Hepatitis C Virus Genotype by Sequencing
ARUP test code 0055593

HCV Genotype by Sequencing

Indeterminate

Hepatitis C GENOTYPING IS INDETERMINATE. This test may be unsuccessful if the HCV RNA viral load is less than log 3.6 or 4000 IU per mL. Repeat testing may be appropriate if and when the viral load becomes greater than log 3.6 or 4000 IU/mL.

In addition to low viral load, other conditions, such as PCR inhibitors, viral genetic variation, etc., may cause RT-PCR failure resulting in an indeterminate result.

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' untranslated 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.

<table>
<thead>
<tr>
<th>Procedure</th>
<th>Accession</th>
<th>Collected</th>
<th>Received</th>
<th>Verified/Reported</th>
</tr>
</thead>
</table>

END OF CHART

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

Unless otherwise indicated, testing performed at: