

Aptima® HCV Quant Dx Assay

- Diagnosis of active infection and viral load monitoring

Sensitive detection. Get accurate and precise results across all major genotypes.

Excellent Sensitivity and High Precision Even with Low-Level Viremia Samples

Performance

LoD	Plasma: 3.9 IU/mL Serum: 3.4 IU/mL
LLoQ*	10 IU/mL
Linear Range	10 to 100 million IU/mL

N	Mean Concentration (log IU/mL)	Inter-day	Inter-run	Intra-run	Total
		SD	SD	SD	SD
126	1.86	0.02	0.06	0.12	0.14
126	2.26	0.00	0.07	0.07	0.10
126	2.79	0.00	0.06	0.08	0.10
126	3.29	0.00	0.07	0.05	0.08
126	3.91	0.00	0.06	0.07	0.10
126	5.79	0.03	0.04	0.06	0.08
125 [†]	7.68	0.05	0.05	0.06	0.09

SD = standard deviation.

[†]Number of valid results within linear range of the assay.

Raising the Standard in HCV Viral Load Testing Sensitivity

Product Design

Intended use	Diagnosis of active HCV infection and viral load monitoring	Genotypes	1 – 6
Technology	Real-time transcription-mediated amplification (TMA)	Sample Types	Plasma Serum
Target Region	Highly conserved region of HCV RNA (5' UTR)	Sample Input Volume	Primary tube (PPT, ACD, EDTA): 1.2 mL Secondary tube: 700 µL 240 µL with automated dilution factor

*The LLoQ was established across genotypes (see package insert "Determination of the Lower Limit of Quantitation (LLoQ) Across HCV Genotypes"). This genotype data establishes an overall LLoQ for the assay of 10 IU/mL.

The Aptima® HCV Quant Dx assay on the Panther® system combines performance and excellent automation.

Sample-to-Result Within a Single Integrated Instrument

Key Automation Characteristics	
Random Access	No more batching; load samples with different test orders as they arrive Run HCV with other assays at the same time
Primary Tube Processing	No need for aliquoting or manual sample transfer Tube flexibility: PPT, ACD and EDTA tubes validated
Flexible Sample and Reagent Loading	Run multiple tests from a single sample No manual sample prep or barcode clips Automated barcode scanning of tubes allows positive sample identification
Rapid Turnaround Time with Stat Result Option	First results in 2 hours, 41 minutes stat result option: ability to prioritize results
Automated QC Analysis	Levey-Jennings plots to track and trend controls
Low Sample Volume Option (240 µL) with Automated Dilution Factor	Specified dilution factor automatically applied versus manual calculations

Ordering Information

Item	Quantity	Catalog #
Aptima HCV Quant Dx Assay Kit (1 assay box, 1 calibrator kit, 1 controls kit)	100 tests	PRD-03705

Primary Tube Sampling

- ✓ Plasma: EDTA, ACD, PPT
- ✓ Serum: SST, serum tubes



Visit USAptimaVirology.com for more information.

References: 1. Aptima HCV Quant Dx Assay [package insert] #AW-14498, San Diego, CA; Hologic, Inc., 2017.

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