omega BIO-TEK
innovations in nucleic acid isolation

Product Manual

MB Fit24™ cfDNA Kit CE IVD

Product	Preps
B3298-10-48PFCEIVD	48 preps

Manual Date: June 2026
Revision Number: v1.4

IVD

For In Vitro Diagnostic Use

CE

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Intended Use

For in vitro diagnostic use.

The MB Fit24™ cfDNA Kit CE IVD is intended for use in a laboratory setting performing cfDNA extractions from up to 4 mL plasma/serum on the MagBinder® Fit^{24} Nucleic Acid Purification System.

Intended User

This kit is intended for professional use.

The MB Fit24™ cfDNA Kit CE IVD is intended 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/or operating magnetic processor platforms.

Product Description

The MB Fit24™ cfDNA Kit CE IVD is designed for rapid and reliable isolation of circulating DNA from up to 4 mL plasma/serum samples with the use of the MagBinder® Fit^{24} Nucleic Acid Purification System. This kit is automation-ready with prefilled with Mag-Bind® cfDNA Kit reagents arrayed into a ready-to-use reagent cartridge specifically configured for the MagBinder® Fit^{24} instrument to provide faster and consistent results. This procedure provides a semi-automated extraction workflow for processing up to 24 samples in less than 55 minutes once loaded onto the MagBinder® Fit^{24}.

The MB Fit24™ cfDNA Kit CE IVD enhances ease of use, convenience, and extraction accuracy and reduces hands-on time by skipping reagent preparation and buffer dispensing steps. The samples are lysed offline, and lysate is transferred to the reagent well containing the binding buffer. The uniquely formulated binding buffer allows for large sample volumes to be processed in semi-automated format with up to 4 mL plasma or serum being processed in one reagent cartridge without sample splitting. The magnetic properties of the Mag-Bind® Particles CH enable fast magnetic separation, especially during steps involving large volumes. The high-binding capacity decreases the amount of magnetic particles required thereby reducing the elution volume. This system combines the reversible nucleic acid-binding properties of Mag-Bind® paramagnetic particles with a unique binding system that targets smaller DNA fragments (150-400 bp) and minimizes binding of larger fragments such as genomic DNA. The purified cfDNA is of high-quality and is suitable for direct use in most downstream applications such as PCR, digital PCR, next generation sequencing, etc.

The MagBinder® Fit^{24} instrument is preprogrammed with purification protocols that are optimized to work with both prefilled as well as user filled reagent cartridges. The instrument requires the user to select the appropriate protocol depending on the kit being used. If using the MB Fit24™ cfDNA Kit CE IVD for sample volumes other than those listed in this manual, please contact your Omega Bio-tek representative for preprocessing instructions.

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

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	B3298-10-48PF
Purifications	48
Elution Tube (2 mL)	50
MagBinder® Tip Comb	2 x 2 comb
Prefilled Reagent Cartridge*	48
DS Buffer	20 mL
Elution Buffer	250 mL
Mag-Bind® Particles CH	1.1 mL
Proteinase K Solution	4 mL

*Buffers and their location in the prefilled reagent cartridges are shown on Page 10.

Storage and Stability

All of the MB Fit24™ cfDNA 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 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.

Quality Control

In accordance with Omega Bio-tek's ISO-certified Quality Management System, all the reagents of MB Fit24™ cfDNA 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.

After extraction, the surface of the MagBinder® 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® cfDNA 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
DS Buffer 	Contains: Anionic detergent. Danger! Causes serious eye damage. Causes skin irritation. Harmful to aquatic life. Wear protective gloves/protective clothing/eye protection/face protection. Avoid release to the environment. 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. Take off contaminated clothing and wash before reuse. ON SKIN: Wash with plenty of water and soap. Get medical advice/attention if skin irritation occurs.
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.
JSB Buffer   	Contains: Guanidine thiocyanate and isopropanol. Danger! Flammable liquid and vapor. Causes serious eye damage. Harmful if swallowed. Causes skin irritation. Harmful to aquatic life with long lasting effects. Keep away from heat, hot surfaces, sparks, open flames and other ignition sources. No smoking. Keep container tightly closed. Ground/bond container and receiving equipment. Use explosion-proof electrical/ventilating/lighting/intrinsically safe equipment. Use only non-sparking tools. Take precautionary measures against static discharge. Wash all exposed external body areas thoroughly after handling. Do not eat, drink or smoke when using this product. Wear protective gloves, protective clothing, eye protection and face protection. Avoid release to the environment. IN CASE OF FIRE: Use alcohol resistant foam or normal protein foam to extinguish. IN EYES: Rinse cautiously with water for several minutes. Remove contact lenses, if present and easy to do. Continue rinsing. Immediately call POISON CENTER/doctor/physician/first aider. ON SKIN (or hair): Take off immediately all contaminated clothing. Rinse skin with water/shower. Wash with plenty of water and soap. Rinse mouth. If skin irritation occurs, get medical advice/attention. Take off contaminated clothing and wash it before reuse.

Precautions

Component	Description
GT7 Buffer v1.1 	Contains: Guanidine thiocyanate. Danger! Harmful if swallowed. Causes severe skin burns and eye damage. Do not breathe mist/vapors/spray. Harmful to aquatic life with long lasting effects. Wear protective clothing, eye protection and face protection. Wash all exposed external body areas thoroughly after handling. Do not eat, drink or smoke when using this product. Avoid release to the environment. 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/shower. Wash contaminated clothing before reuse. 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/doctor/physician/first aider. INHALED: Remove person to fresh air and keep comfortable for breathing.
eSPW Buffer 	Contains: Ethanol. Danger! Highly flammable liquid and vapor. Causes serious eye damage. Keep away from heat, hot surfaces, sparks, open flames, and other ignition sources. No smoking. Keep container tightly closed. Ground/bond container and receiving equipment. Use explosion-proof electrical/ventilating/lighting/intrinsically safe equipment. Use only non-sparking tools. Take precautionary measures against static discharge. Wash all exposed external body areas thoroughly after handling. Wear protective gloves, protective clothing, eye protection, and face protection. IN CASE OF FIRE: Use alcohol resistant foam or normal protein foam to extinguish. IN EYES: Rinse cautiously with water for several minutes. Remove contact lenses, if present and easy to do so. Continue rinsing. If eye irritation persists, get medical advice/attention. ON SKIN (or hair): Take off immediately all contaminated clothing. Rinse skin with water/shower.

Limitations

The performance of the kit was evaluated by isolating cfDNA up to 4 mL of plasma/serum samples and assessing the suitability of purified cfDNA 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 cfDNA purified using the MB Fit24™ cfDNA Kit CE IVD.

Guidelines for cfDNA Quantification

DNA quantification is typically done by spectrophotometric-based (NanoDrop®) or fluorometric-based methods (Qubit®). Both of these methods are inaccurate when it comes to quantifying circulating, cell-free DNA because cfDNA is usually present in low amounts and these methods are unable to distinguish between cfDNA and high molecular weight cellular genomic DNA. It is important to establish accurate strategies to not only precisely quantify cfDNA but also to draw pertinent conclusions about the extraction efficiency. Some of the strategies that can aid in quantification of cfDNA are elucidated below.

Tape Station

The Cell-free DNA ScreenTape assay for TapeStation systems provides accurate sizing and quantification of cfDNA, as well as DNA quality assessment with %cfDNA information. The %cfDNA is indicative of the percentage of cfDNA compared to the genomic DNA in the purified sample.

qPCR

Quantification based on qPCR analysis is effective if the primers are targeting just the cfDNA fraction and not the gDNA fraction. If not, the primers are going to amplify from both the cfDNA and gDNA fractions present in the eluate skewing the results. For example, use of tumor-specific primers if the cfDNA is tumor-derived can analyze the cfDNA fraction without the gDNA interference. For kit evaluation purposes, using a spike-in such as 200 bp sheared bacterial DNA in plasma/serum along with bacterial specific primers can offer information about the extraction efficiency in terms of actual cfDNA present in the total DNA isolated.

cfDNA integrity analysis

cfDNA integrity analysis is done by real-time PCR of ALU-repeats using two sets of primers to amplify different lengths of DNA fragments (115 bp and 247 bp). ALU sequences are highly abundant in the human genome and amplification of the 115-bp ALU amplicon represents the total amount of DNA fragments (both short and long fragments) whereas the 247-bp ALU amplicon primarily reflects the amount of long DNA fragments. cfDNA integrity can be reported as integrity index, which is calculated as the ratio of ALU247 to ALU115. If the isolated DNA is mainly gDNA, ALU247/ALU115 is expected to be 1. The ratio is between 0 to 1 if short fragments (cfDNA) are present. Typically, the higher the amount of cfDNA in the sample, the higher the integrity index.

Plasticware Handling and Preparation

1. Always check reagent cartridges for presence of precipitation before starting extraction. Dissolve precipitates by warming the reagent cartridge at 37°C with gentle shaking.

2. Flick downward or gently tap each reagent cartridge before removing the seal to ensure reagents are in the bottom of the wells and not clinging to the underside of the seal.

3. Carefully remove seal from cartridges and immediately place the cartridge on the tray when ready along with the Elution Tubes into the corresponding positions (Figure 1).

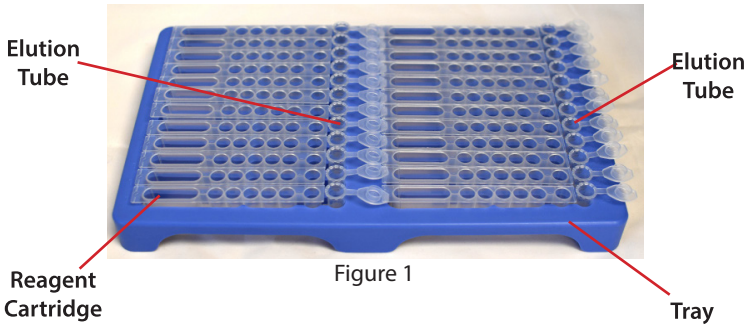


Figure 1

4. Angle the cap downward, then inward, causing the hinge to the attached cap to form a 'Z' shape before loading the elution tube onto the tray (Figure 2).

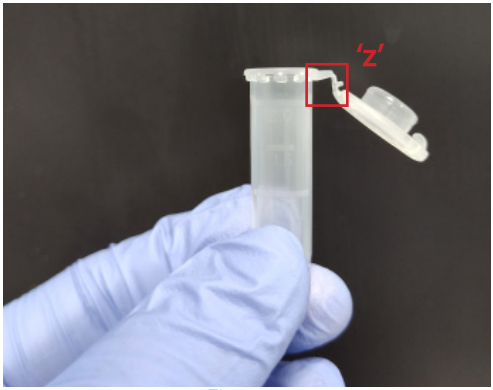


Figure 2

5. Ensure the Elution Tubes are positioned open with caps oriented to the right of the tube and pressed down (Figure 2). If there is another reagent cartridge on the right side, make sure the elution tube caps are tucked under the lip of the first well as shown in Figure 1.

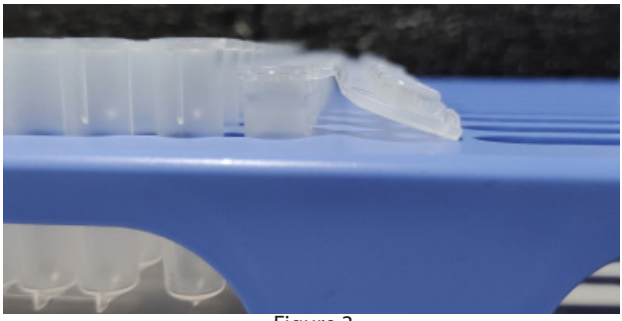
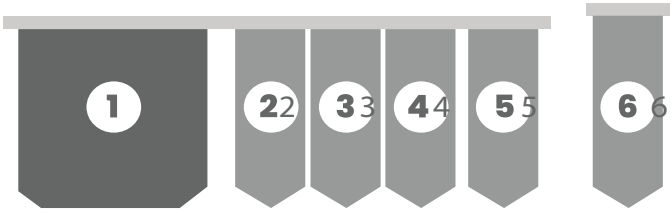


Figure 3

6. The table below details contents of reagent cartridge.



Well Position	Content	Volume per well
1	JSB Buffer	4 mL
2	GT7 Buffer v1.1	1 mL
3	GT7 Buffer v1.1	1 mL
4	eSPW Buffer	1 mL
5	eSPW Buffer	1 mL
6	Elution Buffer[1]	100 µL

[1] Elution Buffer must be added to the Elution Tube prior to starting extraction.

Protocol for up to 4 mL Serum/Plasma

Important: When starting program on the MagBinder® Fit[24] instrument, make sure that the correct protocol, OBTIB3298, is selected.

Materials and Equipment to be Supplied by User:

- Incubator or heat block capable of 60°C
- Vortexer
- Serological pipette capable of 10 mL
- 15 mL centrifuge tubes

Before Starting:

- Prepare reagent cartridges according to the "Plasticware Handling and Preparation" on Page 9.
- Set incubator or heat block to 60°C.

1. Add up to 4 mL plasma/serum sample to a 15 mL centrifuge tube (not provided). Bring volume up to 4 mL with Elution Buffer if the volume of sample is less than 4 mL.

2. Add 60 µL Proteinase K Solution.

3. Add 270 µL DS Buffer.

4. Vortex at maximum speed or pipet up and down to mix thoroughly.

5. Incubate at 60°C for 30 minutes. Mix by inverting or shaking every 10 minutes.

6. Let sit at room temperature for 10 minutes.

7. Remove seal from reagent cartridge and place into the MagBinder® Fit[24] loading tray. Transfer lysate from Step 6 to Well 1 of the reagent cartridge. Pipet up and down 5-10 times to mix thoroughly.

   Note: Prepare reagent cartridge according to the "Plasticware Handling and Preparation" on Page 9.

8. Add 20 µL Mag-Bind® Particles CH to Well 1 of the reagent cartridge. Pipet up and down to mix thoroughly.

   Note: Use an expandable multichannel pipettor to mix multiple cartridges at once thoroughly.

9. Prepare Elution Tube by filling with 100 µL Elution Buffer volume.

10. Load the tip combs on the tip comb holder.

    Note: Ensure the tip comb is pushed all the way back and completely in place.

11. Place loading tray containing reagent cartridges and Elution Tubes onto the instrument deck. Gently press down on the reagent cartridges and Elution tubes so they are secure on the deck. Slide the deck into the instrument and close the door.

    Note: Ensure the Elution Tubes are positioned open with caps oriented to the right of the tube. The orientation of the Elution Tubes is important in preventing an instrument error during the run.

12. Start the program on the MagBinder® Fit[24] instrument.

13. Once run has completed, remove the Elution Tube from instrument and cap tightly.

14. Store DNA at -20°C.

Contact Information

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

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EC REP	European Authorized Representative QbD RepS BV Groenenborgerlaan 16 2610 Wilrijk Belgium SRN: BE-AR-000000040
CH REP	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 QbD RepS UK Ltd Waterside, Unit 33 Schooner Court, 44-48 Wharf Road, London N1 7UX United Kingdom

Symbols

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

Picture	Description
EC REP	EU Authorized Representative
CH REP	Switzerland Authorized Representative
YYYY-MM	Use-by date
	Long term storage temperature range
	Check components for storage conditions
LOT	Lot number
REF	Reference, Part or Catalog Number
SN	Serial Number
QTY	Quantity
	Caution
	Instructions for use
CE	Regulatory Mark
IVD	In vitro diagnostic medical device
UDI	Unique device identifier
	Manufacturer

Symbols

	Damaged Package (Do not use if package is damaged)
No GHS	No additional hazards or not classified as hazardous according to GHS
	Website
	Telephone
	Fax
	Email
	LinkedIn
	Twitter
	Facebook
Recycling	Recycling Information visit www.omega-biotek.com/company/recycling

Document Revision History

Revision	Description
v1.4, June 2026	Added recycling information and updated Qarad UK name and address information.
v1.3, May 2025	Name and address change for EU Authorized Representative Elution tube instructions update Updated mixing instructions for multiple cartridges using expandable multichannel pipettor
v1.2, February 2025	Update to Guidelines for cfDNA Quantification
v1.1, October 2024	Elution tube instructions update
v1.0, October 2023	Initial Release

REACH Disclosure

For European Union Use.

JSB Buffer and GT7 Buffer v1.1 contain 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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