SPECIALTY LABORATORIES
27027 Tourney Road 800•421•7110
Valencia, CA 91355 www.specialtylabs.com

Test Updates

February 20, 2008

Dear Colleague:

Specialty Laboratories is pleased to announce the immediate availability of three molecular diagnostic assays for the confirmation of prenatally-diagnosed aneuploidy of products of conception using formalin-fixed, paraffin-embedded tissues. Our existing studies, Chromosomes X & Y Aneuploidy DetectR™ (5859), Trisomy 13, 18, and 21 DetectR™ (5857) and Aneuploidy 13-18-21-X-Y DetectR™ (5855), can now be requested for tissue block specimens by ordering the test with a "BK" suffix added after the directory of service code.

When sending frozen fluid samples, please note that only one test can be run on a single frozen fluid sample. If you must send a frozen fluid sample, please do send one for each test ordered.

For Clients in New York State, the FLT3 & NPM1 GenotypR™ (5038) is now approved by the NYS Department of Health. The FLT3 & NPM1 GenotypR™ is useful in evaluating prognosis in Acute Myeloid Leukemia (AML) patients with a normal karyotype. FLT3 & NPM1 GenotypR™ can be performed on whole blood, bone marrow and formalin-fixed, paraffin-embedded tissues (5038BK).

Section 79-1 of the New York State Civil Rights Law requires written informed consent of Genetic testing on biological samples prior to testing. When ordering Genetic tests please be sure informed consent is obtained and kept on file in the patient chart. Informed consent forms for *Specialty* tests are available on our website from the menu bar Products & Services/Consent Forms or by going to the following link:

http://www.specialtylabs.com/services/forms/default.asp

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.
Laboratory Director

New Tests:

5859BK Chromosomes X & Y Aneuploidy DetectR™ - Paraffin
(Available Immediately)

Component	Method	Reference Range/Units
Chromosome X & Y Aneuploidy	**PCR**	**By report**

Specimen/Stability	1 paraffin embedded tissue block; Ambient indefinite
Collection	4 sections of 50 microns thick, paraffin embedded tissue may also be submitted
Schedule	Tuesday
Report	5 days
CPT Code	83891, 83900, 83901x8, 83909, 83912, 83907
Clinical Utility	Detects sex chromosome aneuploidies including Turner syndrome (monosomy X) and Klinefelter syndrome (predominantly 47,XXY) and other sex chromosome abnormalities such as 47,XYY and 47,XXX.
Note	This test is not intended to be used as a stand alone assay for making clinical decisions. The test results are intended to be used in conjunction with other clinical information and further confirmatory karyotyping when requested for rapid identification of suspected chromosomal abnormalities. This assay will not detect chromosome mosaicism, duplications, deletions, or structural rearrangements and does not identify all birth and/or developmental abnormalities. This test is not available for patients from New York State.

5857BK Trisomy 13, 18, and 21 DetectR™ - Paraffin
(Available Immediately)

Component	Method	Reference Range/Units
Trisomy 13, 18 & 21	**PCR**	**By report**

Specimen/Stability	1 paraffin embedded tissue block; Ambient indefinite
Collection	4 sections of 50 microns thick, paraffin embedded tissue may also be submitted
Schedule	Tuesday
Report	5 days
CPT Code	83891, 83900, 83901x14, 83909x2, 83912, 83907
Clinical Utility	Assay provides rapid detection of trisomies 13, 18 and 21.
Note	This test is not intended to be used as a stand alone assay for making clinical decisions. The test results are intended to be used in conjunction with other clinical information and further confirmatory karyotyping when requested for rapid identification of suspected chromosomal abnormalities. This assay will not detect chromosome mosaicism, duplications, deletions, or structural rearrangements and does not identify all birth and/or developmental abnormalities. This test is not available for patients from New York State.

New Tests: (cont'd)

5855BK Aneuploidy 13-18-21-X-Y DetectR™- Paraffin

(Available Immediately)

Component	Method	Reference Range/Units
Chromosomes 13, 18, 21, X & Y Aneuploidy	**PCR**	**By report**

Specimen/Stability	1 paraffin embedded tissue block; Ambient indefinite
Collection	4 sections of 50 microns thick, paraffin embedded tissue may also be submitted
Schedule	Tuesday
Report	5 days
CPT Code	83891, 83900, 83901x24, 83909x2, 83912, 83907
Clinical Utility	Assay provides rapid detection of trisomies 13, 18 and 21 and sex chromosome aneuploidies. These conditions account for nearly two-thirds of all abnormalities identified at the time of amniocentesis, and 95-98% of clinically significant chromosomal abnormalities detected in live-born infants.
Note	This test is not intended to be used as a stand alone assay for making clinical decisions. The test results are intended to be used in conjunction with other clinical information and further confirmatory karyotyping when requested for rapid identification of suspected chromosomal abnormalities. This assay will not detect chromosome mosaicism, duplications, deletions, or structural rearrangements and does not identify all birth and/or developmental abnormalities. This test is not available for patients from New York State.

Test Changes:

3945 PTH, C Terminal, including Total Calcium

Effective	Immediately
Ref Range	< 0.9 ng/mL
Also affects	3208, 3213

3445 Lipoprotein Electrophoresis

Effective	Immediately
Specimen/Stability	Serum 2.0 (1.0) mL; Ambient 3 days, Refrigerated 10 days

5857 Trisomy 13, 18 and 21 DetectR™ (PCR)

Effective	Immediately
Specimen/Stability	Whole Blood EDTA 3.0 (2.0) mL; Ambient 7 days, Refrigerated 7 days
Alternate Specimens	Amniotic Fluid 5.0 (2.0) mL; Ambient 3 days, Refrigerated 3 days Tissue 5.0 (3.0) mg; Frozen 12 Months NOTE: Amniotic fluid and Tissue are now acceptable specimens

5859 Chromosomes X & Y Aneuploidy DetectR™

Effective	Immediately
Specimen/Stability	Whole Blood EDTA 3.0 (2.0) mL; Ambient 7 days, Refrigerated 7 days
Alternate Specimens	Amniotic Fluid 5.0 (2.0) mL; Ambient 3 days, Refrigerated 3 days Tissue 5.0 (3.0) mg; Frozen 12 Months NOTE: Amniotic fluid and Tissue are now acceptable specimens

5855 Aneuploidy 13-18-21-X-Y DetectR™ (PCR)

Effective	Immediately
Specimen/Stability	Amniotic Fluid 5.0 (2.0) mL; Ambient 3 days, Refrigerated 3 days
Alternate Specimens	Whole Blood EDTA 3.0 (2.0) mL; Ambient 7 days, Refrigerated 7 days Tissue 5.0 (3.0) mg; Frozen 12 Months NOTE: Whole blood and Tissue are now acceptable specimens

1514 Alpha-1-Antitrypsin PhenotypR™ without Total AAT

Effective	March 11, 2008
Specimen/Stability	Serum 1.0 (0.5) mL; Refrigerated 14 days, Frozen 1 month NOTE: Ambient specimens are no longer acceptable
Also affected	1614

3851 Creatine Kinase (CK) Isoenzymes

Effective	Immediately
Specimen/Stability	Serum 2.0 (1.0) mL; Ambient 3 days, Refrigerated 7 days, Frozen 30 days NOTE: Frozen specimens are now acceptable

1040 Immune Complex DetectR™, Circulating

Effective	March 11, 2008
Component	C1q Binding Immune Complex – REMOVE All other components remain the same

Discontinued Tests:

Effective March 24, 2008:

7467 ***Mycobacterium* DNA DetectR™**
Replaced by: Discontinued - No replacement

1401 **Immune Complex Assay, C1q Binding**
Replaced by: S51585 - Immune Complex Detection by C1q Binding (36735X)

8831 ***Brucella* IgG, IgM & IgA Abs**
Replaced by: S51566 - *Brucella abortus* Ab Panel, IFA (40205)

8836 ***Brucella* IgG Abs**
Replaced by: S51565 - *Brucella* Antibody IgG (0050334)

8833 ***Brucella* IgM Abs**
Replaced by: S51567 - *Brucella* Antibody IgM (0050336)

1140 **Chromatin (Histone-DNA Complex) IgG Autoantibodies**
Replaced by: S51571 - Chromatin (Nucleosomal) Antibody (34088X)

3964 **Proinsulin**
Replaced by: S51596 - Proinsulin (760X)

8442 ***Entamoeba histolytica* IgG Abs [EIA]**
Replaced by: S51572 - *Entamoeba histolytica* Antibody (IgG), ELISA (30262X)

4204 **Fibrin Monomer, Soluble**
Replaced by: S51580 - Fibrin Monomer (11074X)

5939 **Prothrombin Fragment 1.2**
Replaced by: S51597 - Prothrombin Fragment 1.2 (37674X)

1957 **Factor XIII Activity, Qualitative**
Replaced by: S51573 - Factor XIII Activity, Functional (14461X) [Same as Quantitative Activity]

5206 **Ashkenazi-Jewish GenotypR™ - Carrier Panel**
Replaced by: S51560 - Ashkenazi Jewish Panel (10910X)

5216 **Bloom Syndrome GenotypR™ - Carrier Testing**
Replaced by: S51562 - Bloom Syndrome DNA Mutation Analysis-Carrier Testing (10224X)

5217 **Bloom Syndrome GenotypR™ - Diagnostic Testing**
Replaced by: S51563 - Bloom Syndrome DNA Mutation Analysis-Diagnostic Testing (10224X)

5218 **Bloom Syndrome GenotypR™ - Fetal Study w/Reflex to MCC**
Replaced by: S51564 - Bloom Syndrome DNA Mutation Analysis-Fetal Study (10224X)

5226 **Canavan GenotypR™ - Carrier Testing**
Replaced by: S51568 - Canavan Disease Mutation Analysis-Carrier Testing (31650X)

Discontinued Tests: (cont'd)

5227 **Canavan GenotypR™ - Diagnostic Testing**
Replaced by: S51569 - Canavan Disease Mutation Analysis-Diagnostic Testing (31650X)

5228 **Canavan GenotypR™ - Fetal Study w/Reflex to MCC**
Replaced by: S51570 - Canavan Disease Mutation Analysis-Fetal Study (31650X)

5236 **Familial Dysautonomia GenotypR™ - Carrier Testing**
Replaced by: S51574 - Familial Dysautonomia Mutation Analysis-Carrier Testing (16040X)

5237 **Familial Dysautonomia GenotypR™ - Diagnostic Testing**
Replaced by: S51575 - Familial Dysautonomia Mutation Analysis-Diagnostic Testing (16040X)

5238 **Familial Dysautonomia GenotypR™ - Fetal Study w/Reflex to MCC**
Replaced by: S51576 - Familial Dysautonomia Mutation Analysis-Fetal Study (16040X)

5246 **Fanconi Anemia GRPC GenotypR™ - Carrier Testing**
Replaced by: S51577 - Fanconis Anemia DNA Mutation Analysis-Carrier Testing (10221X)

5247 **Fanconi Anemia GRPC GenotypR™ - Diagnostic Testing**
Replaced by: S51578 - Fanconis Anemia DNA Mutation Analysis-Diagnostic Testing (10221X)

5248 **Fanconi Anemia GRPC GenotypR™ - Fetal Study w/Reflex to MCC**
Replaced by: S51579 - Fanconis Anemia DNA Mutation Analysis-Fetal Study (10221X)

5256 **Gaucher Disease GenotypR™ - Carrier Testing**
Replaced by: S51581 - Gaucher Disease, DNA Mutation Analysis-Carrier Testing (21503X)

5257 **Gaucher Disease GenotypR™ - Diagnostic Testing**
Replaced by: S51582 - Gaucher Disease, DNA Mutation Analysis-Diagnostic Testing (21503X)

5258 **Gaucher Disease GenotypR™ - Fetal Study w/Reflex to MCC**
Replaced by: S51583 - Gaucher Disease, DNA Mutation Analysis-Fetal Study (21503X)

5266 **Mucolipidosis Type IV GenotypR™ - Carrier Testing**
Replaced by: S51588 - Mucolipidosis Type IV Mutation Analysis-Carrier Testing (11192X)

5267 **Mucolipidosis Type IV GenotypR™ - Diagnostic Testing**
Replaced by: S51589 - Mucolipidosis Type IV Mutation Analysis-Diagnostic Testing (11192X)

5268 **Mucolipidosis Type IV GenotypR™ - Fetal Study w/Reflex to MCC**
Replaced by: S51590 - Mucolipidosis Type IV Mutation Analysis-Fetal Study (11192X)

5276 **Niemann-Pick Disease GenotypR™ - Carrier Testing**
Replaced by: S51592 - Niemann-Pick Disease Mutation Analysis-Carrier Testing (10222X)

5277 **Niemann-Pick Disease GenotypR™ - Diagnostic Testing**
Replaced by: S51593 - Niemann-Pick Disease Mutation Analysis-Diagnostic Testing (10222X)

Discontinued Tests: (cont'd)

5278 **Niemann-Pick Disease GenotypR™ - Fetal Study w/Reflex to MCC**
Replaced by: S51594 - Niemann-Pick Disease Mutation Analysis-Fetal Study (10222X)

5286 **Tay-Sachs Disease GenotypR™ - Carrier Testing**
Replaced by: S51598 - Tay-Sachs Disease Mutation Analysis-Carrier Testing (21502X)

5287 **Tay-Sachs Disease GenotypR™ - Diagnostic Testing**
Replaced by: S51599 - Tay-Sachs Disease Mutation Analysis-Diagnostic Testing (21502X)

5288 **Tay-Sachs Disease GenotypR™ - Fetal Study w/Reflex to MCC**
Replaced by: S51600 - Tay-Sachs Disease Mutation Analysis-Fetal Study (21502X)

1145 **IgD**
Replaced by: S51584 - IgD, Serum (541X)

1491 **Plasminogen, Quantitative**
Replaced by: S51595 - Plasminogen, Antigenic (5164X)

3294 **Tumor Necrosis Factor-Alpha**
Replaced by: S51601 - Tumor Necrosis Factor-Alpha, Highly Sensitive (34485X)

3828 **Interleukin-6**
Replaced by: S51587 - Interleukin-6, Highly Sensitive ELISA (34473X)

3832 **Interleukin-2 Receptor, Soluble**
Replaced by: S51586 - Interleukin-2 Receptor, EIA (34298X)

3575 **Beta-Hydroxybutyrate**
Replaced by: S51561 - Beta-Hydroxybutyrate (37054Z)

5362 **Fragile X GenotypR™**
Replaced by: S51603 - XSense™, Fragile X w/Reflex (19757X)

5363 **Fragile X Fetal Study w/Reflex to MCC**
Replaced by: S51604 - Fragile X DNA Analysis-Fetus (10227X)

Effective April 14, 2008:

4834 **Voltage-gated Calcium Channel IgG Autoabs**
Replaced by: S51602 - Voltage-Gated Calcium Channel (VGCC) Antibody Assay (34057X)

1170 **Paraneoplastic Syndrome Evaluation w/ VGCCA**
Replaced by: Discontinued - Test 1171 is still offered - Paraneoplastic Syndrome Evaluation