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

October 5, 2006

Dear Colleague:

Specialty Laboratories is pleased to announce the launch of the **HCV Liver Fibrosis GenotypR™** assay, the first clinical laboratory genomic test used to predict progression to advanced liver fibrosis or cirrhosis in hepatitis C virus patients.

- **6810 HCV Liver Fibrosis GenotypR™**

This test identifies a patient's genomic signature based on seven single nucleotide polymorphisms (SNP) which, combined with gender, provide a Cirrhosis Risk Score (CRS) correlating with relative risk of progression to liver fibrosis or cirrhosis compared to other CRS cohorts. The CRS places the patient into one of four risk groups to assist physicians and patients determine for whom early therapy is most warranted. The **HCV Liver Fibrosis GenotypR™** can identify which HCV patients are at essentially no risk of progression to fibrosis versus those with highest risk. A sample report is attached.

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

Regards,

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

New Assay Available from *Specialty*

Effective date as noted

6810 HCV Liver Fibrosis GenotypR™

(effective 10/5/2006)

Component	Method	Reference Range	Units
SNP 1	PCR	By Report	
SNP 2	PCR	By Report	
SNP 3	PCR	By Report	
SNP 4	PCR	By Report	
SNP 5	PCR	By Report	
SNP 6	PCR	By Report	
SNP 7	PCR	By Report	
Gender marker	PCR	By Report	
Cirrhosis Risk Score (CRS)	Calculation	By Report	
Relative Risk	Calculation	By Report	

Reference Range

CRS	Relative Risk
<0.10	See Comment Below
0.10-0.40	1 times the 0.10-0.40 CRS cohort
0.41-0.70	3 times the 0.10-0.40 CRS cohort
>0.70	4 times the 0.10-0.40 CRS cohort

Comment: No patients with a CRS within the 0.00-0.09 (<0.10) cohort have progressed to fibrosis. A relative risk has not been established for patients falling within this group.

Specimen/Stability	5.0 (3.0) mL Whole Blood EDTA, Ambient 7 days, Refrigerated 7days
Unacceptable Specimens	Frozen Specimen
Collection Instructions	Do not freeze. Refrigerated specimens are preferred but ambient is acceptable.
Clinical Utility	Hepatitis C virus is the most common chronic blood-borne infection in the United States. Depending on the population studied, the incidence of cirrhosis ranges from 2-17%, 8 to 25 years post infection. Cirrhosis caused by Hepatitis C is the leading indication for liver transplantation and one of the most common causes of death in liver disease. The HCV Liver Fibrosis GenotypR™ is a genomic test to help identify an individual Hepatitis C virus patient's relative risk for progressing to liver fibrosis. The assay provides the genotype for seven single nucleotide polymorphisms (SNP's) and one gender marker which have collectively demonstrated significant association with advancement to liver fibrosis among Hepatitis C-infected individuals. The Cirrhosis Risk Score (CRS) is calculated based on the weighted genotype of these markers, and reflects the combined impact of the 7 SNP's and gender. The value of the CRS ranges from 0 to 1, with a higher CRS value equating to a higher relative risk.
Performance Schedule	Set-up: Wednesday Reported: 2 days
CPT Code	83891, 83892X2, 83898, 83909, 83914X8, 83912
Notes	The assay is performed on genomic DNA isolated from whole blood using a multiplexed PCR and multiplex Allele Specific Primer Extension (ASPE) with a universal Tag sorting system on the Luminex 100 X MAP platform. The Cirrhosis Risk Score (CRS) is calculated based on seven SNP's and the patient's gender using a proprietary algorithm. The Relative Risk of an HCV infected patient to progress to fibrosis compared to a reference cohort is provided. Relative Risk is calculated by comparing the risk of a patient in one of the following 3 cohorts (defined as having a CRS value within one of three ranges: 0.10-0.40, 0.41-0.70, or >0.70) with the reference HCV cohort with CRS ranging from 0.10-0.40. Comparing the 0.10-0.40 cohort with itself yields a relative risk of 1. No patients with a CRS within the 0.00-0.09 cohort have progressed to fibrosis. Currently not available for patients residing in New York State.

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SPECIALTY TEST CLIENT
SPECIALTY LABORATORIES, INC.
27027 TOURNEY ROAD
VALENCIA, CA 91355-5386
Fax (661) 799-5254

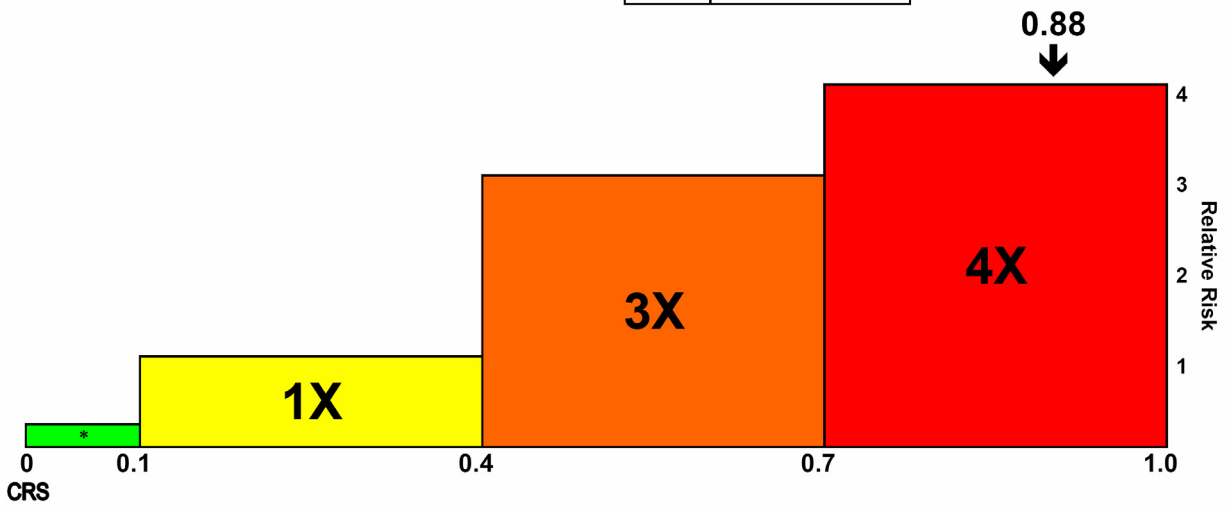
Patient:	Doe, John		
Sex:	Male		
Birth Date:	09/08/1961	Age:	45
Patient ID:	A0123456799		
Physician:	Smith, Jane		
Collection Date:	10/02/2006		

Account Number	Specialty/Client Accession
900	
Receive Date	Printed Date
10/3/2006	**10/5/2006**

6810 · HCV Liver Fibrosis GenotypR™

Patient Summary	
Cirrhosis Risk Score	**0.88**
Relative Risk	**4 Times**

Marker	Patient Genotype
SNP 1	GG
SNP 2	GG
SNP 3	TT
SNP 4	GG
SNP 5	AG
SNP 6	GG
SNP 7	GG
Gender	M



* Note: Patients who have not developed fibrosis. Relative risk of each group is calculated by comparing risks associated with the 1X Group

Interpretation

In a study population of chronic hepatitis C patients (N=708), among those with a CRS of >0.70, 18% had no fibrosis (Stage 0), while 82% had bridging fibrosis/cirrhosis after an average 25 years of infection.

Based on this study population and the CRS result, the patient has a 4X Risk of developing bridging fibrosis/cirrhosis.