

January 25, 2007

Dear Colleague:

We are pleased to announce many new test offerings this month.

In oncology, the molecular-based **BCL2/JH Gene Rearrangement by PCR** assay is now available. BCL2/JH gene rearrangements [t(14;18) translocations] are important features distinguishing Non-Hodgkin's Lymphoma of follicular origin. BCL2/JH identified by PCR is present in 70-90% of follicular lymphomas and 20-30% of diffuse large B-cell lymphomas.

In our Drugs of Abuse (DOA) test menu, several new serum and urine confirmatory tests are now available as well as new screening panels that reflex to confirmation. *Specialty* is pleased to offer confirmation Drugs of Abuse testing utilizing LCMS/MS methodology.

Confirmatory Testing:

4090 Benzodiazepine (serum)
4157 Tricyclic Antidepressants (TCA) (serum)
4154 Tricyclic Antidepressants (TCA) (serum) Extended
4092U Barbituates (urine)
4094U Propoxyphene (urine)

Screens with reflex to confirmations:

4109U Methadone (urine) w/RFX
4109 Methadone (serum) w/RFX
4101U PCP (urine) w/RFX
4101 PCP (serum) w/RFX
4107 Benzodiazepines (serum) w/RFX
4121U Barbituates (urine) w/RFX
4127U Propoxyphene (urine) w/RFX

Billing update: National Provider Identifier

The Administrative Simplification provisions of the *Health Insurance Portability and Accountability Act of 1996 (HIPAA)* mandated the adoption of a standard unique identifier for health care providers. The National Plan and Provider Enumeration System (NPPES) collects identifying information on health care providers and assigns each a unique **National Provider Identifier (NPI)**.

HIPAA requires that covered health care providers use NPIs in standard transactions by the compliance date of May 23, 2007. It will be the only health care provider identifier that can be used in billing transactions and will be the only identifier accepted by *Specialty* on this date. The NPI must replace all requesting physician UPIN, provider and license numbers on requisitions submitted for Medicare, Medicaid or other third party billing. For more information regarding the NPI, please visit the following CMS website: <http://www.cms.hhs.gov/NationalProvIdentStand/>

If you have any questions regarding this requirement, please call Judy Perez at 800-421-7110 ext. 4502.

Medical Necessity/Diagnosis Codes

Every third party bill must have a valid diagnosis code. Please be sure to put the ICD-9 Code(s) applicable to the patient's condition for the specified date of service on the requisition in the box marked "Diagnostic Codes (ICD-9)". Medicare diagnosis codes must be coded to the highest level of specificity. Please refer to the International Classification of Diseases (ICD-9) manual, as well as the Medical Regulations and Manuals issued or authorized by the Center for Medicare and Medicaid Services (CMS) for diagnosis coding rules and regulations.

If the claim is denied due to lack of medical necessity, *Specialty* will send a request for an additional ICD-9 code or other evidence of medical necessity directly to the ordering client. If the claim is denied pending laboratory results, *Specialty* will send a release form directly to the patient for authorization to release laboratory results to the third party payers for HIV-related services.

For additional information, please visit our Web site at www.specialtylabs.com or contact Client Relations at 800-421-4449.



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

4154 Tricyclic Antidepressants (TCA) Confirmation Serum Extended (Available 02/13/07)

Component	Method	Reference Range/Units
Desipramine	HPLC	150-250 ng/mL
Imipramine	HPLC	By Report
Amitriptyline	HPLC	By Report
Nortriptyline	HPLC	50-150 ng/mL
Clomipramine	HPLC	68-272 ng/mL
Desmethylclomipramine	HPLC	218-540 ng/mL

Specimen/Stability 2.0mL (1.0 mL), Serum, Ambient 2 days, Refrigerated 5 days, Frozen 2 months
 Alternate Specimens 2.0mL (1.0 mL), Plasma ACD, Ambient 2 days, Refrigerated 5 days, Frozen 2 months
 2.0mL (1.0 mL), Plasma EDTA, Ambient 2 days, Refrigerated 5 days, Frozen 2 months
 Clinical Utility This panel confirms positive screens for Tricyclic Antidepressants.
 Schedule Monday-Friday
 Report Next Day
 CPT Code Desipramine, 80160 Imipramine, 80174 Amitriptyline 80152, Nortriptyline 80182, Clomipramine 80299
 Desmethylclomipramine 80299
 Note Serum separator tubes are not acceptable. Use polypropylene tubes and ship on cold pack by overnight courier.

4157 Tricyclic Antidepressants (TCA) Confirmation Serum (Available 02/13/07)

Component	Method	Reference Range/Units
Desipramine	HPLC	150-250 ng/mL
Imipramine	HPLC	By Report
Amitriptyline	HPLC	By Report
Nortriptyline	HPLC	50-150 ng/mL

Specimen/Stability 2.0mL (1.0 mL), Serum, Ambient 2 days, Refrigerated 5 days, Frozen 2 months
 Alternate Specimens 2.0mL (1.0 mL), Plasma ACD, Ambient 2 days, Refrigerated 5 days, Frozen 2 months
 2.0mL (1.0 mL), Plasma EDTA, Ambient 2 days, Refrigerated 5 days, Frozen 2 months
 Clinical Utility This panel confirms positive screens for Tricyclic Antidepressants.
 Schedule Monday-Friday
 Report Next Day
 CPT Code Desipramine 80160, Imipramine 80174, Amitriptyline 80152, Nortriptyline 80182
 Note Serum separator tubes are not acceptable. Use polypropylene tubes and ship on cold pack by overnight courier.

5779W Fungus Culture: Yeast Screen-Whole Blood or Bone Marrow (Available 02/13/07)

Component	Method	Reference Range/Units
Preliminary Fungus Report	Culture	By Report
Fungus Culture-Final	Culture	By Report

Specimen/Stability 10.0mL (5.0mL), Whole Blood ACD, Ambient 24 hours
 Alternate Specimens Blood Culture Bottle, Ambient 24 hours
 10.0ml (5.0mL) Bone Marrow ACD, Ambient 24 hours
 Clinical Utility Assay includes the isolation and identification of yeast in culture. Aids in the diagnosis of yeast related infections.
 Schedule Sunday-Saturday
 Report 5 days
 CPT Code 87103
 Note If culture is positive, it will reflex to #5323 Fungus ID Mould, or #5324 Fungus ID Yeast, or #5633 Fungus ID by DNA Probe (*Histoplasma*, *Blastomyces*, *Coccidioides*) at an additional charge. For skin, hair, or nails use 5779. All others use 5779M.

5779M

Fungus Culture: Yeast Screen - Miscellaneous

(Available 02/13/07)

Component	Method	Reference Range/Units
Preliminary Fungus Report	Culture	By Report
Fungus Culture-Final	Culture	By Report
Fungal Stain	Stain	No fungal elements
Specimen/Stability	Culturette/Swab, Ambient - 24 Hour(s), Refrigerated - 72 Hour(s)	
Alternate Specimens	Pure Culture Broth, Ambient - 24 Hour(s), Refrigerated - 72 Hour(s) Pure Culture Agar Slant, Ambient - 24 Hour(s), Refrigerated - 72 Hour(s) 5.0mL (5.0 mL), Urine, Refrigerated - 14 Day(s)	
Clinical Utility	Assay includes the direct examination of specimens for detection of fungal elements, isolation, and identification of yeast in culture. Aids in the diagnosis of yeast related infections.	
Schedule	Sunday-Saturday	
Report	5 days	
CPT Code	87206-Smear, 87102-Culture	
Note	If culture is positive, it will reflex to #5323 Fungus ID Mould, or #5324 Fungus ID Yeast, or #5633 Fungus ID by DNA Probe (<i>Histoplasma</i> , <i>Blastomyces</i> , <i>Coccidioides</i>) at an additional charge. For skin, hair, or nails use 5779. For blood and bone marrow use 5779W There is no stain performed on whole blood or bone marrow.	

4109

Methadone Screen Serum W/RFX Confirmation

(Available 02/13/07)

Component	Method	Reference Range / Units
Methadone	EIA	Negative
Specimen/Stability	3.0mL (2.0 mL), Serum, Refrigerated 2 days, Frozen 14 days	
Clinical Utility	Serum screen for Methadone	
Schedule	Tuesday, Thursday, and Saturday	
Report	Same day NOTE: If Screen is positive allow additional time for confirmation testing.	
CPT Code	80101	
Note	Positive screen results automatically reflex for confirmation at an additional charge.	

4101

Phencyclidine (PCP) Screen Serum W/RFX Confirmation

(Available 02/13/07)

Component	Method	Reference Range / Units
Phencyclidine (PCP)	EIA	Negative
Specimen/Stability	3.0mL (2.0 mL), Serum, Refrigerated 5 days, Frozen 14 days	
Clinical Utility	Serum screen for Phencyclidine (PCP). PCP is classified as a hallucinogen and has many of the same effects as Lysergic Acid Diethylamide (LSD), with more severe psychotropic affects. It acts as a hallucinogen, stimulant, depressant and anesthetic all at the same time.	
Schedule	Tuesday, Thursday, and Saturday	
Report	Same day NOTE: If Screen is positive allow additional time for confirmation testing.	
CPT Code	80101	
Note	Positive screen results automatically reflex for confirmation at an additional charge.	

4107

Benzodiazepine Screen Serum W/RFX Confirmation

(Available 02/13/07)

Component	Method	Reference Range / Units
Benzodiazepines	EIA	Negative
Specimen/Stability	3.0mL (2.0 mL), Serum, Refrigerated 48 hours, Frozen 14 days	
Clinical Utility	Benzodiazepines are widely used as anxiolytics, sedative-hypnotics, muscle relaxants, and anticonvulsants. Benzodiazepines include drugs such as diazepam (Valium®), chlordiazepoxide (Librium®), oxazepam (Serax®), lorazepam (Ativan®), alprazolam (Xanax®), clonazepam (Clonopin®), flurazepam (Dalmane®) and triazolam (Halcion®). Many common benzodiazepines are detected in urine by their metabolites oxazepam and nordiazepam. Psychological and physiological addictions, misuse and abuse of benzodiazepines have been described.	
Schedule	Tuesday, Thursday, and Saturday	
Report	Same day NOTE: If Screen is positive allow additional time for confirmation testing.	
CPT Code	80101	
Note	Positive screen results automatically reflex for confirmation at an additional charge.	

4109U

Methadone Screen Urine W/RFX Confirmation

(Available 02/13/07)

<u>Component</u>	<u>Method</u>	<u>Reference Range / Units</u>
Methadone	EMIT	Not Detected

Specimen/Stability 5.0mL (4.0 mL), Urine, Refrigerated 7 days, Frozen 14 days
 Clinical Utility Urine screen for methadone.
 Schedule Sunday-Saturday
 Report Same day NOTE: If Screen is positive allow additional time for confirmation testing.
 CPT Code 80101
 Note Positive screen results automatically reflex for confirmation at an additional charge.

4101U

Phencyclidine (PCP) Screen Urine W/RFX Confirmation

(Available 02/13/07)

<u>Component</u>	<u>Method</u>	<u>Reference Range / Units</u>
PCP	EMIT	Not Detected

Specimen/Stability 5.0mL (4.0 mL), Urine, Refrigerated 5 days, Frozen 14 days
 Clinical Utility Urine screen for Phencyclidine (PCP). PCP is classified as a hallucinogen and has many of the same effects as Lysergic Acid Diethylamide (LSD), but can be much more dangerous. It acts as a hallucinogen, stimulant, depressant and anesthetic all at the same time.
 Schedule Sunday-Saturday
 Report Same day NOTE: If Screen is positive allow additional time for confirmation testing.
 CPT Code 80101
 Note Positive screen results automatically reflex for confirmation at an additional charge.

4092U

Barbituates Confirmation Urine

(Available 02/13/07)

Replaces S50811 Barbituates Urine Confirmation

<u>Component</u>	<u>Method</u>	<u>Reference Range / Units</u>
Amobarbital	LCMS/MS	Positive Cutoff = 120 ng/mL
Butalbital	LCMS/MS	Positive Cutoff = 120 ng/mL
Butabarbital	LCMS/MS	Positive Cutoff = 120 ng/mL
Phenobarbital	LCMS/MS	Positive Cutoff = 120 ng/mL
Secobarbital	LCMS/MS	Positive Cutoff = 120 ng/mL
Pentobarbital	LCMS/MS	Positive Cutoff = 120 ng/mL
Mephobarbital (Methylphenobarbital)	LCMS/MS	Positive Cutoff = 120 ng/mL

Specimen/Stability 4.0mL (2.0 mL), Urine, Refrigerated 4 weeks, Ambient 4 weeks, Frozen 4 weeks
 Clinical Utility Confirmation of screen-positive results. This panel contains the following analytes: Amobarbital, Butalbital, Butabarbital, Phenobarbital, Secobarbital, Pentobarbital, Mephobarbital (Methylphenobarbital).
 Schedule Tuesday Thursday and Saturday
 Report Next Day
 CPT Code Amobarbital – 82205, Butalbital – 82205, Butabarbital – 82205, Phenobarbital – 80184, Secobarbital – 82205, Pentobarbital – 82205, Mephobarbital - 82205

4090

Benzodiazepines Serum

(Available 02/13/07)

Replaces S50813 Benzodiazepines

Component	Method	Reference Range / Units
Alprazolam	LCMS/MS	Therapeutic 5-25 ng/mL
		Toxic >60 ng/mL
Alpha-Hydroxyalprazolam (Alprazolam Metabolite)	LCMS/MS	Therapeutic 5-25 ng/mL
		Toxic >60 ng/mL
Alpha-Hydroxytriazolam (Triazolam Metabolite)	LCMS/MS	Therapeutic 5-20 ng/mL
		Toxic >100 ng/mL
Chlordiazepoxide	LCMS/MS	Therapeutic 100-3000 ng/mL
		Toxic >5000 ng/mL
Clonazepam	LCMS/MS	Therapeutic 20-60 ng/mL
		Toxic >100 ng/mL
Desalkylflurazepam (Flurazepam Metabolite)	LCMS/MS	Therapeutic 30-150 ng/mL
		Toxic >500 ng/mL
Diazepam	LCMS/MS	Therapeutic 100-1500 ng/mL
		Toxic >3000 ng/mL
Estazolam	LCMS/MS	Therapeutic By Report
		Toxic By Report
Flurazepam	LCMS/MS	Therapeutic 0-30 ng/mL
		Toxic >500 ng/mL
Hydroxyethylflurazepam	LCMS/MS	Therapeutic 30-180 ng/mL
		Toxic >1000 ng/mL
Lorazepam	LCMS/MS	Therapeutic 50-240 ng/mL
		Toxic >500 ng/mL
Midazolam	LCMS/MS	Therapeutic 50-600 ng/mL
		Toxic >2000 ng/mL
Nitrazepam	LCMS/MS	Therapeutic 30-100 ng/mL
		Toxic >300 ng/mL
Norchlordiazepoxide (Chlordiazepoxide Metabolite)	LCMS/MS	Therapeutic 100-3000 ng/mL
		Toxic >5000 ng/mL
Nordiazepam	LCMS/MS	Therapeutic 100-1500 ng/mL
		Toxic >3000 ng/mL
Oxazepam	LCMS/MS	Therapeutic 200-500 ng/mL
		Toxic >2000 ng/mL
Temazepam	LCMS/MS	Therapeutic 50-1000 ng/mL
		Toxic >5000 ng/mL
Triazolam	LCMS/MS	Therapeutic 5-20 ng/mL
		Toxic >100 ng/mL

Specimen/Stability 2.0mL (1.0 mL), Serum, Refrigerated 5 days, Frozen 2 weeks

Alternate Specimens 2.0mL (1.0 mL), Plasma EDTA, Refrigerated 5 days, Frozen 2 weeks

2.0mL (1.0 mL), Plasma Heparinized, Refrigerated 5 days, Frozen 2 weeks

Clinical Utility Benzodiazepines are widely used as anxiolytics, sedative-hypnotics, muscle relaxants, and anticonvulsants. Benzodiazepines include drugs such as diazepam (Valium®), chlordiazepoxide (Librium®), oxazepam (Serax®), lorazepam (Ativan®), alprazolam (Xanax®), clonazepam (Clonopin®), flurazepam (Dalmane®) and triazolam (Halcion®). Many common benzodiazepines are detected in urine by their metabolites oxazepam and nordiazepam. Psychological and physiological addictions, misuse and abuse of benzodiazepines have been described.

Schedule Tuesday Thursday and Saturday

Report Next Day

CPT Code Flurazepam 82742, All other components use 80154

5049

BCL2/JH Gene Rearrangement by PCR

(Available 02/13/07)

Replaces S49290 BCL-2 Gene Rearrangement [PCR]

<u>Component</u>	<u>Method</u>	<u>Reference Range / Units</u>
BCL2 DetectR	PCR	By Report

Specimen/Stability 5.0mL (3.0 mL), Whole Blood EDTA, Ambient 7 days, Refrigerated 7 days
 Alternate Specimens 1.5mL (0.5 mL), Bone Marrow, Ambient 7 days, Refrigerated 7 days
 5.0mL (3.0 mL), Whole Blood ACD/HEP, Ambient 7 days, Refrigerated 7 days
 Clinical Utility BCL2/JH [t(14;18)] translocations are present in 70-90% of follicular lymphomas and 20-30% of diffuse large B-cell lymphomas.
 Schedule Wednesday
 Report 6 days
 CPT Code 83891, 83900, 83901x3, 83909x3, 83912
 Note Refrigerated and Heparin specimens are also acceptable but not preferred. Do not freeze.
 Not available for New York clients until further notice.

5049BK

BCL2/JH Gene Rearrangement by PCR Paraffin Block (Available 02/13/07)

Replaces S49290 BCL-2 Gene Rearrangement [PCR]

<u>Component</u>	<u>Method</u>	<u>Reference Range / Units</u>
BCL2 DetectR	PCR	By Report

Specimen/Stability 4 sections 50 microns thick, paraffin embedded tissue, Ambient indefinite
 Clinical Utility BCL2/JH [t(14;18)] translocations are present in 70-90% of follicular lymphomas and 20-30% of diffuse large B-cell lymphomas.
 Schedule Wednesday
 Report 8 days
 CPT Code 83891, 83900, 83901x3, 83909x3, 83912, 83907
 Not available for New York clients until further notice

4094U

Propoxyphene Confirmation Urine

(Available 02/13/07)

Replaces S50876 Propoxyphene Confirmation

<u>Component</u>	<u>Method</u>	<u>Reference Range / Units</u>
Propoxyphene	LCMS/MS	Positive Cutoff = 25 ng/mL
Norpropoxyphene	LCMS/MS	Positive Cutoff = 25 ng/mL

Specimen/Stability 4.0mL (2.0 mL), Urine, Refrigerated 2 days, Ambient 2 days, Frozen 2 days
 Clinical Utility Confirmation of screen-positive results. This panel contains the following analytes:
 Propoxyphene and Norpropoxyphene.
 Schedule Tuesday, Thursday, Saturday
 Report Next Day
 CPT Code Propoxyphene 80299, Norpropoxyphene 80299

4127U

Propoxyphene Screen Urine W/RFX Confirmation

(Available 02/13/07)

<u>Component</u>	<u>Method</u>	<u>Reference Range / Units</u>
Propoxyphene	Emit	Not Detected

Specimen/Stability 5.0mL (2.5 mL), Urine, Refrigerated 2 days, Frozen 2 days
 Clinical Utility Screen for Propoxyphene in urine.
 Schedule Sunday-Saturday
 Report Same day NOTE: If Screen is positive allow additional time for confirmation testing.
 CPT Code 80101
 Note Positive screen results automatically reflex for confirmation at an additional charge.

4121U

Barbituates Screen Urine W/RFX Confirmation

(Available 02/13/07)

<u>Component</u>	<u>Method</u>	<u>Reference Range / Units</u>
Barbituates	Emit	Not Detected

Specimen/Stability 5.0mL (2.5 mL), Urine, Refrigerated 3 days, Frozen 2 months
 Clinical Utility Screen for barbituates in urine.
 Schedule Sunday-Saturday
 Report Same day NOTE: If Screen is positive allow additional time for confirmation testing.
 CPT Code 80101
 Note Positive screen results automatically reflex for confirmation at an additional charge.