

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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