

Client: Example Client ABC123
123 Test Drive
Salt Lake City, UT 84108
UNITED STATES

Physician: Doctor, Example

Patient: Patient, Example

DOB: 7/31/1947
Sex: Female
Patient Identifiers: 01234567890ABCD, 012345
Visit Number (FIN): 01234567890ABCD
Collection Date: 01/01/2017 12:34

Hepatitis C Virus (HCV) Genotype with Reflex to HCV NS5A Drug Resistance by Sequencing

ARUP test code 2014598

HCV Genotype by Sequencing

1a or 1b

Cannot be further subtyped into Type 1a or Type 1b due to high conservation of the 5' untranslated region of the HCV genome. In addition, Type 6 virus may be misclassified as Type 1 in some cases. Refer to HCV NS5A Drug Resistance by Sequencing portion of the assay for subtyping and resistance associated mutations in the NS5A codons 20-101 for genotypes 1a and 1b.

Hepatitis C Virus (HCV) NS5A Drug Resistance by Sequencing will be added. Additional charges apply.

INTERPRETIVE INFORMATION: Hepatitis C Genotyping

Hepatitis C Viral RNA is tested using reverse transcription polymerase chain reaction (RT-PCR) to amplify a specific portion of the 5' untranslated region (5' UTR) of the viral genome. The amplified nucleic acid is sequenced bi-directionally using dye-terminator chemistry (ABI). Sequencing data is compared to a database of characterized sequences.

Isolates of hepatitis C virus are grouped into six major genotypes (1-6). These genotypes are subtyped according to sequence characteristics. Due to high conservation of the 5' un-translated region of the HCV genome, this test has limitations in differentiating subtype 1a from 1b. Therefore, these subtypes will be reported as 1a or 1b. In rare instances, Type 6 virus may be misclassified as Type 1.

This test was developed and its performance characteristics determined by ARUP Laboratories. It has not been cleared or approved by the US Food and Drug Administration. This test was performed in a CLIA certified laboratory and is intended for clinical purposes.

Hepatitis C Virus (HCV) NS5A Drug Resistance by Sequencing

ARUP test code 2014139

NS5A Genotype

1a

INTERPRETIVE INFORMATION: HCV NS5A Drug Resistance by Sequencing

This assay detects resistance-associated variants in NS5A codons 20-101 for HCV genotypes 1a and 1b. Variants in viral sub-populations below 20 percent of total may not be detected. For further information, please refer to drug package inserts

H=High, L=Low, *=Abnormal, C=Critical

Unless otherwise indicated, testing performed at:

ARUP LABORATORIES | 800-522-2787 | aruplab.com
500 Chipeta Way, Salt Lake City, UT 84108-1221
Jonathan R. Genzen, MD, PhD, Laboratory Director

Patient: Patient, Example
ARUP Accession: 21-106-139481
Patient Identifiers: 01234567890ABCD, 012345
Visit Number (FIN): 01234567890ABCD
Page 1 of 2 | Printed: 10/19/2022 6:47:30 AM

for the applicable direct acting antiviral drug and current HCV treatment guidelines (e.g. AASLD/IDSA guidelines or EASL HCV treatment recommendations).

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NS5A Resistance

See Note

The following resistance-associated variants were identified: Y93H

Ledipasvir Resistance: Predicted
Elbasvir Resistance: Predicted
Ombitasvir Resistance: Possible
Daclatasvir Resistance: Possible
Velpatasvir Resistance: Possible
Pibrentasvir Resistance: Possible

A result of Predicted resistance indicates that one or more resistance-associated variant (RAV) was detected. These RAVs have been known to confer varying levels of resistance to treatment regimens containing the NS5A inhibitors ledipasvir or elbasvir. Resistance and interpretation for these variants is reported based on current EASL HCV treatment guidelines (available: <http://www.easl.eu/research/our-contributions/clinical-practice-guidelines>).

A result of Possible resistance indicates that one or more resistance-associated variant (RAV) was detected. Current guidelines and in vitro and/or clinical studies have identified these variants as having a possible association with resistance but may require additional studies to confirm. Please refer to the individual Direct Acting Antiviral (DAA) package inserts for additional treatment implications and guidance.

A result of Not Predicted resistance indicates that no RAVs were detected and/or variants detected have uncertain or no impact on response to DAA-treatment. Additionally, variants in viral sub-populations below 20 percent of total may not be detected.

VERIFIED/REPORTED DATES

Procedure	Accession	Collected	Received	Verified/Reported
HCV Genotype by Sequencing	21-106-139481	4/16/2021 12:07:00 PM	4/18/2021 11:54:25 AM	4/22/2021 11:41:00 AM
NS5A Genotype	21-106-139481	4/16/2021 12:07:00 PM	4/22/2021 11:41:15 AM	4/27/2021 1:48:00 PM
NS5A Resistance	21-106-139481	4/16/2021 12:07:00 PM	4/22/2021 11:41:15 AM	4/27/2021 1:48:00 PM

END OF CHART

H=High, L=Low, *=Abnormal, C=Critical

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Page 2 of 2 | Printed: 10/19/2022 6:47:30 AM