Test Updates

March 7, 2011

Dear Colleague:

We are pleased to announce nine new SureSwab™ molecular assays for gynecologic infections using real-time PCR and TMA methods to test for multiple organisms on a single swab. SureSwab™ provides results that support a more definitive diagnosis and address a number of infections.

We would also like to request that you pay close attention to the specimen preparation instructions for QuantiFERON®-TB Gold (Incubated) [6100]. Deviation from the procedures may result in increased rates of Indeterminate results. The instructions are shown here again, and should be shared with the personnel responsible for collection, preparation and transportation of specimens.

1. For each patient, collect 1 mL of blood by venipuncture directly into each of the three (3) unique QuantiFERON(R)-TB Gold IT blood collection tubes (Nil, TB Antigen, Mitogen). Under or overfilling of the tubes may lead to erroneous results.
2. Mix the tubes by shaking vigorously for 5 seconds and label tubes appropriately.
3. Incubate the three (3) tubes upright strictly at 37 ± 1 degrees C for 16 to 24 hours.
4. Following incubation either:
   A. Immediately transport the three (3) transport tubes between 2 and 27 degrees C. Samples will be stable for 72 hours at 2-27 degrees C (room temperature or refrigerated).
   OR
   B. Centrifuge each of the three (3) incubated collection tubes for 15 minutes at 2000 to 3000 RCF (g). Label with patient name, identification number and date of collection. Deliver at 2-8 degrees C. Samples will be stable for 28 days at 2-8 degrees C (refrigerated).
5. Transport incubated tubes between 2-27 degrees C.
6. Frozen samples are not acceptable.

We thank you for choosing Quest Diagnostics Nichols Institute, Valencia and look forward to your continued support. For additional information, please visit our Web site at www.NicholsInstitute.com/Valencia or contact Client Relations at 800-421-4449.

Respectfully Yours,

Basel Kashlan, MD, FCAP
Laboratory Director
New Tests (Valencia):

3754 Allergy Panel – Adult Food IgG (Available Immediately)

<table>
<thead>
<tr>
<th>Component</th>
<th>Method</th>
<th>Reference Range/Units</th>
</tr>
</thead>
<tbody>
<tr>
<td>Casein IgG</td>
<td>ImmunoCAP</td>
<td>&lt;2.0 ug/mL</td>
</tr>
<tr>
<td>Cacao (chocolate) IgG</td>
<td>ImmunoCAP</td>
<td>&lt;2.0 ug/mL</td>
</tr>
<tr>
<td>Codfish IgG</td>
<td>ImmunoCAP</td>
<td>&lt;2.0 ug/mL</td>
</tr>
<tr>
<td>Coffee IgG</td>
<td>ImmunoCAP</td>
<td>&lt;2.0 ug/mL</td>
</tr>
<tr>
<td>Corn IgG</td>
<td>ImmunoCAP</td>
<td>&lt;2.0 ug/mL</td>
</tr>
<tr>
<td>Egg white IgG</td>
<td>ImmunoCAP</td>
<td>&lt;2.0 ug/mL</td>
</tr>
<tr>
<td>Peanut IgG</td>
<td>ImmunoCAP</td>
<td>&lt;2.0 ug/mL</td>
</tr>
<tr>
<td>Soybean IgG</td>
<td>ImmunoCAP</td>
<td>&lt;2.0 ug/mL</td>
</tr>
<tr>
<td>Tomato IgG</td>
<td>ImmunoCAP</td>
<td>&lt;2.0 ug/mL</td>
</tr>
<tr>
<td>Wheat IgG</td>
<td>ImmunoCAP</td>
<td>&lt;2.0 ug/mL</td>
</tr>
<tr>
<td>Yeast (bakers/brewers) IgG</td>
<td>ImmunoCAP</td>
<td>&lt;2.0 ug/mL</td>
</tr>
</tbody>
</table>

Specimen/Stability Serum 5.0 (2.0) mL: Ambient 7 days, Refrigerated 14 days, Frozen 30 days
Schedule Tuesday - Saturday
Report Same day
CPT Code 86001x11
Regulatory Status Investigational Use Only
Clinical Utility The reference range listed on the report is the lower limit of quantitation for the assay. The clinical utility of food-specific IgG tests has not been established. These tests can be used in special clinical situations to select foods for evaluation by diet elimination and challenge in patients who have food-related complaints. It should be recognized that the presence of food-specific IgG alone cannot be taken as evidence of food allergy and only indicates immunologic sensitization by the food allergen in question. This test should only be ordered by physicians who recognize the limitations of the test.

Always Statement This test(s) was performed using a kit that has not been cleared or approved by the FDA. The analytical performance characteristics of this test have been determined by Quest Diagnostics Nichols Institute, Valencia, CA. This test should not be used for diagnosis without confirmation by other medically established means.

16898 SureSwab™, Bacterial Vaginosis DNA, Quantitative RT-PCR (Available April 5)

<table>
<thead>
<tr>
<th>Component</th>
<th>Method</th>
<th>Reference Range/Units</th>
</tr>
</thead>
<tbody>
<tr>
<td>Lactobacillus species</td>
<td>Real Time-PCR</td>
<td>W/Rpt Log (cells/mL)</td>
</tr>
<tr>
<td>Atopobium vaginae</td>
<td>Real Time-PCR</td>
<td>W/Rpt Log (cells/mL)</td>
</tr>
<tr>
<td>Megasphaera species</td>
<td>Real Time-PCR</td>
<td>W/Rpt Log (cells/mL)</td>
</tr>
<tr>
<td>Gardnerella vaginalis</td>
<td>Real Time-PCR</td>
<td>W/Rpt Log (cells/mL)</td>
</tr>
</tbody>
</table>

Specimen/Stability Vaginal swab in 0.7 mL: Aptima™ Vaginal Swab Collection Kit (Orange label)
Collection Instructions Follow instructions in the Aptima™ Vaginal Swab Specimen Collection kit for physician collected or self-collection of vaginal specimens.
Schedule Monday - Saturday
Report 2 days
CPT Code 84891 (x4), 87512, 87798, 87799 (x3)
Regulatory Status Laboratory Developed Test
Clinical Utility Concentrations of Lactobacilli are collectively reported under the term 'Lactobacillus spp.', as these species are among the peroxide producing Lactobacilli thought to be protective against bacterial vaginosis. In the absence of peroxide producing Lactobacilli, Atopobium vaginae, Megasphaera spp., and Gardnerella (> 6.0 log (cells/mL)) have been associated with vaginosis.

Always Statement This test(s) was developed and its performance characteristics have been determined by Quest Diagnostics Nichols Institute, Valencia, CA. Performance characteristics refer to the analytical performance of the test.

Note **This test is not available for New York State patient testing. There is no recommended alternative for New York patient testing.
New Tests: (cont.)

### 15509 SureSwab™, Bacterial Vaginosis/Vaginitis  
(Available April 11)

<table>
<thead>
<tr>
<th>Component</th>
<th>Method</th>
<th>Reference Range/Units</th>
</tr>
</thead>
<tbody>
<tr>
<td>T. vaginalis</td>
<td>TMA</td>
<td>Not Detected</td>
</tr>
<tr>
<td>Lactobacillus</td>
<td>Real Time-PCR</td>
<td>W/Rpt Log (cells/mL)</td>
</tr>
<tr>
<td>Atopobium</td>
<td>Real Time-PCR</td>
<td>W/Rpt Log (cells/mL)</td>
</tr>
<tr>
<td>Megasphaera</td>
<td>Real Time-PCR</td>
<td>W/Rpt Log (cells/mL)</td>
</tr>
<tr>
<td>Gardnerella</td>
<td>Real Time-PCR</td>
<td>W/Rpt Log (cells/mL)</td>
</tr>
<tr>
<td>C. albicans</td>
<td>Real Time-PCR</td>
<td>Not Detected</td>
</tr>
<tr>
<td>C. glabrata</td>
<td>Real Time-PCR</td>
<td>Not Detected</td>
</tr>
<tr>
<td>C. tropicalis</td>
<td>Real Time-PCR</td>
<td>Not Detected</td>
</tr>
<tr>
<td>C. parapsilosis</td>
<td>Real Time-PCR</td>
<td>Not Detected</td>
</tr>
</tbody>
</table>

Specimen/Stability: Vaginal swab in 3 mL: Aptima™ Vaginal Swab Collection Kit (Orange label)  
Ambient 48 Hours, Refrigerated 7 days, Frozen 14 days  
Collection Instructions: Follow instructions in the Aptima™ Vaginal Swab Specimen Collection kit for physician collected or self-collection of vaginal specimens.  
Schedule: Monday-Saturday  
Report: 2 days  
CPT Code: 84891 (x4), 87512, 87798, 87799 (x3)  
Regulatory Status: Analyte Specific Reagent, Laboratory Developed Test  
Clinical Utility: To diagnose the causative agent(s) of vaginosis/vaginitis.  
Always Statement: This test(s) was developed and its performance characteristics have been determined by Quest Diagnostics Nichols Institute, Valencia, CA. It has not been cleared or approved by the U.S. Food and Drug Administration. The FDA has determined that such clearance or approval is not necessary. Performance characteristics refer to the analytical performance of the test.  
Note: **This test is not available for New York State patient testing. There is no recommended alternative for New York patient testing.**

### 16495 SureSwab™, Candida albicans DNA  
(Available April 5)

<table>
<thead>
<tr>
<th>Component</th>
<th>Method</th>
<th>Reference Range/Units</th>
</tr>
</thead>
<tbody>
<tr>
<td>C. albicans</td>
<td>Real Time-PCR</td>
<td>Not Detected</td>
</tr>
</tbody>
</table>

Specimen/Stability: Vaginal swab in 0.7 mL: Aptima™ Vaginal Swab Collection Kit (Orange label)  
Ambient 48 Hours, Refrigerated 7 days, Frozen 14 days  
Collection Instructions: Follow the instructions provided in the Aptima Vaginal Swab Collection Kit. Remove the swab from the packaging and insert the swab into the vagina about two inches inside the opening. Gently rotate for 10 to 30 seconds, making sure that the swab touches the wall of the vagina so that moisture is absorbed by the swab. Withdraw the swab without touching the skin. Immediately place the swab into the transport tube so that the tip of the swab is visible below the tube label. Carefully break the swab shaft at the score line against the side of the tube and discard the top portion of the swab shaft. Tightly screw the cap onto the tube.  
Schedule: Monday- Saturday  
Report: 2 days  
CPT Code: 87481  
Regulatory Status: Laboratory Developed Test  
Always Statement: This test(s) was developed and its performance characteristics have been determined by Quest Diagnostics Nichols Institute, Valencia, CA. Performance characteristics refer to the analytical performance of the test.  
Clinical Utility: Diagnosis of Candida vulvovaginitis.  
Note: **This test is not available for New York State patient testing. There is no recommended alternative for New York patient testing.**
New Tests: (cont.)

16494    **SureSwab™, Candidiasis, PCR**    (Available April 5)

<table>
<thead>
<tr>
<th>Component</th>
<th>Method</th>
<th>Reference Range/Units</th>
</tr>
</thead>
<tbody>
<tr>
<td><strong>C. albicans</strong>, DNA</td>
<td>Real Time-PCR</td>
<td>Not Detected</td>
</tr>
<tr>
<td><strong>C. glabrata</strong>, DNA</td>
<td>Real Time-PCR</td>
<td>Not Detected</td>
</tr>
<tr>
<td><strong>C. tropicalis</strong>, DNA</td>
<td>Real Time-PCR</td>
<td>Not Detected</td>
</tr>
<tr>
<td><strong>C. parapsilosis</strong>, DNA</td>
<td>Real Time-PCR</td>
<td>Not Detected</td>
</tr>
</tbody>
</table>

Specimen/Stability: Vaginal swab in 0.7 mL: Aptima™ Vaginal Swab Collection Kit (Orange label)

Collection Instructions: Follow instructions in the Aptima™ Vaginal Swab Specimen Collection kit for physician collected or self-collection of vaginal specimens.

Schedule: Monday-Saturday

Report: 2 days

CPT Code: 87481 (x4)

Regulatory Status: Laboratory Developed Test

Clinical Utility: Diagnosis of *Candida* vulvovaginitis.

Always Statement: This test(s) was developed and its performance characteristics have been determined by Quest Diagnostics Nichols Institute, Valencia, CA. Performance characteristics refer to the analytical performance of the test.

Note: **This test is not available for New York State patient testing. There is no recommended alternative for New York patient testing.**

11363    **SureSwab™, *C. trachomatis/N. gonorrhoeae* RNA, TMA**    (Available April 5)

<table>
<thead>
<tr>
<th>Component</th>
<th>Method</th>
<th>Reference Range/Units</th>
</tr>
</thead>
<tbody>
<tr>
<td><strong>C. trachomatis</strong> RNA</td>
<td>TMA</td>
<td>Not Detected</td>
</tr>
<tr>
<td><strong>N. gonorrhoeae</strong> RNA</td>
<td>TMA</td>
<td>Not Detected</td>
</tr>
</tbody>
</table>

Specimen/Stability: Vaginal swab in 3 mL: Aptima™ Vaginal Swab Collection Kit (Orange label)

Collection Instructions: Follow instructions in the Aptima™ Vaginal Swab Specimen Collection kit for physician collected or self-collection of vaginal specimens.

Schedule: Monday-Saturday

Report: 2 days

CPT Code: 87491, 87591

Regulatory Status: FDA Approved

Clinical Utility: To diagnose two sexually transmitted diseases associated with vaginitis.

16492    **SureSwab™, CT/NG, *T. vaginalis***    (Available April 5)

<table>
<thead>
<tr>
<th>Component</th>
<th>Method</th>
<th>Reference Range/Units</th>
</tr>
</thead>
<tbody>
<tr>
<td><strong>C. trachomatis</strong> RNA, TMA</td>
<td>TMA</td>
<td>Not Detected</td>
</tr>
<tr>
<td><strong>N. gonorrhoeae</strong> RNA, TMA</td>
<td>TMA</td>
<td>Not Detected</td>
</tr>
<tr>
<td><strong>T. vaginalis</strong> RNA, QL, TMA</td>
<td>TMA</td>
<td>Not Detected</td>
</tr>
</tbody>
</table>

Specimen/Stability: Vaginal swab in 3 mL: Aptima™ Vaginal Swab Collection Kit (Orange label)

Collection Instructions: Follow instructions in the Aptima™ Vaginal Swab Specimen Collection kit for physician collected or self-collection of vaginal specimens.

Schedule: Monday-Saturday

Report: 2 days

CPT Code: 87491, 87591, 87798

Regulatory Status: FDA Approved, Analyte Specific Reagent

Clinical Utility: To diagnose three sexually transmitted diseases associated with vaginitis.

Always Statement: This test(s) was developed and its performance characteristics have been determined by Quest Diagnostics Nichols Institute, Valencia, CA. It has not been cleared or approved by the U.S. Food and Drug Administration. The FDA has determined that such clearance or approval is not necessary. Performance characteristics refer to the analytical performance of the test.

Note: **This test is not available for New York State patient testing. There is no recommended alternative for New York patient testing.**
New Tests: (cont.)

### 19550 SureSwab™, Trichomonas vaginalis RNA, Qualitative TMA  (Available April 5)

<table>
<thead>
<tr>
<th>Component</th>
<th>Method</th>
<th>Reference Range/Units</th>
</tr>
</thead>
<tbody>
<tr>
<td>T. vaginalis RNA, QL, TMA</td>
<td>TMA</td>
<td>Not Detected</td>
</tr>
</tbody>
</table>

Specimen/Stability: Vaginal swab in 3 mL: Aptima™ Vaginal Swab Collection Kit (Orange label)
Ambient 48 Hours, Refrigerated 7 days, Frozen 14 days

Collection Instructions: Follow instructions in the Aptima™ Vaginal Swab Specimen Collection kit for physician collected or self-collection of vaginal specimens.

Schedule: Monday-Saturday

Report: 2 days

CPT Code: 87491, 87591, 87798

Regulatory Status: Analyte Specific Reagent

Clinical Utility: This test is used to detect *Trichomonas vaginalis* in clinical specimens. The test has greater analytical sensitivity than culture methods.

Always Statement: This test(s) was developed and its performance characteristics have been determined by Quest Diagnostics Nichols Institute, Valencia, CA. It has not been cleared or approved by the U.S. Food and Drug Administration. The FDA has determined that such clearance or approval is not necessary. Performance characteristics refer to the analytical performance of the test.

Note: **This test is not available for New York State patient testing. There is no recommended alternative for New York patient testing.**

### 16491 SureSwab™, Vaginosis, CT/NG  (Available April 5)

<table>
<thead>
<tr>
<th>Component</th>
<th>Method</th>
<th>Reference Range/Units</th>
</tr>
</thead>
<tbody>
<tr>
<td>Chlamydia trachomatis RNA, TMA</td>
<td>TMA</td>
<td>Not Detected</td>
</tr>
<tr>
<td>Neisseria gonorrhoeae RNA, TMA</td>
<td>TMA</td>
<td>Not Detected</td>
</tr>
<tr>
<td>Lactobacillus species</td>
<td>Real Time-PCR</td>
<td>W/Rpt Log (cells/mL)</td>
</tr>
<tr>
<td>Atopobium vaginae</td>
<td>Real Time-PCR</td>
<td>W/Rpt Log (cells/mL)</td>
</tr>
<tr>
<td>Megasphaera species</td>
<td>Real Time-PCR</td>
<td>W/Rpt Log (cells/mL)</td>
</tr>
<tr>
<td>Gardnerella vaginalis</td>
<td>Real Time-PCR</td>
<td>W/Rpt Log (cells/mL)</td>
</tr>
</tbody>
</table>

Specimen/Stability: Vaginal swab in 3 mL: Aptima™ Vaginal Swab Collection Kit (Orange label)
Ambient 48 Hours, Refrigerated 7 days, Frozen 14 days

Collection Instructions: Follow instructions in the Aptima™ Vaginal Swab Specimen Collection kit for physician collected or self-collection of vaginal specimens.

Schedule: Monday- Saturday

Report: 2 days

CPT Code: 87799 (x3), 87512, 87491, 87591

Regulatory Status: FDA Approved, Laboratory Developed Test

Clinical Utility: To diagnose bacterial vaginosis and concomitant infection with *Chlamydia trachomatis* and/or *Neisseria gonorrhoeae* in sexually active women.

Always Statement: *Lactobacillus, Atopobium, Megasphaera, Gardnerella and Candida:*
This test(s) was developed and its performance characteristics have been determined by Quest Diagnostics Nichols Institute, Valencia, CA. Performance characteristics refer to the analytical performance of the test.

Note: **This test is not available for New York State patient testing. There is no recommended alternative for New York patient testing.**
New Tests: (cont.)

17333 SureSwab™, Vaginosis/Vaginitis Plus (Available April 5)

<table>
<thead>
<tr>
<th>Component</th>
<th>Method</th>
<th>Reference Range/Units</th>
</tr>
</thead>
<tbody>
<tr>
<td><strong>C. trachomatis RNA. TMA</strong></td>
<td>TMA</td>
<td>Not Detected</td>
</tr>
<tr>
<td><strong>N. gonorrhoeae RNA, TMA</strong></td>
<td>TMA</td>
<td>Not Detected</td>
</tr>
<tr>
<td><strong>T. vaginalis RNA, QL, TMA</strong></td>
<td>TMA</td>
<td>Not Detected</td>
</tr>
<tr>
<td><strong>Lactobacillus species</strong></td>
<td>Real Time-PCR W/Rpt Log (cells/mL)</td>
<td>Not Detected</td>
</tr>
<tr>
<td><strong>Atopobium vaginae</strong></td>
<td>Real Time-PCR W/Rpt Log (cells/mL)</td>
<td>Not Detected</td>
</tr>
<tr>
<td><strong>Megasphaera species</strong></td>
<td>Real Time-PCR W/Rpt Log (cells/mL)</td>
<td>Not Detected</td>
</tr>
<tr>
<td><strong>Gardnerella vaginalis</strong></td>
<td>Real Time-PCR W/Rpt Log (cells/mL)</td>
<td>Not Detected</td>
</tr>
<tr>
<td><strong>C. albicans, DNA</strong></td>
<td>Real Time-PCR</td>
<td>Not Detected</td>
</tr>
<tr>
<td><strong>C. glabrata, DNA</strong></td>
<td>Real Time-PCR</td>
<td>Not Detected</td>
</tr>
<tr>
<td><strong>C. tropicalis, DNA</strong></td>
<td>Real Time-PCR</td>
<td>Not Detected</td>
</tr>
<tr>
<td><strong>C. parapsilosis, DNA</strong></td>
<td>Real Time-PCR</td>
<td>Not Detected</td>
</tr>
</tbody>
</table>

Specimen/Stability: Vaginal swab in 3 mL: Aptima™ Vaginal Swab Collection Kit (Orange label)
Ambient 48 Hours, Refrigerated 7 days, Frozen 14 days
Collection Instructions: Follow instructions in the Aptima™ Vaginal Swab Specimen Collection kit for physician collected or self-collection of vaginal specimens.
Schedule: Monday- Saturday
Report: 2 days
CPT Code: 87491, 87512, 87591, 87798, 87799 (x3), 87481 (x4)
Regulatory Status: FDA Approved, Laboratory Developed Test, Analyte Specific Reagent
Clinical Utility: To diagnose the causative agent(s) of vaginosis/vaginitis.
Always Statement: T. vaginalis RNA, QL, TMA:
This test(s) was developed and its performance characteristics have been determined by Quest Diagnostics Nichols Institute, Valencia, CA. It has not been cleared or approved by the U.S. Food and Drug Administration. The FDA has determined that such clearance or approval is not necessary. Performance characteristics refer to the analytical performance of the test.
Lactobacillus, Atopobium, Megasphaera, Gardnerella and Candida:
This test(s) was developed and its performance characteristics have been determined by Quest Diagnostics Nichols Institute, Valencia, CA. Performance characteristics refer to the analytical performance of the test.
Note: **This test is not available for New York State patient testing. There is no recommended alternative for New York patient testing.**
New Tests: (cont.)

3921 Testosterone, Total, LC/MS/MS (Available April 5)

<table>
<thead>
<tr>
<th>Component, Total</th>
<th>Method</th>
<th>Reference Range/Units</th>
</tr>
</thead>
<tbody>
<tr>
<td>Testosterone, Total</td>
<td>LC/MS/MS</td>
<td>SEE BELOW</td>
</tr>
</tbody>
</table>

**Specimen/Stability**
- Serum 0.5 (0.2) mL: Ambient 7 days, Refrigerated 7 days, Frozen 2 years
- Plasma Heparinized 0.5 (0.2) mL: Ambient 7 days, Refrigerated 7 days, Frozen 2 years

**Collection Instructions**
Collect blood in a red-top tube (no gel). Serum separator tubes are unacceptable. Room temperature preferred.

**Schedule**
Monday-Sunday

**Report**
Next day

**Reference Range**

<table>
<thead>
<tr>
<th>Age Group</th>
<th>Male (ng/dL)</th>
<th>Female (ng/dL)</th>
</tr>
</thead>
<tbody>
<tr>
<td>Adult Male 18-69</td>
<td>250-1100</td>
<td></td>
</tr>
<tr>
<td>Adult Male 70-89</td>
<td>90-890</td>
<td></td>
</tr>
<tr>
<td>Adult Female 18-69 Years</td>
<td>2-45</td>
<td></td>
</tr>
<tr>
<td>Adult Female 70-94 Years</td>
<td>2-40</td>
<td></td>
</tr>
</tbody>
</table>

**Reference Range for Adult**

- Male 18-69: 250-1100 ng/dL
- Male 70-89: 90-890 ng/dL
- Female 18-69: 2-45 ng/dL
- Female 70-94: 2-40 ng/dL

Aging men with clinically significant hypogonadal symptoms and testosterone values repeatedly in the range of the 200-300 ng/dL or less may benefit from testosterone treatment after adequate risk and benefits counseling.

**Always Message**
Total Testosterone PEDIATRIC Reference Ranges

*** Unable to flag abnormal result(s); please refer to reference range(s) below:

<table>
<thead>
<tr>
<th>Age Group</th>
<th>Male (ng/dL)</th>
<th>Female (ng/dL)</th>
</tr>
</thead>
<tbody>
<tr>
<td><strong>Cord Blood</strong></td>
<td>17-61</td>
<td>16-44</td>
</tr>
<tr>
<td><strong>1-10 days</strong></td>
<td>187 or less</td>
<td>24 or less</td>
</tr>
<tr>
<td><strong>1-3 months</strong></td>
<td>72-344</td>
<td>17 or less</td>
</tr>
<tr>
<td><strong>3-5 months</strong></td>
<td>201 or less</td>
<td>12 or less</td>
</tr>
<tr>
<td><strong>5-7 months</strong></td>
<td>59 or less</td>
<td>13 or less</td>
</tr>
<tr>
<td><strong>7-12 months</strong></td>
<td>16 or less</td>
<td>11 or less</td>
</tr>
<tr>
<td>1-5.9 years</td>
<td>5 or less</td>
<td>8 or less</td>
</tr>
<tr>
<td>6-7.9 years</td>
<td>25 or less</td>
<td>20 or less</td>
</tr>
<tr>
<td>8-10.9 years</td>
<td>42 or less</td>
<td>35 or less</td>
</tr>
<tr>
<td>11-11.9 years</td>
<td>260 or less</td>
<td>40 or less</td>
</tr>
<tr>
<td>12-13.9 years</td>
<td>420 or less</td>
<td>40 or less</td>
</tr>
<tr>
<td>14-17.9 years</td>
<td>1000 or less</td>
<td>40 or less</td>
</tr>
</tbody>
</table>

**Data from J Clin Invest 1974;53:819-828 and J Clin Endocrinol Metab 1973;36:1132-1142**

Pediatric Reference Ranges by Pubertal Stage for Testosterone, Total (Women and Children), LC/MS/MS (ng/dL)

<table>
<thead>
<tr>
<th>Tanner Stage</th>
<th>Male (ng/dL)</th>
<th>Female (ng/dL)</th>
</tr>
</thead>
<tbody>
<tr>
<td>I</td>
<td>5 or less</td>
<td>8 or less</td>
</tr>
<tr>
<td>II</td>
<td>167 or less</td>
<td>24 or less</td>
</tr>
<tr>
<td>III</td>
<td>21-719</td>
<td>28 or less</td>
</tr>
<tr>
<td>IV</td>
<td>25-912</td>
<td>31 or less</td>
</tr>
<tr>
<td>V</td>
<td>110-975</td>
<td>33 or less</td>
</tr>
</tbody>
</table>

**CPT Code**
- 84403

**Clinical Utility**
Helpful in assessing testicular function in male and managing hirsutism, virilization in females.

**Note**
***This test is not available for New York State patient testing.***
### New Tests: (cont.)

#### 3924 Testosterone, Free, Bioavailable, and Total, LC/MS/MS

<table>
<thead>
<tr>
<th>Component</th>
<th>Method</th>
<th>Reference Range/Units</th>
</tr>
</thead>
<tbody>
<tr>
<td>Testosterone, Total</td>
<td>LC/MS/MS</td>
<td>SEE BELOW</td>
</tr>
<tr>
<td>Testosterone, Free</td>
<td>Calculated, LC/MS/MS</td>
<td>SEE BELOW</td>
</tr>
<tr>
<td>Testosterone, Bioavailable</td>
<td>Calculated, LC/MS/MS</td>
<td>SEE BELOW</td>
</tr>
<tr>
<td>Sex Hormone Binding Globulin</td>
<td>ICMA</td>
<td>SEE BELOW</td>
</tr>
<tr>
<td>Albumin</td>
<td>Spectrometry</td>
<td>SEE BELOW</td>
</tr>
</tbody>
</table>

Effective April 5

Specimen/Stability Serum: 2.8 (1.3) mL: Ambient 7 days, Refrigerated 7 days, Frozen 2 years

Plasma Heparinized 2.8 (1.3) mL: Ambient 7 days, Refrigerated 7 days, Frozen 2 years

Collection Instructions Collect blood in a red-top tube (no gel). Serum separator tubes are unacceptable. Refrigerated preferred.

Schedule Monday-Sunday

Report 3 days

Component Testosterone, Total

Methodology LC/MS/MS

Reference Range

<table>
<thead>
<tr>
<th>Age</th>
<th>Male (ng/dL)</th>
<th>Female (ng/dL)</th>
</tr>
</thead>
<tbody>
<tr>
<td>Adult Male 18-69</td>
<td>250-1100</td>
<td></td>
</tr>
<tr>
<td>Adult Male 70-89</td>
<td>90-890</td>
<td></td>
</tr>
<tr>
<td>Adult Female 18-69</td>
<td>2-45</td>
<td></td>
</tr>
<tr>
<td>Adult Female 70-94</td>
<td>2-40</td>
<td></td>
</tr>
</tbody>
</table>

Aging men with clinically significant hypogonadal symptoms and testosterone values repeatedly in the range of the 200-300 ng/dL or less may benefit from testosterone treatment after adequate risk and benefits counseling.

Always Message Total Testosterone PEDIATRIC Reference Ranges

*** Unable to flag abnormal result(s); please refer to reference range(s) below:

<table>
<thead>
<tr>
<th>Age</th>
<th>Male (ng/dL)</th>
<th>Female (ng/dL)</th>
</tr>
</thead>
<tbody>
<tr>
<td><strong>Cord Blood</strong></td>
<td>17-61</td>
<td>16-44</td>
</tr>
<tr>
<td><strong>1-10 days</strong></td>
<td>187 or less</td>
<td>24 or less</td>
</tr>
<tr>
<td><strong>1-3 months</strong></td>
<td>72 – 344</td>
<td>17 or less</td>
</tr>
<tr>
<td><strong>3-5 months</strong></td>
<td>201 or less</td>
<td>12 or less</td>
</tr>
<tr>
<td><strong>5-7 months</strong></td>
<td>59 or less</td>
<td>13 or less</td>
</tr>
<tr>
<td><strong>7-12 months</strong></td>
<td>16 or less</td>
<td>11 or less</td>
</tr>
<tr>
<td>1-5.9 years</td>
<td>5 or less</td>
<td>8 or less</td>
</tr>
<tr>
<td>6-7.9 years</td>
<td>25 or less</td>
<td>20 or less</td>
</tr>
<tr>
<td>8-10.9 years</td>
<td>42 or less</td>
<td>35 or less</td>
</tr>
<tr>
<td>11-11.9 years</td>
<td>260 or less</td>
<td>40 or less</td>
</tr>
<tr>
<td>12-13.9 years</td>
<td>420 or less</td>
<td>40 or less</td>
</tr>
<tr>
<td>14-17.9 years</td>
<td>1000 or less</td>
<td>40 or less</td>
</tr>
</tbody>
</table>

**Data from J Clin Invest 1974;53:819-828 and J Clin Endocrinol Metab 1973;36:1132-1142

Pediatric Reference Ranges by Pubertal Stage for Testosterone, Total (Women and Children), LC/MS/MS (ng/dL)

<table>
<thead>
<tr>
<th>Tanner Stage</th>
<th>Male (ng/dL)</th>
<th>Female (ng/dL)</th>
</tr>
</thead>
<tbody>
<tr>
<td>I</td>
<td>5 or less</td>
<td>8 or less</td>
</tr>
<tr>
<td>II</td>
<td>167 or less</td>
<td>24 or less</td>
</tr>
<tr>
<td>III</td>
<td>21-719</td>
<td>28 or less</td>
</tr>
<tr>
<td>IV</td>
<td>25-912</td>
<td>31 or less</td>
</tr>
<tr>
<td>V</td>
<td>110-975</td>
<td>33 or less</td>
</tr>
</tbody>
</table>

Component Testosterone, Free

Methodology Calculated (same)

Reference Range

<table>
<thead>
<tr>
<th>Age</th>
<th>Male (pg/mL)</th>
<th>Female (pg/mL)</th>
</tr>
</thead>
<tbody>
<tr>
<td>18 – 69 Years</td>
<td>46.0 – 224.0</td>
<td>0.2 – 5.0</td>
</tr>
<tr>
<td>70 – 89 Years</td>
<td>6.0 – 73.0</td>
<td>0.3 – 5.0</td>
</tr>
</tbody>
</table>

(continued on next page)
### Testosterone, Free, Bioavailable, and Total, LC/MS/MS (cont.)

**New Tests:**

#### Component: Testosterone, Free, Bioavailable

<table>
<thead>
<tr>
<th>Component</th>
<th>Methodology</th>
<th>Reference Range</th>
</tr>
</thead>
<tbody>
<tr>
<td>Testosterone, Bioavailable</td>
<td>Calculated</td>
<td>Adult</td>
</tr>
</tbody>
</table>

<table>
<thead>
<tr>
<th>Age</th>
<th>Male (ng/dL)</th>
<th>Female (ng/dL)</th>
</tr>
</thead>
<tbody>
<tr>
<td>18 – 69 Years</td>
<td>110.0-575.0</td>
<td>0.5-8.5</td>
</tr>
<tr>
<td>70-89 Years</td>
<td>15.0-150.0</td>
<td>0.5-8.8</td>
</tr>
</tbody>
</table>

**Always Message:** Pediatric Reference Ranges for Testosterone, Bio-Available, Calculated, LC/MS/MS (ng/dL) *** Unable to flag abnormal result(s); please refer to reference range(s):**

<table>
<thead>
<tr>
<th>Age</th>
<th>Male (ng/dL)</th>
<th>Female (ng/dL)</th>
</tr>
</thead>
<tbody>
<tr>
<td>&lt; 1 year</td>
<td>Not available</td>
<td>Not available</td>
</tr>
<tr>
<td>1 – 11.9 Years</td>
<td>5.4 or less</td>
<td>3.4 or less</td>
</tr>
<tr>
<td>12 – 13.9 Years</td>
<td>140.0 or less</td>
<td>3.4 or less</td>
</tr>
<tr>
<td>14 – 17.9 Years</td>
<td>8.0 – 210.0</td>
<td>7.8 or less</td>
</tr>
</tbody>
</table>

#### Component: Sex Hormone Binding Globulin

<table>
<thead>
<tr>
<th>Component</th>
<th>Methodology</th>
<th>Reference Range</th>
</tr>
</thead>
<tbody>
<tr>
<td>Sex Hormone Binding Globulin</td>
<td>ICMA</td>
<td>Adult</td>
</tr>
</tbody>
</table>

<table>
<thead>
<tr>
<th>Age</th>
<th>Male (nmol/L)</th>
<th>Female (nmol/L)</th>
</tr>
</thead>
<tbody>
<tr>
<td>18-29 Years</td>
<td>7-49</td>
<td>6-112</td>
</tr>
<tr>
<td>30-39 Years</td>
<td>8-48</td>
<td>14-102</td>
</tr>
<tr>
<td>40-49 Years</td>
<td>9-45</td>
<td>11-100</td>
</tr>
<tr>
<td>50-59 Years</td>
<td>18-47</td>
<td>17-78</td>
</tr>
<tr>
<td>60-69 Years</td>
<td>17-54</td>
<td>17-95</td>
</tr>
<tr>
<td>70-79 Years</td>
<td>23-65</td>
<td>21-90</td>
</tr>
<tr>
<td>80-91 Years</td>
<td>20-63</td>
<td>26-77</td>
</tr>
<tr>
<td>&gt;91 Years</td>
<td>Not Established</td>
<td>Not Established</td>
</tr>
</tbody>
</table>

**Always Message:** Pediatric Reference Ranges for Sex Hormone Binding Globulin, Serum *** Unable to flag abnormal result(s); please refer to reference range(s)***

<table>
<thead>
<tr>
<th>Age</th>
<th>Male (nmol/L)</th>
<th>Female (nmol/L)</th>
</tr>
</thead>
<tbody>
<tr>
<td>&lt;3 Years</td>
<td>Not Established</td>
<td>Not Established</td>
</tr>
<tr>
<td>3-9 Years</td>
<td>18-136</td>
<td></td>
</tr>
<tr>
<td>10-13 Years</td>
<td>17-123</td>
<td></td>
</tr>
<tr>
<td>14-17 Years</td>
<td>11-71</td>
<td></td>
</tr>
</tbody>
</table>

#### Component: Albumin

<table>
<thead>
<tr>
<th>Component</th>
<th>Methodology</th>
<th>Reference Range</th>
</tr>
</thead>
<tbody>
<tr>
<td>Albumin</td>
<td>S</td>
<td>3.6-5.1 g/dL</td>
</tr>
</tbody>
</table>

**CPT Codes:** 82040, 84270, 84403

**Note:** **This test is not available for New York State patient testing.**
Test Changes:
Effective Immediately:

5901 Activated Protein C Resistance w/Reflex Factor V GenotypR™
Effective Immediately
Collection Instructions First Specimen (Same)
Second Specimen (NEW)
For the potential reflex to Factor V GenotypR™, EDTA is the preferred anticoagulant, but ACD (A or B) is also acceptable. Refrigerated and frozen specimens are also acceptable but not preferred. Specimens will be stabilized upon departmental receipt.

2509 Adenovirus Ag Detection
Effective Immediately
Collection Instructions 1. Specimens should be collected early in the acute phase of infection. The chance of viral recovery is best during the first 3 days after onset and is greatly reduced beyond 5 days with many viruses. 2. Source of specimen is recommended.
3. Submit 2 acetone-fixed slides or specimens in viral transport media. These specimens are nasal swab or washings, eye, and rectal. Ship in slide holder at ambient temperature.
4. Unacceptable specimens: Wooden swabs, dry swabs and calcium alginate.
5. Do not freeze specimen at -20C. Virus loses infectivity.
6. Ship specimens on cold pack or on dry ice.
7. M4 transport media (M4) and dacron-tipped swabs with plastic or fine-wire shafts available for use with M4 are provided. Please call Client Services, 800-421-4449 to request media.

5310 BAALC (Brain and Acute Leukemia, Cytoplasmic) UltraQuant®
Effective Immediately
CPT Codes 83891, 83896x2, 83900, 83902, 83912

2412 Clostridium difficile Toxin B Detection
Effective Immediately
Always Statement Please REMOVE the following from the report format: “Screening performed by EIA. Detected results are confirmed by tissue culture assay.”

Effective Immediately
Collection Instructions EDTA is the preferred anticoagulant, but ACD (A or B) is also acceptable. Refrigerated and frozen specimens are also acceptable, but not preferred. Specimens will be stabilized upon departmental receipt.
Also Affected DOS Codes 1515, 1518, 4555, 4562, 5055, 5353, 5369, 5371, 5375, 5383

4983 Hemoglobinopathy Evaluation
Effective Immediately
Collection Instructions Please note: Samples received refrigerated beyond 4 days will not have the following components reported: Hgb, Hct, MCV, MCH, RBC and RDW. Store and ship refrigerated.

3541 Vitamin D, 25-Hydroxy Total [LC/MS/MS]
Effective Immediately
Collection Instructions Serum is the only acceptable specimen type. Do not use any additives. Serum in centrifuged SST that is less than 48 hours from collection is acceptable. Red top tube (with serum not separated) is not acceptable.
Test Changes: (cont’d)

Effective April 2:

1266  **Gliadin IgG & IgA Abs**
- **Effective:** April 2
- **Name:** Gliadin Antibody (IgG, IgA) (NEW)
- **Specimen/Stability:** Serum 1.0 (0.5) mL: Ambient 4 days, Refrigerated 7 days, Frozen 30 days
  - **Note:** Decreased ambient, refrigerated and frozen stability.
- **Component:** Gliadin Antibody, IgG (NEW NAME)
- **Reference Range:** < 11 U/mL (NEW)
- **Methodology:** EIA (same)
- **Always Statement:**
  - REFERENCE RANGE for Gliadin IgG & IgM Abs:
    - < 11 U/mL: Negative
    - 11 – 17 U/mL: Equivocal
    - > 17 U/mL: Positive
- **Also Affected:** DOS Codes 1075, 1076, 1077, 1261, 1286

1286  **Gliadin IgA Abs**
- **Effective:** April 2
- **Name:** Gliadin Antibody, IgA (NEW)

1261  **Gliadin IgG Abs**
- **Effective:** April 2
- **Name:** Gliadin Antibody, IgG (NEW)

Effective April 5:

3131  **Adenosine Deaminase**
- **Effective:** April 5
- **Specimen/Stability:** Serum 1.0 (0.5) mL: Ambient 3 days, Refrigerated 7 days, Frozen 7 days
  - Pleural Fluid 1.0 (0.5) mL: Ambient 3 days, Refrigerated 7 days, Frozen 7 days
  - **Note:** CSF is no longer accepted; decreased refrigerated and frozen stability.
- **Regulatory Status:** Investigational Use Only
- **Always Statement:**
  - REFERENCE RANGE for Adenosine Deaminase:
    - Serum: 0 – 15.0 U/L
    - Pleural Fluid: 0 – 24.0 U/L
  - This test(s) was performed using a kit that has not been cleared or approved by the FDA. The analytical performance characteristics of this test have been determined by Quest Diagnostics Nichols Institute, Valencia, CA. This test should not be used for diagnosis without confirmation by other medically established means.

**Allergens – IgG Specific**
- **Effective:** April 5
- **Always Statement:** Please **REMOVE** the reference range table from the report format.
- **Also Affected:** ***ALL IgG Allergen panels***

4912  **Alprazolam**
- **Effective:** April 5
- **Reference Range:** 10-50 ng/mL (NEW)
- **Always Statement:** **REMOVE**
- **Also Affected:** DOS Code 4090, Reflex of DOS Code 4107
4147  **Amiodarone & Metabolites**
Effective April 5
Name Amiodarone and Metabolite (NEW)
Component Amiodarone
Reference Range 1.5 – 2.5 mcg/mL (NEW)
Component Desethylamiodarone
Reference Range 1.5 – 2.5 mcg/mL (NEW)
Always Statement Toxic: >2.5 mcg/mL. Toxic effects have been observed at levels as low as 2.0 mcg/mL.

4258  **Aripiprazole, Serum/Plasma**
Effective April 5
Name Aripiprazole, Quantitative, Serum (NEW)

4420U  **Buprenorphine Screen**
Effective April 5
Name Buprenorphine Screen, Urine (NEW)
Specimen/Stability Urine 10 (1) mL: Ambient 7 days, Refrigerated 14 days, Frozen 30 days
Note: Ambient specimens are now accepted; increased refrigerated and decreased frozen stability.

1077  **Celiac Disease EvaluatR™**
Effective April 5
Specimen/Stability Serum 4.0 (2.0) mL: Refrigerated 7 days, Frozen 30 days
Note: Decreased frozen stability.
Also Affected DOS Codes 1075, 1076

4918  **Clonazepam**
Effective April 5
Reference Range 30-60 ng/mL (NEW)
Always Statement Potentially toxic: >70 ng/mL
Also Affected DOS Code 4090, Reflex of DOS Code 4107

7670  **Clostridium difficile Toxin Evaluation**
Effective April 5
Name Clostridiun dificile Toxin A and B Detection, EIA (NEW)
Component C. difficile Toxin A and B (ADD)
Reference Range Not detected
Methodology EIA
Component Clostridiun dificile Toxin A (REMOVE)
Component Clostridiun dificile Toxin B (REMOVE)
Always Statement Please REMOVE the following from the report format:
“Toxin B screening performed by EIA. Detected results are confirmed by tissue culture assay.”

4964  **Clozapine & Norclozapine**
Effective April 5
Component Clozapine (Clozaril) (REMOVE)
Reference Range Reference Range for Clozapine:
The therapeutic response begins to appear at 100 ng/mL. Refractory schizophrenia appears to require a therapeutic concentration of at least 350 ng/mL (trough, at steady state).
Component Norclozapine
Reference Range 25 – 400 ng/mL (NEW)
Always Statement Reference Range for Norclozapine:
25 – 400 ng/mL (trough, steady state)
Test Changes: (cont’d)

7534  **CoEnzyme Q10 (Co Q10) AssessR™**
Effective: April 5
Name: Coenzyme Q10 (NEW)
Reference Range: 0.44 – 1.64 mg/L (NEW)
Always Statement: Therapeutic range recommended for cardiovascular disease >2.5 mg/L.

9189  **Cryptococcus Ag**
Effective: April 5
Name: Cryptococcus Antigen Screen with Reflex to Titer (NEW)
Specimen/Stability: Serum 2.0 (0.5): Refrigerated 72 hours, Frozen 60 days
CSF 1.0 (0.5): Refrigerated 72 hours, Frozen 60 days
**Note:** CSF specimens now accepted; ambient specimens no longer accepted; decreased refrigerated and frozen stability.
Collection Instructions: Centrifuge serum specimens within 1 hour of collection. Transfer serum to clean, plastic, screw-capped vial(s). Refrigerate samples and transport on refrigerant coolant or freeze samples and transport on dry ice to the laboratory.
Component Source (ADD)
Component Screen (NEW NAME)
Reference Range: Not detected (NEW)
Units: none (REMOVE existing)
Methodology: Agglutination (NEW)
CPT Code: 86403
Note: Screen detected results will automatically reflex to Titer for an additional fee (add CPT Code 86406).

4924  **Doxepin & Nodoxepin**
Effective: April 5
Methodology: LC/MS/MS (NEW)

4480  **Flunitrazepam & Metabolites Confirmation Serum**
Effective: April 5
Name: Flunitrazepam and Metabolites, Quantitative, Serum (NEW)

4480U  **Flunitrazepam & Metabolites Confirmation Urine**
Effective: April 5
Name: Flunitrazepam and Metabolites, Quantitative, Urine (NEW)

3364  **Gabapentin**
Effective: April 5
Reference Range: (REMOVE)
Always Statement: Reference Range for Gabapentin:
2.7-4.1 mcg/mL (peak) following a single dose of 900-1800 mg/day.
4.0-8.5 mcg/mL (peak) following a multiple dose of 900-1800 mg/day administration. The reference range is evolving. Seizure control has been observed at levels in excess of 4 mcg/mL.

1398  **Glucose-6 Phosphate Dehydrogenase (G-6-PDH)**
Effective: April 5
Specimen/Stability: Whole Blood EDTA 7.0 (2.0) mL: Ambient 48 hours, Refrigerated 4 days
WB EDTA Microtainer 2.0 (1.0) mL: Ambient 48 hours, Refrigerated 4 days
**Note:** Ambient specimens are now accepted.
Reference Range: 4.6 – 13.5 U/g Hb (NEW)
4179U **Heroin Metabolites Urine**
- **Effective:** April 5
- **Name:** Heroin Metabolites, Quantitative, Urine (NEW)

3192 **Insulin**
- **Effective:** April 5
- **Methodology:** Immunoassay (NEW)

4872UR **Manganese Urine Random**
- **Effective:** April 5
- **Component:** Manganese Urine
- **Reference Range:** <5.0 mcg/L (NEW UNITS)
- **Component:** Manganese/Creatinine Ratio
- **Reference Range:** <5.0 mcg/g creat (NEW UNITS)
- **All other components remain the same**

4873UI **Mercury Urine Industrial**
- **Effective:** April 5
- **Reference Range:** <35 mcg/g creat (NEW UNITS)
- **All other components remain the same**

4190 **Nicotine & Metabolite**
- **Effective:** April 5
- **Component:** Nicotine
- **Always Statement:** Reporting Limit: 2 ng/mL
- **Observed concentrations in habitual smokers 3 to 63 ng Nicotine/mL.** (NEW)
- **Component:** Cotinine
- **Always Statement:** Reporting Limit: 2 ng/mL
- **Synonym(s):** Nicotine Metabolite
- **Observed concentrations in habitual smokers 20 to 700 ng Cotinine/mL.** (NEW)

4190U **Nicotine & Metabolite Urine**
- **Effective:** April 5
- **Component:** Nicotine
- **Always Statement:** Reference Range: Not detected
- **Reported Nicotine concentrations in smokers (8-70 cigarettes/day):** Greater than 100 ng Nicotine/mL. (NEW)
- **Component:** Cotinine
- **Always Statement:** Reference Range: Not detected
- **Reported Cotinine concentrations in smokers (8-70 cigarettes/day):** Greater than 200 ng Cotinine/mL. (NEW)

9620 **Nuclear Matrix Proteins (NMP)**
- **Effective:** April 5
- **Reference Range:** <10.1 U/mL (NEW)

4181U **Opiates Confirmation, Enhanced Sensitivity, Urine**
- **Effective:** April 5
- **Name:** Opiates, Quantitative, Enhanced Sensitivity, Urine (NEW)
Test Changes: (cont’d)

4350U  **Oxidant Urine**
Effective April 5
Specimen/Stability Urine 10 (1) mL: Ambient 7 days, Refrigerated 14 days, Frozen 30 days
*Note: Ambient specimens are now accepted; increased refrigerated and decreased frozen stability.*

4176  **Oxycodone & Metabolite Serum**
Effective April 5
Name Oxycodone and Metabolite, Quantitative, Serum *(NEW)*

4176U  **Oxycodone & Metabolite Urine**
Effective April 5
Name Oxycodone and Metabolite, Quantitative, Urine *(NEW)*

3941  **PTH, Intact**
Effective April 5
Methodology Immunoassay *(NEW)*
Also Affected DOS Codes 3213, 3942, 3943, 3943SR, 3944

3218  **Sex Hormone Binding Globulin (SHBG)**
Component Sex Hormone Binding Globulin
Reference Range All reference ranges are the same except results will be reported in **whole numbers**.
Units nmol/L
Methodology ICMA *(NEW)*

3244  **Testosterone, Total, Chemiluminescence**
Effective April 5
Reference Range 0 – 17 Years: REMOVE
> 17 Years Male: 241-827 ng/dL (same)
> 17 Years Female: REMOVE
Note When requesting Total Testosterone for pediatric and females patient please refer to Testosterone, Total [LC/MS/MS] , test code 3921.
Also Affected DOS Codes 2017, 3248

4960  **Trazodone**
Effective April 5
Methodology LC/MS/MS *(NEW)*

3393  **Troponin I-Ultra**
Effective April 5
Methodology Immunoassay *(NEW)*
Also Affected DOS Code 3390

*The CPT Codes provided are based on AMA Guidelines and are for informational purposes only. CPT Coding is the sole responsibility of the billing party. Please direct any questions regarding CPT Coding to the payer being billed.*
Referral Test Changes:

Effective April 4:

S51747  BK Virus, DNA, Qualitative Real-Time PCR, Plasma (48900)
Specimen 0.7mL EDTA (lavender-top) plasma (NEW)
NOTE: CSF, Urine, Serum, Whole Blood, Plasma ACD are unacceptable for this test code. (NEW)
Assay Category: ASR Class 1 (NEW)
For CSF - Please use: S52402 BK Virus DNA, Qualitative Real-Time PCR, CSF (18889)
For Urine - Please use: S52403 BK Virus DNA, Qualitative Real-Time PCR, Urine (48901)

S51745  JC Polyoma Virus DNA, Quantitative Real-Time PCR, Plasma (41446)
**This test is not approved for the testing of patient samples from New York State.** (NEW)
Specimen 0.7mL EDTA (lavender-top) plasma (NEW)
NOTE: CSF, Urine, Serum, Plasma ACD are unacceptable for this test code. (NEW)
Assay Category: Laboratory Developed Test (NEW)
For CSF - Please use: S52406 JC Polyoma Virus DNA, Quantitative Real-Time PCR, CSF (16442)
For Urine - Please use: S52407 JC Polyoma Virus DNA, Quantitative Real-Time PCR, Urine (16446)

S51585  Immune Complex Detection by C1q Binding (36735)
Specimen 1mL red-top (no-gel) serum
NOTE: Plasma is no longer acceptable (NEW)
Reference Range/units: < or = 25.1 mcg Eq/mL (NEW)

S51744  JC Polyoma Virus DNA, Qualitative Real-Time PCR, Plasma (41336)
**This test is not approved for the testing of patient samples from New York State.** (NEW)
Specimen 0.7mL EDTA (lavender-top) plasma (NEW)
NOTE: CSF, Urine, Serum, Plasma ACD are unacceptable for this test code. (NEW)
Assay Category: Laboratory Developed Test (NEW)
For CSF - Please use: S52409 JC Polyoma Virus DNA, Qualitative Real-Time PCR, CSF (16441)
For Urine - Please use: S52408 JC Polyoma Virus DNA, Qualitative Real-Time PCR, Urine (16447)

S51498  BK Virus, DNA, Quantitative Real-Time PCR, Plasma (47900)
Specimen 0.7mL EDTA (lavender-top) plasma (NEW)
NOTE: CSF, Urine, Serum, Whole Blood, Plasma ACD are unacceptable for this test code. (NEW)
Assay Category: ASR Class 1 (NEW)
For CSF - Please use: S52404 BK Virus DNA, Quantitative Real-Time PCR, CSF (18901)
For Urine - Please use: S52405 BK Virus DNA, Quantitative Real-Time PCR, Urine (47901)
Referral Test Changes:  (cont’d)

Effective April 11:

S52044  **HTLV I/II, Confirmatory Assay (8511) (NEW)**
*Former Test Name: HTLV I/II, Western Blot (8511)*
*Methodology: Line Immunoassay (NEW)*
*Specimen: Potassium Oxalate (gray-top) and ACD-B (yellow-top) plasma are no longer acceptable (NEW)*

S51372  **Prolactin, Total and Monomeric (16122X) (NEW)**
*Former Test Name: Macroprolactin (16122X)*
*Reference Range: Prolactin, Total Females (>18 years)*
*Non-pregnant: 3.0-30.0 ng/mL*
*Pregnant: 10.0-209.0 ng/mL*
*Post-menopausal: 2.0-20.0 ng/mL*
*Males (>18 years): 2.0-18.0 ng/mL*
*Tanner Stages*
*Female Observed Range*
*Tanner Stage I: 3.6-12.0 ng/mL*
*Tanner Stage II-III: 2.6-18.0 ng/mL*
*Tanner Stage IV-V: 3.2-20.0 ng/mL*
*Male Observed Range*
*Tanner Stage I: < or = 10.0 ng/mL*
*Tanner Stage II-III: < or = 6.1 ng/mL*
*Tanner Stage IV-V: 2.8-11.0 ng/mL*
*Prolactin, Monomeric (NEW)*
*Adult Females: 3.2-25.2 ng/mL*
*Adult Males: 3.4-14.8 ng/mL*
*Additional Information: remove % Free Prolactin and % Macroprolactin analytes*
New Referral Tests:

The following tests are now available from other Quest Diagnostics laboratories and may be referred through Nichols Institute Valencia.

**S52356**  
*Chlamydia trachomatis*/Neisseria gonorrhoeae RNA, TMA, Throat (70051X)  
Test performed at Quest Diagnostics Nichols Institute, San Juan Capistrano

**S52357**  
*Chlamydia trachomatis*/Neisseria gonorrhoeae RNA, TMA, Rectal (16506X)  
Test performed at Quest Diagnostics Nichols Institute, San Juan Capistrano

**S52359**  
Chromosome Analysis, High Resolution (14595X)  
Test performed at Quest Diagnostics Nichols Institute, San Juan Capistrano

**S52360**  
Thyroglobulin, Fine Needle Aspirate (16559)  
Test performed at Quest Diagnostics Nichols Institute, San Juan Capistrano

**S52371**  
HLA-B51 DNA Typing (16775)  
Test performed at Quest Diagnostics Nichols Institute, Chantilly

**Effective April 4:**

**S52402**  
BK Virus DNA, Qualitative Real-Time PCR, CSF (18889)  
Test performed at Focus Diagnostics

**S52403**  
BK Virus DNA, Qualitative Real-Time PCR, Urine (48901)  
Test performed at Focus Diagnostics

**S52404**  
BK Virus DNA, Quantitative Real-Time PCR, CSF (18901)  
Test performed at Focus Diagnostics

**S52405**  
BK Virus DNA, Quantitative Real-Time PCR, Urine (47901)  
Test performed at Focus Diagnostics

**S52409**  
*JC* Polyoma Virus DNA, Qualitative Real-Time PCR, CSF (16441)  
**This test is not approved for the testing of patient samples from New York State**  
Test performed at Focus Diagnostics

**S52408**  
*JC* Polyoma Virus DNA, Qualitative Real-Time PCR, Urine (16447)  
**This test is not approved for the testing of patient samples from New York State**  
Test performed at Focus Diagnostics

**S52406**  
*JC* Polyoma Virus DNA, Quantitative Real-Time PCR, CSF (16442)  
**This test is not approved for the testing of patient samples from New York State**  
Test performed at Focus Diagnostics

**S52407**  
*JC* Polyoma Virus DNA, Quantitative Real-Time PCR, Urine (16446)  
**This test is not approved for the testing of patient samples from New York State**  
Test performed at Focus Diagnostics

**Effective April 11:**

**S52401**  
Homocysteine, Nutritional and Congenital (36362X)  
Test performed at Quest Diagnostics Nichols Institute, San Juan Capistrano

Please call client relations at 800-421-4449 or visit our website at www.NicholsInstitute.com/valencia for ordering information.
Discontinued Tests:

**Effective Immediately:**

<table>
<thead>
<tr>
<th>Code</th>
<th>Test Description</th>
<th>Replacement</th>
<th>Location</th>
</tr>
</thead>
<tbody>
<tr>
<td>S51837</td>
<td>CA 125, Pleural Fluid (17580X)</td>
<td>No Replacement</td>
<td></td>
</tr>
<tr>
<td>S49023</td>
<td>Cannabinoids Confirmation Fluid [0964]</td>
<td>No Replacement</td>
<td></td>
</tr>
<tr>
<td>7691</td>
<td><em>Clostridium difficile</em> Toxin A Detection</td>
<td>Recommended replacement: 7670 – <em>Clostridium difficile</em> Toxin Evaluation</td>
<td>Test performed at Quest Diagnostics Nichols Institute, Valencia, CA</td>
</tr>
<tr>
<td>S49528NY</td>
<td>Flunitrazepam &amp; Metab. Screen Serum Clinical (NY)</td>
<td>Recommended replacement: 4480 – Flunitrazepam &amp; Metabolites Confirmation, Serum</td>
<td>Test performed at Quest Diagnostics Nichols Institute, Valencia</td>
</tr>
<tr>
<td>S49524NY</td>
<td>Flunitrazepam &amp; Metabolite Screen Urine Clinical (9341) (NY)</td>
<td>Recommended replacement: 4480U – Flunitrazepam &amp; Metabolites Confirmation, Urine</td>
<td>Test performed at Quest Diagnostics Nichols Institute, Valencia</td>
</tr>
<tr>
<td>2445</td>
<td>Hepatitis C Antibody w/Reflex RIBA</td>
<td>Suggested replacement confirmation assay: 7516 – Hepatitis C Virus RNA DetectR™ Assay requires a minimum of 2 mL frozen EDTA or ACD plasma.</td>
<td>Test performed at Quest Diagnostics Nichols Institute, Valencia</td>
</tr>
<tr>
<td>2445B</td>
<td>Hepatitis C Antibody w/Reflex RIBA + Bands</td>
<td>Suggested replacement confirmation assay: 7516 – Hepatitis C Virus RNA DetectR™ Assay requires a minimum of 2 mL frozen EDTA or ACD plasma.</td>
<td>Test performed at Quest Diagnostics Nichols Institute, Valencia</td>
</tr>
<tr>
<td>2447</td>
<td>Hepatitis C Virus Abs [RIBA]</td>
<td>Suggested replacement confirmation assay: 7516 – Hepatitis C Virus RNA DetectR™ Assay requires a minimum of 2 mL frozen EDTA or ACD plasma.</td>
<td>Test performed at Quest Diagnostics Nichols Institute, Valencia</td>
</tr>
<tr>
<td>2447B</td>
<td>Hepatitis C Virus Abs [RIBA] + Bands</td>
<td>Suggested replacement confirmation assay: 7516 – Hepatitis C Virus RNA DetectR™ Assay requires a minimum of 2 mL frozen EDTA or ACD plasma.</td>
<td>Test performed at Quest Diagnostics Nichols Institute, Valencia</td>
</tr>
<tr>
<td>2447T</td>
<td>Hepatitis C Virus Abs [RIBA] [Blood Bank]</td>
<td>Suggested replacement confirmation assay: 7516 – Hepatitis C Virus RNA DetectR™ Assay requires a minimum of 2 mL frozen EDTA or ACD plasma.</td>
<td>Test performed at Quest Diagnostics Nichols Institute, Valencia</td>
</tr>
<tr>
<td>2447BT</td>
<td>Hepatitis C Virus Abs [RIBA] + Bands [Blood Bank]</td>
<td>Suggested replacement confirmation assay: 7516 – Hepatitis C Virus RNA DetectR™ Assay requires a minimum of 2 mL frozen EDTA or ACD plasma.</td>
<td>Test performed at Quest Diagnostics Nichols Institute, Valencia</td>
</tr>
<tr>
<td>7491</td>
<td>Hepatitis C Virus Evaluation [RIBA] w/Reflex TMA</td>
<td>Suggested replacement confirmation assay: 7516 – Hepatitis C Virus RNA DetectR™ Assay requires a minimum of 2 mL frozen EDTA or ACD plasma.</td>
<td>Test performed at Quest Diagnostics Nichols Institute, Valencia</td>
</tr>
</tbody>
</table>
Discontinued Tests: (cont’d)

7491B  **Hepatitis C Virus Evaluation [RIBA] + Bands w/Reflex TMA**
Suggested replacement confirmation assay: 7516 – Hepatitis C Virus RNA DetectR™
Assay requires a minimum of 2 mL frozen EDTA or ACD plasma.
Test performed at Quest Diagnostics Nichols Institute, Valencia.

S51449  **Meprobamate, Urine [3104X]**
Recommended replacement: 3365U – Carisoprodol Metabolite, Quantitative, Urine
Test performed at Quest Diagnostics Nichols Institute, Valencia, CA

S48744  **Surgical Pathology Level Bone Marrow (See Case Comment)**
No Replacement

**Effective March 29:**

3990  **PTH-Related Protein**
Recommended replacement: S51608 – PTH-Related Protein (PTH-RP) (34478Z)
Test performed at Quest Diagnostics Nichols Institute, San Juan Capistrano

5270S  **AccuType™ Metformin, Saliva**
Recommended replacement: 5270 – AccuType™ Metformin
Test performed at Quest Diagnostics Nichols Institute, Valencia, CA

9189C  **Cryptococcus Ag CSF**
Recommended replacement: 9189 – Cryptococcus Antigen Latex
Test performed at Quest Diagnostics Nichols Institute, Valencia, CA

E79  **Allergen – Budgerigar Serum Proteins IgE**
Recommended replacement: None
Test performed at N/A

**Effective April 1:**

S50542  **Cortisol Saliva (84225)**
Recommended replacement: S52400 – Cortisol, Saliva, LC/MS/MS (19897X)
Test performed at Quest Diagnostics Nichols Institute, San Juan Capistrano

S51173  **Procalcitonin, Serum (83169)**
Recommended replacement: S52399 – Procalcitonin (16265)
Test performed at Quest Diagnostics Nichols Institute, Chantilly

**Effective April 5:**

3916  **Testosterone, Bioavailable**
Recommended replacement: 3924 – Testosterone, Free, Bioavailable, and Total, LC/MS/MS
Test performed at Quest Diagnostics Nichols Institute, Valencia, CA

3911  **Testosterone, Bioavailable w/High Sensitivity Total**
Recommended replacement: 3924 – Testosterone, Free, Bioavailable, and Total, LC/MS/MS
Test performed at Quest Diagnostics Nichols Institute, Valencia, CA

3917  **Testosterone, Weakly Binding**
Recommended replacement: 3924 – Testosterone, Free, Bioavailable, and Total, LC/MS/MS
Test performed at Quest Diagnostics Nichols Institute, Valencia, CA
Discontinued Tests: (cont’d)

3913  Testosterone, Weakly Bound w/High Sensitivity Total & Free
Recommended replacement: 3924 – Testosterone, Free, Bioavailable, and Total, LC/MS/MS
Test performed at Quest Diagnostics Nichols Institute, Valencia, CA

Effective April 11:

S51311  Homocysteine Total, Urine (26318)
Recommended replacement: S52401 – Homocysteine, Nutritional and Congenital (36362X)
Test performed at Quest Diagnostics Nichols Institute, San Juan Capistrano