

**UNITED STATES DISTRICT COURT
MASSACHUSETTS**

TRUTHCURES and MOIRA
KERANS, on behalf of themselves and
all others similarly situated,

Plaintiffs,

v.

LetsGetChecked, Inc.,

Defendant,

Case No. _____

Class Action

Jury Trial Demanded

CLASS ACTION COMPLAINT

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I. INTRODUCTION

1. This case is about false advertising with tragic consequences.
2. Defendant LetsGetChecked, Inc. ("**Defendant**") sells a supposed test for Lyme disease (the "**Test**") directly to consumers that it claims will accurately and comprehensively diagnose the presence of Lyme disease.
3. In reality, the Test is non-comprehensive, useless, and inaccurate:
 - **The Test is not comprehensive.** There are dozens of bacterial strains that cause Lyme disease, but Defendant's Test can detect only one strain. Defendant does not warn consumers that its Test cannot detect most disease strains.
 - **The Test is useless.** The CDC instructs that in-person examination by a doctor is the only way to obtain a Lyme disease diagnosis. Doctors cannot rely on Defendant's Test and must rely on doctor-prescribed laboratory testing. Defendant's Test is therefore useless: consumers must pay for a doctor's visit and another doctor-prescribed test to obtain a diagnosis.
 - **The Test is inaccurate.** According to FDA documentation, a positive result using Defendant's Test is accurate only 58% of the time for early-stage infections. Further, the FDA has declared that a negative result using Defendant's Test *must never be trusted*. Defendant does not warn consumers that its Test is no better than a coin flip for a positive diagnosis and utterly useless for a negative diagnosis.
4. Defendant omits these facts because it wants to sell its Test. Lyme disease testing is big business. More than a million Americans contract Lyme disease each year, and the United States healthcare system spends more than a billion dollars annually on Lyme disease. Defendant wants to cash in on Lyme disease by cutting

out the middlemen—the doctors—and selling directly to consumers. Defendant omits material facts because no consumer would buy the Test if they knew it was non-comprehensive, useless, and inaccurate.

5. Deceptively marketing diagnostic devices directly to regular people has dire consequences: people trust Defendant's Test and miss their chance for early diagnosis and treatment.

6. If Lyme disease is not treated early enough, it becomes almost impossible to cure. The disease suppresses the immune system and quickly spreads throughout the body, causing a lifetime of pain and suffering or even death. Complications include crippling fatigue, cardiac arrest, cognitive disfunction, and intractable chronic pain caused by inflammation of the body's tissue and nerves.

7. Untreated Lyme disease may also pass to unborn children, leading to fetal malformations, stillbirths, and complications after birth, including death. Lyme is such a painful and disruptive disease that sufferers face an increased risk of suicide.

8. Defendant cannot be allowed to deceptively market inaccurate direct-to-consumer medical tests for a deadly disease like Lyme disease. Accordingly, by this class action lawsuit, Plaintiff TruthCures and Plaintiff Moria Kerans, on behalf of herself and a class of consumers who purchased Defendant's worthless Test, seek to enjoin Defendant from using deceptive practices to sell its Lyme Disease Test and

recover the money Plaintiff Kerans and the class members paid Defendant to purchase the Test.

II. PARTIES

9. Plaintiff TruthCures is a Kansas nonprofit committed to the pursuit and creation of reliable Lyme disease diagnostics. Defendant's advertising of its Test as reliable and effective frustrates TruthCures' mission by falsely informing the public that the Test is reliable and effective, reducing the need for the pursuit and creation of truly reliable and effective Lyme disease diagnostics. TruthCures brings suit on its own behalf because Defendant's deceptive advertising frustrates TruthCures' mission to inform the public regarding the unreliability of Lyme disease diagnostic tests apart from evaluations by a physician. TruthCures has diverted substantial money and staff time to combat Defendant's deceptive advertising. But for Defendant's deceptive advertising, TruthCures would have used its resources to support its core mission: providing education to the public.

10. Plaintiff Moira Kerans is a citizen of the State of Massachusetts and purchased Defendant's Lyme Disease Test for home use within the applicable limitations period.

11. Defendant is the wholly-owned United States operating subsidiary of the Irish company PrivaPath Diagnostics Limited. Defendant is a Delaware corporation registered to do business and does business in the State of

Massachusetts, including by selling its Test to Plaintiff Kerans. Defendant's principal place of business is at 330 W. 38th Street, Suite 405, New York, NY, 10018.

12. Defendant advertises, markets, distributes, and sells its Lyme Disease Test product directly to consumers in Massachusetts and the United States using the brand name LetsGetChecked.

III. JURISDICTION AND VENUE

13. This Court has jurisdiction over this action pursuant to 28 U.S.C. §1332(d) because at least one member of the Class is a citizen of a state different from that of Defendant and this is a class action in which, on information and belief, the aggregate amount in controversy exceeds \$5,000,000 and the number of Class members exceeds 100.

14. Venue is appropriate within this District under 15 U.S.C. § 22 and 28 U.S.C. § 1391(b) and (c) because Defendant transacts business within this District and the interstate trade and commerce, hereinafter described, is carried out, in substantial part, in this District.

IV. FACTUAL ALLEGATIONS

A. Lyme Disease Infects More Than a Million Americans Each Year.

15. The Centers for Disease Control and Prevention (“CDC”) names Lyme disease “the most common vector-borne disease in the United States.” A “vector-borne” disease is transmitted by mosquitoes, ticks, and fleas.

16. A Lyme disease infection occurs when a tick bites a human and transmits Lyme disease causing bacteria. There are many species of Lyme disease causing bacteria, collectively known as *Borrelia burgdorferi sensu lato*, including the following North American species:

Borrelia andersonii

Borrelia mayonii

Borrelia kurtenbachii

Borrelia californiensis

Borrelia bissettiae

Borrelia burgdorferi sensu stricto

Borrelia carolinensis

Borrelia americana

Borrelia chilensis

17. Experts estimate more than one million Americans are infected with Lyme disease each year. The actual number of infections is likely much higher because many Lyme disease tests sold in the United States are inaccurate, resulting in underdiagnosis. In the words of one prominent Lyme disease researcher, “we should take all *borrelia* test kits in the United States and discard them and start from scratch.” Defendant’s Test is no exception.

B. Lyme Disease Must Be Diagnosed by a Physician.

18. The CDC instructs that Lyme disease should be diagnosed in person by a physician based on the presence of physical symptoms.

19. The CDC warns that at-home laboratory testing products—like the Defendant’s Lyme Disease Test—are not substitutes for in-person examination by a physician. The CDC instructs that laboratory testing products are only helpful in conjunction with physical examination and only “if used correctly and performed with validated methods.”

20. In 1997, the FDA issued a Special Communication to make known its “numerous concerns regarding the potential for misdiagnosis of Lyme disease using commercial assays” like Defendant’s Test. The FDA reviewed the scientific literature to date and warned that tests like Defendant’s “should only be used to *support* a clinical diagnosis [i.e., in person by a physician], not as the primary basis for making diagnostic or treatment decisions.” The FDA further warned that its “findings are troubling and reinforce the maxim that serologic testing [like Defendant’s Test] is of little value in the absence of clinical findings suggestive of Lyme disease.”

21. Similarly, in 2017, the Association of Public Health Laboratories stated that “[n]o one can disagree with the call for better tests for Lyme disease” and emphasized “the need for a health care provider to obtain an exposure history, to

look at signs and symptoms and to include any other relevant clinical history, in addition to the review of pertinent laboratory results in considering a diagnosis of Lyme disease.”

22. Physician oversight is so vital that some regulators have banned the questionable at-home testing industry entirely. The State of New York, for example, has banned “direct access testing” like the Defendant’s Test because without “physician oversight and involvement,” patients are at risk of “unnecessary testing” and “misunderstandings that may ensue from a consumer’s inability to recognize the clinical implications of a test result—for example, incorrectly believing one is free from an infectious disease after receiving false negative results.”

23. The State of New York is right that at-home testing is dangerous for consumers. New York banned Defendant’s Lyme Disease Test for good reasons: consumers have no idea that Defendant’s Test results are meaningless or that, no matter what, they need to see a doctor and pay for another round of doctor-prescribed laboratory testing.

C. If Undiagnosed, Lyme Disease Develops into A Debilitating and Incurable Disease.

24. Lyme disease is treatable if diagnosed early enough. As the CDC explains, “People treated with appropriate antibiotics in the early stages of Lyme disease usually recover rapidly and completely.” The problem is that the treatable stage of Lyme disease is very short, perhaps only 30 days.

25. When Lyme disease goes undiagnosed or is not diagnosed early enough, it causes debilitating and often permanent physical afflictions or even death.

26. Untreated Lyme disease quickly spreads throughout the body to infect bones, muscles, and tendons, organs like the brain, liver, and heart, and the nervous system.

27. Undiagnosed Lyme disease becomes what doctors and scientists call “Chronic Lyme” or “long haul Lyme borreliosis.” Chronic Lyme disease is difficult, if impossible, to cure. That is why early diagnosis is so important.

28. The serious complications caused by Lyme disease are well-documented:

- Infection of unborn fetuses and newborn babies
- Stillbirth
- Fetal malformations of the heart and brain
- Sudden infant death
- Neurological disease
- Intractable chronic pain caused by inflammation of the body’s tissue and nerves
- Immune system suppression
- Sudden onset blindness
- Fatal cardiac arrest
- Destruction of heart valves, requiring cardiac transplantation surgery

- Bell's palsy
- Spinal cord degradation resulting in paralysis
- Fatal swelling of the brain
- Necrosis (death of tissue) in the brain
- Brain infection and dozens of documented psychiatric afflictions
- Increased risk of premature death and suicide

29. The tragedy is that Defendant's deceptive marketing costs consumers their chance at an early diagnosis (or any diagnosis). Consumers purchase Defendant's Test and forego or delay physician examination. Consumers then trust the Test, which, as discussed below, is highly likely to produce an erroneous diagnosis. If consumers ever discover their Lyme disease infection, it is too late, and Chronic Lyme disease has taken hold.

D. Defendant Deceptively Markets its "Lyme Disease Test" Directly to Consumers.

30. Defendant sells its so-called "Lyme Disease Test" directly to United States consumers via its website, www.letsgetchecked.com/home-lyme-disease-test, and third-party websites like Amazon.com.

31. In marketing its Lyme Disease Test, Defendant makes numerous deceptive and material omissions.

1. Defendant's Lyme Disease Test Is Not Comprehensive.

32. Defendant markets its Test as a "Lyme Disease Test," but the Test can only detect one type of Lyme disease causing bacteria, *Borrelia burgdorferi sensu stricto*, whereas multiple strains of Lyme disease-causing *Borrelia* bacteria are found in Massachusetts and North America. Defendant's Test cannot detect these other *Borrelia* strains, including *Borrelia mayonii*, which is known to cause Lyme disease in North America. Defendant knows this but does not disclose to consumers that multiple strains of Lyme disease causing bacteria exist, nor does it disclose that its Test can only detect one such strain. Rather, Defendant claims that the Test detects the presence of "Borrelia IgM Antibodies" and "Borrelia IgG Antibodies" in the customer's body, suggesting that the presence of all *Borrelia* strains are detected.

33. Based on Defendant's omissions, consumers believe they are buying a test that will give them a comprehensive Lyme disease diagnosis, but Defendant's Test cannot do that.

34. If Defendant informed consumers that its Test can detect only one strain of Lyme disease, no one would buy it.

2. Defendant's Lyme Disease Test Is Entirely Useless.

35. The CDC states that Lyme disease must be diagnosed by a physician based on physical symptoms. Defendant knows this but does not disclose to consumers that a physician must diagnose Lyme disease.

36. Based on this omission, consumers erroneously (and tragically) believe they can rely solely on the Defendant's laboratory test to diagnose Lyme disease. Defendant does not inform consumers that to obtain a true diagnosis, they will have to pay for both a doctor's visit and another round of laboratory tests prescribed by their doctor.

37. Consultation with and examination by a physician is necessary to obtain a reliable diagnosis for several reasons. Most significantly, the available diagnostic tests—including Defendant's Test—are not at all predictive during the first few weeks after infection. This is because the tests depend upon measuring the body's response to the infection, not measuring the presence of the infecting bacteria itself, and it takes time for the body to develop antibodies against the infection. A physician can advise a patient as to when a diagnostic test should be taken, if the test should be retaken, what the results mean and do not mean, and whether the patient may be infected despite a negative test based on the patient's symptoms. A negative test result is, on its own, completely useless to a customer. False positive test results also occur, particularly where the customer does not exhibit symptoms indicating infection or when the customer has not had exposure to black-legged ticks.

38. If Defendant informed consumers that physical examination and doctor-prescribed laboratory tests are required for diagnosis, no one would buy Defendant's useless Test.

3. Defendant's Lyme Disease Test Is Shockingly Inaccurate.

39. According to Defendant, its Lyme Disease Test utilizes “chemiluminescence immunoassay (CLIA)” technology. There is only one manufacturer FDA-approved to market CLIA Lyme disease tests. On information and belief, Defendant markets those CLIA tests.

40. The data published in the FDA's marketing approval prove Defendant's Test is alarmingly inaccurate:

- The FDA reports that a positive result produced by Defendant's Test is correct only 58% to 85% of the time for early-stage infections.
- The FDA reports that a negative result produced by Defendant's Test “should not be used to exclude Lyme disease.” This bears repeating: Defendant's Test can *never* be relied upon to diagnosis the absence of Lyme disease.

41. Defendant knows its Test is inaccurate for positive diagnosis and entirely useless for a negative diagnosis, but it does not inform consumers about these material limitations.

42. To the contrary, Defendant suggests on its website that the Test is accurate and reliable. Defendant's website contains the following passage:

How accurate is the testing process?

Your samples are processed in the same labs used by primary care providers, hospitals and government programs.

LetsGetChecked laboratories are CLIA approved and CAP-accredited, which are the highest levels of accreditation.

Sample collection kits are manufactured within our ISO 13485 accredited facility, the highest level of accreditation for medical devices.

This passage is clearly designed to assure customers that the Test is accurate, but the Test is not accurate.

43. In addition, the test kit Defendant sends to customers reinforces the idea that the Test is reliable. The inside top of the box reads: “It’s good to know.” Defendant plainly claims that the Test will tell customers that they will “know” whether they have Lyme disease from taking the Test, when Defendant knows that the Test is wholly unreliable and not fit for the claimed purpose.

44. Defendant knows that if consumers knew how inaccurate and useless its Test is, no one would buy it.

E. Inaccurate Lyme Disease Tests Lead to A Lifetime of Pain and Suffering or Even Death.

45. Defendant’s deceptive marketing of its inaccurate Lyme Disease Test may result in tragedy for American consumers. Defendant surely intends for its customers to rely on the results of its Test, and a person receiving a false negative report on Defendant’s Test may forego other treatment.

46. Failure to seek timely and medically necessary physician diagnosis and treatment for Lyme disease may turn a treatable bacterial infection into a lifetime of pain and suffering.

47. Lyme disease also results in tragic adverse social outcomes. Doctors generally will not treat anyone that does not have a positive Lyme disease test. This means that folks who receive a false negative are ignored by the medical community, incorrectly diagnosed as suffering from something else, or, worse, mocked and accused of “making it all up in their head.”

48. People infected with Lyme disease often suffer such disruptive complications that they cannot work, but without a positive diagnosis, they may be denied disability. This leads to the wrongly diagnosed person being ostracized by their family and friends or ending up on the street, homeless.

49. In one tragic case, undiagnosed Lyme disease drove a young man named Jeremy “Jake” Nodolf to suicide. Jake was born in Wisconsin, a state known for high incidences of Lyme disease infection. Growing up, Jake was a bright, healthy kid active in sports and an Eagle Scout.

50. During his eighth-grade year, Jake began to experience mysterious and excruciating pain in his legs, back, and feet. Jake was soon in so much pain he had difficulty moving. He was forced to drop out of sports, and his friends drifted away.

51. Over the next twenty years, Jake’s physical and mental condition deteriorated. Jake experienced migraines, inflamed joints, muscle spasms, interstitial cystitis, trouble breathing, chronic fatigue, brain fog, decreased brain circulation, and intense depression and anxiety. Jake’s pain spread throughout his body, so he

could not bear to walk or feel fabrics against his skin. Jake saw doctors nationwide and tried every possible physical and emotional treatment. Nothing worked.

52. Then, after twenty years of pain and suffering, a doctor diagnosed Jake with late-stage Lyme disease. Jake had taken two Lyme disease tests early in his illness, but both tests resulted in a false negative. By the time a doctor correctly diagnosed Jake, the chance of reversing his physical and mental condition was remote, if not impossible.

53. At the age of thirty-seven, after a particularly disheartening forecast from his doctor, Jake took his own life. Jake's last words to his mother were, "I want to live! I want to LIVE!" But a lifetime of pain, suffering, and depression caused by undiagnosed Lyme disease is too much for Jake or anyone else to bear. Jake's mother's search for answers led her to an informational video that Plaintiff TruthCures produced and dedicated to Lyme patients who, like Jake, had taken their own lives. Jake's mother is now an active member of TruthCures and spends her time helping others like Jake and herself. In her own words, "I will support TruthCures to my last dying breath!"

54. While this suit seeks only to recover as damages the out-of-pocket costs persons expended on Defendant's worthless Test and injunctive relief, it must not be forgotten that deceptively marketed Lyme disease tests hurt people. Defendant should not be allowed to deceptively market its Test to the public in the pursuit of

profit. That is why, in addition to the costs of the Test, TruthCures seeks to enjoin Defendant from using deceptive practices to sell its Lyme Disease Test.

V. CLASS ACTION ALLEGATIONS

55. Plaintiff Kerans sues on her own behalf and on behalf of a proposed class of all other similarly situated persons consisting of:

All persons or entities who purchased Defendant's Lyme Disease Test, for consumption by themselves, their families, or their members, employees, insureds, participants or beneficiaries, other than for resale. Excluded from the Class are:

- a. The Defendant and its officers, directors, management, employees, subsidiaries or affiliates;
- b. All governmental entities, except for government funded employee benefit plans;
- c. The judges in this case and any members of their immediate families;
- d. All persons who are presently in bankruptcy proceedings or who obtained a bankruptcy discharge in the last three years; and
- e. All persons who are currently incarcerated.

56. The Class consists of thousands of purchasers residing throughout the United States. Accordingly, it would be impracticable to join all Class Members before the Court.

57. There are numerous and substantial questions of law or fact common to all the members of the Class and which predominate over any individual issues. Included within the common question of law or fact are:

- a. whether Defendant deceptively marketed its Lyme Disease Test as capable of accurately and comprehensively diagnosing Lyme disease;
- b. whether Defendant knew or should have known that its Lyme Disease Test is not capable of accurately and comprehensively diagnosing Lyme disease;
- c. whether Defendant deceptively marketed its Lyme Disease Test as a substitute for in-person diagnosis by a physician;
- d. whether Defendant knew or should have known that its Lyme Disease Test is not a substitute for in-person diagnosis by a physician;
- e. whether Defendant sells a Lyme Disease Test that is unfit for use as an “at-home” Lyme disease diagnostic device, thereby breaching Defendant’s implied and express warranties and making its Lyme Disease Test unfit for its intended purpose;
- f. whether Defendant is liable to Plaintiff Kerans and the Class for unjust enrichment;
- g. whether Plaintiff and the Class are entitled to declaratory and injunctive relief;
- h. whether Plaintiff Kerans and the members of the Class are entitled to actual, statutory, and punitive damages.

58. Plaintiff Kerans’s claims are typical of the Class Members’ claims in that they share the above-referenced facts and legal claims or questions, there is a sufficient relationship between the damage to Plaintiff Kerans and Defendant’s conduct affecting Class Members, and Plaintiff Kerans has no interests adverse to the interests of other Class Members.

59. Plaintiff Kerans will fairly and adequately protect the interests of Class Members and has retained experienced and competent counsel.

60. A class action is superior to other methods for the fair and efficient adjudication of this controversy, since individual joinder of all Class Members is impracticable. No other group method of adjudication is more efficient or manageable for at least the following reasons:

- a. The liability claims presented in this case predominate over any questions of law or fact, if any exist at all, affecting any individual member of the Class;
- b. Absent certification of the Class, the Class Members will continue to suffer damage and Defendant's unlawful conduct will continue without remedy while Defendant profits from and enjoys its ill-gotten gains;
- c. Given the size of individual Class Members' claims, few, if any, Class Members could afford to or would seek legal redress individually for the wrongs Defendant committed against them, and absent Class Members have no substantial interest in individually controlling the prosecution of individual actions;
- d. When the liability of Defendant has been adjudicated, claims of all Class Members can be administered efficiently and/or determined uniformly by the Court; and
- e. This action presents no difficulty that would impede its management by the Court as a class action, which is the best available means by which Plaintiff and Class Members can seek redress for the harm caused to them by Defendant.

61. The prosecution of separate actions by individual Class Members would create a risk of inconsistent or varying adjudications with respect to individual

Class Members, which would establish incompatible standards of conduct for Defendant.

62. Further, bringing individual claims would overburden the courts and be an inefficient method of resolving the dispute at the center of this litigation. Adjudications with respect to individual members of the Class would, as a practical matter, be dispositive of the interest of other members of the Class who are not parties to the adjudication and may impair or impede their ability to protect their interests. Consequently, class treatment is a superior method for adjudication of the issues in this case.

VI. CAUSES OF ACTION

COUNT ONE

Violation of Massachusetts Consumer Protection Law

63. Defendant advertised, offered, sold and distributed its Lyme Disease Test in Massachusetts.

64. Defendant knowingly deployed unconscionable, false, misleading and deceptive acts and practices to advertise and sell its Lyme Disease Test in Massachusetts.

65. Defendant's deceptive acts or practices in the conduct of trade or commerce were likely to deceive reasonable consumers to rely on its material misrepresentations, concealment, half-truths, and omissions.

66. Defendant knowingly suppressed material facts from consumers, including Plaintiff Kerans and the Class, who were ignorant and unable to discover the truth through reasonable diligence.

67. These material misrepresentations, concealment, half-truths, and omissions were so fundamental that every customer would necessarily rely on them in making their purchase.

68. Defendant's deceptive acts or practices in the form of its misrepresentations, concealment, omissions, and half-truths about its Lyme Disease Test were material because they involved information that would be important to consumers in making relevant purchasing decisions.

69. Defendant's conduct alleged herein violated the Massachusetts Regulation of Business Practices for Consumers Protection Act (Mass. Gen. Laws Ann. Pt. I, tit. XV, Ch. 93A).

70. As a direct and proximate result of Defendant's unconscionable, false, misleading, and deceptive acts and practices in the conduct of trade or commerce in violation of the foregoing statutes, Plaintiff Kerans and all Class Members suffered losses in the form of monetary and non-monetary damages, including that they purchased Defendant's Lyme Disease Test, which they would not have purchased had they known that (1) the Test was not an accurate and comprehensive test for

Lyme disease, and (2) the Test was not a substitute for in-person diagnosis by a physician based on physical symptoms.

71. Further, Defendant's unconscionable, false, misleading, and deceptive acts or practices were intentional, repetitious, and have harmed a large group of consumers in Massachusetts. Because Defendant put its own pecuniary interest ahead of all else, it sacrificed the safety, health, and well-being of consumers and their families. As a result, Defendant has unfairly profited off unsuspecting purchasers who believed they were buying an accurate and comprehensive Lyme disease test. Therefore, Plaintiff Kerans and the Class are entitled to treble and punitive damages as permitted by law.

72. Plaintiff Kerans and the Class seek all monetary damages allowed by law, including the greater of actual damages or statutory damages; treble and punitive damages; attorneys' fees and costs; and any other relief that is just and proper.

73. Both Plaintiffs seek to permanently enjoin Defendant from deceptively marketing its Lyme Disease Test.

COUNT TWO
Breach of Express Warranty

74. Defendant warranted that its Lyme Disease Test was an accurate and comprehensive tool to diagnose Lyme disease infections.

75. Defendant breached this express warranty in connection with the sale and distribution of its Lyme Disease Test. At the point of sale, the Lyme Disease Test, while appearing normal, contained latent defects as set forth here, rendering it unfit for personal use.

76. Plaintiff Kerans and the Class reasonably expected, at the time of purchase, that Defendant's Lyme Disease Test was fit for its ordinary and intended use.

77. Had Plaintiff Kerans and the Class known the Lyme Disease Test was not an accurate or comprehensive tool to diagnose Lyme disease, they would not have purchased it.

78. As a direct and proximate result of Defendant's breach of express warranty, Plaintiff Kerans and the Class have sustained damages in an amount to be determined at trial.

79. Both Plaintiffs seek to permanently enjoin Defendant from continuing to breach its express warranties in connection with the sale and distribution of its Lyme Disease Test.

COUNT THREE
Breach of Implied Warranty of Merchantability

80. Defendant impliedly warranted to Plaintiff Kerans and the Class that its Lyme Disease Test was of merchantable quality and effective for its ordinary and intended use.

81. Such implied warranty of merchantability, contained in Uniform Commercial Code § 2-314, has been codified in Massachusetts at Mass. Gen. Laws Ann. Ch. 106, §§ 2-314, *et seq.*

82. Defendant breached the implied warranty of merchantability in connection with the sale and distribution of its Lyme Disease Test. At the point of sale, the Lyme Disease Test, while appearing normal, contained latent defects as set forth here, rendering it unfit for personal use.

83. Plaintiff Kerans and the Class reasonably expected, at the time of purchase, that Defendant's Lyme disease test was fit for its ordinary and intended use.

84. Had Plaintiff Kerans and the Class known the Lyme Disease Test was not fit for its ordinary and intended use, they would not have purchased it.

85. As a direct and proximate result of Defendant's breach of express warranty, Plaintiff Kerans and the Class have sustained damages in an amount to be determined at trial.

86. Both Plaintiffs further seek to permanently enjoin Defendant from continuing to breach its implied warranty of merchantability in connection with the sale and distribution of its Lyme Disease Test.

COUNT FOUR
Breach of the Implied Warranty of Usability

87. Defendant impliedly warranted to Plaintiff Kerans and the Class that its Lyme Disease Test was usable for its ordinary and intended use.

88. Such implied warranty of usability, contained in Uniform Commercial Code § 2-314(3), has been codified in Massachusetts at Mass. Gen. Laws Ann. Ch. 106, §§ 2-314, *et seq.*

89. Through usage of trade, manufacturers of bacterial infection diagnostic tests impliedly warrant that their products are usable for the end consumer.

90. Defendant breached the implied warranty of usability in connection with the sale and distribution of its Lyme Disease Test. At the point of sale, the Lyme Disease Test, while appearing normal, contained latent defects as set forth here, rendering it unfit for personal use.

91. Defendant and its agents and employees knew or should have known that the Lyme Disease Test suffers from a defect that causes negative health effects and/or places persons at risk for negative health effects to such an extent that the products are unusable.

92. Plaintiff Kerans and the Class reasonably expected, at the time of purchase, that Defendant's Lyme disease test was usable for its ordinary and intended use.

93. Had Plaintiff Kerans and the Class known the Lyme Disease Test was not usable for its ordinary and intended use, they would not have purchased it.

94. As a direct and proximate result of Defendant's breach of express warranty, Plaintiff Kerans and the Class have sustained damages in an amount to be determined at trial.

95. Both Plaintiffs further seek to permanently enjoin Defendant from continuing to breach its implied warranty of usability in connection with the sale and distribution of its Lyme Disease Test.

COUNT FIVE
Unjust Enrichment

96. Plaintiff Kerans and the Class conferred substantial tangible and material benefits on Defendant through their purchase of its Lyme Disease Test.

97. Defendant knowingly and willingly accepted and enjoyed these benefits.

98. Defendant either knew or should have known that the payments rendered by Plaintiff Kerans and the Class were given with the expectation that Defendant's products had the qualities, characteristics, and suitability for use as represented by Defendant.

99. As such, it would be inequitable for Defendant to retain the benefit of the payments under these circumstances. Defendant should not be able to unlawfully market its Lyme Disease Test then retain all of the profits that it obtained from those unlawful sales. Under these circumstances, disgorgement is appropriate.

100. Defendant's acceptance and retention of these benefits under the circumstances alleged herein make it inequitable for Defendant to retain the benefits without payment of the value to Plaintiff Kerans and the Class.

101. Plaintiff Kerans and the Class are entitled to recover from Defendant all amounts wrongfully collected and improperly retained by Defendant, plus interest thereon.

102. Plaintiff Kerans and the Class seek restitution and/or disgorgement, attorneys' fees, costs, and any other just and proper relief available under the laws.

103. Both Plaintiffs further seek to permanently enjoin Defendant from continuing to unjustly enrich itself by deceptively marketing and selling its Lyme Disease Test.

VII. DEMAND FOR JURY TRIAL

104. Plaintiffs demand a jury trial.

VIII. PRAYER FOR RELIEF

WHEREFORE, the Plaintiffs respectfully request the following relief:

- a. Determine that this action may be maintained as a class action pursuant to Fed. R. Civ. P. 23(a) and (b)(3) and direct that reasonable notice of this action, as provided by Fed. R. Civ. P. 23(c)(2) be given to the Classes;

- b. Require Defendant to pay for sending notice to the certified Classes;
- c. Appoint Plaintiffs as Class Representatives and Plaintiff's counsel as Class Counsel;
- d. Issue an injunction to enjoin Defendant from engaging in the deceptive, unfair, unconscionable, and unlawful business practices alleged in this Complaint;
- e. Award further injunctive relief, as the Court deems appropriate;
- f. Award compensatory damages to Plaintiffs and the proposed Class in an amount to be established at trial, or, alternatively, require Defendant to disgorge or pay restitution in an amount to be determined at trial;
- g. Award treble damages as permitted by law;
- h. Award punitive damages based on Defendant's reprehensible and deliberate conduct;
- i. Award pre- and post-judgment interest;
- j. Award reasonable attorneys' fees and costs; and,
- k. For all such other and further relief as may be just and proper.

Date: June 20, 2023

Respectfully submitted,

/s/ Philip Y. Brown

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