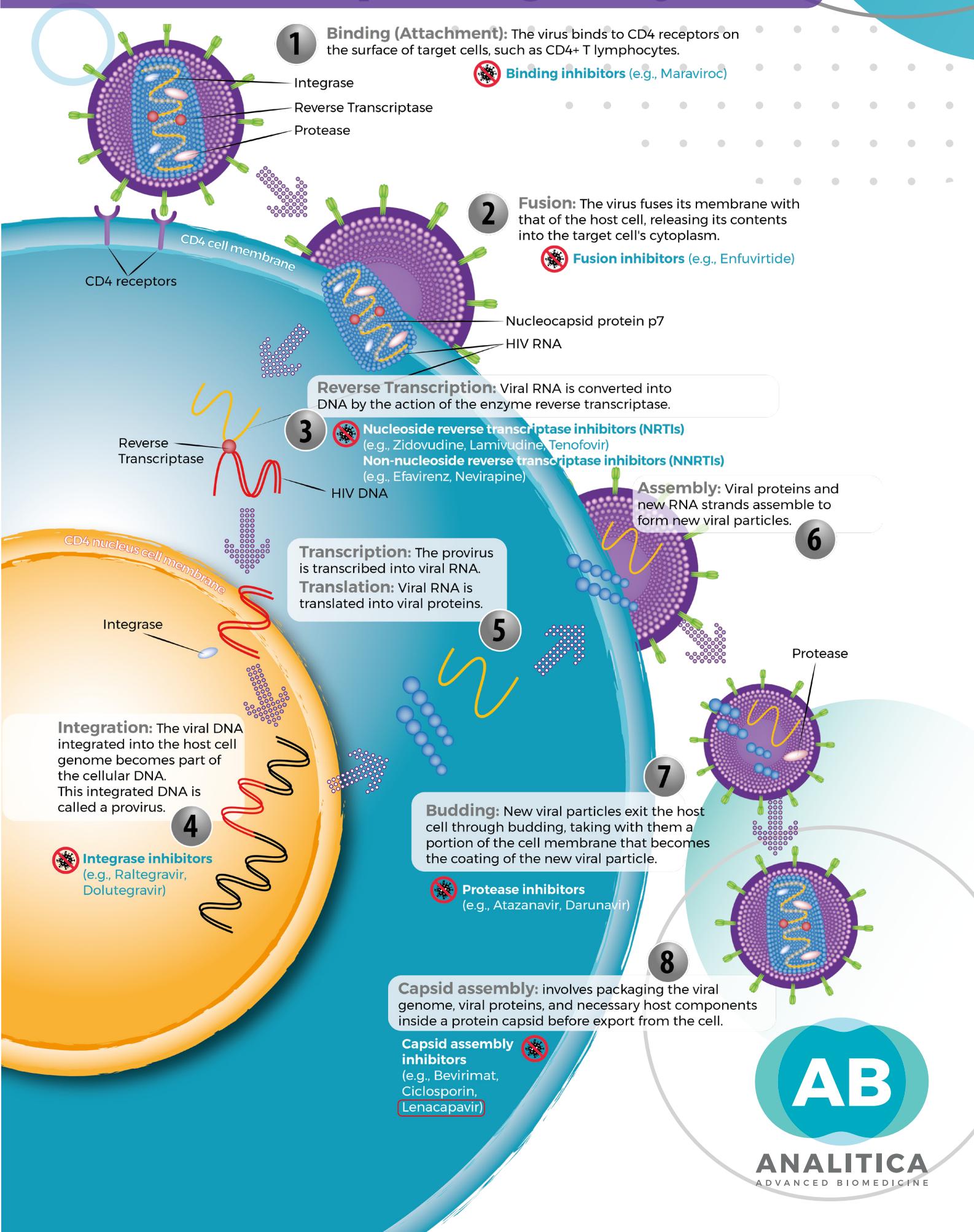


DeepChek® HIV Genotyping & Drug Resistance Sequencing Assays



NGS DeepChek® HIV Genotyping & Drug Resistance Assays Targeting

DEEPCHEK® Software Meets all clinical needs



Features:

- CE-IVD.
 - For both Capillary Sanger (chromatogram editor integrated) and Next Generation Sequencing NGS genetic analyzers.
 - Database / storage.
 - Report customization.
 - Historical data import.
 - HdS Cloud - Highest degree of isolation and data protection, including compliance with ISO 27001 and General Data Protection Regulation (GDPR) requirements.
 - Hosting: Local servers or Cloud (including Health Data Hosting compliance).
 - Access for an unlimited number of users.
 - Annual license with unlimited number of analyses.

Returned information:

- Major & Minor variants detection.
 - Genotyping, Drug resistance and Tropism interpretation.
 - Complete and comprehensive clinical genotyping report.
 - Cumulative and Longitudinal genotyping report.
 - APOBEC mutations detection.
 - Viral or bacterial drug resistance.
 - Vaccine escape and disease prognosis.
 - Viral genotype.
 - Useful for tailoring patient's antiviral or antibacterial drugs based on the virus or bacteria sensitivity level.

DEEPCHEK® HIV Software

Sanger
Clinical genotyping

ABI	Advanced Biological Instrumentation	
Patient/Sample information		
Your patient ID	Analysis RT-PROT	Type of report Initial
Patient name	Christopher	Report date 06/05/2024, 15:13:12
Patient birth date	Type of sample Plasma	Report version 1.3.5
Patient viral load	Date of sample 06/05/2024	Date format dd/mm/yyyy
Your sample ID DEMO_SANGER		
All Mutations Detected (HIVdb reference Sequence) Resistance mutations in bold on HIVdb v8.5 (mutation score ≠ 0)		
Regions	Date of sequencing	Genotyping method
RT	06/05/2024	R8K, K104R, E122K, D123S, S162H, D177E, R211K, L214F, T215F
PROT	06/05/2024	V3I, L19I, E35D, S37N, U8P
Mutations		
Genotypic Interpretation (HIVdb-9.5)		
Class	Drug	HIVdb 9.5 3-2024
NRTI	Zidovudine █ R	T215F
	Didanosine █ I	T215F
	Stavudine █ I	T215F
	Lamivudine █ S	
	Emtricitabine █ S	
	Abacavir █ S	T215F
NNRTI	Tenofovir █ S	T215F
	Nevirapine █ S	
	Efavirenz █ S	
	Etravirine █ S	
	Rilpivirine █ S	
PI	Doravirine █ S	
	Indinavir █ S	
	Saquinavir █ S	
	Nelfinavir █ S	
	Fosamprenavir █ S	
	Lopinavir █ S	
	Atazanavir █ S	
	Tipranavir █ S	
	Darunavir █ S	
HIVdb 9.5		
█ S	Susceptible (S) / Potential low-level resistance (PLR)	
█ I	Low-level resistance (LLR) / Intermediate resistant (IR)	
█ R	High-level resistance (HLR)	
Comments	Region	Comments
	RT	► T215Y/F are TAMs that causes intermediate/high-level resistance to AZT and potentially low-level resistance to ABC
		and TDF.

NGS
Clinical genotyping

Patient / Sample information		Sample		Physician / Project Information	
Patient ID		Alternative ID	Date Collected	Name	Project ID
Name			06/05/2024	Insitution	
DOB			Date Reported	Address	
Gender			06/05/2024		
Sample ID		Specimen Type	Software version		
Sample type			2.0		
			Expert system		
SUBTYPEING [Local similarity testing]					
PROT	02_AG (98.32 %)	RT	G (92.35 %)	PROT	1-99
INT	25_CPV (95.15 %)			INT	45-284
Using distance determined through homology testing of a 20% consensus sequence generated from all the reads mapped in the sample right and wrong or intransigent.					
HIVDR 9.6 drug resistance assessment >3.00%					
Generic name		Assessment		DRMs	
Atazanavir/r		S			
Darunavir/r		S			
Fosamprenavir/r		S			
Indinavir/r		S			
Lopinavir/r		S			
Nelfinavir		S			
Saquinavir/r		S			
Tipranavir/r		S			
Abacavir		I	M184V (99.73%), T215F (91.35%)		
Didanosine		I	M184V (99.73%), T215F (91.35%)		
Emtricitabine		R	M184V (99.73%), T215F (91.35%)		
Lamivudine		R	M184V (99.73%), T215F (91.35%)		
Stavudine		I	M184V (99.73%), T215F (91.35%)		
Tenovudine		S	M184V (99.73%), T215F (91.35%)		
Zidovudine		I	M184V (99.73%), T215F (91.35%)		
Doravirine		R	A98G (99.44%), Y108I (90.91%), Y181C (99.06%), G190A (6.13%), H221Y (92.4%)		
Elavirentz		R	A98G (99.44%), Y108I (90.91%), Y181C (99.06%), G190A (6.13%), H221Y (92.4%)		
Efavirenz		R	A98G (99.44%), Y108I (90.91%), Y181C (99.06%), G190A (6.13%), H221Y (92.4%)		
Etravirine		R	A98G (99.44%), Y108I (90.91%), Y181C (99.06%), G190A (6.13%), H221Y (92.4%)		
Nevirapine		R	A98G (99.44%), Y108I (90.91%), Y181C (99.06%), G190A (6.13%), H221Y (92.4%)		
Rilpivirine		R	A98G (99.44%), Y108I (90.91%), Y181C (99.06%), G190A (6.13%), H221Y (92.4%)		
Bictegravir		S	E138K (3.67%)		
Cabotegravir		I	E138K (3.67%)		
Dolutegravir		S	E138K (3.67%)		
Elvitegravir		I	E138K (3.67%)		
Raltegravir		I	E138K (3.67%)		
S	Susceptible (S) Potential low-level resistance (PLLR)	I	Low-level resistance (LLR) Intermediate resistant (IR)	R	High-level resistance (HLR)
* The following DRMs could reflect APOBEC activity (> 3.00%).					
INT	E138K (3.67%)				

Cumulative Clinical genotyping

DeepChek®

ABL
Advanced
Laboratory

Patient/Sample information

Your patient ID 1 sample nested

Patient

Analysis RT-PROT

Type of report Initial

Patient birth date

Clinician name

Report date 06/05/2024,15:18:49

Genotyping method

Report version 13.6

CUMULATIVE & HISTORY REPORT - VIROSCORE PLUS (Mutations based)

Your sample ID	Type of sample	Date of sample	Date of sequencing
POSITIVE CONTROL 1 fasta	Plasma	14/06/2023	
sample 1 nested	Plasma	14/06/2023	

All Mutations Detected (HXB2 reference Sequence) Resistance mutations in bold based on HIVdb v5.5 (mutation score > 0)

Regions	RT	Genotyping method	Mutations
	/	/	L102W, P14S, M16I, E20A, S48T, V60I, R83K, K104R, T107S, I122P/Y, D123G, I135T, S162H, D171E, R211K, L214F, T215F
	/	/	V31, T125, K14M, L19Q/I, E35D, S37N, L63P, V77I, Q92W/H, I93L, G94V/wt, T96P/wt

Genotypic Interpretation (ANRS-35, HIVdb-9.8)

Class	Drug	ANRS 35 4-2024	HIVdb 9.8 3-2024
NRTI	Zidovudine	■ R	■ R
	Didanosine	■ Not available	■ I
	Stavudine	■ Not available	■ I
	Lamivudine	■ R	■ R
	Emtricitabine	■ R	■ R
	Abacavir	■ I	■ I
NNRTI	Tenofovir	■ S	■ S
	Nevirapine	■ S	■ S
	Efavirenz	■ S	■ S
	Etravirine	■ S	■ S
	Rilpivirine	■ S	■ S
PI	Doravirine	■ S	■ S
	Indinavir	■ Not available	■ S
	Saquinavir	■ Not available	■ S
	Nelfinavir	■ Not available	■ S
	Fosamprenavir	■ Not available	■ S
	Lopinavir	■ S	■ S
	Atazanavir	■ S	■ S
	Tipranavir	■ Not available	■ S
	Danavir	■ Not available	■ S
	Darunavir 600-100 mg BD	■ S	■ Not available
	Darunavir 800-100 mg QD	■ S	■ Not available

ANRS

FR

HIVdb

US

S

I

R

Sensitive

Possible resistance

Resistance

Susceptible (S) / Potential low-level resistance (PLR)

Low-level resistance (LLR) / Intermediate resistant (IR)

High-level resistance (HLR)

Comments

Longitudinal Clinical genotyping

		Analysis:		Compare DC Report						
		Technique:	MicrobioChek Tools (RUO) - Compare DC, ABL							
		Patient:	Test Test							
		Status:	Not reviewed							
Genotypic interpretation										
STAN 9.6										
Class	Drug	PosF 06/05/2024	DNA3 06/05/2024	Echitarin5 06/05/2024						
INTI	Bictegravir	●	●	●						
	Cabotegravir	○	●	●						
	Dolutegravir	○	●	●						
	Elvitegravir	○	●	●						
	Raltegravir	○	●	●						
INHATI	Doravirine	●	●	●	→					
	Efavirenz	●	●	●	→					
	Etravirine	●	●	●	→					
	Nevirapine	●	●	●	→					
	Rilpivirine	●	●	●	→					
INHATI	Lamivudine	●	●	●						
	Abacavir	●	●	●						
	Zidovudine	●	●	●						
	Stavudine	●	●	●						
	Didanosine	●	●	●						
IT	Emtricitabine	●	●	●						
	Tenofovir	●	●	●						
	Atazanavir/r	●	●	●	→					
	Darunavir/r	●	●	●	→					
	Fosamprenavir/r	●	●	●	→					
IT	Indinavir/r	●	●	●						
	Lopinavir/r	●	●	●						
	Nelfinavir	●	●	●						
	Saquinavir/r	●	●	●						
	Tipranavir/r	●	●	●						

APOBEC Detection

DeepChek®

ABL Advanced Biologics Laboratories

DeepChek® - HIV Mutation Analysis

HIV Protease mutations

Position	Mutation	15.00%	10.00%	5.00%	Prevalence %	Q-Score
3	V→I	/	/	/	99.81	38
10	L→I	/	/	/	99.68	38
16	G→A	/	/	/	99.43	38
25	D→W	/	/	/	99.45	38
29	E→K	/	/	/	93.85	39
36	M→I	/	/	/	99.71	39
37	S→D	/	/	/	65.39	38
38	S→Y	/	/	/	99.43	38
40	G→E	/ ^(m)	/	/	93.49	39
41	R→K	/	/	/	33.96	39
46	C→T	/ ^(m)	/	/	33.27	38
49	G→E	/	/	/	33.27	38
50	D→E	/	/	/	65.33	39
60	D→K	/	/	/	34.17	39
61	Q→E	/	/	/	99.64	39
63	L→I	/	/	/	99.67	39
67	C→E	/	/	/	66.67	38
69	C→K	/	/	/	32.53	39
77	H→K	/	/	/	99.63	39
78	V→I	/	/	/	99.48	38
89	L→M	/ ^(m)	/	/	32.47	38
					99.8	38

Subtype B **K03455** was used as the reference sequence for the alignment (using BWA v0.7.15 alignment tool).

Mutations of interest based on ANRS 34 (Bold red text)

Insufficient number of sequences to guarantee, at the 99% confidence level, that all mutations w the given threshold frequency have been found at that position. |

(1) The following 3 APOBEC mutations have been detected [$\geq 15.00\%$]:

D25N (33.46%), G40E (33.49%), G78E (32.47%)

(2) The following DRMs could reflect APOBEC activity [$\geq 15.00\%$]:

M46 (33.27%)

DeepChek® - HIV APOBEC activity assessment

The following 25 APOBEC mutations have been detected [$\geq 15.00\%$]

PROT

D25N (33.46%), G40E (33.49%), G78E (32.47%)

RT

E42K (33.26%), W71 (34.54%), E70K (35.23%), W82* (36.02%), G93K (34.44%), D110N (34.73%), W133* (35.16%), D186N (33.94%), G190K (33.06%), W212* (25.04%), B213E (25.74%), E233K (32.37%), D256N (32.06%), G273E (34.43%), E302K (33.46%), E344K (33.03%), G352E (31.58%), D364N (29.4%), E378K (25%), W410* (34.69%), W414* (34.2%)

INT

E28TK (35.45%)

The following 3 DRMs could reflect APOBEC activity [$\geq 15.00\%$]

PROT

M46 (33.27%)

RT

D67N (32.86%), E138K (35.49%)

ALL ANALYSES

Subtyping, Mutations detection, Tropism, Resistance

ALL GUIDELINES
HIVdb, ANRS, HIV Grade,
Geno2Pheno, REGA, ...

ALL DRUGS
NRTI, NNRTI, PI, Integrase Inh,
Entry Inh, Fusion Inh, Capsid Inh

ALL MUTATIONS COVERED

DeepChek® HIV Assays

Quality and Efficiency Redefined



HIV Whole Genome

Capsid resistance assessment (Lenacapavir)



Drug resistance assessment

All classes including new entry & capsid inhibitors



Proviral DNA

Exactly the same workflow and APOBEC mutations detection



98/79/CE (IVDD)

The Whole Genome HIV-1 Genotyping is also CE-IVD certified



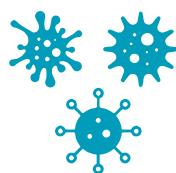
High sensitivity

LoD of 1000 cp/mL (down to 150 cp/mL through dedicated protocols) [V2.x assays]



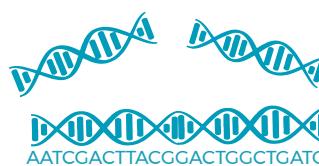
Coverage

9719 bp
High accuracy and reliability
(DeepChek® Whole Genome HIV-1 Genotyping)



Pooling

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



NGS & SANGER

The same kit available for both Sanger and Next Generation Sequencing



Fast library prep.

Extremely fast library preparation protocol for prompt results and reduced manual intervention

Additional assays and reagents for sequencing



DeepChek® Assays - Amplification kits

Target	Assays	Ref. N°	Rxns	Cert.
HCV GT	DeepChek® Assay NS5B / 5'UTR Genotyping V3.x *	110C24	24	RUO
	DeepChek® Assay CORE Genotyping V1.x *	109A24	24	RUO
HCV DR	DeepChek® Assay NS5A Genotyping and Drug Resistance V1.x *	105A24	24	RUO
	DeepChek® Assay NS5A (GT2) Drug Resistance V1.x *	106A24	24	RUO
	DeepChek® Assay NS3 Genotyping and Drug Resistance V1.x *	108A24	24	RUO
	DeepChek® Assay NS5B Genotyping and Drug Resistance V4.x *	107D24	24	RUO
HBV	DeepChek® Assay RT Genotyping and Drug Resistance V1.x *	113A24	24	RUO
	DeepChek® Assay Whole Genome HBV Genotyping V1.x	184A24	24	RUO
HDV	DeepChek® Assay Whole Genome HDV Genotyping V1.x	199A24	24	RUO
HPV	DeepChek® Assay HPV Genotyping V1.x	130A24	24	RUO
RSV	DeepChek® Assay Whole Genome RSV Genotyping V1.x	201A24	24	RUO
CMV	DeepChek® Assay UL54 / UL97 Drug Resistance V1.x	117A24	24	RUO
	DeepChek® Assay UL54 / UL56 / UL97 Drug Resistance V2.x	117B24	24	RUO
HSV	DeepChek® Assay TK / POL Drug Resistance V1.x	119A24	24	RUO
16S	DeepChek® Assay 16S rRNA Bacterial Identification V2.x	131B24	24	RUO
18S	DeepChek® Assay 18S rRNA Fungi Identification V1.x	191A24	24	RUO
TB	DeepChek® Assay 13-Plex KB Drug Susceptibility Testing V1.x	128A24	24	CE-IVD
BKV	DeepChek® Assay Whole Genome BKV Genotyping V1.x	189A24	24	RUO
FluA	DeepChek® Assay Whole Genome Influenza A Genotyping V1.x	192A24	24	RUO
FluA/B	DeepChek® Assay Influenza A/B Genotyping V1.x	193A24	24	RUO
COVID-19	DeepChek® Assay Whole Genome SARS-CoV-2 Genotyping V4.x	159D48	48	RUO

*also applicable for Sanger analysis

Sequencing Reagents

Sequencing	Name	Reference	Pack size	Cert.
Sanger	DeepChek® SANGER SEQUENCING REACTION V1.x	123A24 / 123A48	24 / 48	RUO
	DeepChek® NGS LIBRARY PREPARATION V2.x	116B24 / 116B48 / 116B96 / 116B384	24 / 48 / 96 / 384	RUO
	DeepChek® ADAPTERS V2.x	124B24 / 124B48 / 124B96 / 124B384	(1-24) / (1-48) / (1-96) / (1-384)	RUO
NGS	DeepChek® NGS LIBRARY PREPARATION V3.x	116C24 / 116C96	24 / 96	RUO
	DeepChek® ADAPTERS V3.x	124C24 / 124C96	(1-24) / (1-96)	RUO
	DeepChek® ADAPTERS V4.x	124D24 / 124D96 / 124D384	(1-24) / (1-96) / (1-384)	RUO
	DeepChek® NGS Clean-up beads	N411-01 / N411-02	5mL / 60mL	RUO

The information provided is subject to change without notice.

HIV_NGS_Brochure_e20240708