

December 19, 2006

Dear Colleague:

This client letter details recent changes that have occurred in tests available from *Specialty* as well as a listing of discontinued tests. Please read the following pages carefully, as the new **2007 CPT code** changes are listed. These codes will be updated on our Web site and activated on January 1, 2007.

Also of significance are the new reference ranges established for total testosterone in children and adults. These new ranges apply to several tests so please be sure to see the detailed information on the following pages.

The most noted and welcomed change is the discontinuation of the non-amplified PACE 2 assay for detecting *Chlamydia trachomatis* (CT) and *Neisseria gonorrhoeae* (GC). In the interests of improved patient care and to guarantee maximum sensitivity and specificity, *Specialty* has elected to solely offer amplified methodologies for the detection of both *C. trachomatis* and *N. gonorrhoeae*. *Specialty* will replace the PACE 2 assay with the **GEN-PROBE® APTIMA® Combo 2 Assay**. Prior to amplification, the AMPTIMA® TMA assay includes a **Target Capture** step which purifies the target ribosomal RNA and removes contaminants that might otherwise inhibit the amplification reaction. The APTIMA® Combo 2 with Target Capture leads to sensitivities greater than 94%, superior to any other CT/GC test.

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 shorter 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

Discontinued and Changed Assays at *Specialty*

Effective date as noted

DISCONTINUED:

- | | |
|---------------|---|
| S50399 | B-Cell Gene Rearrangement
Effective Reason
Immediately
<u>Replaced by 5044</u> |
| S50673 | B-Cell Gene Rearrangement Paraffin Block
Effective Reason
Immediately
<u>Replaced by 5044BK</u> |
| S49927 | T-Cell Gene Rearrangement
Effective Reason
Immediately
<u>Replaced by 5042</u> |
| S50364 | T-Cell Gene Rearrangement Paraffin Block
Effective Reason
Immediately
<u>Replaced by 5042BK</u> |
| S50441 | MSI
Effective Reason
Immediately
<u>Replaced by 5046</u> |
| S50353 | Trisomy 13,18,21 XY by Fish
Effective Reason
Immediately
<u>Replaced by 5885</u> |
| S50353 | Trisomy 21 by Fish
Effective Reason
Immediately
<u>Replaced by 5887</u> |
| S50854 | Methadone Confirmation Serum
Effective Reason
Immediately
<u>Replaced by 4192</u> |
| S48872 | Methadone for Therapeutic Monitoring
Effective Reason
Immediately
<u>Replaced by 4192</u> |
| S50868 | Phencyclidine (PCP) Serum
Effective Reason
Immediately
<u>Replaced by 4183</u> |
| 2927 | Chlamydia trachomatis / Neisseria gonorrhoeae [RRNA]
Effective Reason
February 1, 2007
<u>Replaced by 7438SW</u> |
| 2925 | Chlamydia trachomatis Detection [RRNA] |

Effective February 1, 2007
Reason **Replaced by 7437SW**

2930 Neisseria gonorrhoeae AG Detection [RRNA]
Effective February 1, 2007
Reason **Replaced by 2932SW**

Test Changes:

1900 Apolipoprotein Evaluation
Effective Immediately
Component Apolipoprotein B/A-1 Ratio is being added
Apolipoprotein B/A-1 Ratio Risk Ranges:
Male Female
Avg.Risk 0.7 0.6
2X Avg.Risk 0.9 0.9
3X Avg.Risk 1.0 1.0

5713 Aerobic Susceptibility
Effective Immediately
Method Microbroth Dilution for all antibiotics
Component Augmentin is removed from panel

5711 Anaerobic Susceptibility Panel
Effective Immediately
Method E Test for all antibiotics listed
Component Remove Cefotaxime, Ticarcillin/Clavulanic Acid, Cefotetan, Mezlocillin, Chloramphenicol, Tetracycline, Ampicillin/Sulbactam, Ceftriaxone, Ceftizoxime
Change antibiotic name from Piperacillin to Piperacillin/Tazobactam MIC

2650 Enterovirus DetectR™
Effective January 1, 2007
CPT Code 87498

2772 Meningoencephalitis (MEM)
Effective January 1, 2007
CPT Code 86644, 86645, 86651, 86652, 86653, 86654, 86694, 86695, 86696, 86710x4, 86735x2, 86765x2, 86787x2, 86788, 86789, 87498

2773C Meningoencephalomyelitis (MEM)
Effective January 1, 2007
CPT Code 87497, 87530x2, 87498, 87798, 87799

2936 Methicillin Resistant *Staphylococcus aureus*

(MRSA) mecA DetectR™

Effective January 1, 2007
CPT Code 87641

9640 Streptococcus Group B DNA DetectR™

Effective January 1, 2007
CPT Code 87641
Also affected 7442 Chlamydia/Neisseria rRNA & Strep
Group B DNA DetectR™

3243 Testosterone, Total (Prepubertal & Female)

Effective January 9, 2007
Reference range REFERENCE RANGE for TESTOSTERONE, TOTAL

Age	Males (ng/dL)	Females (ng/dL)
26W-28W	59-125	5-16
31W-35W	37-198	5-22
0 - 7 D	20-50	20-65
8 D - 30 D	60-400	20-65
31 D - 60 D	60-400	<10
61 D - 11 M	<6	<10
1 Y - 5 Y	2-25	2-10
6 Y - 9 Y	3-30	2-20
10 Y - 11 Y	5-50	5-25
Pubertal/Adult >11Y	>100	<80
Also affected	3249 Testosterone, Free Dialysis w/ Total Testosterone	
	3911 Testosterone, Bioavailable w/ High Sensitivity	
	3913 Testosterone, Weakly Bound w/ High Sensitivity	
	Total & Free	

3244 Testosterone, Total

Effective January 9, 2007
Reference range REFERENCE RANGE for TESTOSTERONE, TOTAL

Age	Males (ng/dL)	Females (ng/dL)
Prepubertal <12Y	<100	<80
12 Y - 14 Y	10-572	10-40
15 Y - 17 Y	220-800	5-40
> 17 Y	241-827	14-76
Also affected	3248 Testosterone, Free & Total	
	3916 Testosterone, Bioavailable	
	3917 Testosterone, Weakly Binding	
	2017 Infertility: Endocrine Evaluation (Male)	
	2023 Polycystic Ovary Evaluation	
	2025 Recurrent Spontaneous Abortion: Endocrine Evaluation	
	3188 Hirsutism Evaluation, Female	

4911 Alpha-Fetoprotein-L3%

Effective January 1, 2007
CPT Code 82107

9942 Aspergillus galactomannan Antigen

Effective January 1, 2007
CPT Code 87305

8080	West Nile Virus Antibodies IgG & IgM (IFA) Effective January 1, 2007 CPT Code 86788, 86789
8080C	West Nile Virus Antibodies IgG & IgM CSF (IFA) Effective January 1, 2007 CPT Code 86788, 86789
8077	West Nile Virus Antibodies IgG (IFA) Effective January 1, 2007 CPT Code 86789
8077C	West Nile Virus Antibodies IgG (IFA) CSF Effective January 1, 2007 CPT Code 86789
8078	West Nile Virus Antibodies IgM (IFA) Effective January 1, 2007 CPT Code 86788
8078C	West Nile Virus Antibodies IgM CSF (IFA) Effective January 1, 2007 CPT Code 86788
8167C	West Nile Virus IgG (EIA) CSF Effective January 1, 2007 CPT Code 86789
8169	West Nile Virus IgG & IgM (EIA) Effective January 1, 2007 CPT Code 86788, 86789
8169C	West Nile Virus IgG & IgM (EIA) CSF Effective January 1, 2007 CPT Code 86788, 86789
8167	West Nile Virus IgG Antibodies Effective January 1, 2007 CPT Code 86789
8168C	West Nile Virus IgM (EIA) CSF Effective January 1, 2007 CPT Code 86788
8168	West Nile Virus IgM (EIA) Effective January 1, 2007 CPT Code 86788
2408	<i>Ureaplasma urealyticum/Mycoplasma hominis</i> Culture Effective Immediately CPT Code 87109x2