omega BIO-TEK
innovations in nucleic acid isolation

Product Manual

Mag-Bind® cfDNA Kit CE IVD

Product	Preps
M3298-01CEIVD	50 preps
M3298-02CEIVD	200 Preps

Manual Date: July 2023
Revision Number: v1.7

IVD

For In Vitro Diagnostic Use

CE

Omega Bio-tek, Inc.
400 Pinnacle Way, Suite 450
Norcross, GA 30071
www.omegabiotek.com

+1-770-931-8400
+1-770-931-0230
info@omegabiotek.com

omega-bio-tek
omegabiotek
omegabiotek

Mag-Bind® cfDNA Kit CE IVD

Table of Contents

Intended Use and Intended User....2
Product Description....3
Kit Contents/Storage and Stability....4
Preparing Reagents....5
Extraction Process/Quality Control....5
Warning/Safety Information....6
Precautions....7
Limitations....8
Quantification of cfDNA....9
Mag-Bind® DNA Protocol for 1 mL Serum/Plasma....10
Mag-Bind® DNA Protocol for 2 mL Serum/Plasma....14
Mag-Bind® DNA Protocol for 4 mL Serum/Plasma....18
Contact Information....22
Symbols....23
Revision History....25
Notices & Disclaimers....26

Manual Date: July 2023
Revision Number: v1.7

omega BIO-TEK
innovations in nucleic acid isolation

Intended Use

For in vitro diagnostic use.

The Mag-Bind® cfDNA Kit CE IVD is intended for isolation and purification of circulating cell-free DNA (cfDNA) from plasma/serum samples.

The Mag-Bind® cfDNA 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® cfDNA 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

The Mag-Bind® cfDNA Kit CE IVD is designed for rapid and reliable isolation of circulating cell-free DNA from 1-4 mL plasma/serum samples. The Mag-Bind® cfDNA Kit CE IVD can be processed manually with 15 mL centrifuge tubes or on automated platforms with appropriate plasticware. The procedure eliminates the need for funnels and vacuum steps providing hands-free operation in automated protocols. The uniquely formulated binding buffer from Omega Bio-tek allows for large sample volumes to be processed in automated formats with 4 mL serum or plasma being processed in a 24-well plate. The magnetic properties of the Mag-Bind® Particles CH enable fast magnetic separation, especially during steps involving large volumes. The high-binding capability decreases the amount of magnetic particles required thereby reducing the elution volume i.e., cfDNA from up to 4 mL serum or plasma can be eluted in just 50 µL.

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 DNA is of high quality and is suitable for direct use in most downstream applications, such as qPCR and Next Generation Sequencing.

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.

Note: Up to 10 mL sample input volumes can be processed using this kit. Please contact your Omega Bio-tek representative for protocol details.

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	M3298-01CEIVD	M3298-02CEIVD
Purifications	50	200
DS Buffer	20 mL	80 mL
JSB Buffer	9 x 25 mL	4 x 220 mL
GT7 Buffer v1.1	110mL	2 x 220 mL
SPW Buffer	25 mL	2 x 50 mL
Elution Buffer	250 mL	2 x 250 mL
Proteinase K Solution	4 mL	14 mL
Mag-Bind® Particles CH	1.1 mL	4.4 mL

Storage and Stability

All of the Mag-Bind® 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 bottle label. Once product is opened, continue to maintain the product in accordance with labeled instructions. Ensure that caps are properly tightened following each use. During shipment or storage in cool ambient conditions, precipitates may form in some buffers. Dissolve such deposits by warming the solution at 37°C and gently shaking.

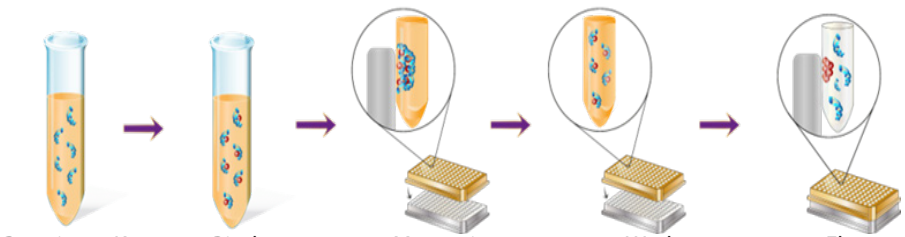
Preparing Reagents

1. Dilute SPW Buffer with 100% ethanol as follows and store at room temperature.

Kit	100% Ethanol to be Added
M3298-01CEIVD	100 mL
M3298-02CEIVD	200 mL per bottle

2. 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.

Extraction Process



Quality Control

In accordance with Omega Bio-tek's ISO-certified Quality Management System, all the reagents of Mag-Bind® 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.

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® 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/docter/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/docter/physician/first aider. INHALED: Remove person to fresh air and keep comfortable for breathing.

Limitations

The performance of the kit was evaluated by isolating cfDNA from 1 – 10 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 Mag-Bind® 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.

TapeStation or Fragment Analyzer

Fragment size profiling can be used for cfDNA quantification. cfDNA are usually small fragments of DNA with a size distribution peak at ~170 bp. The peak heights and separation on the electropherogram corresponding to cfDNA fragment size and gDNA size can shed light on the relative proportions of each and can help draw conclusions about cfDNA extraction efficiency. The regional analysis functionality offered by the software can further assist in approximating the cfDNA concentration. For example, DNA concentration within the 100-300 bp region where cfDNA is most likely to be present can be quantified using the TapeStation software using this functionality.

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.

Protocol for 1 mL Serum/Plasma

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:

- 100% ethanol
- Magnetic separation device for 1.5/2.0 mL microcentrifuge tubes
- Incubator capable of 60°C
- Shaker or rocker for Step 8
- Vortexer
- 15 mL centrifuge tubes
- 1.5 mL microcentrifuge tubes compatible with magnetic separation device used
- Optional: microplate for DNA storage

Before Starting:

- Prepare SPW Buffer according to the "Preparing Reagents" section on Page 5.
- Set incubator to 60°C.
- Shake or vortex the Mag-Bind® Particles CH to fully resuspend the particles before use.

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

2. Add 15 µL Proteinase K Solution.

3. Add 67 µL DS Buffer.

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

5. Incubate at 60°C for 20 minutes. Mix by inverting or shaking every 10 minutes.

6. Let sit at room temperature for 10 minutes.

7. Add 1 mL JSB Buffer. Vortex at maximum speed for 30 seconds or pipet up and down to mix thoroughly.

8. Add 5 µL Mag-Bind® Particles CH. Invert the sample 10 times or pipet up and down to mix. Let sit for 10 minutes at room temperature with continuous mixing. The samples must be mixed throughout the 10 minute incubation period by shaking or rocking. ***Do not vortex at high speeds*** as this will cause excess foaming that can reduce yield. The speed of mixing should be set to continuously keep the Mag-Bind® Particles CH resuspended in solution.

9. Transfer 1 mL lysate to a 1.5 mL microcentrifuge tube (not provided).

10. Place the tube on a 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.

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

12. Transfer the remaining lysate from Step 8 to the 1.5 mL microcentrifuge tube used in the previous steps.

13. Place the tube on a 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.

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

15. Remove the tube containing the Mag-Bind® Particles CH from the magnetic separation device.

16. Add 500 µL GT7 Buffer v1.1.

17. Vortex for 2 minutes to resuspend the Mag-Bind® Particles CH.

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

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.

    Note: GT7 Buffer v1.1 may foam during vortexing. Remove foam from cap then remove supernatant.

20. Repeat Steps 15-19 for a second GT7 Buffer v1.1 step.

21. Remove the tube containing the Mag-Bind® Particles CH from the magnetic separation device.

22. Add 500 µL SPW Buffer.

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

23. Vortex for 2 minutes to resuspend the Mag-Bind® Particles CH.

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. Repeat Steps 21-25 for a second SPW Buffer step.

27. Remove the tube from the magnetic separation device for approximately 30 seconds.

28. Place the tube on the magnetic separation device to magnetize the Mag-Bind® Particles CH.

29. Aspirate and discard the residual SPW Buffer.

30. Leave the tube on the magnetic separation device for 25 minutes to dry the Mag-Bind® Particles CH.

31. Remove the tube containing the Mag-Bind® Particles CH from the magnetic separation device.

32. Add 30-60 µL Elution Buffer.

33. Vortex at room temperature for 5 minutes to resuspend the Mag-Bind® Particles CH.

34. 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.

35. Transfer the cleared supernatant containing purified DNA to a 1.5 mL microcentrifuge tube or clean microplate (not provided).

36. Store DNA at -20°C.

Protocol for 2 mL Serum/Plasma

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:

- 100% ethanol
- Magnetic separation device for 15 mL centrifuge tubes and 1.5/2.0 mL microcentrifuge tubes
- Incubator capable of 60°C
- Shaker or rocker for Step 8
- Vortexer
- 15 mL centrifuge tubes compatible with magnetic separation device used
- 1.5 mL microcentrifuge tubes compatible with magnetic separation device used
- Optional: microplate for DNA storage

Before Starting:

- Prepare SPW Buffer according to the "Preparing Reagents" section on Page 5.
- Set incubator to 60°C.
- Shake or vortex the Mag-Bind® Particles CH to fully resuspend the particles before use.

1. Add up to 2 mL serum/plasma samples to a 15 mL centrifuge tube (not provided). Bring the volume up to 2 mL with Elution Buffer if sample volume is less than 2 mL.

2. Add 30 µL Proteinase K Solution.

3. Add 135 µL DS Buffer.

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

5. Incubate at 60°C for 25 minutes. Mix by inverting or shaking every 10 minutes.

6. Let sit at room temperature for 10 minutes.

7. Add 2 mL JSB Buffer. Vortex at maximum speed for 30 seconds or pipet up and down to mix thoroughly.

8. Add 10 µL Mag-Bind® Particles CH. Invert the sample 10 times or pipet up and down to mix. Let sit for 10 minutes at room temperature with continuous mixing. The samples must be mixed throughout the 10 minute incubation period by shaking or rocking. ***Do not vortex at high speeds*** as this will cause excess foaming that can reduce yield. The speed of mixing should be set to continuously keep the Mag-Bind® Particles CH resuspended in solution.

9. Place the tube on a 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.

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

11. Remove the tube containing the Mag-Bind® Particles CH from the magnetic separation device.

12. Add 1 mL GT7 Buffer v1.1.

13. Vortex for 2 minutes to resuspend the Mag-Bind® Particles CH.

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

14. Transfer the resuspended Mag-Bind Particles CH to a new 1.5 mL centrifuge tube (not provided). Use a magnetic separation device designed for 1.5/2.0 mL tubes for the remaining procedure.

15. Place the tube on a 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.

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

17. Remove the tube containing the Mag-Bind® Particles CH from the magnetic separation device.

18. Add another 1 mL GT7 Buffer v1.1.

19. Vortex for 2 minutes to resuspend the Mag-Bind® Particles CH.

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

20. Place the tube on a 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.

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

22. Remove the tube containing the Mag-Bind® Particles CH from the magnetic separation device.

23. Add 1 mL SPW Buffer.

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

24. Vortex for 2 minutes to resuspend the Mag-Bind® Particles CH.

25. 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.

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

27. Repeat Steps 22-26 for a second SPW Buffer step.

28. Remove the tube from the magnetic separation device for approximately 30 seconds.

29. Place the tube on the magnetic separation device to magnetize the Mag-Bind® Particles CH.

30. Aspirate and discard the residual SPW Buffer.

31. Leave the tube on the magnetic separation device for 25 minutes to dry the Mag-Bind® Particles CH.

32. Remove the tube containing the Mag-Bind® Particles CH from the magnetic separation device.

33. Add 50-100 µL Elution Buffer.

34. Vortex at room temperature for 5 minutes to resuspend the Mag-Bind® Particles CH.

35. 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.

36. Transfer the cleared supernatant containing purified DNA to a 1.5 mL microcentrifuge tube or clean microplate (not provided).

37. Store DNA at -20°C.

Protocol for 4 mL Serum/Plasma

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:

- 100% ethanol
- Magnetic separation device for 24-well deep-well plates (Alpaqua Magnum FLX®*24*, Cat #A000440) or for 15 mL centrifuge tubes and 1.5/2.0 mL microcentrifuge tubes
- Incubator capable of 60°C
- Shaker or rocker for Step 8
- Vortexer
- 24-well deep-well plate or 15 mL centrifuge tubes compatible with magnetic separation device used
- 1.5 mL microcentrifuge tubes compatible with magnetic separation device used
- Optional: microplate for DNA storage

Before Starting:

- Prepare SPW Buffer according to the "Preparing Reagents" section on Page 5.
- Set incubator to 60°C.
- Shake or vortex the Mag-Bind® Particles CH to fully resuspend the particles before use.

1. Add up to 4 mL serum/plasma samples to a 15 mL centrifuge tube or 24-well deep-well plate (not provided). Choose the correct plasticware depending on the magnetic separation device being used. 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. Add 4 mL JSB Buffer. Vortex at maximum speed for 30 seconds or pipet up and down to mix thoroughly.

8. Add 20 µL Mag-Bind® Particles CH. Invert the sample 10 times or pipet up and down to mix. Let sit for 10 minutes at room temperature with continuous mixing. The samples must be mixed throughout the 10 minute incubation period by shaking or rocking. ***Do not vortex at high speeds*** as this will cause excess foaming that can reduce yield. The speed of mixing should be set to continuously keep the Mag-Bind® Particles CH resuspended in solution.

9. Place the tube/plate on a 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.

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

11. Remove the tube/plate containing the Mag-Bind® Particles CH from the magnetic separation device.

12. Add 1 mL GT7 Buffer v1.1.

13. Vortex for 5 minutes to resuspend the Mag-Bind® Particles CH.

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

14. Transfer the resuspended Mag-Bind® Particles CH to a new 1.5 mL centrifuge tube (not provided) if using a 15 mL centrifuge tube for Steps 1-13. Use a magnetic separation device designed for 1.5/2.0 mL tubes for the remaining procedure. If using a 24-well deep-well plate for Steps 1-13, continue to use the 24-well deep-well plate and a 24-well magnet.

15. Place the tube/plate 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.

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

17. Remove the tube/plate containing the Mag-Bind® Particles CH from the magnetic separation device.

18. Add another 1 mL GT7 Buffer v1.1.

19. Vortex for 5 minutes to resuspend the Mag-Bind® Particles CH.

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

20. Place the tube/plate 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.

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

22. Remove the tube/plate containing the Mag-Bind® Particles CH from the magnetic separation device.

23. Add 1 mL SPW Buffer.

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

24. Vortex for 5 minutes to resuspend the Mag-Bind® Particles CH.

25. Place the tube/plate 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.

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

27. Repeat steps 22-26 for a second SPW Buffer step.

28. Remove the tube/plate from the magnetic separation device for approximately 30 seconds.

29. Place the tube on the magnetic separation device to magnetize the Mag-Bind® Particles CH.

30. Aspirate and discard the residual SPW Buffer.

31. Leave the tube/plate on the magnetic separation device for 25 minutes to dry the Mag-Bind® Particles CH.

32. Remove the tube/plate containing the Mag-Bind® Particles CH from the magnetic separation device.

33. Add 50-100 µL Elution Buffer.

34. Vortex at room temperature for 5 minutes to resuspend the Mag-Bind® Particles CH.

35. 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.

36. Transfer the cleared supernatant containing purified DNA to a 1.5 mL microcentrifuge tube or clean microplate (not provided).

37. 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
	LinkedIn
	Twitter
	Facebook

Document Revision History

Revision	Description
v1.7,Jul 2023	Added Switzerland Authorized Representative to Symbol section
v1.6, Jul 2023	Added Switzerland Authorized Representative information
v1.5, May 2023	JSB Buffer in kit M3298-01 is now provided in 9 individual bottles instead of one bulk bottle to comply with primary package volume requirements for the shipment of flammable liquids.
v1.4, Nov 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.

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.

Trademarks and Licenses

Mag-Bind®, HiBind®, E.Z.N.A.®, and MicroElute® are registered trademarks of Omega Bio-tek, Inc.
PCR is a patented process of Hoffman-La Roche. Use of the PCR process requires a license.