

Mag-Bind® Blood DNA HV Kit CE IVD

Product
M3292-03CEIVD

Preps
96 preps

Manual Date: April 2024
Revision Number: v2.1



For In Vitro Diagnostic Use



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Mag-Bind® Blood DNA HV Kit CE IVD

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Intended Use

For in vitro diagnostic use.

The Mag-Bind® Blood DNA HV Kit CE IVD is intended for isolation and purification of genomic DNA from up to 4 mL whole blood samples.

The Mag-Bind® Blood DNA HV 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. The Mag-Bind® Blood DNA HV Kit CE IVD can be used to process up to 2 mL whole blood samples on Omega Bio-tek's MagBinder® Fit²⁴ Nucleic Acid Purification System when user-filled into MagBinder compatible cartridges.

Intended User

This kit is intended for professional use.

The Mag-Bind® Blood DNA HV Kit CE IVD is for in vitro use and to be used by or under the supervision of 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

The Mag-Bind® Blood DNA HV Kit CE IVD is designed for rapid and reliable isolation of high-quality genomic DNA from up to 4 mL whole blood samples. The Mag-Bind® Blood DNA HV Kit CE IVD has been optimized for up to 2 mL whole blood samples on Omega Bio-tek's MagBinder® Fit²⁴ Nucleic Acid Purification System when user-filled into MagBinder compatible cartridges. Mag-Bind® Particles CH 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 DNA isolation system to provide a fast and convenient method to isolate DNA. Utilizing paramagnetic particles provides high-quality DNA that is suitable for direct use in most downstream applications, such as amplification and enzymatic reactions.

If using the Mag-Bind® Blood DNA HV Kit CE IVD for the first time, please read this manual in its entirety to become familiar with the procedures. Samples are lysed in a buffer system tailored for large volume blood samples. DNA is isolated from the lysates by binding to the surface of the paramagnetic particles. 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 | M3292-03CEIVD |
|------------------------|---------------|
| Purifications | 96 |
| AL Buffer | 360 mL |
| HDQ Binding Buffer | 200 mL |
| KWB Buffer | 3 x 250 mL |
| Elution Buffer | 250 mL |
| Mag-Bind® Particles CH | 30 mL |
| Proteinase K Solution | 4 x 9 mL |

Storage and Stability

All of the Mag-Bind® Blood DNA HV 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 KWB Buffer at room temperature and away from bright light. Store all other components at recommended temperatures as mentioned on the bottle label and away from bright light. 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 HDQ Binding Buffer with 800 mL 100% isopropanol and store at room temperature.
2. Prepare stock solution of 400 mL 70% ethanol and store at room temperature.
3. Shake or vortex the Mag-Bind® Particles CH 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 DNA HV 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 DNA HV 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. |
| 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> |
| KWB Buffer     | <p>Contains: Guanidine hydrochloride, sodium perchlorate, and ethanol. Danger! Flammable liquid and vapor. Harmful if swallowed. Causes skin irritation. Causes serious eye irritation. May cause fire or explosion; strong oxidizer. May cause damage to organs through prolonged or repeated exposure (Oral, Dermal). Do not eat, drink or smoke when using this product. Keep away from heat, hot surfaces, sparks, open flames and other ignition sources. Take any precaution to avoid mixing with combustibles/organic material. Keep container tightly closed. Do not breathe mist/vapors/spray. Wear protective gloves, protective clothing, eye protection and face protection. Wash all exposed external body areas thoroughly after handling. In case of fire: Use water spray/fog to extinguish. In case of major fire and large quantities: Evacuate area. Fight the fire remotely due to the risk of explosion. 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 irritation persists. SWALLOWED: Rinse mouth. Call a POISON CENTER/doctor/physician/first aider/if you feel unwell. ON SKIN (or hair): wash with plenty of water. Take off immediately all contaminated clothing. Rinse skin with water/shower. Get medical advice/attention if irritation persists. ON CLOTHING: Rinse immediately contaminated clothing and skin with plenty of water before removing clothes. Take off contaminated clothing and wash it before reuse.</p> |

Limitations

The performance of the kit was evaluated by isolating genomic DNA from 4 mL whole blood samples and assessing the suitability of purified genomic DNA in direct downstream analysis by standard amplification method. Similar performance evaluation was carried out on MagBinder® Fit²⁴ Nucleic Acid Purification System from 2 mL whole blood samples with reagents from this kit user-filled into cartridges compatible with MagBinder. 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 DNA HV Kit CE IVD.

Mag-Bind® Blood DNA HV Kit CE-IVD

Protocol for 4 mL Whole Blood

The procedure below has been optimized for use with 4 mL FRESH or FROZEN whole blood samples.

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 for 2 mL and 15 mL tubes
- Heat block, incubator, or water bath capable of 70°C
- Vortexer
- 15 mL centrifuge tube compatible with the magnetic separation device
- 2 mL microcentrifuge tubes compatible with magnetic separation device
- 100% ethanol
- 70% ethanol
- 100% isopropanol
- Nuclease-free water
- Optional: RNase A (25 mg/mL)
- Optional: PBS

Before Starting:

- Prepare HDQ Binding Buffer and 70% ethanol according to the "Preparing Reagents" section on Page 5.
 - Set heat block, incubator, or water bath to 70°C.
 - Heat Elution Buffer to 70°C.
1. Add a 4 mL blood sample to a 15 mL centrifuge tube (not provided). Bring the volume up to 4 mL with PBS (not provided) if volume of blood is less than 4 mL.
 2. Prepare a mastermix of AL Buffer and Proteinase K Solution only for the samples to be extracted according to the table below:

| Component | Amount Per Purification | Total Amount Per 24-well plate |
|-----------------------|-------------------------|--------------------------------|
| AL Buffer | 3.4 mL | 89.7 mL * |
| Proteinase K Solution | 320 µL | 8.4 mL* |

*10% excess volume has been calculated for a 24-well plate.

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3. Add 3.72 mL AL Buffer/Proteinase K Solution mastermix to each sample. Vortex for 1 minute 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 25 minutes.

Optional: Add 100 µL RNase A (25 mg/mL) to each sample. Vortex or pipet up and down 20 times to mix. For automated protocols, tip mixing yields best results and is recommended.

5. Add 5.4 mL HDQ Binding Buffer and 240 µL Mag-Bind® Particles CH. Vortex for 20 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 CH can be prepared as a mastermix. Mix only what is needed for immediate processing.
- If constant vortexing for 20 minutes is not possible, vortex for 30 seconds every 2-3 minutes for 20 minutes.

6. Place the tube on a magnetic separation device to magnetize the Mag-Bind® Particles CH. Let sit at room temperature for 2 minutes until the Mag-Bind® Particles CH are completely cleared from solution.

Note: Time may be increased or decreased depending on the strength of the magnet used.

7. Aspirate and discard the cleared supernatant. Do not disturb the Mag-Bind® Particles CH.

8. Remove the tube from the magnetic separation device.

9. Add 2 mL KWB Buffer.

10. Vortex for 1 minute.

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

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11. Place the tube on the magnetic separation device to magnetize the Mag-Bind® Particles CH. Let sit at room temperature until the Mag-Bind® Particles CH are completely cleared from solution.
12. Aspirate and discard the cleared supernatant. Do not disturb the Mag-Bind® Particles CH.
13. Remove the tube from the magnetic separation device.
14. Repeat Steps 9 -13 for a second KWB Buffer step.
15. Repeat Steps 9 -13 for a third KWB Buffer step.
16. Add 2 mL 70% ethanol (not provided).
17. Vortex for 1 minute or pipet up and down 20 times to mix.
18. Place the tube on the magnetic separation device to magnetize the Mag-Bind® Particles CH. Let sit at room temperature until the Mag-Bind® Particles CH are completely cleared from solution.
19. Aspirate and discard the cleared supernatant. Do not disturb the Mag-Bind® Particles CH.
20. Remove the tube from the magnetic separation device.
21. Add 2 mL 70% ethanol.
22. Vortex for 1 minute or pipet up and down 20 times to mix.
23. Transfer all of the DNA-bound Mag-Bind® Particles CH along with 70% ethanol they are suspended in to a new 2 mL microcentrifuge tube (not provided).

Note: This tube transfer step mitigates the loss of beads during the subsequent water wash step.

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24. Place the tube on the magnetic separation device to magnetize the Mag-Bind® Particles CH. Let sit at room temperature until the Mag-Bind® Particles CH are completely cleared from solution.
25. Aspirate and discard the cleared supernatant. Do not disturb the Mag-Bind® Particles CH.
26. Leave the tube on the magnetic separation device. Add 1 mL nuclease-free water (not provided) and immediately aspirate. Do not leave the nuclease-free water on Mag-Bind® Particles CH for more than 60 seconds.
27. Remove the tube from the magnetic separation device.
28. Add 400 – 1000 µL Elution Buffer preheated to 70°C to elute DNA from the Mag-Bind® Particles CH.

Note: Heat Elution Buffer to 70°C to improve yield.


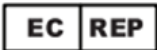

29. Vortex for 5 minutes to mix.

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

30. Place the tube on the magnetic separation device to magnetize the Mag-Bind® Particles CH. Let sit at room temperature until the Mag-Bind® Particles CH are completely cleared from solution.
31. Transfer the cleared supernatant containing purified DNA to a new microcentrifuge tube. Store DNA at -20°C.


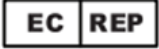












Contact Information

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 |
| United Kingdom | United Kingdom Authorized Representative Qarad UK Ltd 8 Northumberland Ave Westminster, London WC2N 5BY United Kingdom |

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 |
|----------------|--|
| v2.1, Apr 2024 | Removed magnetic separation device information. |
| v2.0, Mar 2024 | KWB Buffer replaced RMP Buffer as product enhancement. Adjusted packaging and volumes accordingly. Added United Kingdom Authorized Representative contact information. |
| 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. |

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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MicroLab® STAR™ is a trademark of Hamilton.

PCR is a patented process of Hoffman-La Roche. Use of the PCR process requires a license.