

## Hepatitis C Virus Genotyping Technical Sheet

University of Florida (By LiPA Method 2.0)

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<b>Test Mnemonic:</b>	Hepatitis C Virus Genotyping
<b>Test Order Number:</b>	N/A
<b>Sample types:</b>	<p><u>For Whole blood</u> One 4 mL whole blood in EDTA (Lavender Top), ACD Solution A (Yellow top), or Serum Separator Tube (PPT sterile tube - Pearl/White Top).</p> <p><u>Serum or Plasma:</u> Minimum 0.5 mL plasma is requirement. Remarks: <b>CRITICAL FROZEN. Separate serum or plasma from cells within four hours of collection.</b> This test may be unsuccessful if the HCV RNA viral load is less than 3,000 HCV RNA copies/ mL of plasma. Comments: Requests for genotyping may be added to previous viral load testing conducted on samples drawn within the past 30 days.</p>
<b>Transport:</b>	<p><u>For whole blood:</u> Ship whole blood collection tube in a Styrofoam container with coolant packs DO NOT FREEZE, protect specimen by wrapping in bubble-wrap or toweling. Specimen should be collected and packaged as close to shipping time as possible. Maintain sterility and forward promptly to lab. Recommend express mail or equivalent if not on courier service. Samples must be received within <b>24</b> hours of collection.</p> <p><u>For Plasma:</u> Ship the plasma specimens on dry ice with overnight service. Note: Federal requirements for packaging must be met when specimens are transported by common land and air carriers. Refer to 42 CFR, Part 72. The most current requirements may be obtained from the Centers for Disease Control and Prevention Office of Health and Safety in Atlanta, Georgia at 1-800-311-3435.</p>
<b>Unacceptable Conditions:</b>	Non-frozen plasma or heparinized specimens. Specimens exposed to repeated freeze/thaw cycles.
<b>Stability:</b>	After separation from cells: Ambient: 30 minutes; Refrigerated: 2 hours; Frozen: 4 months
<b>Methodology:</b>	LiPA 2.0 method
<b>In house turn-around time:</b>	7 business days
<b>Reference values:</b>	<3000 copies/ mL
<b>Note:</b>	The performance characteristics of this test were validated by the University of Florida, Diagnostic Reference Laboratories (UF DRL). The test is not FDA approved. The results are not intended to be used as the sole means for clinical diagnosis or patient management decisions. High-complexity testing by UF DRL is authorized by CLIA as well as both state and federal licensure and certification.
<b>CPT Code(s):</b>	87902 (with 87522 if sample preparation is required)

**Applications:**

The hepatitis C virus is categorized into six major genotypes. Each of these six groups is further classified into different subtypes based on their sequence variations. The reporting types from our laboratory are HCV genotype 1-6.

The HCV genotype is determined by using the VERSANT® HCV amplification LiPA 2.0 method. Genotyping is currently indicated for patients who are candidates for antiviral therapy and helps determine the appropriate duration and Ribavirin dose for Interferon-based treatment regimens.

**Sensitivity & Specificity:**

Detects all 6 HCV genotypes.

Less than 3,000 copies/ mL viral load or repeatedly frozen and thaw may cause unsuccessful amplification.