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UNITED STATES DISTRICT COURT

FOR THE CENTRAL DISTRICT OF CALIFORNIA

QIAGEN GMBH, Plaintiff, vs. ZYMO RESEARCH CORPORATION, Defendant.	**Case No.** **COMPLAINT FOR PATENT INFRINGEMENT** **JURY TRIAL DEMANDED**

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Attorneys for Plaintiff
QIAGEN GMBH

Plaintiff QIAGEN GmbH ("QIAGEN" or "Plaintiff"), through its attorneys and for their claims against Zymo Research Corporation ("Zymo" or "Defendant"), allege as follows:

I. INTRODUCTION AND FACTUAL BACKGROUND

1. This dispute centers on Zymo's unauthorized use of QIAGEN's groundbreaking and patented technology that allows researchers to extract nucleic acids, like DNA that circulates in our bodies outside of our cells. DNA, which stands for "deoxyribonucleic acid," is the molecule that carries the genetic instructions for the development, function, growth, and reproduction of all living organisms. In humans, most of our DNA exists within our cells. However, some DNA is degraded into fragments and released outside of our cells to circulate throughout our bodies. This kind of DNA is called "circulating free" or "cell-free" DNA and is abbreviated "cfDNA."

2. This cfDNA can include useful markers or indicators for various diseases and ailments. The collection of cfDNA provides several advantages over the collection of cellular DNA. The collection of cfDNA is minimally invasive and can be achieved serially to monitor the progress of a disease. For instance, cfDNA provides real-time information that can be used to monitor diseases like cancer in a simple blood test.

3. QIAGEN is a pioneer in developing technology that improves the reliability and efficiency of recovery of cfDNA. QIAGEN has protected its inventions in this field by seeking and receiving United States patents. Among these are United States Patent Nos. 10,184,145 (the '145 Patent) and 11,021,736 (the '736 Patent) (together, the "Asserted Patents").

4. QIAGEN offers several products that practice the Asserted Patents, including but not limited to QIAsymphony PAXgene Blood ccfDNA Kit and QIAamp MinElute ccfDNA Kit.

5. Zymo's website describes Zymo as "a globally established biotechnology company and industry leader in the fields of epigenetics, microbiomics and the emerging Next-Gen Sequencing space." Ex. 1, Zymo About Page, at 1. Zymo offers a variety of products in the biomedical industry. Among its portfolio, Zymo offers a line of products directed to isolating and extracting cfDNA.

6. For example, Zymo manufactures and sells a product it markets as its MAGicBead™ cfDNA Isolation Kit (the "Zymo Accused Product").

7. Through at least the Accused Products, Zymo competes with QIAGEN, which practices the Asserted Patents at least through the products described above, in the cfDNA recover, isolation, and analysis market.

8. On November 27, 2023, QIAGEN sent Zymo a letter describing one type of QIAGEN's cfDNA technology, and specifically referenced the '145 and '736 Patents. A true and correct copy of this letter is attached as Exhibit 2. QIAGEN notified Zymo that "based upon publicly available information, it appear[ed to QIAGEN] that the use of Zymo's MAGicBead™ cfDNA Isolation Kit practices at least claim 1 of the '145 Patent and claim 1 of the '736 Patent—and likely numerous other claims in those patents." Ex. 2, at 2.

9. As explained below, the Zymo Accused Product or its sale and use infringes at least the Asserted Patents.

II. THE PARTIES

10. QIAGEN GmbH is a Gesellschaft mit beschränkter Haftung ("GmbH") (a company with limited liability) headquartered at Qiagen Str. 1, 40724 Hilden, North Rhine-Westphalia in the Federal Republic of Germany.

11. On information and belief, Defendant Zymo is a California corporation with its principal place of business at 17062 Murphy Ave., Irvine, California 92614. Upon information and belief, Zymo has consented to and agreed that the courts of California have jurisdiction to resolve disputes between itself and other parties. Zymo

can be served through its registered officer, Xi Yu Jia, at 17062 Murphy Avenue, Irvine, CA 92614.

III. JURISDICTION AND VENUE

12. This civil action contains claims for patent infringement arising under the patent laws of the United States, 35 U.S.C. § 1, *et seq.*

13. This Court has subject matter jurisdiction under 28 U.S.C. §§ 1331 and 1338(a) because this action arises under the patent laws of the United States, 35 U.S.C. § 1, *et seq.*

14. This Court has personal jurisdiction over Zymo because Zymo has substantial, systematic, and continuous contacts with this District. Zymo's principal place of business is located within this District. Consequently, it also has a regular and established place of business within this District. This Court also has personal jurisdiction over Zymo because it has committed acts within this District that give rise to all claims of infringement alleged herein.

15. Venue is proper within this District under the provisions of 28 U.S.C. §§ 1391 and 1400(b) because this is the District in which Zymo resides. Venue is also proper within this District because Zymo has a regular and established place of business within this District and has committed acts of infringement therein.

IV. THE ASSERTED PATENTS

16. The '145 Patent is titled "Rapid Method for Isolating Extracellular Nucleic Acids" and issued on January 22, 2019, to inventors Martin Horlitz, Annette Nocon, Markus Sprenger-Haussels, Peter Grünefeld, and Christoph Erbacher. It is assigned to QIAGEN GmbH. The '145 Patent claims priority to U.S. Patent Application No. 14/347,452, the national phase of Patent Cooperation Treaty ("PCT") Application No. PCT/EP2012/068847, which was filed on September 25, 2012, and to European Patent Organization application 11007824 filed on September 26, 2011. The '145 Patent is

valid and enforceable against Zymo. A true and correct copy of the '145 Patent is attached as Exhibit 3.

17. The '736 Patent is titled "Rapid Method for Isolating Extracellular Nucleic Acids" and issued on June 1, 2021, to inventors Martin Horlitz, Annette Nocon, Markus Sprenger-Haussels, Peter Grünefeld, and Christoph Erbacher. It is assigned to QIAGEN GmbH. The '736 Patent claims priority to U.S. Patent Application No. 16/204,332, which is a continuation of Application No. 14/347,452 (which eventually issued as the '145 Patent), which claimed priority to Application No. PCT/EP2012/068847 filed on September 25, 2012, and to European Patent Organization application 11007824 filed on September 26, 2011. The '736 Patent is valid and enforceable against Zymo. A true and correct copy of the '736 Patent is attached as Exhibit 4.

V. FIRST CLAIM FOR RELIEF

(Infringement of United States Patent No. 10,184,145)

18. QIAGEN realleges and incorporates by reference the allegations of the preceding paragraphs of this Complaint as if fully set forth herein.

19. In violation of one or more of subsections (a), (b), and/or (c) of 35 U.S.C. § 271, Zymo has infringed and is currently infringing, directly and/or indirectly through intermediaries, customers, or end-users, one or more claims of the '145 Patent by making, using, selling, offering for sale, and/or importing into the United States, without authority, its MAGicBead™ cfDNA Isolation Kit, the use of which practices at least claim 1 of the '145 Patent. Zymo has infringed and is currently infringing this claim literally and/or under the doctrine of equivalents.

20. Exemplary claim 1 of the'145 Patent claims:

> 1. A method for isolating extracellular nucleic acids from a sample by binding the extracellular nucleic acids to a solid phase which carries anion exchange groups, comprising:

a. acidifying the sample to establish the binding conditions and binding the extracellular nucleic acids to the solid phase in a binding mixture having a first pH of ≤6.5 which allows binding the extracellular nucleic acids to the anion exchange groups of the solid phase, wherein the solid phase is provided by magnetic particles;

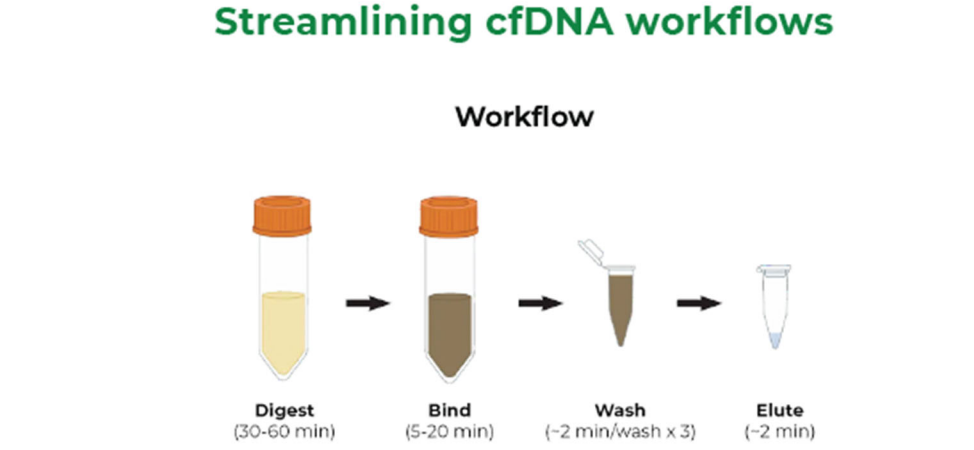
b. separating the solid phase with the bound extracellular nucleic acids from the remaining sample;

c. optionally washing the extracellular nucleic acids; and

d. eluting extracellular nucleic acids from the solid phase, wherein elution occurs at a second pH lying in the range of ≥8 to ≤14;

wherein the sample is a cell-free or cell-depleted sample which was obtained from a cell-containing sample by removing cells, and wherein the extracellular nucleic acids are extracellular DNA.

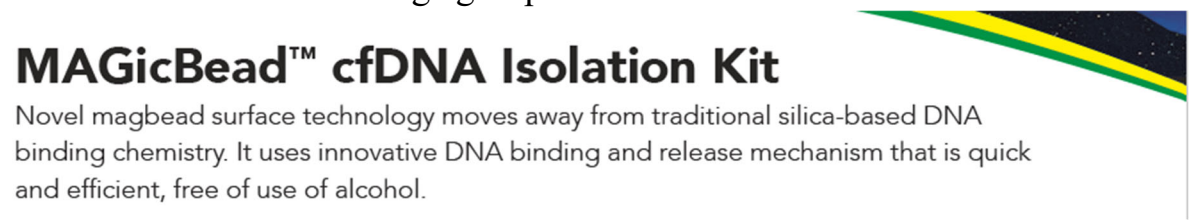
21. A promotional flyer for the MAGicBead™ cfDNA Isolation Kit (attached hereto as Exhibit 5) describes the steps performed to use Zymo's product:



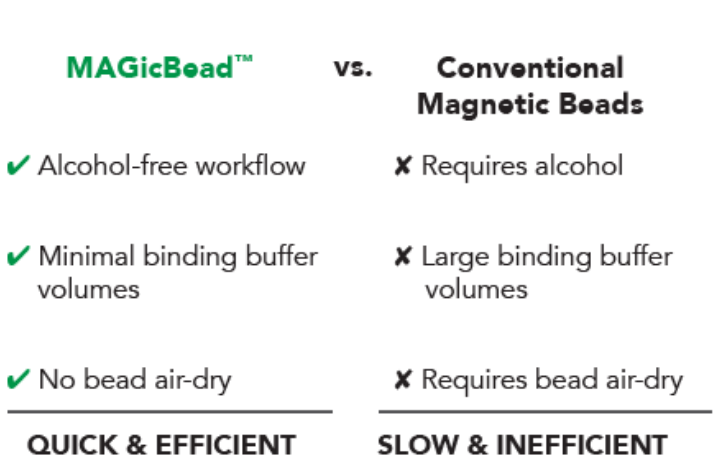
Ex. 5, at 1.

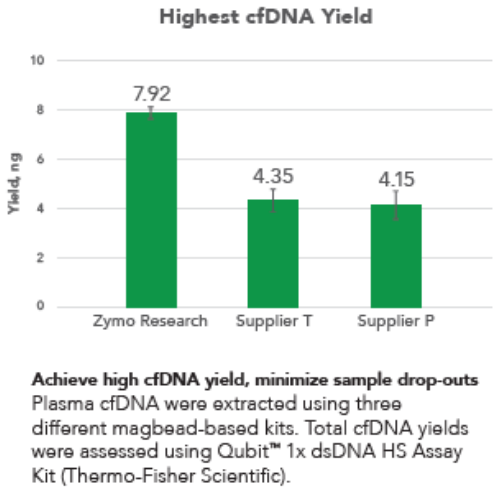
22. As is evident by the title and the exemplary workflow, the MAGicBead™ cfDNA Isolation Kit is a method for extracting extracellular nucleic acids from a sample.

23. Additional details within the flyer make is clear that the kit uses a solid phase that carries anion exchange groups:



Id.





Id.

24. Zymo provides a "Quick Protocol" sheet instructing users on how to use Zymo's kit. A true and correct copy of this is attached as Exhibit 6. The protocol is excerpted below:

cfDNA Extraction Procedure

Input Volume	MAGicBead™ cfDNA Digestion Buffer	Proteinase K	MAGicBead™ cfDNA Binding Buffer	MAGicBeads™ cfDNA	Final Reaction Volume
0.2 mL	50 µL	8 µL	50 µL	10 µL	**318 µL**
1 mL	250 µL	40 µL	250 µL	10 µL	**~1.6 mL**
2 mL	500 µL	80 µL	500 µL	10 µL	**~3.1 mL**
10 mL	2.5 mL	400 µL	2.5 mL	10 µL	**~15.5 mL**

1. Referring to the table (*above*), add a cell-free biofluid[1] sample into a clean tube that can comfortably accommodate (~70% capacity) the final reaction volume (*Note: for other sample volumes, scale other components proportionally EXCEPT the beads*[2]).
2. Add the **Digestion Buffer** and **Proteinase K**. Mix thoroughly by vortexing or pipetting for 5 seconds.
3. Digest lysate mixture according to the sample collection method (*below*):

Collection Tube	Digestion Condition
K_2EDTA, Na-Citrate, NaF/K-Oxalate, non-plasma biofluids[1]	37 °C for 30 minutes or RT for 2 hours
Streck Cell-Free DNA BCT®	55 °C for 30 minutes or RT for 2 hours
K_3EDTA and Na_2EDTA	37 °C for 60 minutes

4. Add the **Binding Buffer**. Mix thoroughly by vortexing or pipetting for 5 seconds.
   (The Binding Buffer must be added prior to MAGicBeads™ cfDNA)
5. Completely resuspend **MAGicBeads™ cfDNA** by vortexing and inverting vigorously until there is no clump of beads.
6. Add 10 µL **MAGicBeads™ cfDNA** and mix thoroughly by vortexing or pipetting for 5 seconds.
7. Incubate at room temperature with constant agitation[3] using a rotator (at ~30 rpm) for the sample input volumes indicated (*below*).

Sample Input Volume	Incubation Time
≤ 1 mL	5 minutes
> 1 mL and ≤ 3 mL	10 minutes
> 3 mL and ≤ 10 mL	20 minutes

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Ex. 6, at 1.

cfDNA Extraction Procedure (Cont.)

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8. After taking sample out of a rotator, flick sample tube down to move residual lysates to the bottom of the tube. Carefully open the cap prior applying them on magnetic stand to prevent loss of lysates.
9. Apply sample to a magnetic stand until beads are fully pelleted.
10. Carefully discard the supernatant, then remove sample from magnetic stand.
11. Add 800 µL the **Wash Buffer**, mix thoroughly well by pipetting[4].
12. Apply sample to a magnetic stand until beads are fully pelleted.
13. Carefully discard the supernatant, then remove sample from magnetic stand.
14. Repeat Steps 11 – 13 with 300 µL the **Wash Buffer** for two additional times.
15. Apply sample to a magnetic stand until beads are fully pelleted. Remove residual wash buffers by pipetting[5].
16. Add ≥ 15 µL the **Elution Buffer**[6] gently resuspend beads.
17. Incubate at room temperature for 1 minute.
18. Apply sample to a magnetic stand until beads are fully pelleted.
19. Carefully transfer the eluate to a clean microcentrifuge tube. The purified cfDNA is ready for immediate use or can be stored (-20 °C) for long-term storage.

Id. at 2.

25. Upon information and belief, this protocol requires "acidifying the sample to establish the binding conditions and binding the extracellular nucleic acids to the solid phase in a binding mixture having a first pH of ≤6.5 which allows binding the extracellular nucleic acids to the anion exchange groups of the solid phase, wherein the solid phase is provided by magnetic particles."

26. This protocol further requires "separating the solid phase with the bound extracellular nucleic acids from the remaining sample," "optionally washing the extracellular nucleic acids," and "eluting extracellular nucleic acids from the solid phase, wherein elution occurs at a second pH lying in the range of ≥8 to ≤14."

27. Finally, these documents and the title of Zymo's product, "MAGicBead™ cfDNA Isolation Kit," (Ex. 5, at 1) make it clear that the sample being analyzed is "a cell-free or cell-depleted sample which was obtained from a cell-containing sample by removing cells, and wherein the extracellular nucleic acids are extracellular DNA" ('145 Patent at Cl. 1).

28. Further, Zymo had actual knowledge of its and its customers' infringement of the'145 Patent since at least November 27, 2023, the date on which QIAGEN first sent a letter to Zymo regarding its and its customers' infringement.

29. On information and belief, Zymo knows that the Zymo Accused Product is specially made or specially adapted for use in the infringement of the'145 Patent. The infringing components of this product are not staple articles or commodities of commerce suitable for substantial noninfringing use, and the infringing components of this product are a material part of the invention of the '145 Patent. Accordingly, in violation of 35 U.S.C. § 271(c), Zymo is also contributing to the direct infringement of the'145 Patent by at least its customers and/or end users of this Zymo Accused Product. The customers and/or end users of the Zymo Accused Product directly infringe one or more claims of the '145 Patent by making or using, without QIAGEN's authority, the Zymo Accused Product.

30. As a result of Zymo's infringement of the '145 Patent, QIAGEN has suffered, and will continue to suffer, substantial damages. Accordingly, Zymo is liable to QIAGEN for damages adequate to compensate for Zymo's acts of infringement, in an amount to be proved at trial but in no event less than a reasonable royalty for the use made of QIAGEN's patented invention by Zymo under 35 U.S.C. § 284.

31. In addition, Zymo's acts of infringement have caused QIAGEN irreparable harm that is not compensable by monetary damages. The hardships that an injunction would impose are less than those faced by QIAGEN should an injunction not issue. The public interest would be served by issuance of an injunction. Thus, QIAGEN is entitled to a permanent injunction against further infringement. Therefore, QIAGEN is entitled to injunctive relief under 35 U.S.C. § 283.

32. Further, since at least November 27, 2023, Zymo has known of the '145 Patent and known of its and its customers' infringement thereof. Yet, Zymo has continued to make available the Zymo Accused Product, and has deliberately and intentionally, and therefore willfully, infringed the '145 Patent. Zymo's acts of infringement constitute willful, egregious, and bad-faith misconduct, and consequently QIAGEN is entitled to a discretionary increase of its damages award up to three times the amount found or assessed, costs, and attorneys' fees under 35 U.S.C. § 284.

33. Based on the foregoing facts, QIAGEN requests that this Court declare this an exceptional case, and award Plaintiffs their costs and attorneys' fees under 35 U.S.C. § 285.

VI. SECOND CLAIM FOR RELIEF

(Infringement of United States Patent No. 11,021,736)

34. QIAGEN realleges and incorporates by reference the allegations of the preceding paragraphs of this Complaint as if fully set forth herein.

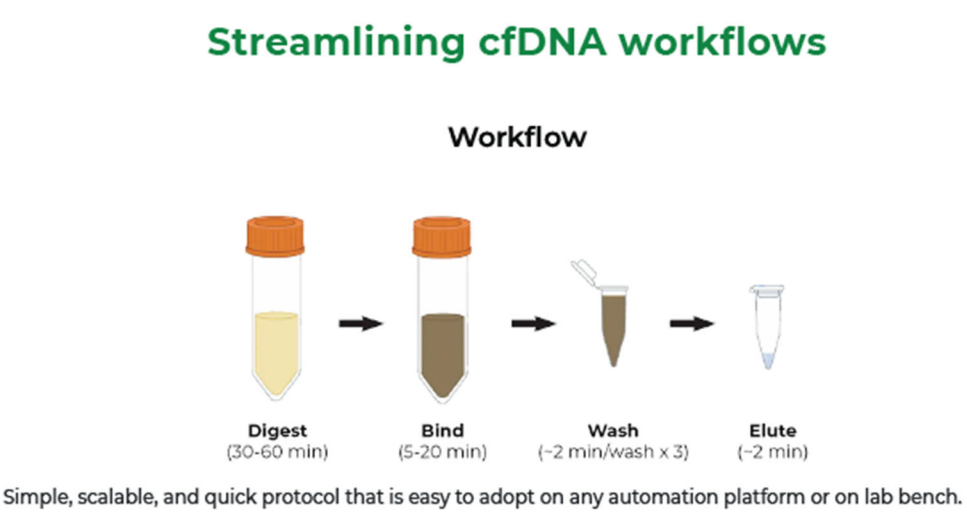
35. In violation of one or more of subsections (a), (b), and/or (c) of 35 U.S.C. § 271, Zymo has infringed and is currently infringing, directly and/or indirectly through

intermediaries, customers, or end-users, one or more claims of the '736 Patent by making, using, selling, offering for sale, and/or importing into the United States, without authority, its MAGicBead™ cfDNA Isolation Kit, the use of which practices at least claim 1 of the '736 Patent. Zymo has infringed and is currently infringing this claim literally and/or under the doctrine of equivalents.

36. Exemplary claim 1 of the '736 Patent claims:

> 1. A method for isolating extracellular nucleic acids from a sample by binding the extracellular nucleic acids to a solid phase which carries anion exchange groups, wherein said method comprises the following steps:
>
> > a. binding the extracellular nucleic acids to the solid phase in a binding mixture having a first pH which allows binding the extracellular nucleic acids to the anion exchange groups of the solid phase, wherein magnetic particles are used as solid phase;
> >
> > b. separating the solid phase with the bound extracellular nucleic acids from the remaining sample;
> >
> > c. optionally washing the extracellular nucleic acids; and
> >
> > d. optionally eluting extracellular nucleic acids from the solid phase; wherein the sample is a cell free or cell-depleted sample which was obtained from a body fluid by removing cells from said body fluid.

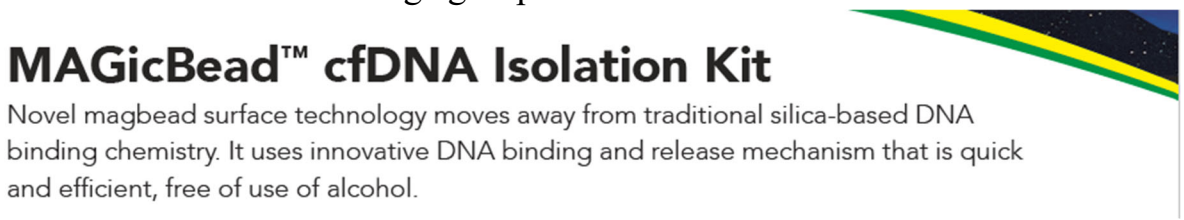
37. A promotional flyer for the MAGicBead™ cfDNA Isolation Kit (attached hereto as Exhibit 5) describes the steps performed to use Zymo's product:



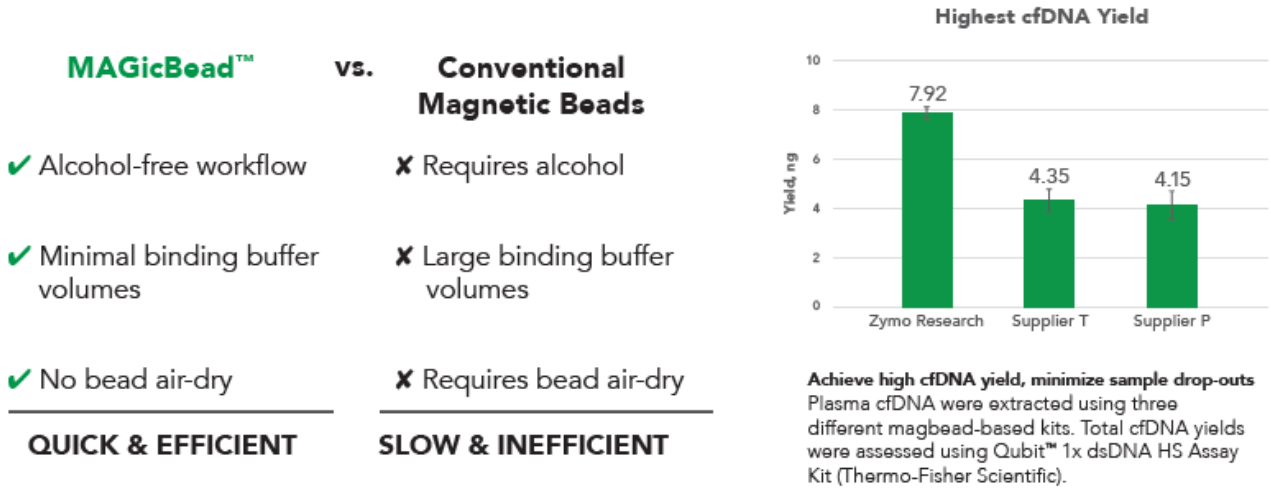
Ex. 5, at 1.

38. As is evident by the title and the exemplary workflow, the MAGicBead™ cfDNA Isolation Kit is a method for extracting extracellular nucleic acids from a sample.

39. Additional details within the flyer make is clear that the kit uses a solid phase that carries anion exchange groups:



Id.



Id.

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2 mL	500 µL	80 µL	500 µL	10 µL	**~3.1 mL**
10 mL	2.5 mL	400 µL	2.5 mL	10 µL	**~15.5 mL**

1. Referring to the table (*above*), add a cell-free biofluid[1] sample into a clean tube that can comfortably accommodate (~70% capacity) the final reaction volume (*Note: for other sample volumes, scale other components proportionally EXCEPT the beads*[2]).
2. Add the **Digestion Buffer** and **Proteinase K**. Mix thoroughly by vortexing or pipetting for 5 seconds.
3. Digest lysate mixture according to the sample collection method (*below*):

Collection Tube	Digestion Condition
K_2EDTA, Na-Citrate, NaF/K-Oxalate, non-plasma biofluids[1]	37 °C for 30 minutes or RT for 2 hours
Streck Cell-Free DNA BCT®	55 °C for 30 minutes or RT for 2 hours
K_3EDTA and Na_2EDTA	37 °C for 60 minutes

4. Add the **Binding Buffer**. Mix thoroughly by vortexing or pipetting for 5 seconds.
   (The Binding Buffer must be added prior to MAGicBeads™ cfDNA)
5. Completely resuspend **MAGicBeads™ cfDNA** by vortexing and inverting vigorously until there is no clump of beads.
6. Add 10 µL **MAGicBeads™ cfDNA** and mix thoroughly by vortexing or pipetting for 5 seconds.
7. Incubate at room temperature with constant agitation[3] using a rotator (at ~30 rpm) for the sample input volumes indicated (*below*).

Sample Input Volume	Incubation Time
≤ 1 mL	5 minutes
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> 3 mL and ≤ 10 mL	20 minutes

Ver. 1.1.0 April 2023

Ex. 6, at 1.

cfDNA Extraction Procedure (Cont.)

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8. After taking sample out of a rotator, flick sample tube down to move residual lysates to the bottom of the tube. Carefully open the cap prior applying them on magnetic stand to prevent loss of lysates.
9. Apply sample to a magnetic stand until beads are fully pelleted.
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11. Add 800 µL the **Wash Buffer**, mix thoroughly well by pipetting[4].
12. Apply sample to a magnetic stand until beads are fully pelleted.
13. Carefully discard the supernatant, then remove sample from magnetic stand.
14. Repeat Steps 11 – 13 with 300 µL the **Wash Buffer** for two additional times.
15. Apply sample to a magnetic stand until beads are fully pelleted. Remove residual wash buffers by pipetting[5].
16. Add ≥ 15 µL the **Elution Buffer**[6] gently resuspend beads.
17. Incubate at room temperature for 1 minute.
18. Apply sample to a magnetic stand until beads are fully pelleted.
19. Carefully transfer the eluate to a clean microcentrifuge tube. The purified cfDNA is ready for immediate use or can be stored (-20 °C) for long-term storage.

Id. at 2.

41. Upon information and belief, this protocol requires "separating the solid phase with the bound extracellular nucleic acids from the remaining sample," "optionally washing the extracellular nucleic acids," and "optionally eluting extracellular nucleic acids from the solid phase."

42. Finally, these documents and the title of Zymo's product, "MAGicBead™ cfDNA Isolation Kit," (Ex. 5, at 1) make it clear that the sample being analyzed is "cell free or cell-depleted sample which was obtained from a body fluid by removing cells from said body fluid" ('736 Patent at Cl. 1).

43. Further, Zymo had actual knowledge of its and its customers' infringement of the '736 Patent since at least November 27, 2023, the date on which QIAGEN first sent a letter to Zymo regarding its and its customers' infringement.

44. On information and belief, Zymo knows that the Zymo Accused Product is specially made or specially adapted for use in the infringement of the '736 Patent. The infringing components of this product are not staple articles or commodities of commerce suitable for substantial noninfringing use, and the infringing components of this product are a material part of the invention of the '736 Patent. Accordingly, in violation of 35 U.S.C. § 271(c), Zymo is also contributing to the direct infringement of the '736 Patent by at least its customers and/or end users of this Zymo Accused Product. The customers and/or end users of the Zymo Accused Product directly infringe one or more claims of the '736 Patent by making or using, without QIAGEN's authority, the Zymo Accused Product.

45. As a result of Zymo's infringement of the '736 Patent, QIAGEN has suffered, and will continue to suffer, substantial damages. Accordingly, Zymo is liable to QIAGEN for damages adequate to compensate for Zymo's acts of infringement, in an amount to be proved at trial but in no event less than a reasonable royalty for the use made of QIAGEN's patented invention by Zymo under 35 U.S.C. § 284.

46. In addition, Zymo's acts of infringement have caused QIAGEN irreparable harm that is not compensable by monetary damages. The hardships that an injunction would impose are less than those faced by QIAGEN should an injunction not issue. The public interest would be served by issuance of an injunction. Thus, QIAGEN is entitled to a permanent injunction against further infringement. Therefore, QIAGEN is entitled to injunctive relief under 35 U.S.C. § 283.

47. Further, since at least November 27, 2023, Zymo has known of the '736 Patent and known of its and its customers' infringement thereof. Yet, Zymo has continued to make available the Zymo Accused Product, and has deliberately and intentionally, and therefore willfully, infringed the '736 Patent. Zymo's acts of infringement constitute willful, egregious, and bad-faith misconduct, and consequently QIAGEN is entitled to a discretionary increase of its damages award up to three times the amount found or assessed, costs, and attorneys' fees under 35 U.S.C. § 284.

48. Based on the foregoing facts, QIAGEN requests that this Court declare this an exceptional case, and award Plaintiffs their costs and attorneys' fees under 35 U.S.C. § 285.

VII. JURY DEMAND

49. QIAGEN demands a jury trial on all claims so triable.

VIII. PRAYER FOR RELIEF

WHEREFORE, QIAGEN respectfully requests:

A. That Judgment be entered that:

1. Zymo has infringed one or more claims of the '145 Patent;
2. Zymo has infringed one or more claims of the '736 Patent;

B. That, in accordance with 35 U.S.C. § 283, Zymo, and all of its affiliates, employees, agents, officers, directors, attorneys, successors, and assigns, and all those acting on behalf of or in active concert or participation with any of them,

be permanently enjoined from (1) infringing the Asserted Patents and (2) making, using, selling, and offering for sale the Zymo Accused Product;

C. An order directing Zymo to file with the Court and serve upon QIAGEN's counsel within thirty (30) days after entry of the order of injunction, a report setting forth the manner and form in which Zymo has complied with the injunction, including the provision relating to destruction and recall of infringing products and materials;

D. An award of damages sufficient to compensate QIAGEN for Zymo's infringement under 35 U.S.C. § 284, including an enhancement of damages on account of Zymo's willful infringement;

E. That the case be found exceptional under 35 U.S.C. § 285 and that QIAGEN be awarded its reasonable attorneys' fees;

F. Costs and expenses in this action;

G. An award of prejudgment and post-judgment interest; and

H. Such other and further relief as the Court may deem just and proper.

Dated: August 20, 2024

Respectfully submitted,

By: /s/ *Diana Hughes Leiden*

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