The Hepatitis C Viral RNA Genotype 1 NS5B Drug Resistance assay determines the HCV genotype (1a, 1b, or 1) and detects mutations associated with resistance to sofosbuvir. The identification of specific mutations or polymorphisms may be useful to optimize treatment selection.

**INDIVIDUALS SUITABLE FOR TESTING**
- Individuals with genotype 1 HCV infection who experience treatment failure with sofosbuvir

**METHOD**
- Reverse transcription polymerase chain reaction (PCR) and DNA sequencing of NS5B codons 270 to 530
- Analytical sensitivity: >95% for viral loads ≥700 IU/mL
- Results reported:
  - HCV genotype: 1a, 1b, 1, or not detected (genotypes other than 1 may not be detected)
  - Sofosbuvir resistance: predicted or not predicted

**INTERPRETIVE INFORMATION**
An interpretation of “resistance predicted” suggests that treatment failure with sofosbuvir may be due to the presence of an NS5B mutation (S282T). An interpretation of “resistance not predicted” indicates that the S282T sofosbuvir resistance mutation was not detected.6

Resistance may also be affected by as yet uncharacterized mutations and interactions among mutations. Failure to obtain a genotype may be due to insufficient virus, a non-1 genotype, mutations in the viral genome at the assay priming sites, or the presence of an inhibitory substance in the sample.

**References**
Test Summary


* The CPT code provided is based on AMA guidelines and is for informational purposes only. CPT coding is the sole responsibility of the billing party. Please direct any questions regarding coding to the payer being billed.

This test was developed and its performance characteristics have been determined by Focus Diagnostics. Performance characteristics refer to the analytical performance of the test.