

March 26, 2008

Dear Colleague:

Specialty Laboratories is pleased to announce the April 25th availability of BAALC (Brain and Acute Leukemia, Cytoplasmic) UltraQuant[®] (5310), a new genetic marker that is most useful in determining prognosis for patients with Acute Myeloid Leukemia who have normal cytogenetics. Compared to low expressers, high BAALC expressers show significantly inferior overall survival, event-free survival and disease-free survival.

In our efforts to provide our clients with the most relevant laboratory information, we have updated our drugs of abuse tests to be consistent and clinically correct. For drugs of abuse detected in urine, the concept of a reference range is incorrect. We will, therefore, no longer include reference ranges in these patient reports.

Please note that the reference range for Histoplasma Antigen Urine (8315UR) has been changed to provide a more clinically relevant value for Weak Positive, 2.0 to 4.0 EIA Units. Values greater than 4.0 EIA Units will continue to be reported as Positive.

To protect specimen integrity during periods of cold or hot weather, *Specialty* now offers an Insulated Envelope Gel Wrap Combo to prevent hemolyzed samples. Simply use order code 0003187 to receive a supply of Insulated Envelope Gel Wrap Combo when requesting your supplies.

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:

5310 BAALC (Brain and Acute Leukemia, Cytoplasmic) UltraQuant® (Available April 25, 2008)

<u>Component</u>	<u>Method</u>	<u>Reference Range/Units</u>
BAALC UltraQuant®	RT-PCR	By report

Specimen/Stability	Whole Blood EDTA 5.0 (3.0) mL; Refrigerated 5 days
Alternate Specimen	Bone Marrow EDTA 1.5 (0.5) mL; Refrigerated 5 days
Collection	Collect whole blood and bone marrow in EDTA. Heparin is not recommended. Contaminated, grossly hemolyzed or heavily lipemic samples should not be analyzed. Frozen or clotted specimens are not acceptable.
Schedule	Monday
Report	Within 3 days
CPT Code	83891, 83913, 83902, 83900, 83896x2, 83912
Clinical Utility	Among patients with acute myeloid leukemia (AML), those overexpressing BAALC (Brain and Acute Leukemia, Cytoplasmic) show distinctly poor prognosis, pointing to a key role of the BAALC products in leukemia. BAALC expression predicts an adverse prognosis and may define an important risk factor in AML with normal cytogenetics.
Note	This test is not approved for the testing of patient samples from New York State.

4490 Hydrocodone Serum AccuQuant® (including Hydromorphone) (Available Immediately)

<u>Component</u>	<u>Method</u>	<u>Reference Range/Units</u>
Hydrocodone Free	LC-MS-MS	5.0 – 24.0 ng/mL
Hydromorphone Free	LC-MS-MS	5.0 – 30.0 ng/mL

Specimen/Stability	Serum 5.0 (2.5) mL; Ambient 7 days, Refrigerated 14 days, Frozen 14 days
Collection	Serum separator tubes are not acceptable.
Schedule	Tuesday & Friday
Report	Next day
CPT Code	82646
Clinical Utility	Therapeutic drug monitoring and confirmation of screen-positive results. Hydrocodone is an active component of Vicodin, Lorcet, Lortab, etc. Serum half-life is 3.4 to 8.8 hours. Hydromorphone is an active ingredient in Dilaudid and Palladone. Serum half-life is 1.5 to 3.8 hours.

9335 Herpes Simplex Virus Type 1 IgM Abs [IFA] (Available Immediately)

<u>Component</u>	<u>Method</u>	<u>Reference Range/Units</u>
HSV 1 IgM Abs	IFA	Not detected

Specimen/Stability	Serum 1.0 (0.5) mL; Ambient 7 days, Refrigerated 14 days, Frozen 2 months
Alternate Specimen	Plasma EDTA 1.0 (0.5) mL; Ambient 7 days, Refrigerated 14 days, Frozen 2 months
Collection	...
Schedule	Wednesday-Sunday
Report	Same day
CPT Code	86695

New Tests: (cont'd)

9337 Herpes Simplex Virus Type 2 IgM Abs [IFA] (Available Immediately)

<u>Component</u>	<u>Method</u>	<u>Reference Range/Units</u>
HSV 2 IgM Abs	IFA	Not detected

Specimen/Stability Serum 1.0 (0.5) mL; Ambient 7 days, Refrigerated 14 days, Frozen 2 months
Alternate Specimen Plasma EDTA 1.0 (0.5) mL; Ambient 7 days, Refrigerated 14 days, Frozen 2 months
Collection ...
Schedule Wednesday-Sunday
Report Same day
CPT Code 86696

9339 Herpes Simplex Virus Type 1 & 2 IgM Abs [IFA] (Available Immediately)

<u>Component</u>	<u>Method</u>	<u>Reference Range/Units</u>
HSV 1 IgM Abs	IFA	Not detected
HSV 2 IgM Abs	IFA	Not detected

Specimen/Stability Serum 1.0 (0.5) mL; Ambient 7 days, Refrigerated 14 days, Frozen 2 months
Alternate Specimen Plasma EDTA 1.0 (0.5) mL; Ambient 7 days, Refrigerated 14 days, Frozen 2 months
Collection ...
Schedule Wednesday-Sunday
Report Same day
CPT Code 86695 & 86696

Test Changes:

8315UR *Histoplasma* Antigen Urine

Effective	Immediately
Ref Range	< 2.0 EIA Units
	< 2.0 Negative
	2.0 – 4.0 Weak positive
	> 4.0 Positive

4962 Clomipramine & Desmethylclomipramine

Effective	April 15
Ref Range	Clomipramine 68-272 ng/mL Desmethylclomipramine 150-300 ng/mL
Component	Clomipramine + Desmethyl REMOVE
Note	Desired Clomipramine (Anafranil®) concentration for the treatment of chronic pain: 20-85 ng/mL

4926 Diazepam

Effective	April 15
Name	Diazepam & Metabolite
Ref Range	Diazepam Not applicable Nordiazepam Not applicable Diazepam + Nordiazepam 100-1500 ng/mL Therapeutic range: 100-1500 ng/mL Potentially toxic: >3000 ng/mL

4300U Meperidine & Normeperidine Urine

Effective	April 15
Ref Range	Not applicable
Limit of Quantitation	Meperidine 12 ng/mL Normeperidine 8 ng/mL

4939U Clonazepam & 7-amino Clonazepam Urine

Effective	April 15
Ref Range	Not applicable
Limit of Quantitation	Clonazepam 5.0 ng/mL 7-amino Clonazepam 5.0 ng/mL

4302U Fentanyl & Norfentanyl Urine

Effective	April 15
Ref Range	Not applicable
Limit of Quantitation	Fentanyl 0.05 ng/mL Norfentanyl 0.05 ng/mL

4480U Flunitrazepam & Metabolites Confirmation Urine

Effective	April 15
Ref Range	Not applicable
Limit of Quantitation	Flunitrazepam 10 ng/mL 7-Aminoflunitrazepam 10 ng/mL N-Desmethyflunitrazepam 10 ng/mL

Test Changes: (Cont'd)

4480	Flunitrazepam & Metabolites Confirmation Serum	
Effective	April 15	
Ref Range	Not applicable	
Limit of Quantitation	Flunitrazepam	3 ng/mL
	7-Aminoflunitrazepam	3 ng/mL
	N-Desmethylflunitrazepam	3 ng/mL
4192U	Methadone Confirmation Urine	
Effective	April 15	
Ref Range	Not applicable	
Limit of Quantitation	Methadone	6 ng/mL
	EDDP	6 ng/mL
Also affects	Reflex of 4109U & 4129U	
4192	Methadone Confirmation Serum	
Effective	April 15	
Ref Range	Methadone	50-1000 ng/mL
	EDDP	Not applicable
Also affects	Reflex of 4109	
4133U	Cannabinoids Confirmation Urine	
Effective	April 15	
Ref Range	Not applicable	
Limit of Quantitation	Cannabinoids	7.5 ng/mL
Also affects	Reflex of 4254U & 4129U	
4170U	Cocaine & Metabolites Confirmation Urine	
Effective	April 15	
Ref Range	Not applicable	
Limit of Quantitation	Cocaine	50 ng/mL
	Benzoylecgonine	50 ng/mL
	Ecgonine Methylester	100 ng/mL
	Cocaethylene	50 ng/mL
Also affects	4171U, 4172U, Reflex of 4252U & 4129U	
4170	Cocaine & Metabolites Confirmation Serum	
Effective	April 15	
Ref Range	Not applicable	
Limit of Quantitation	Cocaine	100 ng/mL
	Benzoylecgonine	50 ng/mL
	Ecgonine Methylester	50 ng/mL
	Cocaethylene	50 ng/mL
	Peak concentration of cocaine after nasal administration of 100 mg is 200-400 ng/mL	
Also affects	4171, 4172, Reflex of 4252	

Test Changes: (Cont'd)

4094U Propoxyphene Confirmation Urine

Effective	April 15	
Ref Range	Not applicable	
Limit of Quantitation	Propoxyphene	4 ng/mL
	Norpropoxyphene	4 ng/mL
Also affects	Reflex of 4127U & 4129U	

4176U Oxycodone & Metabolite Urine

Effective	April 15	
Ref Range	Not applicable	
Limit of Quantitation	Oxycodone	5 ng/mL
	Oxymorphone	5 ng/mL

4186UR Opiates Confirmation w/6-MAM Urine

Effective	April 15	
Ref Range	Not applicable	
Limit of Quantitation	Codeine	25 ng/mL
	Hydrocodone	25 ng/mL
	Hydromorphone	25 ng/mL
	Morphine	25 ng/mL
	Oxycodone	25 ng/mL
	6-Monoacetylmorphine	1.0 ng/mL
Note	This test is not approved for the testing of patient samples from New York State	
Also affects	4185UR, 4187UR, 4490UR, 4492UR, 4494UR, Reflex of 4250U & 4129U	

4185 Opiates Confirmation Serum

Effective	April 15	
Ref Range	Not applicable	
Limit of Quantitation	Codeine Free	5 ng/mL
	Hydrocodone Free	5 ng/mL
	Hydromorphone Free	5 ng/mL
	Morphine Free	5 ng/mL
	Oxycodone Free	5 ng/mL
Also affects	Reflex of 4250	

4092U Barbiturates Confirmation Urine

Effective	April 15	
Ref Range	Not applicable	
Limit of Quantitation	Amobarbital	2 ng/mL
	Butalbital	2 ng/mL
	Butobarbital	2 ng/mL
	Phenobarbital	2 ng/mL
	Secobarbital	2 ng/mL
	Pentobarbital	2 ng/mL
	Mephobarbital	2 ng/mL
Also affects	Reflex of 4121U & 4129U	

Test Changes: (Cont'd)

4189U Amphetamines Confirmation Urine

Effective	April 15	
Ref Range	Not applicable	
Limit of Quantitation	Amphetamine	20 ng/mL
	Methamphetamine	20 ng/mL
	Ephedrine/Pseudoephedrine	25 ng/mL
	PPA	50 ng/mL
	Phentermine	20 ng/mL
	Phenmetrazine	50 ng/mL
	Phendimetrazine	2 ng/mL
	MDA	7 ng/mL
	MDMA	7 ng/mL
	MDEA	15 ng/mL
Also affects	Reflex of 4109U & 4129U	

4183U Phencyclidine (PCP) Confirmation Urine

Effective	April 15	
Ref Range	Not applicable	
Limit of Quantitation	Phencyclidine	1 ng/mL
Also affects	Reflex of 4101U & 4129U	

4183 Phencyclidine (PCP) Confirmation Serum

Effective	April 15	
Ref Range	Not applicable	
Limit of Quantitation	Phencyclidine	3 ng/mL
Also affects	Reflex of 4101	

4090U Benzodiazepines Confirmation Urine

Effective	April 15	
Ref Range	Not applicable	
Limit of Quantitation	Alpha-Hydroxyalprazolam	10 ng/mL
	Alpha-Hydroxytriazolam	10 ng/mL
	Alprazolam	20 ng/mL
	Chlordiazepoxide	20 ng/mL
	Diazepam	20 ng/mL
	Lorazepam	10 ng/mL
	Midazolam	20 ng/mL
	Norchlordiazepoxide	20 ng/mL
	Nordiazepam	50 ng/mL
	Desalkylflurazepam	10 ng/mL
	Oxazepam	20 ng/mL
	Temazepam	20 ng/mL
	Triazolam	10 ng/mL
Also affects	Reflex of 4107U & 4129U	

4168 Kidney Stone Risk AssessR™

Effective	April 15	
Component	Comment	REMOVE
	All other components remain the same	

Test Changes: (Cont'd)

1557 Oligoclonal Bands

Effective April 15
Ref Range Oligoclonal Bands in CSF No bands
Also affects 1055

5701 Stool Routine Culture w/Reflex Susceptibility

Effective April 15
Component Culture Site ADD
Also affects 5700

9436 Cytomegalovirus IgG & IgM Abs [EIA]

Effective Immediately
Specimen/Stability Serum 1.0 (0.5) mL; Ambient 7 days, Refrigerated 14 days, Frozen 2 months
Alternate Specimens Plasma EDTA 1.0 (0.5) mL; Ambient 7 days, Refrigerated 14 days, Frozen 2 months
Note: Plasma EDTA is now an acceptable specimen.
Also affected 2486, 9431

4125U Drugs of Abuse Screen Urine

Effective Immediately
Specimen/Stability Urine 10 (5) mL; Ambient 7 days, Refrigerated 7 days, Frozen 2 months
Note: Ambient specimens are now acceptable
Also affected 4106U, 4108U, 4111U, 4113U, 4117U, 4118U, 4132U, 4138U, 4149U

12992 Amniocyte Culture

Effective Immediately
Specimen/Stability Amniocytes, Cultured; Ambient 12 months, Refrigerated 12 months
Note: Tissue specimens are no longer acceptable

Test Changes: (Cont'd)

7435SW ***Chlamydia trachomatis* Confirmation [TMA]**

2937SW ***Neisseria gonorrhoeae* Confirmation [TMA]**

Effective	Immediately
Specimen/Stability	Gen-Probe (Aptima) Swab; Ambient 60 days, Refrigerated 60 days, Frozen 3 months
Alternate Specimens	M4 Transport Media/Swab; Ambient 4 days, Refrigerated 4 days, Frozen 60 days Universal Transport Media; Ambient 4 days, Refrigerated 4 days, Frozen 60 days AutoCyte PREP Tube; Ambient 28 days, Refrigerated 6 months ThinPrep Vial; Ambient 21 days, Refrigerated 21 days SurePath Vial; Ambient 28 days, Refrigerated 6 months GenProbe PACE Swab; Ambient 7 days, Refrigerated 7 days, Frozen 2 months GenProbe (Apt) Vag Swab; Ambient 60 days, Refrigerated 60 days, Frozen 3 months Note: AutoCyte, ThinPrep, SurePath, GenProbe PACE and GenProbe (Apt) collected specimens are now acceptable.
Collection Instructions	ThinPrep Pap Test Specimens: Specimens collected using broom-type device and placed in Cytoc PreservCyt solution for use in making ThinPrep Pap Test slides can be used for CT/GC testing. Collect specimens in routine manner; 4 mL PreservCyt solution required for CT/GC test. PreservCyt specimens stable 3 weeks ambient following collection and prior to processing. Specimens in alternate transport media (M4, ThinPrep, SurePath, culturette swabs) have been validated by Specialty Laboratories.

Discontinued Tests:

Effective March 31, 2008:

- 3193 Insulin Free & Bound**
Replaced by: S51630 Insulin, Total (Free and Antibody Bound) (36702X)
- 3616 Glucagon**
Replaced by: S51631 Glucagon (519X)

Effective April 15, 2008:

- 3874 Pancreatic Polypeptide**
Replaced by: S51632 Pancreatic Polypeptide (4789X)

Effective April 21, 2008:

- 3266 Heat Shock Protein 70 (HSP70) Autoantibodies**
Replaced by: S51633 HSP-70 Antibody (Anti-68 kd Antigen) (36734Z)
- 1481 Hyaluronic Acid**
Replaced by: S51634 Hyaluronic Acid (19480X)
- 5911 Human Anti-Mouse Antibodies (HAMA)**
Replaced by: S51635 Human Anti-Mouse Antibody (HAMA), ELISA (41882)
- 1040 Immune Complex DetectR™, Circulating**
Replaced by: 1230 Immune Complex Assay, Raji Cell and 1500 Complement C3 & C4
- 4086 Nitrazepam**
Replaced by: S48310 Nitrazepam [3175 S,P]
- 4495 Hydrocodone**
Replaced by: 4490 Hydrocodone Serum AccuQuant® (Including Hydromorphone)
- 3354W Histamine Whole Blood**
No replacement
- 3354P Histamine Plasma**
Replaced by: S51637 Histamine, Plasma (36586X)
- 3354U Histamine, Urine w/Creatinine**
Replaced by: S51638 Histamine, 24-Hour Urine (4946X)
- 5365 Maternal Cell Contamination (MCC) Detection**
No replacement
- 8230 Leishmania DNA DetectR™**
No replacement

Discontinued Tests: (cont'd)

- 4493** **Dihydrocodeine Serum**
Replaced by: S51643 Dihydrocodeine - Free (Unconjugated), Serum/Plasma (8662 S,P)
- 1139** **Cystatin C**
Replaced by: S51640 Cystatin C (10570X)
- 1512** **Alpha-2-Macroglobulin**
Replaced by: S51641 Alpha-2-Macroglobulin (228X)
- 1525** **Alpha-1-Acid Glycoprotein**
Replaced by: S51642 Alpha-1-Acid Glycoprotein (469X)

CPT Coding Change Recommendations

The following CPT code changes are part of an ongoing CPT coding standardization. The CPT codes provided are based upon AMA guidelines and are for informational purposes only. CPT coding is the sole responsibility of the billing party. If you have any questions, please refer to the Current Procedural Terminology (CPT) Manual published by the American Medical Association. To verify reimbursement, or to ask questions regarding usage of a CPT code, please contact your local Medicare carrier. Please contact Specialty Client Services at 800-421-4449 if you have questions regarding CPT coding changes to custom panels.

***Effective: Immediately**

DOS CODE	TEST DESCRIPTION	CPT CODE
1151	Cryofibrinogen	84999
1158	Cryoglobulin & Cryofibrinogen	82595, 84999
1520	Transferrin Receptor (TfR), Soluble	84238
1687	CD16/56 Surface Marker	86357
3109F	Alpha-Fetoprotein (AFP) Tumor Marker Body Fluid	86316
3262	Pheochromocytoma Evaluation	83835, 82382
3356	Isohemagglutinin Titer	86886x3
3535	Iron Status MonitR™	84238, 83540, 83550, 82728
3970UR	Citrate Urine Random	82507
4937	Oxcarbazepine (Trileptal)	82491
4970	Beta-Thalassemia Screen	83021
5322M	Fungus Culture & Stain - Miscellaneous	87206, 87102
5355	Cystic Fibrosis 40 (CF40) GenotypR™: Carrier Study	83891, 83892x2, 83900, 83901x14, 83914x23, 83909, 83912
5697	Respiratory Syncytial Virus Ag Detection	87999
5702	<i>Yersinia</i> Culture	87046
5779M	Fungus Culture: Yeast Screen - Miscellaneous	87206, 87102
5945	Heparin-PF4 Antibodies (HIT)	86022
6810	HCV Liver Fibrosis GenotypR™	87902
XAE	No Growth – Amniotic Fluid	88235
XAG	No Growth – Hematologic/Neoplastic Disorders, Blood	88237
XAI	No Growth – Bone Marrow	88237
XAN	No Growth – Solid Tumor	88239
XAP	No Growth – Products of Conception	88233
XAV	No Growth – Congenital Disorders, Blood	88230