OxMag Viral RNA Purification Kit

High-Throughput Technology

For Use with Automated and Manual Extraction Systems

INSTRUCTION FOR USE

Version 4. MAG-009.10.25

CE-IVDR

REF MAG-009

OxGEn Solutions,14th km, Natakhtari,
Mtskheta Municipality 3308, Georgia

EC REP MDSS GmbH 41 Schiffgraben, 30175,
Hannover, Germany

List of content

Description of the kit

Intended use

The OxMag Viral RNA Purification Kit was certified according "EU Regulation 2017/746 on In Vitro Diagnostic Medical Devices" for isolation of the viral RNA/DNA from nasopharyngeal and oral swabs, sputum, broncho-alveolar lavage[1]. The technology allows high-throughput analyses, requires low handling, gives an advantage in simplicity and speed, and reduces the risk of contamination. The analytical performance and sensitivity of the kit were thoroughly tested in laboratory and clinical settings.

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 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**	**2000 rxn**
Solution A	Lysis/Binding Buffer	56 ml	70 ml x 2	112 ml x 5
Solution W1 (conc.)	Wash Buffer 1	31 ml	79 ml	317 ml
Solution W2 (conc.)	Wash Buffer 2	14 ml x 2	70 ml	140 ml x 2
Solution E	Elution Buffer	42 ml	105 ml	105 ml x 4
OxMag® Beads* *Magnetite*	Synthetic Magnetic Beads	2.1 ml	5.25 ml	21 ml
Proteinase K	Enzyme *Lyophilized Powder*	20 mg	25 mg x 2	20 mg x 10
Proteinase K Storage Buffer	Storage Buffer for Enzyme	1.1 ml	1.4 ml x 2	11ml
Carrier RNA	Synthetic Oligo Mix *Lyophilized Powder*	100 µg	125 µg x 2	100 µg x 10

* Store OxMag® Beads at 2–8 °C after delivery. Do not freeze.

[1] The kit can be also used as a Research Use Only (RUO) product for rapid and reliable isolation of total viral nucleotides from other human and animal liquid samples and body fluids such as (plasma and serum, saliva, urogenital swabs, urine and seminal fluids, milk).

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”. If the labels of Solution W1 indicate that ethanol has already been added by the manufacturer, omit this step.

Table 2. Preparation of Solution Wash 1

No. Reactions	Solution W1	Ethanol ≥95%	Final Volume
200	31 ml	74 ml	105 ml
500	79 ml	184 ml	263 ml
2000	317 ml	733 ml	1,050 ml

Solution W2

Wash Buffer 2 comes as a concentrate. Before 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”. If the labels of Solution W2 indicate that ethanol has already been added by the manufacturer, omit this step.

Table 3. Preparation of Solution Wash 2

No. Reactions	Solution W2	Ethanol ≥95%	Final Volume
200	14 ml x 2	70 ml (In each bottle)	84 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 with Carrier RNA (For Routine Testing)

Prepare Solution A with Magnetic Beads and Carrier RNA for routine testing. Add the appropriate volume of components indicated in "Table 6. Preparation of Solution A with Magnetic Beads" for same-day use. To calculate volumes for other sample numbers, refer to the per-well volume and add 5% overage of Solution A and OxMag® Beads.

Table 6. Preparation of Solution A with Magnetic Beads and Carrier RNA

No. Reactions	Solution A	OxMag® Beads	Carrier RNA	Final Volume
1	265 µl	10 µl	5 µl	280 µl
96	26.71 ml	1.01 ml	0.48 ml	28.2 ml
192	53.42 ml	2.02 ml	0.96 ml	56.4 ml

Recommended Sample Pretreatment

Based on the required RNA quantity and considering the various specimen types, the yield can be optimised by increasing the sample volume from 200 µL to 250 µL, without modifying the buffer concentrations in the subsequent steps. For larger input materials (e.g., 400 µl), scale up all buffer volumes proportionally according to the increased sample input.

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 1X PBS or 0.9 % saline buffer. Vortex the mixture vigorously at the highest setting for 30-45 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 1X 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.

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 1X PBS tubes 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.

Plasma/Serum

Centrifuge the blood samples at 1500-2000 g for 10–15 minutes at room temperature to separate the plasma or serum from the cellular components. After centrifugation, carefully transfer the plasma or serum layer into a new microcentrifuge tube using a pipette, ensuring that no cellular material is carried over.

Urine

Centrifuge 2 ml urine samples at 2250 g for 15 minutes before processing. After centrifugation, re-suspend the resulting pellet in 200 µl of 1X PBS buffer, and transfer 200 µl to the lysis plate.

Seminal fluid

Vortex the samples vigorously for no more than 15-20 seconds, and then transfer the clarified sample into a micro-well plate or micro-centrifuge tube.

Milk

Depending on sample quality, centrifugation at 11000 × g for 2 to 10 min may be required. The supernatant should be collected by carefully pushing aside the top layer disc.

The List of Materials to be Supplied by the User

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

Equipment	Consumables
Thermoshaker or Thermomixer	Ethanol ≥95%
Magnetic separation rack	RNase/DNase-free 1.5 ml microcentrifuge tubes
Pipette 0.5 - 10 µl	Adhesive plate seals
Pipette 20 - 200 µl	0.5 - 10 µl pipette filter tips
Pipette 100 - 1000 µl	20 – 200 µl pipette filter tips
Magnetic rod–based platforms (e.g. KingFisher Flex)	100 - 1000 µl pipette filter tips
Liquid handlers (e.g. Tecan Fluent)	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). Solution A may form precipitates upon storage. Warm it up to 60°C until the residues have fully dissolved.

Protocol for magnetic rod–based platforms

Stage ▼	Description
Prepare Lysis /Binding Bead Mix with Carrier RNA ►	1. 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.
Prepare the processing plates ►	1. Plate wash (plate position 2): Add 500 µl of Solution W1 to each well in the plate; 2. Plate wash (plate position 3): Add 800 µl of Solution W2 to each well in the plate; 3. Plate elution (plate position 4): Add 50-200 µl of Solution E to each well in the plate.
Prepare sample plate ►	1. Add 5 µl of Proteinase K to each sample well; 2. Add 200-250 µl of sample to each sample well; 3. Add 200 µl of Nuclease-free Water to the Negative Control well. 4. Invert Solution A mixed with Magnetic Beads and Carrier RNA gently to have a homogeneous mixture, then add 280 µl to each well.
Run the instrument ►	1. Load the prepared plates into the appliance according to the relevant appliance instructions e.g. “MVP_2Wash_200_Flex” . 2. Run the instrument.

Protocol for liquid handlers

This procedure can also be applied for manual purification of viral RNA using the appropriate plasticware and a magnetic rack compatible with the RNase/DNase-free 1.5-2.0 ml tubes.

Stage ▼	Description
Lysis/binding stage ►	1. Add 5 µL of Proteinase K to the well of a 2 mL deep-well plate, followed by 200-250 µL of the sample. Mix by shaking at 100 rpm. 2. Add 280 µl of premixed Solution A with Magnetic Beads and Carrier RNA (For one reaction 265 µl of Solution A, 10 µl of OxMag Beads and 5 µl of Carrier RNA. For routing testing use Table 6.) 3. Seal the plate with a clear adhesive film. Mix and incubate the sample at 65 °C for 15 minutes with shaking at 800-1000 rpm.
Washing stage ►	1. Place the deep-well plate on the magnetic separation rack for 3-5 min. Note: Wait for the solution to become transparent/clear before proceeding to the next step. 2. Keep the deep-well plate on the magnetic separation rack and remove the solution by pipette without disturbing the pellet/ring of separated magnetic beads. 3. Remove the deep-well plate from the magnetic separation rack, add 500 µl of Solution W1. Seal the plate with a clear adhesive film and shake at 800-1000 rpm for 1 minute. 4. Put the deep-well plate on the magnetic separation rack. Wait 1-2 min for precipitation or until the solution becomes transparent/clear. 5. Remove the solution by pipette without disturbing the pellet/ring of separated magnetic beads. 6. Remove the deep-well plate from the magnetic separation rack, add 800 µl of Solution W2. Seal the plate with a clear adhesive film and shake at 800-1000 rpm for 1 minute. 7. Put the deep-well plate on the magnetic separation rack. Wait 1-2 min for precipitation or until the solution becomes transparent/clear. 8. Remove the solution by pipette without disturbing the pellet/ring of beads. Do not leave any traces of Solution W2. 9. Leave the sample to air-dry for 2-3 min. Caution must be taken not to over-dry the pellet.
Elution stage ►	1. Add from 50-200 µl of Solution E (Elution Buffer). Seal the plate with a clear adhesive film. 2. Incubate sealed plate at 65 °C for 5-7 minutes with shaking at 800-1000 rpm. 3. Place the sealed plate on the magnetic separation rack for 1 min. 4. Transfer the eluate to a new microfuge tube or standard 96-well plate. Seal the eluate plate with adhesive firm. deep-well plate and store at -20°C.

Troubleshooting RNA purification

Table 8. Possible causes and solutions for problems that may occur during RNA preparation

Problem	Possible Cause	Corrective Action
Agglomerated Magnetic Nanoparticle Solution	Magnetic Nanoparticle Solution has been frozen or stored below the recommended temperature	Do not freeze Magnetic Nanoparticle Solution. Store according to the manufacturer's recommended conditions. Discard if aggregation is observed, as performance will be compromised.
Low Yield	Incorrect preparation or storage of buffers and reagents	Store OxMag Magnetic Beads at room temperature (do not freeze). Freezing affects performance. Vortex immediately before use. Prepare Lysis/Binding Bead Mix immediately before use and ensure it is homogeneous.
	Beads over-dried	After final wash, ensure ethanol is completely removed but do not overdry; this reduces yield.
	Incomplete elution	Thoroughly mix beads with elution buffer incubate at 65 °C with mixing for full recovery.
Purified Nucleic Acid is Degraded	Improper handling or storage of sample	Follow collection and storage instructions carefully.
	RNase/DNase contamination	Always wear gloves; use RNase/DNase-free tips and tubes. Keep all reagents tightly sealed.

Precautions for Users

- The kit is intended to be used by laboratory and healthcare professionals. It is not intended for self-testing and near patient testing.
- 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.
- Handle all biological samples as potentially infectious and avoid direct contact.
- Follow relevant national biosafety regulations and WHO and CDC guidelines for specimen collection and processing.
- Trained professionals should only use the kit in a diagnostic or research laboratory with appropriate equipment and safety standards.
- Review the safety data sheets (MSDS) provided with the kit.
- Use designated laboratory equipment, consumables, and personal protective equipment in each room.
- Follow Good Laboratory Practices by wearing protective clothing, gloves, goggles, and a mask. Avoid eating, drinking, smoking, or applying cosmetics in the working area.
- Do not mix reagents from different sources or kits.
- Clean equipment and surfaces regularly with appropriate bleach concentration or equivalent decontaminants that remove nucleic acids, followed by 70% ethanol.

Chemical Safety

The components of the kit with hazardous content and handling instructions are summarized in “Table 9. Hazardous content and handling instructions”. Wear gloves, goggles and protective equipment and follow the safety instructions given in the table.

Component	GHS symbol	Category	Statements
Solution A	 GHS05, GHS07	Acute Toxicity (Oral) – Category 4 SKIN CORROSION/IRRITATION-Category 2 SERIOUS EYE DAMAGE/EYE IRRITATION – CATEGORY 2 A	**Hazard Statements:** H302; H312; H332; H14; H412 **Precautionary Statements:** P260, P273, P280, P303 + P353, P306 + P361 + P353, P304 + P340 + P312, P305 + P351 + P338 + P310
Solution W 1 and W2	 GHS02	Acute Toxicity (Oral) – Category 4 SKIN CORROSION/IRRITATION - Category 2 SERIOUS EYE DAMAGE/EYE IRRITATION –CATEGORY 2 A	**Hazard Statements:** H225; H302; H332; H315; H319 **Precautionary Statements**: P210, P280, P301 + P310 + P330, P302 + P352 + P312, P304 + P340 + P311
Proteinase K	 GHS07, GHS08	SKIN IRRITATION, Category 2 EYE IRRITATION, Category 2 RESPIRATORY SENSITIZATION - Category 1	**Hazard Statements:** H315; H317; H319; H334; H335 **Precautionary Statements:** P260, P285, P304 + P341, P342 + P311

Table 9. Hazardous content and handling instructions

Hazard Statements	
H302+H332	Harmful if swallowed, Harmful if inhaled
H315	Causes skin irritation
H317	May cause an allergic skin reaction
H319	Causes serious eye irritation
H225	Highly Flammable liquid and vapor
H301+H311+ H331	Toxic if swallowed, in contact with skin or if inhaled
H319	Causes serious eye irritation
H334	May cause allergy or asthma symptoms or breathing difficulties if inhaled
H335	May cause respiratory irritation

Precaution Statements	
P210	Keep away from heat, hot surface, sparks, open flames and other ignition sources. - No smoking.
P260	Do not breathe dust/fume/gas/mist/vapors/spray.
P273	Avoid release to the environment.
P280	Wear protective gloves/protective clothing/eye protection/face protection.
P285	In case of inadequate ventilation wear respiratory protection
P301 + P310 + P330	IF SWALLOWED: Immediately call a POISON CENTER or doctor/physician. Rinse mouth.
P302 + P352 + P312	IF ON SKIN: Wash with plenty of water. Call a POISON CENTER or doctor if you feel unwell.

P303 + P353	IF ON SKIN (or hair): Rinse skin with water [or shower].
P304 + P340 + P311	IF INHALED: Remove victim to fresh air and keep at rest in a position comfortable for breathing. Call a POISON CENTER or doctor.
P304 + P340 + P312	IF INHALED: Remove victim to fresh air and keep at rest in a position comfortable for breathing. Call a POISON CENTER or doctor if you feel unwell.
P304 + P341	IF INHALED: If breathing is difficult, remove person to fresh air and keep comfortable for breathing.
P305 + P351 + P338 + P310	IF IN EYES: Rinse cautiously with water for several minutes. Remove contact lenses, if present and easy to do. Continue rinsing. Immediately call a POISON CENTER or doctor/physician.
P306 + P361 + P353	IF ON CLOTHING: Take off immediately all contaminated clothing.
P342 + P311	If experiencing respiratory symptoms: Call a POISON CENTER/ doctor.

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

Instruction for Use Version 4. MAG-009. October, 2025. EN.

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

OxMag is a trademark of OxGEn, LLC. AM 2021 11324.

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