New test – Hepatitis C Virus NS5A Drug Resistance Assay

WHAT’S NEW?
Effective October 1, 2016, Hepatitis C Virus (HCV) Drug Resistance Assay LAB6761 will be offered.

INDICATIONS FOR ORDERING
Recommended for:

- Individuals with genotype 1a, 1b or 3 HCV infection who are being considered for an NS5A inhibitor
- Individuals with genotype 1a, 1b or 3 HCV infection who experience treatment failure with an NS5A inhibitor

BACKGROUND
Of the 6 major HCV genotypes, genotype 1 (including subtypes 1a and 1b) is the most prevalent by far in the United States. The availability of DAAs has led to PEG-free treatment options for all HCV genotypes. DAAs interrupt HCV replication by targeting specific HCV proteins, such as the NS5A protein.

Determining viral resistance to DAA corresponds to the selection during treatment of viral variants that bear amino acid substitutions altering the drug target, and that are therefore less susceptible to the drug’s inhibitory activity. These drug-resistant variants pre-exist as minor populations within the variant populations present in a given individual. This degree of drug resistance can be measured in vitro.

METHODOLOGY
Polymerase chain reaction (PCR) amplification and DNA next generation sequencing.

The HCV NS5A Drug Resistance Assay is a genotypic (sequencing) resistance assay that analyzes the nonstructural (NS5A) region of HCV genotypes 1a or 1b or genotype 3, using next-generation sequencing (NGS) techniques. Amino acid substitutions in the NS5A region are identified, and a viral susceptibility call for the DAA that inhibit the NS5A proteins is reported as either “resistance possible” or “none/undetermined.”

INTERPRETIVE INFORMATION
Resistance Possible
An interpretation of “resistance possible” suggests that the patient’s viral population may show reduced susceptibility to NS5A inhibitor-containing regimens and lists all amino acid variants and polymorphisms detected.

None/Undetermined
An interpretation of “non/undetermined” suggests that resistance to NS5A inhibitors is unlikely or undetermined.

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## ORDERING INFORMATION

### Hepatitis C Virus (HCV) NS5A Drug Resistance Assay (LAB6761)

<table>
<thead>
<tr>
<th>Methodology</th>
<th>Polymerase Chain Reaction &amp; DNA Next Generation Sequencing</th>
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</thead>
<tbody>
<tr>
<td>Performed</td>
<td>Daily</td>
</tr>
<tr>
<td>Released</td>
<td>10-12 days after receipt at reference laboratory</td>
</tr>
<tr>
<td>CPT</td>
<td>87900, 87902</td>
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</tbody>
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### Specimen Requirements

<table>
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<tr>
<th>Collection</th>
<th>Collect specimen in 2 lavender-top (EDTA) tubes. Centrifuge specimen within 2 hours of collection. Remove plasma, transfer plasma to a screw-cap polypropylene transport tube (not &quot;pop-top&quot; or &quot;snap-cap&quot;), and freeze.</th>
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<tbody>
<tr>
<td>Handling</td>
<td>Submit 2 mL frozen plasma.</td>
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</table>
| Stability           | **Frozen:** 14 days  
**Refrigerated:** Unacceptable >72 hours  
**Ambient:** Unacceptable >24 hours                                                                                      |
| Rejection           | Specimens received exceeding listed temperature stabilities; serum; plasma other than EDTA; insufficient volume; specimens exposed to repeated freeze/thaw cycles; specimen received in "pop-top" or "snap-cap" or non-polypropylene tubes |

### QUESTIONS?

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