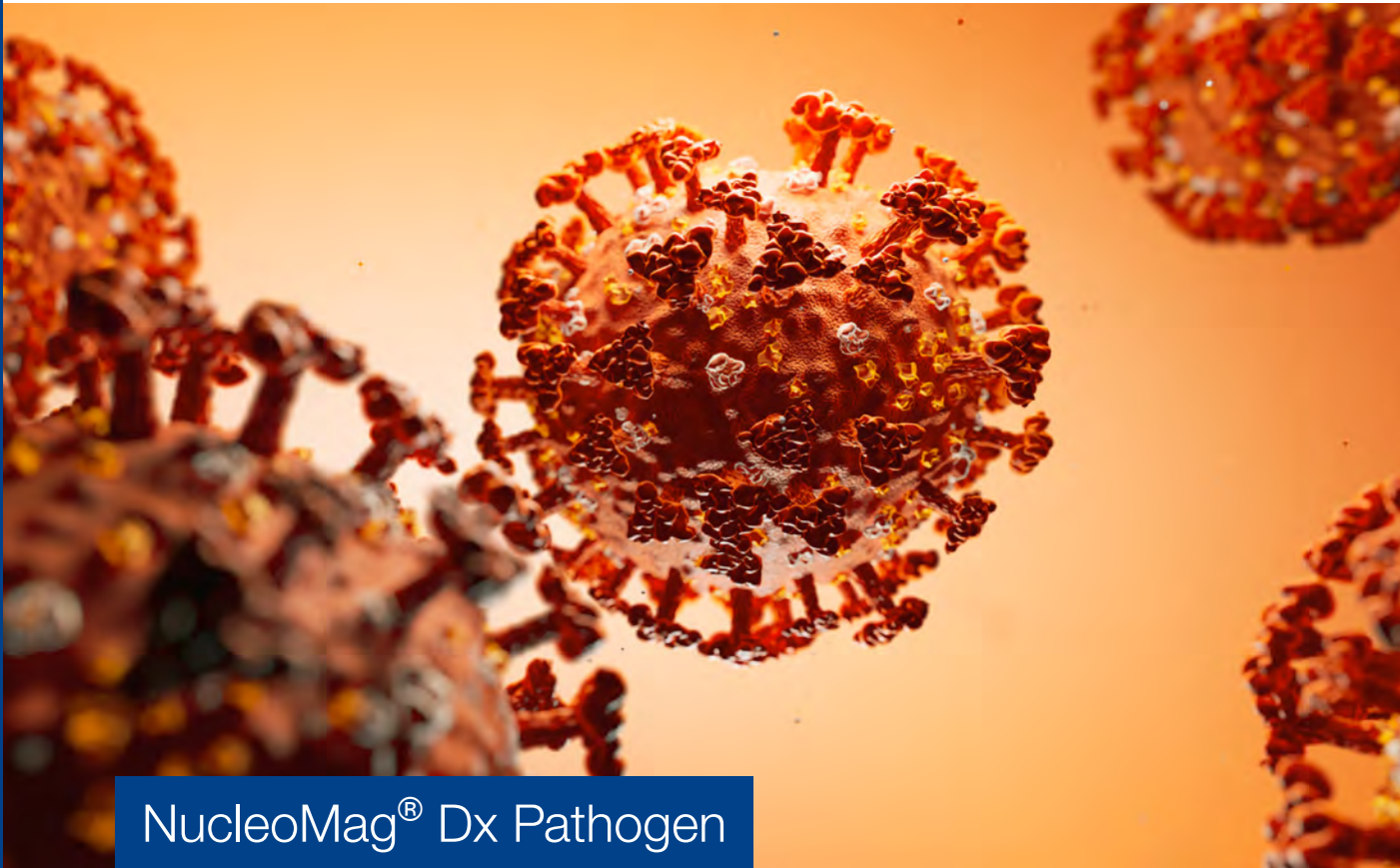


MACHEREY-NAGEL

CE-IVD marked  
viral RNA/DNA isolation

Bioanalysis



NucleoMag<sup>®</sup> Dx Pathogen

- Intended use for human respiratory swabs, saliva and stool
- Validated for SARS-CoV-2 diagnostic workflows
- Magnetic bead based purification with proven automation concepts

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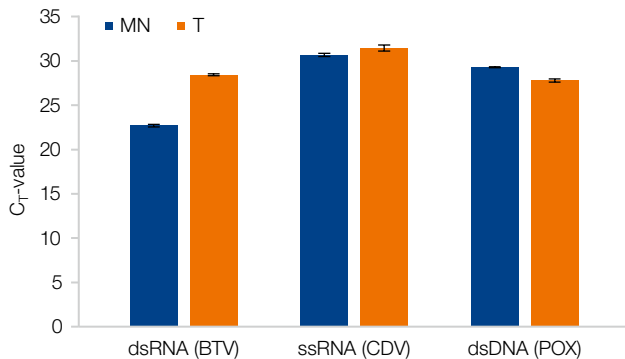
# Viral RNA/DNA isolation for IVD

## NucleoMag® Dx Pathogen

NucleoMag® Dx Pathogen is compliant with European IVD Regulation 2017/746. The intended use covers isolation of viral RNA from both human saliva and respiratory swabs. By September 2025 the intended use will be extended to include viral RNA and DNA from human stool samples. The NucleoMag® Dx Pathogen can be automated on common automation platforms.

The kit shows market-leading performance enabling reliable detection of RNA and DNA viruses from clinical samples. The kit is available as research-use-only product, as IVD product compliant with European IVD Regulation and as pre-filled plates for convenient automated use. These kits feature ready-to-use buffers, Proteinase K, and Carrier RNA.

### Application data

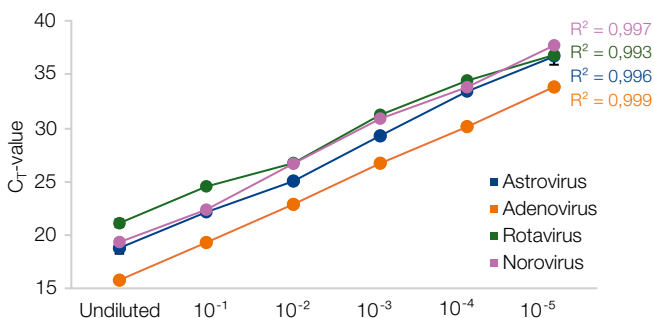


#### Efficient isolation of viral nucleic acids

Human stool samples were spiked with dsRNA- (BTV – bluetongue virus), ssRNA- (CDV – canine distemper virus) and dsDNA (POX - vaccinia virus) representing exemplary virus genomes. Viral nucleic acids were extracted with the NucleoMag® Dx Pathogen kit (MN) and with supplier T kit following each manufacturer's protocols (n = 4). Subsequently, viral nucleic acids were analyzed via specific qRT-PCR (AgPath-ID™ One-Step RT-PCR kit) or qPCR (QuantiTect® Multiplex PCR kit).

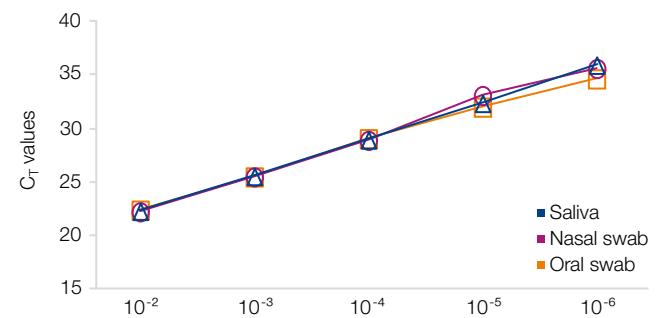
### Product at a glance

Technology and Format	Magnetic beads
Sample material	Human respiratory swabs (nasal / oral), human saliva, human stool sample
Sample amount	≤ 200 µL swabs wash solution ≤ 200 µL saliva ≤ 200 µL stool suspension
Intended Use	Swabs: viral RNA Saliva: viral RNA Stool: viral RNA and viral DNA
Diagnostic use	Yes, CE-IVD marked
Processing	Manual or automated (compatible with most open robotic platforms)
Processing time	40 – 120 min / 96 samples (depending on instrumentation)
Elution volume	50 – 100 µL



#### Sensitivity screening for pathogen detection from human stool samples

A six-fold dilution series was created from human stool samples. Viral RNA/DNA was extracted using the NucleoMag® Dx Pathogen kit and eluates were analyzed using the RIDA® GENE Viral Stool Panel I (R-Biopharm). Viral nucleic acids were detected over 6 order magnitude with an excellent linearity.



#### Consistent performance with different sample types

A dilution series of inactivated SARS-CoV-2 viruses was created in nasal swabs, oral swabs and saliva. Viral RNA was extracted using the NucleoMag® Dx Pathogen on a KingFisher™ Flex system and eluates were quantified via specific qRT-PCR (AgPath-ID™ One Step RT-PCR + nCoV IP4 assay, Institute Pasteur, Paris). Viral RNA was reliably detected across five log<sub>10</sub> dilution steps independent of the sample material.

### Ordering information

Product	Preps	REF
NucleoMag® Dx Pathogen (IVD)	4 × 96	744215.4
NucleoMag® Pathogen (RUO)	1 / 4 × 96 / 100 × 96	744210.1 / .4 / .100
NucleoMag® Pathogen Pre-filled Plates (RUO)	6 × 16 (96 preps)	744211

CE-IVD marked kit: Not available in the USA and other countries, please inquire. NucleoMag® is a registered trademark of MACHERY-NAGEL GmbH & Co. KG, Germany. KingFisher and AgPath-ID are trademarks of Thermo Fisher Scientific, USA. RIDA® is a registered trademark of R-Biopharm AG, Germany. QuantiTect® is a registered trademark of QIAGEN, Netherlands.

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MACHERY-NAGEL GmbH & Co. KG · Valencienner Str. 11 · 52355 Düren · Germany

DE +49 24 21 969-0 info@mn-net.com

CH +41 62 388 55 00 sales-ch@mn-net.com

FR +33 388 68 22 68 sales-fr@mn-net.com

US +1 888 321 62 24 sales-us@mn-net.com