

July 26, 2011

Dear Health Care Provider,

LabCorp and Monogram Biosciences are pleased to announce the launch of **HCV GenoSure® NS3/4A**, a protease inhibitor drug resistance assay for the clinical management of patients with hepatitis C.

HCV GenoSure NS3/4A provides a comprehensive sequence-based analysis of a patient's hepatitis C virus to assess drug resistance (or susceptibility) to the NS3/4A protease inhibitors, boceprevir¹ and telaprevir². It also includes a detailed understanding of the viral population for the entire region of the non-structural proteins NS3 and NS4A for hepatitis C virus genotypes 1a or 1b.

Other assay features include

- Highly reproducible for patient specimens with viral loads ≥ 2000 IU/mL
- Sensitive to detect mixtures of wild-type and drug-resistant viruses when present at levels as low as 10% of the total population
- Uses Monogram's HCV genotypic rules-based algorithm to provide a result of "sensitive," "resistant," or "resistance possible" for each protease inhibitor. The algorithm is reviewed and updated regularly.
- Includes HCV genotype (subtype) assignment for the NS3/4A region, providing information that may be important for long-term drug treatment strategy and drug resistance assay interpretation.
- A turnaround time of approximately 7 to 10 days

HCV GenoSure NS3/4A can be ordered using Monogram test number C5000 (LabCorp test number 550540).

LabCorp and Monogram have applied their expertise in HIV drug resistance to the newly approved, direct-acting antiviral agents for hepatitis C. In clinical studies of boceprevir and telaprevir, a significant portion of patients who did not achieve sustained viral response (SVR) were found to have treatment-emergent mutations.^{1,2} HCV GenoSure NS3/4A can help identify which patients have developed resistance to these protease inhibitors.

If you have questions or would like additional information regarding **HCV GenoSure NS3/4A**, please contact your local Monogram or LabCorp representative or call Monogram Client Services at 800-777-0177.

Sincerely,



Charles M. Walworth, MD
Senior Director, Global Medical Affairs & Education

To remove your fax number from future marketing announcements, please write your fax number here _____ - _____ - _____ and fax this notice to 650-615-0177 or call 800-777-0177. Monogram will comply with your request within 30 days of receipt. (Note: We will continue to send notifications about important test changes.)

1. Prescribing Information for boceprevir, Merck & Co., Inc, Whitehouse Station, NJ 08889, May 2011.

2. Prescribing Information for telaprevir, Vertex Pharmaceuticals Inc, Cambridge, MA 02139, May 2011.