

To whom it may concern

Comparison of NucleoSpin® RNA Virus (REF 740956) and NucleoSpin® Dx Virus (CE-IVD) REF 740895

The CE-IVD marked **NucleoSpin® Dx Virus Kit** is based on our well-established **NucleoSpin® RNA Virus Kit**. Both products provide an easy way to isolate viral RNA from 150 µL of serum or plasma samples.

Both Nucleic Acid Purification Kits are produced in the same facility under identical quality standards:

- Quality Management System according to ISO 9001:2015 and EN ISO 13485:2016,
- Implementation of ISO 18385:2016 “Minimizing the risk of human DNA contamination in products used to collect, store and analyze biological material for forensic purposes – requirements”,
- Environmental control including positive air pressure with HEPA filters and locks between manufacturing areas and grey room areas; implemented pest control.

Compared to **NucleoSpin® RNA Virus** the **NucleoSpin® Dx Virus** contains additional components; Proteinase K for isolation of viral DNA as well as elution and lysis tubes are provided.

	740895.50, NucleoSpin® Dx Virus	740956.50 NucleoSpin® RNA Virus	
1	Lysis Buffer RAV1 35 mL	Lysis Buffer RAV1 35 mL	identical
2	Wash Buffer RAW 30 mL	Wash Buffer RAW 30 mL	identical
3	Wash Buffer RAV3 (Concentrate)* 12 mL	Wash Buffer RAV3 (Concentrate)* 12 mL	identical
4	RNase-free H2O 13 mL	RNase-free H2O 13 mL	identical
5	Elution Buffer RE 13 mL	Elution Buffer RE 13 mL	identical
6	Carrier RNA (lyophilized) 1 mg	Carrier RNA (lyophilized) 1 mg	identical
7	Proteinase Buffer PB 1.8 mL	-/-	
8	Proteinase K (lyophilized)* 30 mg	-/-	
9	NucleoSpin® Dx Virus Columns (dark blue rings - plus Collection Tubes, individually blistered)	NucleoSpin® Dx Virus Columns (dark blue rings - plus Collection Tubes, in bags of 50 columns)	identical
10	Collection Tubes (2 mL) 4 x 50	Collection Tubes (2 mL) 3 x 50	
11	Lysis Tubes (1.5 mL) 50	-/-	
12	Elution Tubes (1.5 mL) 50	-/-	
13	User manual	User manual	



Clinical use of the **NucleoSpin® Dx Virus** is limited to the intended use of the product, i.e. serum or plasma.

NucleoSpin® RNA Virus kits are designed for the rapid preparation of highly pure viral nucleic acids (e.g., HCV, HIV, CMV) from fluid biological samples, for example plasma, serum, urine, swab wash solution, liquefied sputum.

See additionally our protocol recommendations for use with swabs, sputum and broncho-alveolar lavage.

We hope that this statement is helpful to show the similarities between both products.

Sincerely yours,

MACHEREY-NAGEL GmbH & Co. KG



Düren, 27.03.2020

Dr. Markus Meusel
QAM, Manager Regulatory Affairs

www.mn-net.com



MACHEREY-NAGEL GmbH & Co. KG · Neumann-Neander-Str. 6-8 · 52355 Düren · Germany

DE / International:

Tel.: +49 24 21 969-0

Fax: +49 24 21 969-199

E-mail: info@mn-net.com

CH:

Tel.: +41 62 388 55 00

Fax: +41 62 388 55 05

E-mail: sales-ch@mn-net.com

FR:

Tel.: +33 388 68 22 68

Fax: +33 388 51 76 88

E-mail: sales-fr@mn-net.com

US:

Tel.: +1 484 821 0984

Fax: +1 484 821 1272

E-mail: sales-us@mn-net.com