SPECIALTY LABORATORIES
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# Test Updates

April 29, 2010

**Dear Colleague:**

In this client update, we bring several new test additions to our Heavy Metals offering. We have also updated and standardized our reference ranges for the analysis of trace elements, including the heavy metals. This client letter contains many changes to our reference ranges in the area of trace element analysis, along with minor changes to some specimen requirements and test information. Please take note. These changes become necessary, as new studies are performed and we continue to improve our analytical sensitivity for these challenging assays. We are acutely aware of the inconvenience that reference range changes create and we will make every effort to keep them to a minimum. However, please realize that they facilitate our mission to provide you, our clients, with quality results that reflect the highest degree of accuracy currently possible.

We would also like to prompt a reminder that **coagulation testing** requires special attention for good results. When sending samples for coagulation studies, please be sure to **provide platelet-poor plasma by spinning the specimen twice**. After the first spin, draw off the plasma into another tube and spin a second time, to assure a platelet concentration of $<10 \times 10^9$/L. Remember, the only anticoagulant acceptable for coagulation studies is Sodium Citrate. The presence of >10,000 platelets may cause the neutralization of heparin, if present in plasma. (Specimens with high platelet counts, upon freezing, release PF4, which is a powerful neutralizer of heparin and will result in inaccurate heparin monitoring by the APTT test.) For your convenience, we have attached a copy of our protocol for obtaining platelet-poor plasma. For a full description of specimen preparation for coagulation studies, please go to the Specialty Labs Web site or refer to our Directory of Services.

Finally, we are very pleased to inform you of *Specialty's* recent New York approval for RAS (**Test Code 5034**), KRAS (**Test Code 5032**) and NRAS (**Test Code 5030**) mutation testing. This will enable our New York clients and those serving New York residents to have this testing provided within our facility.

We thank you for choosing *Specialty* and look forward to your continued support. 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 (*Specialty*):

## 4868U Cadmium 24 Hour Urine (Available May 25)

| Component | Method | Reference Range/Units |
|---|---|---|
| **Cadmium Urine** | **ICP/MS** | **<5.1 mcg/L** |

| | |
|---|---|
| Specimen/Stability | Urine 24 hr 2.0 (1.0) mL: Ambient 5 days, Refrigerated 14 days, Frozen 30 days |
| Collection Instructions | To avoid contamination, do not measure 24-hour volume. Avoid worksite collection. Patient should refrain from eating seafood at least three days prior to specimen collection. Acidify with acetic or nitric acid (1 mL of concentrated acid for each 100 mL urine). Do not use hydrochloric acid (HCl). Rejection criteria: grossly decomposed specimen; use of metal based preservative.<br>Send aliquot in a Specialty transfer tube. Ship refrigerated. |
| Schedule | Monday, Wednesday, Friday |
| Report | Next day |
| CPT Code | 82300 |
| Regulatory Status | Laboratory Developed Test |
| Clinical Utility | Cadmium is a naturally occurring element that is mined and used in industrial production because of its durability. Excessive cadmium exposure can damage lungs, kidneys and the digestive tract. |

## 4856UR Magnesium Random Urine [ICP-OES] (Available May 25)

This test is not approved for the testing of patient samples from New York State.

| Component | Method | | Reference Range/Units |
|---|---|---|---|
| **Magnesium/Creatinine Ratio** | **ICP/OES** | | **22-130 mg/g creat** |
| **Creatinine Urine** | **S** | **0 – 6 Months** | **2.0 – 32.0 mg/dL** |
| | | **7 – 11 Months** | **2.0 - 36.0 mg/dL** |
| | | **1 - 2 Years** | **2.0 - 128.0 mg/dL** |
| | | **3 – 8 Years** | **2.0 - 149.0 mg/dL** |
| | | **9 – 12 Years** | **2.0 - 183.0 mg/dL** |
| | | **>12 Years (Male)** | **20.0 - 370.0 mg/dL** |
| | | **>12 Years (Female)** | **20.0 – 320.0 mg/dL** |

| | |
|---|---|
| Specimen/Stability | Urine 10 (5) mL: Ambient 7 days, Refrigerated 14 days, Frozen 60 days |
| Collection Instructions | Please submit 10mL of a well-mixed random collection. Adjust pH to <3.0 with 6N HCl prior to aliquoting for testing. Refrigerate during and after collection. Ship ambient. |
| Schedule | Monday-Saturday |
| Report | 2 days |
| CPT Code | 83735, 82570 |
| Regulatory Status | Laboratory Developed Test |
| Note | This test is not approved for the testing of patient samples from New York State. |
| Clinical Utility | Urinary magnesium concentrations often decline before serum concentrations. Adverse effects, such as cardiac arrhythmias, can be observed while serum concentrations are within range. |

# New Tests (*Specialty*): (cont'd)

## 4075U Heavy Metals 24 Hour Urine with Cadmium (Available May 25)

| Component | Method | Reference Range/Units |
|---|---|---|
| **Arsenic Urine** | **ICP/MS** | **<81 mcg/L** |
| **Lead Urine** | **ICP/MS** | **<81 mcg/L** |
| **Mercury Urine** | **ICP/MS** | **<21 mcg/L** |
| **Cadmium Urine** | **ICP/MS** | **<5.1 mcg/L** |

| | |
|---|---|
| Specimen/Stability | Urine 24 hr 10 (5) mL: Ambient 5 days, Refrigerated 14 days, Frozen 30 days |
| Collection Instructions | To avoid contamination, do not measure 24-hour volume. Avoid worksite collection. Patient should refrain from eating seafood at least three days prior to specimen collection. Acidify with acetic or nitric acid (1 mL of concentrated acid for each 100 mL urine). Do not use hydrochloric acid (HCl). Rejection criteria: grossly decomposed specimen; use of metal based preservative.<br>Send aliquot in a Specialty transfer tube. Ship refrigerated. |
| Schedule | Monday, Wednesday, Friday |
| Report | Next day |
| CPT Code | 82175, 83655, 83825, 82300 |
| Regulatory Status | Laboratory Developed Test |
| Always Statement | Mercury Toxic Level: Greater than or equal to 150 mcg/L |
| Clinical Utility | Excessive exposure to Heavy Metals can cause acute and chronic toxicity. Heavy Metals Panel is intended to evaluate and monitor exposure to heavy metals and evaluate the process of detoxification.<br>Excessive cadmium exposure can damage lungs, kidneys, and the digestive tract. |

# Test Changes:

## I6 Allergen – Cockroach IgE

| | |
|---|---|
| Effective | May 18 |
| Name | Allergen – Cockroach, German (*Blatella germanica)* IgE |
| Component | Cockroach, German IgE **(NEW NAME)** |
| Also Affected | DOS Codes 3724, 3725, 3726, 3727, 3728, 3729, 3730, 3731, 3732, 3733, 3734, 3735, 3736, 3737, 3738, 3739, 3740, 3741, 3743, 3747, 3749 |

## 3146 Dehydroepiandrosterone (DHEA)

Effective: May 18

Reference Range:

| | | |
|---|---|---|
| > 18 Years | (Male): | 1.80 – 12.50 (same) |
| | (Female): | 1.30 – 9.80 (same) |

Always Statement:

Pediatric Ranges:

| Age | Male (ng/mL) | Female (ng/mL) |
|---|---|---|
| 0 - 1 D | 3.20 – 11.00 (same) | 4.60 – 12.00 (same) |
| 1 - 7 D | 0.90 – 8.70 (same) | 1.20 – 9.30 (same) |
| 7 -28 D | 0.45 - 5.80 (same) | 0.90 - 5.80 (same) |
| 1 -12 M | 0.09 - 2.90 (same) | 0.17 - 1.70 (same) |
| 1 - 4 Y | 0.12 - 0.90 (same) | 0.20 - 0.45 (same) |

Tanner Stage Ranges: **(ALL NEW)**

| Stage | Male | ng/mL | Female | ng/mL |
|---|---|---|---|---|
| 1 | 4-9.8 Y | 0.25–3.00 | 4-9.2 Y | 0.12–2.00 |
| 2 | 9.8-14.5 Y | 0.50–5.80 | 9.2-13.7 Y | 0.60–17.00 |
| 3 | 10.7-15.4 Y | 1.30–6.40 | 10.0-14.4 Y | 1.25–19.00 |
| 4 | 11.8-16.2 Y | 1.90–7.30 | 10.7-15.6 Y | 1.70–17.00 |
| 5 | 12.8-17.3 Y | 2.30–7.30 | 11.8-18.6 Y | 2.20–8.10 |

Source: Pediatric reference ranges, by J. Soldin, Carol Brugnara and Edward Wong, Sixth Edition.

## 5947 Heparin (Anti-Xa), Low Molecular Weight (LMWH)

Effective: May 18

Always Statement:

Enoxaparin (Lovenox)

| | |
|---|---|
| Prophylaxis | 0.30 – 0.60 IU/mL |
| Therapeutic BID | 0.60 – 1.00 IU/mL |

Therapeutic ranges vary for other agents and dosing schedules. The measured peak of anti-factor Xa activities varies among individual LMWH preparations given in the same anti-factor Xa dose, due to variations in pharmacokinetics. In order to avoid an increased risk of bleeding, levels of 1.0 IU/mL or greater should be avoided if the appropriateness of the dose is in question in patients with renal impairment or severe obesity. The peak therapeutic anti-factor Xa for the once daily administration is less clear, but target therapeutic means are suggested as follows:

| | |
|---|---|
| Enoxaparin (Lovenox) | >1.00 IU/mL |
| Tinzaparin (Novo, Logiparin) | 0.85 IU/mL |
| Nadroparin | 1.30 IU/mL |
| Dalteparin (Fragmin) | 1.05 IU/mL |

The target therapeutic mean is measured approximately 4 hours after administration.

(Source: Heparin and Low Molecular Weight Heparin. The Seventh ACCP Conference on Antithrombotic and Thrombolytic Therapy – Chest 2004; 126; 188-203).

# Test Changes: (cont'd)

## 4861W Lead Whole Blood

| | |
|---|---|
| Effective | May 25 |
| Reference Range | 0 – 6 Years: < 5.0 mcg/dL (same)<br>> 6 Years: < 10.0 mcg/dL (same) |
| Always Statement | **(For Pediatric Patients < 15 Years)**<br>Blood lead levels in the range of 5-9 mcg/dL have been associated with adverse health effects in children aged 6 years and younger. For this age group, case management varies by CDC Blood Level range. Refer to current guidelines for recommended interventions.<br><br>CDC Ranges (mcg/dL):<br>CHILDREN: (<15 years old):<br>0- 9.9 No significant lead exposure<br>10.0-14.9 Repeat to confirm within 1-3 months<br>15.0-19.9 Repeat to confirm within 1-2 months; start educational intervention to reduce exposure<br>20.0-44.9 Repeat to confirm within 1 week; aggressive environmental intervention to reduce exposure<br>45.0-69.9 Repeat to confirm within 1 week; consider chelation therapy<br>>or= 70.0 Medical emergency; repeat to confirm immediately; begin chelation therapy; hospitalize patient<br>American Academy of Pediatrics, Pediatrics 1995;96:155-160.<br>Capillary blood levels >10 mcg/dL may be due to contamination from lead found on finger surface and require confirmation with venous blood.<br><br>**(For Adolescents/Adults (> or = 15 Years)**<br>CDC Ranges (mcg/dL):<br>ADOLESCENTS/ADULTS (>or= 15 years old):<br>0- 9.9 No significant lead exposure<br>10.0-24.9 Minimize exposure<br>25.0-49.9 Remove from exposure if symptomatic<br>50.0-79.9 Remove from exposure; medical evaluation; consider chelation therapy<br>>or= 80.0 Initiate chelation therapy<br>Trachtenbarg DE. Postgrad. Med. 1996; 99:207-218.<br>Capillary blood levels >10 mcg/dL may be due to contamination from lead found on finger surface and require confirmation with venous blood. |
| Also Affected | DOS Code 4080W, 4861CP, 4861X, 4863 |

## 4867W Arsenic Whole Blood

| | |
|---|---|
| Effective | May 25 |
| Reference Range | < 23 mcg/L **(NEW)** |
| Always Statement | A whole blood arsenic level > 100 mcg/L is indicative of acute/chronic exposure.<br>Urine is usually the best specimen for the analysis of arsenic in body fluids. Blood levels tend to be low even when urine concentrations are high. |
| Also Affected | DOS Code 4080W |

# Test Changes: (cont'd)

## 4868W Cadmium Whole Blood

| | | |
|---|---|---|
| Effective | May 25 | |
| Reference Range | < 5.1 mcg/L **(NEW)** | |
| Always Statement | Adults, Non-Smokers: | Less than or equal to 1.7 mcg/L |
| | Adults, Smokers: | Less than or equal to 5.0 mcg/L |
| | OSHA Reference Range: | 5.0 mcg/L |
| | Toxic Concentration: | Early signs of toxicity have been observed at 30 mcg/L |
| Also Affected | DOS Code 4500I | |

## 4873W Mercury Whole Blood

| | |
|---|---|
| Effective | May 25 |
| Reference Range | < 11 mcg/L **(NEW)** |
| Always Statement | Whole blood mercury level > 50 mcg/L is indicative of significant acute/chronic exposure. |
| Also Affected | DOS Code 4080W |

## 4870R Copper RBC

| | |
|---|---|
| Effective | May 25 |
| Reference Range | 0.53 – 0.77 mg/L **(NEW)** |
| Also Affected | DOS Code 4165 |

## 4877R Zinc RBC

| | |
|---|---|
| Effective | May 25 |
| Reference Range | 9.0 – 14.7 mg/L **(NEW)** |
| Also Affected | DOS Code 4165 |

## 4875 Selenium

| | | |
|---|---|---|
| Effective | May 25 | |
| Reference Range | < 2 Years: | 16-71 mcg/L **(NEW)** |
| | 2 – 3 Years: | 40-103 mcg/L **(NEW)** |
| | 4-16 Years: | 55-134 mcg/L **(NEW)** |
| | > 16 Years: | 63-160 mcg/L **(NEW)** |

## 4867UR Arsenic Urine Random

| | |
|---|---|
| Effective | May 25 |
| Reference Range | < 51 mcg/g creat **(NEW)** |
| Always Statement | For Nonexposed Adults: Less than or equal to 50 mcg/g creatinine<br>Biological Exposure Index (end of shift/work week): Less than or equal to 50 mcg/g creatinine |
| Also Affected | DOS Code 4080UR |

## 4873UR Mercury Urine Random

| | |
|---|---|
| Effective | May 25 |
| Reference Range | < 5 mcg/g creat **(NEW)** |
| Always Statement | For Nonexposed Adults: Less than or equal to 4 mcg/g creatinine<br>Biological Exposure Index (preshift): Less than or equal to 35 mcg/g creatinine |
| Also Affected | DOS Code 4080UR |

# Test Changes: (cont'd)

**4861UR Lead Urine Random**

| | |
|---|---|
| Effective | May 25 |
| Reference Range | < 10 mcg/g creat **(NEW)** |
| Always Statement | For Non-exposed Adults: Less than 10 mcg/g creatinine |
| Also Affected | DOS Code 4080UR |

**4868UR Cadmium Urine Random**

| | |
|---|---|
| Effective | May 25 |
| Reference Range | < 3.1 mcg/g creat **(NEW)** |
| Always Statement | For Unexposed Adult: Less than or equal to 1.2 mcg/g creatinine<br>OSHA Reference Range for Industrial Exposure: Less than or equal to 3.0 mcg/g creatinine |
| Also Affected | DOS 4500I, 4500URI |

**4867U Arsenic 24 Hour Urine**

| | |
|---|---|
| Effective | May 25 |
| Reference Range | < 81 mcg/L **(NEW)** |
| Component | Total Urine Volume **(REMOVE)**<br>**NOTE: Total 24 hour urine volume is no longer required. Results will be reported as mcg/L** |

**4873U Mercury 24 Hour Urine**

| | |
|---|---|
| Effective | May 25 |
| Reference Range | < 21 mcg/L **(NEW)** |
| Component | Total Urine Volume **(REMOVE)**<br>**NOTE: Total 24 hour urine volume is no longer required. Results will be reported as mcg/L** |
| Always Statement | Toxic Level: Greater than or equal to 150 mcg/L |

**4861U Lead 24 Hour Urine**

| | |
|---|---|
| Effective | May 25 |
| Reference Range | < 81 mcg/L **(NEW)** |
| Component | Total Urine Volume **(REMOVE)**<br>**NOTE: Total 24 hour urine volume is no longer required. Results will be reported as mcg/L** |

**4080U Heavy Metals 24 Hour Urine**

| | |
|---|---|
| Effective | May 25 |
| Reference Range | Arsenic: < 81 mcg/L **(NEW)**<br>Mercury: <21 mcg/L **(NEW)**<br>Lead: <81 mcg/L **(NEW)** |
| Component | Total Urine Volume **(REMOVE)**<br>**NOTE: Total 24 hour urine volume is no longer required. Results will be reported as mcg/L** |

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**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.**

# New Referral Tests:

The following tests are now available from Quest Diagnostics and may be referred through Specialty Laboratories.

**S52038** **Cryoglobulin (% Cryocrit), Serum [51177P]**
Test performed at Quest Diagnostics, San Juan Capistrano

**S52046** **Renin Activity Plasma, LC/MS/MS [16846]**
Test performed at Quest Diagnostics, San Juan Capistrano

**S52047** **Aldosterone/Plasma Renin Activity Ratio, LC/MS/MS [16845]**
Test performed at Quest Diagnostics, San Juan Capistrano

**S52121** **Free Kappa & Lambda, with K/L Ratio, Urine [11233X]**
Test performed at Quest Diagnostics, Chantilly

**S52122** **HLA-B*1502 Typing [40045X]**
Test performed at Quest Diagnostics, Chantilly

Please call client relations at 800-421-4449 or visit our website at www.specialtylabs.com for ordering information.

# Discontinued Tests:

## Effective May 18:

**1876** **Diagnostic Consultation by Organ-Specific AP Specialist**
No replacement

**2950** **Bacterial Identification, Aerobic Organism ID**
Recommended replacement: S49971 – Bacterial Identification Aerobic [51255]
Test performed at Focus Diagnostics

**2951** **Aerobic Bacterial Identification Reflex to Susceptibility**
No replacement

**4200** **D-Dimer**
Recommended replacement: 4202 – D-Dimer Quantitative
Test performed at Specialty Laboratories

**S44045** **PBG Deaminase**
Recommended replacement: S51158 – PBG Deaminase, Erythrocyte [0099550]
Please note change in sample type to EDTA Whole Blood
Test performed at ARUP

**Instructions for obtaining platelet-poor plasma**:

1. Draw a plain red top tube to remove tissue fluid contamination. **Discard this tube.**
2. Draw blood into a buffered citrate collection tube (light blue top) filled to proper level. **Do not overfill**.
3. The blood-to-anticoagulant ratio should be 9:1; inadequate filling of the collection device will decrease this ratio and may lead to inaccurate results.
4. Adjust the final citrate concentration in the blood of patients who have hematocrit value above 0.55 (55%). For hematocrits below 20%, there is no current data to support a recommendation for adjusting the citrate concentration.
5. The needle gauge could be between 19-22. For pediatric patients a 21-23 gauge needle may be used.
6. Invert gently 6 times to mix. **Process immediately**.
7. Centrifuge for 15 min at 2500 x g.
8. Remove plasma using a **plastic pipette** to transfer into a new tube.
9. **Repeat centrifugation** at 2500 x g for 15 minutes to assure complete platelet removal.
10. Dispense the plasma into 2 or more plastic tubes using a plastic transfer pipette. Label tubes appropriately.
11. Freeze immediately at -70 C.
12. Specimen must remain frozen at all times. Ship to *Specialty* within 24 hours on dry ice.
13. Specimen **should not** be submitted if:
    * it is hemolyzed
    * microclots are present
    * the tube is less than 90% filled
    * a specimen with hematocrit >55% is collected without anticoagulant adjustment.