HOLOGIC
The Science of Sure

The Aptima® HCV Quant Dx assay on the Panther® system:

Expand the hunt for viral load.

The Aptima® HCV Quant Dx assay: Health Canada approved for confirmation of active HCV infection and monitoring of HCV viral load on the fully automated Panther® system.

- Accurate detection and quantitation across all HCV genotypes 1 - 6.
- Excellent sensitivity and precision across a broad dynamic range, from 10 IU/mL up to 10^8 IU/mL.
- Proven assay design strategy to ensure accurate detection and quantitation.

Accurate detection and quantitation across all HCV genotypes 1 - 6.

HCV Genotype	LoD (IU/mL)[1]		LLoQ (IU/mL)[1]	
	Plasma	Serum	Plasma	Serum
1	3.8	5.1	8	8
2	2.8	4.0	6	6
3	4.3	3.4	6	5
4	4.8	2.3	7	4
5	2.1	3.2	7	5
6	3.9	3.9	6	10

LoD and LLoQ were determined by testing dilutions of HCV positive clinical specimens for genotypes 1 - 6 in HCV negative human plasma and serum.

*LLoQ was calculated across HCV genotypes 1 - 6, and the highest of all the resulting numbers was chosen in order to ensure confidence in the LLoQ.

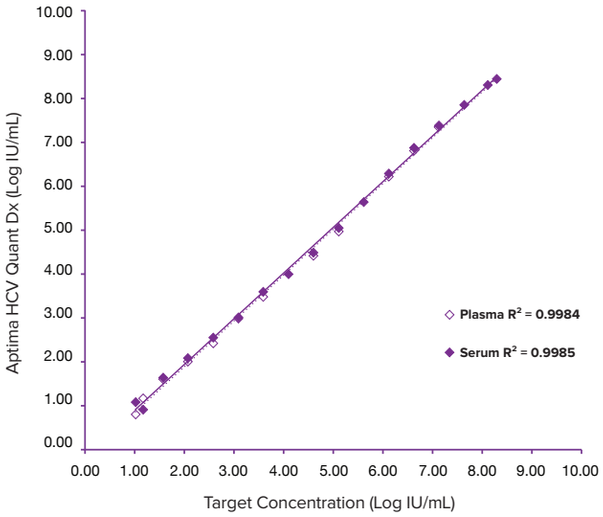
- The Aptima HCV Quant Dx assay has an analytical sensitivity of 4.3 IU/mL for plasma and 3.9 IU/mL for serum samples, respectively, testing panels of the WHO 2nd International Standard for Hepatitis C Virus RNA.
- Lower Limit of Quantitation (LLoQ) has been thoroughly established and verified across HCV genotypes 1 - 6*.

Aptima® HCV
Quant Dx Assay

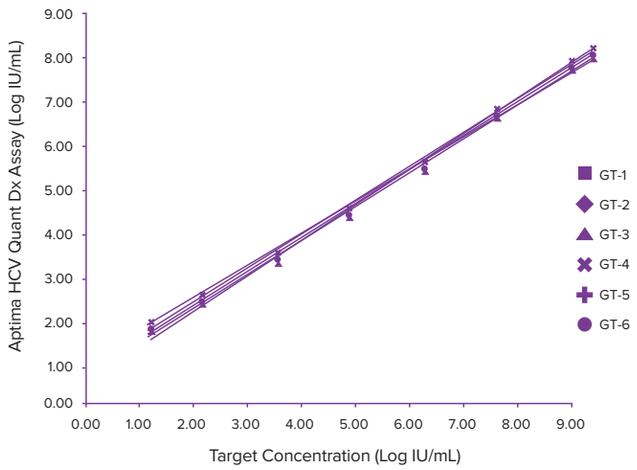
Performance you can count on.

Broad linear range and high accuracy across all HCV genotypes 1 – 6.

Linearity in Plasma and Serum[1]



Linearity across HCV Genotypes 1 - 6[1]



The Aptima® HCV Quant Dx assay has been established and thoroughly verified across all HCV genotypes 1 - 6.

Excellent sensitivity. High precision.

Precision of the Aptima HCV Quant Dx Assay[1]

Matrix	Mean Concentration (log IU/mL)	Total*	
		SD	Coefficient of Variation (%)
Plasma	1.23	0.14	11.34
Plasma	2.06	0.14	6.88
Plasma	3.02	0.11	3.77
Plasma	4.87	0.10	2.04
Plasma	7.16	0.09	1.27
Serum	1.27	0.17	13.31
Serum	2.17	0.12	5.61
Serum	3.09	0.11	3.44
Serum	4.86	0.13	2.65
Serum	7.16	0.10	1.35

*Includes inter-instrument, inter-operator, inter-lot and inter-run analysis.

- The Aptima HCV Quant Dx assay performs with low inter- and intra-assay variation and high precision over the whole dynamic range.
- Less than 15% CV at important clinical decision point for plasma as well as for serum samples.

Aptima HCV Quant Dx – The assay for diagnosis, confirmation and viral load monitoring of HCV infection with high sensitivity, accuracy and precision.

Diagnostic Solutions | Hologic.ca | info-canada@hologic.com

References:

1. Aptima HCV Quant Dx Assay [package insert] #AW-13249-REG Rev 002. San Diego, CA; Hologic, Inc., 2015.

Visit AptimaVirology.com

Aptima® HCV
Quant Dx Assay