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*****Example Report*****

Patient Age/Gender: 45 years Female
Printed: 18-Jun-20 10:11:42

Procedure	Result	Units	Ref Interval	Accession	Collected	Received	Reported/ Verified
EER HCV GenoSure NS3 and NS4A	See Note f			20-167-900023	15-Jun-20 08:23:00	15-Jun-20 10:14:00	18-Jun-20 10:07:34
HCV GenoSure NS3 and NS4A	See Comments f			20-167-900023	15-Jun-20 08:23:00	17-Jun-20 10:00:00	17-Jun-20 14:35:59
HCV GenoSure NS3 and NS4A Interpretation	See Comments f			20-167-900023	15-Jun-20 08:23:00	17-Jun-20 10:00:00	17-Jun-20 14:35:59

15-Jun-20 08:23:00 EER HCV GenoSure NS3 and NS4A:
Access ARUP Enhanced Report using the link below:

-Direct access:

***** Abnormal, **#** = Corrected, **C** = Critical, **f** = Footnote, **H** = High, **L** = Low, **t** = Interpretive Text, **@** = Reference Lab

15-Jun-20 08:23:00 HCV GenoSure NS3 and NS4A:
HCV GenoSure(TM) NS3/4A

Comments: Q80K DETECTED. The Q80K polymorphism significantly impacts sustained virologic response in HCV GT 1a infected patients that (a) are treated with simeprevir in combination with pegylated interferon and ribavirin, or (b) have compensated cirrhosis and are treated with simeprevir plus sofosbuvir. In these clinical settings, a regimen that does not include simeprevir should be considered.

HCV Genotype: 1a

Drug Generic Name	Brand/ Regimen	Genotypic Assessment	Comments
PI			
Glecaprevir	Mavyret	None/Undetermined	
GLE RAVs*: None			
Grazoprevir	Zepatier	None/Undetermined	
GZR RAVs*: None			
Paritaprevir	Viekira Pak	None/Undetermined	
PTV/r RAVs*: Q80K			
Simeprevir	Olysio	Resistance Possible	
SMV RAVs*: Q80K			
Voxilaprevir	Vosevi	None/Undetermined	
VOX RAVs*: None			

*RAVs = Resistance Associated Variants detected

Summary of All Variants Observed:

NS3 (Protease: aa 1-181, Helicase: aa 182-644)
Q80K, L153I, N174S, P264S, V329I, S332P, I386V, S410A, F418Y, I586T

NS4A (Protease cofactor: aa 1-54)
I29V, Q46R

Important Definitions

Resistance Possible - Resistance Associated Variants (RAVs) detected that (a) represent naturally-occurring polymorphisms or treatment-emergent variants associated with reductions in sustained virologic response (SVR) rates, (b) emerge during direct-acting antiviral (DAA)-treatment or relapse, and/or (c) may confer reductions in susceptibility based on in vitro data. Refer to prescribing information for specific details regarding the impact of these variants on treatment response in defined patient populations and when administered in combination with other antiviral agents.

None/Undetermined - None; no RAVs detected. Undetermined; variants detected that have a subtle or uncertain impact on DAA-treatment responses.

All variants are reported relative to the HCV genotype/subtype specific reference H77.

Assessment is based on a rules-based algorithm (version 6).

Naturally-occurring polymorphisms may impact the emergence

of resistance, leading to failure of DAA combination therapy

Naturally-occurring DAA resistance-associated polymorphisms identified at baseline may impact SVR if the treatment regimen, or adherence, is suboptimal. The impact of these polymorphisms may vary in treatment-naive and treatment-experienced patients and with varying disease states (e.g. non-cirrhotic vs cirrhotic)

Reduced susceptibility to any one component of a DAA-containing regimen may be overcome by the activity of the other components of the regimen and/or longer treatment duration

Treatment emergent RAVs may persist for prolonged periods of time and may impact subsequent treatment regimens

15-Jun-20 08:23:00 HCV GenoSure NS3 and NS4A 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 Pacific Time Monday through Friday.

This assay is performed using a next-generation sequencing platform that analyzes the specified non-structural coding regions of HCV. Variants are reported at a sensitivity that has been demonstrated to be equivalent to that of Sanger/population sequencing. Genotype assignment is determined from the sequence of the specified regions that are derived using subtype specific methodology, and should not be used to establish or confirm the HCV genotype. HCV genotype determination should only be done with an assay intended for that purpose. 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. This assay meets the standards for performance characteristics and all other quality control and assurance requirements established by CLIA. The results should not be used as the sole criteria for patient management. This test was developed and its performance characteristics determined by Monogram Biosciences. It has not been cleared or approved by the FDA. This document contains private and confidential health information protected by state and federal law. If you have received this document in error, please call 800-777-0177.

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