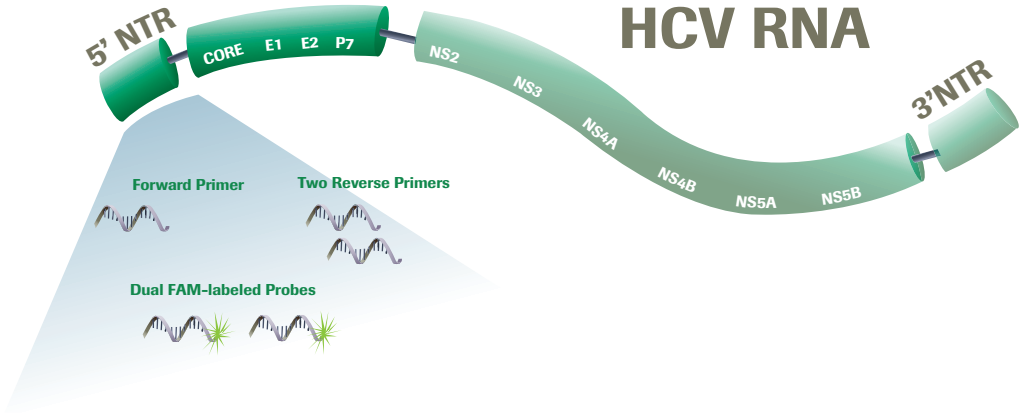
COBAS® AmpliPrep/COBAS® TaqMan® HCV Quantitative Test, v2.0

See what truly matters

The COBAS® AmpliPrep/COBAS® TaqMan® HCV Quantitative Test, v2.0 delivers robust, clinically relevant assay performance based on a novel dual-probe design with built-in redundancy for broad genotype coverage, improved mismatch tolerance for confidence in viral load monitoring, high sensitivity to meet the requirements of current and future therapies, and efficient workflow for laboratories.

Robust performance

Viral evolution represents a continuous challenge for molecular diagnosis of viral diseases. Hepatitis C virus (HCV) is characterized by high replication rate and extreme genetic variability. As new Direct Acting Antivirals (DAAs) are developed, HCV will be under greater selective pressure, creating new polymorphisms. The ability of a quantitative HCV RNA test to tolerate sequence mismatches is thus critical for accurate and reliable results since treatment decisions are made based on viral load results.



Technological advances for better reliability:

- **Two non-overlapping detection probes in combination with two staggered downstream primers ensure to maintain assay performance with HCV isolates presenting sequence heterogeneity.**
- **A new blend of two DNA polymerases improves RT-PCR efficiency and mismatch tolerance in combination with an optimized thermal cycling protocol.**
- **The new dual-probe HCV RNA test accurately detects and quantifies all HCV genotypes 1 through 6 while maintaining high specificity.**

Roche

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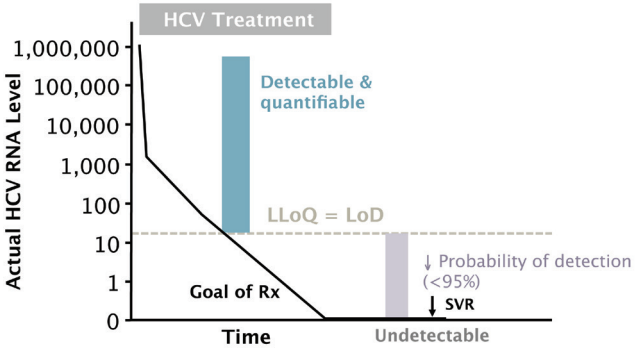
Life needs answers

Clinical relevance

Clinicians rely on HCV RNA viral load results for response-guided therapy to make critical medical decisions to shorten, extend, or stop treatment. The COBAS® AmpliPrep/COBAS® TaqMan® HCV Quantitative Test, v2.0 delivers:

- Tight precision at medically relevant decision points
- Increased sensitivity in anticipation of new therapies
- Greater clarity in result interpretation with LoD=LLoQ at 15 IU/mL
- Excellent correlation with the COBAS® TaqMan® HCV Test, v2.0 For Use With The High Pure System used in the clinical validation trials for DAAs.*



Efficient workflow

Laboratories experience greater productivity with the COBAS® AmpliPrep/COBAS® TaqMan® system, a proven platform for viral load monitoring:

- Decreased sample input volume of 650 µL allows for archiving or use in other applications
- Fully automated workflow, including the optional pre-analytics **cobas p** 630 Instrument, maximizes laboratory efficiency
- Consolidates testing for HIV-1, HBV and CMV IVD viral load monitoring with parallel processing and continuous loading capabilities

Analytical parameters of test

Parameter	Performance
Sample input volume	650 µL
LoD* (by Hit Rate, ≥95%)	plasma, serum: 15 IU/mL
LoD* (by PROBIT at 95% hit rate) *genotype 1a	plasma: 12 IU/mL; serum: 11 IU/mL
LLoQ	15 IU/mL
Linear range	15 to 1×10^8 IU/mL
Genotype inclusivity	1-6
Precision	0.04 to 0.22 $\log_{10}$ S.D. across an HCV RNA concentration range of 300 - 1×10^8 IU/mL
Accuracy	0.2 $\log_{10}$ for serum/plasma across the linear range
Specificity	100%
Kit configuration	72 tests/kit
Sample types	EDTA plasma and serum
Specimen storage	Whole blood stored at 2-25°C up to 24 hours

As a leader in virology, Roche continues to invest in the development of next-generation assays to keep pace with the changing environment of viral load monitoring. The COBAS® AmpliPrep/COBAS® TaqMan® HCV Quantitative Test, v2.0, provides accurate and reliable HCV viral load results that are required in the era of new, more potent therapies for chronic hepatitis C — today and into the future.

* Bacon BR et al. N Engl J Med 2011;364:1207–17. Poordad F et al. N Engl J Med 2011;364:1195–206. Zeuzem S et al. N Engl J Med 2011;364:2417–28. Jacobson IM et al. N Engl J Med 2011;364:2405–16.

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