SPECIALTY LABORATORIES
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Test Updates

August 7, 2007

Dear Colleague:

In an effort to ensure the most effective and accurate patient reporting, *Specialty* recognizes the need for clarification of our policy regarding specimen types that are acceptable for testing. Federal law* requires all clinical testing to be performed only after the performance characteristics of the test have been verified, either by the kit manufacturer (and validated by the clinical lab), or by the clinical laboratory itself in the case of a user-developed assay or a modification of a marketed assay. This includes a validation for each acceptable specimen type (whole blood, serum, plasma, CSF, and urine etc). These validations are available for all tests that *Specialty* offers, and information can be verified by utilizing our web-based test directory or by calling Client Relations. Requests for non-validated specimen types will be rejected, and you will be notified by client relations.

Specialty recognizes the need to provide standard-of-care for patients where analyzing uncommon specimen types are of medical importance, and will continue to collect scientific information to expand specimen type acceptability. If you have any questions about this policy, please contact Client Relations.

If you have any interest in a clinical collaboration to help validate an uncommon specimen type, please contact Ryan McCoy, Product Manager, at 800-421-7110 Ext. 6721 or e-mail to rmccoy@specialtylabs.com . We sincerely appreciate your attention to such a critical step in the testing process and look forward to assisting you in the future.

On the following pages are changes to our testing protocols that require your immediate attention. In the area of infectious disease testing we are pleased to announce a lower detection limit for the **Hepatitis B Virus DNA UltraQuant®** (down to 100 copies/mL) and the addition of Universal Transport Media (UTM) as an acceptable alternate specimen for ***Chlamydia trachomatis/N. gonorrhoeae* rRNA PLUS [TMA] Swab (7438SW).**

NY Clients please note that ***Borrelia burgdorferi* DNA DetectR™ (7570)** is currently in the NY approval process and is not yet available for NY patients.

For additional information, please visit our Web site at www.specialtylabs.com or contact Client Relations at 800-421-4449.

Christopher Lockhart, M.D.
Laboratory Director

* Denise Driscoll, MS, MT (ASCP) SBB, Director, Accreditation Cycle, Laboratory Accreditation Programs, College of American Pathologists: See Federal Register 1992(Feb 28):7164 [42CFR493.1213], 1994(Dec 6):62607-62608 [42CFR43.1449], CAP Laboratory General (GEN) Inspection Checklist, Items GEN.42020, GEN.42025, GEN.42030, GEN.42140, GEN.42160.

Discontinued

Effective August 31, 2007:

4427 **Fecal Fat, Quantitative**
Replaced by: S51333

2936 **Methicillin-Resistant *Staphylococcus aureus* (MRSA) *mecA* DetectR™**
Replaced by: S51334

4993 **Amino Acid Profile, Quant, Plasma with reflex Interpretation**

4991 **Amino Acid Profile, Quantitative, Plasma**
Replaced by: S51335

4998 **Amino Acid Profile, Qualitative, Plasma**

Effective Immediately:

5888 **Array CGH**
Replaced by: S51332

7711SF ***Borrelia burgdorferi* IgG & IgM Antibodies Synovial Fluid [IB]**
Replaced by: S51336

7711SFB ***Borrelia burgdorferi* IgG & IgM Antibodies + Bands Syn FL IB [CDC]**
1060 **Lymphocyte Mitogen Proliferation Analysis**
1648 **Lymphocyte Antigen Proliferation Analysis**
1640 **Lymphocyte Mitogen Proliferation Analysis, PHA**
1641 **Lymphocyte Mitogen Proliferation Analysis, PWM**
1642 **Lymphocyte Mitogen Proliferation Analysis, Con A**
1643 **Lymphocyte Antigen Proliferation Analysis, Candida**
1645 **Lymphocyte Antigen Proliferation Analysis, PPD**
1644 **Lymphocyte Antigen Proliferation Analysis, Tetanus**
1062 **Lymphocyte Antigen & Mitogen Proliferation Analysis**

Test Changes:

3895 **Activated Partial Thromboplastin Time**

Effective	Immediately
Ref. Range	27.0 – 38.0 seconds
Also Affected	3896, 5961, 5962, 5963, 5976, 1910

5900 **Activated Protein C Resistance**

Effective	Immediately
Interpretation	Greater than 2.22.....Negative Less than or = 2.22.....Positive
CPT Code	85307x1
Also Affected	5901, 5971, 5872, 5973

7570 *Borrelia burgdorferi* DNA DetectR™

Effective	Immediately
Note	This test is not approved for the testing of patient samples from New York State.
Also Affected	7570, 7570T, 7521, 2936, 7494, 7785, 7587, 7588, 7524, 7523, 7520, 7519, 7517, 1828

7438SW *Chlamydia trachomatis/N. gonorrhoeae* rRNA PLUS [TMA] Swab

Effective	Immediately
Alt. Specimen	1 (1) mL Universal Transport Media (UTM); Ambient – 4 Days, Refrigerated – 4 Days
Also Affected	2932SW, 2937SW, 7435SW, 7437SW, 7440SW

1530 Complement C1 Esterase Inhibitor

Effective	September 5, 2007
Ref. Range	21 – 39 mg/dL
Also Affected	1529

8137 Hepatitis B Virus DNA UltraQuant®

Effective	Immediately
Ref. Range	< 100 copies/mL < 19 IU/mL
Clinical Utility	Quantitates Hepatitis B Virus DNA down to 100 copies/mL for establishment of a baseline and to monitor viral load. Viral loads greater than 100,000,000 copies/mL will be run on dilution. The most important test for determining the efficacy of antiviral treatment is quantitative HBV DNA monitoring. HBV DNA testing is useful in detecting potential disease transmission from prospective donors and for post-transplantation monitoring. Although HBeAg is considered an indirect monitor of viral replication, high viral replication may occur without circulating HBeAg, due to mutations of the virus preventing the production of HBeAg.
Also Affected	2479

1911 Lupus Anticoagulant: DRVVT reflex to Confirmation

Effective	Immediately
Ref. Range	LAC Screen Result Not detected Abnormal results will be confirmed: Normalized LAC Ratio < 1.2 LAC Interpretation: Normalized LAC Ratio <1.2 LA is not detected Normalized LAC Ratio between 1.2 – 1.5 LA is present (weak) Normalized LAC Ratio greater than 1.5 – 2.0 LA is present (moderate) Normalized LAC Ratio greater than 2.0 LA is present (strong)
Note	Heparin therapy range removed.
Also Affected	1081, 1910, 5963, 5962, 5976, 1082

2945 Malaria Organism Detection

Effective	Immediately
Collection	1- Prepare thick and thin smears within 1 hour of collection. 2- Send all three specimen types (whole blood EDTA, thin smears, and thick smears).

3892 Prothrombin Time

Effective	Immediately
Ref. Range	10.4 – 13.5 seconds
INR (Int. Norm. Ratio)	0.90 – 1.12
Also Affected	5962, 5976, 3893

4210 Thrombin Time

Effective	Immediately
Ref. Range	11.4 – 15.9 seconds
Also Affected	5962, 5976

1907 Von Willebrand Factor Antigen

Effective	Immediately
Ref. Range	61 – 164 %
Note	Reference range of group O Blood may have 30% less than value listed above.
Also Affected	1905, 5961, 5981, 5991, 5984