



SPECIALTY LABORATORIES

2211 Michigan Avenue
Santa Monica, CA 90404

800•421•4449

July - August, 2004

Dear Colleague:

While there are no new tests this month, we have a number of new introductions planned for September and October, including: Accumin™ for direct measurement of intact urinary albumin, Cocaine and metabolites (parent drug and 4 metabolites) confirmation in urine and serum, Metapneumovirus PCR for detection of this prevalent virus in at-risk populations and MRSA PCR for help in determining the appropriate treatment of drug-resistant Staphylococcal infections.

To improve workflow and extend specimen stabilities we have consolidated all automated chemistry into a new platform and re-validated all affected reference ranges. The resultant changes in reference range and extended stabilities are listed in a table attached to this month's letter. We are also providing more comprehensive reference ranges specific for pediatric age groups, including infants and adolescent Tanner Stages for several endocrine assays.

Please note in the "Tests Discontinued" section that at this time we are unable to continue offering the Melanoma MonitR™ assay for TA90-IC beyond our 30-day notification period due to the supplier's discontinuation of an agreement by which we obtained this reagent. We are currently assessing alternate assays for patient monitoring. The test is not currently commercially available through any other reference laboratory. As soon as it becomes available, Specialty will create a sendout code for this assay. Please contact Client Services if you would like additional information.

Changes have been made to Hexosaminidase Testing by the referral lab, please note the following:

- S50585 Hexosaminidase A & B Serum, Diagnosis
The deficiency of Hexosaminidase A results in Tay-Sachs disease and the deficiency of both Hexosaminidase A & B is Sandhoff's disease. This test is appropriate for diagnosis of a symptomatic patient of any ethnicity.
- S50616 Hexosaminidase Tay Sachs Carrier Testing
This procedure is utilized to revise Tay Sachs carrier risk for a patient of any ethnicity but a serum test cannot be performed on women during pregnancy. This test is the only appropriate test for carrier risk revision for asymptomatic, non-Ashkenazi Jewish males and non-Ashkenazi non-pregnant females.
- S49273 Hexosaminidase, Leukocytes
This serum test is appropriate for carrier risk revision for asymptomatic pregnant females of any ethnicity. NOTE: All abnormal results for this test will automatically reflex to the DNA test at an additional cost.
- S50598 Tay Sachs DNA
This whole-blood test is another method to assess carrier status of Ashkenazi Jewish males and females, regardless of pregnancy state by detection of the mutations at high frequency in this ethnic group. It can also be used for diagnosis of Tay Sachs in symptomatic Ashkenazi Jewish patients. For prenatal studies of pregnancies at risk for TSD, both DNA and biochemical analyses are recommended by the referral lab.

For additional information, please contact Client Services at 800-421-4449.

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



Coming Soon...

Metapneumovirus by PCR

MRSA PCR antibiotic-resistant *Staphylococcus aureus* (including methicillin-resistant *S. aureus* [MRSA])

Accumin™ for direct measurement of intact urinary albumin -- can detect microalbuminuria missed by conventional urine testing.

Dihydrotestosterone (DHT)

Cocaine and Metabolites Confirmation (parent drug and 4 metabolites) in urine and serum

Test Changes

Effective Tuesday, August 24, 2004 or as noted

| <u>Test Code</u> | <u>Test Name</u> | <u>Specific Change</u> | <u>Also Affected</u> |
|------------------|-------------------------------------|---|----------------------|
| 3974 | Alkaline Phosphatase, Bone Specific | <u>Reference Range</u> 0 - 2yo 90-250 U/L 3 - 9yo 50-190 U/L <u>Tanner Stage</u> 1 & 2 60-200 U/L 3 90-250 U/L 4 40-150 U/L 5 30-70 U/L 18 y - 44 yo 11.6 - 29.6 U/L >44yo Males: 15.0 - 41.3 U/L >44yo Females: 14.2 - 42.7 U/L | |
| 3146 | Dehydroepiandrosterone (DHEA) | <u>Reference Range</u> 0-7 d DHEA levels are highly elevated at birth (up to 1500 ng/mL). Even higher levels are seen in premature infants. 8d - 1m 400-2300 ng/dL 2m - 1y 40-700 ng/dL 2y - 4y 50-350 ng/dL 5y - 9y 70-300 ng/dL <u>Tanner Stage</u> 1 70-350 ng/dL 2 150-500 ng/dL 3 180-800 ng/dL 4 200-900 ng/dL 5 250-1000 ng/dL >18yo 140-850 ng/dL | |

| 3155 | Estradiol | <p><u>Reference Range</u></p> <table border="1"> <thead> <tr> <th></th> <th>Males</th> <th>Females</th> </tr> </thead> <tbody> <tr> <td>0 - 30 d</td> <td><70pg/mL</td> <td>26-83 pg/mL</td> </tr> <tr> <td>31d - 182d</td> <td><26pg/mL</td> <td><25 pg/mL</td> </tr> <tr> <td>6m - 6y</td> <td><22pg/mL</td> <td><22 pg/mL</td> </tr> <tr> <td>7y - 9y</td> <td><23pg/mL</td> <td><22 pg/mL</td> </tr> <tr> <td>10y - 12y</td> <td><24pg/mL</td> <td><35 pg/mL</td> </tr> <tr> <td>13y - 15y</td> <td><23pg/mL</td> <td><48 pg/mL</td> </tr> <tr> <td>16y - 18y</td> <td><35pg/mL</td> <td><65 pg/mL</td> </tr> <tr> <td>>18y</td> <td><57pg/mL</td> <td>see below</td> </tr> <tr> <td colspan="3"><u>>18yo Females:</u></td> </tr> <tr> <td>Untreated Postmenopausal</td> <td></td> <td><31 pg/mL</td> </tr> <tr> <td>Treated Postmenopausal</td> <td></td> <td><94 pg/mL</td> </tr> <tr> <td>Oral Contraceptives</td> <td></td> <td><103 pg/mL</td> </tr> <tr> <td>Ovulating, Follicular</td> <td></td> <td><267 pg/mL</td> </tr> <tr> <td>Ovulating, Midcycle</td> <td></td> <td>118-355 pg/mL</td> </tr> <tr> <td>Ovulating, Luteal</td> <td></td> <td>26-165 pg/mL</td> </tr> </tbody> </table> | | Males | Females | 0 - 30 d | <70pg/mL | 26-83 pg/mL | 31d - 182d | <26pg/mL | <25 pg/mL | 6m - 6y | <22pg/mL | <22 pg/mL | 7y - 9y | <23pg/mL | <22 pg/mL | 10y - 12y | <24pg/mL | <35 pg/mL | 13y - 15y | <23pg/mL | <48 pg/mL | 16y - 18y | <35pg/mL | <65 pg/mL | >18y | <57pg/mL | see below | <u>>18yo Females:</u> | | | Untreated Postmenopausal | | <31 pg/mL | Treated Postmenopausal | | <94 pg/mL | Oral Contraceptives | | <103 pg/mL | Ovulating, Follicular | | <267 pg/mL | Ovulating, Midcycle | | 118-355 pg/mL | Ovulating, Luteal | | 26-165 pg/mL | 3166 Estrogens, Fractionated Serum | | | | |
|---------------------------|---|---|--|----------------|-------------------|---------------|---------------|-------------|-------------------------------|----------|-------------|-------------|----------|-----------|------------|----------|-----------|---------------|----------|--------------|----------------|----------|--------------|----------------|-------------|-----------|---------------|-------------------------|-----------|--------------------------|------------------|--|--------------------------|--------------|-----------|------------------------|------------------|-----------|---------------------|----------------|------------|-----------------------|------------------|------------|---------------------|---------------------------|---------------|-------------------|---------------------------|--------------|------------------------------------|---------------------------|--|------------------|---|
| | Males | Females | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | |
| 0 - 30 d | <70pg/mL | 26-83 pg/mL | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | |
| 31d - 182d | <26pg/mL | <25 pg/mL | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | |
| 6m - 6y | <22pg/mL | <22 pg/mL | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | |
| 7y - 9y | <23pg/mL | <22 pg/mL | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | |
| 10y - 12y | <24pg/mL | <35 pg/mL | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | |
| 13y - 15y | <23pg/mL | <48 pg/mL | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | |
| 16y - 18y | <35pg/mL | <65 pg/mL | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | |
| >18y | <57pg/mL | see below | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | |
| <u>>18yo Females:</u> | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | |
| Untreated Postmenopausal | | <31 pg/mL | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | |
| Treated Postmenopausal | | <94 pg/mL | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | |
| Oral Contraceptives | | <103 pg/mL | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | |
| Ovulating, Follicular | | <267 pg/mL | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | |
| Ovulating, Midcycle | | 118-355 pg/mL | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | |
| Ovulating, Luteal | | 26-165 pg/mL | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | |
| 4871 | Lithium | <p><u>Specimen Requirement</u></p> <p>1.0 (0.5) mL Serum</p> <p>Heparinized plasma and Serum Trace Metal are also acceptable</p> | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | |
| 6102 | Platelet Glycoprotein (Indirect) Autoabs | <p><u>Specimen/Stability</u></p> <p>Serum Frozen – 2 Month(s)</p> <p>Ambient or Refrigerated is NOT acceptable</p> | <p>6100 Platelet Glycoprotein (Direct & Indirect) Abs</p> <p>5955 Platelet Glycoprotein IB/IX Total Autoantibodies</p> <p>5956 Platelet Glycoprotein Iib/IIIa Autoantibodies</p> <p>5957 Platelet Glycoprotein IA/IIA Total Autoantibodies</p> | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | |
| 3163 | Progesterone | <p><u>Reference Range</u></p> <table border="1"> <tbody> <tr> <td>0 - 6d</td> <td>0.2-14.0 ng/mL</td> </tr> <tr> <td>7d - 10y</td> <td>0.2-0.8 ng/mL</td> </tr> </tbody> </table> <p><u>Tanner Stage</u></p> <table border="1"> <thead> <tr> <th></th> <th>Males</th> <th>Females</th> </tr> </thead> <tbody> <tr> <td>1</td> <td>< 0.5 ng/mL</td> <td>< 0.5 ng/mL</td> </tr> <tr> <td>2</td> <td><0.5ng/mL</td> <td><0.7 ng/mL</td> </tr> <tr> <td>3</td> <td><0.6ng/mL</td> <td>0.2-5.7 ng/mL</td> </tr> <tr> <td>4</td> <td>0.2-1.4ng/mL</td> <td>0.2-17.0 ng/mL</td> </tr> <tr> <td>5</td> <td>0.4-1.1ng/mL</td> <td>0.4-11.9 ng/mL</td> </tr> <tr> <td>>18y Males:</td> <td></td> <td>0.3-1.2 ng/mL</td> </tr> <tr> <td colspan="3"><u>>18y Females:</u></td> </tr> <tr> <td>Follicular Phase</td> <td></td> <td>0.2-1.4 ng/mL</td> </tr> <tr> <td>Luteal Phase</td> <td></td> <td>3.3-25.0 ng/mL</td> </tr> <tr> <td>Mid-luteal phase</td> <td></td> <td>4.4-28.0 ng/mL</td> </tr> <tr> <td>Postmenopausal</td> <td></td> <td><0.7 ng/mL</td> </tr> <tr> <td colspan="3"><u>Pregnant:</u></td> </tr> <tr> <td>1st Trimester</td> <td></td> <td>11.2-90.0 ng/mL</td> </tr> <tr> <td>2nd Trimester</td> <td></td> <td>25.6-89.4 ng/mL</td> </tr> <tr> <td>3rd Trimester</td> <td></td> <td>48.4-422.5 ng/mL</td> </tr> </tbody> </table> | 0 - 6d | 0.2-14.0 ng/mL | 7d - 10y | 0.2-0.8 ng/mL | | Males | Females | 1 | < 0.5 ng/mL | < 0.5 ng/mL | 2 | <0.5ng/mL | <0.7 ng/mL | 3 | <0.6ng/mL | 0.2-5.7 ng/mL | 4 | 0.2-1.4ng/mL | 0.2-17.0 ng/mL | 5 | 0.4-1.1ng/mL | 0.4-11.9 ng/mL | >18y Males: | | 0.3-1.2 ng/mL | <u>>18y Females:</u> | | | Follicular Phase | | 0.2-1.4 ng/mL | Luteal Phase | | 3.3-25.0 ng/mL | Mid-luteal phase | | 4.4-28.0 ng/mL | Postmenopausal | | <0.7 ng/mL | <u>Pregnant:</u> | | | 1 st Trimester | | 11.2-90.0 ng/mL | 2 nd Trimester | | 25.6-89.4 ng/mL | 3 rd Trimester | | 48.4-422.5 ng/mL | 2016 Infertility: Endocrine Evaluation (Female) |
| 0 - 6d | 0.2-14.0 ng/mL | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | |
| 7d - 10y | 0.2-0.8 ng/mL | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | |
| | Males | Females | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | |
| 1 | < 0.5 ng/mL | < 0.5 ng/mL | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | |
| 2 | <0.5ng/mL | <0.7 ng/mL | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | |
| 3 | <0.6ng/mL | 0.2-5.7 ng/mL | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | |
| 4 | 0.2-1.4ng/mL | 0.2-17.0 ng/mL | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | |
| 5 | 0.4-1.1ng/mL | 0.4-11.9 ng/mL | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | |
| >18y Males: | | 0.3-1.2 ng/mL | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | |
| <u>>18y Females:</u> | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | |
| Follicular Phase | | 0.2-1.4 ng/mL | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | |
| Luteal Phase | | 3.3-25.0 ng/mL | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | |
| Mid-luteal phase | | 4.4-28.0 ng/mL | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | |
| Postmenopausal | | <0.7 ng/mL | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | |
| <u>Pregnant:</u> | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | |
| 1 st Trimester | | 11.2-90.0 ng/mL | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | |
| 2 nd Trimester | | 25.6-89.4 ng/mL | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | |
| 3 rd Trimester | | 48.4-422.5 ng/mL | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | |
| 1445 | <i>Saccharomyces cerevisiae</i> IgG & IgM Antibodies DetectR™ | <p><u>Specimen/Stability</u></p> <p>Ambient – 7 Day(s), Refrigerated – 14 Day(s), Frozen – 2 Month(s)</p> | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | |
| 3255 | Thyroglobulin Serum | <p><u>Reference Range</u></p> <table border="1"> <tbody> <tr> <td>Prepubertal children</td> <td>3-56 ng/mL</td> </tr> <tr> <td>Pubertal children</td> <td>1-37 ng/mL</td> </tr> <tr> <td>Adults (>18y)</td> <td><60 ng/mL</td> </tr> </tbody> </table> | Prepubertal children | 3-56 ng/mL | Pubertal children | 1-37 ng/mL | Adults (>18y) | <60 ng/mL | 3251 Thyroglobulin Evaluation | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | |
| Prepubertal children | 3-56 ng/mL | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | |
| Pubertal children | 1-37 ng/mL | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | |
| Adults (>18y) | <60 ng/mL | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | |

3238

Thyroxine Binding Globulin

Reference Range

| | |
|-----------|-------------|
| 0 - 12mo | 16-33 ug/mL |
| 1y - 3y | 16-34 ug/mL |
| 4y - 6y | 16-31 ug/mL |
| 7y - 12y | 15-30 ug/mL |
| 13y - 18y | 13-29 ug/mL |
| >18y | 14-31 ug/mL |

Discontinued Tests

Effective Tuesday, August 24, 2004 or as noted

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 | Alternate or Replacement Tests |
|-----------|----------------------------|------------------------|---|
| 4112U | Amphetamines Screen Urine | Same test as 4106U | 4106U Amphetamine/Methamphetamine Urine |
| 1986 | Complement Factor I | Reagents not available | S48700 Complement Factor I |
| 3925 | Melanoma MonitR™ (TA90-IC) | Reagents not available | None available at this time |

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

During these hot summer months, *Specialty* advises clients to ship specimens on cold pack rather than at ambient temperature – unless the collection instructions indicate “ambient only”. Ambient specimens shipped from hot locations should be packaged in containers designed to insulate against extreme temperatures. For more information regarding shipping and courier requirements, please contact Client Services.