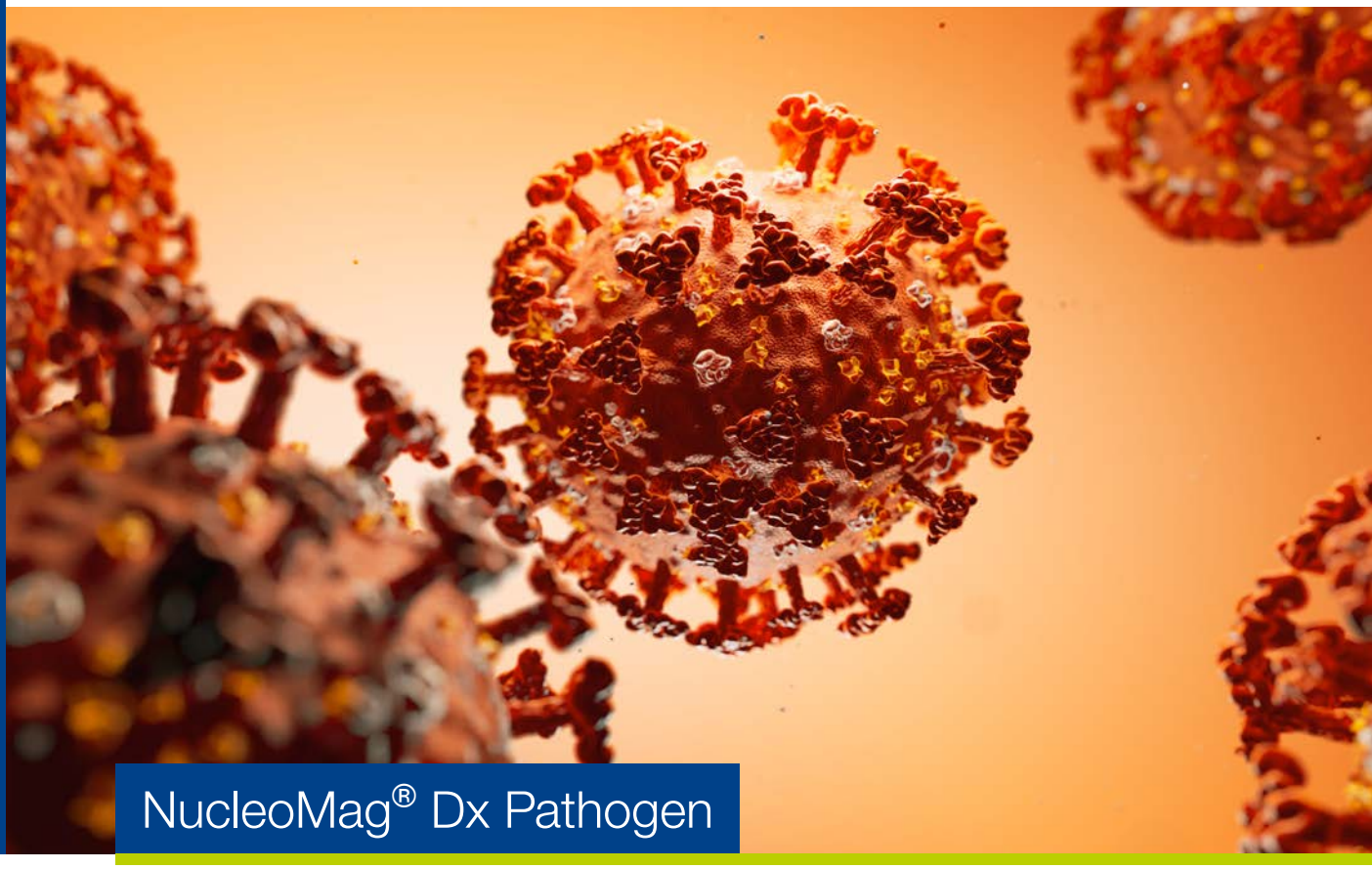
Bioanalysis

MACHEREY-NAGEL

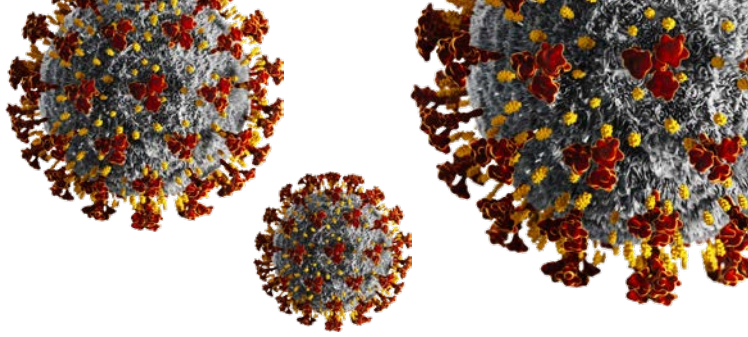
CE-IVD marked viral RNA isolation



NucleoMag® Dx Pathogen

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

Viral RNA isolation for IVD



NucleoMag® Dx Pathogen

CE-IVD certified viral RNA isolation

The NucleoMag® Dx Pathogen kit is intended for the isolation of viral RNA from human respiratory samples, including nasal and oral swabs as well as saliva. The kit includes ready to use buffers, Proteinase K and Carrier RNA. The purification of viral RNA is based on the reversible binding of nucleic acids to the NucleoMag® magnetic beads.

The NucleoMag® Dx Pathogen kit can be automated on common automation platforms.

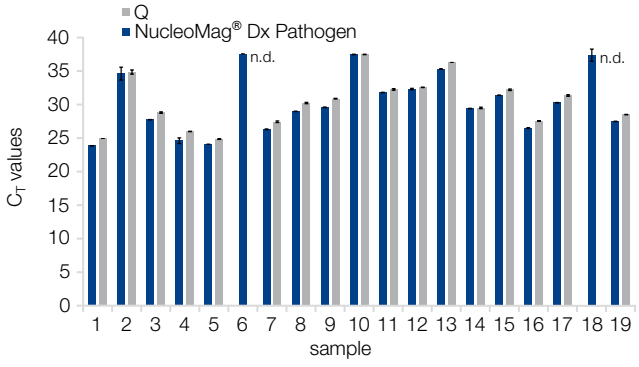
The kit has been validated for SARS-CoV-2 specific diagnostic workflows and shows a market leading performance enabling reliable detection of RNA viruses from clinical samples. The kit can be combined with sample collection devices and downstream assays of your choice*. Components and protocol of the NucleoMag® Dx Pathogen kit are identical to the kit for research purposes. However, the intended use is limited to viral RNA from swabs and saliva.

Product at a glance

Mag

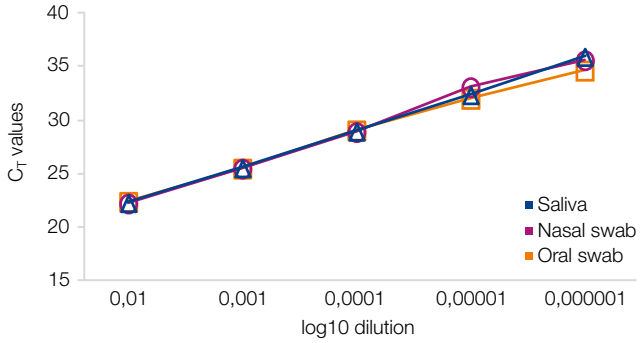
Technology & Format	Magnetic beads
Sample material	Human respiratory swabs (nasal / oral), human saliva
Sample amount	≤ 200 µL swab wash solution, ≤ 200 µL saliva
Diagnostic use	Yes, CE-IVD marked
Processing	Manual or automated (e.g. on HAMILTON, TECAN and others)
Processing time	40–120 min / 96 samples (depending on instrumentation)
Elution volume	50–100 µL

Application data



Excellent diagnostic sensitivity – competitor comparison

Viral RNA from 19 SARS-CoV-2 positive samples (duplicates) was extracted with the NucleoMag® Dx Pathogen on a KingFisher™ Flex and a competitor kit (Q). Viral RNA was quantified with a SARS-CoV-2 specific qRT-PCR assay (qScript® XLT One Step RT qPCR ToughMix + nCoV IP4 assay; Institute Pasteur, Paris). The NucleoMag® Dx Pathogen kit performed equally well (3/19) or better (14/19) than the competitor kit. For two samples extracted with Q the C_T could not be determined (n.d.).



Consistent performance with different sample types

A dilution series of inactivated SARS-CoV-2 viruses was created in three different sample types (nasal swabs, oral swabs, saliva). RNA was extracted using the NucleoMag® Dx Pathogen on a KingFisher™ Flex system. Viral RNA was quantified via specific qRT-PCR (AgPath ID™ One Step RT PCR mix + nCoV IP4 assay, Institute Pasteur, Paris). Viral RNA was detected consistently and reliably over a a range of five log10 dilutions.

Ordering information

Product	Specifications	Preps	REF
NucleoMag® Dx Pathogen (IVD)	CE-IVD certified kit for the isolation of viral RNA from human respiratory swabs and saliva	4 x 96	744215.4
NucleoMag® Pathogen (RUO)	kit for the isolation of pathogen DNA/RNA from diverse clinical samples	1 / 4 x 96	744210.1 / .4

* It is the sole responsibility of the user to validate the performance in combination with a particular downstream assay and / or automation device.

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