Q&A | HCV NS5A DRUG RESISTANCE ASSAY

Q: What is the HCV NS5A Drug Resistance Assay?

A: The HCV NS5A assay is a genotypic (sequencing) resistance assay that analyzes the non-structural (NS) 5A region of hepatitis C virus (HCV) genotypes 1a or 1b using next-generation sequencing (NGS) techniques. Amino acid substitutions in the NS5A region are identified, and a viral susceptibility call is made for the direct acting agents (DAAs) which inhibit HCV NS5A. The susceptibility calls include sensitive, resistant or resistance possible.

Q: Is the HCV NS5A Drug Resistance Assay indicated for use as a baseline assessment tool (prior to initiation of therapy)?

A: The role of HCV NS5A resistance testing at baseline to determine effective HCV treatment is less well defined relative to resistance testing for NS3/4A protease inhibitors. Clinicians should use their judgment to determine the clinical applicability of this assay. At this time, baseline resistance testing for NS5A inhibitors has not been formally recommended as the body of evidence continues to evolve.[1,2]

Q: Are there other situations in which the HCV NS5A Drug Resistance Assay might be indicated?

A: Resistance testing with HCV NS5A may be considered for patients who fail treatment which includes an NS5A inhibitor to determine the presence of resistant variants which may impact future treatment options. Data from clinical trials suggest the possibility that treatment emergent amino acid substitutions in the HCV NS5A region may limit the effectiveness of NS5A DAAs. [1,2]

Q: What are the features of the HCV NS5A Drug Resistance Assay?

- Assessment of HCV susceptibility for currently available DAAs, including ombitasvir and ledipasvir, which inhibit NS5A.
- Identification of amino acid variants within the NS5A protein of HCV genotypes 1a or 1b.
- Detection of mixtures of wild-type and drug-resistant variants when present at levels as low as 10% of the total population.[3]
- Use of Monogram's HCV genotypic interpretation database to derive a susceptibility assessment of sensitive, resistant, or resistance possible for each DAA

Q: How is the HCV NS5A Drug Resistance Assay performed?

A: The NS5A region of HCV from patient plasma samples is amplified by RT-PCR using either genotype 1a or 1b specific primers. Nucleic acid sequences are determined using NGS methods and then compared to subtype-specific reference sequences. Amino acid differences from the references sequences are reported. Analysis based on Monogram's HCV genotypic interpretation database yields an assessment of sensitive, resistant or resistance possible for each currently available NS5A inhibitor.

Q: Where is the HCV NS5A Drug Resistance Assay performed?

A: The assay is performed at Monogram BioSciences, a member of the LabCorp Specialty Testing Group.

Q: How often are the NS5A resistance mutations and susceptibility interpretation database updated?

A: The interpretation database and relevant resistance-associated mutations are updated as new data emerges.

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Q: Can the HCV NS5A Drug Resistance Assay be used to assess NS5A inhibitor susceptibility for other HCV genotypes such as 2 or 3?

A: The HCV NS5A assay is only indicated for HCV genotypes 1a and 1b. The HCV strain genotype and subtype (1a or 1b) should be indicated on the test requisition form (TRF) at sample submission.

Q: How long has the HCV NS5A Drug Resistance Assay been available?

A: The HCV NS5A assay was validated for use in August 2012 and has been used in clinical trials for NS5A inhibitors. The assay was made commercially available in March of 2015 subsequent to the approval of NS5A polymerase inhibitors for HCV treatment.

Q: Has the HCV NS5A Drug Resistance Assay been validated?

A: HCV NS5A has been validated according to CAP/CLIA specifications in Monogram's CAP/CLIA accredited clinical reference laboratory in South San Francisco, California.

Q: What is the turnaround time for the HCV NS5A Drug Resistance Assay?

A: The turnaround time is approximately 7-10 days from sample receipt at Monogram Biosciences.

Q: What is the viral load requirement for the HCV NS5A Drug Resistance Assay?

A: The viral load requirement is 500 IU/mL.

Q: How do I order the HCV NS5A Drug Resistance Assay?

A: HCV NS5A is available as a standalone assay.
The LabCorp test number is 550325
The Monogram test number is C6200

Q: What are the CPT Codes for the HCV NS5A Drug Resistance Assay?

A: The CPT codes for the HCV NS5A Drug Resistance Assay are 87902 and 87900. CPT coding may vary based on individual patient insurance plans. Please contact the specific insurance carrier for their requirements.

Q: Is the HCV NS5A Drug Resistance Assay covered by insurance?

A: Monogram offers Gateway, an insurance benefits investigation program, which provides verification of assay coverage. Gateway also seeks a patient assistance program for uninsured, low-income patients. For more information, contact Monogram's Gateway at 1-877-436-6243.

Q: Where can I learn more about the HCV NS5A Drug Resistance Assay?

A: Monogram's Client Services group is available to answer questions. Call 1-800-777-0177 or visit the Monogram website at www.monogrambio.com.

References:
1. Viekira PAK [Highlights of Prescribing Information], North Chicago, IL: AbbVie Inc; 2014
2. Harvonii [Highlights of Prescribing Information], Foster City, CA: Gilead Sciences; 2014
3. Whitcomb J. Data Analysis Review of DeepLogic Files [standard operating procedure]. South San Francisco, Calif: Monogram BioSciences Inc; March 12, 2015.

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