

December 19, 2006

Dear Colleague:

We are pleased to announce many new test offerings this month. In oncology, several new molecular-based DetectR™ assays are now available. The **MSI DetectR™** (Microsatellite Instability) has been found to be present in 90% of colon cancers arising in patients with hereditary non-polyposis colorectal cancer (HNPCC) and 10-15% of sporadic colorectal carcinomas. The MSI status of a tumor is predictive of clinical outcome and response to adjuvant therapies.

B-Cell Gene Rearrangement DetectR™ and **T-Cell Gene Rearrangement DetectR™** are now available to aid in the diagnosis, staging and post-treatment monitoring of a variety of B-cell and T-cell neoplasms. These assays are particularly useful to help distinguish lymphomas from reactive lymphoid proliferations in skin and lymph node or to evaluate status of disease (e.g. lymphoma staging) in bone marrow or blood.

Several new FISH tests are also now available:

Oncology

- FISH - RB1 13q14
- FISH - 20q12 D20S108
- FISH - p53 17p13.1
- FISH - IGH 14q32
- FISH - MALT1 18q21

Prenatal/Congenital Disorder Testing

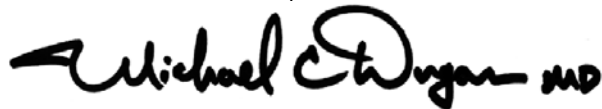
- FISH - TRISOMY 13, 18, 21, X & Y PRENATAL (AneuVysion™)
- FISH - TRISOMY 21
- FISH - SUBTELOMERE ABNORMALITIES (Totelvysion™)

Preferred Shipping Temperature update: When sending patient samples for analysis please pay particular attention to the preferred temperature in the specimen shipping requirements. *Specialty* receives many patient samples "frozen" for tests not requiring such handling. When acceptable, please send specimens ambient or refrigerated as it will help expedite analysis. Please review the published Specimen Requirements available online at www.specialtylabs.com for optimal specimen handling instructions.

Cytogenetics update: Please note the change in all chromosome analysis testing: If no mitotic activity is seen in samples processed, a fee for "no growth" cell culture will be assessed in the amount of \$150.00 and no charge will be assessed for the originally ordered test. If you need additional details on this "no growth" fee, please contact client relations at 1-800-421-4449.

DPMD update: The DatapassportMD® (DPMD) website was upgraded on December 3, 2006 to enable the entry of up to six character ICD-9 codes and provide input validation upon data entry. This enhancement was designed to reduce billing errors and client support time. DPMD previously supported only four character ICD-9 codes and no data input validation was being performed. Additionally, the migration includes code enhancements to improve application performance as well as a few minor cosmetic corrections on the Web site.

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

<u>Component</u>	<u>Method</u>	<u>Reference Range / Units</u>
B-Cell Gene Rearrangement PCR DetectR™	PCR	By Report

Specimen/Stability 2 sections 50 microns thick, paraffin embedded tissue, Ambient indefinite
 Clinical Utility The immunoglobulin heavy chain (IgH) gene rearrangement PCR assay can detect clonal populations of lymphoid cells in mixed cell populations from specimens such as tissues and body fluids. This assay is therefore useful as an aid in the diagnosis or confirmation of lymphoid neoplasms of B-cell lineage, treatment selection for such diseases, detection of sub-clinical minimal residual disease and for the monitoring of disease recurrence.
 Schedule Monday and Thursday
 Report 4 days
 CPT Code 83891, 83898x3, 83909x3, 83912, 83907
 Note Not offered to NY patients until further notice.

5044 B-Cell Gene Rearrangement DetectR™ (Available 01/03/07)

<u>Component</u>	<u>Method</u>	<u>Reference Range / Units</u>
B-Cell Gene Rearrangement PCR DetectR™	PCR	By Report

Specimen/Stability 5.0 (3.0) mL Whole Blood EDTA, Ambient 1 week, Refrigerated 1 week
 Alternate Specimens 1.5 (0.5) mL Bone Marrow, Ambient 1 week, Refrigerated 1 week
 5.0 (3.0) mg Fresh Tissue, Frozen 1 year
 Cell Pellet, Ambient 72 hours
 5.0 (3.0) mL Whole Blood Heparinized, Ambient 1 week, Refrigerated 1 week
 5.0 (3.0) mL Whole Blood ACD, Ambient 1 week, Refrigerated 1 week
 Clinical Utility The immunoglobulin heavy chain (IgH) gene rearrangement PCR assay can detect clonal populations of lymphoid cells in mixed cell populations from specimens such as tissues and body fluids. This assay is therefore useful as an aid in the diagnosis or confirmation of lymphoid neoplasms of B-cell lineage, treatment selection for such diseases, detection of sub-clinical minimal residual disease and for the monitoring of disease recurrence.
 Schedule Monday and Thursday
 Report 4 days
 CPT Code 83891, 83898x3, 83909x3, 83912,
 Note Not offered to NY patients until further notice.

5040BK B-Cell and T-Cell Gene Rearrangement DetectR™ - Paraffin Block (Available 01/03/07)

<u>Component</u>	<u>Method</u>	<u>Reference Range / Units</u>
B-Cell and T-Cell Gene Rearrangement DetectR™	PCR	By Report

Specimen/Stability 4 sections 50 microns thick, paraffin embedded tissue, Ambient indefinite
 Clinical Utility This assay is useful as an aid in the diagnosis or confirmation of lymphoid neoplasms of B-cell and T-cell lineage, treatment selection for such diseases, detection of sub clinical minimal residual disease and for the monitoring of disease recurrence.
 Schedule Monday and Thursday
 Report 5 days
 CPT Code 83891, 83898x3, 83900, 83901x2, 83909x4, 83912, 83907
 Note Not offered to NY patients until further notice.

5040 B-Cell and T-Cell Gene Rearrangement DetectR™ (Available 01/03/07)

<u>Component</u>	<u>Method</u>	<u>Reference Range / Units</u>
B-Cell and T-Cell Gene Rearrangement DetectR™	PCR	By Report

Specimen/Stability 5.0 (3.0) mL Whole Blood EDTA, Ambient 1 week, Refrigerated 1 week
 Alternate Specimens 1.5 (0.5) mL Bone Marrow, Ambient 1 week, Refrigerated 1 week
 5.0 (3.0) mg Fresh Tissue, Frozen 1 year
 Cell Pellet, Ambient 72 hours
 5.0 (3.0) mL Whole Blood Heparinized, Ambient 1 week, Refrigerated 1 week
 5.0 (3.0) mL Whole Blood ACD, Ambient 1 week, Refrigerated 1 week
 Clinical Utility This assay is useful as an aid in the diagnosis or confirmation of lymphoid neoplasms of B-cell and T-cell lineage, treatment selection for such diseases, detection of sub clinical minimal residual disease and for the monitoring of disease recurrence.
 Schedule Monday and Thursday
 Report 5 days
 CPT Code 83891, 83898x3, 83900, 83901x2, 83909x4, 83912,
 Note Not offered to NY patients until further notice.

5863 FISH - IGH 14q32 (Available 01/03/07)

<u>Component</u>	<u>Method</u>	<u>Reference Range / Units</u>
FISH - IGH 14q32	FISH	By Report

Specimen/Stability 3.0 (1.0) mL Bone Marrow, Ambient 72 hours

Alternate Specimens 5.0 (3.0) mL Whole Blood Heparinized
 Clinical Utility Translocations of the immunoglobulin heavy chain locus (IGH) located at 14q32 are frequently observed in patients with various hematological disorders. To detect chromosomal breakage at J or switch regions of the (IGH) locus that is associated with 14q32 translocations involving a variety of other loci. Breakpoints within the IGH locus may occur at either the J segments e.g., breakpoints commonly observed with t(14;18), or within switch sequences located within the constant gene segments. These IGH translocations result in the upregulation of oncogenes due to the juxtaposition of IGH enhancers with these oncogenes.

Schedule Sunday - Saturday
 Reported 7 days
 CPT Code 88291,88237,88271x2,88275

5869 FISH - 20q12 D20S108 (Available 01/03/07)

Component	Method	Reference Range / Units
FISH - 20q12 D20S108	FISH	By Report

Specimen/Stability 3.0 (1.0) mL Bone Marrow Heparinized, Ambient 72 hours
 Alternate Specimens 5.0 (3.0) mL Whole Blood Heparinized
 Clinical Utility To identify deletions on the long arm of chromosome 20, a relatively common abnormality found in myeloid neoplasias. A tumor suppressor gene is believed to reside within 20q12.

Schedule Sunday - Saturday
 Reported 7 days
 CPT Code 88237,88271,88275,88291

5861 FISH - p53 17p13.1 (Available 01/03/07)

Component	Method	Reference Range / Units
FISH - p53 17p13.1	FISH	By Report

Specimen/Stability 3.0 (1.0) mL Bone Marrow Heparinized, Ambient 72 hours
 Alternate Specimens 5.0 (3.0) mL Whole Blood Heparinized
 Clinical Utility To detect the deletion (not mutation) or amplification of the p53 locus. In some malignancies, a mutation of one p53 gene allele is accompanied by a deletion of the other allele and results in the absence of wild-type p53 protein. Monoallelic deletion of p53 is common in many disorders. Loss of heterozygosity of p53 has been identified in many tumors.

Schedule Sunday - Saturday
 Reported 7 days
 CPT Code 88291,88237,88271,88275

5865 FISH - MALT1 18q21 (Available Immediately)

Component	Method	Reference Range / Units
FISH - MALT1 18q21	FISH	By Report

Specimen/Stability 3.0 (1.0) mL Bone Marrow Heparinized, Ambient 72 hours
 Alternate Specimens 5.0 (3.0) mL Whole Blood Heparinized
 Clinical Utility To identify chromosomal rearrangements of the MALT1 gene region on chromosome 18q21 or aneuploidy of chromosome 18. Chromosome rearrangements involving the MALT1 (MALT lymphoma-associated translocation 1) gene on chromosome 18q21 has been observed in several types of lymphoma.

Schedule Sunday - Saturday
 Reported 7 days
 CPT Code 88237,88271x2,88275,88291

5867 FISH - RB1 13q14 (Available 01/03/07)

Component	Method	Reference Range / Units
FISH - RB1 13q14	FISH	By Report

Specimen/Stability 3.0 (1.0) mL Bone Marrow Heparinized, Ambient 72 hours
 Alternate Specimens 5.0 (3.0) mL Whole Blood Heparinized
 Clinical Utility To identify deletions of the RB1 locus at 13q14. Deletions of the long arm of chromosome 13 are common in myeloid neoplasias. A candidate tumor suppressor gene resides telomeric of the RB1 gene.

Schedule Sunday - Saturday
 Reported 7 days
 CPT Code 88237,88271,88275,88291

5843 FISH - SUBTELOMERE ABNORMALITIES (Totalvision™) (Available Immediately)

Component	Method	Reference Range / Units
FISH - SUBTELOMERE ABNORMALITIES	FISH	By Report

Specimen/Stability 3.0 (1.0) mL Whole Blood Heparinized
 Clinical Utility For the detection of subtle deletions or rearrangements involving the subtelomeric regions of all human chromosomes. Approximately 5% of patients with idiopathic mental retardation/developmental delay have subtelomeric abnormalities. Due to staining characteristics and resolution limits, abnormalities involving these regions are usually difficult or impossible to detect with routine chromosome analysis.

Schedule Monday-Saturday
 Reported 5 days

CPT Code 88271x41, 88272X15, 88291
 Note Run in conjunction with congenital blood chromosome analysis test #5814

5885 FISH - TRISOMY 13, 18, 21, X & Y (PRENATAL) (AneuVysion™) (Available 01/03/07)

Component	Method	Reference Range / Units
FISH - TRISOMY 13, 18, 21, X & Y (PRENATAL) FISH		By Report

Specimen/Stability 5.0 (5.0) mL Amniotic Fluid, Ambient 72 hours
 Clinical Utility To provide rapid detection of trisomies 13, 18, and 21 and sex chromosome aneusomies on uncultured amniocytes. Together these conditions account for nearly 2/3 of all abnormalities identified at the time of amniocentesis, and 85-90% of clinically significant chromosomal abnormalities detected in live-born infants. This test is not intended to be used as a stand alone assay for making clinical decisions. These FISH results are intended to be used in conjunction with other information currently used in prenatal diagnosis, consistent with professional standards of practice. This FISH assay will not detect structural chromosome abnormalities that can also result in birth defects.
 Schedule Monday-Saturday
 Reported 24 Hrs If received Mon-Thu, 48-72 Hrs If received Fri-Sat
 CPT Code 88271x5, 88274, 88291
 Note Run in conjunction with amniotic fluid chromosome analysis, test #5822

5887 FISH - TRISOMY 21 (Available 01/03/07)

Component	Method	Reference Range / Units
FISH - TRISOMY 21	FISH	By Report

Specimen/Stability 5.0 (1.0) mL Whole Blood Heparinized, Ambient 72 hours
 Clinical Utility For the identification and enumeration of chromosome 21.
 Schedule Monday-Saturday
 Reported Next Day
 CPT Code 88271, 88275, 88291
 Note In conjunction with congenital blood chromosome analysis (test #5814).

4192U Methadone Confirmation Urine (Available 01/03/07)

Component	Method	Reference Range / Units
Methadone	LCMS/MS	< 50 ng/mL
EDDP (d,1-2-ethyl-1,5-dimethyl-3,3-diphenylpyrrolinium)	LCMS/MS	< 50 ng/mL
EMDP (d,1-2-ethyl,5-methyl-3,3-diphenyl-1-pyrroline)	LCMS/MS	< 50 ng/mL

Specimen/Stability 4.0mL (2.0), Urine, Ambient 5 days, Refrigerated 2 weeks, Frozen 2 weeks
 Clinical Utility Confirmation of screen-positive results for methadone. This panel contains the following analytes: Methadone, EDDP (d,1-2-ethyl-1,5-dimethyl-3,3-diphenylpyrrolinium), and EMDP (d,1-2-ethyl,5-methyl-3,3-diphenyl-1-pyrroline).
 Schedule Wednesday
 Report Next day
 CPT Code 83840x3

4192 Methadone Confirmation Serum (Available 01/03/07)

Component	Method	Reference Range / Units
Methadone	LCMS/MS	< 50 ng/mL
EDDP (d,1-2-ethyl-1,5-dimethyl-3,3-diphenylpyrrolinium)	LCMS/MS	< 50 ng/mL

Specimen/Stability 2.0mL (1.0 mL), Serum, Ambient 2 weeks, Refrigerated 2 weeks, Frozen 2 weeks
 Alternate Specimens 2.0mL (1.0 mL), Plasma Heparinized, Ambient 2 weeks, Refrigerated 2 weeks, Frozen 2 weeks
 2.0mL (1.0 mL), EDTA Plasma, Ambient 2 weeks, Refrigerated 2 weeks, Frozen 2 weeks
 Clinical Utility Confirmation of screen-positive results for methadone. This panel contains the following analytes: Methadone and EDDP (d,1-2-ethyl-1,5-dimethyl-3,3-diphenylpyrrolinium).
 Schedule Wednesday
 Report Next day
 CPT Code 83840x2

5046 MSI DetectR™ (Available 01/03/07)

Component	Method	Reference Range / Units
MSI DetectR™	PCR	By Report

Tumor Specimen/Stability 5.0 (3.0) mg Fresh Tissue, Frozen 1 year
 Normal Specimen/Stability 5.0 (3.0) mL Whole Blood EDTA, Ambient 1 week, Refrigerated 1 week
 1.5 (0.5) mL Bone Marrow, Ambient 1 week, Refrigerated 1 week
 5.0 (3.0) mg Fresh Tissue, Frozen 1 year
 5.0 (3.0) mL Whole Blood Heparinized, Ambient 1 week, Refrigerated 1 week
 5.0 (3.0) mL Whole Blood ACD, Ambient 1 week, Refrigerated 1 week
 Clinical Utility Microsatellite instability (MSI) is predictive of clinical outcome and response to adjuvant therapies for colorectal carcinomas. MSI analysis involves comparison of allelic profiles of 5 mononucleotide markers generated by amplification of DNA from matching normal and tumor samples. Alleles present in the tumor sample that are not found in the corresponding normal samples indicate MSI.
 Schedule Monday
 Report 5 days
 CPT Code 83891x2, 83900, 83901x12, 83909x2, 83912
 Note Both normal and tumor specimens must be received to perform the assay.
 Not offered to NY patients until further notice.

5046BK MSI DetectR™ – Paraffin Block

(Available 01/03/07)

Component	Method	Reference Range / Units
MSI DetectR™	PCR	By Report
Tumor Specimen/Stability	4 sections 50 microns thick, paraffin embedded tissue, Ambient indefinite	
Normal Specimen/Stability	5.0 (3.0) mL Whole Blood EDTA, Ambient 1 week, Refrigerated 1 week 1.5 (0.5) mL Bone Marrow, Ambient 1 week, Refrigerated 1 week 5.0 (3.0) mg Fresh Tissue, Frozen 1 year 5.0 (3.0) mL Whole Blood Heparinized, Ambient 1 week, Refrigerated 1 week 5.0 (3.0) mL Whole Blood ACD, Ambient 1 week, Refrigerated 1 week 5.0 (3.0) mg Frozen Tissue, Frozen 1 year 4 sections 50 microns thick, paraffin embedded tissue, Ambient indefinite	
Clinical Utility	Microsatellite instability (MSI) is predictive of clinical outcome and response to adjuvant therapies for colorectal carcinomas. MSI analysis involves comparison of allelic profiles of 5 mononucleotide markers generated by amplification of DNA from matching normal and tumor samples. Alleles present in the tumor sample that are not found in the corresponding normal samples indicate MSI.	
Schedule	Monday	
Report	5 days	
CPT Code	83891x2, 83900, 83901x12, 83909x2, 83912, 83907	
Note	<u>Both normal and tumor specimens must be received to perform the assay</u> Not offered to NY patients until further notice.	

4183 Phencyclidine (PCP) Confirmation Serum

(Available 01/03/07)

Component	Method	Reference Range / Units
PCP	LCMS/MS	< 8 ng/mL
Specimen/Stability	2.0mL (1.0 mL), Serum, Ambient 2 weeks, Refrigerated 2 weeks, Frozen 2 weeks	
Alternate Specimens	2.0mL (1.0 mL), Plasma Heparinized, Ambient 2 weeks, Refrigerated 2 weeks, Frozen 2 weeks 2.0mL (1.0 mL), EDTA Plasma, Ambient 2 weeks, Refrigerated 2 weeks, Frozen 2 weeks	
Clinical Utility	Confirmation of screen-positive results 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	Thursday	
Report	Next day	
CPT Code	83992	

5042BK T-Cell Gene Rearrangement DetectR™ - Paraffin Block

(Available 01/03/07)

Component	Method	Reference Range / Units
T-Cell Gene Rearrangement PCR DetectR™	PCR	By Report
Specimen/Stability	4 sections 50 microns thick, paraffin embedded tissue, Ambient indefinite	
Clinical Utility	The T-cell receptor gamma (TCR) gene rearrangement PCR assay can detect clonal populations of lymphoid cells in mixed cell populations from specimens such as tissues and body fluids. This assay is therefore useful as an aid in the diagnosis or confirmation of lymphoid neoplasms of T-cell lineage, treatment selection for such diseases, detection of sub-clinical minimal residual disease and for the monitoring of disease recurrence.	
Schedule	Monday and Thursday	
Report	4 days	
CPT Code	83891, 83898, 83900, 83901x2, 83909x2, 83912, 83907	
Note	Not offered to NY patients until further notice.	

5042 T-Cell Gene Rearrangement DetectR™

(Available 01/03/07)

Component	Method	Reference Range / Units
T-Cell Gene Rearrangement DetectR™	PCR	By Report
Specimen/Stability	5.0 (3.0) mL Whole Blood EDTA, Ambient 1 week, Refrigerated 1 week	
Alternate Specimens	1.5 (0.5) mL Bone Marrow, Ambient 1 week, Refrigerated 1 week 5.0 (3.0) mg Fresh Tissue, Frozen 1 year Cell Pellet, Ambient 72 hours 5.0 (3.0) mL Whole Blood Heparinized, Ambient 1 week, Refrigerated 1 week 5.0 (3.0) mL Whole Blood ACD, Ambient 1 week, Refrigerated 1 week	
Clinical Utility	The T-cell receptor gamma (TCR) gene rearrangement PCR assay can detect clonal populations of lymphoid cells in mixed cell populations from specimens such as tissues and body fluids. This assay is therefore useful as an aid in the diagnosis or confirmation of lymphoid neoplasms of T-cell lineage, treatment selection for such diseases, detection of sub-clinical minimal residual disease and for the monitoring of disease recurrence.	
Schedule	Monday and Thursday	
Report	4 days	
CPT Code	83891, 83898, 83900, 83901x2, 83909x2, 83912	
Note	Not offered to NY patients until further notice.	

4166 Tricyclic Antidepressants (TCA) screen serum

(Available 01/03/07)

Component	Method	Reference Range/Units
Desipramine	HPLC	Cutoff 250 Detected

Imipramine
Amitriptyline
Nortriptyline

HPLC
HPLC
HPLC

Cutoff 350 Detected
Cutoff 250 Detected
Cutoff 150 Detected

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 screens for Tricyclic Antidepressants
 Schedule Monday-Friday
 Report 2 to 4 days
 CPT Code 80100
 Note Serum separator tubes are not acceptable; use polypropylene tubes and ship on cold pack by overnight courier.

5825 Cytogenetics: Solid Tumors (Available 01/03/07)

Component	Method	Reference Range / Units
Solid Tumors	Karyotype	By Report

Specimen/Stability 1.0mL (0.5) mL Tumor Tissue, Ambient 72 hours
 Clinical Utility Determine cytogenetic abnormalities with subgroup specific diagnostic and prognostic significance in neoplasms.
 Schedule Sunday-Saturday
 Reported 7 days
 CPT Code 88239, 88262, 88291

1904 Apolipoprotein A-1 & B (Available Immediately)

Component	Method	Reference Range/Units
Apolipoprotein A-1	Turb	128-276 mg/dL
Apolipoprotein B	Turb	40-130 mg/dL
Apolipoprotein B/A-1 Ratio	Calc	(see below)

Specimen/Stability 2.0mL (0.6 mL), Serum, Ambient 7 days, Refrigerated 14 days, Frozen 2 months
 Clinical Utility Apo A-1 comprises 60-70% of the protein content of HDL. Decreased serum HDL cholesterol levels have been reported to correlate with increased risk of coronary artery disease (CAD). However Apo A-1 has been suggested for better discrimination of CAD than HDL or apolipoprotein B. Studies have shown that the ratio of apolipoprotein B to apolipoprotein A-1 may correlate better with increased risk of CAD than total cholesterol, and LDL/HDL ratio. LDL and its major protein, apolipoprotein B, play an essential role in lipid transport and metabolism. Low apolipoprotein A-1, high apolipoprotein B and high lipoprotein A correlate with increased risk of MI or stroke.
 Schedule Monday-Saturday
 Report 1 to 2 days
 CPT Code 82172x2
 Note Patient should fast 12 hours prior to testing. Moderately or grossly lipemic, icteric, or hemolyzed samples are not suitable for analysis.
 Ratio Range Apolipoprotein B/A-1 Ratio Risk Ranges:

	Male	Female
Avg.Risk	0.7	0.6
2X Avg.Risk	0.9	0.9
3X Avg.Risk	1.0	1.0