omega BIO-TEK
innovations in nucleic acid isolation

Product Manual

MB Fit24™ Blood & Tissue DNA Kit
CE IVD

Product	Preps
B6399-5-48PFCEIVD	48 preps

Manual Date: October 2024
Manual Revision: v1.1

IVD

For In Vitro Diagnostic Use

CE

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MB Fit24™ Blood & Tissue DNA Kit
CE IVD

Table of Contents

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Intended Use

For in vitro diagnostic use.

The MB Fit24™ Blood & Tissue DNA Kit CE IVD is intended for isolation and purification of genomic DNA from fresh or frozen cultured cells and tissue, up to 250 µL whole blood, buccal swabs, and up to 500 µL saliva using the MagBinder® Fit^{24} Nucleic Acid Purification System.

Intended User

This kit is intended for professional use.

The MB Fit24™ Blood & Tissue DNA 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™ Blood & Tissue DNA Kit CE IVD is designed for rapid and reliable isolation of genomic DNA from a variety of samples including blood, saliva, fresh or frozen animal cultured cells and tissues using the MagBinder® Fit^{24} Nucleic Acid Purification System. This kit is automation-ready, prefilled with reagents arrayed into a ready-to-use reagent cartridge specifically configured for the MagBinder® Fit^{24} instrument to provide faster and consistent results. The procedure provides a semi-automated extraction workflow for processing up to 24 samples in less than 50 minutes once loaded onto the MagBinder® Fit^{24}.

The MB Fit24™ Blood & Tissue DNA 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 appropriate reagent well containing the binding buffer. This system combines the reversible nucleic acid binding properties of Mag-Bind® Particles PF-HDQ 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 sample types. The purification procedure provides high-quality DNA that is suitable for direct use in most downstream applications such as PCR amplification, next generation sequencing and enzymatic reactions.

The MagBinder® Fit^{24} instrument is preprogrammed with purification protocols that are optimized to work with prefilled reagent cartridges. The instrument requires the user to select the appropriate protocol depending on the kit being used. If using the MB Fit24™ Blood & Tissue DNA Kit CE IVD for sample types other than those listed in this manual, please contact your Omega Bio-tek representative for sample-specific 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	B6399-5-48PF
Purifications	48
Elution Tubes (2 mL)	50
MagBinder® Tip Comb	2 x 2 combs
Prefilled Reagent Cartridge*	48
AL Buffer	20 mL
TL Buffer	15 mL
Elution Buffer	30 mL
Proteinase K Solution	1.4 mL
User Manual	✓

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

Storage and Stability

All of the MB Fit24™ Blood & Tissue DNA Kit components are guaranteed for at least 12 months from the date of puchase 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. During shipment or storage in cool ambient conditions, precipitates my form in some buffers. Dissolve such deposits by warming the solution and/or reagent cartridge 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™ 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 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 MB Fit24™ Blood & Tissue DNA Kit 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 irriation. 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
eVHB Buffer  	Contains: Guanidine hydrochloride and ethanol. Danger! Causes skin irritation and serious eye irritation. Highly flammable liquid and vapor. Harmful if swallowed. Keep away from heat, hot surfaces, sparks, open flames, and other ignition sources. Use explosion-proof electrical/ventilating/ lighting/intrinsically safe equipment. Use only non-sparking tools. Take precautionary measures against static discharge. Keep container tightly closed. Wash all exposed external body areas thooughly after handling. Do not eat, drink, or smoke when using this product. Wear protective gloves/clothing/ eye/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. Get medical attention/advice if irritation persists. SWALLOWED: Call a POISON CENTER/doctor/physician/first aider/if you feel unwell. ON SKIN (or hair): Wash with plenty of water and soap. Take off immediately all contaminated clothing. Rinse skin with water/shower. Rinse mouth. If irritation occurs, get medical attention/advice. Take off contaminated clothing and wash it before reuse.
eSPM Buffer 	Contains: Ethanol. Danger! Causes serious eye irritation. Highly flammable liquid and vapor. Keep away from heat, hot surfaces, sparks, open flames, and other ignition sources. No smoking. Keep containter tightly closed. Use explosion-proof electrical/ventilating/lighting/instrinsically 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/clothing/ eye/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. Continue rinsing. Get medical advice/attention if eye irritation persists. ON SKIN (or hair): Take off immediately all contaminated clothing. Rinse skin with water/shower.

Precautions

Component	Description
iHDQ Binding Buffer 	Contains: Sodium perchlorate and isopropanol. Danger! Causes skin irritation and serious eye irritation. Flammable liquid and vapor. May cause fire or explosion; strong oxidizer. May cause drowsiness or dizziness. Avoid breathing mist/ vapors/spray. Keep away from heat, hot surfaces, sparks, open flames, and other ignition sources. Use explosion-proof electrical/ventilating/lighting/intrinsically safe equipment. Use only non-sparking tools. Take precautionary measures against static discharge. Keep container tightly closed. Take any precaution to avoid mixing with combustibles/organic material. Keep/store away from clothing/organic material/ combustible materials. Wear fire/flame resistant retardant clothing. Wash all exposed external body areas thoroughly after handling. Wear protective gloves/clothing/eye/face protection. In case of fire: Use alcohol resistant foam or normal protein foam to extinguish. In case of major fire and large quantities: Evacuate area. Fight 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 so. Continue rinsing. ON CLOTHING: Rinse immediately contaminated clothing and skin with plenty of water before removing clothes. ON SKIN (or hair): Take off immediately all contaminated clothing. Rinse skin with water/shower. Wash with plenty of water and soap. Get medical attention/advice if irritation persists. INHALED: Remove person to fresh air and keep comfortable for breathing. Call a POISON CENTER/ doctor/physician/first aider if you feel unwell.

Limitations

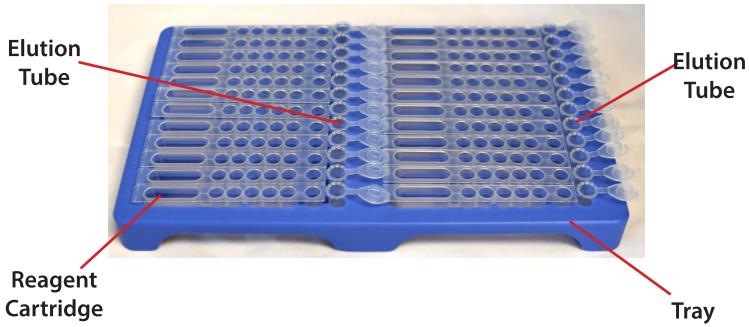
The performance of the kit was evaluated by isolating genomic DNA from 250 µL whole blood, 500 µL preserved saliva, and up to 10 mg tissue. Kit performace was further validated by assessing the suitability of purified genomic DNA in direct downstream analysis by standard amplification method. Please 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 MB Fit24™ Blood & Tissue DNA Kit CE IVD.

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).



4. Angle the cap downwards 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 3). 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.

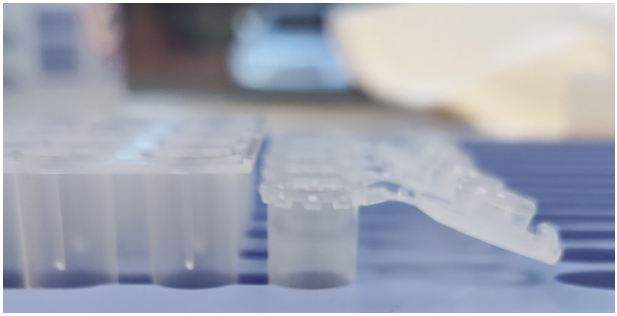
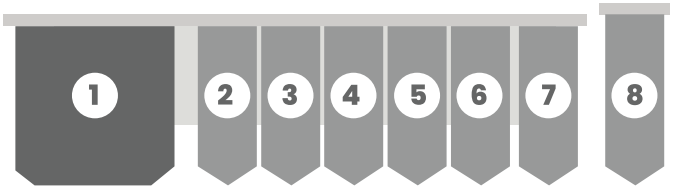


Figure 3

6. The table below details contents in the wells of reagent cartridge.



Well Position	Content	Volume per well
1	Empty	0 µL
2	iHDQ Binding Buffer	400 µL
3	eVHB Buffer	600 µL
4	eVHB Buffer	600 µL
5	eSPM Buffer	600 µL
6	Mag-Bind® Particles PF-HDQ	100 µL
7	Empty	0 µL
8	Elution Buffer[1]	100 µL

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

Protocol for Blood (250 µL)

The procedure below has been optimized for use with 250 µL FRESH or FROZEN blood samples. Buffy coat can also be used (up to 100 µL).

Important: When starting program on the MagBinder® Fit[24] instrument, make sure that the correct protocol, **OBTIB6399**, is selected.

Materials and Equipment to be Supplied by User:

- Incubator or heat block capable of 70°C
- Vortexer
- Nuclease-free 1.5 or 2.0 mL microcentrifuge tube
- Optional: RNase A (10 mg/mL)
- Optional: PBS

Before Starting:

- Prepare reagent cartridges according to the "Plasticware Handling and Preparation" on Page 9.
- Set incubator or heat block to 70°C.

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

Component	Amount per Prep	Total Amount per 24 samples
AL Buffer	290 µL	7.65 mL*
Proteinase K Solution	20 µL	530 µL*

*10% excess volume has been calculated for 24 samples.

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

2. Add up to 250 µL blood sample to a 1.5 mL microcentrifuge tube (not provided). Bring volume up to 250 µL with Elution Buffer or PBS (not provided) if volume of sample is less than 250 µL.

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

4. Incubate at 70°C for 10 mintues.

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

5. Remove seal from reagent cartridge and place into the MagBinder® Fit^{24} loading tray. Transfer lysate from Step 4 to Well 2 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.

6. Prepare the Elution Tubes by filling with 100 µL Elution Buffer.

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

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

8. 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.

9. Start the program on MagBinder® Fit^{24} instrument.

10. Once run has completed, remove the Elution Tubes from instrument and cap tightly.

11. Store DNA at -20°C.

Protocol for Tissue

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

Important: When starting program on the MagBinder® Fit^{24} instrument, make sure that the correct protocol, **OBTIB6399**, is selected.

Materials and Equipment to be Supplied by User:

- Centrifuge capable of ≥10,000*g* for microcentrifuge tubes
- Incubator, water bath, or heat block capable of 55°C
- Vortexer
- Nuclease-free 1.5 or 2.0 mL microcentrifuge tube
- Optional: Liquid nitrogen and mortar pestle
- Optional: RNase A (10 mg/mL)
- Recommend: 1M Dithiothreitol (DTT)

Before Starting:

- Prepare reagent cartridges according to the "Plasticware Handling and Preparation" on Page 9.
- Set water bath to 55°C.
- Recommend: 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 nuclease-free 1.5 mL or 2.0 mL microcentrifuge tube (not provided). Add 300 µL TL Buffer and proceed to Step 3 on the next page.

1. Mince up to 10 mg tissue and transfer to a nuclease-free 1.5 mL or 2.0 microcentrifuge tube.

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

2. Add 250 µL TL Buffer

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

- 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. Vortex to mix.

4. Incubate at 55°C in a shaking water bath for 3 hours.

   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 (not provided) and pipet up and down several times to mix thoroughly. Let sit at room temperature for 2 minutes.

5. Centrifuge at ≥10,000*g* for 5 minutes to pellet undigested tissue debris.

6. Carefully transfer 200 µL of the supernatant to a new nuclease-free 1.5 mL or 2.0 mL microcentrifuge tube without disturbing the undigested pellet.

7. Add 230 µL AL Buffer. Vortex for 10 mintues to mix. Proper mixing is crucial for good yield.

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

8. Remove seal from reagent cartridge and place into the MagBinder® Fit[24] loading tray. Transfer lysate from Step 7 to Well 2 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.

9. Prepare the Elution Tubes by filling with 100 µL Elution Buffer.

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 Tubes from instrument and cap tightly.

14. Store DNA at -20°C.

Protocol for Cultured Cells

This protocol is designed for rapid isolation of genomic DNA from up to 5 x 10^6 cultured cells.

Important: When starting program on the MagBinder® Fit^{24} instrument, make sure that the correct protocol, **OBTIB6399**, is selected.

Materials and Equipment to be Supplied by User:

- Centrifuge capable of ≥10,000*g* for microcentrifuge tubes
- Incubator, water bath, or heat block capable of 55°C
- Vortexer
- Nuclease-free 1.5 or 2.0 mL microcentrifuge tube
- Cold PBS
- Optional: Liquid nitrogen and mortar pestle
- Optional: RNase A (10 mg/mL)

Before Starting:

- Prepare reagent cartridges according to the "Plasticware Handling and Preparation " on Page 9.
- Set water bath to 55°C.

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 250 µL cold PBS. Proceed with Step 2 of this protocol.

   1b. For cells grown in suspension, pellet 5 x 10^6 cells at 1,200*g* in a centrifuge tube. Discard the supernatant, wash the cells once with cold PBS (4°C), and resuspend cells in 250 µL cold PBS. Proceed with Step 2 of this protocol.

   1c. For cells grown in 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 250 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 24 samples
AL Buffer	230 µL	6.07 mL*
Proteinase K Solution	20 µL	530 µL*

*10% excess volume has been calculated for 24 samples.

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 the cells prepared in Step 1.

4. Pipet up and down to mix thoroughly or vortex for 10 minutes. Proper mixing is crucial for good yield.

5. 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.

Optional: Add 5 µL RNase A. Pipet up and down several times to mix thoroughly. Let sit at room temperature for 2 minutes.

6. Remove seal from reagent cartridge and place into the MagBinder® Fit^{24} loading tray. Transfer lysate from Step 5 to Well 2 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.

7. Prepare the Elution Tubes by filling with 100 µL Elution Buffer.

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

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

9. Place loading tray, with reagent cartridges and Elution Tubes, into the loading tray and place into instrument deck. Gently press down on the reagent cartridges and Elution Tubes so they are secure on the deck. Push 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.

10. Start the program on the MagBinder® Fit^{24} instrument.

11. Once run has completed, remove the Elution Tubes from instrument and cap tightly.

12. Store DNA at -20°C.

Protocol for Saliva

Important: When starting program on the MagBinder® Fit[24] instrument, make sure that the correct protocol, **OBTIB6399**, is selected.

Materials and Equipment to be Supplied by User:

- Shaking water bath capable of 55°C
- Vortexer
- Nuclease-free 1.5 or 2.0 mL microcentrifuge tube
- Optional: RNase A (10 mg/mL)
- Optional: PBS

Before Starting:

- Prepare reagent cartridges according to the "Plasticware Handling and Preparation " on Page 9.
- Set shaking water bath to 55°C.

1. Centrifuge the saliva tube at 2,000*g* for 5 minutes.

2. Transfer 500 µL stabilized saliva samples (e.g., DNA Genotek Oragene®, Mawi iSWAB™, Biomatrica® DNAgard® Saliva) to a 1.5 mL microcentrifuge tube (not provided).

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

Component	Amount per Prep	Total Amount per 24 samples
AL Buffer	200 µL	5.28 mL*
Proteinase K Solution	20 µL	530 µL*

*10% excess volume has been calculated for 24 samples.

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

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

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

   Note: If a shaking water bath is not available, vortex the microcentrifuge tube 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. Pipet up and down several times to mix thoroughly. Let sit at room temperature for 2 minutes.

6. Remove seal from reagent cartridge and place into the MagBinder® Fit^{24} loading tray. Transfer lysate from Step 5 to Well 2 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.

7. Prepare the Elution Tubes by filling with 100 µL Elution Buffer.

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

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

9. Place loading tray, with reagent cartridges and Elution Tubes, into the loading tray and place into instrument deck. Gently press down on the reagent cartridges and Elution Tubes so they are secure on the deck. Push 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.

10. Start the program on the MagBinder® Fit^{24} instrument.

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

12. Store DNA at -20°C.

Protocol for Buccal Swabs

Important: When starting program on the MagBinder® Fit[24] instrument, make sure that the correct protocol, **OBTIB6399**, is selected.

Materials and Equipment to be Supplied by User:

- Centrifuge capable of 10,000*g*
- Shaking water bath capable of 55°C
- Vortexer
- Nuclease-free 1.5 or 2.0 mL microcentrifuge tube
- Optional: RNase A (10 mg/mL)
- Optional: PBS

Before Starting:

- Prepare reagent cartridges according to the "Plasticware Handling and Preparation " on Page 9.
- Set shaking water bath to 55°C.

1. Cuf off the buccal brush or swab head and place each swab into a 1.5 mL or 2.0 mL microcentrifuge tube (not provided).

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 24 samples
AL Buffer	290 µL	7.65 mL*
Proteinase K Solution	20 µL	530 µL*
Elution Buffer	250 µL	6.6 mL*

*10% excess volume has been calculated for 24 samples.

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.

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.

5. Centrifuge at 10,000*g* for 2 minutes.

Optional: Add 5 µL RNase A. Pipet up and down several times to mix thoroughly. Let sit at room temperature for 2 minutes.

6. Remove seal from reagent cartridge and place into the MagBinder® Fit^{24} loading tray. Transfer 500 µL lysate to Well 2 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.

7. Prepare the Elution Tubes by filling with 100 µL Elution Buffer.

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

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

9. Place loading tray, with reagent cartridges and Elution Tubes, into the loading tray and place into instrument deck. Gently press down on the reagent cartridges and Elution Tubes so they are secure on the deck. Push 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.

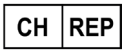
10. Start the program on the MagBinder® Fit^{24} instrument.

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

12. 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
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 additional hazards or not classified as hazardous according to GHS

Website

Telephone

Fax

Email

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Document Revision History

Revision	Description
v1.1, October 2024	Elution tube instructions update.
v1.0, October 2023	Initial Release.

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 Authorization 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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