

# cobas<sup>®</sup> HCV

## See what truly matters

The **cobas<sup>®</sup>** HCV quantitative nucleic acid test for use on the **cobas<sup>®</sup>** 6800/8800 Systems delivers robust, clinically relevant assay performance based on Roche's proprietary dual-probe assay design. **cobas<sup>®</sup>** HCV provides built-in redundancy with broad genotype coverage and incorporates mismatch tolerance to ensure confidence in viral load monitoring. **cobas<sup>®</sup>** 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<sup>®</sup> HCV accurately detects and quantifies all HCV genotypes 1 through 6

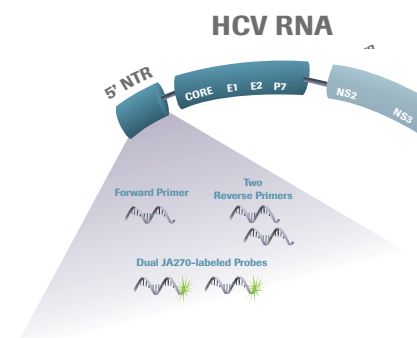
- **Two non-overlapping detection probes**, when combined with two staggered primers, ensure assay performance with HCV isolates containing sequence heterogeneity.
- **Mismatch tolerance** that enables the test to accurately quantify the target despite nucleotide changes in the viral genome while maintaining 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<sup>®</sup> 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<sup>®</sup> AmpliPrep/COBAS<sup>®</sup> TaqMan<sup>®</sup> HCV Quantitative Test, v2.0



### cobas<sup>®</sup> 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<sup>®</sup>** 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).

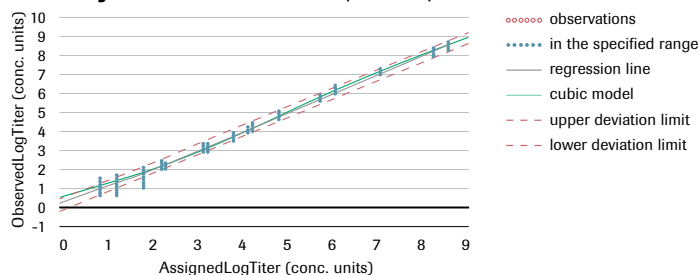


Broad linear range of **cobas**<sup>®</sup> HCV in EDTA plasma and serum ensures sensitive viral load results and decreases the need for dilution:

500 µL processing volume: 15 IU/mL to 1 × 10<sup>8</sup> IU/mL

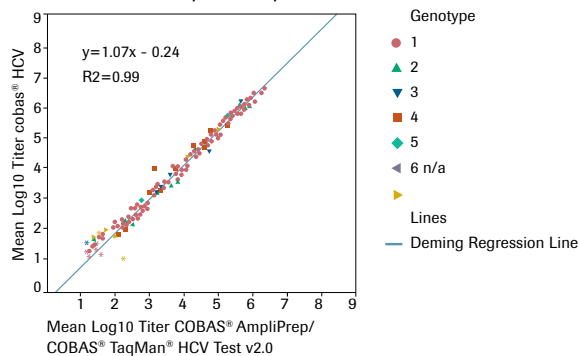
200 µL processing volume: 40 IU/mL to 1 × 10<sup>8</sup> IU/mL

### Linearity for **cobas**<sup>®</sup> HCV (500 µL EDTA plasma)



Excellent correlation of **cobas**<sup>®</sup> HCV with the COBAS<sup>®</sup> AmpliPrep/COBAS<sup>®</sup> TaqMan<sup>®</sup> HCV Quantitative Test, v2.0

### Correlation (500 µL EDTA plasma)



### **cobas**<sup>®</sup> 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 <sup>8</sup> IU/mL 200 µL: 40 IU/mL – 1 × 10 <sup>8</sup> IU/mL
Specificity	100% (one-sided 95% confidence interval: 99.5%)
Genotypes detected	HCV genotypes 1-6

### **cobas**<sup>®</sup> HCV ordering information

Material number	Product name	Kit size
06997732190	<b>cobas</b> <sup>®</sup> HCV	96 tests
06997767190	<b>cobas</b> <sup>®</sup> HBV/HCV/HIV Control Kit	8 runs
07002220190	<b>cobas</b> <sup>®</sup> NHP Negative Control Kit	16 runs

### Comprehensive menu for viral load testing

- cobas**<sup>®</sup> HIV-1\*
- cobas**<sup>®</sup> HBV\*
- cobas**<sup>®</sup> HCV\*
- cobas**<sup>®</sup> CMV\*

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

\*For use with the **cobas**<sup>®</sup> 6800/8800 Systems