omega BIO-TEK
innovations in nucleic acid isolation

Product Manual

Mag-Bind® Viral DNA/RNA Xpress Kit
CE IVD

Product	Preps
M6219-2304CEIVD	24 x 96 preps

Manual Date: July 2023
Manual Revision: v1.6

IVD

For In Vitro Diagnostic Use

CE

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CE IVD

Table of Contents

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Intended Use

For in vitro diagnostic use.

The Mag-Bind® Viral DNA/RNA Xpress Kit CE IVD is intended for isolation and purification of viral DNA and RNA from nasopharyngeal (NP) swab specimens that are dry or in viral transport media (VTM), from saliva and other sample sources.

The Mag-Bind® Viral DNA/RNA Xpress Kit CE IVD utilizes magnetic bead-based technology and can be processed either manually or automated on most open-ended liquid handling platforms as well as magnetic processors.

Intended User

This kit is intended for professional use.

The Mag-Bind® Viral DNA/RNA Xpress Kit CE IVD is for in vitro use and to be used by professional users, such as laboratory personnel, technicians, researchers and physicians specifically instructed and trained in molecular biology techniques and familiar with magnetic bead-based purification, either manual or automated.

Product Description

Mag-Bind® Viral DNA/RNA Xpress Kit CE IVD follows a magnetic bead-based approach for the rapid and reliable isolation of viral DNA and RNA from nasopharyngeal (NP) swab specimens that are dry or in viral transport media (VTM), from saliva and other sample sources. The extraction methodology is easily adaptable to various automated systems and can also be scaled up or down depending on the amount of starting sample amount used. The kit utilizes the proven Mag-Bind® technology that enables the purification of high-quality nucleic acids that are free of proteins, nucleases, and other impurities. The purified nucleic acids are ready for direct use in downstream applications such as qPCR, RT-qPCR, and more.

If using the Mag-Bind® Viral DNA/RNA Xpress Kit CE IVD for the first time, please read this manual to become familiar with the procedure. The samples are first lysed in TNA Lysis Buffer under highly denaturing conditions to inactivate the RNases and to preserve the integrity of viral RNA. Carrier RNA is added to the lysis buffer to enhance the binding of viral nucleic acids to the magnetic beads and to maximize the recovery from low viral titer samples. The lysate is then mixed with Mag-Bind® Particles RQ along with isopropanol to bind viral nucleic acids to the magnetic beads. The viral nucleic acid-bound Mag-Bind® Particles RQ are washed twice in 80% ethanol and then eluted in Nuclease-free Water. Please note that the kit is not designed to separate cellular nucleic acids from viral nucleic acids, therefore cellular nucleic acids will be co-purified if present.

A review of methods for isolation and purification of DNA/RNA is provided in the following referenced literature[1,2].

Important:

1. If automating this procedure on a liquid handler or a magnetic processor, please contact your Omega Bio-tek representative for instrument-specific instructions.

2. Kits include enough reagents for the specified number of preparations plus an additional 10% overage to ensure there is sufficient volume. Please be aware that the actual number of preparations may be lower due to pre-aliquoting of reagents, processing partial plates, and automation platform used etc.

1 Ali, N., Rampazzo, R., Costa, A., & Krieger, M. A. (2017). Current Nucleic Acid Extraction Methods and Their Implications to Point-of-Care Diagnostics. BioMed research international, 2017, 9306564. https://doi.org/10.1155/2017/9306564
2 Geciova, J., Bury, D., & Jelen, P. (2002). Methods for disruption of microbial cells for potential use in the dairy industry—a review. International Dairy Journal, 12(6), 541-553.

Kit Contents

Product	M6219-2304CEIVD
Purifications	24 x 96
TNA Lysis Buffer	640 mL
RMP Buffer	500 mL
Nuclease-free Water	250 mL
Carrier RNA	3 mg
Mag-Bind® Particles RQ	13 mL

Storage and Stability

All of the Mag-Bind® Viral DNA/RNA Xpress Kit CE IVD components are guaranteed for at least 12 months from the date of purchase when stored as follows. Carrier RNA should be stored at -10 to -30°C. All remaining components should be stored at recommended temperatures as mentioned on the bottle label. Once product is opened, continue to maintain the product in accordance with labeled instructions. Ensure that caps are properly tightened following each use. During shipment or storage in cool ambient conditions, precipitates may form in some buffers. Dissolve such deposits by warming the solution at 37°C and gently shaking.

Preparing Reagents

1. Dilute RMP Buffer with 500 mL 100% isopropanol and store at room temperature.

2. Add 3 mL Nuclease-free Water to the tube containing lyophilized Carrier RNA to obtain a solution of 1 µg/µL. Dissolve the Carrier RNA thoroughly, divide it into conveniently sized aliquots, and store at -20°C. Do no freeze-thaw the aliquots of Carrier RNA more than 3 times.

Quality Control

In accordance with Omega Bio-tek's ISO-certified Quality Management System, all the reagents of Mag-Bind® Viral DNA/RNA Xpress Kit CE IVD are routinely tested against predetermined specifications on a lot-to-lot basis to ensure reliability in performance and consistency in product quality.

Warnings

This kit is for in vitro diagnostic use.

Please read all instructions carefully before using the kit.

Please decontaminate and dispose all potentially infectious materials in accordance with applicable local, state, and European regulations. For customers in the European Union, please be aware that you are required to report serious incidents that have occurred in relation to the device to the manufacturer and the competent authority of the Member State in which the user and/or the patient is established. For any assistance, please contact Omega Bio-tek at **info@omegabiotek.com**.

If you use this kit following an automated extraction workflow, the surface of the automated platform is considered a biohazard. Use appropriate decontamination and disposal methods in adherence to all applicable local state/provincial, and/or national regulations.

Safety Information

All chemicals and biological materials are potentially hazardous.

Biological samples such as plasma, serum, tissues, body fluids, blood, etc. are potentially infectious and must be treated as biohazardous materials. Conduct all work in properly equipped facilities following universal precautions and using appropriate personal safety equipment such as disposable gloves, lab coats, safety glasses, etc. as required by policies and procedures outlined by your facility.

Please refer to safety data sheets (SDSs) for information on safe handling, transport and disposal of different reagents included in this kit. SDSs are made available in PDF format on the product page at **www.omegabiotek.com**. Discard all waste in accordance with the local safety regulations.

Precautions

Some of the buffers included in the Mag-Bind® Viral DNA/RNA Xpress Kit CE IVD contain guanidine-based chaotropic agents, which can form highly reactive compounds when combined with bleach. **DO NOT add bleach or acidic solutions** to guanidine containing sample-preparation waste. Please access the SDSs online for detailed information on the reagents.

Component	Description
TNA Lysis Buffer  	Contains: Guanidine thiocyanate and anionic detergent. Danger! Harmful if swallowed. Causes severe skin burns and eye damage. May cause an allergic skin reaction. Harmful if inhaled. Harmful to aquatic life with long lasting effects. Contact with acids liberates very toxic gas. Do no breathe mist/vapors/spray. Wash all exposed external body areas thoroughly after handling. Do no eat, drink, or smoke when using this product. Use only outdoors or in a well-ventilated area. Contaminated work clothing should not be allowed out of the workplace. Avoid release to the environment. Wear protective gloves, protective clothing, eye protection, and face protection. SWALLOWED: Rinse mouth. DO NOT induce vomiting. Call a POISON CENTER/doctor/physician/first aider if you feel unwell. ON SKIN (or hair): Take off immediately all contaminated clothing. Rinse skin with water [or shower]. Wash with plenty of soap and water. Take off contaminated clothing and wash it before reuse. If skin irritation or rash occurs: Get medical advice/attention. INHALED: Remove person to fresh air and keep comfortable for breathing. IN EYES: Rinse cautiously with water for several minutes. Remove contact lenses, if present and easy to do. Continue rinsing.
RMP Buffer 	Contains: Guanidine hydrochloride. Warning! Causes skin irritation. Causes serious eye irritation. Wear protective gloves/ protective clothing/eye protection/face protection. IN EYES: Rinse cautiously with water for several minutes. Remove contact lenses, if present and easy to do. Continue rinsing. Get medical advice/attention if eye irritation persists. ON SKIN: Wash with plenty of water and soap. Get medical advice/ attention if skin irritation occurs. Take off contaminated clothing and wash before reuse.

Limitations

The performance of the kit was evaluated by isolating viral RNA from samples in PBS or viral transport medium, and preserved saliva spiked with viral particles. Evaluation studies were also performed for purification of viral DNA from samples in PBS spiked with viral particles. Kit performance was further validated by assessing the suitability of purified viral DNA/RNA in direct downstream analysis by standard amplification method. Please be advised that the user is responsible for verifying performance characteristics for any procedure not covered by Omega Bio-tek's performance evaluation studies. The user is also responsible for establishing performance metrics necessary for their downstream diagnostic application of choice. Appropriate and adequate controls must be employed in any downstream diagnostic application using viral DNA/RNA purified using the Mag-Bind® Viral DNA/RNA Xpress Kit CE IVD.

Optional Protocol Modifications: Different Sample Types

The standard protocol can be modified for extraction with viscous saliva/sputum and BAL samples or stabilized saliva from collection devices. Refer to the sections below to determine which protocol to use for the different sample types.

For nasopharyngeal swabs (dry) or nasopharyngeal swabs, nasopharyngeal aspirates and bronchoalveolar lavage samples in Viral Transport Medium (VTM), refer to the protocol on Page 10.

1. Viscous saliva/sputum and BAL samples

   Note: The following protocol is based on CDC guidelines for treatment of viscous sputum specimens. Please visit *https://www.cdc.gov/coronavirus/2019-ncov/downloads/processing-sputum-specimens.pdf* for more information.

   a. Add 100 µL of freshly prepared DTT solution (500 mM) to 5 mL cold sterile 0.01 M PBS (pH 7.2) and vortex breifly.

      Note: DTT must be prepared fresh. Discard any unused DTT solution.

   b. Add an equal volume of diluted DTT/PBS solution and sputum specimen (e.g. 200 µL sputum + 200 µL DTT/PBS solution).
   c. Incubate at room temperature for up to 30 minutes with moderate shaking to liquify sample.
   d. Transfer 200 µL liquified sample to each well of a 96-well deep-well plate (not provided).
   e. Continue to Step 4 on Page 11 of the Mag-Bind® Viral DNA/RNA Xpress Kit Protocol.

2. Stabilized saliva from collection devices

   a. Add 200 µL saliva from collection device to each well of a 96-well deep-well plate (not provided).
   b. Continue to Step 4 on Page 11 of the Mag-Bind® Viral DNA/RNA Xpress Kit Protocol.

Mag-Bind® Viral DNA/RNA Xpress Kit Protocol

Important: If automating this procedure on a liquid handler or a magnetic processor, please contact your Omega Bio-tek representative for instrument-specific instructions.

Materials and Equipment to be Supplied by User:

- Vortexer
- Magnetic separation device for 96-well plate (Recommend Alpaqua Magnum™ EX, Cat# A000380)
- 96-well deep-well plate capable of 2 mL (Recommend VWR, Cat# 73520-476)
- 96-well microplate capable of 500 µL
- 80% ethanol
- 100% isopropanol
- 1X PBS
- Optional: Sealing film

Before Starting:

- Prepare RMP Buffer and Carrier RNA according to "Preparing Reagents" section on Page 5.
- Prepare 80% ethanol.
- Vortex Mag-Bind® Particles RQ to completely resuspend.

1. Select one of the following procotols for removing the viral particles depending on swab transport method.

   A. Universal Transport Media (UTM)/Viral Transport Media (VTM) Swabs: Vortex the swabs for 30 minutes.

   OR

   B. Dry Swabs: Submerge the swab in 1X PBS (not provided). Incubate at 56°C for 30 minutes with constant mixing. Centrifuge at 10,000*g* (or maxmimum speed) for 30 seconds.

2. Freshly prepare a mastermix of TNA Lysis Buffer and Carrier RNA according to the table below:

Component	Amount per Purification	Total Amount per 96-well Plate
TNA Lysis Buffer	240 µL	25.3 mL*
Carrier RNA	1 µL	105 µL*

* 10% excess volume has been calculated for a 96-well plate.

3. Transfer 200 µL UTM/VTM or PBS to each well of a 96-well deep-well plate (not provided).

4. Add 241 µL TNA Lysis Buffer/Carrier RNA mastermix to each sample. Vortex or pipet up and down 20 times.

5. Prepare a mastermix of 100% isopropanol and Mag-Bind® Particles RQ according to the table below:

Buffer	Amount per Purification	Total Amount per 96-well Plate
100% isopropanol	280 µL	30 mL*
Mag-Bind® Particles RQ	5 µL	530 µL*

*10% excess volume has been calculated for a 96-well plate.

6. Add 285 µL 100% isopropanol/Mag-Bind® Particles RQ mastermix. Pipet up and down 20 times.

   Note: Make sure Mag-Bind® Particles RQ are completely resuspended in mastermix before use.

7. Vortex for 10 minutes.

   Note: If constant vortexing for 10 minutes is not possible, vortex for 30 seconds every 2 minutes for 10 minutes.

8. Place the plate on the magnetic separation device to magnetize the Mag-Bind® Particles RQ. Let sit at room temperature until the Mag-Bind® Particles RQ are completely cleared from solution.

9. Aspirate and discard the cleared supernatant. Do not disturb the Mag-Bind® Particles RQ.

10. Remove the plate from the magnetic separation device.

11. Add 350 µL RMP Buffer. Vortex for 5 minutes.

    Note: RMP Buffer must be diluted with ethanol prior to use. Please see Page 5 for instructions.

12. Place the plate on the magnetic separation device to magnetize the Mag-Bind® Particles RQ. Let sit at room temperature until the Mag-Bind® Particles RQ are completely cleared from solution.

13. Aspirate and discard the cleared supernatant. Do not disturb the Mag-Bind® Particles RQ.

14. Add 350 µL 80% ethanol (not provided). Vortex for 5 minutes.

15. Place the plate on the magnetic separation device to magnetize the Mag-Bind® Particles RQ. Let sit at room temperature until the Mag-Bind® Particles RQ are completely cleared from solution.

16. Aspirate and discard the cleared supernatant. Do not disturb the Mag-Bind® Particles RQ.

17. Repeat Steps 14-16 for a second 80% ethanol step.

18. Leave the plate on the magnetic separation device. Wait 1 minute. Remove residual liquid with a pipettor. Dry the Mag-Bind® Particles RQ for an additional 5-10 minutes.

19. Remove the plate from the magnetic separation device.

20. Add 50-100 µL Nuclease-free Water.

21. Vortex for 10 minutes.

    Note: If constant vortexing for 10 minutes is not possible, vortex for 30 seconds every 2 minutes for 10 minutes.

22. Place the plate on the magnetic separation device to magnetize the Mag-Bind® Particles RQ. Let sit at room temperature until the Mag-Bind® Particles RQ are completely cleared from solution.

23. Transfer the cleared supernatant containing purified RNA to a 96-well microplate (not provided) and seal with sealing film (not provided).

24. Store RNA at -80°C.

Contact Information

To reorder supplies, report a device failure or complaint, please contact:

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	**European Authorized Representative** Qarad EC-REP BV Pas 257 2440 Geel Belgium SRN: BE-AR-000000040
	**Switzerland Authorized Representative** Qarad Suisse S.A. World Trade Center Avenue Gratta-Paille 2 1018 Lausanne Switzerland CHRN: CHRN-AR-20002058

Symbols

The following symbols may appear in the instructions for use or on the packaging and labeling:

Picture	Description
	Damaged Package (Do not use if package is damaged)
	EU Authorized Representative
	Switzerland Authorized Representative
	Use-by date
	Long term storage temperature range
	Check components for storage conditions
	Lot number
	Reference, Part or Catalog Number
	Serial Number
	Quantity
	Caution
	Instructions for use
	Regulatory Mark
	In vitro diagnostic medical device

Symbols

	Unique device identifier
	Manufacturer
	No additional hazards or not classified as hazardous according to GHS
	Website
	Telephone
	Fax
	Email
	LinkedIn
	Twitter
	Facebook

Revision History

Revision	Description
v1.6, Jul 2023	Added Switzerland Authorized Representative to Symbol section
v1.5, Jul 2023	Added Switzerland Authorized Representative Information
v1.4, Dec 2022	Revised Precautions section.
v1.3, Jul 2022	Revised name for consistency.
v1.2, Jul 2022	Revised based on comments from Authorized Representative for clarity.
v1.1, Jun 2022	Revised based on comments from Authorized Representative for clarity.
v1.0, May 2022	Initial Release

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