

Instruction for Use

NukEx Virus

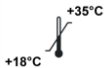
For extraction of viral RNA and DNA.

REF

G05027-64



64



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Editorial changes to Chapters 1 (Intended Purpose), 6 (General Information) and 12 (Abbreviations and Symbols)



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1 Intended Purpose

The kit is designed for magnetic bead based purification of nucleic acids (RNA / DNA) from serum and other liquid samples. The kit can be used as an accessory in combination with a downstream in vitro diagnostic procedure and is intended to be used by professional users in a laboratory environment. It can be performed using automated platforms such as LINEAR NEOS-32 XT Nucleic Acid Extraction System or Biocomma M32/M48 Extraction Systems or equivalent.

2 Mode of Action

In certain conditions, the Magnetic Beads bind the negatively charged nucleic acid. The Magnetic Beads that have bound nucleic acids are magnetized, transferred and released via the specialized magnetic rods during the process of nucleic acid extraction.

3 Components

NukEx Virus is designed for 64 isolations, 4 plates with 16 extractions, each.

Table 1: Components of the NukEx Virus extraction kit.

Labelling	Content – Cat. G05027
Extraction Plate	4x
Magnet Cover Tip	8x

Figure 1: Plate setup.

	1	2	3	4	5	6	7	8	9	10	11	12
A												
B		INHIBITOR REMOVAL BUFFER						INHIBITOR REMOVAL BUFFER				
C	LYSIS BUFFER	INHIBITOR REMOVAL BUFFER	WASH BUFFER	WASH BUFFER	MAGNETBEAD BUFFER	ELUTION BUFFER	LYSIS BUFFER	INHIBITOR REMOVAL BUFFER	WASH BUFFER	WASH BUFFER	MAGNETBEAD BUFFER	ELUTION BUFFER
D	LYSIS BUFFER	INHIBITOR REMOVAL BUFFER	WASH BUFFER	WASH BUFFER	MAGNETBEAD BUFFER	ELUTION BUFFER	LYSIS BUFFER	INHIBITOR REMOVAL BUFFER	WASH BUFFER	WASH BUFFER	MAGNETBEAD BUFFER	ELUTION BUFFER
E	LYSIS BUFFER	INHIBITOR REMOVAL BUFFER	WASH BUFFER	WASH BUFFER	MAGNETBEAD BUFFER	ELUTION BUFFER	LYSIS BUFFER	INHIBITOR REMOVAL BUFFER	WASH BUFFER	WASH BUFFER	MAGNETBEAD BUFFER	ELUTION BUFFER
F	LYSIS BUFFER	INHIBITOR REMOVAL BUFFER	WASH BUFFER	WASH BUFFER	MAGNETBEAD BUFFER	ELUTION BUFFER	LYSIS BUFFER	INHIBITOR REMOVAL BUFFER	WASH BUFFER	WASH BUFFER	MAGNETBEAD BUFFER	ELUTION BUFFER
G		INHIBITOR REMOVAL BUFFER			MAGNETBEAD BUFFER			INHIBITOR REMOVAL BUFFER			MAGNETBEAD BUFFER	
H		INHIBITOR REMOVAL BUFFER			MAGNETBEAD BUFFER			INHIBITOR REMOVAL BUFFER			MAGNETBEAD BUFFER	

4 Applicable Instruments

Neos-32 XT Nucleic Acid Extraction System or Biocomma M32/M48 Extraction Systems (or equivalent). Use of NukEx Virus with equivalent instruments needs to be verified by the user.

5 Transport, Storage and Stability

NukEx Virus Kit components are shipped at ambient temperature. Kits must be stored at +18 to +35°C. If properly stored, all kit components are stable until the date of expiry printed on the label.

Please note that improper storage at +2 to +8°C (refrigerator) or $\leq -18^{\circ}\text{C}$ (freezer) will adversely impact nucleic acid purification when precipitates form in the solutions. Storage must be done in an upright position.

6 General Information

- Read the Instruction for Use carefully before using the product.
- The NukEx Virus Kit must be utilised by qualified personnel only.
- Good Laboratory Practice (GLP) has to be applied.
- Clinical samples must always be regarded as potentially infectious and all equipment used has to be treated as potentially contaminated.
- Do not let the buffers touch your skin, eyes, or mucous membranes. If contact does occur, wash the affected area immediately with large amounts of water; otherwise, the reagent may cause burns. If you spill the reagent, dilute the spill with water before wiping it up.
- Always wear gloves and follow standard safety precautions.
- Do not use a kit after its expiration date.
- The Nucleic Acid Extraction System should be disinfected by UV light before use. After the experiment, it is recommended to clean the instrument cabin using 75% ethanol and to perform UV-decontamination for 15 min, subsequently.
- Make sure to place the NukEx Extraction Plate in the correct position into the Nucleic Acid Extraction Instrument.
- Make sure, that Magnet Cover Tips have been inserted before starting the extraction process.
- Magnetic beads may occasionally appear in the elution buffer. If so, please avoid pipetting of the magnetic beads while transferring the eluate.
- Serious incidents are to be reported to gerbion GmbH & Co. KG and the national regulatory authorities.
- This product has been produced and placed on the market in accordance with the regulation (EU) 2017/746 (IVDR).

6.1 Waste Handling

- Dispose of unused reagents and waste should occur in accordance with country, federal state and local regulations.
- Material Safety Data Sheets (MSDS) are available from gerbion upon request.

7 Sample Requirements

1. Sample type: Swab and other liquid samples.
2. Sample Storage: Fresh or stored at +2°C to +8°C for up to 24 hours. For long-term storage, freezing at ≤-18°C is recommended.

8 Extraction of Nucleic Acids

8.1 Reagents Preparation

Take out the plates from the kit box. Carefully tear down the aluminium foil to avoid liquid splash.

8.2 Automated Extraction Steps

- a. Add 200µl sample to the 1st and 7th columns of the plates, respectively.
- b. Edit and run the experiment program as follows:

Table 2: Instrument Settings.

No.	Column	Name	Waiting (sec)	Mixing (sec)	Magnet (sec)	Speed	Volume (µl)	Heating State	Temp (°C)
1	5	Bead Pick Up	0	60	15	8	500	Elution	30
2	1	Lysis	0	300	90	8	800	Lysis	90
3	2	Washing 1	0	60	60	8	700	Elution	90
4	3	Washing 2	0	60	60	8	800	Elution	90
5	4	Washing 3	0	60	60	8	800	Elution	90
6	6	Elution	60	300	120	8	100	Elution	90
7	2	Release bead	0	60	0	8	700	Elution	30

- c. After the experiment program is finished, please transfer the extracted products located at 6th and 12th columns into nuclease-free tubes, store at ≤-18°C.

9 Limitations for Use

1. The extraction kit is intended for extraction of Nucleic acids from clinical diagnostic samples, forensic materials and scientific research samples. The concentration and purity of its extraction product are affected by instruments and operators.
2. The extraction kit includes a special elution buffer, which will affect the absorbance value for the UV-visible spectrophotometer. Therefore, it is not recommended to directly measure the concentration and purity of extraction products by UV- spectrometry.

10 Kit Performance



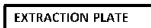

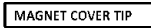







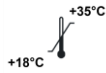


1. The extraction kit allows high-efficiency extraction of nucleic acids from swabs in Virus Transport Medium or resuspended e. g. in physiological saline and extraction from other liquid samples such as serum or plasma samples.
2. The extraction kit allows the extraction of 1 - 32 samples simultaneously via Neos-32 XT Nucleic Acid Extraction System or equivalent. Further information and validation data are available from gerbion.

11 Troubleshooting

The following troubleshooting guide is included to help you with possible problems that may arise when isolating nucleic acids. For further questions concerning nucleic acid extraction, please do not hesitate to contact our scientists on info@gerbion.com.

Magnetic beads attached to magnetic rods	Make sure to always insert magnet cover tips into the Nucleic Acid Extraction Instrument before use. Magnet cover tips included in NukEx Pure Virus can be used for Neos-32 XT Nucleic Acid Extraction System or Biocomma M32/M48 Extraction Systems. Please make sure, that the cover tips fit into your instrument.
Insufficient nucleic acid yield	Make sure that magnet cover tips have been inserted before starting the extraction process. Make sure to place the NukEx Extraction Plate in the correct position into the Nucleic Acid Extraction Instrument. Programming of extraction steps must be done according to table 2.

12 Abbreviations and Symbols

DNA	Deoxyribonucleic Acid		Catalog number
RNA	Ribonucleic Acid		Contains sufficient for <n> test
	Extraction Plate		Manufacturer
	Magnet Cover Tip		Batch code
	European Conformity		Content
	<i>In vitro</i> diagnostic medical device		Use by YYYY-MM-DD
	Unique Device Identification		Consult instructions for use
			Storage temperature
The product has been classified and marked in accordance with EU Directives / Ordinance on Hazardous Materials	 	Acute toxicity, Category 4, H302 Acute toxicity, Category 4; H332 Skin irritation, Category 2; H315 Eye irritation, Category. 2; H319 Flammable liquid, Category 3, H226 Eye irritation, Category 2; H319	