



DEEPCHEK®-HCV ASSAYS & SOFTWARE

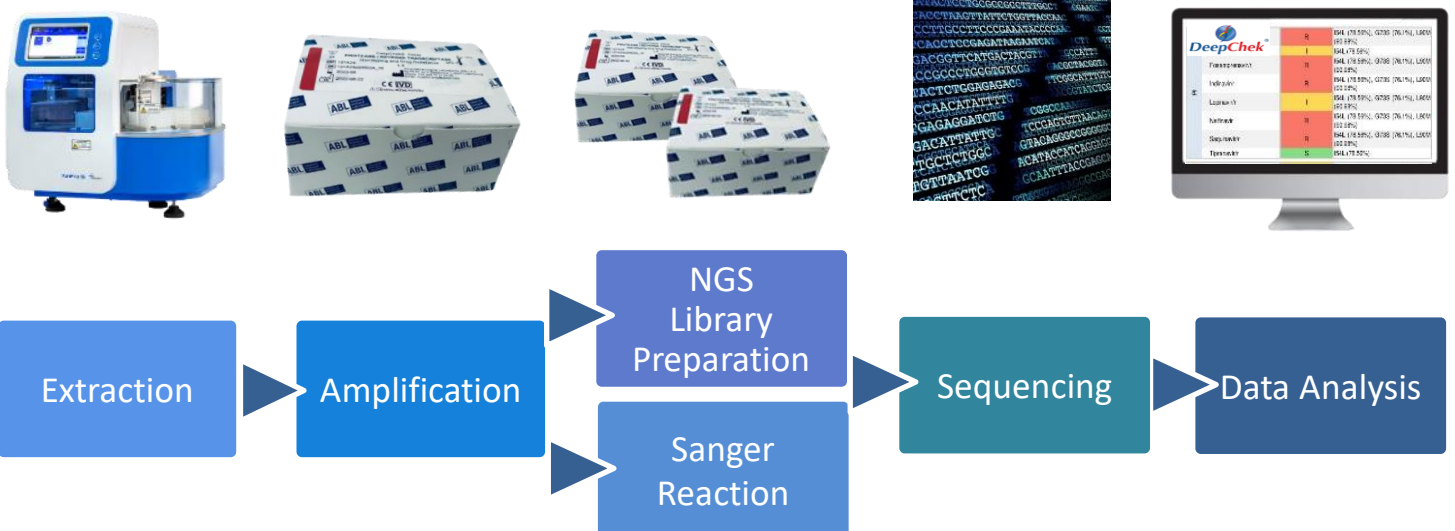
NS3 - NS5A - NS5B – Core - 5' UTR

A unique and complete portfolio for HCV genotyping through Sanger & Next Generation (NGS) sequencing

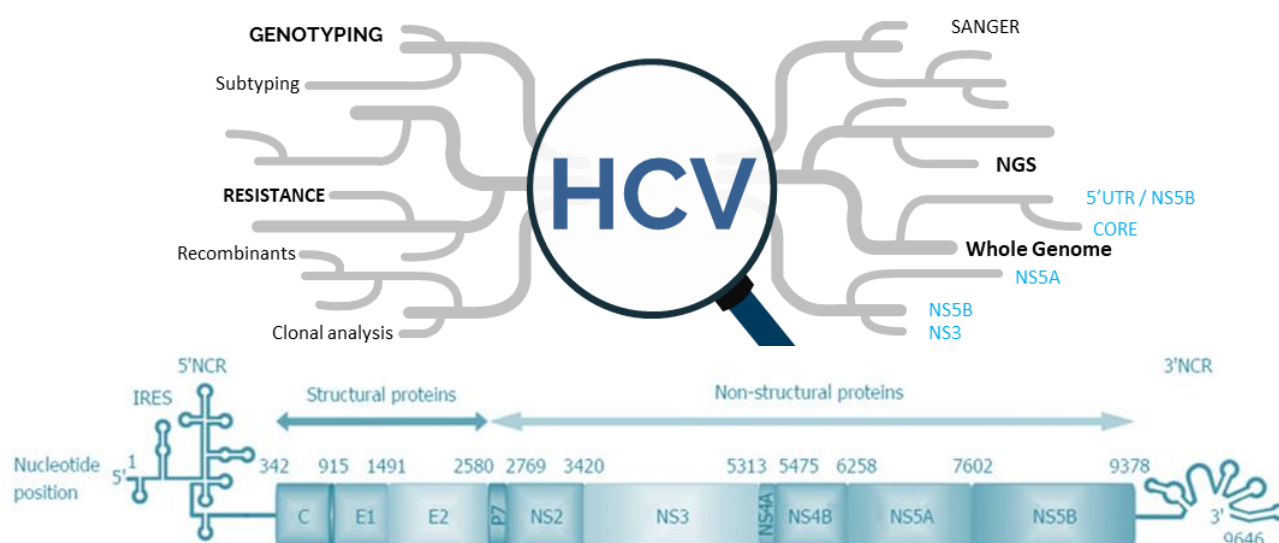
These assays are a unique line of products dedicated to HCV Genotyping and resistance determination through Sanger and NGS sequencing.

- DeepChek®-HCV NS5B + 5'UTR Genotyping Assay V3
- DeepChek®-HCV NS5A DR Assay V1
- DeepChek®-HCV NS5B + 5'UTR Genotyping Assay V2.x
- DeepChek®-HCV NS3 Genotyping and DR Assay V1
- DeepChek®-HCV Core Genotyping Assay V1
- DeepChek®-HCV NS5B Genotyping and DR Assay V4.x

Workflow overview



PRODUCT OVERVIEW



DeepChek®-HCV NS5B + 5'UTR Genotyping Assay V3 (Reference 110C24)

- Viral Hepatitis C (HCV) genotyping and subtyping
- Multiplex
- Including Nested PCR for NS5B
- 5'UTR: 244 bp and NS5B: 1048 bp

DeepChek®-HCV NS5A DR Assay V1 (Reference 105A24)

- HCV genotyping and drug susceptibility of a patient's hepatitis C virus (HCV) to the NS5A inhibitors
- Including Nested PCR
- NS5A: codons 1 to 222

DeepChek®-HCV NS5B + 5'UTR Genotyping Assay V2.x (Reference 110B24)

- Viral Hepatitis C (HCV) genotyping and subtyping
- Multiplex
- 5'UTR: 244 bp and NS5B: 420 bp

DeepChek®-HCV NS3 Genotyping and DR Assay V1 (Reference: 108A24)

- HCV genotyping and drug susceptibility of a patient's hepatitis C virus (HCV) to the NS3 inhibitors
- Including Nested PCR
- NS3: codons 1 to 206

DeepChek®-HCV Core Genotyping Assay V1 (Reference 109A24)

- Viral Hepatitis C (HCV) genotyping and subtyping
- Core: 463 bp

DeepChek®-HCV NS5B Genotyping and DR Assay V4.x (Reference: 107D24)

- HCV genotyping and drug susceptibility of a patient's hepatitis C virus (HCV) to the NS5B inhibitors
- Including Nested PCR
- NS5B: codons 1 to 579



HIGHLIGHTS

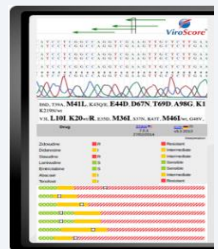
- **TARGET-SPECIFIC AMPLIFICATION** (24 samples/kit)
 - Validated on all genotypes (pangenotypic)
 - Sensitivity: 1000 UI/mL from 400 µL plasma/serum
 - Reproducibility >99%
 - **PCR instruments also available through reagent rental**



- **SEQUENCING**
 - For **Sanger & Next Generation Sequencing (NGS)**
 - SANGER: DeepChek® SANGER Sequencing Assay
 - NGS: DeepChek® Library Preparation Assays (incl. 24/48/96/384 indexes)
 - **Sanger & NGS sequencing devices also available through reagent rental**



- **DATA ANALYSIS**
 - Sequencing analysis and interpretation with **CE-IVD** software
 - Sanger (AB1, FASTA) & NGS (FASTA/FASTQ - including paired sequencing, BAM/SAM)
 - Target specific data (5'UTR, NS5B, CORE, NS3, NS5A)
 - Chromatogram editor integrated
 - High resolution subtyping, amino-acid mutations detection, nucleotide changes detection
 - Drug resistance assessment (for NS3, NS5A and NS5B inhibitors) from several up-to-date guidelines
 - Complete and comprehensive reporting
 - Hosting: On premise (local servers) or Cloud (including Health Data Hosting compliance)
 - **Servers also available through reagent rental**



- **EXTRACTION (KITS & INSTRUMENTS)**
 - Manual or automated
 - Optimized magnetic beads for fast extraction
 - Easy to prepare and very good performance
 - Fast Protocol : 96 samples within 24 minutes
 - **Extraction instrument also available through reagent rental**



- **AUTOMATION**
 - Pipetting robot – open system to be used for pre- or post-PCR automation
 - IT Services (customization, data import, integration / LIS connectivity ...)
 - **Pipetting Robot also available through reagent rental**



HIGHLIGHTS on the DeepChek® technology

ROBUST
CE-IVD and RUO

FLEXIBLE
For low to high
throughput (1-384
samples in one run)

FAST
~1-2 days (SANGER)
~2-4 days (NGS)

STANDARDIZED
Kits, Software, Support,
Integration with
LIMS/HIS, Automation

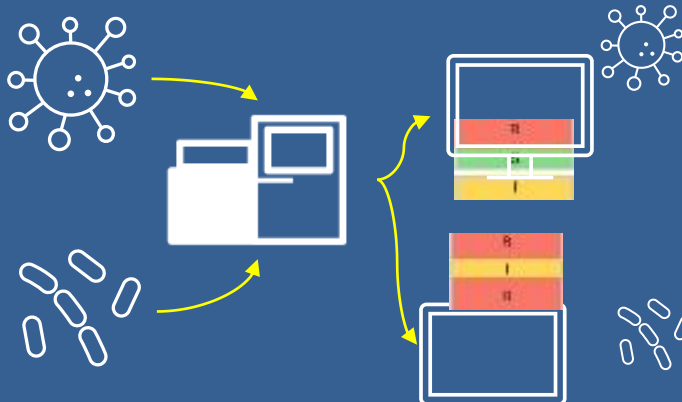
COMPREHENSIVE
Genotyping, Drug
Resistance, Tropism,
Reporting, Storage...

SECURED
Healthcare Cloud Access,
Local installation

COST EFFECTIVE

POOLING CAPACITY

*Pool several
DeepChek®
Libraries (samples)
from different
applications in the
same NGS run*



- HIV
- SC2
- TB
- HCV
- HBV
- CMV
- HSV
- 16s RNA
- HPV
- BKV
- ...

REPORTING



Position	Mutation	20.00%	10.00%	5.00%	1.00%	Prevalence %
13	C<=>S					2.35
17	T<=>S					99.13
20	A<=>R					99.3
36	F<=>I					1.85
37	F<=>L					80.93
43	Y<=>H					33.78
44	K<=>R					99.48
54	Q<=>H					8.61
76	K<=>R					1.12
78	K<=>G					1.69
85	K<=>R					98.02
87	T<=>A					7.61
92	A<=>T					1.38
93	Y<=>H					1.1
103	A<=>T					2.37
105	N<=>S					1.33
113	V<=>A					2.22
114	A<=>G					1.94
116	E<=>G					1.94
117	E<=>G					1.94
118	V<=>G					4.11
119	V<=>A					1.94
120	V<=>G					2.05
121	V<=>G					3.23
122	T<=>R					1.48
123	R<=>G					0.76
124	V<=>A					1.24
125	D<=>G					8.26

Position	Mutation	20.00%	10.00%	5.00%
13	C<=>S			
17	T<=>S			
20	A<=>R			
36	F<=>I			
37	F<=>L			
43	Y<=>H			
44	K<=>R			
54	Q<=>H			
76	K<=>R			
78	K<=>G			

Genotype		Subtype	
Name	Prevalence (3)	Name	Prevalence
1	82.83%	a	81.69%
3	15.55%	c	1.14%



ABL

Advanced
Biological
Laboratories

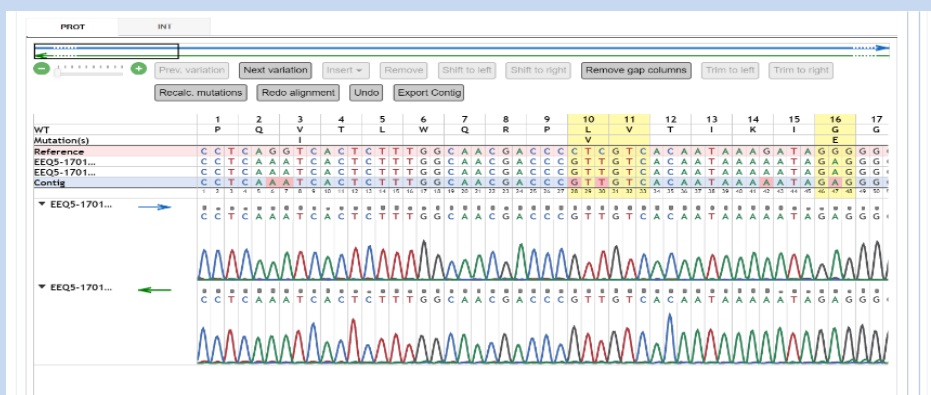
Diagnostics

Improving Disease Management



KEY FEATURES

EMBEDDED CHROMATOGRAM EDITOR

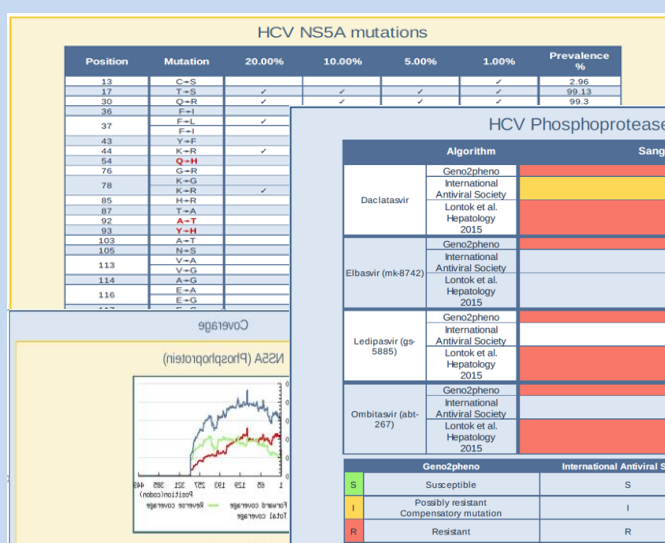


HIGH RESOLUTION SUBTYPING

NS5B (Polymerase)					
Genotype		Subtype			
Name	Prevalence (3)	Name	Prevalence	Number of reads	Confidence (1)
1	82.83%	a	81.69%	52169	100%
3	15.55%	c	1.14%	728	100%
		a	15.55%	9933	100%

5'-UTR					
Genotype		Subtype			
Name	Prevalence (3)	Name	Prevalence	Number of reads	Confidence (1)
1	82.87%	a	81.71%	52236	100%
		c	1.17%	745	100%
3	15.55%	a	15.55%	9938	100%

MUTATION DETECTION DRUG RESISTANCE ASSESSMENT



OTHER FEATURES



Technology

- Web-based (browser only)
- Software & database
- Local or Cloud (+HDS) hosting
- Unlimited user accounts
- Unlimited analyses



Security

- Data access restriction (pools, read-only mode...)
- Logging of user accesses
- Encrypted database
- Reports validation



Main features

- SANGER data management (AB1, FASTA) with embedded chromatogram editor
- NGS data management (FASTQ) with dedicated pipeline
- Manual or automated base calling
- Variant calling
- Genotyping (per sample & cumulative)
- Subtyping
- Virtual-phenotyping
- Drug resistance through up-to-date guidelines
- Reporting & labelling



Additional features

- Report customization
- Contamination check
- Quality control
- Export (reports, FASTA, XML...)
- Batch mode analysis
- Data mining



Services

- Constant updates
- Annual upgrades (versions)
- Historical data import
- LIMS integration
- HIS integration
- Support
- Trainings

REFERENCES & CONTACT

Product

DeepChek® Assays

- DeepChek® Assay NS5B / 5'UTR Genotyping V2.x
- DeepChek® Assay NS5B / 5'UTR Genotyping V3
- DeepChek® Assay HCV-CORE Genotyping V1.x
- DeepChek® Assay NS5A Genotyping and Drug Resistance V1.x
- DeepChek® Assay NS5A (GT2) Drug Resistance V1
- DeepChek® Assay NS3 Genotyping and Drug Resistance V1.x
- DeepChek® Assay NS5B Genotyping and Drug Resistance V4.x

General Laboratory Products

- DeepChek® SANGER SEQUENCING REACTION V2 (24rx/48rx)
- DeepChek® NGS LIBRARY PREPARATION V1 (24 indexes)
- DeepChek® NGS LIBRARY PREPARATION V1 (48 indexes)
- DeepChek® NGS LIBRARY PREPARATION V1 (96 indexes)
- DeepChek® NGS LIBRARY PREPARATION V1 (384 indexes)
- DeepChek® NGS Clean-up beads (60mL)
- DeepChek® 96x0.2 mL well plate (25 units)

Software

- DeepChek® - HCV Software (CE-IVD) Licence
- DeepChek® - HCV Software (CE-IVD) Module

Reference

- 110B24
- 110C24
- 109A24
- 105A24
- 106A24
- 108A24
- 107D24
- 123A24/123A48
- 116B24+124B24
- 116B48+124B48
- 116B96+124B96
- 116B384+124B384
- N411-02
- B70501-01
- S-12-023 (CL)
- S-12-023 (CM)

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