SPECIALTY LABORATORIES
27027 Tourney Road 800•421•7110
Valencia, CA 91355 www.specialtylabs.com

New Test Announcements

August 7, 2007

Dear Colleague:

.

Specialty is proud to introduce the FLT3 and NPM1 GenotypR™ to aid oncologists in the diagnosis and treatment of AML. Mutations in the genes, FLT3 and NPM1 (nucleophosmin), were shown to be commonly associated with AML cases with normal karyotype (AML-NK). Mutations in the FLT3 gene impart a relatively poor prognosis and were described in 30% of AML. ITD, the most frequent mutation in the FLT3 gene, occurs in 20-25% of adult AML patients; whereas the D835 mutation occurs in 5-10% of patients with AML-NK. Mutations in the NPM1 gene occur in 50% to 60% of AML-NK cases and in the absence of FLT3 mutations, are associated with a good prognosis.

In the area of infectious disease detection the *Leishmania* DNA DetectR™ will be available August 14th with a 2 day report time. This assay supports the diagnosis of *Leishmania* infection by the detection of *Leishmania* species in tissue and fluids. This assay is not designed to differentiate species. Detection is solely genus specific.

For thyroid cancer treatment monitoring, *Specialty* has developed the Thyroglobulin Tumor Marker. Thyroglobulin determinations have been widely used to complement radioiodine scanning and other techniques such as ultrasound or immunohistochemical staining as an aid in identifying the presence or absence of functioning thyroid tissue. With a detection range down to 0.2 ng/mL and same day reporting we are certain this assay will be benefit your patients immensely.

For physicians commonly prescribing warfarin, we strongly urge the use of our Warfarin Sensitivity DetectR™ (VKORC1 and CYP2C9). Mutations in Cytochrome P450 2C9 (CYP2C9) and VKORC1 genes are estimated to account for 40%-63% of the variability in therapeutic warfarin dose. Genetic information available from this test will help define optimal patient-specific warfarin dosage. In an effort to best utilize this technology, the setup schedule is daily (Monday thru Friday) with same day reporting.

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

Christopher Lockhart, M.D.
Laboratory Director

5038 FLT3 and NPM1 GenotypR™ (Available 08/21/07)

Component	Method	Reference Range/Units
FLT3 and NPM1 GenotypR™	PCR	By Report

Specimen/Stability	5 (3) mL Whole Blood; Ambient – 1 Weeks, Refrigerated – 1 Week
Alternate Specimen	1.5 (0.5) mL Bone Marrow; Ambient – 1 Week, Refrigerated – 1 Week
Clinical Utility	Mutations in two genes, FLT3 and NPM1 (nucleophosmin), were shown to be commonly associated with AML cases with normal karyotype (AML-NK). Mutations in the FLT3 gene impart a relatively poor prognosis and were described in 30% of AML. ITD, the most frequent mutation in the FLT3 gene, occurs in 20-25% of adult AML patients; whereas D835 mutation occurs in 5-10% of patients with AML-NK. Mutations in the NPM1 gene occur in 50% to 60% of AML-NK cases and in the absence of FLT3 mutations, are associated with a good prognosis.
Schedule	Wednesday
Report	3 days
CPT Code	83891, 83900, 83901, 83892, 83909, 83912
Note	NY approval status pending. Please contact client services for latest information.
Collection	EDTA is the preferred anticoagulant, but ACD (A or B) and Heparin is also acceptable. Refrigerated specimens are also acceptable but not preferred. Do not freeze.

5038BK FLT3 and NPM1 GenotypR™-Paraffin Block (Available 08/21/07)

Component	Method	Reference Range/Units
FLT3 and NPM1 GenotypR™-Paraffin Block	PCR	By Report

Specimen/Stability	2X 5-50 (1X 5-50) Micron Sections Paraffin Embedded Tissue; Ambient – Indefinitely
Clinical Utility	Mutations in two genes, FLT3 and NPM1 (nucleophosmin), were shown to be commonly associated with AML cases with normal karyotype (AML-NK). Mutations in the FLT3 gene impart a relatively poor prognosis and were described in 30% of AML. ITD, the most frequent mutation in the FLT3 gene, occurs in 20-25% of adult AML patients; whereas D835 mutation occurs in 5-10% of patients with AML-NK. Mutations in the NPM1 gene occur in 50% to 60% of AML-NK cases and in the absence of FLT3 mutations, are associated with a good prognosis.
Schedule	Wednesday
Report	4 days
CPT Code	83907, 83891, 83900, 83901, 83892, 83909, 83912
Note	NY approval status pending. Please contact client services for latest information.
Collection	Shipment should be by overnight courier to arrive at Specialty within 24 h of collection. Specimens will be stabilized upon departmental receipt.

8230 *Leishmania* DNA DetectR™ (Available 08/14/07)

Component	Method	Reference Range/Units
Leishmania DNA Source	PCR	Not Detected

Specimen/Stability	Tissue; Frozen – 1 Month
Alternate Specimen	Tissue Paraffin Block; Ambient – 1 Month, Refrigerated – 1 Month
Clinical Utility	This assay supports the diagnosis of *leishmania* infection by detection of *Leishmania* spp. in tissue and fluids. The absence of detectable DNA does not rule out infection.
Schedule	Tuesday, Friday
Report	2 days
CPT Code	87798
Note	This assay is not designed to differentiate species. Detection is solely genus specific.
Collection	1) Place fresh tissue or needle biopsy in sterile saline and freeze prior to shipment.

3235 Thyroglobulin Tumor Marker (Available Immediately)

Component	Method	Reference Range/Units
Thyroglobulin Tumor Marker	CL	< 0.2 ng/mL

Specimen/Stability	2 (0.5) mL Serum; Ambient – 5 Days, Refrigerated – 7 Days, Frozen – 2 Months
Clinical Utility	Thyroglobulin determinations have been widely used to complement radioiodine scanning and other techniques such as ultrasound or immunohistochemical staining as an aid in identifying the presence or absence of functioning thyroid tissue.
Schedule	Monday – Sunday
Report	Same day
CPT Code	84432
Note	Thyroglobulin autoantibodies can interfere with the determination of thyroglobulin. If specimen contains Thyroglobulin autoantibodies, interpret thyroglobulin result with caution. When monitoring patients over time, TG values obtained with different methods cannot be used interchangeably due to differences in methods and reagent specificity.

5055 Warfarin Sensitivity DetectR™ (VKORC1 and CYP2C9) (Available 08/07/07)

Component	Method	Reference Range/Units
Warfarin Sensitivity DetectR™	PCR	By Report

Specimen/Stability	5 (3) mL Whole Blood; Ambient – 1 Week, Refrigerated – 1 Week
Clinical Utility	Mutations in Cytochrome P450 2C9 (CYP2C9) and VKORC1 genes are estimated to account for 40%-63% of the variability in therapeutic warfarin dose. Genetic information available from this test will help define optimal patient-specific warfarin dosage.
Schedule	Monday - Friday
Report	Next day
CPT Code	83891, 83900, 83901, 83914x3, 83909, 83912
Note	NY approval status pending. Please contact client relations for latest information.
Collection	EDTA is the preferred anticoagulant. ACD and Heparin is also acceptable but not preferred. Refrigerated specimens are also acceptable but not preferred. Do not freeze.