OxMag Pathogen DNA/RNA Purification Kit

High-Throughput Technology

For Use with Automated and Manual Extraction Systems

INSTRUCTION FOR USE

RUO

REF

Version 4. MAG-008.10.25

Research Use Only

MAG-008

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List of content

Description of the kit

Intended use

The OxMag Pathogen DNA/RNA Purification Kit is designed for the efficient isolation of microbial nucleic acids from a wide range of clinical and environmental samples. It is especially suited for microbiome research, enabling the extraction of total nucleic acids (DNA and RNA) from bacteria, fungi, and viruses present in complex sample matrices such as respiratory, oral, urogenital, and skin swabs, biofluids, stool, milk and environmental (e.g. potable and/or sewage water) samples. 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 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 pathogen DNA/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 Pathogen DNA/RNA Purification Kit		**200 rxn**	**500 rxn**	**2000 rxn**
Solution A	Lysis/Binding Buffer	57 ml	71 ml x 2	114 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

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

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

Lysis/Binding Bead Mix (For Routine Testing)

Prepare Solution A with Magnetic Beads 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

No. Reactions	Solution A	OxMag® Beads	Final Volume
1	270 µl	10 µl	280 µl
96	27.22 ml	1.01 ml	28.23 ml
192	54.43 ml	2.02 ml	56.45 ml

Recommended Sample Pretreatment

Based on the required DNA/RNA quantity and considering the various specimen types, the yield can be optimized 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.

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.

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.

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.

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.

Stool

Weigh a 20-60 mg stool sample and place it in a 2 mL microfuge tube filled with OxBeads Zirconia Beads (Cat. No. OXBB-001/002, not provided). Add 1000 µL OxGEn Specimen Storage Buffer (Cat. No. OXGE-002, not provided) and mix vigorously with a bead beating machine at high speed (~ 4000 rpm) for 5-10 minutes. Spin down at a low setting for ~3 seconds to collect the suspension at the bottom of the tube. Note: Do not centrifuge at higher speeds or for longer than 5 seconds, as this may cause the bacteria to precipitate. Use the suspension for DNA extraction.

Environment

Environmental samples (e.g., potable and/or sewage water) should be concentrated according to standard filtration procedures. Afterward, the filtrate should be mixed with 1 mL 1X PBS buffer, vortexed, and spin down at a low setting for ~3 seconds. Note: Do not centrifuge at higher speeds or for longer than 5 seconds, as this may cause the bacteria to precipitate. Use the suspension for DNA extraction.

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
Bead Beater Machine (optional)	OxBeads Zirconia Beads - OXBB-001/002 (optional)
Vortex (optional)	OxGEn Specimen Storage Buffer - OXGE-002 (optional)

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►	1. For one reaction, add 10 µl of OxMag Beads to 270 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 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 nucleic acid purification 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 (For one reaction 270 µl of Solution A and 10 µl of OxMag Beads. 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 DNA/RNA purification

Table 8. Possible causes and solutions for problems that may occur during DNA/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.
	Improper storage of eluted nucleic acid	Store eluates on ice if used immediately, or at –80 °C for long-term storage. Avoid repeated freeze–thaw cycles.

Magnetic Beads in Eluate	Bead carryover	Small bead carryover may occur and typically does not affect downstream applications. To remove, place eluate tube on a magnetic rack and transfer the clear supernatant to a new RNase/DNase-free tube.
Inhibition of downstream applications (e.g., PCR, RT-PCR)	Excess sample material or improper elution volume	Optimize input sample amount. Adjust the elution buffer volume (increase or decrease as needed).
	Residual salts, ethanol, or contaminants in the eluate	Ensure all wash steps are performed correctly. Use fresh wash buffers. Completely dry magnetic beads before elution to prevent ethanol carryover.

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 Acute Toxicity (Dermal) – Category 4 Skin Corrosion/Irritation – Category 1B Hazardous to the Aquatic Environment (Chronic) – Category 3	**Hazard Statements:** H302, H312, H314, H412 **Precautionary Statements:** P260, P273, P280, P303 + P361 + P353, P304 + P340 + P312, P305 + P351 + P338 + P310, P301 + P312 + P330, P363
Solution W1	 GHS07	Acute Toxicity (Oral) – Category 4 Skin Corrosion/Irritation – Category 2 Serious Eye Damage/Eye Irritation – Category 2A	**Hazard Statements:** H302, H315, H319 **Precautionary Statements**: P264, P270, P280, P301 + P312, P302 + P352, P305 + P351 + P338, P330, P332 + P313, P337 + P313, P362 + P364
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	Harmful if swallowed
H312	Harmful in contact with skin
H314	Causes severe skin burns and eye damage
H315	Causes skin irritation
H317	May cause an allergic skin reaction
H319	Causes serious eye irritation
H334	May cause allergy or asthma symptoms or breathing difficulties if inhaled
H335	May cause respiratory irritation
H412	Harmful to aquatic life with long lasting effects

Precaution Statements

P260	Do not breathe dust/fume/gas/mist/vapours/spray.
P264	Wash hands thoroughly after handling.
P270	Do not eat, drink or smoke when using this product.
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 + P312 + P330	IF SWALLOWED: Call a POISON CENTER or doctor if you feel unwell. Rinse mouth.
P302 + P352	IF ON SKIN: Wash with plenty of soap and water.
P303 + P361 + P353	IF ON SKIN (or hair): Remove immediately all contaminated clothing. Rinse skin with water/shower.
P304 + P340 + P312	IF INHALED: Remove victim to fresh air and keep 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.
P342 + P311	If experiencing respiratory symptoms: Call a POISON CENTER or doctor.
P362 + P364	Take off contaminated clothing and wash it before reuse.

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-008. 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

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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