

cobas[®] HCV

See what truly matters

The **cobas[®]** HCV quantitative nucleic acid test for use on the **cobas[®]** 6800/8800 Systems delivers robust, clinically relevant assay performance based on Roche's proprietary dual-probe assay design. **cobas[®]** HCV provides built-in redundancy with broad genotype coverage and incorporates mismatch tolerance to ensure confidence in viral load monitoring. **cobas[®]** HCV is designed to deliver high sensitivity to meet the requirements of current and future chronic hepatitis C therapies.

HCV – an ever changing virus

The combination of error-prone RNA replication with a high rate of virus production results in extreme genetic variability of hepatitis C virus (HCV). A quantitative HCV RNA test must thus be able to tolerate sequence mismatches for accurate and reliable results.

cobas[®] HCV accurately detects and quantifies all HCV genotypes 1 through 6

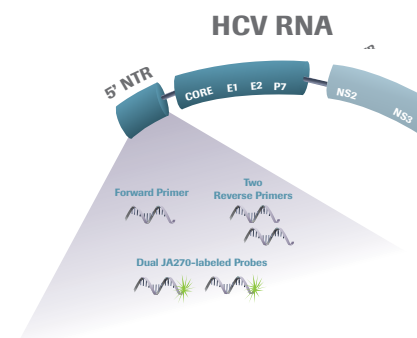
- **Two non-overlapping detection probes**, when combined with two staggered primers, ensure assay performance with HCV isolates containing sequence heterogeneity.
- **Mismatch tolerance** that enables the test to accurately quantify the target despite nucleotide changes in the viral genome while maintaining high specificity for HCV RNA.

Clinical relevance

For hepatitis C therapy, clinicians rely on HCV RNA viral load results to assess whether their patients have achieved sustained virological response (SVR), to verify adherence to therapy, and to detect treatment non-responders.

cobas[®] HCV delivers:

- Tight precision at medically-relevant decision points
- Accurate detection and quantification of HCV genotypes 1 through 6
- High sensitivity suitable for use with new HCV therapies
- Excellent correlation with the COBAS[®] AmpliPrep/COBAS[®] TaqMan[®] HCV Quantitative Test, v2.0



cobas[®] HCV limit of detection

Genotype	EDTA plasma (IU/mL)	Serum (IU/mL)
1a	8.46	9.61
1b	11.32	15.24
2	9.10	12.51
3	8.68	7.21
4	12.78	11.62
5	11.63	13.06
6	12.58	11.15

Accurate detection and quantitation of all HCV genotypes 1 through 6. **cobas[®]** HCV detects 7 genotypes/subtypes at a concentration of 9 to 15 IU/mL by PROBIT at 95% hit rate analysis (500 µL sample processing volume).

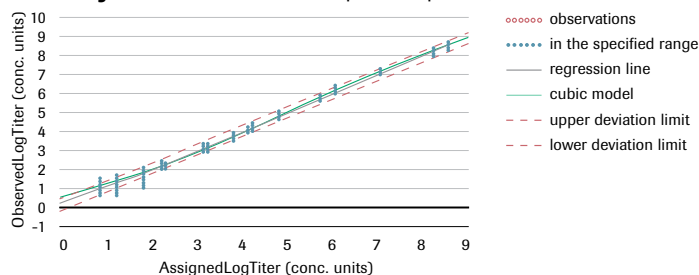


Broad linear range of **cobas**[®] HCV in EDTA plasma and serum ensures sensitive viral load results and decreases the need for dilution:

500 µL processing volume: 15 IU/mL to 1 × 10⁸ IU/mL

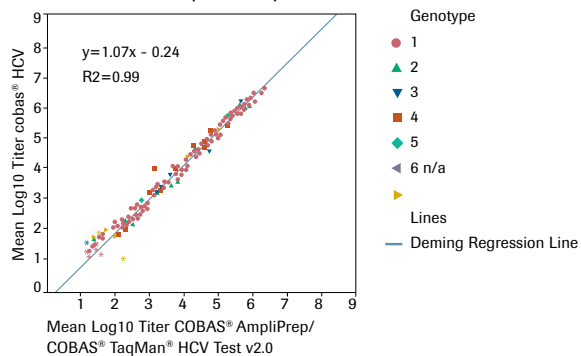
200 µL processing volume: 40 IU/mL to 1 × 10⁸ IU/mL

Linearity for **cobas**[®] HCV (500 µL EDTA plasma)



Excellent correlation of **cobas**[®] HCV with the COBAS[®] AmpliPrep/COBAS[®] TaqMan[®] HCV Quantitative Test, v2.0

Correlation (500 µL EDTA plasma)



cobas[®] HCV performance summary

Parameter	Performance
Sample type	EDTA plasma, serum
Minimum amount of sample required	650 µL or 350 µL
Sample processing volume	500 µL or 200 µL*
Analytical sensitivity (LoD by hit rate of 95%)	15 IU/mL (500 µL) 40 IU/mL (200 µL)
Linear range	500 µL: 15 IU/mL – 1 × 10 ⁸ IU/mL 200 µL: 40 IU/mL – 1 × 10 ⁸ IU/mL
Specificity	100% (one-sided 95% confidence interval: 99.5%)
Genotypes detected	HCV genotypes 1-6

cobas[®] HCV ordering information

Material number	Product name	Kit size
06997732190	cobas [®] HCV	96 tests
06997767190	cobas [®] HBV/HCV/HIV Control Kit	8 runs
07002220190	cobas [®] NHP Negative Control Kit	16 runs

Comprehensive menu for viral load testing

- [cobas[®] HIV-1*](#)
- [cobas[®] HBV*](#)
- [cobas[®] HCV*](#)
- [cobas[®] CMV*](#)

*200 µL processing volume not commercially available in the United States

*For use with the **cobas**[®] 6800/8800 Systems