



ULTRAGENE HCV

QUAL & QUANT VIRAL LOAD ASSAYS

**RAPID & ULTRA SENSITIVE MOLECULAR
TESTING FOR VIRAL HEPATITIS C**



Providing Lab Efficiency for Optimized
Patient Monitoring

Research Use Only - Proprietary, ABL S.A.



THE SOLUTION

The **ULTRAGENE HCV QUAL & QUANT** Viral Load Assays are fast and ultra-sensitive real-time PCR tests that provide qualitative detection and quantification of HCV RNA from plasma, serum, whole blood or dried blood spot samples.

The **ULTRAGENE HCV QUAL & QUANT** Viral Load Assays generate PCR amplicons of the 5'UTR and NS5B genes and which can be used as a reflex testing on positive samples for subtyping through Sanger or Next-Generation sequencing.



Intended uses

- Diagnosis and screening of acute and chronic Hepatitis C
- Treatment selection
- Treatment monitoring



Extraction

30 min

Plate Preparation

10 min

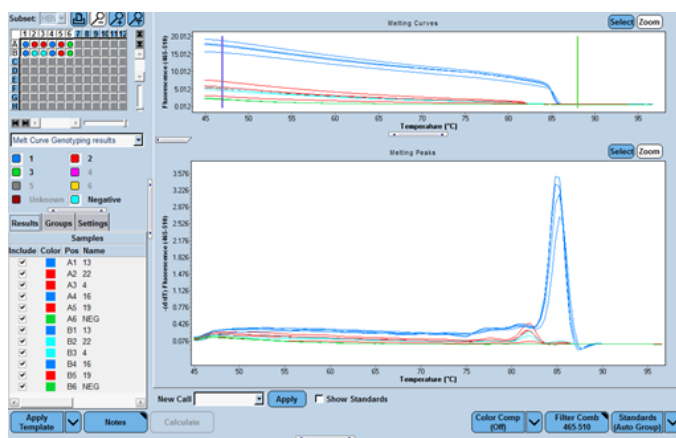
qRT-PCR

1h

Virus Detection

10 min

QUAL ASSAY



Negative

Viral load not detectable

Positive => Viral load > 15 UI/mL

Reflex
Genotyping
Testing

GENOTYPING

DEEPCHEK®-HCV
PREMIUM ASSAY



EFFICIENCY

Amplicons ready for sequencing:

- Genotyping
- Time efficiency
- Cost efficiency
- Sample volume efficiency
- Patient does come twice at the lab

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COMPOSITION



FORMAT

- From 1 to 24 sample reactions per assay
- Format suited to 96 reactions is available

CONTENT

- Real-time PCR enzyme
- Real-time PCR Master Mix
- HCV NS5B & 5'UTR amplification primers
- Water
- Calibrated positive controls (QUANT version only)

PERFORMANCES



LIMIT OF DETECTION

- Serum/Plasma samples: 15 UI/mL (95% CI 20-30)
- Dried Blood Spot: 400 UI/mL (95% CI 380-420)

CHARACTERISTICS

- 500µL plasma/serum/whole blood
- Pan-genotypic
- Reproducibility >99%

EASY & RAPID

- 110 minutes run time
- Hands-on time: <30 min

EFFICIENCY

- Cost-effective
- From 1 to 96 samples per run
- Reflex genotyping testing on 5'UTR/NS5B (using the DeepChek®-HCV Premium assay), compatible with SANGER & Next Generation Sequencing CE-IVD software for genotyping analysis



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REFERENCES & CONTACT



ULTRAGENE **HCV** Viral Load QUAL Assay (RUO)

- Up to 24 samples K-17-UHCV24
- Up to 96 samples K-17-UHCV96

ULTRAGENE **HCV** Viral Load QUANT Assay (RUO)

- Up to 24 samples K-17-UQTHCV24
- Up to 96 samples K-17-UQTHCV96

RELATED PRODUCTS

- DeepChek®-HCV NS5B / 5'UTR (PREMIUM) Genotyping Assay (RUO) K-16-NS5B5UTR
- DeepChek®-HCV CORE Genotyping Assay (RUO) K-16-CORE
- DeepChek®-HCV NS5A Drug Resistance Assay (RUO) K-16-NS5ADR
- DeepChek®-HCV NS3 Drug Resistance Assay (RUO) K-16-NS3DR
- DeepChek®-HCV NS5B Drug Resistance Assay (RUO) K-16-NS5BDR
- DeepChek®-HCV Software (CE-IVD) S-12-023 (CUS)

ULTRAGENE Viral Load Assays (RUO) also available for: HIV, HBV, Tuberculosis



IMPROVE DISEASE MANAGEMENT

CONTACT

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