SPECIALTY LABORATORIES
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Test Updates

November 25, 2009

Dear Colleague:

Specialty Laboratories is pleased to announce the immediate availability of **Influenza Virus Type A and B RNA, Qualitative Real-Time PCR [7515]**, performed at our Valencia, CA facility. Influenza A & B testing by the highly sensitive and specific RT-PCR methodology provides results more rapidly than other methods, including immunological methods and culture. To receive results as quickly as possible, Influenza A & B virus can also be ordered with an automatic reflex to the 2009 H1N1 influenza virus by ordering **Influenza A & B RT-PCR with Reflex to Influenza A H1N1 (2009) [7505]**. These tests, in addition to **Influenza A H1N1 (2009) Real-Time PCR [7510]**, aid in the detection and differentiation of seasonal influenza virus infection and 2009 H1N1 influenza virus infection.

Also newly available are several Varicella Zoster assays: **Varicella-zoster Virus DNA DetectR™ [7585]**, **Varicella-zoster Virus DNA UltraQuant® [8760]**, and **Varicella-zoster Virus DNA UltraQuant® CSF [8760C]** for viral DNA detection and/or quantitation on blood, amniotic fluid and cerebral spinal fluid, respectively.

Important note: Vitamin D, 25-Hydroxy Total [LC-MS-MS] [3541] is the replacement for the discontinued **Vitamin D, 25-Hydroxy (Calcifediol) [3521]** that will no longer be available after December 15th. Please be sure to order the correct Vitamin D assay.

Available December 22nd, **Properdin Factor B [1511]** aids in the diagnosis of several kidney diseases, such as chronic glomerulonephritis (inflammation of the glomeruli of the kidney), lupus nephritis and may be useful for rheumatoid arthritis, sickle cell anemia, and gram negative bacteremia.

In our continuing initiatives to improve the notification time of samples that may be deemed as "Quantity Not Sufficient" (QNS), we are introducing a new pre-analytical specimen review in our Specimen Management area. In cases where it appears that quantity of specimen may be insufficient, we will inform you of the **"Potential QNS"**. All efforts will still be taken by the laboratory to complete the order, but this proactive notification will enable you to take precautionary measures, such as sequestering any residual specimen stored at your location, promptly forwarding available sample or obtaining additional specimen in cases where a patient may be scheduled for discharge. The notification will be handled in the same manner as other pre- and post-analytical issues.

JAK2 V617F Mutation Ql, w/Rfx Exons 12, 13 & MPL W515, S505 [5396] and **MPL W515 & MPL S505 Mutation Analysis, Qualitative, Plasma [5398]** have been approved by the Wadsworth Center and are now available for ordering on patients from New York State.

We thank you for choosing *Specialty* and look forward to your continued support. For additional information, please visit our Web site at *www.specialtylabs.com* or contact Client Relations at 800-421-4449.

Respectfully Yours,

Christopher Lockhart, M.D.

Christopher Lockhart, M.D.
Laboratory Director

New Tests (*Specialty*):

7585 Varicella-zoster Virus DNA DetectR™ (Available November 24)

Component	Method	Reference Range/Units
Specimen Source		
Varicella-zoster Virus DNA	**PCR**	**Not detected**

Specimen/Stability	Whole Blood ACD 10.0 (2.0) mL: Ambient 72 hours
Alternate Specimen	Whole Blood EDTA 10.0 (2.0) mL: Ambient 72 hours Amniotic Fluid 2.0 (0.5) mL: Ambient 4 days, Refrigerated 4 days, Frozen 2 months CSF 2.0 (0.5): Frozen 2 months Culturette/Swab: Ambient 72 hours M4 Transport Media/Swab: ambient 72 hours Tissue: Frozen 2 months
Collection Instructions	Submit throat swab in M4 transport media. Other acceptable specimens: vesicle fluid or scrapping. Do not refrigerate or freeze whole blood. Ship CSF (unspun) and tissue on dry ice. Ship within 24 hours of collection by overnight courier. Please specify specimen source on container and requisition.
Schedule	Tuesday-Saturday
Report	Within 3 days
CPT Code	87798
Regulatory Status	Laboratory Developed Test
Always Statement	This test(s) was developed and its performance characteristics have been determined by Specialty Laboratories. Performance characteristics refer to the analytical performance of the test.
Note	If submitting CSF specimen, please order Varicella-zoster Virus DNA UltraQuant® CSF, test code 8760C. Culturette/Swab, M4 Transport Media, and Tissue are not approved for the testing of patient samples from New York State.
Clinical Utility	Detects presence of Varicella-zoster virus DNA down to 100 copies/mL to aid in the diagnosis of Varicella-zoster viral infection. PCR is superior to viral culture (both in timeliness of result and in sensitivity).

8760 Varicella-zoster Virus DNA UltraQuant® (Available November 24)

Component	Method	Reference Range/Units
Specimen Source		
Varicella-zoster Virus	**PCR**	**<100 copies/mL**

Specimen/Stability	Whole Blood ACD 10.0 (2.0) mL: Ambient 24 hours, Refrigerated 24 hours
Alternate Specimen	Amniotic Fluid 2.0 (0.5) mL: Ambient 4 days, Refrigerated 4 days, Frozen 2 months Whole Blood EDTA 10.0 (2.0) mL: Ambient 24 hours, Refrigerated 24 hours
Collection Instructions	Specify specimen source on container and test requisition form. Ship whole blood within 24 hours of collection. Split amniotic fluid into 2 plastic vials and freeze immediately.
Schedule	Tuesday-Saturday
Report	Within 3 days
CPT Code	87799
Regulatory Status	Laboratory Developed Test
Always Statement	This test(s) was developed and its performance characteristics have been determined by Specialty Laboratories. Performance characteristics refer to the analytical performance of the test.
Note	If submitting CSF specimen, please order Varicella-zoster Virus DNA UltraQuant® CSF, test code 8760C. If submitting tissue, please order Varicella-zoster Virus DNA DetectR™, test code 7585.
Clinical Utility	Quantitates Varicella-zoster virus DNA down to 100 copies/mL to monitor viral load and therapeutic efficacy, primarily in immunocompromised patients.

New Tests (*Specialty*): (cont'd)

8760C Varicella-zoster Virus DNA UltraQuant® CSF (Available November 24)

Component	Method	Reference Range/Units
Varicella-zoster Virus CSF	**PCR**	**<100 copies/mL**

Specimen/Stability	CSF 2.0 (0.5) mL: Frozen 2 months
Collection Instructions	Split specimen into 2 plastic vials and ship frozen on dry ice by overnight courier. Use specially marked FROZEN specimen bags for priority processing.
Schedule	Sunday-Saturday
Report	Next day
CPT Code	87799
Regulatory Status	Laboratory Developed Test
Always Statement	This test(s) was developed and its performance characteristics have been determined by Specialty Laboratories. Performance characteristics refer to the analytical performance of the test.
Clinical Utility	Quantitates Varicella-zoster virus DNA down to 100 copies/mL to rapidly detect VZV encephalitis or monitor CSF viral load, primarily in immunocompromised patients.

7505 Influenza A&B RT-PCR w/Reflex to Influenza A H1N1 (2009) (Available November 24)

Component	Method	Reference Range/Units
Specimen Source		
Influenza A RNA	**RT-PCR**	**Not detected**
Influenza B RNA	**RT-PCR**	**Not detected**

Specimen/Stability	Swab Viral Transport 3.0 (0.4) mL: Ambient 48 hours, Refrigerated 7 days, Frozen 30 days
Alt Specimen	M4 Transport Media/Swab 3.0 (0.4) mL: Ambient 48 hours, Refrigerated 7 days, Frozen 30 days Universal Transport Media: Ambient 48 hours, Refrigerated 7 days, Frozen 30 days
Collection Instructions	Collect nasal swab, nasopharyngeal swab, throat swab or nasal aspirate in 3 mL viral transport media, V-C-M media (green-cap) tube or equivalent universal transport media (UTM) or multimicrobe media (M4). Use only sterile swabs: dacron, nylon or rayon with plastic shafts. Label the container with two unique patient identifiers. Ship overnight at 2-8 degrees Celsius.
Schedule	Sunday-Saturday
Report	Same day
CPT Code	87798x2
Regulatory Status	Laboratory Developed Test
Always Statement	This test(s) was developed and its performance characteristics have been determined by Specialty Laboratories. Performance characteristics refer to the analytical performance of the test.
Note	Influenza A detected results will automatically reflex to Influenza A H1N1 (2009) Real-Time RT-PCR for an additional fee (CPT code 87798x2). This test is not approved for the testing of patient samples from New York State.
Clinical Utility	This test is used to determine the presence of Influenza A or B in a patient's specimen. Organisms may be detected by PCR before diagnosis by immunological methods. PCR provides more rapid results than other methods, including culture.

New Tests (*Specialty*): (cont'd)

7515 Influenza Virus Type A and B RNA, Qual Real-Time PCR

(Available November 24)

Component	Method	Reference Range/Units
Specimen Source		
Influenza A RNA	**RT-PCR**	**Not detected**
Influenza B RNA	**RT-PCR**	**Not detected**

Specimen/Stability	Swab Viral Transport 3.0 (0.4) mL: Ambient 48 hours, Refrigerated 7 days, Frozen 30 days
Alt Specimen	M4 Transport Media/Swab 3.0 (0.4) mL: Ambient 48 hours, Refrigerated 7 days, Frozen 30 days Universal Transport Media: Ambient 48 hours, Refrigerated 7 days, Frozen 30 days
Collection Instructions	Collect nasal swab, nasopharyngeal swab, throat swab or nasal aspirate in 3 mL viral transport media, V-C-M media (green-cap) tube or equivalent universal transport media (UTM) or multimicrobe media (M4). Use only sterile swabs: dacron, nylon or rayon with plastic shafts. Label the container with two unique patient identifiers. Ship overnight at 2-8 degrees Celsius.
Schedule	Sunday-Saturday
Report	Same day
CPT Code	87798x2
Regulatory Status	Laboratory Developed Test
Always Statement	This test(s) was developed and its performance characteristics have been determined by Specialty Laboratories. Performance characteristics refer to the analytical performance of the test.
Note	This test is not approved for the testing of patient samples from New York State.
Clinical Utility	This test is used to determine the presence of Influenza A or B in a patient's specimen. Organisms may be detected by PCR before diagnosis by immunological methods. PCR provides more rapid results than other methods, including culture.

1511 Properdin Factor B

(Available December 22)

Component	Method	Reference Range/Units
Properdin Factor B	**NEPH**	**23 – 67 mg/dL**

Specimen/Stability	Serum 1.0 (0.5) mL: Ambient 3 days, Refrigerated 3 days, Frozen 1 month
Collection Instructions	Serum should be physically separated from contact with cells within 2 hours from the time of collection.
Schedule	Tuesday, Thursday, Saturday
Report	Same day
CPT Code	83883
Regulatory Status	FDA-approved
Clinical Utility	The deposition of properdin factor B (PFB) in body tissue, or a corresponding depression in the amount of PFB in serum, is evidence of the involvement of the alternative to the classical pathway of activation of complement (a group of plasma proteins which cause the destruction of cells which are foreign to the body). Measurement of PFB aids in the diagnosis of several kidney diseases e.g., chronic glomerulonephritis (inflammation of the glomeruli of the kidney), lupus nephritis as well as several other skin diseases. Other diseases in which the alternate pathway of complement activation has been implicated include rheumatoid arthritis, sickle cell anemia, and gram negative bacteremia.

New Tests (*Specialty*): (cont'd)

1780 Phosphatidylglycerol Antibody (IgG) (Available January 18)

Component	Method	Reference Range/Units
Phosphatidylglycerol IgG Autoantibodies	**EIA**	**<10 U/mL**

Specimen/Stability	Serum 1.0 (0.5) mL: Refrigerated 14 days, Frozen 2 months
Schedule	Tuesday, Thursday
Report	Same day
CPT Code	84081
Regulatory Status	Research Use Only
Always Statement	This test(s) 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 Specialty Laboratories. This test should not be used for diagnosis without confirmation by other medically established means.
Note	This test is not approved for the testing of patient samples from New York State.
Clinical Utility	Detect antibodies directed at phospholipid epitopes.

1781 Phosphatidylglycerol Antibody (IgM) (Available January 18)

Component	Method	Reference Range/Units
Phosphatidylglycerol IgM Autoantibodies	**EIA**	**<10 U/mL**

Specimen/Stability	Serum 1.0 (0.5) mL: Refrigerated 14 days, Frozen 2 months
Schedule	Tuesday, Thursday
Report	Same day
CPT Code	84081
Regulatory Status	Research Use Only
Always Statement	This test(s) 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 Specialty Laboratories. This test should not be used for diagnosis without confirmation by other medically established means.
Note	This test is not approved for the testing of patient samples from New York State.
Clinical Utility	Detect antibodies directed at phospholipid epitopes.

1782 Phosphatidylglycerol Antibody (IgA) (Available January 18)

Component	Method	Reference Range/Units
Phosphatidylglycerol IgA Autoantibodies	**EIA**	**<10 U/mL**

Specimen/Stability	Serum 1.0 (0.5) mL: Refrigerated 14 days, Frozen 2 months
Schedule	Tuesday, Thursday
Report	Same day
CPT Code	84081
Regulatory Status	Research Use Only
Always Statement	This test(s) 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 Specialty Laboratories. This test should not be used for diagnosis without confirmation by other medically established means.
Note	This test is not approved for the testing of patient samples from New York State.
Clinical Utility	Detect antibodies directed at phospholipid epitopes.

New Tests (*Specialty*): (cont'd)

1770 Phosphatidic Acid Antibody (IgG) (Available January 18)

Component	Method	Reference Range/Units
Phosphatidic Acid IgG Autoantibodies	**EIA**	**<10 U/mL**

Specimen/Stability	Serum 1.0 (0.5) mL: Refrigerated 14 days, Frozen 2 months
Schedule	Tuesday, Thursday
Report	Same day
CPT Code	83520
Regulatory Status	Research Use Only
Always Statement	This test(s) 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 Specialty Laboratories. This test should not be used for diagnosis without confirmation by other medically established means.
Note	This test is not approved for the testing of patient samples from New York State.
Clinical Utility	Detect antibodies directed at phospholipid epitopes.

1768 Phosphatidic Acid Antibody (IgM) (Available January 18)

Component	Method	Reference Range/Units
Phosphatidic Acid IgM Autoantibodies	**EIA**	**<10 U/mL**

Specimen/Stability	Serum 1.0 (0.5) mL: Refrigerated 14 days, Frozen 2 months
Schedule	Tuesday, Thursday
Report	Same day
CPT Code	83520
Regulatory Status	Research Use Only
Always Statement	This test(s) 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 Specialty Laboratories. This test should not be used for diagnosis without confirmation by other medically established means.
Note	This test is not approved for the testing of patient samples from New York State.
Clinical Utility	Detect antibodies directed at phospholipid epitopes.

1769 Phosphatidic Acid Antibody (IgA) (Available January 18)

Component	Method	Reference Range/Units
Phosphatidic Acid IgA Autoantibodies	**EIA**	**<10 U/mL**

Specimen/Stability	Serum 1.0 (0.5) mL: Refrigerated 14 days, Frozen 2 months
Schedule	Tuesday, Thursday
Report	Same day
CPT Code	83520
Regulatory Status	Research Use Only
Always Statement	This test(s) 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 Specialty Laboratories. This test should not be used for diagnosis without confirmation by other medically established means.
Note	This test is not approved for the testing of patient samples from New York State.
Clinical Utility	Detect antibodies directed at phospholipid epitopes.

Test Changes:

5971 **Thrombotic Risk Evaluation 2**

Effective	Immediately
Specimen/Stability #1	Plasma Citrated 4.0 (2.0) mL: Frozen 14 days
Specimen/Stability #2	Serum 2.0 (1.0) mL: Ambient 48 hours, Refrigerated 14 days, Frozen 2 months **Note: Ambient and refrigerated serum now accepted.**

5973 **Thrombotic Risk Evaluation 3**

Effective	Immediately
Specimen/Stability #1	Plasma Citrated 6.0 (3.0) mL: Frozen 14 days
Specimen/Stability #2	Serum 2.0 (1.0) mL: Ambient 48 hours, Refrigerated 7 days, Frozen 2 months **Note: Ambient serum now accepted.**

3220 **Insulin-Like Growth Factor 1 (IGF-1)**

Effective	Immediately
Collection Instructions	Avoid freeze/thaw cycles. Rejection criteria: moderate hemolysis; specimens received at room temperature.
Also affected	DOS Code 3178

4866R **Magnesium RBC**

Effective	Immediately
Specimen/Stability	RBC from WB EDTA Trace Metal 2.0 (1.0) mL: Refrigerated 72 hours
Alt Specimen	RBC from WB Heparin Trace Metal 2.0 (1.0) mL: Refrigerated 72 hours Whole Blood EDTA Trace Metal 2.0 (1.0) mL: Refrigerated 72 hours Whole Blood Heparin Trace Metal 2.0 (1.0) mL: Refrigerated 72 hours **Note: Whole Blood specimens are now accepted.**

2386P ***Streptococcus pneumoniae* IgG Abs, 14 Serotypes, Pre/Post**

Effective	Immediately
Collection Instructions	Post sample is collected 4-6 weeks after vaccination and submitted together with frozen pre-sample.
Also affected	DOS Codes 2384P, 2388P

3550 **Osteocalcin**

Effective	Immediately
Collection Instructions	Patient should fast for 12 hours prior to collection. Hemolyzed specimens are not suitable for analysis.

7510 **Influenza A H1N1 (2009) Real-Time RT-PCR**

Effective	November 30
Component 1	Specimen Source (no change)
Component 2	Influenza A RNA (no change)
Component 3	2009 H1N1 Influenza RNA **(NEW NAME)**

Test Changes: (cont'd)

3525 Vitamin A & Vitamin D, 25-Hydroxy

Effective	December 15
Component 1	Vitamin A (Retinol) (no change)
Component 2	Vitamin D, 25-OH, Total **(NEW NAME)**
Methodology	LC-MS-MS **(NEW)**
Reference Range	20-100 ng/mL **(NEW)**
Component 3	Vitamin D, 25-OH, D2 **(NEW)**
Methodology	LC-MS-MS
Component 4	Vitamin D, 25-OH, D3 **(NEW)**
Methodology	LC-MS-MS
Specimen/Stability	Serum Foil Wrapped 4.0 (2.0) mL: Ambient 48 hours, Refrigerated 14 days, Frozen 21 days **Note: Increased refrigerated and decreased frozen stability.**
Collection Instructions	Serum is the only acceptable specimen type. Do not use any additives. Protect from light: use foil wrapping or amber tubes.

1831 ER (Estrogen Receptor), Breast Cancer

Effective	December 22
FDA Status	Analyte Specific Reagent
Always Statement	This test(s) was developed and its performance characteristics have been determined by Specialty Laboratories. 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.
Also affected	DOS Codes 1813, 1817, 1818, 1819, 1830, 1833, 1839, 1840, 1842

1832 PR (Progesterone Receptor), Breast Cancer

Effective	December 22
FDA Status	Analyte Specific Reagent
Always Statement	This test(s) was developed and its performance characteristics have been determined by Specialty Laboratories. 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.
Also affected	DOS Codes 1813, 1817, 1818, 1819, 1830, 1833, 1839, 1840, 1842

1845 Ki-67 (MIB-1), Breast Cancer

Effective	December 22
FDA Status	Analyte Specific Reagent
Always Statement	This test(s) was developed and its performance characteristics have been determined by Specialty Laboratories. 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.
Also affected	DOS Codes 1813, 1817, 1833, 1839

1846 HER-2/*neu* [IHC], Breast Cancer

Effective	December 22
FDA Status	Analyte Specific Reagent
Always Statement	This test(s) was developed and its performance characteristics have been determined by Specialty Laboratories. 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.
Also affected	DOS Codes 1817, 1818, 1819, 1833, 1839, 1840, 1842, 5846

Test Changes: (cont'd)

3114 Angiotensin Converting Enzyme (ACE)

Effective	December 22	
Reference Range	0 – 17 years	13 – 100 U/L **(NEW)**
	> 17 years	9 – 67 U/L **(NEW)**

3123 Cholinesterase Serum

Effective	January 5	
Specimen/Stability	Serum 2.0 (1.0) mL: Ambient 2 weeks, Refrigerated 2 weeks, Frozen 1 month **Note: Increased ambient and refrigerated; decreased frozen stability.**	
Reference Range	Female	2673 – 6592 IU/L **(NEW)**
	Male	3342 – 7586 IU/L **(NEW)**

3123R Cholinesterase RBC

Effective	January 5
Specimen/Stability	Whole Blood EDTA 2.0 (1.0) mL: Ambient 8 hours, Refrigerated 1 week **Note: Decreased ambient; increased refrigerated stability.**
Reference Range	9572 – 15031 IU/L **(NEW)**

3123PL Cholinesterase Plasma

Effective	January 5	
Specimen/Stability	Plasma EDTA 2.0 (1.0) mL: Ambient 2 weeks, Refrigerated 2 weeks, Frozen 1 month **Note: Increased ambient and refrigerated; decreased frozen stability.**	
Reference Range	Female	2504 – 6297 IU/L **(NEW)**
	Male	3334 – 7031 IU/L **(NEW)**
Also affected	DOS Code 3123PLSR	

4311 Cyclosporine A & Metabolites Whole Blood [FPIA-Monoclonal]

Effective	January 5		
Name	Cyclosporine A in Whole Blood [Immunoassay]		
Specimen/Stability	Whole Blood EDTA 5.0 (2.0) mL: Ambient 7 days, Refrigerated 7 days, Frozen 1 month **Note: Frozen specimens now accepted; increased ambient and decreased refrigerated stability. Heparin specimens are no longer accepted.**		
Reference Range	Trough	100 – 300 ng/mL **(NEW)**	
	Peak	300 – 1700 ng/mL **(NEW)**	
Always Statement	No definitive therapeutic or toxic ranges have been established. Optimal blood drug levels are influenced by type of transplant, patient response, time post-transplant, co-administration of other drugs and drug formulation. The following trough/peak level ranges are suggested guidelines.		
	Trough	Kidney Transplantation:	100-200 ng/mL
		Other Organ Transplantation:	200-300 ng/mL
	Peak	de Novo:	1500-1700 ng/mL
		1st 6 months:	800-1000 ng/mL
		6-12 months:	600-800 ng/mL
		Greater than 1 year:	300-600 ng/mL
Also affected	DOS Code 4311SR		

Test Changes: (cont'd)

5948 Tacrolimus

Effective	January 5
Specimen/Stability	Whole Blood EDTA 5.0 (0.5) mL: Ambient 7 days, Refrigerated 7 days, Frozen 2 months **Note: Increased ambient and decreased refrigerated stability.**
Methodology	Immunoassay

1771 Phosphatidic Acid IgG, IgM & IgA Autoabs

Effective	January 18
Name	Phosphatidic Acid Antibodies (IgG, IgA, IgM)
Reference Range	IgG < 10 U/mL (same) IgM < 10 U/mL (same) IgA < 10 U/mL **(NEW)**
FDA Status	Research Use Only
Always Statement	This test(s) 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 Specialty Laboratories. This test should not be used for diagnosis without confirmation by other medically established means.
Also affected	DOS Codes 1082, 1776

1775 Phosphatidylglycerol IgG, IgM & IgA Autoabs

Effective	January 18
Name	Phosphatidylglycerol Antibodies (IgG, IgA, IgM)
Reference Range	IgG < 10 U/mL (same) IgM < 10 U/mL (same) IgA < 10 U/mL **(NEW)**
FDA Status	Research Use Only
Always Statement	This test(s) 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 Specialty Laboratories. This test should not be used for diagnosis without confirmation by other medically established means.
Also affected	DOS Code 1776

The CPT Codes provided 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 CPT Coding to the payer being billed.

New Referral Tests:

The following tests are now available from Quest Diagnostics and may be referred through Specialty Laboratories.

S52089 **Culture, Fungus, other than Hair, Skin, Nail, w/Fluorescent**
This test is not approved for the testing of patient samples from New York State.
Test performed by Quest Diagnostics, West Hills

Please call client relations at 800-421-4449 or visit our website at *www.specialtylabs.com* for ordering information.

Discontinued Tests:

Effective November 24:

S52074 **Influenza A/B RT-PCR Rfx to Influenza A H1N1 (09) RT-PCR [42699]**
Recommended replacement: 7505 – Influenza A&B RT-PCR w/Reflex to Influenza A H1N1 (2009)
Performed at Specialty Laboratories

S52073 **Influenza A and B RNA, Qual. Real-Time RT-PCR [42684]**
Recommended replacement: 7515 – Influenza Virus Type A and B RNA, Qual Real-Time PCR
Performed at Specialty Laboratories

Effective December 21:

3114C **Angiotensin Converting Enzyme (ACE) CSF**
Recommended replacement: S52055 – Angiotension Converting Enzyme (ACE), CSF [34692X]
Performed at Quest Diagnostics, San Juan Capistrano