

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

Physician: Doctor, Example

**Patient: Patient, Example**

**DOB** 2/17/1988  
**Gender:** Male  
**Patient Identifiers:** 01234567890ABCD, 012345  
**Visit Number (FIN):** 01234567890ABCD  
**Collection Date:** 00/00/0000 00:00

**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.

Test developed and characteristics determined by ARUP Laboratories. See Compliance Statement B: aruplab.com/CS

**Hepatitis C Virus (HCV) NS5A Drug Resistance by Sequencing**

ARUP test code 2014139

**NS5A Genotype**

1a

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

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

Test developed and characteristics determined by ARUP Laboratories. See Compliance Statement B: aruplab.com/CS

NS5A Resistance

See Note

The following resistance-associated variants were identified:  
None

- Ledipasvir Resistance: Not Predicted
- Elbasvir Resistance: Not Predicted
- Ombitasvir Resistance: Not Predicted
- Daclatasvir Resistance: Not Predicted
- Velpatasvir Resistance: Not Predicted
- Pibrentasvir Resistance: Not Predicted

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.

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

VERIFIED/REPORTED DATES

| Procedure                  | Accession     | Collected        | Received         | Verified/Reported |
|----------------------------|---------------|------------------|------------------|-------------------|
| HCV Genotype by Sequencing | 19-123-402551 | 00/00/0000 00:00 | 00/00/0000 00:00 | 00/00/0000 00:00  |
| NS5A Genotype              | 19-123-402551 | 00/00/0000 00:00 | 00/00/0000 00:00 | 00/00/0000 00:00  |
| NS5A Resistance            | 19-123-402551 | 00/00/0000 00:00 | 00/00/0000 00:00 | 00/00/0000 00:00  |

END OF CHART

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