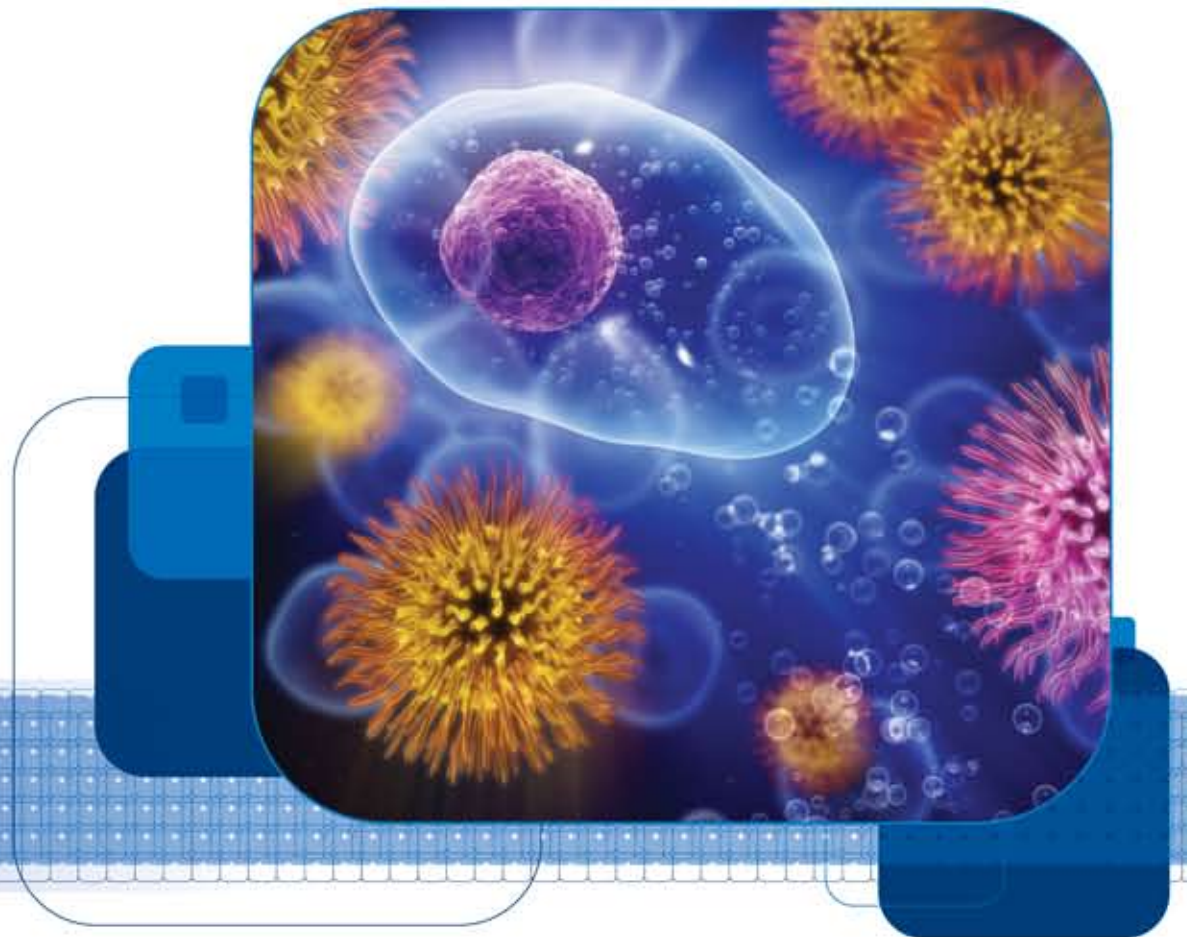


# HCV GenoSure® NS3/4A

Breaking ground in HCV  
drug resistance testing



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**LabCorp**  
Laboratory Corporation of America

# Bringing diagnostic excellence to HCV

**HCV GenoSure<sup>®</sup>**  
Drug Resistance Assay NS3/4A

## Introducing HCV GenoSure NS3/4A—a new HCV protease inhibitor resistance assay

- HCV GenoSure NS3/4A provides a comprehensive sequence-based analysis of drug resistance for HCV protease inhibitors (PIs)
- Helps clinicians identify drug resistance mutations that may impact the efficacy of protease inhibitor therapy
- Developed by LabCorp's Monogram Biosciences, a leader in diagnostic innovation in infectious disease

## Background

HCV research has progressed rapidly, leading to a recent surge in the development of direct-acting antiviral (DAA) therapies that target viral proteins important for the replication of HCV. HCV replicates to high levels and with poor fidelity; therefore, it can rapidly accumulate mutations that may confer drug resistance.<sup>1</sup> LabCorp and Monogram are dedicated to improving the clinical management of patients with HCV through the development of new molecular diagnostics to identify these mutations and drug-resistant variants.

## HCV GenoSure NS3/4A provides comprehensive resistance data for new HCV PIs


- Analyzes the genetic sequence for the nonstructural proteins NS3 and NS4A of HCV genotypes 1a and 1b
- Detects mutations in NS3 and NS4A and identifies drug-resistant variants for protease inhibitors boceprevir and telaprevir
- Sensitivity to detect minor variant levels as low as 10% provides a detailed understanding of the patient's viral population for informed treatment decisions.
- A susceptibility result of "sensitive," "resistant," or "resistance possible" is provided for each drug.

Test Name	HCV GenoSure NS3/4A
LabCorp Test Number	550540
Monogram Test Number	C5000
CPT Code	87902
Limitation	For patients with HCV genotype (subtype) 1a or 1b and a viral load $\geq 2000$ IU/mL
Specimen Collection	3mL plasma, EDTA or PPT tube, shipped frozen
Turnaround Time	7 to 10 days


**HCV GenoSure NS3/4A is also available as a reflex when a patient's viral load is  $\geq 2000$  IU/mL.**

Test Name	LabCorp Test Number	Monogram Test Number
HCV, quantitative, RT-PCR (nongraphical) with reflex to HCV GenoSure	550072	C1010
HCV, quantitative, RT-PCR (graphical) with reflex to HCV GenoSure	550066	C1110

# Your HCV protease inhibitor resistance information at a glance



**HCV GenoSure**  
Drug Resistance Assay NS3/4A



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South San Francisco, CA 94080 - Tel: (800) 777-0177

Patient Name	DOB	Patient ID/Medical Record #	Gender	Monogram Accession # 61-100380
Date Collected	Date Received	Date Reported	Mode	Report Status
Referring Physician			Reference Lab ID/Order #	
Comments				

Drug			HCV GenoSure <sup>®</sup> NS3/4A		Assessment	Comments	
Generic Name	Brand Name	Region	Drug Resistance Associated Mutations Detected	Drug			
PI	Boceprevir	Victrelis	NS3	V55I	BOC	Resistant	
			NS4A	None			
	Telaprevir	Incivek	NS3	V55I	TVR	Resistance Possible	
			NS4A	None			

**Important Definitions**

- All mutations are reported relative to the HCV genotype/subtype specific reference Cont
- Assessment of drug susceptibility is based on detecting mutations and interpreted using a rules based algorithm (version 1.1)
- Protease Inhibitors are indicated by the abbreviation PI

Region	Genotype	Summary of All Mutations Observed
NS3	1b	N27N/I, V55I, E176G, T254I
NS4A		None

**Assay Performance Characteristics**

- Assay is highly reproducible and sufficiently sensitive to allow testing of patient samples with viral loads as low as 2000 IU/mL.
- Detects mixtures of wild-type and drug-resistant viruses when present at levels as low as 10% of the total population
- Provides sequence information for the entire region of non-structural protein 3 (NS3) and 4A (NS4A) of hepatitis C virus genotypes 1a or 1b
- Uses Monogram's HCV genotypic rules-based algorithm which is reviewed and updated on a regular basis
- Includes HCV genotype/subtype assignment for the NS3/4A region, providing information that may be important for long-term drug-treatment strategy and genotypic resistance assay interpretation

For more information on interpreting this report, please call Monogram Customer Service at 800-777-0177 between the hours of 6:30am to 5:00pm PST Monday through Friday.

HCV GenoSure NS3/4A is a sequence-based resistance assay that analyzes the continuous NS3/4A coding regions of HCV genotypes 1a or 1b. Genotype assignment is determined from the sequence of the HCV NS3/4A regions. This assay meets the standards for performance characteristics and all other quality control and assurance requirements established by the Clinical Laboratory Improvement Amendments. This assay was validated by testing samples with viral loads equal to or above 2000 IU/mL and should be interpreted only on such specimens. The results should not be used as the sole criteria for patient management. The results have been disclosed to you from confidential records protected by law and are not to be disclosed to unauthorized persons. Further disclosure of these results is prohibited without specific consent of the persons to whom it pertains, or as permitted by law.

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Drug-resistant mutations are found by sequencing the NS3/4A region of the viral genome.

HCV GenoSure determines whether a patient's virus is "sensitive," "resistant," or "resistance possible" to each drug.

A comprehensive summary of drug-resistance mutations is listed for better understanding of patient "failure" on current therapy.

Indicated for patients with genotype 1a and 1b who experience virologic failure on protease inhibitor therapy

**Mutations identified at treatment failure are associated with a decrease in antiviral activity against protease inhibitors. This information can help guide future treatment decisions.**

## Innovation in HCV diagnostics

LabCorp offers a full range of HCV assays to help clinicians identify appropriate patients who will benefit most from available agents, individualizing their treatment and enabling improved clinical outcomes.

Test Name	Clinical Use	LabCorp Test Number	Monogram Test Number
HCV Viral Load	Quantifies amount of HCV viral RNA	550080 (non-graphical) 550070 (graphical)	C1000 C1100
HCV Genotype (subtype)	Determines viral genotype (subtype) 1 thru 6	550475	C1200
Interleukin 28B (IL28B) Polymorphism	Determines IL28B polymorphism associated with response to peg IFN/ribavirin	480630	C1300
HCV GenoSure NS3/4A Drug Resistance	Determines genotypic resistance for NS3/4A protease inhibitors	550540	C5000
HCV FibroSURE®	An assessment of fibrosis and necroinflammatory activity in the liver	550123	

## On the cutting edge of new HCV discoveries

With additional vital therapeutic agents on the horizon, LabCorp and Monogram continue to be at the forefront of assay development for clinical management of patients with HCV infection.

### References

1. Schinazi RF, Bassit L, Gavegnano C. HCV discovery aimed at viral eradication. *J Viral Hepat.* 2010;17(2):77-90.



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