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This product is intended to be used to guide the selection of treatment type and duration for individuals being considered for antiviral treatment who are chronically infected with HCV. Thus, the assay is intended to be used with samples known to be positive for HCV RNA. The VERSANT HCV Genotype 2.0 assay (LiPA) is not intended to be used as a screening test for HCV or as a diagnostic test to confirm the presence of HCV.

Product availability may vary from country to country and is subject to varying regulatory requirements. Please contact your local representative for availability.

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Optimize Treatment Decisions with Universal Genotyping Technology

VERSANT HCV Genotype 2.0 Assay (LiPA)

siemens.com/molecular

Trusted results the first time.



Optimize your laboratory's testing with the leading, most widely used HCV-genotyping technology available—the VERSANT® HCV Genotype 2.0 Assay (LiPA)*. LiPA utilizes the trusted reverse-hybridization technology to detect genotypes 1–6 and 15 subtypes, including 1a, 1b, and 6 (c-I). LiPA provides highly accurate identification of HCV genotypes and subtypes for optimal and personalized patient therapy.

*CE-marked for IVD use in the EU. For research use only in the U.S.

“Precise determination of HCV genotype and HCV subtypes 1a and 1b is of major importance when selecting an optimal direct antiviral therapy for our patients. The VERSANT HCV Genotype 2.0 assay (LiPA), which uses sequence information from both core and 5’ untranslated regions of HCV, provides our routine laboratory with accurate distinction between HCV genotypes as well as between subtypes 1a and 1b.”

Christoph Sarrazin, MD
J.W. Goethe-University Hospital Frankfurt am Main
Associate Director and Professor of Medicine, Medizinische Klinik 1
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Germany

With LiPA results, clinicians can decide whether to begin antiviral therapy in patients with chronic hepatitis C virus (HCV) infection as well as determine duration and dosage of therapy. The LiPA assay analyzes variations in the 5’ untranslated region (5’ UTR) and core region to improve accuracy and provide more precise distinction between subtypes 1a and 1b and 6 (c-I).

- HCV infection is a serious public-health problem, with an estimated 150 million people infected worldwide. (<http://www.who.int/mediacentre/factsheets/fs164/en/>).
- Highly efficacious HCV treatment regimens including direct antiviral agents (DAA) are now available. These regimens can lead to a high rate of cured infections.†
- Treatment regimens are not effective on all HCV genotypes. Therefore, the HCV genotype must be assessed prior to treatment initiation.†
- Effective genotyping must be performed with an assay that accurately discriminates subtype 1a from 1b.†



†EASL clinical practice guidelines: Recommendations on the treatment of hepatitis, 2015.

Flexible laboratory solutions—only from Siemens Healthcare.



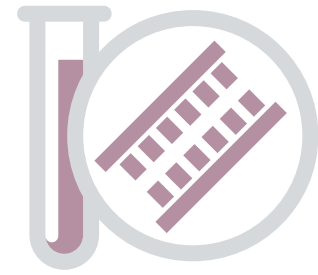
1 Extraction

High-quality RNA for genotyping.



Flexible Extraction Options

- Manual or automated extraction
- Efficient automated extraction using the VERSANT kPCR Sample Prep Module



2 Amplification

Easy-to-use, one-step RT-PCR master mix configuration amplifies HCV targets.



Amplification and Detection Flexibility

- Adaptable to most laboratory-validated thermal cyclers
- Simultaneous amplification of HCV 5' UTR and core region for accurate detection of genotypes 6 (c-I) and subtypes 1a vs. 1b



3 Genotyping

Trusted reverse hybridization technology using 22 genotype- and subtype-specific probes.



Scalable Strip Processing

- Manual processing
- Automated AutoBlot 3000H Genotyping Instrument (delivers up to 20 samples per run)
- Automated Auto-LiPA 48 Genotyping Instrument (delivers up to 48 samples per run)



4 Interpretation

Genotype and subtype determined from the band pattern using an interpretation chart.



Result Interpretation Options

- Visual or software-based interpretation of results
- Easy-to-use interpretation chart
- Multiple software features and bidirectional LIS compatibility for management of results data



VERSANT kPCR Sample Preparation (SP) Module^{‡1}



VERSANT kPCR Amplification Detection (AD) Module^{‡1}



AutoBlot 3000H Genotyping Instrument



Auto-LiPA 48 Genotyping Instrument



LiPA-Scan Software

[‡]Under development and not for sale in the U.S.
¹Use of VERSANT kPCR SP and AD Modules are not presently validated for use with LiPA HCV Assay by Siemens.

Perform HCV genotyping and subtyping with greater accuracy.

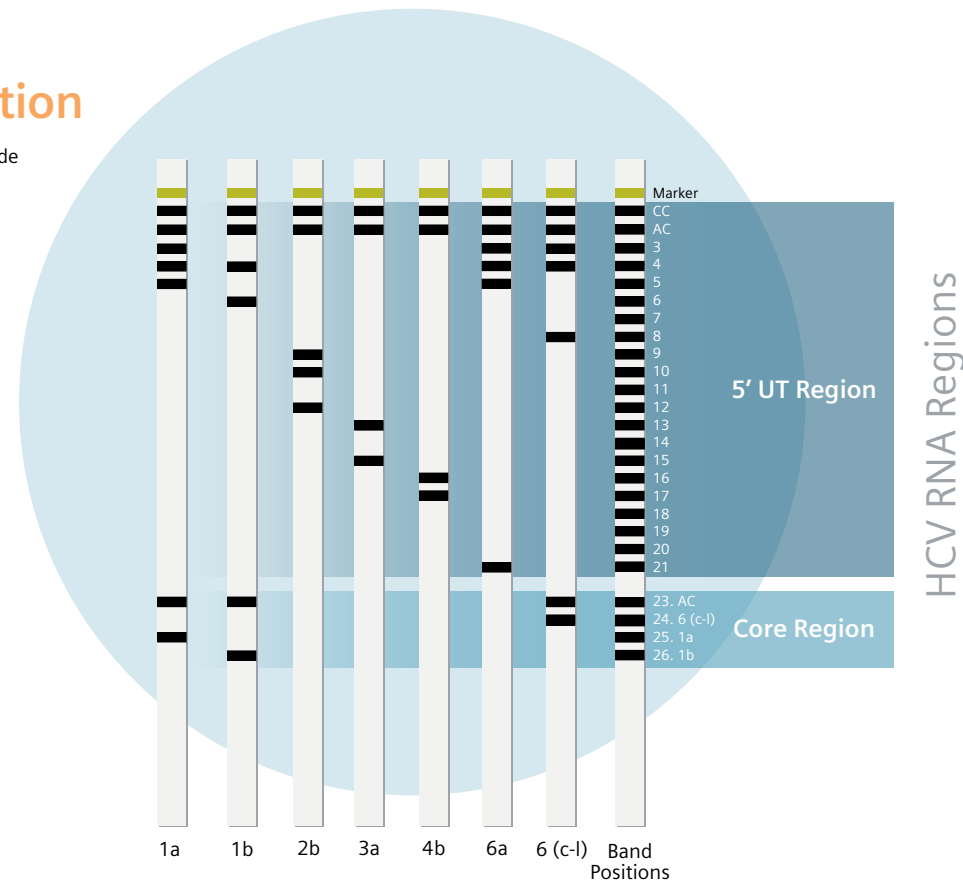
Proven technology, optimized assays.

Based on sequences from the core region and the 5' UTR, the VERSANT HCV Genotype 2.0 Assay (LiPA) uses trusted reverse hybridization technology to provide accurate identification of HCV genotype- and subtype-specific data for optimal patient therapy.

- Identification of more than 15 different subtypes
- Analysis of 5' UTR and core regions
- Highly accurate differentiation of subtypes 1a vs. 1b
- Easy-to-use interpretation chart

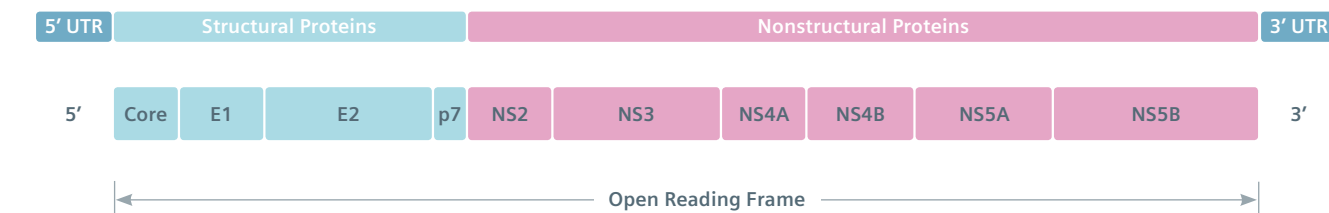
Interpretation

VERSANT LiPA Strips provide convenient and easy interpretation.



Hepatitis C Viral RNA Genome

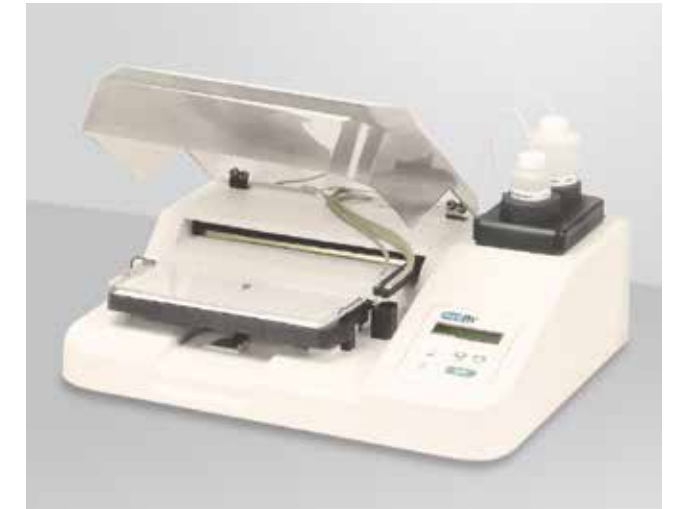
Target: HCV 5' UTR and Core Region



Optimize your HCV testing efficiency with LiPA.



Auto-LiPA 48 Genotyping Instrument



AutoBlot 3000H Genotyping Instrument

High Volume

Low to Mid Volume

Ordering Information			
	Catalog No.	Product	No. of Tests
Systems	10313066	Auto-LiPA 48 Genotyping Instrument	48 Tests/Run
	10315618	AutoBlot 3000H Genotyping Instrument	20 Tests/Run
	10325050	VERSANT HCV LiPA 2.0 Amplification Kit	40 Tests
	10325052	VERSANT HCV LiPA 2.0 Genotype Kit	40 Tests
	10325051	VERSANT HCV LiPA 2.0 Control Kit	6 Vials
Software and Scanner	10697641	LiPA-Scan Software CD	1 Unit
	10322207	Scanner, LiPA-Scan-verified (110 V)	1 Unit

Siemens Healthcare offers laboratories a complete and flexible HCV genotyping solution matched to your testing volume.

Take the Next Step

Contact your local Siemens representative to learn more or visit www.siemens.com/molecular.