SPECIALTY LABORATORIES
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May 2006

Dear Colleague:

We are changing the format of our client letters with this issue. From now on, information on new tests will be provided separately from test changes and routine announcements. This will give us an opportunity to provide more detail in our descriptions of new tests and their clinical utility. Clients will be able to find specific test changes more readily in our new format.

New Tests

In a separate letter you will find information on our newest test offerings:

- #5390 JAK-2 Mutation DetectR™
- #5384 UGT1A1 GenotypR™

Accumin Microalbumin Assay Not Available

Accumin Diagnostics, Inc. has advised the Food and Drug Administration of non-conformity of the column component of the Accumin Direct Total Intact Albumin Assay manufactured by Agilent Technologies, Inc. and distributed by Accumin Diagnostics. Agilent and Accumin Diagnostics are currently conducting testing to determine if the difference in packing material has an effect on the diagnostic specificity, sensitivity and/or accuracy of the Accumin Direct Total Intact Albumin Assay.

Thus, the following *Specialty* tests will not be available until further notice. Please call Client Services at 800-421-4449 to determine availability after June 1, 2006.

3443U Accumin (Intact Microalbumin) Timed Urine
3443UR Accumin (Intact Microalbumin) Urine Random W/Creat

24-Hour Urine Total Volumes

Please note that valuable time is lost in reporting results of tests performed on aliquots of 24-hour urine when the total 24-hour urine volume is not specified on the requisition and the aliquot tube. Please include the total urine volume for all tests for which urine is collected over a 24-hour period. Containers for 24-hour urine collections and aliquots are available from *Specialty*.

State Reporting Requirements -- Lead

Many states have determined that lead exposure represents a significant environmental health problem and have stringent requirements for reporting the results of lead testing. Although these requirements vary somewhat from state-to-state, they generally include information on patient gender, age and race as well as contact information for the patient and his/her physician. Specific requirements for individual states are listed on the *Specialty* Website under “Products and Services”. Please include the information required by your state with any requests for lead testing. For more information on state reporting requirements, please contact Support Systems at 800-421-7110, ext. 6770.

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

Michael C. Dugan, M.D.
Vice President and Laboratory Director

Test Changes

2419 AFB Culture and Stain
(effective 6-20-06)

Specimen — Whole Blood is now an acceptable specimen.
However, mycobacteria are often present in either very low concentrations or intermittently in peripheral blood. AFB blood stains may, therefore, yield false-negative results. Interpret these results with caution.
Also Affects — 5320 AFB Stain

4991 Amino Acid Profile, Quantitative, Plasma
(effective immediately)

CPT Code — 82139x1
Also affects — 4993 Amino Acid Profile, Quant, Plasma with reflex Interpretation

4998 Amino Acid Profile, Qualitative, Plasma
(effective immediately)

CPT Code — 82128x1

2376 Antistreptolysin O antibodies (ASO)
(effective immediately)

CPT Code — 83883
Also affects — 1726 Rapidly Progressive Glomerulonephritis Evaluation

1650 Cellular Immune Dysfunction Evaluation
(effective immediately)

CPT Code — 85048, 86355, 86359, 86360, **86586x3** (replacing 88184 and 88185x2)
Also affects — 1651 Chronic Fatigue & Immune Dysfunction Syndrome Evaluation

7438SW *Chlamydia trachomatis/N. gonorrhoeae* rRNA PLUS [TMA) ~~Swab~~
(effective 6/20/06)

New Name — *Chlamydia trachomatis/N. gonorrhoeae* rRNA PLUS [TMA]
The "swab" was deleted. The "swab" designation was used to differentiate this test from test on urine. However, a swab is not the only acceptable sample type for this assay as liquid cytology media can be used.

Also affects
7435SW *Chlamydia trachomatis* Confirmation [TMA] ~~Swab~~
7437SW *Chlamydia trachomatis* rRNA Detection [TMA] ~~Swab~~
2937SW *Neisseria gonorrhoeae* Confirmation [TMA] ~~Swab~~
2932SW *Neisseria gonorrhoeae* rRNA Detection [TMA] ~~Swab~~

7440SW *Chlamydia trach/Neisseria* rRNA PLUS [TMA] ~~Swab~~ w/rfx Confirm
(effective 6/20/06)

New Name — *Chlamydia trach/N. gonorrhoeae* rRNA PLUS [TMA] w/rfx Confirm

1101 Mitochondrial (M2) IgG Autoantibody
(effective immediately)

New Name — Mitochondrial M2 **EP (MIT3)** IgG Autoantibody
Component — AMA-M2 EP (MIT3) IgG Autoabs
Ref Range — Negative < 20.1 Units
Equivocal 20.1 – 24.9 Units
Positive > 24.9 Units
Also affects — 1002 Tissue Total Autoantibodies Screen
5906 Hepatitis Autoimmune EvaluatR™ PLUS
5908 Hepatitis Autoimmune EvaluatR™

Due to manufacturer's replacement with an improved kit for Mitochondrial Autoantibody testing, *Specialty* was unable to provide notification of test change earlier. We regret any inconvenience this may cause our clients. Note that the MIT3 antigen used for detection of mitochondrial M2 autoantibodies contains immunodominant epitopes of the E2 subunits of the pyruvate dehydrogenase complex (PDC-E2), the branched-chain 2-oxo-acid dehydrogenase complex (BCOADC-E2), and the 2-oxo glutarate dehydrogenase complex (OGDC-E2). Reference – Moteki, S. et al. Use of a designer triple expression hybrid clone for three different lipoyl domains for the detection of antimitochondrial autoantibodies. Hepatology 1996; 24:97-103.

1337 *Streptococcus pyogenes*, Group A Antibodies (Streptozyme®)

(effective immediately)

CPT Code 86060

4046 Sulfoglucuronyl Paragloboside (SGPG) IgM Autoabs

(effective 6/20/06)

Ref Range Negative <1.0 Positive > or = 1.0
New Name **Sulfate-3-Glucuronyl** Paraglaboside (SGPG) IgM Autoabs
Also Affects 4020 Motor & Sensory Neuropathy EvaluatR™
4021 Motor & Sensory Neuropathy Evaluation
4026 Motor Neuropathy Evaluation
4030 Sensory Neuropathy EvaluatR™
4031 Sensory Neuropathy Evaluation
4051 MAG & SGPG IgM Autoabs

2410 Viral Culture

(effective immediately)

Specimen/ Stability for CSF Frozen 7 days

Test Discontinuations

The following test(s) are no longer routinely available from *Specialty*. Whenever possible, alternate tests are recommended. Please note that if a test is designated as a "replacement," contractual pricing will be copied from discontinued test to replacement test. Contractual pricing does not apply to alternate tests or sendout tests. Please contact Client Services or your Sales Representative if you have any questions.

Test Code	Test Name	Reason/Date	Alternate or Replacement Tests
3443U	Accumin (Intact Microalbumin) Timed Urine	Kit manufacturer problem - temporarily unavailable (see front page)	3441U Microalbumin 24 hour Urine
3443UR	Accumin (Intact Microalbumin) Urine Random w/Creat	Kit manufacturer problem - temporarily unavailable (see front page)	3441UR Microalbumin UrineRandom
3137	YKL-40 (Human Cartilage Glycoprotein 39)	Low volume discontinued 6/20/06	n/a
S51074	JAK2 (sendout)	Replaced by in house test/7/5/06	5390 JAK-2 Mutation DetectR™
9921NY	HIV-2 IgG Abs w/Reflex IB New York	Comparable tests approved for New York; discontinue 6/20/06	9921 HIV-2 IgG Abs w/Reflex IB
9915NY	HIV-1/HIV-2 Antibodies [EIA] w/Reflex IB New York	Comparable tests approved for New York; discontinue 6/20/06	9915 HIV-1/HIV-2 Antibodies [EIA] w/Reflex IB
9915NYB	HIV-1/HIV-2 Antibodies [EIA] w/Reflex IB + Bands New York	Comparable tests approved for New York; discontinue 6/20/06	9915B HIV-1/HIV-2 Antibodies [EIA] w/Reflex IB + Bands
3012NY	HIV-1 Abs [IB] New York	Comparable tests approved for New York; discontinue 6/20/06	3012 HIV-1 Abs [IB]
3012NYB	HIV-1 Abs [IB] + Bands New York	Comparable tests approved for New York; discontinue 6/20/06	3012B HIV-1 Abs [IB] + Bands
9926BNY	HIV-2 IgG Antibodies [IB] + Bands New York	Comparable tests approved for New York; discontinue 6/20/06	9926B HIV-2 IgG Antibodies [IB] + Bands

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