



DEEPCHEK[®]-HCV ASSAYS & SOFTWARE

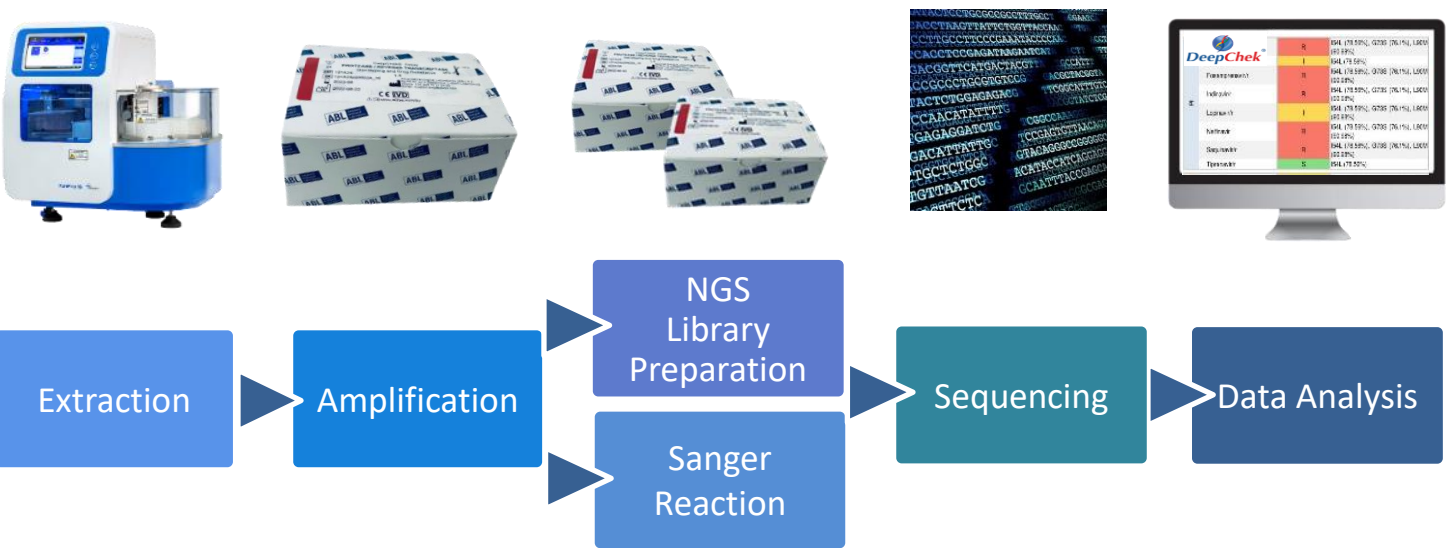
NS3 - NS5A - NS5B – Core - 5' UTR

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

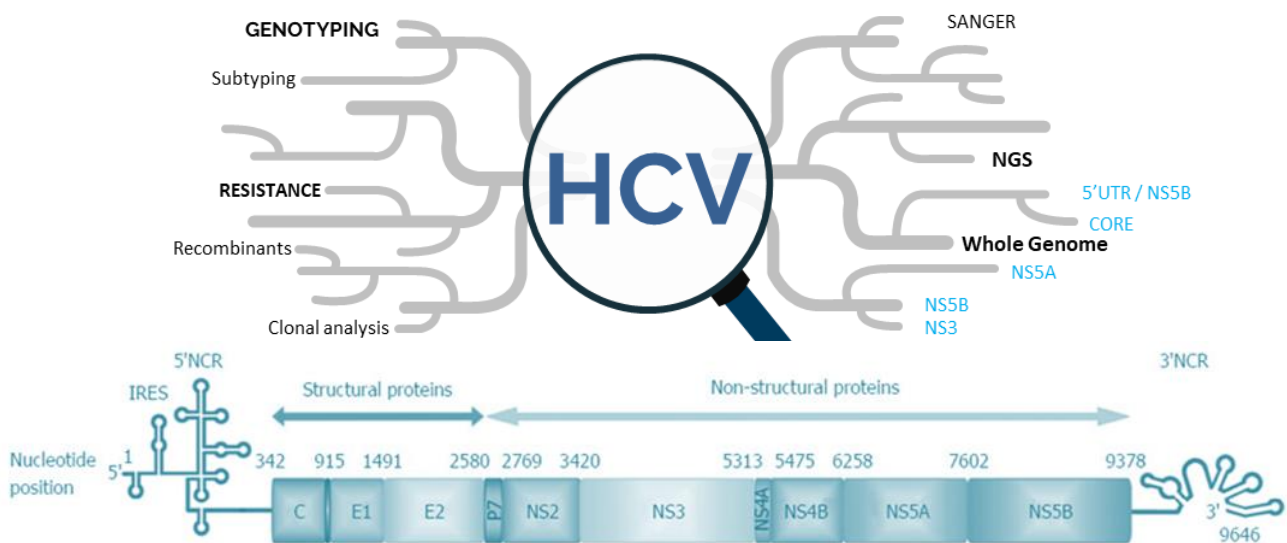
These assays are a unique line of products dedicated to HCV Genotyping and resistance determination through Sanger and NGS sequencing.

- 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

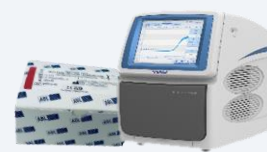
DeepChek®-HCV NS5B Genotyping and DR Assay V4.x (Reference: 107D24)

- 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

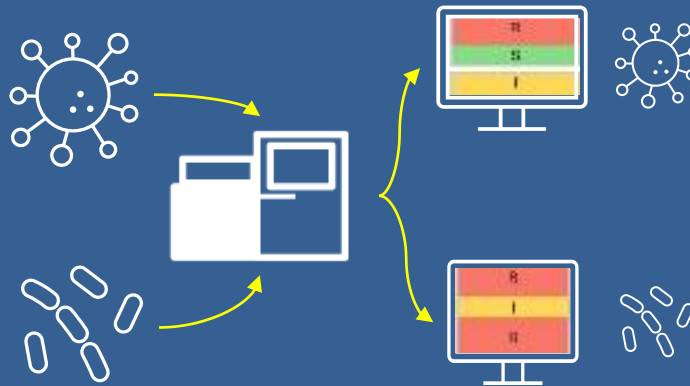
COMPREHENSIVE
Genotyping, Drug
Resistance, Tropism,
Reporting, Storage...

SECURED
Healthcare Cloud Access,
Local installation

POOLING CAPACITY

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

COST EFFECTIVE



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

REPORTING



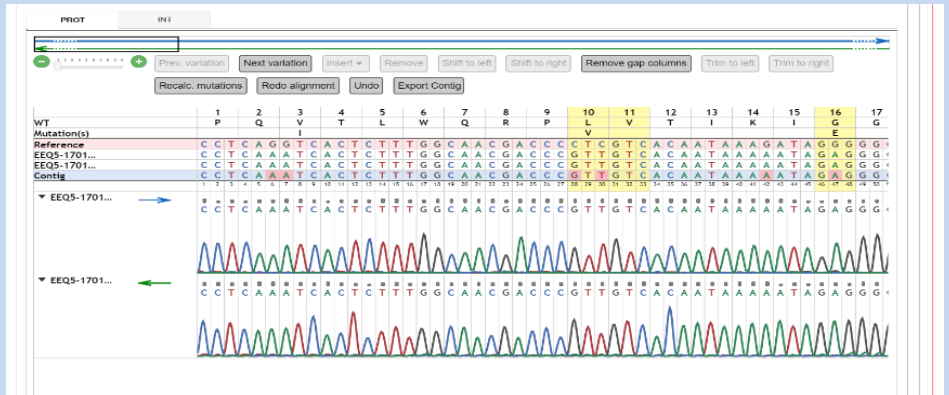
HCV NS5A mutations						
Position	Mutation	20.00%	10.00%	5.00%	1.00%	Prevalence %
13	C>S					7.25
17	V>S	✓				99.13
30	V>R	✓	✓	✓	✓	99.3
36	F>I					1.85
37	F>L					80.51
43	Y>F		✓	✓	✓	13.78
44	K>R	✓	✓	✓	✓	99.48
54	Q>H					8.81
76	K>S					1.12
78	K>G					1.95
85	H>R	✓	✓	✓	✓	99.02
87	T>A					7.51
92	A>T					1.36
93	T>A					1.81
103	A>T					2.37
105	H>S					1.05
113	V>A			✓	✓	2.22
114	A>S					1.94
116	E>A					1.11
116	E>G					1.94
117	E>S					3.98
118	V>S					4.11
119	V>A					1.11
120	V>S					2.01
120	E>G					7.85
121	V>S					2.21
121	V>I					9.45
122	T>R			✓	✓	1.46
123	R>G					6.76
124	V>A					1.24
125	V>S					1.25
126	D>G					8.25

HCV NS5A mutations				
Position	Mutation	20.00%	10.00%	5.00%
13	C>S			
17	V>S	✓		
30	V>R	✓	✓	✓
36	F>I			
37	F>L			
43	Y>F		✓	✓
44	K>R	✓	✓	✓
54	Q>H			
76	K>S			
78	K>G			
85	H>R	✓	✓	✓
87	T>A			
92	A>T			
93	T>A			
103	A>T			
105	H>S			
113	V>A			✓
114	A>S			
116	E>A			
116	E>G			
117	E>S			
118	V>S			
119	V>A			
120	V>S			
120	E>G			
121	V>S			
121	V>I			
122	T>R			✓
123	R>G			
124	V>A			
125	V>S			
126	D>G			



KEY FEATURES

EMBEDDED
CHROMATOGRAM
EDITOR

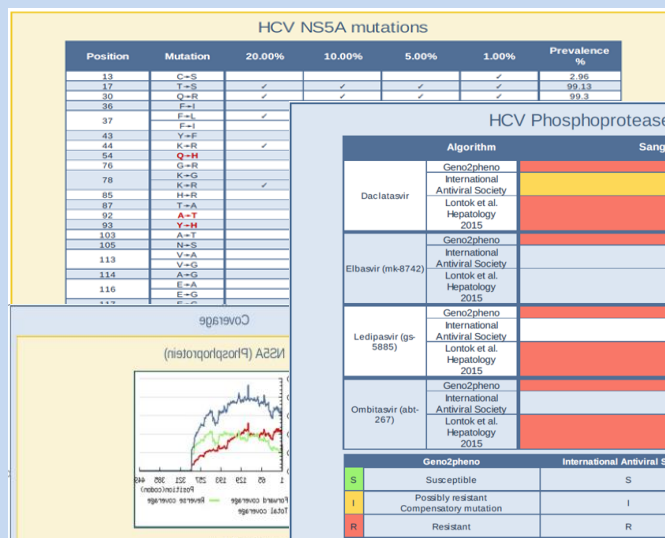


HIGH RESOLUTION
SUBTYPING

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



HCV Phosphoprotease Inhibitors																				
Algorithm	Sanger based sequencing																			
	Geno2pheno	International Antiviral Society	Lontok et al. Hepatology 2015																	
Daclatasvir	Geno2pheno	International Antiviral Society	Lontok et al. Hepatology 2015	R																
	Geno2pheno	International Antiviral Society	Lontok et al. Hepatology 2015	I																
	Geno2pheno	International Antiviral Society	Lontok et al. Hepatology 2015	R																
Elbasvir (mk-8742)	Geno2pheno	International Antiviral Society	Lontok et al. Hepatology 2015	NA																
	Geno2pheno	International Antiviral Society	Lontok et al. Hepatology 2015	NA																
	Geno2pheno	International Antiviral Society	Lontok et al. Hepatology 2015	NA																
Ledipasvir (gs-5885)	Geno2pheno	International Antiviral Society	Lontok et al. Hepatology 2015	R																
	Geno2pheno	International Antiviral Society	Lontok et al. Hepatology 2015	NA																
	Geno2pheno	International Antiviral Society	Lontok et al. Hepatology 2015	R																
Ombitasvir (abt-267)	Geno2pheno	International Antiviral Society	Lontok et al. Hepatology 2015	R																
	Geno2pheno	International Antiviral Society	Lontok et al. Hepatology 2015	NA																
	Geno2pheno	International Antiviral Society	Lontok et al. Hepatology 2015	R																
<table border="1"> <thead> <tr> <th></th> <th>Geno2pheno</th> <th>International Antiviral Society</th> <th>Lontok et al. Hepatology 2015</th> </tr> </thead> <tbody> <tr> <td>S</td> <td>Susceptible</td> <td>S</td> <td>S</td> </tr> <tr> <td>I</td> <td>Possibly resistant Compensatory mutation</td> <td>I</td> <td>I</td> </tr> <tr> <td>R</td> <td>Resistant</td> <td>R</td> <td>R</td> </tr> </tbody> </table>						Geno2pheno	International Antiviral Society	Lontok et al. Hepatology 2015	S	Susceptible	S	S	I	Possibly resistant Compensatory mutation	I	I	R	Resistant	R	R
	Geno2pheno	International Antiviral Society	Lontok et al. Hepatology 2015																	
S	Susceptible	S	S																	
I	Possibly resistant Compensatory mutation	I	I																	
R	Resistant	R	R																	



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



Additional features

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



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



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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Laboratories

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Improving Disease Management