the tube label.</p>
<b>Specimen Stability</b>	<p><b>Liquid cytology (PreservCyt® preservative (ThinPrep®)</b>  <b>Room temperature: 14 days</b>  <b>Refrigerated: 30 days</b>  <b>Frozen: Not established</b></p> <p><b>SurePath® preservative fluid:</b>  <b>Room temperature and Refrigerated 14 days</b>  <b>Frozen: Not established</b></p> <p>Urine in APTIMA® Transport medium:                      Room temperature and Refrigerated: 30 days                      Frozen: 1 year</p> <p>Cervical/Vaginal swabs in APTIMA® transport:                      Room temperature and Refrigerated: 60 days</p>

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	Frozen 1 year  Urethral swabs in APTIMA® transport: Room temperature and Refrigerated: 60 days Frozen: 6 months
Performing Site	Quest Diagnostics Nichols Institute, Valencia

HPV mRNA E6/E7					
Effective Date	10/7/2013				
Former Test Name	HPV RNA, HR E6/E7, TMA				
Test Code	90887				
Always Message	This assay detects E6/E7 viral messenger RNA (mRNA) from 14 high-risk HPV types (16, 18, 31, 33, 35, 39, 45, 51, 52, 56, 58, 59, 66, 68).				
Performing Site	Quest Diagnostics Nichols Institute, Valencia				
CPU Mappings	<table border="1"> <thead> <tr> <th>Result Code</th> <th>Result Name</th> </tr> </thead> <tbody> <tr> <td>86008309</td> <td>HPV mRNA E6/E7</td> </tr> </tbody> </table>	Result Code	Result Name	86008309	HPV mRNA E6/E7
Result Code	Result Name				
86008309	HPV mRNA E6/E7				

HPV mRNA E6/E7 Reflex to Genotypes 16,18/45																	
Effective Date	10/7/2013																
Former Test Name	HPV RNA, HR E6/E7, TMA with Reflex to Genotypes 16,18																
Test Code	90942																
Always Message	This assay detects E6/E7 viral messenger RNA (mRNA) from 14 high-risk HPV types (16, 18, 31, 33, 35, 39, 45, 51, 52, 56, 58, 59, 66, 68).																
Performing Site	Quest Diagnostics Nichols Institute, San Juan Capistrano																
CPU Mappings	<table border="1"> <tr> <td colspan="2">90942-1-HPV RNA, High Risk, E6/E7, TMA</td> </tr> <tr> <th>Result Code</th> <th>Result Name</th> </tr> <tr> <td>86008309</td> <td>HPV mRNA E6/E7</td> </tr> <tr> <td colspan="2"><b>*TR 91826-2 HPV Genotypes 16,18/45</b></td> </tr> <tr> <th>Result Code</th> <th>Result Name</th> </tr> <tr> <td>86010019</td> <td>HPV 16 RNA</td> </tr> <tr> <td>86010020</td> <td>HPV 18/45 RNA</td> </tr> <tr> <td colspan="2"> <b>*TR (True Reflex Flag)</b>                      CPU interface clients: If you are set up to use our True Reflexing option, build the unit codes with the TR flag (indicated above) separately.                 </td> </tr> </table>	90942-1-HPV RNA, High Risk, E6/E7, TMA		Result Code	Result Name	86008309	HPV mRNA E6/E7	<b>*TR 91826-2 HPV Genotypes 16,18/45</b>		Result Code	Result Name	86010019	HPV 16 RNA	86010020	HPV 18/45 RNA	<b>*TR (True Reflex Flag)</b> CPU interface clients: If you are set up to use our True Reflexing option, build the unit codes with the TR flag (indicated above) separately.	
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Babesia Organism Detection	
Effective Date	10/8/2013
Test Code	2146

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Specimen Requirements	5.0 mL (3.0 mL) whole blood EDTA (lavender-top), <b>3 thin blood smears, and 3 thick blood smears</b>
Instructions	<ol style="list-style-type: none"> <li>1. Prepare thick and thin smears within 1 hour of collection.</li> <li>2. Send all three specimen types (whole blood EDTA, thin smears, and thick smears).</li> <li>3. Prepare thin smears using the blood differential method. Air dry for 10 minutes. Fix with methanol for 5 seconds.</li> <li>4. For thick smears, add 1 drop of the EDTA blood onto a clean microscopic slide. Spread the blood into a dime-sized area. Dry for 30 minutes. Do not fix with methanol.</li> <li>5. Submit thin and thick slides in cardboard slide holder. These slides and the EDTA specimen should be submitted to the laboratory within 24 hours of collection.</li> </ol>
Transport Temperature	Room temperature
Specimen Stability	Room temperature: 24 hours Refrigerated: Unacceptable Frozen: Unacceptable
Additional Information	Provide travel history of the patient.

Neutrophil Function, Oxidative Burst					
Message	<b>**This test is not available for New York patient testing**</b>				
Effective Date	10/28/2013				
Former Test Code	A52339				
Test Code	37523				
Specimen Requirements	7 mL ( <b>4 mL minimum</b> ) whole blood collected in a sodium heparin (green-top) tube				
Reject Criteria	Hemolysis; lipemia; icterus; clotted specimens; refrigerated and frozen specimens				
Instructions	<p>Specimen must arrive at the referral laboratory within 72 hours of collection in order to meet sample stability requirements. Specimens are accepted &lt;72 hours post collection. No other preservatives are acceptable.</p> <p>Specify time of day specimen was collected.</p> <p>Clients may send 7 mL whole blood in sodium heparin from a healthy donor unrelated to the patient, drawn at the same time as the patient sample to run in parallel with the patient's specimen. The outermost label of the tube must be clearly labeled as "Transport Control". If the draw date is not indicated on the specimen, the client must be called and this information obtained.</p>				
Specimen Stability	Room temperature: 72 hours Refrigerated and Frozen: Unacceptable				
Set-up/Analytic Time	Set up: Daily; Report available: 2-3 days				
Reference Range	<table border="1"> <tr> <td rowspan="3">%Oxidation Pos Neutrophils</td> <td>24 hours: &gt; or = 93%</td> </tr> <tr> <td>48 hours: &gt; or = 83%</td> </tr> <tr> <td>72 hours: &gt; or = 82%</td> </tr> </table>	%Oxidation Pos Neutrophils	24 hours: > or = 93%	48 hours: > or = 83%	72 hours: > or = 82%
%Oxidation Pos Neutrophils	24 hours: > or = 93%				
	48 hours: > or = 83%				
	72 hours: > or = 82%				
Always Message	<p>This assay measures the capability of neutrophils (PMN) to undergo oxidative metabolism to produce superoxide anion and hydrogen peroxide, as detected by oxidation of dihydrorhodamine (DHR). Patients with Chronic Granulomatous Disease (CGD) are unable to oxidize DHR due to defects in oxidative metabolism. The proportion of neutrophils with intact oxidative capacity slowly decreases as the specimen age (hours post-collection) increases. It is thus important that the reference range value appropriate for the specimen age be utilized when assessing the reported results.</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>				
Performing Site	This test previously performed at Focus Diagnostics, Inc. will now be performed at Quest Diagnostics				



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Nichols Institute, San Juan Capistrano.			
CPU Mappings	<b>Result Code</b>	<b>Type</b>	<b>Result Name</b>
	85992637		%Oxidation Pos Neutrophils
	85992638	Prompt-Result	Specimen Age

**Discontinued Tests**

Niacin	
<b>Effective Date</b>	9/17/2013
Test Code	S41930
Additional Information	Recommended alternative is: 91029 Vitamin B3

Phagocytic Index, FC	
<b>Effective Date</b>	10/28/2013
Test Code	S48877
Additional Information	There is no recommended alternative.

**Test Send Outs (Referrals)**

Due to these assays being performed by outside vendors, we are unable to use our normal method of communication. Some of the changes listed in this document may be effective in less than 30 days. Please note the individual effective dates below, as these changes may require **IMMEDIATE ACTION**.

Prostate Cancer Gene 3 (PCA3)	
Clinical Significance	<p>Prostate cancer gene (PCA3) is strongly expressed in 95% of primary prostate cancer specimens. The PCA3 test is indicated for use in conjunction with other patient information to aid in the decision for repeat biopsy in men age 50 or older who have had one or more previous negative prostate biopsies and for whom a repeat biopsy would be recommended by a urologist based on current standard of care. The PCA3 result provides a risk assessment of a positive biopsy.</p> <p>This assay should not be used for men with atypical small acinar proliferation (ASAP) on their most recent biopsy. Men with ASAP on their most recent biopsy should be treated in accordance with current medical guidelines.</p>
<b>Effective Date</b>	9/24/2013
Test Code	S52276
Specimen Requirements	2.5 mL (2.0 mL) Urine
Reject Criteria	Specimen volume <2 mL; incorrect collection kit; unfrozen specimen received after five days
Instructions	<p><b>**TEST REQUIRES SPECIAL KIT**</b> (Stock Clerk order number 167792)</p> <p>Before collection, the patient should undergo an attentive digital rectal exam (three strokes per lobe).</p> <p>1. Collect a first-catch (approximately 20 to 30 mL of the initial stream) urine sample in a urine collection cup after DRE has been performed. Urine sample should be processed immediately following steps 2 and 3.</p>

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	<p>2. Invert the sample five times to resuspend the cells. Transfer 2.5 mL of urine (fill until the fluid level is between the black lines) into the urine specimen transport tube using the disposable pipette provided.</p> <p>3. Recap the urine specimen transport tube tightly and invert five times to mix.</p> <p>Processed urine specimens must be shipped at 30 degrees C or below (may be frozen) and should be received by the test facility within five days of collection.  <b>FREEZE</b> sample and ship frozen if specimen storage will be greater than five days.</p>
Transport Temperature	<b>Frozen</b>
Specimen Stability	Room temperature: Unacceptable <b>Refrigerated: 5 days</b> <b>Frozen: Indefinite</b>
Reference Range	<b>Result (PCA3 Score):</b> <b>&lt; 25 is negative; &gt;/25 is positive</b>
Assay Category	<b>FDA Approved</b>
Performing Site	Dianon Systems

<b>Bicarbonate, Urine</b>	
<b>Effective Date</b>	<b>10/7/2013</b>
Test Code	S46515
Specimen Requirements	1 mL (0.3 mL minimum) urine collected in a plastic, preservative-free urine container
Set-up/Analytic Time	<b>Set up: Mon, Thurs; Report available: 1 day</b>

<b>Bromide, Serum/Plasma</b>	
<b>Effective Date</b>	<b>10/7/2013</b>
<i>Former Test Name</i>	<i>Bromide</i>
<i>Former Test Code</i>	<i>S43160</i>
Test Code	<b>30540</b>
Specimen Requirements	<p><b>Preferred:</b>            1 mL (0.3 mL minimum) serum collected in a red-top tube (no gel)</p> <p><b>Acceptable:</b>            Plasma collected in a Sodium fluoride/Potassium oxalate (gray-top) tube or Sodium heparin (green-top) tube</p>
Reject Criteria	Serum separator tube; polymer gel separation tube; <b>EDTA (lavender-top) tube</b>
Instructions	<b>Promptly centrifuge and separate Serum or Plasma into a plastic screw capped vial using approved guidelines.</b>
Specimen Stability	<b>Room temperature, Refrigerated and Frozen: 30 days</b>
Set-up/Analytic Time	<b>Set up: Mon, Thurs; Report available: 2 days</b>
Reference Range	<p>The general range of normal levels is 0.3 – 1.2 mg/dL with an average of approximately 0.5 mg/dL. Background concentrations are diet dependent. Workers exposed to methyl bromide with blood bromide concentrations greater than 1.2 mg/dL have shown 3.5 times higher risk of electroencephalogram disturbances than compared to those with normal levels. The bromide concentration may be elevated beyond normal levels if the individual is using bromides therapeutically. The antiepileptic effects of bromides are generally associated with plasma levels ranging from 75 - 150 mg/dL. The ratio of blood to plasma concentrations is 0.7 - 0.8.</p>

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CPU Mappings	<b>Result Code</b>	<b>Result Name</b>
	85847800	Bromide, Serum/Plasma

<b>Glutethimide, Serum/Plasma</b>	
<b>Effective Date</b>	10/7/2013
Test Code	S43900
Reject Criteria	<b>Polymer gel separation tube</b> (serum separator tube or PST)
Instructions	<b>Promptly centrifuge and separate serum or plasma into a plastic, screw-capped, preservative free vial using approved guidelines.</b>
Transport Temperature	<b>Refrigerated</b>
Set-up/Analytic Time	<b>Set up: Mon;</b> Report available: 5 days
Reference Range	Usual sedative-hypnotic range: 2 - 6 mcg/mL.  <b>Hexobarbital interferes with glutethimide in this analysis. The presence of hexobarbital will adversely affect the quantitation of glutethimide. If an individual has taken hexobarbital call the laboratory for alternate quantitative procedures.</b>

<b>Methyl Bromide as Metabolite, Blood</b>	
<b>Effective Date</b>	10/7/2013
Test Code	S52174
Specimen Requirements	<b>1 mL (0.3 mL minimum) blood collected in a Sodium fluoride/Potassium oxalate (gray-top) tube or Sodium heparin (green-top) tube.</b>
Reject Criteria	<b>EDTA (lavender-top) tube</b>
Specimen Stability	<b>Room temperature, Refrigerated and Frozen: 30 days</b>
Set-up/Analytic Time	<b>Set up: Mon, Thurs; Report available: 2 days</b>
Reference Range	<b>The general range of normal levels is 0.3 – 1.2 mg/dL with an average of approximately 0.5 mg/dL. Background concentrations are diet dependent. Workers exposed to methyl bromide with blood bromide concentrations greater than 1.2 mg/dL have shown 3.5 times higher risk of electroencephalogram disturbances than compared to those with normal levels.</b>