MAYO CLINIC LABORATORIES

Test Definition: FH1N5

HCV RNA Genotype 1 NS5a Drug Resist

Overview

Method Name
Polymerase Chain Reaction (PCR); Sequencing

NY State Available
Yes

Specimen

Specimen Type
Varies

Specimen Required
Please submit one of the following:

Plasma:

Specimen Type: Plasma (Preferred)

Container/Tube: EDTA (lavender-top) tube(s).

Specimen volume: 2 mL

Collection Instructions: Draw blood in an EDTA (lavender-top) tube(s). (Plasma gel tube is acceptable.) Spin down and send 2 mL plasma refrigerated in a plastic vial.

Serum:

Specimen Type: Serum

Container/Tube: Red-top tube, serum gel is acceptable.

Specimen volume: 2 mL

Collection Instructions: Draw blood in a plain red-top tube(s). (Serum gel tube is acceptable.) Spin down and send 2 mL serum refrigerated in a plastic vial.

Reject Due To

Hemolysis	Mild OK, Gross reject
Lipemia	Mild OK, Gross reject
Icterus	NA
Other	Heparin plasma

Specimen Minimum Volume

0.6 mL

Specimen Stability Information

Specimen Type	Temperature	Time	Special Container
Varies	Refrigerated (preferred)	14 days	
	Frozen	42 days	
	Ambient		

Clinical & Interpretive

Clinical Information

The clinical significance of NS5a resistance associated variants for antiviral therapy may vary according to the clinical status and antiviral treatment experience of the HCV-infected patient.

Testing for NS5a resistance-associated variants prior to initiation of treatment with elbasvir plus grazoprevir in HCV genotype 1a infected patients is recommended.

Reference Values

HCV NS5a Subtype: Not Detected

Performance

Method Description

This assay is designed to amplify HCV genotypes 1a and 1b and may not successfully amplify other HCV genotypes.

This test utilizes RT-PCR and DNA sequencing to detect the presence of treatment-emergent HCV NS5a variants

associated with NS5a inhibitor antiviral therapy.

PDF Report

No

Performing Laboratory Location

Quest Diagnostics

Fees & Codes

Test Classification

This test was developed and its analytical performance characteristics have been determined by Quest Diagnostics. It has not been cleared or approved by the FDA. This assay has been validated pursuant to the CLIA regulations and is used for clinical purposes.

CPT Code Information

87902

LOINC® Information

Test ID	Test Order Name	Order LOINC Value
FH1N5	HCV RNA Genotype 1 NS5a Drug Resist	82525-7

Result ID	Reporting Name	LOINC®
Z4846	HCV NS5a Subtype	82380-7
Z4847	Daclatasvir Resistance	82379-9
Z4848	Ledipasvir Resistance	82377-3
Z4849	Ombitasvir Resistance	82378-1
Z4850	Elbasvir Resistance	82376-5
Z4851	Velpatasvir Resistance	82520-8