

January 25, 2007

Dear Colleague:

This client letter details recent changes that have occurred in tests available from *Specialty* as well as a listing of discontinued tests. A new section in this communication will be titled "**SENDOUT REPLACEMENTS**". These are current sendout tests that are going to be brought in-house. Please note the effective dates that the replacements will go into effect and update accordingly. The replacement tests will also be listed in the NEW TEST client letter along with the test code that the in-house test is replacing.

Another notable change this month is the **removal of whole blood ACD as an acceptable sample for DNA-based HLA assays**. Please review the list of affected tests and update accordingly.

In regards to *Chlamydia trachomatis* (CT) and *Neisseria gonorrhoeae* (GC) testing, the **GEN-PROBE® APTIMA® Combo 2 Assay** with target capture for greater sensitivities and specificity is our preferred method. However, the non-amplified PACE 2 method will remain active and available until further notice. To eliminate any confusion on the collection of samples for CT/GC, the **PACE collection kits can be used** for either method until sufficient supplies of the Aptima Unisex Swab collection kit are obtained and clients have had ample time to convert from the PACE kit. If you have any questions regarding CT/GC testing, please contact your Specialty Representative.

Advantages of the APTIMA® Combo 2 Assay

- Specimens are more easily obtained than those required for other assays for CT and GC.
- Sensitivity is >94%, and specificity is >97% for both CT and GC with swab or urine.
- The APTIMA transcription-mediated amplification (TMA) assays for *C. trachomatis* and *N. gonorrhoeae* have the greatest sensitivity of all the commercial nucleic acid amplification tests for the diagnosis of infections from noninvasive samples, due to the large number of rRNA copies inherent per organism.
- Turn-around times are **two times faster** than for bacterial cell culture.
- Sample handling is less stringent than required for cell culture.
- Compared to PACE 2, **sensitivity is 7-10 times greater**, specificity is higher, and specimen collection is easier.
- For the annual or bi-annual screening of sexually active adolescents and women under 25 years of age for *C. trachomatis* (CT) and *N. gonorrhoeae* (GC).
- For the screening of individuals with the symptoms of *C. trachomatis* (CT) or *N. gonorrhoeae* (GC) infection.

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



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

Sendout Replacements:

S49290 BCL-2 Gene Rearrangement [PCR]
Replaced by #5049 BCL2/JH Gene Rearrangement by PCR
#5049BK BCL2/JH Gene Rearrangement by PCR
Effective February 13, 2007

S50811 Barbiturates, Urine Confirmation
Replaced by #4092U Barbiturates Confirmation Urine
Effective February 13, 2007

S50876 Propoxyphene Confirmation
Replaced by #4094U Propoxyphene Confirmation Urine
Effective February 13, 2007

S50813 Benzodiazepines
Replaced by #4090 Benzodiazepines Serum
Effective February 13, 2007

Test Changes:

5779 Fungus Culture
Effective Immediately
New Name Fungus Culture: Yeast Screen-Skin, Hair, or Nail
CPT Code 87206, 87101
Specimen(s) Specimen 1: Culturette/Swab 0.0 (0.0) AR*
Ambient - 24 Hour(s) / Refrigerated - 72 Hour(s)

Alternate: Pure Culture Broth 0.0 (0.0) AR*
Ambient - 24 Hour(s) / Refrigerated - 72 Hour(s)

Alternate: Pure Culture Agar Slant 0.0 (0.0) AR*
Ambient - 24 Hour(s) / Refrigerated - 72 Hour(s)

3123PL Cholinesterase Plasma
Effective Immediately
Collection Using proper venipuncture technique, draw 7 ml lavender top tube. Centrifuge lavender (EDTA) tube at 1000-2000 rpm for 15 minutes. Separate plasma from red cells, as soon as possible. Transfer plasma into plastic vial(s). Clearly identify with patient information, draw date, and type of anticoagulant. Document the anticoagulant type under "specimen source" in the test requisition. Transport this tube to Specialty. Discard the lavender tube with the RBC portion on the bottom. Note: Avoid hemolysis and icteric samples
3123PLSR

Also Affected

4912	Alprazolam	February 13, 2007
Effective		
Ref. Range		Therapeutic Range: 5 - 25 ng/mL Potentially Toxic: >60 ng/mL
4916	Chlordiazepoxide	February 13, 2007
Effective		
Ref. Range		Therapeutic Range: 100 - 3000 ng/mL Potentially Toxic: >5000 ng/mL
Method		LCMS/MS
4918	Clonazepam	February 13, 2007
Effective		
Ref. Range		Therapeutic Range: 20 - 60 ng/mL Potentially Toxic: >100 ng/mL
4926	Diazepam	February 13, 2007
Effective		
Ref. Range		Therapeutic Range: 100 - 1500 ng/mL Potentially Toxic: >3000 ng/mL
Method		LCMS/MS
Also Affected		4928
4934	Oxazepam	February 13, 2007
Effective		
Ref. Range		Therapeutic Range: 200 - 500 ng/mL Potentially Toxic: >2000 ng/mL
Method		LCMS/MS
4920	Flurazepam	February 13, 2007
Effective		
Ref. Range		Therapeutic Range: 30 - 150 ng/mL Potentially Toxic: >500 ng/mL
Method		LCMS/MS
Component		Flurazepam Therapeutic Range: 0 - 30 ng/mL Potentially Toxic: >500 ng/mL
3945	PTH-C Terminal	February 13, 2007
Effective		
Ref. Range		14 - 80 ng/dL
Also Affected		3208, 3213
4166	TCA Screen	Immediately
Effective		
Ref. Range		Detected Cutoff =25 ng/mL (For all components)

4862	Aluminum	
	Effective Collection	Immediately Carefully clean skin prior to venipuncture with alcohol swab. Use powderless gloves. Avoid hemolysis. Avoid worksite collection. Avoid fruits, juices, and tea for 24h before collection. Plasma is not acceptable.
3515W	Vitamin B1	
	Effective Alternate Sample	Immediately EDTA Whole Blood
4891	Leptin	
	Effective Ref. Range	Immediately MALE: <11.2 ng/mL FEMALE: <32.1 ng/mL
3127	Disaccharidases	
	Effective CPT Code	Immediately 84379
1592U	Monoclonal Gammopathy Evaluation 24HR Urine	
	Effective CPT Code	Immediately 86325
1078	Celiac GenotypR™	
	Effective Specimen	February 13, 2007 Whole Blood ACD is no longer an acceptable specimen
	Also Affected	1634, 1368, 1369, 1376, 1377, 1378, 1379, 4527
8941	<i>Borrelia burgdorferi</i> IgG & IgM	
	Effective Ref. Range	Immediately Negative <=0.80 Equivocal 0.81-1.19 Positive >=1.20
	Also Affected	7970, 7846, 7716, 7716B, 7716BNY, 8961, 8951,8954, 8942, 8942NY, 8956, 8938, 8968,6906
8771	Measles IgG & IgM	
	Effective Ref. Range	Immediately Negative <=0.90 Equivocal 0.91-1.09 Positive >=1.10
	Also Affected	8781, 2772, 1341, 8776
2486	CMV IgM	
	Effective Ref. Range	Immediately Negative <=0.90 Equivocal 0.91-1.09 Positive >=1.10
	Also Affected	2486C, 9436, 9436C, 2231, 9901, 2772

9431	CMV IgG Effective Ref. Range Also Affected	Immediately Negative <=0.79 Equivocal 0.80-0.99 Positive >=1.00 9436, 8560, 9901, 9911, 2772, 9436C, 9431C
9716	Mumps IgG Effective Ref. Range Also Affected	Immediately Negative <=0.90 Equivocal 0.91-1.09 Positive >=1.10 9711, 2772, 1341
9721	Mumps IgM Effective Ref. Range Also Affected	Immediately Negative <=0.79 Equivocal 0.80-1.20 Positive >=1.21 9711, 2772
8756	VZV IgG & IgM Effective Ref. Range Also Affected	Immediately Negative <=0.90 Equivocal 0.91-1.09 Positive >=1.10 8761, 8766, 2772
7675	<i>Toxoplasma</i> IgM Antibodies Effective Ref. Range Also Affected	Immediately Negative <=0.80 Equivocal 0.81- 0.99 Positive >=1.00 7675C, 2263, 2263C, 2261, 9901, 2231
9426	<i>Toxoplasma</i> IgG Antibodies Effective Ref. Range Also Affected	Immediately Negative <=0.90 Equivocal 0.91- 1.09 Positive >=1.10 9901, 9911, 8972, 2261, 8970, 2263, 2263C, 9426C
9446	Herpes Simplex Virus 1 & 2 IgG Antibodies Effective Ref. Range Also Affected	Immediately Negative <=0.89 Equivocal 0.90- 1.10 Positive >=1.11 9451, 9461, 9496, 8051, 9901, 9911, 2772

5808	Trisomy 8	Effectively	Immediately
		CPT Code	Remove code 88237
		Also Affected	5834, 5838, 5840, 5850, 5852, 5854, 5856, 5858, 5860, 5862, 5864, 5866, 5868, 5870, 5870, 5872, 5874, 5878, 5880, 5882, 5880, 5882, 5884, 5886, 5890, 5892, 5894, 5896, 5898, 5865, 5863, 5861, 5869, 5867
5850	Cytogenetics - T(8;21) by FISH	Effectively	Immediately
		CPT Code	88271 to new CPT 88271x2
		Also Affected	5854, 5856, 5896
5860	Chronic Lymphocytic Leukemia (CLL) by FISH	Effectively	Immediately
		CPT Code	88275x2
5864	Multiple Myeloma by FISH	Effectively	Immediately
		CPT Code	88271x13 to new CPT 88271x9, 88275x9 to new CPT 88275x4
5874	Acute Myeloid Leukemia/High Grade Myelodysplasia By FISH	Effectively	Immediately
		CPT Code	88271x12 to new CPT 88271x14
5878	Myelodysplastic Syndromes (MDS)Low Grade By FISH	Effectively	Immediately
		CPT Code	88271x6 to new CPT 88271x8
4501	Jak2 GenotypR™	Effectively	Immediately
		This test is now available for New York patients	
8746	<i>M. Pneumoniae</i> IgG	Effectively	Immediately
		Ref. Range	Negative <=0.90 Equivocal 0.91-1.09 Positive >=1.10
		Also Affected	8741, 2011

5365

5356 Cystic Fibrosis 70 GenotypR: Carrier Study

Effective February 27, 2007

Reporting Message Cystic Fibrosis (CF) Carrier Study reporting messages are updated:

- Revised carrier risks are updated based on American College of Medical Genetics (ACMG) Technical Standards and Guidelines for CFTR Mutation Testing, 2006 edition.
- Revised carrier risks are now available for Asian-American patients.
- For improved patient care we will no longer wait to report results for patient samples lacking specific ethnic background information. Rather, each report will include revised carrier risks for all 5 ethnicities (Caucasian, African-Americans, Ashkenazi Jewish, Hispanic-American and Asian-American).
- CF polymorphisms, I506V, I507V and F508C, will not be reported. I148T will not be reported in CF 70 requests. These benign missense mutations do not cause disease and are included in the assay for technical reasons only. The results of these benign polymorphisms can be reported upon request.

Also Affected

5355