

August 2006

*Specialty* is pleased to continue its implementation of useful FISH assays for the evaluation of chromosomal abnormalities associated with the presence and/or prognosis in various oncologic conditions. This month we are introducing the following FISH assays:

- 5880 Acute Lymphoblastic Leukemia by FISH
- 5884 del(4)(q12) by FISH (FIP1L1-CHIC2-PDGFR)
- 5882 t(12;21) TEL/AML1 by FISH
- 5886 Trisomy 11 by FISH

As part of our comprehensive drug screening and confirmation offering, we are now finalizing validation on assays for:

- 4189U Amphetamines Confirmation Urine (13 drugs/metabolites)
- 4480 Flunitrazepam and Metabolites Confirmation Serum
- 4480U Flunitrazepam and Metabolites Confirmation Urine

We are also introducing new HPLC tests for Homovanillic Acid on 24-hour and Random Urine samples as well as a sensitive, quantitative PCR for *Bordetella pertussis/parapertussis*.

**Special Notice:**

**Clients sending samples for test panels with *C. trachomatis*, *N. gonorrhoeae* and Human Papillomavirus should split samples into two or more tubes before sending to *Specialty* – so tests can be run concurrently rather than consecutively and improve turnaround time on receiving results.**

For additional information, please visit our Web site at [www.specialtylabs.com](http://www.specialtylabs.com) or contact Client Services at 800-421-4449.



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

# New Assays Available from *Specialty*

Effective date as noted

## 5880 Acute Lymphoblastic Leukemia by FISH (available 08-23-06)

Component	Method	Reference Range	Units
Acute Lymphoblastic Leukemia	FISH	By Report	
Specimen/Stability	3.0 (1.0) mL Sodium Heparinized Bone Marrow; Ambient 72 hrs		
Alternate Specimens	5.0 (3.0) mL Sodium Heparinized Whole Blood; Ambient 72 hrs		
Unacceptable specimens	Lithium heparinized specimens are not acceptable. Do not refrigerate or freeze.		
Clinical Utility	To evaluate prognostically relevant genetic abnormalities in ALL when cytogenetic studies are limited or unavailable. Acute lymphoblastic leukemia (ALL) is characterized by the accumulation of malignant, immature lymphoid cells in the bone marrow and in most cases also in peripheral blood. Clonal karyotypic abnormalities are found in ~1/2 of all patients with ALL, including t(9;22), 11q23, MLL gene rearrangements, t(12;21), and numerical chromosomal anomalies of chromosomes 4, 6, 10 and 21. The t(12;21) is the most common chromosomal anomaly detected in childhood ALL pre-B cell or B-cell lineage, occurring in ~1/3 of the cases. For most patients, the presence of TEL-AML1 transcripts suggests excellent chemosensitivity and a favorable prognosis, but some patients with these transcripts have a different outcome.		
Performance Schedule	Set-up: daily	Reported: within 7 days	
CPT Code	88237, 88271x10, 88275x7, 88291		

## 4189 U Amphetamines Confirmation Urine (available 09/12/06)

Component	Method	Reference Range	Units
Amphetamine	LCMS-MS	Cut off <200	ng/mL
Methamphetamine	LCMS-MS	Cut off <200	ng/mL
Ephedrine/Pseudoephedrine	LCMS-MS	Cut off <200	ng/mL
Norpseudoephedrine/Phenylpropanolamine (PPA)	LCMS-MS	Cut off <200	ng/mL
Phentermine	LCMS-MS	Cut off <200	ng/mL
Chloroamphetamine	LCMS-MS	Cut off <200	ng/mL
Phenmetrazine	LCMS-MS	Cut off <200	ng/mL
Phendimetrazine	LCMS-MS	Cut off <200	ng/mL
Benzphetamine	LCMS-MS	Cut off <200	ng/mL
Mephentermine	LCMS-MS	Cut off <200	ng/mL
α-Methyl-1,3-benzodioxole-5-ethanamine (MDA)	LCMS-MS	Cut off <200	ng/mL
N,α-Dimethyl-1,3-benzodioxole-5-ethanamine (MDMA)	LCMS-MS	Cut off <200	ng/mL
N-Ethyl-3,4-Methylenedioxy-amphetamine (MDEA)	LCMS-MS	Cut off <200	ng/mL
Specimen/Stability	4.0 (2.0) mL Urine Random; Ambient 2 weeks, Refrigerated 2 weeks, Frozen 2 months		
Collection Instructions	Do not use any preservatives or additives.		
Clinical Utility	Confirmation of screen-positive results. This panel contains the following 13 analytes: Amphetamine, Methamphetamine, Ephedrine/Pseudoephedrine, Norpseudoephedrine/Phenylpropanolamine (PPA), Phentermine, Chloroamphetamine, Phenmetrazine, Phendimetrazine, Benzphetamine, Mephentermine, α-Methyl-1,3-benzodioxole-5-ethanamine (MDA), N,α-Dimethyl-1,3-benzodioxole-5-ethanamine (MDMA), N-Ethyl-3,4-Mehtylenedioxy-amphetamine (MDEA).		
Performance Schedule	Set-up: Wednesday, Saturday	Reported: within 2 days	
CPT Code	82145x13		
Notes	Cut off <200 ng/mL		

Sendout test # S50809 AMPHETAMINES URINE CONFIRMATION will be discontinued 9/26/06.

**7920 Bordetella pertussis/parapertussis DNA DetectR™**  
(available 09/12/06)

Component	Method	Reference Range	Units
<i>B. pertussis</i>	PCR	Not Detected	
<i>B. parapertussis</i>	PCR	Not Detected	
Specimen/Stability	Nasopharyngeal swab; Refrigerated 7 days, Frozen 1 year		
Collection Instructions	Collect specimen with Dacron swab with either an aluminum or plastic shaft. Place in Regan-Lowe charcoal agar or modified Amies with charcoal.		
Alternate Specimen	Nasopharyngeal aspirate in sterile container; Refrigerated 7 days, Frozen 1 year		
Clinical Utility	<i>Bordetella</i> spp. DNA detection by PCR has a greater than 2-fold higher specificity than culture and can detect the presence of bacterial nucleic acid from non-viable pathogens compromised by either transit or antibiotic therapy.		
Performance Schedule	Set-up: Daily	Reported: next day	
CPT Code	87801		
Notes	1. Preferred sample is a rayon or synthetic swab with either a flexible aluminum wire or plastic shaft. 2. Calcium alginate swabs fully inhibit PCR amplification and will be rejected. 3. The lower limit of detection for both <i>B. pertussis</i> and <i>B. parapertussis</i> is 10 CFU (colony forming units) per mL.		

Sendout test # S50885 *BORDETELLA PERTUSSIS/PARAPERTUSSIS* PCR will be discontinued 9/26/06.

**5884 del(4)(q12) by FISH (FIP1L1-CHIC2-PDGFR)**  
(available 08-23-06)

Component	Method	Reference Range	Units
del(4)(q12)	FISH	By report	
Specimen/Stability	3.0 (1.0) mL Sodium Heparinized Bone Marrow; Ambient 72 hrs		
Alternate Specimens	5.0 (3.0) mL Sodium Heparinized Whole Blood; Ambient 72 hrs		
Unacceptable specimens	Lithium heparinized specimens are not acceptable. Do not refrigerate or freeze.		
Clinical Utility	For the detection of deletions/translocations involving 4q12 (FIP1L1-CHIC2-PDGFR) region. Hyper-eosinophilic syndrome (HES) and chronic eosinophilic leukemia (CEL) comprise a spectrum of indolent to aggressive diseases characterized by unexplained, persistent hyper-eosinophilia. Reports indicate the HES and CEL are Imatinib (Glivec®)-responsive malignancies due to a novel constitutively activated fusion tyrosine kinase at 4q12, derived from an interstitial deletion that fuses the platelet-derived growth factor receptor- $\alpha$ gene (PDGFR $\alpha$ ) to FIP1-like-1 gene (FIP1L1). The fusion is caused by the del(4)(q12), an 800-kb deletion involving the CHIC2 gene region. Translocation at 4q12 involving PDGFR $\alpha$ have also been described [e.g., t(4;22)(q12;q11.2)].		
Performance Schedule	Set-up: daily	Reported: within 7 days	
CPT Code	88237, 88271x3, 88275, 88291		

**4480 Flunitrazepam and Metabolites Confirmation Serum**  
(available 09/12/06)

Component	Method	Reference Range	Units
Flunitrazepam	LCMS-MS	<5	ng/mL
7-Aminoflunitrazepam	LCMS-MS	<5	ng/mL
N-Desmethyflunitrazepam	LCMS-MS	<5	ng/mL
Specimen/Stability	2.0 (1.0) mL Serum; Refrigerated 2 weeks, Frozen 2 months		
Clinical Utility	In Latin America and Europe, Rohypnol (Flunitrazepam) is prescribed to patients as a short-term treatment for insomnia, and as a preanesthetic medication. Flunitrazepam is considered a drug of abuse when used to enhance the effect of other substances such as marijuana, heroin, and ethanol. The combination of ethanol and flunitrazepam may lead to sedation, loss of motor control, impaired judgment, behavioral changes, and anterograde amnesia.		
Performance Schedule	Set-up: Thursday	Reported: next day	
CPT Code	80154x3		
Notes	Reference range is equivalent to lower limit of detection for this assay. Flunitrazepam is typically ingested in small doses and is rapidly metabolized; hence, it has a relatively short half-life in serum. Flunitrazepam metabolites may be detected in urine 5 days or more post ingestion, however as small doses are typically ingested, detection in urine is typically limited to the first 24-72 hours.		

Sendout test # S49528 FLUNITRAZEPAM & METAB SCREEN SERUM CLINICAL will be discontinued 9/26/06.

## 4480U Flunitrazepam and Metabolites Confirmation Urine (available 09/12/06)

Component	Method	Reference Range	Units
Flunitrazepam	LCMS-MS	<10	ng/mL
7-Aminoflunitrazepam	LCMS-MS	<10	ng/mL
N-Desmethyflunitrazepam	LCMS-MS	<10	ng/mL
Specimen/Stability	2.0 (1.0) mL Urine; Refrigerated 2 weeks, Frozen 2 months		
Collection Instructions	Do not use any preservatives or additives.		
Clinical Utility	In Latin America and Europe, Rohypnol (Flunitrazepam) is prescribed to patients as a short-term treatment for insomnia, and as a preanesthetic medication. Flunitrazepam is considered a drug of abuse when used to enhance the effect of other substances such as marijuana, heroin, and ethanol. The combination of ethanol and flunitrazepam may lead to sedation, loss of motor control, impaired judgment, behavioral changes, and anterograde amnesia.		
Performance Schedule	Set-up: Thursday	Reported: next	
CPT Code	80154x3		
Notes	Reference range is equivalent to lower limit of detection for this assay.		
Sendout test # S50834 FLUNITRAZEPAM URINE will be discontinued 9/26/06.			

## 3946U Homovanillic Acid 24hr Urine (available 09/12/06)

Component	Method	Reference Range	Units
Homovanillic Acid 24 hr Urine	HPLC	<8	mg/24hr
Specimen/Stability	5.0 (2.5) mL aliquot of 24hr Urine Collection; Refrigerated 14 days, Frozen 14 days		
Collection Instructions	If possible, patient should discontinue all drugs at least 1 week prior to collection. 1. Refrigerate during and after collection. 2. After collection, mix the specimen, measure the total volume and transfer a 5 mL aliquot to a clean, leak proof screw cap container. 3. Record the 24 hr total volume on the requisition form or shipping manifest. 4. Store and ship refrigerated. 5. Acid additive (Hydrochloric, nitric or acetic acid) is acceptable, but not necessary, if the specimen is refrigerated during collection and transportation.		
Clinical Utility	Useful in the diagnosis of suspected neuroblastoma; however, not currently recommended for childhood screening programs.		
Performance Schedule	Set-up: Tuesday-Saturday	Reported: within 2 days	
CPT Code	83150		
Sendout test # S50105 HOMO VANILLIC ACID, URINE 24HR will be discontinued 9/26/06.			

## 3946UR Homovanillic Acid Urine Random (available 09/12/06)

Component	Method	Reference Range	Units
Homovanillic Acid Urine Random	HPLC	see age adjusted ranges below 0-1 year <33 mg/g creatinine 2-4 years <22 mg/g creatinine 5-9 years <15 mg/g creatinine 10-18 years <13 mg/g creatinine >18 years <7.6 mg/g creatinine	
Specimen/Stability	5.0 (2.5) mL Urine Random; Refrigerated 14 days, Frozen 14 days		
Collection Instructions	If possible, patient should discontinue all drugs at least 1 week prior to collection. Store and ship refrigerated. Acid additive (Hydrochloric, nitric or acetic acid) is acceptable, but not necessary, if the specimen is refrigerated.		
Clinical Utility	Useful in the diagnosis of suspected neuroblastoma; however, not currently recommended for childhood screening programs.		
Performance Schedule	Set-up: Tuesday-Saturday	Reported: within 2 days	
CPT Code	83150		
Sendout test # S50106 HOMO VANILLIC ACID, URINE RANDOM will be discontinued 9/26/06.			

**5882 t(12;21) TEL/AML1 by FISH**  
(available 08-23-06)

Component	Method	Reference Range	Units
t(12;21)TEL/AML1	FISH	By report	
Specimen/Stability	3.0 (1.0) mL Sodium Heparinized Bone Marrow; Ambient 72 hrs		
Alternate Specimens	5.0 (3.0) mL Sodium Heparinized Whole Blood; Ambient 72 hrs		
Unacceptable specimens	Lithium heparinized specimens are not acceptable. Do not refrigerate or freeze.		
Clinical Utility	To detect the TEL(ETV6)/AML1 gene fusion that occurs as a result of a translocation between chromosomes 12p13 and 21q22. Cytogenetically, the t(12;21) is a subtle abnormality and thus not easily detectable with standard cytogenetic banding techniques. The t(12;21) is the most common chromosomal anomaly detected in childhood ALL pre-B cell or B-cell lineage, occurring in ~1/3 of the cases. For most patients, the presence of TEL-AML1 transcripts suggests excellent chemosensitivity and a favorable prognosis, but some patients with these transcripts have a different outcome.		
Performance Schedule	Set-up: daily	Reported: within 7 days	
CPT Code	88237, 88271x2, 88275, 88291		

**5886 Trisomy 11 by FISH**  
(available 08-23-06)

Component	Method	Reference Range	Units
Trisomy 11	FISH	By report	
Specimen/Stability	3.0 (1.0) mL Sodium Heparinized Bone Marrow; Ambient 72 hrs		
Alternate Specimens	5.0 (3.0) mL Sodium Heparinized Whole Blood; Ambient 72 hrs		
Unacceptable specimens	Lithium heparinized specimens are not acceptable. Do not refrigerate or freeze.		
Clinical Utility	Isolated trisomy 11 is the third most common sole trisomy in de novo acute myeloid leukemia (AML). Most cases have been classified to FAB subgroups M1, M2 and M4. Trisomy 11 is also fairly common in MDS.		
Performance Schedule	Set-up: daily	Reported: within 7 days	
CPT Code	88237, 88271, 88275, 88291		

**Other New Tests (comprised of existing tests)**

Test Code	Test Name/Components	Test Code	Test Name/Components
1418	Acetylcholine Receptor Panel		Also:
	Acetylcholine Receptor Binding Autoabs	8290C	Arbovirus IgG & IgM Abs CSF(see below)
	Acetylcholine Receptor Blocking Autoabs	8120C	Calif-LaCrosse Virus IgG & IgM Abs CSF
	Acetylcholine Receptor Modulating Autoabs	8124C	Eastern Equine IgG & IgM Abs CSF
8290	Arbovirus IgG & IgM Abs (see below)	8122C	St. Louis Encephalitis IgG & IgM Abs CSF
8120	Calif-LaCrosse Virus Enceph IgG & IgM Abs	8128C	Western Equine IgG & IgM Abs CSF
8124	Eastern Equine Encephalitis IgG & IgM Abs		
8122	St. Louis Encephalitis IgG & IgM Abs	2263	<i>Toxoplasma gondii</i> IgG & IgM Antibodies
8128	Western Equine Encephalitis IgG & IgM Abs	2263C	<i>Toxoplasma gondii</i> IgG & IgM Antibodies CSF (replaces 2261C as of 8-15-06)