

MutaCLEAN[®] Virus

extraction kit

*For the rapid extraction of RNA and DNA
using magnetic beads*

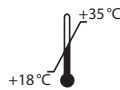
Valid from 2022-05-23



KG1025-24
KG1025-96



384/1536



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1 INTENDED USE

MutaCLEAN® Virus is a magnetic bead-based extraction kit for nucleic acids (RNA and DNA) which may be used e.g. for subsequent real time PCR analysis. The kit is an accessory for an in vitro diagnostic device. Any in vitro diagnostic use of this sample preparation procedure in combination with a downstream nucleic acid test must be evaluated for the parameter in question. The nucleic acids can be extracted from clinical samples including serum and other liquid samples. The kit is intended to be used by professional users in a laboratory environment and the extraction can be performed using an automated platform (Neos-32 XT Nucleic Acid Extraction System or Biocomma M32/M48 Extraction Systems or equivalent).

2 MODE OF ACTION

- a) Samples are lysed by incubation in lysis buffer. Nucleic acids are bound to the magnetic beads.
- b) Bound nucleic acids are washed with Inhibitor removal buffer in order to remove PCR inhibitors from the sample.
- c) Bound nucleic acids are washed with Wash Buffer in order to purify them from salts, proteins and other cellular impurities.
- d) Purified nucleic acids are eluted from the magnetic beads with elution buffer.

Purified nucleic acids can be used directly for downstream applications.

3 COMPONENTS

The reagents supplied are sufficient for 384 isolations, 24 plates with 16 extractions, each, KG1025-24 or 1536 isolations, 96 plates with 16 extractions, KG1025-96, respectively.

Table 1: Components of the MutaCLEAN® Virus extraction kit.

Label	Content	
	KG1025-24	KG1025-96
Extraction Plate	24 x	96 x
Magnet Cover Tip	48 x	192 x

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

Figure 1: Plate setup.

4 APPLICABLE INSTRUMENTS

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

5 TRANSPORT, STORAGE AND STABILITY

The MutaCLEAN® Virus extraction 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 ≤ -18 °C (freezer) will adversely impact nucleic acid purification when precipitates form in the solutions. Storage must be done in an upright position.

6 GENERAL NOTES ON THE TEST AND TEST PROCEDURE

- Read the Instruction for Use carefully before using the product.
- This instruction for use replaces the version dated 2022-01-19.
- This product has been produced and placed on the market in accordance with the regulation (EU) 2017/746 (IVDR).
- All serious incidents occurring in connection with the product must be reported to Immundiagnostik AG and (within the Union market) to the competent reporting authority of the respective member state.
- The MutaCLEAN® Virus extraction 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 MutaCLEAN® 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.

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 our scientists on info@immundiagnostik.com, 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 $\leq -18^{\circ}\text{C}$ 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

1. Add 200 µl sample to the 1st and 7th columns of the plates, respectively.
2. 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

3. 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

- 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.
- 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

- 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.
- 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 at Immundiagnostik AG. Please address your inquiry to info@immundiagnostik.com.

Detailed information based on the latest state of knowledge is available at Immundiagnostik AG. Please address your inquiry to info@immundiagnostik.com.

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@immundiagnostik.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 MutaCLEAN® Virus extraction kit 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 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	Ribonucleid acid		Contains sufficient for <n> test
	Extraction Plate		Manufacturer
	Magnet Cover Tip		Batch code
	European Conformity		Content
	<i>In vitro</i> diagnostic medical device		Storage temperature
	Consult instructions for use		Use by YYYY-MM-DD
	Unique Device Identification		Attention

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

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