

New Test Highlight

Hepatitis C Virus NS5A Drug Resistance by Sequencing

ARUP Now Offers Hepatitis C Virus NS5A Drug Resistance by Sequencing

This assay detects resistance-associated variants in NS5A codons 20–101 for HCV genotypes 1a and 1b. The continuous improvement in treatments for chronic hepatitis C virus (HCV) infection has been one of the most important medical achievements of our time. A disease that affects more than 3 million individuals in the United States alone can now be cured in more than 90 percent of cases.

A critical breakthrough was the introduction of direct acting antivirals (DAAs) in 2011. Several classes of these drugs are now available for use either with interferon or more recently in interferon-free formulations. One of the most effective classes is the NS5A inhibitors.

- Approximately 10–15 percent of HCV genotype 1-infected patients without prior exposure to NS5A inhibitors are found to have resistance-associated variants, commonly called RAVs, prior to treatment.
- Patients with genotype 1a infection with specific NS5A RAVs causing more than five-fold reduction in the activity of NS5A inhibitors are found to have significantly lower rates of response.

Test Code	Test Name	Ordering Recommendations
2014139	Hepatitis C Virus NS5A Drug Resistance by Sequencing	Order before initiating treatment with NS5A inhibitors. Do not order prior to molecular confirmation of positive HCV screen and confirmation of genotype 1a or 1b.
2014598	Hepatitis C Virus (HCV) Genotype with Reflex to HCV NS5A Drug Resistance by Sequencing	Order before initiating treatment with NS5A inhibitors. Use to determine HCV type 1-6 after molecular confirmation of positive HCV screen. If genotype "1a or 1b" is determined, testing will reflex to HCV NS5A for genotype differentiation and drug resistance by sequencing.

Testing Recommendations

- Currently, testing for the presence of NS5A RAVs is recommended at baseline for patients with HCV genotype 1a prior to initiation of treatment with elbasvir plus grazoprevir.
- Testing should also be considered for patients with genotype 1a and cirrhosis prior to sofosbuvir plus daclatasvir treatment.

Limitations

- This test may be unsuccessful if the HCV RNA viral load is less than log 3.4 or 2500 IU/mL and/or if the HCV RNA genotype is not 1a or 1b.

For More Information

- ARUP Consult® HCV topic: www.arupconsult.com/content/hepatitis-c-virus
- ARUP Hepatitis C topic: www.aruplab.com/topics/liver
- Spotlight on HCV NS5A RAV testing: www.arup.utah.edu/education/shortTopics/spot_hillyard_hepCVirusDrugResistance_2017.php
- Email inquiries to: ProductManagersTechnical@aruplab.com



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