NeuMoDx 288 and NeuMoDx 96

Introducing the next generation of molecular diagnostics

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NeuMoDx – platform key features

- **High throughput**
- **Ultra-fast results**
- **Easy to use, always ready**
- **IVD & LDT* in parallel**
- **True random access**
- **Cost efficiency**

Specification	NeuMoDx 288	NeuMoDx 96
Sample throughput:	High-throughput	Mid-throughput
Samples per 8-hour shift	Up to 288	Up to 144
Maximal sample loading	288	96
Walk-away capability	~8 hours	~6 hours
Extraction & PCR technology	Microfluidic	Microfluidic
Time to first result	40 to 80 min	40 to 80 min
True random access	Up to 30 assays	Up to 20 assays
Bi-directional LIS	Yes	
STAT capability	Yes	
Footprint	183 cm x 109 cm	136 cm x 108 cm
Storage conditions	Room temperature	
Onboard stability	Up to 28 days	
Consumables & reagents	Unitized	
Contingency	Inbuilt	

*** Laboratory developed tests**

NeuMoDx chemistry: delivering enhanced performance and workflow through design innovation

Sample lysis

8 generic lysis reagents optimized for sample types and targets

- Plasma, Serum, universal/viral transport media, CSF, whole-blood, growth media and cytology media

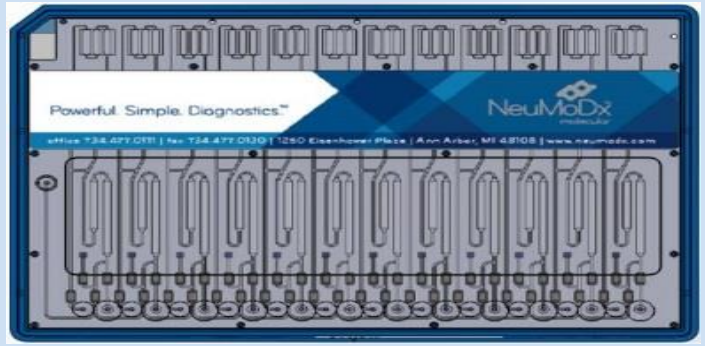
Nucleic acid extraction and purification

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

Polymerase Chain Reaction (PCR)

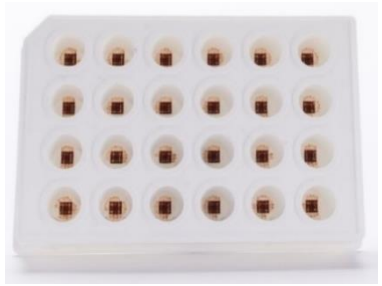
Proprietary process for dehydrated reagents, which are stable at room temperature and provides great efficiency

- Reduced waste and cold storage compared to conventional chemistries



NeuMoDx consumables

Magnetic microparticle Extraction Plate



24 well plate which can run in parallel with 24 independent temperatures

Dehydrated paramagnetic particles for sample prep

Includes the IC template

No wet components therefore no stability issues

The sample lysate reconstitutes the particles

Assay test strip

16 well reagent test strip

Each position acts independently

NeuDry™ master mix

Target and IC primers and (TaqMan™) probes

No liquid components

The eluate reconstitutes the assay

NeuMoDx ™ CE-IVD Assay Menu and Pipeline

Blood Borne Virus	Transplant	Sexual and Reproductive Health	Respiratory	Laboratory Developed Tests
HCV	CMV Quant	CT/NG	SARS-CoV-2	DNA
HBV	EBV Quant	TV/MG	Flu A/B/RSV/SARS-CoV-2	RNA
HIV-1	BKV Quant	GBS	Strep A/C/G	
	HSV-1/2 Quant	HPV	Flu A/B/RSV/SARS-CoV-2 v2.0	
	HHV-6 A/B Quant			
	EBV Quant 2.0			
	HAdV Quant			

BBV

The NeuMoDx HBV Quant Assay Key features

- Wide dynamic range
- All major genotypes covered
- Plasma samples
- Primary and secondary tubes

Intended use: The NeuMoDx HBV Test is a quantitative *in vitro* diagnostic test to quantify Hepatitis B Virus (HBV) DNA from human plasma specimens.

Specification	**NeuMoDx 96 & 288**
Quant/qual:	Quantitative to 4th WHO IS
Targets	Single spanning x protein & pre C
LOD	6.2 IU/mL
LOQ	7.6 IU/mL
Dynamic range	7.6 IU/mL to 9.02 Log_{10} IU/mL
Sample type/s	Plasma in primary or secondary tubes (EDTA, ACD, or PPT)
Time to 1st result	~60 mins
Sample stability	24 hrs onboard, 7 days @ 2–8°C, 8 weeks -20°C
Sample volume	550 µL
Minimum volume	0.7–1.2 mL
Elution volume	~ 19 µL
Onboard stability	Up to 14 days
Calibration period	90 days
Control run	Every 24 hours IC = SPC1

The NeuMoDx HCV Quant Assay Key features

- Wide dynamic range
- Main genotypes covered
- Plasma and serum samples
- Primary and secondary tubes

Intended use: The NeuMoDx HCV Test is a quantitative *in vitro* diagnostic test to quantify Hepatitis C Virus (HCV) RNA from human serum and plasma specimens.

Specification	**NeuMoDx 96 & 288**
Quant/qual:	Quantitative to 5th WHO IS
Targets	Dual (UTR)
LOD	7.4 IU/mL
LOQ	8.4 IU/mL
Dynamic range	8.4 IU/mL to $1x10^8$
Sample type/s	Plasma/Serum in primary or secondary tubes (EDTA, ACD, PPT or SST)
Time to 1st result	~80 mins
Sample stability	24 hrs onboard, 7 days @ 2–8°C, 8 weeks -20°C
Sample volume	550 µL
Minimum volume	0.7–1.2 mL
Elution volume	~ 19 µL
Onboard stability	Up to 14 days
Calibration period	90 days
Control run	Every 24 hours IC = SPC2

The NeuMoDx HIV-1 Quant Assay Key features

- Quantification and detection
- Wide dynamic range
- Low LOD
- Extensive group and subtypes covered
- Primary and secondary tubes

Intended use: The NeuMoDx HIV-1 Test is a quantitative and qualitative *in vitro* diagnostic test for the quantitation and detection of human immunodeficiency virus type 1 (HIV-1) RNA in human plasma.

Specification	**NeuMoDx 96 & 288**
Quant/Qual:	Both, calibrated to 3rd WHO IS
Target	Dual (LTR and Integrase)
LOD	8.9 cop/mL
LOQ	8.9 cop/mL
Dynamic range	8.9 to 1.3 x 10^7 cop/mL
Sample type/s	Plasma in primary or secondary tubes (EDTA, ACD, or PPT)
Time to 1st result	~80 mins
Sample stability	24 hrs onboard, 7 days @ 2–8°C, 8 weeks -20°C
Sample volume	600 µL
Minimum volume	0.7–1.2 mL
Elution volume	~ 20 µL
Onboard stability	Up to 14 days
Calibration period	90 days
Control run	Every 24 hours IC = SPC2

TPx

The NeuMoDx CT/NG Assay Key features

- No preservatives
- Multiplexed and differentiating
- Fast TTFR
- Urine and swab in UTM

Intended use: The NeuMoDx CT/NG Test is a qualitative test designed for direct detection and differentiation of *Chlamydia trachomatis* (CT) and *Neisseria gonorrhoeae* (NG) DNA using neat urine specimens from male and female individuals.

Specification	**NeuMoDx 96 & 288**
Quant/qual:	Qualitative
Target	Dual (CT: putative porin protein & cryptic plasmid encoding DNA helicase; NG: multi-copy opacity gene)
LOD	6 EB/mL for CT 5 cells/mL for NG
Sample Type/s	Male and female urine (neat) Swab in Universal Transport Medium
Time to 1st result	60 mins
Sample Stability	24 hrs onboard, 7 days @ 2–8°C
Sample volume	600 µL
Minimum volume	1.0 mL
Elution volume	~ 19 µL
Onboard stability	Up to 14 days
Control run	User define Positive and Negative IC = SPC1

The NeuMoDx TV/MG Assay Key features

- Multiplexed and differentiating
- Fast TTFR
- Urine and swab in UTM

Intended use: The NeuMoDx TV/MG Test is a qualitative test designed for direct detection and differentiation of *Trichomonas vaginalis* (TV) and/or *Mycoplasma genitalium* (MG) DNA in clinical urogenital specimens from male or female individuals.

Specification	**NeuMoDx 96 & 288**
Quant/qual:	Qualitative
Target	Single: TV - hypothetical protein (TVAG_305840) Dual: MG - IgG-blocking protein M and thymidylate kinase
LOD	0.025 cell/mL for TV 8.4 cop/mL for MG
Sample type/s	Male and female urine (neat) Swab in Universal Transport Medium
Time to 1st result	~60 mins
Sample stability	8 hrs onboard, 7 days @ 2–8°C
Sample volume	550 µL
Minimum volume	1.0 mL
Elution volume	~ 19 µL
Onboard stability	Up to 14 days
Control run	User define Positive and Negative IC = SPC1

The NeuMoDx HPV Assay key features

- Genotyping
- PreservCyt*
- TTFR

Intended use: The NeuMoDx HPV Test is a qualitative test designed for screening patients for high-risk types of human papillomavirus (HPV) DNA in cervical specimens.

Specification	NeuMoDx 96 & 288
Quant/qual:	Qualitative
Target	E6/E7 oncogenes
LOD in Copies/mL	HPV16 – 8,230; HPV18 – 2,743; HPV31 – 24,691; HPV33,35,39,45,51,56,66,67 – 74,074; HPV52,58,59 – 222,222; HPV68 – 666,667; ß-globin – 74,074
Sample type/s	Cervical scrapes, cervical samples collected in LBC, PreservCyt, Surepath*
Time to 1st result	~60 mins
Sample stability	6 weeks @ 15-25°C, 3 months @ 2–8°C, 8 years @ -80°C
Sample volume	50 µL
Minimum volume	250–850 uL (rack dependent)
Elution volume	~ 20 µL
Onboard stability	Up to 14 days
Control run	User define Positive and Negative IC = ß-globin

*** Claim extension to follow**

The NeuMoDx EBV Quant Assay key features

- Low input volume
- Accurate
- WHO calibrated
- Reproducible

Intended use: The NeuMoDx EBV Quant Assay is an automated, *in vitro* nucleic acid amplification test for the quantitation of human Epstein-Barr Virus (EBV) DNA in plasma.

Specification	**NeuMoDx 96 & 288**
Quant/qual:	Quantitative to 1st WHO IS
Target	Dual (BALF & BXLFL1)
LOD	29.3 IU/mL
LOQ	30 IU/mL
Dynamic range	1.48 - 8.0 Log_{10} IU/mL
Sample type/s	Plasma in primary or secondary tubes (EDTA, ACD, or PPT)
Time to 1st result	60 mins
Sample stability	8 hrs onboard, 7 days @ 2–8°C
Sample volume	550 µL
Minimum volume	700 µL
Elution volume	8 hrs onboard, 7 days @ 2–8°C
Onboard stability	Up to 14 days
Calibration period	90 days
Control run	Every 24 hours

The NeuMoDx CMV Quant Assay key features

- Wide dynamic range
- Sensitivity
- gB1-gB4 genotypes covered
- Plasma samples
- IVD & LDT in parallel

Intended use: The NeuMoDx CMV Quant Assay is an automated, *in vitro* nucleic acid amplification test for the quantitation of cytomegalovirus (CMV) DNA in human plasma specimens for CMV genotypes gB1 through gB4 of CMV-infected individuals.

Specification	**NeuMoDx 96 & 288**
Quant/qual:	Quantitative to 1st WHO IS
Target	Dual (UL54 & UL71)
LOD	20 IU/mL
LOQ	20 IU/mL
Dynamic range	20 IU/mL to 8.0 Log_{10} IU/mL
Sample type/s	Plasma in primary or secondary tubes (EDTA, ACD, or PPT)
Time to 1st result	60 mins
Sample stability	8hrs onboard, 7 days @ 4°C ,8 weeks -20°C
Sample volume	550 µL
Minimum volume	1 mL
Elution volume	~19 µL
Onboard stability	Up to 14 days
Calibration period	90 days
Control run	Every 24 hours

The NeuMoDx BKV Quant Assay key features

- Wide dynamic range
- All major genotypes covered
- >30 days on board

Intended use: The NeuMoDx BKV Test is a quantitative in vitro diagnostic test to quantify BK Virus (BVV) DNA from human plasma serum and urine specimens.

Specification	**NeuMoDx 96 & 288**
Quant/Qual:	Quantitative to 1st WHO IS
Targets	Dual
LOD & LOQ	200 IU/mL (100 µL input serum/plasma/urine) 20 IU/mL (550 µL input serum/plasma/urine)
Dynamic range	20 IU/mL to 8.0 Log_{10} IU/mL
Sample type/s	Neat urine, Plasma/Serum in primary or secondary tubes (EDTA, PT or SST)
Time to 1st result	~60 mins
Sample stability	24 hrs onboard, 7 days @ 2–8°C, 8 weeks -20°C
Sample volume	100 & 550 µL
Minimum volume	0.25–1.1 mL
Elution volume	~ 19 µL
Onboard stability	Up to 32 days
Calibration period	90 days
Control run	Every 24 hours IC = SPC1

Respiratory

The NeuMoDx SARS-CoV-2 Assay key features

- Dual target
- Sensitivity & specificity
- Low LOD
- Fast time to first result

Intended use: The NeuMoDx SARS-CoV-2 Test is a qualitative in vitro real-time RT-PCR diagnostic test for the direct detection of SARS-CoV-2 coronavirus RNA from individuals with signs and symptoms of infection who are suspected of COVID-19.

Parameter	Specification
Type	Qualitative
Targets	Dual: Nsp2 and N-gene
LOD	150 copies/mL
Sample type/s	Nasopharyngeal, oropharyngeal, or nasal swab specimens in Universal or Viral Transport Medium Saliva using the saliva collection kit
Time to 1st result	~90 mins
Sample stability	48hrs @ 2–25°C
Sample volume	400 µL
Minimum volume	700 µL
Elution volume	~ 20 µL
Onboard stability	Up to 15 days
Controls period	User define Positive and Negative IC = SPC2

The NeuMoDx Flu A-B/RSV/SARS-CoV-2 Vantage Assay key features

- 4-Plex and differentiation of targets
- Sensitivity & specific
- Low LOD
- 90 min time to first result

Intended use: The NeuMoDx Flu A-B/RSV/SARS-CoV-2 Assay is a qualitative in vitro real-time RT-PCR diagnostic test for the direct detection and differentiation of influenza A, influenza B, respiratory syncytial virus and SARS-CoV-2 RNA from individuals with signs and symptoms of respiratory tract infections

Parameter	Specification
Type	Qualitative
Targets	Flu A, Flu B, RSV : all M gene, SARS-CoV-2 : Nsp2 gene
LOD	Flu A : 0.5 $TCID_{50}$/mL, Flu B : 0.01 $TCID_{50}$/mL, RSV : 1.0 $TCID_{50}$/mL, SARS-CoV-2 : 250 copies/mL
Sample type/s	Nasopharyngeal in Universal or Viral Transport Medium
Time to 1st result	~80 mins
Sample stability	Up to 8hrs on board, 7 days @ 2–8°C
Sample volume	550 µL
Minimum volume	700 µL
Elution volume	20 µL
Onboard stability	Up to 15 days
Controls period	User define positive and Negative IC = SPC2

The NeuMoDx Strep Group A/C/G Assay key features

- Differentiation of targets
- Sensitivity & specific
- For symptomatic and asymptomatic
- ~45 mins time to first result

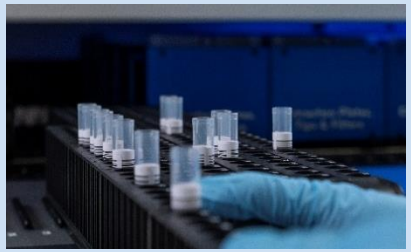
Intended use: The NeuMoDx Strep A/C/G Vantage Assay, is a rapid, automated, qualitative in vitro nucleic acid amplification test for the direct detection and differentiation of Streptococcus pyogenes (Group A β-hemolytic Streptococcus [GAS]) and Streptococcus dysgalactiae (pyogenic Group C and G β-hemolytic Streptococcus, including subsp. dysgalactiae group C, and Streptococcus dysgalactiae subsp. equilisimilis Group C and G [GCS/GGS]) in throat swab specimens obtained from patients with signs and symptoms of pharyngitis.

Parameter	Specification
Type	Qualitative
Targets	All single target
LOD	GAS: 50 CFU/mL GCS: 2500 CFU/mL GGS: 10000 CFU/mL
Sample type/s	Swab in liquid amies transport medium
Time to 1st result	~46–60 mins
Sample stability	8hrs on board, 2 days @ 2–8°C
Sample volume	550 µL
Minimum volume	700 µL
Elution volume	20 µL
Onboard stability	Up to 14 days
Controls period	User define Positive and Negative IC = SPC1

NeuMoDx – revolutionizing in house testing

The NeuMoDx 288 and 96 platforms allow true, seamless integration of in-house tests (lab developed tests/LDTs) alongside regulated assays, with minimal additional steps

LDT workflow



Load specimens

Add primers/probes to LDT test strip

Integrated operation: Integrates all steps of molecular diagnostics starting from raw clinical specimens to providing real-time PCR results in a fully automated process

True random access: Unlimited ability to mix specimen types, in house and regulated tests

High throughput: Up to 340 DNA tests in an 8-hour shift for the 288

Fast time to first results: <60 min for DNA Targets

Continuous loading: Specimens and Reagents can be loaded/unloaded at any time

Seamless on demand operation: Automated inventory management of consumables and reagents

Long in-use shelf life: On-board room temperature stable reagents

Real-time PCR: Five-color fluorescence detection offers real-time PCR multiplexing ability

Thank you for your attention.
Questions?