

SPECIMEN SUBMISSION GUIDELINES
HIV Diagnostics and Reference Laboratory, Diagnostics and Countermeasures Branch
Center for Infectious Disease Research Walter Reed Army Institute of Research
508 Research Dr., Silver Spring, MD, 20910

Hologic Panther HCV Quant Dx Assay Test Specifications

Test Name: HCV Panther Quant Dx (Qualitative/Quantitative)				
Clinical Significance	Specimen Requirements	Transport/Storage Temperature	Test Approved For	Turn Around Time (After Receipt at HDRL)
<p>1. In vitro nucleic acid amplification test for qualitative detection and quantification of RNA from patients infected with HCV (Subtypes 1-6).</p> <p>2. Intended use of the Assay:</p> <ul style="list-style-type: none"> To aid in the diagnosis of active HCV infection in individuals with antibody evidence of HCV infection with liver disease; individuals suspected to be actively infected with HCV; and individuals with antibodies to HCV and at high risk for HCV infection. As an aid in clinical monitoring of viral burden and effectiveness of antiretroviral therapy in plasma specimens. <p>3. Test employed: FDA-approved, commercially available test kit from Hologic: Panther HCV Quant Dx Assay.</p> <ul style="list-style-type: none"> Analytical measurement range: 10 to 100,000,000 International Units per mL (IU/mL) <p>Reference Range HCV Quantitative – Not Detected Copies/mL Not Detected Log copies/mL HCV Qualitative – Not Detected</p>	<p>Quantitative Testing:</p> <ul style="list-style-type: none"> 3mLs of Plasma <p>Qualitative Testing:</p> <ul style="list-style-type: none"> 3 mL of Serum or Plasma <p>PPT Tubes: Centrifuge immediately or within 2 hours of collection at 1100 x g for 10 minutes minimum.</p> <p>EDTA Plasma: Store blood at 25°C until centrifuged. Centrifuge at ≤1300 x g for 10 minutes within 4 hours of blood collection. Ship frozen if transport will take longer than overnight delivery.</p> <p>Serum Tubes: Allow blood to clot in upright position for 30-60 minutes before centrifugation. If transferring to secondary tube, indicate “serum” on plastic screw-cap tube for transport.</p>	<p>EDTA / PPT or Serum:</p> <p>Store serum or plasma refrigerated (2-8°C) for overnight or same day delivery.</p> <p>Ship frozen if transport will take longer than same day or overnight. Store plasma frozen (-70°C or colder).</p> <p>When shipping frozen, use 2+ lbs. dry ice per day of transport.</p> <p>Ship with an additional 6 lbs. dry ice in case of shipment delay.</p>	<p>FDA approved for patient management.</p>	<p>5 business days</p>

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