

PCR Core Labs | NeuMoDx



Streamline your blood-borne virus testing with NeuMoDx

No batching, less waste, 3-step workflow

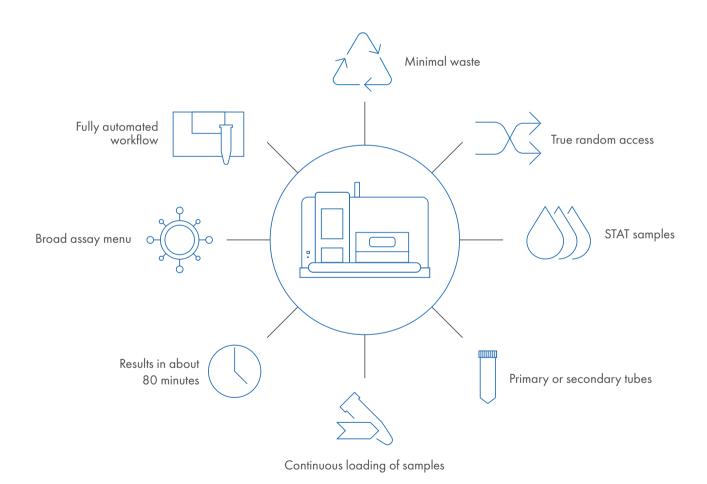
Benefit from a simplified workflow for blood-borne virus testing with NeuMoDx

Every day, millions of patients infected with blood-borne viruses such as HIV and viral hepatitis require routine testing to quantify viral load in order to help assess the need to start, modify or stop antiviral therapy.

The high-throughput NeuMoDx™ platforms utilize innovative microfluidic

technology and proprietary NeuDry™ chemistry to deliver accurate and timely results with an enhanced laboratory workflow.

Consolidate your blood-borne virus testing with other infectious disease assays on a single automated, flexible, random access platform.



NeuMoDx HIV-1, HCV and HBV Quant Assays

NeuMoDx HIV-1 Quant Assay

The NeuMoDx HIV-1 Quant Assay is intended for the quantitation and detection of human immunodeficiency virus type 1 (HIV-1) RNA in human plasma. It can be used as an aid in clinical management of HIV-1 infected patients and monitoring the effects of anti-retroviral treatment, as measured by changes in plasma HIV-1 RNA levels, and as an aid in the diagnosis of HIV-1 infection, including acute or primary infection. The assay includes dual-target amplification and detection, targeting two independent regions of the HIV-1 genome.

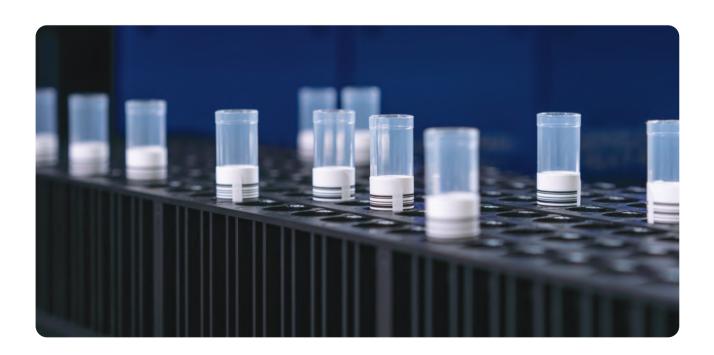
NeuMoDx HCV Quant Assay

The NeuMoDx HCV Quant Assay is intended for the quantitation of hepatitis

C virus (HCV) RNA in human plasma and serum specimens for HCV antibody positive individuals as an aid in the management of patients with HCV infections+. The assay offers reliable accurate detection for HCV genotypes 1 to 6. The NeuMoDx HCV Quant Assay targets two highly conserved regions of the HCV genome to increase the robustness of the assay.

NeuMoDx HBV Quant Assay

The NeuMoDx HBV Quant Assay is intended for the quantitation of hepatitis B virus (HBV) DNA in human plasma and serum specimens for HBV genotypes A through H of HBV-infected individuals. The assay targets highly conserved sequences in the Hepatitis B viral genome.



Intuitive 3-step workflow



Assay design

B, C, D, F, G, H, K, CRF01_AE, CRF02_AG) N, O, and P Standardisation 3rd WHO International Standard 4th WHO International Standard 5th WHO International standard Internal control Yes Yes Yes Validated specimen types Plasma Plasma/Serum Plasma/Serum (EDTA, ACD, or PPT) (EDTA, ACD, PPT or SST) Primary or secondary tubes Yes Yes Yes		HIV-1	HBV	HCV
B, C, D, F, G, H, K, CRF01_AE, CRF02_AG) N, O, and P Standardisation 3rd WHO International Standard 4th WHO International Standard 5th WHO International standard Internal control Yes Yes Yes Validated specimen types Plasma Plasma/Serum (EDTA, ACD, or PPT) (EDTA, ACD, PPT or SST) Primary or secondary tubes Yes Yes Yes Yes	Target regions	Dual (LTR and Integrase)	X protein and preC protein	Dual (UTR)
Internal control Yes Yes Yes Yes Yes Yes Yes Ye	Genotype coverage	B, C, D, F, G, H, K, CRF01_AE,	А-Н	1 to 6
Validated specimen types Plasma (EDTA, ACD, or PPT) Primary or secondary tubes Plasma (EDTA, ACD, PPT or SST) Primary or secondary tubes Plasma/Serum (EDTA, ACD, PPT or SST) Yes Yes	Standardisation	3rd WHO International Standard	4th WHO International Standard	5th WHO International standard
(EDTA, ACD, or PPT) (EDTA, ACD, PPT or SST) (EDTA, ACD, PPT or SST) Primary or secondary tubes Yes Yes Yes	Internal control	Yes	Yes	Yes
	Validated specimen types		•	· · · · · · · · · · · · · · · · · · ·
Sample volume † 600 μ L 550 μ L 550 μ L	Primary or secondary tubes	Yes	Yes	Yes
	Sample volume [†]	600 μL	550 μL	550 μL

[†] Refer to Instructions For Use for low volume claims

Product performance

	HIV-1	HBV	HCV
Limit of Detection	34.2 IU/mL (8.9 cop/mL)	8.0 IU/mL	8.0 IU/mL
Lower Limit of Quantitation	34.2 IU/ml (8.9 cop/ml)	8.0 IU/mL	8.4 IU/mL
Linear range (Log10 IU/mL)	1.5-7.7	0.9 to 9.02	0.9 to 8.2
Time to 1st result	~80 mins	~60 mins	~80 mins

Calibration and Control

QC interval	Every 24 hours	
Calibration interval	90 days	

Innovative technology

The NeuMoDx Molecular Systems integrate robotics with advanced microfluidics to deliver enhanced performance, increased efficiency, and rapid turnaround.



Sample lysis

Dehydrated, room temperature stable components combined with heating of sample provides great efficiency and less waste compared to traditional reagents requiring lyophilization.



Nucleic acid extraction

Patented, universal extraction chemistry uses paramagnetic beads with a patented affinity coating to extract nucleic acids based on charge.



Amplification and detection

Proprietary process for dehydrated, room temperature stable TaqMan PCR reagents maximizes concentration and patented real time SiMS PCR for precise, sensitive automated amplification and detection.



NeuDry reagent chemistry

Ready-to-use, room temperature stable reagents capable of providing long open-shelf life for active reagents used in molecular diagnostic testing. Proprietary NeuDry test strip reagents and consumables are ready to use and room temperature stable, stored or on board.

Patented microfluidic cartridges: capable of performing independent sample processing and real-time PCR

- 12 lane NeuMoDx microfluidics cartridge
- Real time, multicolor PCR and RT-PCR
- Concentration of nucleic acid (release)
- Reduction of PCR inhibitors (washing)
- Nucleic acid isolation (magnetic bead capture)



Ordering Information

Product	Contents	Cat. no.
HIV		
NeuMoDx HIV-1 Quant Test Strip	96 tests	300500
NeuMoDx HIV-1 External Controls	15 sets	900301
NeuMoDx HIV-1 Calibrators	3 sets	800304
Hepatitis C		
NeuMoDx HCV Quant Test Strip	96 tests	300300
NeuMoDx HCV External Controls	15 sets	900202
NeuMoDx HCV Calibrators	3 sets	800202
Hepatitis B		
NeuMoDx HBV Quant Test Strip	96 tests	201300
NeuMoDx HBV External Controls	15 sets	900102
NeuMoDx HBV Calibrators	3 sets	800102

Consultancy Services

Service	Description
NeuMoDx Consultancy Evaluation	Consultancy Evaluation Service helps identify productivity improvement needs according to customer expectations and defined project plan.
NeuMoDx Consultancy Workshop	Consultancy Workshop Service helps implement workflow optimization according to customer expectations and defined project plan. Includes travel, labor and instrument handling.
NeuMoDx Verification Method Support	On-site service to help customers verify their method on the NeuMoDx instrument for obtaining ISO 15189 standard accreditation.



Visit www.qiagen.com/NeuMoDx for more information

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