



Mag-Bind® Blood & Tissue DNA Kit CE IVD

Product

M6399-01CEIVD

Preps

4 x 96 preps

Manual Date: July 2023

Revision Number: v1.6



For In Vitro Diagnostic Use



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Mag-Bind® Blood & Tissue DNA Kit CE IVD

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Intended Use

For in vitro diagnostic use.

The Mag-Bind® Blood & Tissue DNA Kit CE IVD is intended for isolation and purification of genomic DNA from fresh or frozen cultured cells and tissues, up to 250 µL whole blood, buccal swabs, up to 500 µL saliva, and dried blood spots.

The Mag-Bind® Blood & Tissue DNA 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® Blood & Tissue DNA 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® Blood & Tissue DNA Kit CE IVD offers a versatile method for the isolation of high-quality DNA from a wide variety of samples including fresh or frozen animal cultured cells and tissues, up to 250 µL whole blood, buccal swabs, up to 500 µL saliva, and dried blood spots. Mag-Bind® Particles HDQ provide a quick magnetic response time reducing overall processing time. This system combines the reversible nucleic acid-binding properties of Mag-Bind® paramagnetic particles with the time-proven efficiency of Omega Bio-tek's buffer chemistries to provide a fast and convenient method to isolate DNA from a variety of samples. The purification procedure provides high-quality DNA that is suitable for direct use in most downstream applications, such as amplification, next generation sequencing and enzymatic reactions.

If using the Mag-Bind® Blood & Tissue DNA Kit CE IVD for the first time, please read this booklet in its entirety to become familiar with the procedures. Samples are lysed in buffer systems that are tailored specifically for each type of starting material. After lysis, samples are mixed with HDQ Binding Buffer and Mag-Bind® Particles HDQ to bind DNA to the magnetic beads. The paramagnetic particles are separated from the lysates by using a magnetic separation device. After a few rapid wash steps to remove trace contaminants, DNA is eluted in Elution Buffer.

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	M6399-01CEIVD
Purifications	4 x 96
AL Buffer	125 mL
TL Buffer	120 mL
HDQ Binding Buffer	40 mL
VHB Buffer	230 mL
SPM Buffer	150 mL
Elution Buffer	250 mL
Proteinase K Solution	9 mL
Mag-Bind® Particles HDQ	9 mL

Storage and Stability

All of the Mag-Bind® Blood & Tissue DNA Kit CE IVD components are guaranteed for at least 12 months from the date of purchase when stored as follows. Proteinase K Solution can be stored at room temperature for up to 12 months. For long-term storage, store Proteinase K Solution at 2-8°C. Store all other components 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.

Magnetic Separation Devices and Plasticware

While many brands of magnetic separation devices are compatible with the Mag-Bind® Blood & Tissue DNA Kit CE IVD, we recommend using Alpaqua's Magnum™ EX Universal Magnet Plate (Part# A000380) in conjunction with Nunc 2 mL DeepWell™ plates (Part# 278752). This combination provides quick magnetization times, only 1 minute for complete magnetization during wash steps and 5 minutes for lysate clearance steps.

Regardless of the magnetic separation device selected, ensure the device is compatible with the plasticware necessary for this kit.

Preparing Reagents

1. Dilute SPM Buffer with 350 mL 100% ethanol and store at room temperature.
2. Prepare VHB Buffer with 290 mL 100% ethanol and store at room temperature.
3. Prepare HDQ Binding Buffer with 160 mL 100% isopropanol and store at room temperature.
4. Shake or vortex the Mag-Bind® Particles HDQ to fully resuspend the particles before use. The particles must be fully suspended during use to ensure proper binding.

Quality Control

In accordance with Omega Bio-tek's ISO-certified Quality Management System, all the reagents of Mag-Bind® Blood & Tissue DNA 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® Blood & Tissue DNA 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
AL Buffer 	Contains: Guanidine hydrochloride. Warning! Causes serious eye irritation. Causes skin irritation. Harmful if swallowed. Do not eat, drink or smoke when using this product. Wash all exposed external body areas thoroughly after handling. Wear protective gloves, protective clothing, eye protection, and 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. Take off contaminated clothing and wash before reuse. ON SKIN: Wash with plenty of water and soap. Get medical advice/attention if skin irritation or rash occurs. SWALLOWED: Rinse mouth. Call a poison center or doctor/physician if you feel unwell.
TL Buffer 	Contains: Anionic detergent. Warning! Causes serious eye irritation. May cause an allergic skin reaction. Avoid breathing mist/vapors/spray. Contaminated work clothing should not be allowed out of the workplace. 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 or rash occurs. Wash contaminated clothing before reuse.
Proteinase K Solution 	Contains: Proteinase K. Danger! Causes mild skin irritation. May cause allergy or asthma symptoms or breathing difficulties if inhaled. Avoid breathing dust/fume/gas/mist/vapors/spray. Wear protective gloves/protective clothing/eye protection/face protection. Wear respiratory protection. If exposed or concerned: Call a poison center or doctor/physician. Remove victim to fresh air and keep at rest in a position comfortable for breathing.

Precautions

Component	Description
HDQ Binding Buffer   	<p>Contains: Sodium perchlorate. Danger! May cause damage to organs through prolonged or repeated exposure. May cause fire or explosion; strong oxidizer. Harmful if swallowed. Keep away from heat, hot surfaces, sparks, open flames and other ignition sources. No smoking. Keep away from clothing and other combustible materials. Do not breathe mist/vapors/spray. Wash all exposed external body areas thoroughly after handling. Do not eat, drink, or smoke when using this product. Wear protective gloves and protective clothing. SWALLOWED: Rinse mouth. Call a POISON CENTER/doctor/physician/first aider if you feel unwell. ON CLOTHING: Rinse immediately contaminated clothing and skin with plenty of water before removing clothes. Get medical advice/attention if you feel unwell. In case of fire: Use ... to extinguish. In case of major fire and large quantities: Evacuate area. Fight fire remotely due to the risk of explosion.</p>
VHB Buffer 	<p>Contains: Guanidine hydrochloride. Warning! Causes serious eye irritation. Causes skin irritation. May cause an allergic skin reaction. Harmful if swallowed. Avoid breathing mist/vapors/spray. Do not eat, drink or smoke when using this product. Contaminated work clothing should not be allowed out of the workplace. Wear protective gloves/protective clothing/eye protection/face protection. If exposed or concerned: call a poison center or doctor/physician. 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. Take off contaminated clothing and wash before reuse. ON SKIN: Wash with plenty of water and soap. Get medical advice/attention if skin irritation or rash occurs. SWALLOWED: Rinse mouth. Call a poison center or doctor/physician if you feel unwell.</p>

Limitations

The performance of the kit was evaluated by isolating genomic DNA from 250 µL whole blood, buccal swabs, 500 µL preserved saliva and cultured cells. Kit performance was further validated by assessing the suitability of purified genomic DNA 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 genomic DNA purified using the Mag-Bind® Blood & Tissue DNA Kit CE IVD.

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Protocol for Blood

The procedure below has been optimized for use with 250 µL FRESH or FROZEN blood samples. Buffy coat can also be used.

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 Reagents to be Supplied by User:

- Magnetic separation device (Recommend Alpaqua Magnum™ EX, Part#A000380)
- Vortexer
- Heat block, incubator, or water bath capable of 70°C
- 96-well Microplate (500 µL) or desired elution plate
- 2 mL 96-well deep-well plate (Recommend Nunc, Part#278752) or desired plate compatible with the magnetic separation device
- Multichannel pipettes and reagent reservoirs
- 100% ethanol
- 100% isopropanol
- Nuclease-free water
- Optional: RNase A (10 mg/mL)
- Optional: PBS

Before Starting:

- Prepare SPM Buffer, VHB Buffer, and HDQ Binding Buffer according to the "Preparing Reagents" section on Page 5.
- Set heat block, incubator, or water bath to 70°C.

1. Prepare a mastermix of AL Buffer and Proteinase K Solution only for samples to be extracted according to the table below:

Component	Amount per Prep	Total Amount per 96-well Plate
AL Buffer	290 µL	30.6 mL*
Proteinase K Solution	20 µL	2.1 mL*

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

Important: Only prepare as much AL Buffer/Proteinase K Solution mastermix that will be used within 4 hours of preparation.

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2. Add 250 µL blood sample to a 2 mL 96-well deep-well plate (not provided). If the volume of blood is less than 250 µL, bring the volume up to 250 µL with PBS (not provided) or Elution Buffer (provided with this kit).

3. Add 310 µL AL Buffer/Proteinase K Solution mastermix to each sample. Vortex or pipet up and down 20 times to mix. Proper mixing is crucial for good yield.

Note: For automated protocols tip mixing yields best results and is recommended.

4. Incubate at 70°C for 10 minutes.

Optional: Add 5 µL RNase A to each sample. Vortex to mix. Let sit at room temperature for 2 minutes.

5. Add 400 µL HDQ Binding Buffer and 20 µL Mag-Bind® Particles HDQ to each sample. Vortex for 10 minutes to mix.

Note:

- HDQ Binding Buffer must be diluted with 100% isopropanol prior to use. Please see Page 5 for instructions. HDQ Binding Buffer and Mag-Bind® Particles HDQ can be prepared as a mastermix. Prepare only what is needed for each run.
- If constant vortexing for 10 minutes is not possible, vortex for 30 seconds every 2 minutes for 10 minutes.

6. Place the plate on a magnetic separation device to magnetize the Mag-Bind® Particles HDQ. Let sit at room temperature until the Mag-Bind® Particles HDQ are completely cleared from solution.
7. Aspirate and discard the cleared supernatant. Do not disturb the Mag-Bind® Particles HDQ.
8. Remove the plate from the magnetic separation device.
9. Add 600 µL VHB Buffer to each sample.

Note: VHB Buffer must be diluted with 100% ethanol prior to use. Please see Page 5 for instructions.

10. Vortex for 15 seconds to mix.

Note: Complete resuspension of the Mag-Bind® Particles HDQ is critical for obtaining good purity.

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11. Place the plate on the magnetic separation device to magnetize the Mag-Bind® Particles HDQ. Let sit at room temperature until the Mag-Bind® Particles HDQ are completely cleared from solution.
12. Aspirate and discard the cleared supernatant. Do not disturb the Mag-Bind® Particles HDQ.
13. Remove the plate from the magnetic separation device.
14. Repeat Steps 9-13 for a second VHB Buffer step.
15. Add 600 µL SPM Buffer to each sample.

Note: SPM Buffer must be diluted with 100% ethanol prior to use. Please see Page 5 for instructions.
16. Vortex for 15 seconds to mix.
17. Place the plate on the magnetic separation device to magnetize the Mag-Bind® Particles HDQ. Let sit at room temperature until the Mag-Bind® Particles HDQ are completely cleared from solution.
18. Aspirate and discard the cleared supernatant. Do not disturb the Mag-Bind® Particles HDQ.
19. Select one of the following ethanol removal steps:
 - A. Leave the plate on the magnetic separation device. Add 500 µL nuclease-free water (not provided), leave on magnet for 20-30 seconds, and then aspirate. Do not leave nuclease-free water on Mag-Bind® Particles HDQ for more than 60 seconds. Continue to Step 20.

OR

- B. Leave the plate on the magnetic separation device. Wait 1 minute. Remove residual liquid with a pipettor. Dry the Mag-Bind® Particles HDQ for an additional 10 minutes. Continue to Step 20.

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20. Remove the plate from the magnetic separation device.
21. Add 50-200 µL Elution Buffer or nuclease-free water to elute DNA from the Mag-Bind® Particles HDQ.

Note: Heat Elution Buffer or nuclease-free water to 70°C to improve yield.

22. Vortex for 5 minutes to mix.

Note: If constant vortexing for 5 minutes is not possible, vortex for 15 seconds every 1-2 minutes for 5 minutes.

23. Place the plate on the magnetic separation device to magnetize the Mag-Bind® Particles HDQ. Let sit at room temperature until the Mag-Bind® Particles HDQ are completely cleared from solution.
24. Transfer the cleared supernatant containing purified DNA to a 96-well microplate (not provided). Store DNA at -20°C.

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Protocol for Tissue

This method allows genomic DNA isolation from up to 10 mg tissue. Yields will vary depending on the source.

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:

- Magnetic separation device (Recommend Alpaqua Magnum™ EX, Part#A000380)
- Vortexer
- Centrifuge with swing-bucket rotor capable of 4,000g
- Centrifuge adapter for 96-well plates
- Shaking water bath capable of 55°C
- 96-well Microplate (500 µL) or desired elution plate
- 2 mL 96-well deep-well plates (Recommend Nunc, Part#278752) or desired plate compatible with the magnetic separation device
- Multichannel pipettes and reagent reservoirs
- 100% ethanol
- 100% isopropanol
- Nuclease-free water
- Recommended: 1M Dithiothreitol (DTT)
- Optional: RNase A (10 mg/mL)
- Optional: Heat block, incubator, or water bath capable of 70°C
- Optional: Liquid nitrogen and mortar and pestle

Before Starting:

- Prepare SPM Buffer, VHB Buffer, and HDQ Binding Buffer according to the "Preparing Reagents" section on Page 5.
- Set water bath to 55°C.
- Optional: Set water bath, incubator, or heat block 70°C.
- Recommended: Add 40 µL 1M DTT per 1 mL TL Buffer before use.

OPTIONAL: Although mechanical homogenization of tissue is not necessary, pulverizing the samples in liquid nitrogen will improve lysis and reduce incubation time. Once the liquid nitrogen has evaporated, transfer the powdered tissue to a clean 96-well deep-well plate (not provided). Add 250 µL TL Buffer and proceed to Step 3 on the next page.

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1. Mince up to 10 mg tissue and transfer to a 96-well deep-well plate (not provided).

Note: Cutting the tissue into small pieces can speed up lysis.

2. Add 250 µL TL Buffer to each sample.

Optional: For lysis of hair or other tough-to-lyse tissues, a mastermix of TL Buffer and DTT is recommended.

- Dilute DTT to a final concentration of 40 mM in TL Buffer.
- Add 40 µL 1M DTT per 1 mL TL Buffer before use.
- Only prepare as much TL Buffer/DTT mastermix that will be used immediately.

3. Add 20 µL Proteinase K Solution to each sample. Vortex to mix.

4. Incubate at 55°C in a shaking water bath.

Note: If a shaking water bath is not available, vortex the sample every 20-30 minutes. Lysis time depends on amount and type of tissue, but is usually under 3 hours. The lysis can proceed overnight.

Optional: Add 5 µL RNase A to each sample. Vortex to mix. Let sit at room temperature for 2 minutes.

5. Centrifuge at maximum speed ($\geq 4,000g$) for 5 minutes to pellet undigested tissue debris.
6. Carefully transfer 200 µL of the supernatant to a new 96-well deep-well plate without disturbing the undigested pellet.
7. Add 230 µL AL Buffer to each sample. Vortex for 10 minutes to mix. Proper mixing is crucial for good yield.

Note:

- For automated protocols tip mixing yields best results and is recommended.
- If constant vortexing for 10 minutes is not possible, vortex for 30 seconds every 2 minutes for 10 minutes.

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8. Add 320 µL HDQ Binding Buffer and 20 µL Mag-Bind® Particles HDQ to each sample. Vortex for 10 minutes to mix.

Note:

- HDQ Binding Buffer must be diluted with 100% isopropanol prior to use. Please see Page 5 for instructions. HDQ Binding Buffer and Mag-Bind® Particles HDQ can be prepared as a mastermix. Prepare only what is needed for each run.
- If constant vortexing for 10 minutes is not possible, vortex for 30 seconds every 2 minutes for 10 minutes.

9. Place the plate on a magnetic separation device to magnetize the Mag-Bind® Particles HDQ. Let sit at room temperature until the Mag-Bind® Particles HDQ are completely cleared from solution.
10. Aspirate and discard the cleared supernatant. Do not disturb the Mag-Bind® Particles HDQ.
11. Remove the plate containing the Mag-Bind® Particles HDQ from the magnetic separation device.
12. Add 600 µL VHB Buffer to each sample.

Note: VHB Buffer must be diluted with 100% ethanol prior to use. Please see Page 5 for instructions.

13. Vortex for 15 seconds to mix.

Note: Complete resuspension of the Mag-Bind® Particles HDQ is critical for obtaining good purity.

14. Place the plate on the magnetic separation device to magnetize the Mag-Bind® Particles HDQ. Let sit at room temperature until the Mag-Bind® Particles HDQ are completely cleared from solution.
15. Aspirate and discard the cleared supernatant. Do not disturb the Mag-Bind® Particles HDQ.
16. Remove the plate containing the Mag-Bind® Particles HDQ from the magnetic separation device.

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17. Repeat Steps 12-16 for a second VHB Buffer step.

18. Add 600 µL SPM Buffer to each sample.

Note: SPM Buffer must be diluted with 100% ethanol prior to use. Please see Page 5 for instructions.

19. Vortex for 15 seconds to mix.

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

21. Aspirate and discard the cleared supernatant. Do not disturb the Mag-Bind® Particles HDQ.

22. Select one of the following ethanol removal steps:

A. Leave the plate on the magnetic separation device. Add 500 µL nuclease-free water (not provided), leave on magnet for 20-30 seconds, and then aspirate. Do not leave nuclease-free water on Mag-Bind® Particles HDQ for more than 60 seconds. Continue to Step 23.

OR

B. Leave the plate on the magnetic separation device. Wait 1 minute. Remove residual liquid with a pipettor. Dry the Mag-Bind® Particles HDQ for an additional 10 minutes. Continue to Step 23.

23. Remove the plate containing the Mag-Bind® Particles HDQ from the magnetic separation device.

24. Add 100-200 µL Elution Buffer or nuclease-free water to elute DNA from the Mag-Bind® Particles HDQ.

Note: Heat Elution Buffer or nuclease-free water to 70°C to improve yield.

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25. Vortex for 5 minutes to mix.

Note: If constant vortexing for 5 minutes is not possible, vortex for 15 seconds every 1-2 minutes for 5 minutes.

26. Place the plate on the magnetic separation device to magnetize the Mag-Bind® Particles HDQ. Let sit at room temperature until the Mag-Bind® Particles HDQ are completely cleared from solution.
27. Transfer the cleared supernatant containing purified DNA to a 96-well microplate (not provided). Store DNA at -20°C.

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Protocol for Cultured Cells

This protocol is designed for rapid isolation of up to 25 µg genomic DNA from up to 5 x 10⁶ cultured cells.

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:

- Magnetic separation device (Recommend Alpaqua Magnum™ EX, Part#A000380)
- Vortexer
- Centrifuge with swing-bucket rotor capable of 4,000g
- Shaking water bath capable of 55°C
- 96-well Microplate (500 µL) or desired elution plate
- 2 mL 96-well deep-well plates (Recommend Nunc, Part#278752) or desired plate compatible with the magnetic separation device
- Multichannel pipettes and reagent reservoirs
- Cold PBS (4°C)
- 100% ethanol
- 100% isopropanol
- Nuclease-free water
- Optional: RNase A (10 mg/mL)
- Optional: Heat block, incubator, or water bath capable of 70°C
- Optional: Trypsin and cell scraper

Before Starting:

- Prepare SPM Buffer, VHB Buffer, and HDQ Binding Buffer according to the "Preparing Reagents" section on Page 5.
- Set shaking water bath to 55°C.
- Optional: Set water bath, incubator, or heat block 70°C.

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1. Prepare the cell suspension.
 - 1a. Frozen cell samples should be thawed before starting this protocol. Pellet cells by centrifugation. Wash the cells with cold PBS (4°C) and resuspend cells in 180 µL cold PBS. Proceed with Step 2 of this protocol.
 - 1b. For cells grown in suspension, pellet 5×10^6 cells at 1,200g in a centrifuge tube. Discard the supernatant, wash the cells once with cold PBS (4°C), and resuspend cells in 180 µL cold PBS. Proceed with Step 2 of this protocol.
 - 1c. For cells grown in a monolayer, harvest the cells by either using a trypsin treatment or cell scraper. Wash cells twice in cold PBS (4°C) and resuspend the cells with 180 µL cold PBS. Proceed with Step 2 of this protocol.
2. Prepare a mastermix of AL Buffer and Proteinase K Solution only for samples to be extracted according to the table below:

Component	Amount per Prep	Total Amount per 96-well Plate
AL Buffer	230 µL	24.3 mL*
Proteinase K Solution	20 µL	2.1 mL*

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

Important: Only prepare as much AL Buffer/Proteinase K Solution mastermix that will be used within 4 hours of preparation.

3. Add 250 µL AL Buffer/Proteinase K Solution mastermix to each sample. Vortex for 10 minutes to mix. Proper mixing is crucial for good yield.

Note:

- For automated protocols tip mixing yields best results and is recommended.
- If constant vortexing for 10 minutes is not possible, vortex for 30 seconds every 2 minutes for 10 minutes.

4. Incubate at 55°C in a shaking water bath for 10 minutes.

Note: If a shaking water bath is not available, vortex the samples every 2-3 minutes.

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5. Transfer the samples to a 96-well deep-well plate (not provided).

Optional: Add 5 µL RNase A to each sample. Vortex to mix. Let sit at room temperature for 2 minutes.

6. Add 320 µL HDQ Binding Buffer and 20 µL Mag-Bind® Particles HDQ to each sample. Vortex for 10 minutes to mix.

Note:

- HDQ Binding Buffer must be diluted with 100% isopropanol prior to use. Please see Page 5 for instructions. HDQ Binding Buffer and Mag-Bind® Particles HDQ can be prepared as a mastermix. Prepare only what is needed for each run.
- If constant vortexing for 10 minutes is not possible, vortex for 30 seconds every 2 minutes for 10 minutes.

7. Place the plate on a magnetic separation device to magnetize the Mag-Bind® Particles HDQ. Let sit at room temperature until the Mag-Bind® Particles HDQ are completely cleared from solution.
8. Aspirate and discard the cleared supernatant. Do not disturb the Mag-Bind® Particles HDQ.
9. Remove the plate containing the Mag-Bind® Particles HDQ from the magnetic separation device.
10. Add 600 µL VHB Buffer to each sample.

Note: VHB Buffer must be diluted with 100% ethanol prior to use. Please see Page 5 for instructions.

11. Vortex for 15 seconds to mix.

Note: Complete resuspension of the Mag-Bind® Particles HDQ is critical for obtaining good purity.

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

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13. Aspirate and discard the cleared supernatant. Do not disturb the Mag-Bind® Particles HDQ.
14. Remove the plate containing the Mag-Bind® Particles HDQ from the magnetic separation device.
15. Repeat Steps 10-14 for a second VHB Buffer step.
16. Add 600 µL SPM Buffer to each sample.

Note: SPM Buffer must be diluted with 100% ethanol prior to use. Please see Page 5 for instructions.
17. Vortex for 15 seconds to mix.
18. Place the plate on the magnetic separation device to magnetize the Mag-Bind® Particles HDQ. Let sit at room temperature until the Mag-Bind® Particles HDQ are completely cleared from solution.
19. Aspirate and discard the cleared supernatant. Do not disturb the Mag-Bind® Particles HDQ.
20. Select one of the following ethanol removal steps:
 - A. Leave the plate on the magnetic separation device. Add 500 µL nuclease-free water (not provided), leave on magnet for 20-30 seconds, and then aspirate. Do not leave nuclease-free water on Mag-Bind® Particles HDQ for more than 60 seconds. Continue to Step 21.

OR

- B. Leave the plate on the magnetic separation device. Wait 1 minute. Remove residual liquid with a pipettor. Dry the Mag-Bind® Particles HDQ for an additional 10 minutes. Continue to Step 21.

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21. Remove the plate containing the Mag-Bind® Particles HDQ from the magnetic separation device.
22. Add 50-200 µL Elution Buffer or nuclease-free water to elute DNA from the Mag-Bind® Particles HDQ.

Note: Heat Elution Buffer or nuclease-free water to 70°C to improve yield.

23. Vortex for 5 minutes to mix.

Note: If constant vortexing for 5 minutes is not possible, vortex for 15 seconds every 1-2 minutes for 5 minutes.

24. Place the plate on the magnetic separation device to magnetize the Mag-Bind® Particles HDQ. Let sit at room temperature until the Mag-Bind® Particles HDQ are completely cleared from solution.
25. Transfer the cleared supernatant containing purified DNA to a 96-well microplate (not provided). Store DNA at -20°C.

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Protocol for Saliva

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:

- Magnetic separation device (Recommend Alpaqua Magnum™ EX, Part#A000380)
- Vortexer
- Shaking water bath capable of 55°C
- 96-well Microplate (500 µL) or desired elution plate
- 2 mL 96-well deep-well plates (Recommend Nunc, Part#278752) or desired plate compatible with the magnetic separation device
- Multichannel pipettes and reagent reservoirs
- 100% ethanol
- 100% isopropanol
- Nuclease-free water
- Optional: RNase A (10mg/mL)
- Optional: Heat block, incubator, or water bath capable of 70°C

Before Starting:

- Prepare SPM Buffer, VHB Buffer, and HDQ Binding Buffer according to the "Preparing Reagents" section on Page 5.
- Set shaking water bath to 55°C.
- Optional: Set water bath, incubator, or heat block 70°C.

1. Centrifuge the saliva tube at 2,000g for 5 minutes.
2. Transfer 500 µL stabilized saliva samples (e.g., DNA Genotek Oragene®, Mawi iSWAB™, Biomatrix® DNAGard® Saliva) to a 96-well deep-well plate (not provided).
3. Prepare a mastermix of AL Buffer and Proteinase K Solution only for samples to be extracted according to the table below:

Component	Amount per Prep	Total Amount per 96-well Plate
AL Buffer	200 µL	21.12 mL*
Proteinase K Solution	20 µL	2.1 mL*

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

Important: Only prepare as much AL Buffer/Proteinase K Solution mastermix that will be used within 4 hours of preparation.

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4. Add 220 µL AL Buffer/Proteinase K Solution to each sample. Vortex for 10 minutes to mix. Proper mixing is crucial for good yield.

Note:

- For automated protocols tip mixing yields best results and is recommended.
- If constant vortexing for 10 minutes is not possible, vortex for 30 seconds every 2 minutes for 10 minutes.

5. Incubate at 55°C in a shaking water bath for 10 minutes.

Note: If a shaking water bath is not available, vortex the plate every 2-3 minutes. If DNA Genotek Oragene® tube was used and incubation step was already performed, skip to Step 6.

Optional: Add 5 µL RNase A to each sample. Vortex to mix. Let sit at room temperature for 2 minutes.

6. Add 400 µL HDQ Binding Buffer and 20 µL Mag-Bind® Particles HDQ to each sample. Vortex for 10 minutes to mix.

Note:

- HDQ Binding Buffer must be diluted with 100% isopropanol prior to use. Please see Page 5 for instructions. HDQ Binding Buffer and Mag-Bind® Particles HDQ can be prepared as a mastermix. Prepare only what is needed for each run.
- If constant vortexing for 10 minutes is not possible, vortex for 30 seconds every 2 minutes for 10 minutes.

7. Place the plate on a magnetic separation device to magnetize the Mag-Bind® Particles HDQ. Let sit at room temperature until the Mag-Bind® Particles HDQ are completely cleared from solution.
8. Aspirate and discard the cleared supernatant. Do not disturb the Mag-Bind® Particles HDQ.
9. Remove the plate containing the Mag-Bind® Particles HDQ from the magnetic separation device.
10. Add 600 µL VHB Buffer to each sample.

Note: VHB Buffer must be diluted with 100% ethanol prior to use. Please see Page 5 for instructions.

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11. Vortex for 15 seconds to mix.

Note: Complete resuspension of the Mag-Bind® Particles HDQ is critical for obtaining good purity.

12. Place the plate on the magnetic separation device to magnetize the Mag-Bind® Particles HDQ. Let sit at room temperature until the Mag-Bind® Particles HDQ are completely cleared from solution.
13. Aspirate and discard the cleared supernatant. Do not disturb the Mag-Bind® Particles HDQ.
14. Remove the plate containing the Mag-Bind® Particles HDQ from the magnetic separation device.
15. Repeat Steps 10-14 for a second VHB Buffer step.
16. Add 600 µL SPM Buffer to each sample.

Note: SPM Buffer must be diluted with 100% ethanol prior to use. Please see Page 5 for instructions.
17. Vortex for 15 seconds to mix.
18. Place the plate on the magnetic separation device to magnetize the Mag-Bind® Particles HDQ. Let sit at room temperature until the Mag-Bind® Particles HDQ are completely cleared from solution.
19. Aspirate and discard the cleared supernatant. Do not disturb the Mag-Bind® Particles HDQ.

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20. Select one of the following ethanol removal steps:

- A. Leave the plate on the magnetic separation device. Add 500 µL nuclease-free water (not provided), leave on magnet for 20-30 seconds, and then aspirate. Do not leave nuclease-free water on Mag-Bind® Particles HDQ for more than 60 seconds. Continue to Step 21.

OR

- B. Leave the plate on the magnetic separation device. Wait 1 minute. Remove residual liquid with a pipettor. Dry the Mag-Bind® Particles HDQ for an additional 10 minutes. Continue to Step 21.

21. Add 100-200 µL Elution Buffer or nuclease-free water to elute DNA from the Mag-Bind® Particles HDQ.

Note: Heat Elution Buffer or nuclease-free water to 70°C to improve yield.

22. Vortex for 5 minutes to mix.

Note: If constant vortexing for 5 minutes is not possible, vortex for 15 seconds every 1-2 minutes for 5 minutes.

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

24. Transfer the cleared supernatant containing purified DNA to a 96-well microplate (not provided). Store DNA at -20°C.

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Protocol for Buccal Swabs

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:

- Magnetic separation device (Recommend Alpaqua Magnum™ EX, Part#A000380)
- Vortexer
- Centrifuge with swing-bucket rotor capable of 4,000g
- Centrifuge adapter for 96-well plates
- Shaking water bath capable of 55°C
- 96-well Microplate (500 µL) or desired elution plate
- 2 mL 96-well deep-well plates (Recommend Nunc, Part#278752) or desired plate compatible with the magnetic separation device
- Multichannel pipettes and reagent reservoirs
- 100% ethanol
- 100% isopropanol
- Optional: RNase A (10 mg/mL)
- Optional: Nuclease-free water
- Optional: Heat block, incubator, or water bath capable of 70°C

Before Starting:

- Prepare SPM Buffer, VHB Buffer, and HDQ Binding Buffer according to the "Preparing Reagents" section on Page 5.
 - Set shaking water bath to 55°C.
 - Optional: Set water bath, incubator, or heat block 70°C.
-
1. Cut off the buccal brush or swab head and place each swab into a well of a 96-well deep-well plate (not provided).

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2. Prepare a mastermix of AL Buffer, Proteinase K Solution, and Elution Buffer only for samples to be extracted according to the table below:

Component	Amount per Prep	Total Amount per 96-well Plate
AL Buffer	290 µL	30.6 mL *
Proteinase K Solution	20 µL	2.1 mL*
Elution Buffer	250 µL	26.4 mL

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

Important: Only prepare as much AL Buffer/Proteinase K Solution/Elution Buffer mastermix that will be used within 4 hours of preparation.

3. Add 560 µL AL Buffer/Proteinase K Solution/Elution Buffer mastermix to each sample. Vortex or pipet up and down 20 times to mix.

Note: For automated protocols tip mixing yields best results and is recommended.

4. Incubate at 55°C in a shaking water bath for 10 minutes.

Note: If a shaking water bath is not available, vortex the plate every 2-3 minutes.

5. Centrifuge at 3,000g for 2 minutes.

6. Transfer 500 µL lysate into a new 96-well deep-well plate. Do not transfer the swabs to the new plate.

Optional: Add 5 µL RNase A to each sample. Vortex to mix. Let sit at room temperature for 2 minutes.

7. Add 350 µL HDQ Binding Buffer and 20 µL Mag-Bind® Particles HDQ to each sample. Vortex for 10 minutes to mix.

Note:

- HDQ Binding Buffer must be diluted with 100% isopropanol prior to use. Please see Page 5 for instructions. HDQ Binding Buffer and Mag-Bind® Particles HDQ can be prepared as a mastermix. Prepare only what is needed for each run.
- If constant vortexing for 10 minutes is not possible, vortex for 30 seconds every 2 minutes for 10 minutes.

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8. Place the plate on a magnetic separation device to magnetize the Mag-Bind® Particles HDQ. Let sit at room temperature until the Mag-Bind® Particles HDQ are completely cleared from solution.
9. Aspirate and discard the cleared supernatant. Do not disturb the Mag-Bind® Particles HDQ.
10. Remove the plate containing the Mag-Bind® Particles HDQ from the magnetic separation device.
11. Add 600 µL VHB Buffer to each sample.

Note: VHB Buffer must be diluted with 100% ethanol prior to use. Please see Page 5 for instructions.

12. Vortex for 15 seconds to mix.

Note: Complete resuspension of the Mag-Bind® Particles HDQ is critical for obtaining good purity.

13. Place the plate on the magnetic separation device to magnetize the Mag-Bind® Particles HDQ. Let sit at room temperature until the Mag-Bind® Particles HDQ are completely cleared from solution.
14. Aspirate and discard the cleared supernatant. Do not disturb the Mag-Bind® Particles HDQ.
15. Remove the plate containing the Mag-Bind® Particles HDQ from the magnetic separation device.
16. Repeat Steps 11-15 for a second VHB Buffer step.
17. Add 600 µL SPM Buffer to each sample.

Note: SPM Buffer must be diluted with 100% ethanol prior to use. Please see Page 5 for instructions.

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18. Vortex for 15 seconds to mix.
19. Place the plate on the magnetic separation device to magnetize the Mag-Bind® Particles HDQ. Let sit at room temperature until the Mag-Bind® Particles HDQ are completely cleared from solution.
20. Aspirate and discard the cleared supernatant. Do not disturb the Mag-Bind® Particles HDQ.
21. Leave the plate on the magnetic separation device for 10 minutes to air dry the Mag-Bind® Particles HDQ. Remove any residual liquid from the wells.

Note: All liquid must be aspirated at this step. It is helpful to remove all liquid from the well then wait one minute and remove any residual liquid from the well.


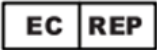

22. Remove the plate containing the Mag-Bind® Particles HDQ from the magnetic separation device.
23. Add 100-200 µL Elution Buffer or nuclease-free water (not provided) to elute DNA from the Mag-Bind® Particles HDQ.

Note: Heat Elution Buffer or nuclease-free water to 70°C to improve yield.

24. Vortex for 5 minutes to mix.
Note: If constant vortexing for 5 minutes is not possible, vortex for 15 seconds every 1-2 minutes for 5 minutes.
25. Place the plate on the magnetic separation device to magnetize the Mag-Bind® Particles HDQ. Let sit at room temperature until the Mag-Bind® Particles HDQ are completely cleared from solution.
26. Transfer the cleared supernatant containing purified DNA to a 96-well microplate (not provided). Store DNA at -20°C.


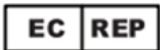












Contact Information

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

	Manufacturer Omega Bio-tek, Inc. 400 Pinnacle Way Suite #450 Norcross, GA 30071, USA Website: www.omegabiotek.com Email: info@omegabiotek.com SRN: US-MF-000024148
	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



Linked-In



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 kit 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

Notices & Disclaimers

REACH Disclosure

For European Union Use.

AL Buffer contains Triton X-100, 2-[4-(2,4,4-trimethylpentan-2-yl)phenoxy]ethanol (CAS 9002-93-1), a substance included in the European Authorisation list (Annex XIV) of REACH Regulation (EC) No 1907/2006. Substances and mixtures used for the purpose of Scientific Research and Development (SR&D) are exempt from authorization requirements if used below 1 tonne per year in volume.

Scientific Research and Development includes experimental research or analytical activities at a laboratory scale such as synthesis and testing of applications of chemicals, release tests, etc. as well as the use of the substance in monitoring and routine quality control or in vitro diagnostics.

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