
Reporting Title: HCV Genotypic Drug Resistance, S**Performing Location:** Rochester**Ordering Guidance:**

This test is intended for detection of preexisting antiviral drug resistance-associated substitutions in individuals known to be infected with hepatitis C virus (HCV) genotype 1a, 1b, or 3 (any subtype) and being considered for HCV NS3, NS5A, and NS5B inhibitor combination therapy.

Additional Testing Requirements:

Prior to requesting this test, patients must have a confirmed serum or plasma hepatitis C virus (HCV) RNA level of 5000 IU/mL or higher within the preceding 30 days and a known HCV genotype result of 1a, 1b, or 3 (any subtype). The following tests are available to provide these prerequisite results:

- HCVQG / Hepatitis C Virus (HCV) RNA Quantification with Reflex to HCV Genotype, Serum
- HCVQN / Hepatitis C Virus (HCV) RNA Detection and Quantification by Real-Time Reverse Transcription-PCR, Serum
- HCVG / Hepatitis C Virus Genotype, Serum

Shipping Instructions:

1. Ship specimen frozen on dry ice only.
2. If shipment will be delayed for more than 24 hours, freeze serum at -20 to -80 degrees C before shipment, and transport on dry ice.

Necessary Information:

The following 2 questions must be answered at the time of test ordering (if not ordering electronically, note the answers on the test request):

1. What Is the Hepatitis C Virus (HCV) RNA level in IU/mL within the last 30 days? Provide an answer using the following ranges:

- <5000
- 5000 to 1,000,000
- 1,000,001 to 10,000,000
- 10,000,001 to 100,000,000
- >100,000,000

Note: If the answer to this question is not answered or is "Unknown," testing will be canceled.

2. Does the patient have a known hepatitis C genotype of 1a, 1b, or 3 (any subtype)? Yes or No.

Note: If the answer to this question is "No," testing will be canceled.

Specimen Requirements:

Supplies: Sarstedt Aliquot Tube, 5 mL (T914)

Collection Container/Tube: Serum gel

Submission Container/Tube: Plastic vial

Specimen Volume: 2.5 mL

Collection Instructions:

1. Centrifuge blood collection tube per manufacturer's instructions (eg, centrifuge and aliquot within 2 hours of collection for BD Vacutainer tubes).
2. Aliquot serum into a plastic vial.

Specimen Minimum Volume:

1.6 mL

Forms:

If not ordering electronically, complete, print, and send a Microbiology Test Request (T732) with the specimen.

Specimen Type	Temperature	Time	Special Container
Serum SST	Frozen (preferred)	60 days	ALIUQUOT TUBE
	Refrigerated	7 days	ALIUQUOT TUBE

Ask at Order Entry (AOE) Questions:

Test ID	Question ID	Description	Type	Reportable
HCVDR	HCVLR	HCV RNA level IU/mL last 30 days =: <ul style="list-style-type: none">• 5,000 to 1,000,000• 1,000,001 to 10,000,000• 10,000,001 to 100,000,000• >100,000,000	Answer List	Yes
HCVDR	HCVKG	Is known HCV genotype 1a, 1b, or 3?: <ul style="list-style-type: none">• Yes• No	Answer List	Yes

Result Codes:

Result ID	Reporting Name	Type	Unit	LOINC®
604410	HCV Genotypic Drug Resistance, S	Alphanumeric		77202-0
604376	HCV Genotype	Alphanumeric		92731-9
604377	HCV NS3 RAS	Alphanumeric		73654-6
604378	Sequence failure at codons:	Alphanumeric		92732-7
604379	Glecaprevir resistance	Alphanumeric		92733-5

Result ID	Reporting Name	Type	Unit	LOINC®
604380	Grazoprevir resistance	Alphanumeric		82523-2
604382	Voxilaprevir resistance	Alphanumeric		92734-3
604383	HCV NS5A RAS	Alphanumeric		73655-3
604384	Sequence failure at codons:	Alphanumeric		92732-7
604385	Daclatasvir resistance	Alphanumeric		82379-9
604386	Elbasvir resistance	Alphanumeric		82376-5
604387	Ledipasvir resistance	Alphanumeric		82377-3
604388	Pibrentasvir resistance	Alphanumeric		92735-0
604389	Velpatasvir resistance	Alphanumeric		82520-8
604390	HCV NS5B RAS	Alphanumeric		73655-3
604391	Sequence failure at codons:	Alphanumeric		92732-7
604392	Sofosbuvir resistance	Alphanumeric		82382-3
604393	HCV Genotype	Alphanumeric		92731-9
604394	HCV NS3 RAS	Alphanumeric		73654-6
604395	Sequence failure at codons:	Alphanumeric		92732-7
604396	Glecaprevir resistance	Alphanumeric		92733-5
604397	Grazoprevir resistance	Alphanumeric		82523-2
604399	Voxilaprevir resistance	Alphanumeric		92734-3
604400	HCV NS5A RAS	Alphanumeric		73655-3
604401	Sequence failure at codons:	Alphanumeric		92732-7
604402	Daclatasvir resistance	Alphanumeric		82379-9
604403	Elbasvir resistance	Alphanumeric		82376-5
604404	Ledipasvir resistance	Alphanumeric		82377-3
604405	Pibrentasvir resistance	Alphanumeric		92735-0
604406	Velpatasvir resistance	Alphanumeric		82520-8
604407	HCV NS5B RAS	Alphanumeric		73655-3
604408	Sequence failure at codons:	Alphanumeric		92732-7
604409	Sofosbuvir resistance	Alphanumeric		82382-3
HCVLR	HCV RNA level IU/mL last 30 days =	Alphanumeric		86955-2
HCVKG	Is known HCV genotype 1a, 1b, or 3?	Alphanumeric		86955-2

LOINC and CPT codes are provided by the performing laboratory.

Supplemental Report:

No

CPT Code Information:

87900

87902

87999 (if appropriate for government payers)

Reference Values:

An interpretive report will be provided.