

Specialty Laboratories is pleased to offer two new genetic tests (Alpha-1-Antitrypsin, Plasminogen Activator Inhibitor), a new therapeutic monitoring test (Oxcarbazepine) as well as updated assays for Narcolepsy and Troponin T. We reviewed the specimen requirements for a number of tests to determine whether test performance is comparable on alternate specimens and report those findings in this issue.

New from Specialty

effective March 25, 2003 or as noted

1515 Alpha-1-Antitrypsin GenotypR™

| Component | Method | Reference Range | | |
|---|--|-----------------|--|---|
| Alpha-1-Antitrypsin Z and S Alle | ele Invader [®] | By report | | |
| Specimen Requirement 1 | 5 (3.0) mL Whole Blood EDTA Lavender; Ambient | | | |
| | Heparinized whole blood is not acceptable. Do not freeze. | | | |
| | Refrigerated whole blood acceptable but not preferred. Ship immediately by | | | |
| | overnight courier. Specimens will be stabilized upon department | tal receipt. | | |
| Specimen Requirement 2 | 5 (3.0) mL Whole Blood ACD Yellow; Ambient | · | | |
| | Heparinized whole blood is not acceptable. Do not freeze. | | | |
| | Refrigerated whole blood acceptable but not preferred. Ship imn | nediately by | | |
| | overnight courier. Specimens will be stabilized upon department | tal receipt. | | |
| CPT Code | · | | | |
| Clinical Utility Detection of the common Z and S alleles for: (1) diagnosis of alpha-1-antitrypsin deficiency in a symptomatic patient; analysis of serum l Alpha-1-Antitrypsin, #1513 or Alpha-1-Antitrypsin Phenotyping will be recommended for sy | | | | |
| | | | | , . |
| | | | | (2) identification of the familial mutation(s) in an at-risk relative o |

Notes Test NOT AVAILABLE for residents of New York.

1518 Alpha-1-Antitrypsin Deficiency Fetal Study

| Component | Method | Reference Range | | |
|----------------------------------|--|--|--|--|
| Alpha-1-Antitrypsin Z and S Alle | ele Invader® | By report | | |
| Specimen Requirement 1 | 20 (10) mL Amniotic Fluid; Sterile; Ambient | | | |
| | Order DOS #5822 for fetal chromosome analysis. | An internal code #12990 will be added at the laboratory | | |
| | for cell culture for samples sent for DNA analysis or | nly. | | |
| Specimen Requirement 2 | Cultured amniotic fluid cells; Ambient; Ship flask at | confluency, topped off with culture media. | | |
| | An internal code#12992 will be added at the laboratory for cell culture. Do not refrigerate or freeze. | | | |
| | For chorionic villus specimens, please contact Tech | nnical Services. | | |
| CPT Code | 83891, 83822x4, 83896x10, 83903x2, 83912 | | | |
| Clinical Utility | Assay of the common Z and S mutations for prenat | al diagnosis of a fetus at 1 in 4 risk for alpha-1-antitrypsin | | |
| | deficiency. Both parents must be previously and/or | concurrently tested at <i>Specialty</i> and both demonstrated | | |
| | to be heterozygous for either the Z or the S mutatio | n. | | |
| Notes | Mother's Blood - 5.0(3.0) mL of Whole Blood, EDTA | A or ACD must accompany any prenatal specimen for | | |
| | potential studies of maternal cell contamination of fe | etal DNA. Test NOT AVAILABLE for residents of New York. | | |

ZZ or SZ genotype. Prenatal (fetal) studies should be ordered using test # 1518.

4937 Oxcarbazepine (Trileptal®)

ComponentMethodReference RangeOxcarbazepine metaboliteHPLC10 - 35 ug/mL

Specimen Requirement 2.0 (1.0) mL Serum; Ambient, Refrigerated, Frozen

Serum separator tubes are not acceptable.

CPT Code 80299

Clinical Utility Therapeutic drug monitoring of antiepileptic therapy. Oxcarbazepine is measured as its

10-hydroxy metabolite.

5375 Plasminogen Activator Inhibitor (PAI-1) GenotypR™

| Component | Method | Reference Range | |
|------------------------|--|-----------------|--|
| PAI-1 5G/4G allele | Invader [®] | By report | |
| Specimen Requirement 1 | 5 (3.0) mL Whole Blood EDTA Lavender; Ambient | | |
| | Heparinized whole blood is not acceptable. Do not freeze. | | |
| | Refrigerated whole blood acceptable but not preferred. Ship immediately | <i>i</i> by | |
| | overnight courier. Specimens will be stabilized upon departmental receip | ot. | |
| Specimen Requirement 2 | uirement 2 5 (3.0) mL Whole Blood ACD Yellow; Ambient | | |
| | Heparinized whole blood is not acceptable. Do not freeze. | | |
| | Refrigerated whole blood acceptable but not preferred. Ship immediately | <i>i</i> by | |
| | overnight courier. Specimens will be stabilized upon departmental receip | ot. | |
| CPT Code | 83891, 83892x2, 83896x5, 83903, 83912 | | |
| Oliviani I IIIII. | Hamazingoity or heterogygoity for the AC DAL1 allala is appointed with | h ! | |

Clinical Utility Homozygosity or heterozygosity for the 4G PAI-1 allele is associated with increased thrombotic risk,

pregnancy complications, and risk of meningococcal sepsis in children.

Notes Test NOT AVAILABLE for residents of New York.

4985 Sickle Cell MonitR™

| 7303 | Sickic och Morniti | | | | |
|----------|--------------------|--------|---------------|-----------|---------------|
| Componer | nt | Method | | Refer | ence Range |
| Hb A | | HPLC | | | 93.5 - 98.3 % |
| Hb A2 | | HPLC | | | 2.4 - 3.5 % |
| Hb F | | HPLC | <u>Age N</u> | fales (%) | Females (%) |
| | | | 0 - 10 D | 56.0-87.0 | 56.0-87.0 |
| | | | 11 D - 20 D | 55.0-83.0 | 55.0-83.0 |
| | | | 21 D - 30 D | 51.0-76.0 | 51.0-76.0 |
| | | | 31 D - 40 D | 46.0-70.0 | 46.0-70.0 |
| | | | 41 D - 50 D | 38.0-62.0 | 38.0-62.0 |
| | | | 51 D - 60 D | 31.0-54.0 | 31.0-54.0 |
| | | | 61 D - 70 D | 24.0-44.0 | 24.0-44.0 |
| | | | 71 D - 80 D | 17.0-34.0 | 17.0-34.0 |
| | | | 81 D - 90 D | 12.0-28.0 | 12.0-28.0 |
| | | | 91 D - 100 D | 8.0-24.0 | 8.0-24.0 |
| | | | 101 D - 110 D | 7.0-18.0 | 7.0-18.0 |
| | | | 111 D - 120 D | 5.0-15.0 | 5.0-15.0 |
| | | | 121 D - 130 D | 4.0-10.0 | 4.0-10.0 |
| | | | 131 D - 140 D | <6.1 | <6.1 |
| | | | 141 D - 364 D | <4.1 | <4.1 |
| | | | > 364 D | <2.1 | <2.1 |
| Hb S | | HPLC | | | <0.1 % |

Specimen Requirement 2.0 (0.5) mL Whole Blood EDTA; Refrigerated

CPT Code 83021

Clinical Utility This test is useful for monitoring the treatment of previously diagnosed sickle cell patients.

This test alone is not diagnostic for patients with Sickle Cell Trait or Sickle Cell Disease.

To screen and confirm the presence of abnormal hemoglobin variants, order Hemoglobin Variant

Screen Reflex to Electrophoresis (DOS code #4984).

REACTIVATED TESTS

effective March 25, 2003 or as noted

1705 Narcolepsy EvaluatR™

ComponentMethodReference RangeHLA-DQA1*0102 & HLA-DQB1*0602PCR, SSPBy report

Specimen Requirement 5.0 (3.0) mL Whole Blood EDTA Lavender; Ambient

Heparinized whole blood is not acceptable. Do not freeze. Refrigerated whole blood acceptable but

not preferred. Ship immediately by overnight courier. Specimens will be stabilized upon departmental receipt.

CPT Code 83891, 83901x4, 83894x4, 83912

Clinical Utility Detects the HLA-DQB1*0602 & DQA1*0102 alleles that are found in 85-95% of patients with narcolepsy.

Notes Test AVAILABLE for residents of New York. Informed consent is required. Consent form is available

on the www.specialtylabs.com Website.

3392 Troponin T

 Component
 Method
 Reference Range

 Troponin T
 ECL
 <0.01 ng/mL</td>

Specimen Requirement 2 (0.8) mL Serum; Refrigerated or Frozen

CPT Code 84484

Notes Also available #3390 Troponin (I & T) DetectR[™] and #3393 Troponin I

3390 Troponin I & T DetectR™

 Component
 Method
 Reference Range

 Troponin T
 ECL
 <0.01 ng/mL</td>

 Troponin I
 MEIA
 <1.5 ng/mL</td>

Specimen Requirement 2 (0.8) mL Serum; Refrigerated or Frozen

specificity

CPT Code 84484x2

Test Changes

Whole Blood

effective March 25, 2003 or as noted

| | | | 21.001.10 | ==,====== |
|--------|---|-------------------------------|--|---|
| Test C | code Test Name R | Reason for Change | Specific Change | Also Affected |
| 5648 | Acid-fast Bacilli Identification Mycobacterium spp reflex to Susceptibility | Clarify test process | Notes Send PURE Culture only. If the specimen submitted is mixed, there will be separate charges for each organism that require <i>Mycobacterium</i> identification. | |
| 2935 | AFB Identification <i>Mycobacterium</i> spp rRNA [GenProbe®] | Clarify test process | Notes Send PURE culture only. If the specimen submitted is mixed, there will be separate charges for each organism that require <i>Mycobacterium</i> identification. | |
| 4102 | Alcohol, Ethyl | | Reference Range Cut off is 25 mg/dL. | 4102U Alcohol, Ethyl Urine 4102W Alcohol, Ethyl Whole Blood |
| 1862 | Antineutrophil Cytoplasmic Autoantibodies (ANCA) | Clarify specimen requirements | Specimen Serum is the only acceptable sample. Plasma is not acceptable. | 1866 PAN-ANCA™ Evaluation 1868 PAN-ANCA™ Plus 7531 Primary Sclerosing Cholangitis Evaluation 1726 Rapidly Progressive Glomerulonephritis 5906 Hepatitis Autoimmune EvaluatR™ Plus |
| 5344 | BCR/ABL UltraQuant® For ALL Bone Marrow | Clarify test specificity | Name BCR/ABL UltraQuant®, minor 190 KD Transcript, Bone N | |
| 5354 | BCR/ABL UltraQuant® For ALL | Clarify test | <u>Name</u> | |

Whole Blood

BCR/ABL UltraQuant®, minor190 KD Transcript,

| 5342 | BCR/ABL UltraQuant® For CML Bone Marrow | Clarify test specificity | Name BCR/ABL UltraQuant®, major210 KD Transcript, Bone N | Лаггоw |
|-------|--|---|--|---|
| 5352 | BCR/ABL UltraQuant® for CML Whole Blood | Clarify test specificity | Name BCR/ABL UltraQuant®, major 210 KD Transcript, Whole Blood | |
| 8076 | Chlamydia pneumoniae IgG, IgM & IgA Antibodies | Avoid possible interference due to anticoagulants | Specimen Serum is only acceptable sample. Plasma is not acceptable. | 9437 <i>Chlamydia pneumoniae</i> lgG Antibodies UltraQuant® 8084 <i>Chlamydia pneumoniae</i> lgG & lgM Abs 8081 <i>Chlamydia pneumoniae</i> lgM Antibodies 1537 Treatable Ischemia PredictR™ |
| 8026 | Chlamydia psittaci IgG, IgM, IgA Antibodies | Avoid possible interference due to anticoagulants | <u>Specimen</u> Serum is only acceptable sample. Plasma is not acceptable. | 8021 Chlamydia psittaci IgM Antibodies 8024 Chlamydia psittaci IgG & IgM Abs 8011 Chlamydia spp. IgM Antibodies |
| 8041 | Chlamydia trachomatis IgG, IgM & IgA Antibodies | Avoid possible interference due to anticoagulants | <u>Specimen</u> Serum is only acceptable sample. Plasma is not acceptable. | 8044 Chlamydia trachomatis IgG & IgM Abs 8046 Chlamydia trachomatis IgM Antibodies 8061 Lymphogranuloma Venereum Antibodies |
| 5356 | Cystic Fibrosis GenotypR™ Carrier Study | Clarify methodology | Method PCR and reverse line blot analysis | 5357 Cystic Fibrosis GenotypR™ Diagnostic Study 5358 Cystic Fibrosis GenotypR™ Fetal Study |
| 1201 | DNA Autoantibodies, Double-Stranded (Farr) | Clarify specimen requirements | Specimen Serum is only acceptable sample. Plasma is not acceptable. | 1118 ANA with reflex to ANAlyzer® 1121 Antinuclear Antibodies reflex to Profile 1006 ANA/yzer® without Rheumatoid Factor 1126 Antinuclear Antibodies Profile #2 1005 ANA/yzer® without ANA 1004 Rheumatic Evaluation 1000 ANAlyzer® 1094 Lupus Activity Reporter 1094 Lupus Renal Evaluation: dsDNA, C3, C4 1127 ANA, dsDNA, SS-A/SS-B, ENA, ScI-70 Autoantibodies 1124 ANA Reflex Profile 2 + Cardiolipins & TPO 1120 ANA Reflex to Profile #1 |
| 7844C | Ehrlichia equi (HGE) IgG & IgM Antibodies CSF | Clarify specimen requirements | <u>Specimen</u> CSF only. Other fluids are not acceptable. | |
| 1966 | Factor V [Leiden] Mutation | Clarify specimen requirements | <u>Specimen</u> ACD or EDTA whole blood are the only acceptable specimens. Heparinized or Citrated whole blood is not acceptable. | |
| 5362 | Fragile X DNA Probe Analysis | Clarify specimen requirements and coding | Specimen ACD or EDTA whole blood are the only acceptable specimens. Heparinized or Citrated whole blood is not acceptable. Ambient preferred; Refrigerated acceptable. Do Not Freeze. CPT Code The CPT codes for this procedure are as follows: PCR analysis: 83890, 839194, 83898, 83912 Southern analysis, if applicable, also add: 83892x2, 8389. Collection Instructions Ship immediately by overnight courier. Specimens will be stabilized upon departmental receipt. Notes Test AVAILABLE for residents of New York. Informed coconsent form is available on the www.specialtylabs.com | 4, 83897, 83896 onsent is required. |

| 3184 | Human Chorionic Gonadotropin, Bo | eta | Method Chemiluminescence | 3028 Alpha-Fetoprotein & Human Chorionic Gonadotropin; 3028SR Alpha-Fetoprotein & Human Chorionic Gonadotropin with serial rpt 3187 Beta hCG Pregnancy 3092 Alpha-Fetoprotein Quad, 2.5 MoM 3110 Alpha-Fetoprotein Triple Marker 2.0 MoM 3091 Alpha-Fetoprotein Triple Marker 2.5 MoM 3184SR Human Chorionic Gonadotropin Beta 3184C Human Chorionic Gonadotropin Beta CSF 3184F Human Chorionic Gonadotropin Beta Fluid |
|-------|---|---|---|--|
| 3860 | Neuron-Specific Enolase | Extended specimen stability | Stability Ambient - 48 hours, Refrigerated - 7 days, Frozen - 2 months | 3860C Neuron-Specific Enolase CSF |
| 7530 | Pro-BNP DetectR™ for Congestive Heart Failure | Method change | Method ECL (electrochemiluminescence) immunoassay Reference Range <=75 years old: < 125 pg/mL >75 years old: < 450 pg/mL Specimen Serum or Heparinized Plasma samples are acceptable Stability Refrigerated - 5 days, Frozen - 2 months | |
| 3100 | Prostatic Acid Phosphatase | Extended specimen stability | Stability Ambient - 7 days, Refrigerated - 7 days, Frozen - 2 months | 3100SR Prostatic Acid Phosphatase with serial reporting |
| 3243 | Testosterone, Total [Pediatric] | Extended specimen stability | <u>Stability</u> Refrigerated - 7 days | |
| 4333U | R Uric Acid Random Urine | Clarify optimal specimen collection procedure | Collection Instructions After the collection is complete, do not refrigerate. Adjus pH to >8 with NaOH and transfer a 10 mL, well-mixed aliquot, of urine to Specialty transfer tube. Close tightly to | |

Late-Breaking News

call Client Services 800-421-4449 for more information

• Now that the winter/ flu season is here, *Specialty* would like to remind you that Viral Culture, Respiratory #2503 is specifically intended for sensitive detection of respiratory viruses and has a turn-around time of 14 days. The standard Viral Culture #2410 has a TAT of 21 days.

overnight courier.

avoid leakage. Ship within 24 hours of collection by

- Please note that for test #9878, HIV-1 RNA UltraQuant® reflex to HIV-1 Phenoscript™, it is necessary to meet the requested specimen requirements for successful reflex testing. If HIV-1 RNA is greater than or equal to 1,000 copies/mL, the reflex phenotyping test is performed. Add CPT codes 87903, 87904 and 15 days to Turnaround Time if reflexed; an additional fee will be billed.
 - This assay quantitates HIV-1 virus RNA down to 75 copies/mL to monitor viral load in established HIV-1 infected individuals. Accurate for quantitation of Group M subtypes (A-G). The assay provides an assessment of viral load prior to initiation of therapy, and is helpful in early detection of potential therapeutic failure and/or disease progression. Reflex phenotyping may be useful in the assessment of antiviral therapeutic efficacy. The HIV-1 Phenoscript assay aids in the selection of optimal therapy for HIV-infected individuals.
- Specialty's primary vendor for toxicology send-out testing National Medical Services has increased their pricing. We have negotiated discounts that will minimize the increases to our clients and will result in price reductions for some of the commonly ordered drugs of abuse panels. New prices are expected to take effect March 17th.
 - Although send-out pricing is subject to change without notice, *Specialty* is making efforts to minimize the impact of these changes through negotiated discounts and advance notice of significant price increases. We are currently negotiating with Focus Technologies regarding price changes scheduled for late March. Your *Specialty* representative can provide you with a complete Referral Testing Fee Schedule on request.

Discontinued Tests and Evaluations

effective March 25, 2003 or as noted

The following test(s) are no longer available routinely from *Specialty*. Whenever possible, replacement or alternate tests are recommended.

Please note that if a test is designated as a "replacement", contractual pricing will be copied from the discontinued test to the replacement test. Contractual pricing does not apply to alternate tests or tests replacing send-out tests. Please contact your Sales Representative if you have any questions.

| Test Code 9898C | Test Name HTLV I/II IgG Antibodies CSF | Reason Low volume | Alternate or Replacement Tests 9898 HTLV I/II IgG Antibodies [replacement] |
|--------------------|--|-----------------------------------|--|
| | | | 7780C HTLV I/II Antibodies Immunoblot CSF [alternate] |
| | | | 7780CB HTLV I/II Antibodies Immunoblot + bands CSF [alternate] |
| S49002 | Oxcarbazepine (Trileptal) & Metabolite [432] | Assay will be performed in-house. | 4937 Oxcarbazepine (Trileptal®) [replace sendout] |
| S49851 | Troponin T [98803] | Assay will be performed in-house. | 3393 Troponin I [replace sendout] 3390 Troponin (I & T) [alternate] |
| S50009 | Narcolepsy | Assay will be performed in-house. | 1705 Narcolepsy EvaluatR™ [replace sendout] |

Tom England, Ph.D.

Vice President of Operations

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