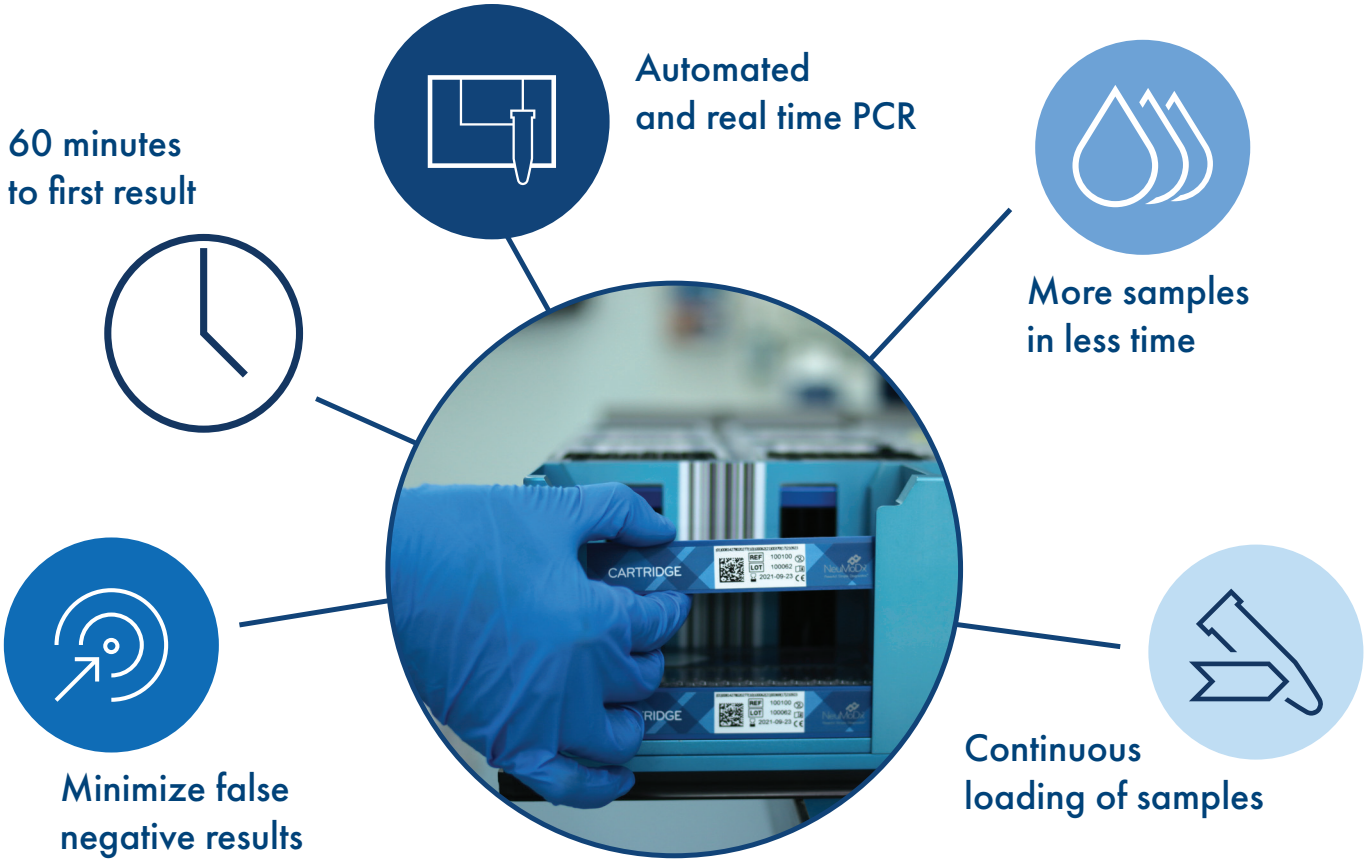
NeuMoDx™ | Molecular Diagnostics

Easier and faster PCR testing with NeuMoDx HPV Test Strip



The NeuMoDx HPV Test Strip, implemented on the NeuMoDx Systems, is an automated, IVD real-time PCR-based nucleic acid amplification assay. The test specifically identifies HPV16 and HPV18 while detecting the other high risk types at clinically relevant infection levels. The ability to load samples and testing consumables on the fly offers up to 8 hours of operator walkaway capability.

NeuMoDx HPV Strip Test Key features

Specification	NeuMoDx 288 & 96
Quant/Qual	Qualitative
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
Cycles	40/run
Sample type/s	Physician collected cervical specimen with LBCs ThinPrep/PreserveCyt and SurePath
Throughput	~ 40 results/hour
Time to first result	60 mins
Sample stability	6 weeks @15-25˚C, 3 months @2-8˚C, 8 years @ -180˚C
Sample volume	50µl
Minimum volume	32-tube-carrier - 400µl, 24-tube-carrier - 850µl, 1.5mL low vol 32-tube - 250µl
Elution volume	20µl
Onboard stability	Up to 14 days
Calibration period	Qual assay
Control run	Every 24 hours

Intended use: The NeuMoDx HPV Assay is an automated, in vitro diagnostic real-time PCR-based nucleic acid amplification assay for the qualitative detection of high-risk types of human papillomavirus (HPV) DNA in cervical specimens. The test specifically identifies HPV16 and HPV18 while concurrently detecting the other high risk types (31, 33, 35, 39, 45, 51, 52, 56, 58, 59, 66, 67 and 68) at clinically relevant infection levels. The assay is intended to be used as a primary test in screening of women of 21 years and older for the risk of cervical (pre)cancer and as a follow-up test for women with Pap test results with atypical squamous cells of undetermined significance (ASC-US) or low-grade squamous intra-epithelial neoplasia (LSIL) to determine the need for referral to colposcopy or other follow-up procedures.

Ordering Information

Product	Contents	Cat. no.
NeuMoDx HPV Test Strip	Dried PCR reagents containing HPV and ßG specific TaqMan® probe and primers. Each package contains 96 tests.	617007

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