Clean Quick Viral DNA/RNA

Instructions for Use

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CE IVD

REF CQV-DR0500, CQV-DR0050

CleanNA, Coenecoop 75, 2741 PH, Waddinxveen, the Netherlands

Intended for in vitro diagnostic use.

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Intended Purpose

The intended purpose of the device is to extract Viral DNA and/or RNA from nasopharyngeal and oropharyngeal swabs, immersed in an inactivating viral transport medium, in a sufficient purity to be used in downstream detection procedures based on the principle of Polymerase Chain Reaction (PCR).

Intended User

The intended users are laboratory employees trained in molecular biology techniques.

Introduction and Principle

Clean Quick Viral DNA/RNA is an efficient viral DNA and/or RNA extraction reagent, based on magnetic particles. The Clean Quick Viral DNA/RNA is produced under RNase-free conditions, allowing for the extraction of RNA and DNA from viral nasopharyngeal and oropharyngeal swabs stored in inactivating transport medium.

Our Clean Quick Viral DNA/RNA contains magnetic particles that bind the viral nucleic acids and allow for purification of DNA and RNA by removing unwanted potentially inhibitory biomolecular components such as fatty acids, proteins and viral- and cellular debris. Extracted DNA and/or RNA is of sufficient purity to use in downstream detection procedures based on the principle of Polymerase Chain Reaction (PCR).

The protocol can be automated on liquid handlers or nucleic acid extraction instruments, such as our CleanXtract 96 with standard protocol, or it can be performed manually.

Schematic Overview

The extraction procedure starts by adding Clean Quick Viral DNA/RNA to the swab sample in transport medium. DNA and RNA from the sample will bind to the magnetic particles. By placing the tubes on a magnetic separation device, the magnetic particles with DNA and/or RNA are separated from the solution. Following a few rapid ethanol wash steps to remove trace contaminants (e.g. proteins and cellular debris), the purified DNA and/or RNA is eluted from the CleanNA particles using nuclease free water or a low ionic strength buffer for use in downstream applications.

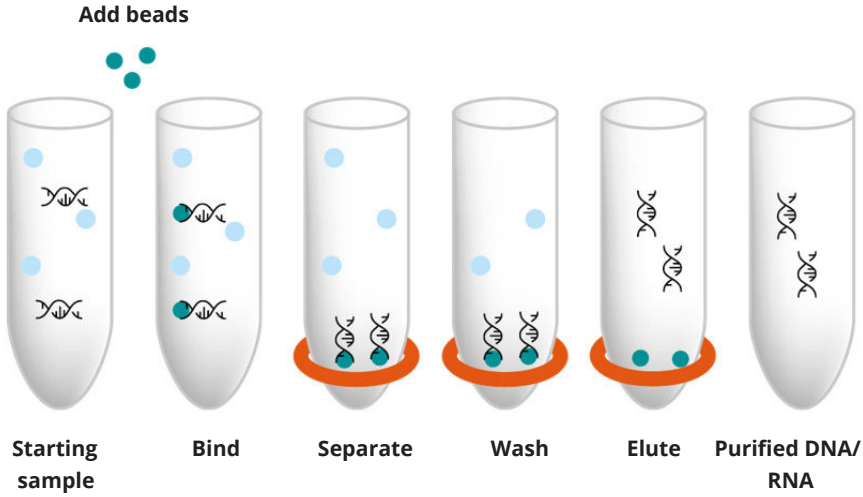

Figure 1: Schematic overview of the Clean Quick Viral DNA/RNA procedure.

Materials Provided

Kit Contents:

Component	Volume CQV-DR0050	Volume CQV-DR0500
Clean Quick Viral DNA/RNA	50 ml	500 ml

Reagent Shipping, Storage and handling

Shipping of Clean Quick Viral DNA/RNA should be done at room temperature (15-25 °C).

Do not freeze the Clean Quick Viral DNA/RNA. After the Clean Quick Viral DNA/RNA has been frozen, it is no longer suitable for use.

COMPONENT	Storage
Clean Quick Viral DNA/RNA	2-8°C

In use stability: After opening the Clean Quick Viral DNA/RNA bottle, the product can be used safely for a period of 11 months.

Do not use Clean Quick Viral DNA/RNA after the expiration date on the label.

Warnings

Read the instructions carefully before using the kit.

Do not mix several kit LOT numbers.

Make sure that the kit bottles are not damaged and that no liquid leaked from the bottles. Do not use a kit that has been damaged.

Oropharyngeal and nasopharyngeal swab samples are potentially infectious and must be treated as biohazardous materials. Take appropriate measures while handling them.

Any serious incident that has occurred in relation to the device shall be reported to the manufacturer and the competent authority of the Member State in which the user and/or the patient is established.

Precautions

For all safety information, please consult the safety data sheet (SDS). Request your SDS via cleanna.com/sds-request.

Clean Quick Viral DNA/RNA	
No hazard pictogram	No precautionary statement(s) Prevention or Response.

Note: For safe disposal, please consult your local waste regulations.

Quality Control

CleanNA produces each lot of the Clean Quick Viral DNA/RNA according to predetermined and validated protocols in the Quality Management System (QMS). Additionally, a quality check after production of each lot is performed to secure consistent product quality. CleanNA's QMS is EN-ISO 13485 certified.

Limitations

The performance of the Clean Quick Viral DNA/RNA has been established in combination with the exemplary sampling device, Viral Transport Media and virus types below:

Sampling:

- ∑-VIROCULT® (MWE, England)

Transport Media:

- InActive BlueTM (reference: IB500, InActive Blue bv, Belgium).

Virus types:

- Adeno Virus (DNA virus)
- Influenza A (RNA virus)
- Respiratory Syncytial Virus (RSV, RNA virus)
- SARS-CoV-2 (RNA virus)

It is the user's responsibility to validate the performance of sample material not used in the performance evaluation.

We recommend the use of an internal extraction control per sample to identify a false negative result in downstream detection methods, caused by potentially unknown inhibitory agents in individual patient samples.

The performance of the kit has been established with downstream detection methods based on Polymerase Chain Reaction. It is the user's responsibility to validate the performance of the device when used with other downstream detection methods.

Diagnostic results generated after using the Clean Quick Viral DNA/RNA must be interpreted in conjunction with other clinical or laboratory findings.

Collection and storage of specimen

It is the responsibility of the user to follow the manufacturers' instructions regarding the use of both the sampling device and the transport medium, and follow the instructions on sample stability. The user is also responsible for the validation of the specimen collection swab and transport medium used in their laboratory workflow in combination with the Clean Quick Viral DNA/RNA.

Materials and Equipment to be Supplied by User

Clean Quick Viral DNA/RNA - Single Tube Protocol

Materials and Reagents to be supplied by user for the Clean Quick Viral DNA/RNA - Single Tube Protocol:

- Magnetic separation device for 1.5/2.0 mL tubes
- Pipettes and pipette (filter) tips
- 1.5 mL centrifuge tubes conical bottom with cap
- Single tube rack
- 80% ethanol freshly prepared from non-denatured alcohol
- RNase free molecular biology grade water or elution Buffer (10mM Tris-HCl pH 8.0)

Working RNase Free

For RNA applications it is important to work RNase free. RNases are present everywhere and general precautions should be taken to avoid the introduction of RNases and other contaminating nucleases while working with RNA. The most common sources of RNases are hands, dust particles and contaminated laboratory solutions, equipment and glassware.

To minimize the risk of RNase contamination we recommend the following precautions:

- Always use gloves when handling RNA samples. Change your gloves frequently, to avoid contaminations;
- Ensure to use RNase free filter tips for pipetting;
- Use materials such as disposable consumables, which are guaranteed RNase free;
- Use reagents which are guaranteed RNase free. Creating aliquots from buffers lowers the risk of RNase contamination in buffers, reagents, etc.;
- Avoid using reagents, consumables and equipment dedicated for common use or general lab processes;
- If possible work in a separate room, fume hood or lab space;
- Clean all working surfaces with commercial RNase inhibiting surfactant or 70% ethanol before starting your work / experiment.

Clean Quick Viral DNA/RNA - Single Tube Protocol

Protocol:

1. Bring the Clean Quick Viral DNA/RNA to room temperature prior to use.
2. Mix the Clean Quick Viral reagent carefully yet thoroughly to fully resuspend the magnetic particles prior to use.
3. Transfer 200 µl viral transfer buffer with lysed nasopharyngeal swab material to a 1.5 mL single tube.
4. Add 360 µL Clean Quick Viral particles to each tube.
5. Pipet up and down 10-15 times or vortex for 30 seconds.
6. Incubate at room temperature (15-25°C) for 5 minutes.

⚠ **Note:** Incubating for too long or too short can cause lower yield.

7. Place the tube in the magnetic separation stand to bind the Clean Quick Viral particles to the magnet. Incubate at room temperature (15-25°C) until the Clean Quick Viral particles are completely cleared from solution.
8. Aspirate and discard the cleared supernatant.

⚠ **Note:** Do not disturb or pipet Clean Quick Viral magnetic particles. This can cause lower yield.

9. Remove the tube from the magnetic separation stand.
10. Add 350 µL freshly made 80% ethanol to each tube.
11. Briefly resuspend the Clean Quick Viral particles by pipetting up and down and incubate at room temperature (15-25°C) for 1 minute.
12. Place the tube in the magnetic separation stand to bind the Clean Quick Viral particles to the magnet. Incubate at room temperature (15-25°C) until the Clean Quick Viral particles are completely cleared from solution.
13. Aspirate and discard the cleared supernatant.

⚠ **Note:** Do not disturb or pipet Clean Quick Viral magnetic particles. This can cause lower yield.

14. Repeat Steps 9-13 for a total of three 80% ethanol wash steps.
15. Leave the tube in the magnetic separation stand for 10-15 minutes to air dry the Clean Quick Viral particles. Remove any residue liquid with a pipette without disturbing the Clean Quick Viral particles.

⚠ **Note:** It is important to dry the Clean Quick Viral particles before elution. Residual ethanol may interfere with downstream applications. Do not overdry.

16. Remove the tube from the magnetic separation stand.

17. Add 100 µL molecular biology grade water or elution buffer (not provided) to each tube.

⚠ **Note:** Using less than the recommended elution volume can cause loss of yield.

18. Pipet up and down 20 times or vortex for 30 seconds.
19. Incubate at room temperature (15-25°C) for 5 minutes.
20. Place the tube in the magnetic separation stand to magnetize the Clean Quick Viral particles. Incubate at room temperature (15-25°C) until the Clean Quick Viral particles are completely cleared from solution.
21. Transfer the cleared supernatant containing purified DNA and/or RNA to a new (RNase-free) tube or microplate and seal with non-permeable sealing film.

⚠ **Note:** Take care that no Clean Quick Viral magnetic particles are carried over to the eluate, this may cause interference in downstream applications.

22. Store the tube(s) at 2-8°C if storage is only for a few days. For long-term storage, samples should be kept at -20°C.

Troubleshooting Guide

Please use this guide to troubleshoot any problems that may arise. For further assistance, please contact your local distributor.

Possible Problems and Suggestions

Problem	Cause	Solution
Low yield	Insufficient viral material in starting sample	Perform swab according to protocol of manufacturer
	Particle loss during the procedure	Do not pipette magnetic particles during washing and elution steps
	Ethanol traces during elution step	Increase drying time
	DNA and/or RNA remains bound to particles	Increase amount of elution buffer or increase drying time
	RNA degradation	Use sample as fresh as possible and avoid freezing and thawing
	Incomplete resuspension of the particles during elution	Make sure all particles are resuspeded in the elution step
	Low percentage of ethanol used	Use the correct percentage of ethanol
Problems in downstream applications	Ethanol carryover	Increase drying time
	Inhibiting agents in eluate	Perform detection on diluted eluate

Symbols

	In-vitro Diagnostics
	CE mark. This product meets the requirements for CE-IVD device under the EU Regulation for In Vitro Diagnostic Medical Devices (2017/746)
	Reference number
	Manufacturer
	Caution
	Temperature limit
	Use by
	Lot number

Ordering Information

Contact your local distributor to order.

Product	Part Number
Clean Quick Viral DNA/RNA (500 mL)	CQV-DR0500
Clean Quick Viral DNA/RNA (50 mL)	CQV-DR0050

Document Revision History

Manual Version	Date of revision	Revised Chapter	Explanation of revision
1	02/MAR/2023	N/A	N/A
2	28/FEB/2024	Total revision	Added text in Workflow Overview, updated workflow image, Limitations, Warnings, small textual changes

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