OxMag Viral RNA/DNA Purification Kit

High-Throughput Technology

Qualitative Assay for Automatic Extraction Systems

INSTRUCTION FOR USE

REF

RUO

Version 3. MAG-009-01.03.24

MAG-009-01

Research Use Only

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List of content

Description of the kit

Intended use

OxMag Viral RNA/DNA Purification Kit is a universal magnetic bead-based product for rapid and reliable isolation of viral nucleotides (RNA&DNA) from human liquid samples and body fluids such as (whole blood, plasma and serum, saliva, nasopharyngeal, oral and urogenital swabs, sputum, broncho-alveolar lavage, urine and seminal fluids, milk)[1]. The technology allows high-throughput analyses, requires low handling, gives an advantage in simplicity and speed, reduces the risk of contamination. The analytical performance and sensitivity of the kit were thoroughly tested in laboratory and clinical settings according to the "EU Regulation 2017/746 on In Vitro Diagnostic Medical Devices."

The kit components

- The kit composition is described in "**Table 1. The buffers and components of the kit.**"
- Instructions for Use (IFU) – detailed guidelines for high-quality Viral RNA /DNA Purification methodology which could be easily adapted to the various automated systems and samples.
- Material Safety Data Sheet (MSDS) – the documents contain information about hazard identification, first aid measures, firefighting, accidental release measures, handling and storage, exposure control, and personal protection.

Table 1. The buffers and components of the kit

OxMag Viral RNA Purification Kit		200 rxn	500 rxn	2,000 rxn	Transportation and Storage
Solution A	Lysis /Binding Buffer	55 ml	70 ml x 2	107 ml x 5	Room temperature
Solution W1 (conc.)	Wash Buffer 1	30 ml	75 ml	295 ml	Room temperature
Solution W2 (conc.)	Wash Buffer 2	14 ml x 2	70 ml	140 ml x 2	Room temperature
Solution E	Elution Buffer	50 ml	105 ml	105 ml x 4	Room temperature
OxMag® Beads* *Magnetite*	Synthetic Magnetic Beads	2 ml	5 ml	20 ml	Room temperature
Proteinase K	Enzyme *Lyophilized Powder*	20 mg	25 mg x 2	20 mg x 10	Room temperature
Proteinase K Storage Buffer	Storage Buffer for Enzyme	1.5 ml	1.5 ml x 2	15 ml	Room temperature
Carrier RNA	Synthetic Oligo Mix *Lyophilized Powder*	100 µg	125 µg x 2	100 µg x10	Room temperature

* Do not freeze OxMag® Beads solution. Store at 2-8 ºC

[1] The kit can be extended towards veterinary and zoonotic research and diagnostics.

Reagents Preparation

Solution W1

Wash Buffer 1 comes as a concentrate. Prior to initial use, combine the recommended quantity of ethanol, which must be at least ≥95% pure, as specified in "Table 2. Preparation of Solution Wash 1"

Table 2. Preparation of Solution Wash 1

No. Reactions	Solution W1	Ethanol ≥95%	Final Volume
200	30 ml	75 ml	105 ml
500	75 ml	180 ml	255 ml
2000	295 ml	715 ml	1010 ml

Solution W2

Wash Buffer 2 comes as a concentrate. Prior to initial use, combine the recommended quantity of ethanol, which must be at least ≥95% pure, as specified in "Table 3. Preparation of Solution Wash 2"

Table 3. Preparation of Solution Wash 2

No. Reactions	Solution W2	Ethanol ≥95%	Final Volume
200	14 ml x 2	71 ml (In each bottle)	85 ml x 2 bottles
500	70 ml	350 ml	420 ml
2000	140 ml x 2	700 ml (In each bottle)	840 ml x 2 bottles

Proteinase K

Proteinase K is supplied as a lyophilized powder. Before using it for the first time, add the appropriate amount of Proteinase K Storage Buffer, as indicated in "Table 4. Preparation of Proteinase K enzyme". Aliquoted Proteinase K should be stored at -20 °C.

Table 4. Preparation of Proteinase K enzyme

No. Reactions	Proteinase K	Proteinase K Storage Buffer	Final Volume
200	20 mg	1 ml	1 ml x 1 vial
500	25 mg x 2	1.25 ml (In each vial)	1.25 ml x 2 vials
2000	20 mg x 10	1 ml (In each vial)	1 ml x 10 vials

Carrier RNA

Carrier RNA is supplied as a lyophilized powder. Before using it for the first time, add the appropriate amount of Solution E (Elution Buffer) as indicated in "Table 5. Preparation of Carrier RNA." Aliquoted Carrier RNA should be stored at -20°C. Do not freeze-thaw Carrier RNA more than 5 times.

Table 5. Preparation of Carrier RNA

No. Reactions	Carrier RNA	Solution E	Final Volume
200	100 µg	1 ml	1 ml x 1 vial
500	125 µg x 2	1.25 ml (In each vial)	1.25 ml x 2 vials
2000	100 µg x 10	1 ml (In each vial)	1 ml x 10 vials

Lysis/Binding Bead Mix (For Routine Testing)

Prepare Solution B with Magnetic Beads for routine testing. Add the appropriate volume of components indicated in "Table 6. Preparation of Solution B with Magnetic Beads" for same-day use.

Table 6. Preparation of Solution B with Magnetic Beads

No. Reactions	Solution B	OxMag® Beads	Final Volume
200	55 ml	2 ml	57 ml
500	70 ml	2.5 ml	72.5 ml
2000	107 ml	4 ml	111 ml

Specimen

Whole Blood

Before processing, ensure that entire blood samples are fully liquefied to prevent clot carryover, which could interfere with nucleic acid purification.

Plasma/Serum

When handling plasma and serum samples, carefully transfer the clear, yellowish fluid, not disturbing the underlying buffy coat or red blood cell layer.

Saliva

Thoroughly rinse the mouth with water at least 30 minutes before collection. Collect up to 500 µl of saliva in a 15 ml in cold PBS tube and keep on ice. Transfer the sample to a 1.5 ml reaction tube and centrifuge at 1000 × g for 1 minute in a pre-chilled (4°C) centrifuge. Carefully remove the supernatant without disturbing the pellet. Add 1 ml cold PBS, vortex, and transfer 200 µl to the lysis plate.

Swabs

Swabs (nasopharyngeal, oral, urogenital) samples may contain mucus, blood, or other materials that can negatively affect purification. In case of sample high viscosity thoroughly mix the swab in PBS or 0.9 % saline buffer. Vortex the mixture vigorously at the highest setting for 15 seconds, then transfer the clear sample into a micro-well plate.

Sputum

Viscous sputum should be liquefied prior to purification. Centrifuge the sample at 1000 × g for 1 minute. Discard the supernatant and re-suspend the pellet in 1 ml cold PBS. Vortex briefly to ensure uniformity.

Bronchoalveolar Lavage (BAL)

BAL samples are typically low in viscosity and can be processed directly. Vortex the sample briefly to ensure homogeneity. If debris or mucus is visible, centrifuge at 1000 × g for 1 minute and use the clear supernatant for purification.

Urine

Please centrifuge 2 ml urine samples at 2,250 g for 15 minutes before processing. After centrifugation, re-suspend the resulting pellet in 200 µl of PBS buffer, and transfer 200 µl to the lysis plate.

Seminal fluids

Vortex the samples vigorously for no more than 15 seconds, and then transfer the clarified sample into a micro-well plate or micro-centrifuge tube.

Milk

Milk samples are directly compatible with the OxMag Viral RNA/DNA purification kit. Depending on sample quality, centrifugation (5000 x g for 2 minutes) may be required for separating milk in different phases. The supernatant/clear phase should be collected by carefully pushing aside the top layer.

The List of Materials to be Supplied by the User

Table 7. Equipment and Reagents to be Supplied by the User

Equipment	Consumables
Thermoblock or thermomixer	Ethanol ≥95%
Centrifuge	OxBeads zirconia/steel beads (optional)
Vortex	RNase-free 1.5 ml micro-centrifuge tubes
Pipette 0.5 - 10 µl	Benchtop cooler or ice box
Pipette 20 - 200 µl	0.5 - 10 µl pipette tips with filter
Pipette 100 - 1000 µl	20 – 200 µl pipette tips with filter
Bead Beating Machine (optional)	100 - 1000 µl pipette tips with filter
Tecan, King Fisher Flex or other liquid handlers	Automation platform-compatible plastics

Instructions for Automated Purifications

The sample should be stored according to "Interim Guidelines for Collecting and Handling of Clinical Specimens (Center for Disease Control, CDC)". Before analysis, ensure the samples do not contain inhibiting mucus and sediments.

Before starting the procedure, prepare the solutions and enzymes according to the solution preparation guide (Table 2-6). **Do not freeze OxMag® Beads solution**. Before pipetting, ensure that the OxMag® Beads solution is homogeneous and has an even distribution of nanoparticles (use a vortex or HulaMixer). Solution A may form precipitates upon storage. Warm it up to 60°C until the residues have fully dissolved.

1. Set up the instrument (200 µl sample input volume).

2. Prepare Solution A with Magnetic Beads and Carrier RNA: For one reaction, add 10 µl of OxMag® Beads and 5 µl of Carrier RNA to 265 µl Solution A (Lysis/Binding buffer). For routing testing, use Table 6.

3. Prepare the processing plates:

- Plate wash (plate position 2): Add 500 µl of Solution W1 to each well in the plate;
- Plate wash (plate position 3): Add 800 µl of Solution W2 to each well in the plate;
- Plate elution (plate position 4): Add 50-200 µl of Solution E to each well in the plate.

4. Prepare sample plate:

- Add 5 µl of Proteinase K to each sample well;
- Add 200 µl of sample to each sample well;
- Add 200 µl of Nuclease-free Water to the Negative Control well.
- Invert Solution A mixed with Magnetic Beads and Carrier RNA gently to have a homogeneous mixture, then add 280 µl to each well.

5. Load the prepared plates into the appliance according to the relevant appliance instructions.

Disposal

Dispose of used kit reagents, human clinical samples, and sealed amplification plates as laboratory clinical waste according to local, state, and federal regulations.

Version History

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Quality Control System

The Kit is in accordance with 2017/746-EN Medical Device Regulations.

Technical support

For technical support, please contact our dedicated Technical Support Team at:

TEL: +995 599 374 374, Email: info@oxgen.ge

Trademarks and Disclaimers

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Explanation of Symbols

	Attention
	Lot Number
	Catalogue Number
	Production Date
	Refer to the Operating Instructions
	Shelf life
	If the Package Is Damaged “Do Not Use It”
	Manufacturer Information
	EC Representative
	Temperature limit