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Test Updates

February 26, 2010

**Dear Colleague:**

Specialty Laboratories is pleased to announce an expansion of our cancer diagnostics with the addition of **KRAS Mutation Analysis [5032], NRAS Mutation Analysis [5020], and RAS Mutation Analysis, Cell-Based [5034].** *RAS* is a family of genes encoding proteins that are involved in transmitting signals that influence cell growth and survival. Mutations in the *RAS* family of cancer-promoting oncogenes, which include *KRAS* and *NRAS*, are implicated in several cancers, including colorectal cancer. *RAS* gene mutations have been reported in malignant tumors of the pancreas [80-90%, *KRAS*), in colorectal carcinomas [30-60%, *KRAS*), in non-melanoma skin cancer [30-50%, *HRAS*), and in hematopoietic neoplasia of myeloid origin [18-30%, *KRAS* or *NRAS*). These mutations may indicate prognosis and predict drug response, and many new cancer therapies are being targeted to the K-ras pathway. Tests detect mutations at codons 12, 13, and 61.

We are also pleased to inform you of a menu expansion in our Urine Toxicology area. In this letter we introduce additional drug tests often utilized in pain management programs. Specifically, **Buprenorphine [4420U], Oxycodone w/Reflex Confirmation [4422U], Expanded Drugs of Abuse Screen Urine w/Reflex Confirmation [4470U], Expanded Drugs of Abuse Scr. Urine + Fentanyl w/Reflex Conf [4472U]** will now be available. Oxycodone is now separately orderable and has been added to our standard urine drug of abuse screen. Although oxycodone is an opiate in chemical structure, it has significantly lower immunoassay cross-reactivity and therapeutic use will often be missed with the standard assay. Oxycodone is a medication that is commonly used for the treatment of pain and has a stronger analgesic effect than morphine and, thus, has a high potential for abuse. Buprenorphine is widely used in the treatment of opiate addiction and has proven to be more effective than standard methadone maintenance therapy. Physicians prescribing buprenorphine will want to ensure that their patients are taking the medication. Our highly-sensitive test will produce positive results, if the patient has ingested buprenorphine within the last 2-4 days.

Specialty Laboratories encourages all clients and physicians to verify adequate HCV RNA viral load prior to submission for our **Hepatitis C Virus SubtypR™ [7473]** assay, to avoid unnecessary delay or assay failure. This assay recommends a minimal HCV RNA viral load of 1,000 IU/mL for subtyping. While moderately successful at lower viral loads, significantly decreased or negative viral loads may result in assay failure, delay, and incremental, but non-billable, costs.

If HCV RNA viral load testing is performed at the client laboratory and ordered simultaneously with *Specialty's* **Hepatitis C Virus SubtypR™ [7473]**, shipment of the frozen specimen for subtyping should be delayed until adequate viral load is verified. The client may also refer to recent, but not concurrent, viral load data to determine whether the viral load is sufficient for subtyping. Please communicate these suggestions to your ordering physicians.

For clients **not** providing HCV RNA viral load testing within their own laboratory, *Specialty* offers **HCV RNA, Quantitative [Real Time PCR] w/reflex to HCV SubtypR™ [7489], Hepatitis C Virus RNA AccuQuant® [bDNA] w/reflex HCV SubtypR™ [7476],** and **Hepatitis C Virus RNA UltraQuant® [bDNA] w/reflex HIV-1 SubtypR™ [7578]**. Specimens with viral loads greater than or equal to 1,000 IU/mL will be automatically reflexed to the subtyping assay, for an additional fee.

When ordering **Hepatitis B Virus Drug Resistance DetectR™ [8132]**, **Hepatitis B Virus GenotypR™ [8134]**, and/or **Hepatitis B Virus [Core/Precore Mutant DetectR™ [8144]**, please also verify adequate HBV DNA viral load, prior to submission. A minimal HBV DNA viral load of 450 copies/mL is recommended. Significantly decreased or negative viral loads may result in assay failure, delay, and incremental, but non-billable costs. Please notify your physicians that assessment of adequate HBV DNA viral load (recent or concurrent) should always precede requests for these three assays.

Also of note, in our November, 2009 communication, we announced the implementation of a pre-analytical QNS review. The intent of the program was to shorten the notification time of possible QNS specimens. Based on the statistical results of this program, it has been determined that we are able to complete testing on identified samples, in the large majority of instances. Therefore, we will discontinue this process, effective immediately. We will contact you regarding samples that are not of sufficient quantity upon identification in the performing laboratory department(s).

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*):

## 4470U Expanded Drugs of Abuse Screen Urine w/Reflex Confirmation (Available March 23)

| Component | Method | Reference Range/Units |
|---|---|---|
| **Amphetamine/Methamphetamine** | **EMIT** | **Not Detected** |
| **Cocaine Metabolites** | **EMIT** | **Not Detected** |
| **Cannabinoids (THC)** | **EMIT** | **Not Detected** |
| **Barbiturates** | **EMIT** | **Not Detected** |
| **Benzodiazepines** | **EMIT** | **Not Detected** |
| **Methadone** | **EMIT** | **Not Detected** |
| **Opiates** | **EMIT** | **Not Detected** |
| **Phencyclidine (PCP)** | **EMIT** | **Not Detected** |
| **Propoxyphene** | **EMIT** | **Not Detected** |
| **Oxycodone** | **EIA** | **Not Detected** |

| | |
|---|---|
| Specimen/Stability | Urine 16 (8) mL: Refrigerated 7 days, Frozen 7 days |
| Collection Instructions | After voided midstream collection is complete, mix the specimen and transfer a 16 mL aliquot of urine to Specialty transfer tube with a screw cap closed tightly to avoid leakage. Transfer tubes are available from Specialty. Refrigerated specimen is preferred (store at 2-8 degrees C). Ship refrigerated. |
| Schedule | Monday, Wednesday, Friday |
| Report | Next day |
| CPT Code | 80101x10 |
| Regulatory Status | FDA approved |
| Always Statement | Cut-off values:<br>Amphetamines=1000 ng/mL<br>Barbiturates=200 ng/mL<br>Benzodiazepines=300 ng/mL<br>Cannabinoids (THC)=50 ng/mL<br>Cocaine Metabolites=300 ng/mL<br>Methadone=300 ng/mL<br>Opiates=300 ng/mL<br>Phencyclidine (PCP)=25 ng/mL<br>Propoxyphene=300 ng/mL<br>Oxycodone=100 ng/mL |
| Note | Cut-offs: Amphetamines=1000 ng/mL; Barbiturates=200 ng/mL; Benzodiazepines=300 ng/mL; Cannabinoids=50 ng/mL; Cocaine Metabolites=300 ng/mL; Methadone=300 ng/mL; Opiates=300 ng/mL; Phencyclidine (PCP)=25 ng/mL; Propoxyphene=300 ng/mL and Oxycodone=100 ng/mL.<br>All Positive screen results will reflex to confirmation for an additional fee: Amphetamines Confirmation Urine (test code 4189U), Cocaine & Metabolites Confirmation Urine (test code 4170U), Cannabinoids Confirmation Urine (test code 4133U), Barbiturates Confirmation Urine (test code 4092U), Benzodiazepines Confirmation Urine (test code 4090U), Methadone Confirmation Urine (test code 4192U), Opiates Confirmation Urine (test code 4185UR), Phencyclidine (PCP) Confirmation Urine (test code 4183U), Propoxyphene Confirmation Urine (test code 4094U) and Oxycodone & Metabolite Urine (test code 4176U). |
| Clinical Utility | Illicit drug use and abuse are widespread in society, and public awareness has been heightened as to their impact on public safety and on lost productivity in industry. Moreover, drug abuse during pregnancy is of concern, both medically and socially. Oxycodone has become important pain medication and has also become a popular drug of abuse. |

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

## 4472U Expanded Drugs of Abuse Scr. Urine + Fentanyl w/Reflex Conf (Available March 23)

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

| Component | Method | Reference Range/Units |
|---|---|---|
| **Amphetamine/Methamphetamine** | **EMIT** | **Not Detected** |
| **Cocaine Metabolites** | **EMIT** | **Not Detected** |
| **Cannabinoids (THC)** | **EMIT** | **Not Detected** |
| **Barbiturates** | **EMIT** | **Not Detected** |
| **Benzodiazepines** | **EMIT** | **Not Detected** |
| **Methadone** | **EMIT** | **Not Detected** |
| **Opiates** | **EMIT** | **Not Detected** |
| **Phencyclidine (PCP)** | **EMIT** | **Not Detected** |
| **Propoxyphene** | **EMIT** | **Not Detected** |
| **Fentanyl** | **EIA** | **Negative** |
| **Oxycodone** | **EIA** | **Not Detected** |

| | |
|---|---|
| Specimen/Stability | Urine 20 (10) mL: Refrigerated 7 days, Frozen 7 days |
| Collection Instructions | After voided midstream collection is complete, mix the specimen and transfer a 20 mL aliquot of urine to Specialty transfer tube with a screw cap closed tightly to avoid leakage. Transfer tubes are available from Specialty. Refrigerated specimen is preferred (store at 2-8 degrees C). Ship refrigerated. |
| Schedule | Wednesday |
| Report | 1-7 days |
| CPT Code | 80101x11 |
| Regulatory Status | Fentanyl is Research Use Only, remainder is FDA approved |
| Always Statement | Cut-off values:<br>Amphetamines=1000 ng/mL<br>Barbiturates=200 ng/mL<br>Benzodiazepines=300 ng/mL<br>Cannabinoids (THC)=50 ng/mL<br>Cocaine Metabolites=300 ng/mL<br>Methadone=300 ng/mL<br>Opiates=300 ng/mL<br>Phencyclidine (PCP)=25 ng/mL<br>Propoxyphene=300 ng/mL<br>Fentanyl=Index of 1.0=0.3 ng/mL<br>Oxycodone=100 ng/mL |
| Note | Cut-offs: Amphetamines=1000 ng/mL; Barbiturates=200 ng/mL; Benzodiazepines=300 ng/mL; Cannabinoids=50 ng/mL; Cocaine Metabolites=300 ng/mL; Methadone=300 ng/mL; Opiates=300 ng/mL; Phencyclidine (PCP)=25 ng/mL; Propoxyphene=300 ng/mL; Fentanyl=Index of 1.0=0.3 ng/mL and Oxycodone=100 ng/mL.<br>All Positive screen results will reflex to confirmation for an additional fee: Amphetamines Confirmation Urine (test code 4189U), Cocaine & Metabolites Confirmation Urine (test code 4170U), Cannabinoids Confirmation Urine (test code 4133U), Barbiturates Confirmation Urine (test code 4092U), Benzodiazepines Confirmation Urine (test code 4090U), Methadone Confirmation Urine (test code 4192U), Opiates Confirmation Urine (test code 4185UR), Phencyclidine (PCP) Confirmation Urine (test code 4183U), Propoxyphene Confirmation Urine (test code 4094U), Oxycodone & Metabolite Urine (test code 4176U) and Fentanyl & Norfentanyl Urine (test code 4302U).<br>This test is not approved for the testing of patient samples from New York State. |
| Clinical Utility | Illicit drug use and abuse are widespread in society, and public awareness has been heightened as to their impact on public safety and on lost productivity in industry. Moreover, drug abuse during pregnancy is of concern, both medically and socially. Fentanyl and oxycodone have become important pain medications and have also become popular drugs of abuse. |

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

## 1328U Protein, Total w/Creatinine 12-Hour Urine (Available March 23)

| Component | Method | Reference Range/Units |
|---|---|---|
| Creatinine 12 hr Urine | S | Female: 160-1241 mg/12hr<br>Male: 314-1773 mg/12hr |
| Protein 12 hr Urine | S | 8-98 mg/12hr |
| Protein/Creat/12 hr | CALC | Female: 15-127 mg/g creat/12hr<br>Male: 22-83 mg/g creat/12 hr |
| Protein/Creat Ratio | CALC | Female: <0.128<br>Male: <0.084 |

| | |
|---|---|
| Specimen/Stability | Urine 12 hour 10 (5) mL: Ambient 7 days, Refrigerated 14 days, Frozen 2 months |
| Collection Instructions | 1. The 12 hour collection container and transfer tubes are available from Specialty.<br>2. The patient should collect in the plastic container all subsequent urine passed in the 12 hour period.<br>3. Record the 12 hour urine total volume in mL on the container and the Test Requisition Form as the total volume is required for calculating results.<br>4. After the collection is complete, mix the specimen and transfer a 10 mL aliquot of urine to a clean, leak proof screw cap container, closed tightly to avoid leakage. |
| Schedule | Monday-Sunday |
| Report | Same day |
| CPT Code | 82570, 84156 |
| Regulatory Status | FDA Approved |
| Clinical Utility | The determination of proteinuria is a well established laboratory procedure for the evaluation of renal disease (glomerular, tubular and overflow proteinuria), urinary tract inflammation, orthostatic proteinuria and preeclampsia. A more rapid clinical assessment of proteinuria using 12 hour specimen enables a faster diagnosis with subsequent intervention in several of the clinical conditions cited above. |

## 4420U Buprenorphine (Available March 23)

| Component | Method | Reference Range/Units |
|---|---|---|
| Buprenorphine | EIA | Negative |

| | |
|---|---|
| Specimen/Stability | Urine 10.0 (1.0) mL: Refrigerated 7 days, Frozen 2 months |
| Collection Instructions | After voided midstream collection is complete, mix the specimen and transfer a 10 mL aliquot of urine to Specialty transfer tube with a screw cap closed tightly to avoid leakage. |
| Schedule | Tuesday, Thursday, Saturday |
| Report | Same day |
| CPT Code | 80101 |
| Regulatory Status | FDA approved |
| Always Statement | Cut-off = 5 ng/mL |
| Note | Also known as Subutex® and Suboxone®. |
| Clinical Utility | Buprenorphine is a semi-synthetic opioid analgesic derived from thebaine, a compound of opium. Buprenorphine resembles morphine structurally but has both antagonist and agonist properties. Buprenorphine has a longer duration of action than morphine and can be administered sublingually as an analgesic. Subutex®, a higher dose buprenorphine formulation, is widely used in Europe and elsewhere as a substitution treatment for opiate addiction. |

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

## 4422U Oxycodone w/Reflex Confirmation (Available March 23)

| Component | Method | Reference Range/Units |
|---|---|---|
| **Oxycodone** | **EIA** | **Not Detected** |

| | |
|---|---|
| Specimen/Stability | Urine 10.0 (1.0) mL: Refrigerated 7 days, Frozen 7 days |
| Collection Instructions | After voided midstream collection is complete, mix the specimen and transfer a 10 mL aliquot of urine to Specialty transfer tube with a screw cap closed tightly to avoid leakage. Ship refrigerated. |
| Schedule | Tuesday, Thursday, Saturday |
| Report | Same day |
| CPT Code | 80101 |
| Regulatory Status | FDA approved |
| Always Statement | Cut-off = 100 ng/mL |
| Note | Positive screen results will automatically reflex to confirmation for an additional fee (CPT Code 83925). |
| Clinical Utility | Oxycodone is an opioid analgesic medication synthesized from opium-derived thebaine. |

## 4350U Oxidants Urine (Available March 23)

| Component | Method | Reference Range/Units |
|---|---|---|
| **Oxidants Urine** | **S** | **Negative** |

| | |
|---|---|
| Specimen/Stability | Urine 10.0 (1.0) mL: Refrigerated 7 days, Frozen 2 months |
| Collection Instructions | After voided midstream collection is complete, mix the specimen and transfer a 10 mL aliquot of urine to Specialty transfer tube with a screw cap closed tightly to avoid leakage. Transfer tubes are available from Specialty. Refrigerated specimens are preferred (store at 2-8 degrees C). Ship refrigerated. |
| Schedule | Tuesday, Thursday, Saturday |
| Report | Same day |
| CPT Code | 84311 |
| Regulatory Status | FDA exempt |
| Always Statement | Cut-off = 200 mcg/mL |
| Clinical Utility | Many drug users will attempt to evade detection by adulterating the specimen in order to produce false negative results during the initial immunoassay screening. Adulteration methods include dilution with water, substitution with a drug free liquid, addition of readily available household materials (e.g., vinegar, baking soda, liquid drain opener, detergent, etc.) or tampering with certain chemicals (e.g., Urine-Aid, which contains glutaraldehyde or Klear, which contains potassium nitrite). Several oxidizing adulterants are being sold with a claim to clear all positive drug test results. The most commonly used oxidizing adulterants are Nitrite (Klear™), Chromate (Urine Luck™), Iodine, Bleach and Horse Radish Peroxidase/H2O2 Stealth™). When added to urine, there is no significant change to the appearance, pH, specific gravity or creatinine concentration. Marijuana samples adulterated with oxidants can produce a positive result, during initial screening by immunoassay, notably the marijuana metabolite (THC). However, they can not be confirmed by GC/MS. This method is designed to detect these oxidizing adulterants. |

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

## 5030 NRAS Mutation Analysis (Available April 1)

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

| Component | Method | Reference Range/Units |
|---|---|---|
| **NRAS Mutation Analysis** | **PCR** | **Negative** |

| | |
|---|---|
| Specimen/Stability | Whole Blood EDTA 4.0 (2.0) mL: Ambient 72 hours, Refrigerated 72 hours |
| Alt Specimen | Bone Marrow EDTA 4.0 (2.0) mL: Ambient 72 hours, Refrigerated 72 hours<br>Whole Blood ACD 4.0 (2.0) mL: Ambient 72 hours, Refrigerated 72 hours<br>Bone Marrow ACD 4.0 (2.0) mL: Ambient 72 hours, Refrigerated 72 hours<br>FFPE Tissue (Block or Slide): Ambient 24 months, Refrigerated 24 months<br>Fresh Tissue 5 (3) gm: Frozen 1 year |
| Collection Instructions | Follow standard whole blood collection procedure. Collect 2-4 mL whole blood samples in EDTA or ACD tube. Blood samples are shipped at room temperature or 4 degrees C. Do not freeze whole blood.<br>Preferred shipping for whole blood and bone marrow specimens is room temperature; refrigerated acceptable; frozen unacceptable.<br>Fresh tissue specimens should be shipped frozen. |
| Schedule | Monday, Wednesday |
| Report | 4 to 5 days |
| CPT Code | 83891, 83912, 83892x2, 83898x2, 83904x4, 83909x4 |
| Regulatory Status | Laboratory Developed Test |
| Always Statement | This test(s) was developed and its performance characteristics have been determined by Specialty Laboratories. Performance characteristics refer to the analytical performance of the test. |
| Note | This test is not approved for the testing of patient samples from New York State. |
| Clinical Utility | Activating NRAS mutations can be found in 3% of colorectal cancer, 1% of lung cancer and 25% of small intestine cancer. Presence of NRAS mutation in colorectal cancer has been reported to render the tumor resistant to anti-EGFR therapy. |

## 5032 KRAS Mutation Analysis (Available April 1)

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

| Component | Method | Reference Range/Units |
|---|---|---|
| **KRAS Mutation Analysis** | **PCR** | **Negative** |

| | |
|---|---|
| Specimen/Stability | Whole Blood EDTA 4.0 (2.0) mL: Ambient 72 hours, Refrigerated 72 hours |
| Alt Specimen | Bone Marrow EDTA 4.0 (2.0) mL: Ambient 72 hours, Refrigerated 72 hours<br>Whole Blood ACD 4.0 (2.0) mL: Ambient 72 hours, Refrigerated 72 hours<br>Bone Marrow ACD 4.0 (2.0) mL: Ambient 72 hours, Refrigerated 72 hours<br>FFPE Tissue (Block or Slide): Ambient 24 months, Refrigerated 24 months<br>Fresh Tissue 5 (3) gm: Frozen 1 year |
| Collection Instructions | Follow standard whole blood collection procedure. Collect 2-4 mL whole blood samples in EDTA or ACD tube. Blood samples are shipped at room temperature or 4 degrees C. Do not freeze whole blood.<br>Preferred shipping for whole blood and bone marrow specimens is room temperature; refrigerated acceptable; frozen unacceptable.<br>Fresh tissue specimens should be shipped frozen. |
| Schedule | Monday, Wednesday |
| Report | 4 to 5 days |
| CPT Code | 83891, 83912, 83892x2, 83898x2, 83904x4, 83909x4 |
| Regulatory Status | Laboratory Developed Test |
| Always Statement | This test(s) was developed and its performance characteristics have been determined by Specialty Laboratories. Performance characteristics refer to the analytical performance of the test. |
| Note | This test is not approved for the testing of patient samples from New York State. |
| Clinical Utility | Activating KRAS mutations can be found in 30-40% of colorectal cancer, 15-20% of lung cancer and 60% of pancreatic cancer. Presence of KRAS mutation in colorectal cancer has been reported to render the tumor resistant to anti-EGFR therapy. |

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

## 5034 RAS Mutation Analysis, Cell-Based (Available April 1)

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

| Component | Method | Reference Range/Units |
|---|---|---|
| **RAS Mutation Analysis** | **PCR** | **Negative** |

| | |
|---|---|
| Specimen/Stability | Whole Blood EDTA 4.0 (2.0) mL: Ambient 72 hours, Refrigerated 72 hours |
| Alt Specimen | Bone Marrow EDTA 4.0 (2.0) mL: Ambient 72 hours, Refrigerated 72 hours<br>Whole Blood ACD 4.0 (2.0) mL: Ambient 72 hours, Refrigerated 72 hours<br>Bone Marrow ACD 4.0 (2.0) mL: Ambient 72 hours, Refrigerated 72 hours<br>FFPE Tissue (Block or Slide): Ambient 24 months, Refrigerated 24 months<br>Fresh Tissue: Frozen 1 year |
| Collection Instructions | Follow standard whole blood collection procedure. Collect 2-4 mL whole blood samples in EDTA or ACD tube. Blood samples are shipped at room temperature or 4 degrees C. Do not freeze whole blood.<br>Preferred shipping for whole blood and bone marrow specimens is room temperature; refrigerated acceptable; frozen unacceptable.<br>Fresh tissue specimens should be shipped frozen. |
| Schedule | Monday, Wednesday |
| Report | 4 to 6 days |
| CPT Code | 83891, 83912, 83898x3, 83904x3, 83909x6 |
| Regulatory Status | Laboratory Developed Test |
| Always Statement | This test(s) was developed and its performance characteristics have been determined by Specialty Laboratories. Performance characteristics refer to the analytical performance of the test. |
| Note | This test is not approved for the testing of patient samples from New York State. |
| Clinical Utility | Activating RAS mutations can be found in human malignancies with an overall frequency of 15-20%. A high incidence of RAS gene mutations has been reported in malignant tumors of the pancreas (80-90%, KRAS), in colorectal carcinoma (30-60%, KRAS), in non-melanoma skin cancer (30-50%, HRAS) and in hematopoietic neoplasia of myeloid origin (18-30%, KRAS or NRAS). |

## 4971 Hemoglobin A1c with eAG (Available April 13)

| Component | Method | Reference Range/Units |
|---|---|---|
| **Hemoglobin A1c** | **TURB** | **< 5.7 %** |
| **eAG** | **CALC** | **mg/dL** |
| **eAG** | **CALC** | **mmol/L** |

| | |
|---|---|
| Specimen/Stability | Whole Blood EDTA 2.0 (0.3) mL: Ambient 7 days, Refrigerated 7 days, Frozen 6 months |
| Alt Specimen | Whole Blood Hep Lithium 2.0 (0.3) mL: Ambient 7 days, Refrigerated 7 days, Frozen 6 months |
| Schedule | Monday-Saturday |
| Report | Same day |
| CPT Code | 83036 |
| Regulatory Status | FDA approved |
| Always Statement | A1c Value (% of Total Hemoglobin) — Interpretation<br>< 5.7 — Non-diabetic<br>5.7 – 6.4 — Increased risk of diabetes<br>> or = 6.5 — Consistent with diabetes<br><br>Standards of Medical Care in Diabetes – 2010. Diabetes Care, 33(Supp 1): S1-S61, 2010. |
| Clinical Utility | In the erythrocytes, the relative amount of HbA converted to stable HbA1c increases with the average concentration of glucose in the blood. The conversion to stable HbA1c is limited by the erythrocyte's life span of approximately 100 to 120 days. As a result, HbA1c reflects the average blood glucose level during the preceding 2 to 3 months. HbA1c is thus suitable to monitor long-term glucose control in individuals with diabetes mellitus. More recent glucose levels have a greater influence on the HbA1c level. |

# Test Changes:

## 1518 Alpha-1-Antitrypsin Deficiency Fetal Study /Reflex to MCC

| | |
|---|---|
| Effective | Immediately |
| Methodology | PCR |

## 4940 Sirolimus MonitR™

| | |
|---|---|
| Effective | Immediately |
| Always Statement | Test performed by LC-MS-MS |

## 6110 QuantiFERON®-TB Gold (Incubated)

| | |
|---|---|
| Effective | March 30 |
| Collection Instructions | 1. For each patient, collect 1 mL of blood by venipuncture directly into each of the three (3) unique QuantiFERON®-TB Gold IT blood collection tubes (Nil, TB Antigen, Mitogen). Under or overfilling of the tubes may lead to erroneous results.<br>2. Mix the tubes by shaking vigorously for 5 seconds and label tubes appropriately.<br>3. Incubate the three (3) tubes upright at 37 degrees C for 16 to 24 hours.<br>4. Following incubation either:<br>A. Immediately transport the three (3) transport tubes to Specialty Laboratories between 2 and 27 degrees C. Samples will be stable for 72 hours at 2-27 degrees C (room temperature or refrigerated).<br>OR<br>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 to Specialty Laboratories at 2-8 degrees C. Samples will be stable for 28 days at 2-8 degrees C (refrigerated).<br>5. Transport incubated tubes to Specialty between 2-27 degrees C.<br>6. Frozen and unspun collection tubes are not acceptable. |

## 4175 Fentanyl Screen Urine w/Reflex Confirmation

| | |
|---|---|
| Effective | March 30 |
| DOS Code | Please change the DOS ordering code to **4175U** |

## 4972 Hemoglobin A1c AccuQuant®

| | |
|---|---|
| Effective | April 13 |
| Reference Range | < 5.7 % **(NEW)** |
| Always Statement | A1c Value (% of Total Hemoglobin — Interpretation<br>< 5.7 — Non-diabetic<br>5.7 – 6.4 — Increased risk of diabetes<br>> or = 6.5 — Consistent with diabetes<br><br>Standards of Medical Care in Diabetes – 2010. Diabetes Care, 33(Supp 1): S1-S61, 2010. |
| Also Affected | DOS Codes 4972SR, 4975 |

# Test Changes: (cont'd)

## 3218 Sex Hormone Binding Globulin (SHBG)

Effective: April 13

Reference Range: **NEW**

| Age | Male | Female |
|---|---|---|
| < 3 years | Not established | |
| 3 – 9 years | 18 – 136 | 18 – 136 nmol/L |
| 10 – 13 years | 17 – 123 | 17 – 123 nmol/L |
| 14 – 17 years | 11 – 71 | 11 – 71 nmol/L |
| 18 – 29 years | 7 – 49 | 6 – 112 nmol/L |
| 30 – 39 years | 8 – 48 | 14 – 102 nmol/L |
| 40 – 49 years | 9 – 45 | 11 – 100 nmol/L |
| 50 – 59 years | 18 – 47 | 17 – 78 nmol/L |
| 60 – 69 years | 17 – 54 | 17 – 95 nmol/L |
| 70 – 79 years | 23 – 65 | 21 – 90 nmol/L |
| 80 – 91 years | 20 – 63 | 26 – 77 nmol/L |
| > 91 years | Not established | |

Always Statement: Tanner Stages (7 – 17 years)

| | | |
|---|---|---|
| Tanner I | 39 – 155 | 38 – 114 nmol/L |
| Tanner II | 33 – 135 | 24 – 90 nmol/L |
| Tanner III | 21 – 72 | 22 – 112 nmol/L |
| Tanner IV | 11 – 92 | 22 – 69 nmol/L |
| Tanner V | 18 – 54 | 18 – 76 nmol/L |

## 4862U Aluminum, 24-Hour Urine

Effective: April13

Component: Total Urine Volume **(ADD)**

Units: mL

**NOTE: Total Volume will be included on the patient report.**

## 4870U Copper, 24-Hour Urine

Effective: April13

Component: Total Urine Volume **(ADD)**

Units: mL

**NOTE: Total Volume will be included on the patient report.**

## 4877U Zinc, 24-Hour Urine

Effective: April13

Component: Total Urine Volume **(ADD)**

Units: mL

**NOTE: Total Volume will be included on the patient report.**

# Test Changes: (cont'd)

## 1121 ANA Reflex to Profile

| | |
|---|---|
| Effective | April13 |
| Always Statement | **(ADD)** 20% of a healthy population exhibit weak positivity for Anti-nuclear antibody at 8 to 15 IU/mL. Also, the elderly, pregnant females and patients with tumors or chronic infections frequently have a low titers of ANA. |
| Also Affected | DOS Code 1004, 1006, 1010, 1726, 1862, 1866, 1868, 5906, 5908 |

## 1741U Kappa & Lambda Light Chain, Quantitative 24Hr Urine

| | |
|---|---|
| Effective | April 13 |
| Specimen/Stability | Urine 24 Hour 1.0 (0.5) mL: Refrigerated 9 days<br>**Note: Ambient and frozen specimens no longer accepted; decreased refrigerated stability.** |
| Also Affected | DOS Code 1584U, 1584UR, 1731U, 1731UR, 1736U, 1736UR, 1741UR |

## 5651 AFB Suscept: MAI (MAC) by Radiometric Method

| | |
|---|---|
| Effective | April13 |
| Component | Clofazimine MIC **(REMOVE)**<br>**NOTE: Clofazimine will no longer be included on the panel** |
| CPT Code | 87190x6 |

**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.

**S52102** **von Willebrand Disease (vWD) Type 2N (vWF:Factor VIII) [70068]**
Performed at Quest Diagnostics, San Juan Capistrano

**S52103NY** **Vanillylmandelic Acid 24hr Urine [934X] [NY]**
Performed at Quest Diagnostics, San Juan Capistrano

**S52105** **Gliadin (Deamidated Peptide) Antibodies (IgG, IgA) [20760]**
Performed at Focus Diagnostics

**S52108** **Legionella Culture, Environmental [51710]**
Performed at Focus Diagnostics

**S52109** ***Clostridium difficile* DNA and Toxin B Gene, QL. RT-PCR [81435]**
Performed at Focus Diagnostics

**S52110** **JC Virus DNA Ultrasensitive Quant. RT-PCR [43536]**
Performed at Focus Diagnostics

**S52111** **Epidermal Growth Factor Receptor (EGFR), ELISA [10920X]**
Performed at Quest Diagnostics, San Juan Capistrano

**S52112** **HIV-1 gp41 Envelope Genotype [11367X]**
Performed at Quest Diagnostics, San Juan Capistrano

**S52113** **HIV-1 Integrase Genotype [16868]**
Performed at Quest Diagnostics, San Juan Capistrano

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

# Discontinued Tests:

## Effective Immediately:

**S51182 Interferon Beta Neutralizing Ab [20468]**
Recommended replacement S52051 Interferon Beta 1a (IFNB-1a) Antibody [20555] or S52052 Interferon Beta 1b (IFNB-1b) Antibody [20777] (depends on drug the patient is taking)
Performed by Focus Diagnostics

## Effective March 2:

**4115 Carbamazepine & Metabolites (10, 11 Epoxide)**
Recommended replacement S40960 Carbamazepine-10, 11-Epoxide, Serum/Plasma [0975SP]
Test performed at National Medical Services

## Effective March 29:

**3214 Renin Activity Plasma**
Recommended replacement S52046 Plasma Renin Activity, LC/MS/MS [16846]
Test performed at Quest Diagnostics, San Juan Capistrano

**3113 Aldosterone/Renin Ratio**
Recommended replacement S52047 Aldosterone/Plasma Renin Activity Ratio, LC/MS/MS [16845]
Test performed at Quest Diagnostics, San Juan Capistrano

**3220 Insulin-Like Growth Factor 1 (IGF-1)**
Recommended replacement S51997 IGF-I [839X]
Test performed at Quest Diagnostics, San Juan Capistrano

**3178 Growth Hormone Deficiency MonitR™**
Recommended replacement 3959 Insulin-Like Growth Factor Binding Protein (IGFBP-3) & S51997 IGF-I [839X]
Test performed at Specialty Laboratories and Quest Diagnostics, San Juan Capistrano

**3184F Human Chorionic Gonadotropin, Beta Fluid**
No replacement

# Discontinued Tests: (cont'd)

## Effective April 19:

**7780** **HTLV-I/II Abs (Confirmation by LIA)**
Recommended replacement S52044 HTLV-I/II Abs (LIA) [88012]
Test performed at Quest Diagnostics, Chantilly

**7780B** **HTLV-I/II Abs (Confirmation by LIA) + Bands**
Recommended replacement S52044 HTLV-I/II Abs (LIA) [88012]
Test performed at Quest Diagnostics, Chantilly

**7780T** **HTLV-I/II Abs (Confirmation by LIA) [Blood Bank]**
Recommended replacement S52044 HTLV-I/II Abs (LIA) [88012]
Test performed at Quest Diagnostics, Chantilly

**7780BT** **HTLV-I/II Abs (Confirmation by LIA) + Bands [Blood Bank]**
Recommended replacement S52044 HTLV-I/II Abs (LIA) [88012]
Test performed at Quest Diagnostics, Chantilly

**7780C** **HTLV-I/II Abs (Confirmation by LIA) CSF**
Recommended replacement S52043 HTLV-I/II Antibody, WB (CSF) [61105]
Test performed at Focus Diagnostics (Not approved for New York patients)

**7780CB** **HTLV-I/II Abs (Confirmation by LIA) + Bands CSF**
Recommended replacement S52043 HTLV-I/II Antibody, WB (CSF) [61105]
Test performed at Focus Diagnostics (Not approved for New York patients)

**7782B** **HTLV-I/II Abs [LIA] + Bands w/Reflex RIPA [Blood Bank]**
Recommended replacement S52044 HTLV-I/II Abs (LIA) [88012]
Test performed at Quest Diagnostics, Chantilly

**9898** **HTLV-I/II Abs**
Recommended replacement S52045 HTLV-I/-II, Progressive [36175X]
Test performed at Quest Diagnostics, Chantilly

**9899** **HTLV-I/II Abs [EIA] w/Reflex HTLV-I/II LIA + Bands**
Recommended replacement S52045 HTLV-I/-II, Progressive [36175X]
Test performed at Quest Diagnostics, Chantilly