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**UNITED STATES DISTRICT COURT  
NORTHERN DISTRICT OF CALIFORNIA**

ASHLEY CARROLL, individually and on  
behalf of all others similarly situated,

Plaintiff,

v.

MYRIAD GENETICS, INC.,

Defendant.

Case No.

**CLASS ACTION COMPLAINT**

**JURY TRIAL DEMANDED**

1 Plaintiff Ashley Carroll (“Plaintiff”) brings this action on behalf of herself and all others  
2 similarly situated against Defendant Myriad Genetics Inc. (“Defendant” or “Myriad”). Plaintiff  
3 makes the following allegations pursuant to the investigation of her counsel and based upon  
4 information and belief, except as to the allegations specifically pertaining to herself, which are  
5 based upon personal knowledge.

6 **NATURE OF THE ACTION**

7 1. This is a putative class action lawsuit on behalf of purchasers of Myriad’s Prequel  
8 Prenatal Screen (“Prequel Test” or collectively, the “Tests”). Defendant markets and sells the  
9 Tests as genetic, prenatal screening tests for pregnant women that screen for various  
10 chromosomal and genetic conditions affecting a baby’s health. Defendant markets these tests as  
11 accurate. However, unbeknownst to consumers, Prequel Test results indicating a genetic  
12 disorder are incorrect approximately 85 percent of the time.<sup>1</sup> Thus, the Tests are worth far less  
13 than their market price. In addition, as a result of these false results, expecting mothers are often  
14 unnecessarily subjected to further diagnostic testing, genetic counseling, and the even erroneous  
15 termination of a viable pregnancy.

16 2. Prenatal testing in recent years has moved towards non-invasive methods to  
17 determine the fetal risk for genetic disorders, including Non-Invasive Prenatal Testing  
18 (“NIPT”).<sup>2</sup>

19 3. NIPT analyzes DNA fragments from the blood of a pregnant women to estimate  
20 the risk that the fetus will be born with certain genetic abnormalities, including chromosomal  
21 disorders like Down Syndrome and Trisomy 18, or other, more rare disorders, like Prader-Willi  
22 and Angelman Syndrome.

23 4. NIPT is incredibly popular. However, many of these tests are often inaccurate,  
24 giving pregnant women false positive results for genetic conditions that their fetuses do not have.

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26 <sup>1</sup> <https://www.nytimes.com/2022/01/01/upshot/pregnancy-birth-genetic-testing.html>

27 <sup>2</sup> <https://www.ncbi.nlm.nih.gov/pmc/articles/PMC6545823/>

1           5.       In fact, a recent New York Times investigation found that for every 15 times an  
2 NIPT screening correctly identifies a fetal disorder, the screening is wrong 85 times, meaning  
3 that 85 percent of all positive results are false positives.<sup>3</sup>

4           6.       Despite this inaccurate testing, Defendant falsely advertises their findings as  
5 reliable, accurate and offering peace of mind for patients regarding the viability of their  
6 pregnancies. These false positives can lead to devastating personal consequences and painful  
7 decisions that are premised upon this wrong information.

8           7.       Plaintiff and Class Members purchased the Tests designed, marketed,  
9 manufactured, distributed, and sold by Defendant as accurate and reliable. Plaintiff and Class  
10 Members would not have purchased Defendant’s Tests – or, at minimum, would have paid  
11 significantly less for the Tests– had they known the Tests were inaccurate. Plaintiff and Class  
12 Members thus suffered monetary damages as a result of Defendant’s deceptive and false  
13 representations.

14   **PARTIES**

15           8.       Plaintiff Ashley Carroll is a resident of Menlo Park, California and has an intent to  
16 remain there, and is therefore a domiciliary of California. In or about June 2021, Plaintiff visited  
17 her doctor’s office in California, where she received a brochure about Defendant’s Myriad Prequel  
18 Test. After reviewing Defendant’s brochure, Plaintiff decided to purchase Defendant’s Prequel  
19 Test in California because Defendant described the Test as accurate. Specifically, Defendant  
20 represented that the Test “has the lowest test failure rate in the industry, which translates to a lower  
21 chance of needing a repeat test or an unnecessary invasive diagnostic procedure.” Defendant  
22 further represented that its Tests are “more accurate than maternal serum screening” and tells  
23 women that the Tests will “reduc[e] the chances you’ll need an unnecessary invasive follow-up  
24 test.” Plaintiff paid \$295 for the Prequel Test out of pocket. Plaintiff relied on Defendant’s  
25 representations and warranties in deciding to purchase the Prequel Test. Accordingly, Defendant’s  
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27 <sup>3</sup> <https://www.nytimes.com/2022/01/01/upshot/pregnancy-birth-genetic-testing.html>  
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1 representations and warranties were part of the basis of the bargain, in that she would not have  
2 purchased the Prequel Test on the same terms had she known the Test's representations about  
3 accuracy and trustworthiness were not true, or at least would have paid significantly less for the  
4 Prequel Test.

5 9. Defendant Myriad Genetics, Inc. is a corporation organized and existing under the  
6 laws of the state of Delaware, with its principal place of business in Salt Lake City, Utah. Myriad  
7 is a molecular diagnostic company specializing in genetic tests that determine the risk of  
8 developing disease, assess the risk of disease progression, and guide treatment decisions.

### 9 JURISDICTION AND VENUE

10 10. This Court has subject matter jurisdiction pursuant to 28 U.S.C § 1332(d)(2)(a)  
11 because this case is a class action where the aggregate claims of all members of the proposed  
12 class are in excess of \$5,000,000.00, exclusive of interest and costs, there are over 100 members  
13 of the putative class, and Plaintiff, as well as most members of the proposed class, are citizens of  
14 states different from Defendant.

15 11. This Court has personal jurisdiction over Defendant because it conducts  
16 substantial business within California, such that Defendant has significant, continuous, and  
17 pervasive contacts within the State of California and because a substantial portion of the events  
18 that gave rise to this cause of action occurred here.

19 12. Venue is proper in this Court pursuant to 28 U.S.C. § 1391(b) because Defendant  
20 transacts significant business within this District and because Plaintiff purchased and used the  
21 Prequel Test in this District.

### 22 FACTUAL ALLEGATIONS

#### 23 **A. Myriad's "Prequel" NIPT**

24 13. The discovery of fetal DNA in maternal blood has led to changes in prenatal  
25 screening. Following this discovery, many companies began working on blood tests, otherwise  
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1 known as NIPT, aimed at detecting chromosomal abnormalities without the invasive and risky  
2 nature of amniocentesis and chorionic villus sampling (“CVS”).<sup>4</sup>

3 14. Myriad’s Prequel Prenatal Screen NIPT is a noninvasive blood screen for  
4 pregnant women to find out if their babies have an increased risk for chromosomal conditions  
5 like Down syndrome (Trisomy 21) and Edwards Syndrome (Trisomy 18).

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The Myriad Prequel™ Prenatal Screen provides early insight into your baby’s development, giving you information about the chance of a chromosome condition like Down syndrome.

- Red blood cell
- Maternal DNA
- Placental DNA

Normal developmental processes cause small pieces of DNA from your baby’s placenta to enter your bloodstream. The Prequel Prenatal Screen analyzes these fragments, called cell-free DNA.

MYRIAD  
Prequel™  
Prenatal Screen

Early insight into  
your baby’s  
development

for Pregnant  
Women

Lacey D.  
Used the Prequel Prenatal Screen  
while expecting her daughter

As early as week 10, take a noninvasive blood  
screen to find out if your baby has an increased risk  
for a chromosome condition like Down syndrome.

27 <sup>4</sup> <https://blog.seracare.com/ngs/evolution-of-non-invasive-prenatal-testing-nipt-testing>

1           15.     In 2019, Myriad announced an expansion of its Prequel Test, claiming that the  
2 Tests would now check all 23 chromosome pairs rather than just the standard five chromosomes  
3 (13, 18, 21, X and Y) previously tested.<sup>5</sup>

4           16.     Prequel also claims the ability to “assess if your baby is missing a tiny piece of a  
5 chromosome (called a ‘microdeletion’), which can lead to birth defects and intellectual  
6 disabilities.”

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8           Your healthcare provider can help you  
9           decide whether you may want to screen for  
10           additional conditions  
11           The Prequel Prenatal Screen can also assess if your baby  
12           has the correct number of sex chromosomes, which  
13           can impact health issues like fertility. Additionally, the  
14           screen can assess if your baby is missing a tiny piece of a  
15           chromosome (called a “microdeletion”), which can lead  
16           to birth defects and intellectual disabilities.

17           17.     In 2020, Myriad launched its propriety “AMPLIFY” technology, which Myriad  
18 claimed further increased the performance of its Prequel test, thereby reducing the rate of false  
19 positive and false negative results.

20           18.     Nicole Lambert, president of Myriad International, Oncology and Women’s  
21 Health, claimed:

22           Prequel already provided *highly accurate* results and this proprietary  
23 technology further increases the sensitivity of our test ... With AMPLIFY,  
24 Prequel maintains its industry-leading low rate of failed samples—delivering  
25 results to 99.9 percent of patients. The important clinical benefits are that each  
26 woman who receives the test can expect *highly accurate* NIPS results,  
27 regardless of body mass index (BMI), race, or ethnicity.”<sup>6</sup>

28           19.     Myriad also claims that Prequel reduces the need for unnecessary invasive  
diagnostic testing like amniocentesis and CVS testing and tells women that there is “power in

<sup>5</sup> <https://investor.myriad.com/news-releases/news-release-details/myriad-announces-prequeltm-prenatal-screen-expanded-aneuploidy>

<sup>6</sup> <https://investor.myriad.com/news-releases/news-release-details/myriad-launches-proprietary-amplifytm-technology-further> (emphasis added).

1 being prepared” for the birth of their babies. Myriad also touts that its Tests are “more accurate  
2 than maternal serum screening” and “reduc[e] the chances you’ll need an unnecessary invasive  
3 follow-up test.”

4 **Screening reduces the need for unnecessary  
5 invasive diagnostic tests**

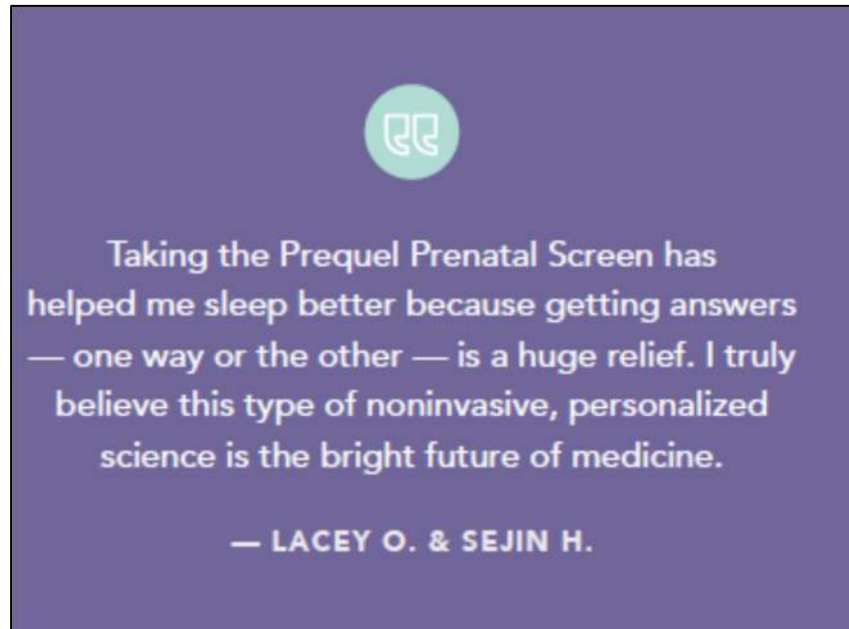
6 Noninvasive prenatal screening using cell-free DNA  
7 has been shown to be more accurate than maternal  
8 serum screening, reducing the chances you’ll need an  
9 unnecessary invasive follow-up test like chorionic villus  
10 sampling (CVS) or amniocentesis.

11 Our results are personalized based on your age and how  
12 far along you are in your pregnancy, so you have the  
13 clearest picture of your risk, which can help you decide if  
14 you’d like to pursue additional testing.

15 **THERE'S POWER IN BEING PREPARED**

16 Noninvasive prenatal screening gives you important information. Your healthcare provider can help you determine if testing is  
17 right for you.

18 20. Further, Myriad advertises Prequel as providing patients with peace of mind  
19 regarding the viability of their pregnancies by posting customer testimonials praising the Test:  
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11 21. NIPT screening tests like Prequel are costly, with an average out-of-pocket cost of  
12 \$279.<sup>7</sup>

13 **B. Defendant’s False Advertising of the Tests**

14 22. Since the launch of Prequel, Defendant has consistently advertised the Tests as  
15 “highly accurate” and trustworthy. Unfortunately for pregnant women, the Tests are alarmingly  
16 inaccurate.

17 23. A recent investigation by the New York Times found that despite the Tests and  
18 other NIPT tests being advertised as “reliable,” “highly accurate,” and offering “total  
19 confidence” and “peace of mind” for patients, the tests are inaccurate more than 85 percent of the  
20 time.

21 24. Specifically, the tests are unable to accurately discover microdeletions like the  
22 ones Defendant claims Prequel can correctly detect. Microdeletions can have a wide range of  
23 symptoms, including intellectual disability, a shortened life span, and a high infant mortality rate.

24 25. As a result of these false positive screenings, women are forced to undergo the  
25 very invasive testing that Defendant claims its Tests help women avoid, including amniocentesis

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27 <sup>7</sup> <http://www.mothersofmicrobes.com/the-nipt-test-costs-less-than-you-think-but-beware-of-insurance-surprises/>



1 and CVS. During an amniocentesis, a needle is used to remove amniotic fluid from the uterus  
2 for testing. Similarly, during a CVS procedure, a catheter or needle is used to biopsy placental  
3 cells that are derived from the same fertilized egg as the fetus. Both procedures include an  
4 increased risk of miscarriage.<sup>8</sup>

5 26. Many women also have abortions after obtaining positive results from NIPT  
6 screens, even though those results may very well be inaccurate. For example, a 2014 study  
7 found that six percent of patients who screened positive obtained an abortion without getting  
8 another test to confirm the result.<sup>9</sup>

9 27. Consumers are therefore paying hundreds of dollars for testing that is highly  
10 inaccurate and untrustworthy.

11 28. Plaintiff brings this action on behalf of herself and the Class for equitable relief  
12 and to recover damages and restitution for: (i) breach of express warranty; (ii) breach of implied  
13 warranty; (iii) unjust enrichment; (iv) fraud; (v) fraudulent omission; (vi) violation of  
14 California's Unfair Competition Law ("UCL"), Cal. Bus. & Prof. Code §§ 17200, *et seq.*;  
15 (vii) violation of California's Consumers Legal Remedies Act ("CLRA"), Civil Code §§ 1750,  
16 *et seq.*; and (viii) violation of California's False Advertising Law ("FAL"), Cal. Bus & Prof  
17 Code § 17500.

### 18 **CLASS ALLEGATIONS**

19 29. Plaintiff seeks to represent a class defined as all persons in the United States who  
20 purchased a Prequel test (the "Nationwide Class").

21 30. Plaintiff also seeks to represent a class defined as all persons who reside in the  
22 state of California who purchased a Prequel test (the "California Subclass") (collectively with the  
23 Nationwide Class, "Class").

24 31. Specifically excluded from the Class are persons who made such purchase for the  
25 purpose of resale, Defendants, Defendants' officers, directors, agents, trustees, parents, children,

26 <sup>8</sup> <https://www.nytimes.com/2022/01/01/upshot/pregnancy-birth-genetic-testing.html>

27 <sup>9</sup> <https://www.nytimes.com/2022/01/01/upshot/pregnancy-birth-genetic-testing.html>

1 corporations, trusts, representatives, employees, principals, servants, partners, joint ventures, or  
2 entities controlled by Defendants, and their heirs, successors, assigns, or other persons or entities  
3 related to or affiliated with Defendant and/or Defendant's officers and/or directors, the judge  
4 assigned to this action, and any member of the judge's immediate family.

5 32. Subject to additional information obtained through further investigation and  
6 discovery, the foregoing definition of the Class may be expanded or narrowed by amendment or  
7 amended complaint.

8 33. **Numerosity.** The members of the Class are geographically dispersed throughout  
9 the United States and are so numerous that individual joinder is impracticable. Upon  
10 information and belief, Plaintiff reasonably estimates that there are hundreds of thousands of  
11 members in the Class. Although the precise number of Class members is unknown to Plaintiff,  
12 the true number of Class members is known by Defendant and may be determined through  
13 discovery. Class members may be notified of the pendency of this action by mail and/or  
14 publication through the distribution records of Defendant and third-party retailers and vendors.

15 34. **Existence and predominance of common questions of law and fact.** Common  
16 questions of law and fact exist as to all members of the Class and predominate over any  
17 questions affecting only individual Class members. These common legal and factual questions  
18 include, but are not limited to, the following:

- 19 (a) whether the Prequel manufactured, distributed, and sold by Defendant was  
20 unfit for use as screening test, thereby breaching express and implied  
21 warranties made by Defendant and making the Prequel Test unfit for its  
22 intended purpose;
- 23 (b) whether Defendant knew or should have known that the Prequel Test would  
24 often provide false positive results prior to selling the Tests, thereby  
25 constituting fraud and/or fraudulent omission;
- 26 (c) whether Defendant is liable to Plaintiff and the Class for unjust enrichment;
- 27 (d) whether Plaintiff and the Class have sustained monetary loss and the proper  
28 measure of that loss;
- (e) whether Plaintiff and the Class are entitled to declaratory and injunctive relief;

1 (f) whether Plaintiff and the Class are entitled to restitution and disgorgement  
from Defendants; and

2 (g) whether the marketing, advertising, packaging, labeling, and other  
3 promotional materials for Prequel are deceptive.

4 35. **Typicality.** Plaintiff's claims are typical of the claims of the other members of  
the Class in that Defendant mass marketed and sold defective Prequel tests to consumers  
5 throughout the United States. This defect was present in all of the Prequel tests manufactured,  
6 distributed, and sold by Defendants. Therefore, Defendant breached their express and implied  
7 warranties to Plaintiff and Class members by manufacturing, distributing, and selling the  
8 defective Prequel tests. Plaintiff's claims are typical in that she was uniformly harmed in  
9 purchasing and using defective a Prequel Test. Plaintiff's claims are further typical in that  
10 Defendant deceived Plaintiff in the very same manner as they deceived each member of the  
11 Class. Further, there are no defenses available to Defendant that are unique to Plaintiff.

12 36. **Adequacy of Representation.** Plaintiff will fairly and adequately protect the  
13 interests of the Class. Plaintiff has retained counsel that is highly experienced in complex  
14 consumer class action litigation, and Plaintiff intends to vigorously prosecute this action on  
15 behalf of the Class. Furthermore, Plaintiff has no interests that are antagonistic to those of the  
16 Class.

17 37. **Superiority.** A class action is superior to all other available means for the fair  
18 and efficient adjudication of this controversy. The damages or other financial detriment suffered  
19 by individual Class members are relatively small compared to the burden and expense of  
20 individual litigation of their claims against Defendants. It would, thus, be virtually impossible  
21 for the Class, on an individual basis, to obtain effective redress for the wrongs committed against  
22 them. Furthermore, even if Class members could afford such individualized litigation, the court  
23 system could not. Individualized litigation would create the danger of inconsistent or  
24 contradictory judgments arising from the same set of facts. Individualized litigation would also  
25 increase the delay and expense to all parties and the court system from the issues raised by this  
26 action. By contrast, the class action device provides the benefits of adjudication of these issues  
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1 in a single proceeding, economies of scale, and comprehensive supervision by a single court, and  
2 presents no unusual management difficulties under the circumstances.

3 38. In the alternative, the Class may also be certified because:

- 4 (a) the prosecution of separate actions by individual Class members would  
5 create a risk of inconsistent or varying adjudications with respect to  
6 individual members that would establish incompatible standards of conduct  
7 for the Defendant;
- 8 (b) the prosecution of separate actions by individual Class members would  
9 create a risk of adjudications with respect to them that would, as a practical  
10 matter, be dispositive of the interests of other Class members not parties to  
11 the adjudications, or substantially impair or impede their ability to protect  
12 their interests; and/or
- 13 (c) Defendant has acted or refused to act on grounds generally applicable to the  
14 Class as a whole, thereby making appropriate final declaratory and/or  
15 injunctive relief with respect to the members of the Class as a whole.

## 12 CAUSES OF ACTION

### 13 COUNT I

#### 14 **Breach Of Express Warranty**

15 39. Plaintiff incorporates by reference the allegations contained in all preceding  
16 paragraphs of this complaint.

17 40. Plaintiff brings this claim individually and on behalf of the Class against  
18 Defendant.

19 41. In connection with the sale of the Tests, Defendant, as the designer, manufacturer,  
20 marketers, distributor, and/or seller issued written warranties by representing that the Tests  
21 “ha[ve] the lowest test failure rate in the industry, which translates to a lower chance of needing  
22 a repeat test or an unnecessary invasive diagnostic procedure.” Defendant further represents that  
23 its Tests are “more accurate than maternal serum screening” and tells women that the Tests will  
24 “reduc[e] the chances you’ll need an unnecessary invasive follow-up test.”

25 42. In fact, the Tests do not conform to the above-referenced representations because  
26 the tests are inaccurate approximately 85 percent of the time.

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1           43. Plaintiff and Class Members were injured as a direct and proximate result of  
 2 Defendant’s breaches because they would not have purchased the Tests if they had known that  
 3 the Tests did not work as warranted.

4           44. On January 20, 2022, prior to the filing of this action, Defendant was served with  
 5 a notice letter on behalf of Plaintiff and the Class that complied in all respects with U.C.C. §§ 2-  
 6 313 and 2-607. Plaintiff’s counsel sent Defendant a letter advising Defendant that it breached an  
 7 express warranty and demanded that Defendant cease and desist from such breaches and make  
 8 full restitution by refunding the monies received therefrom. A true and correct copy of this letter  
 9 is attached hereto as **Exhibit 1**.

10   **COUNT II**  
 11   **Breach Of Implied Warranty**

12           45. Plaintiff hereby incorporates by reference the allegations contained in all  
 13 preceding paragraphs of this complaint.

14           46. Plaintiff brings this claim individually and on behalf of the members of the  
 15 proposed Class against Defendant.

16           47. Defendant, as the designer, manufacturer, marketer, distributor, and/or seller,  
 17 impliedly warranted that the Tests were suited for use to detect chromosomal abnormalities with  
 18 a high degree of accuracy. Defendant breached the warranty implied in the contract for the sale  
 19 of the Tests because the Tests could not “pass without objection in the trade under the contract  
 20 description,” the Tests were not “of fair average quality within the description,” the Tests were  
 21 not “adequately contained, packaged, and labeled as the agreement may require,” and the Tests  
 22 did not “conform to the promise or affirmations of fact made on the container or label.” *See*  
 23 U.C.C. § 2-314(2) (listing requirements for merchantability). As a result, Plaintiff and Class  
 24 Members did not receive the goods as impliedly warranted by Defendant to be merchantable.

25           48. Plaintiff and the Class Members purchased the Tests in reliance upon Defendant’s  
 26 skill and judgment in properly packaging and labeling the Tests.

27           49. The Tests were not altered by Plaintiff and Class Members.  
 28

1           50.     The Tests were not fit for their intended purpose when they left the exclusive  
2 control of Defendant.

3           51.     Defendant knew that the Tests would be purchased and used without additional  
4 testing by Plaintiff and Class Members.

5           52.     The Tests were defectively designed and unfit for their intended purpose, and  
6 Plaintiff and Class Members did not receive the Tests as warranted.

7           53.     Plaintiff and Class Members and Subclass Members were injured as a direct and  
8 proximate result of Defendant’s breach because (i) they would not have purchased the Tests if  
9 they had known that the Tests were highly inaccurate, not dependable, and therefore unsuitable  
10 for their stated and advertised purpose of detecting chromosomal abnormalities with a high  
11 degree of accuracy, and (ii) they overpaid for the Tests on account of its misrepresentations that  
12 it was capable of detecting chromosomal abnormalities with a high degree of accuracy.

13          54.     On January 20, 2022, prior to the filing of this action, Defendant was served with  
14 a notice letter on behalf of Plaintiff and the Class that complied in all respects with U.C.C. §§ 2-  
15 313 and 2-607. Plaintiff’s counsel sent Defendant a letter advising Defendant that it breached an  
16 implied warranty and demanded that Defendant cease and desist from such breaches and make  
17 full restitution by refunding the monies received therefrom. A true and correct copy of this letter  
18 is attached hereto as **Exhibit 1**.

19                         **COUNT III**  
20                         **Unjust Enrichment**

21          55.     Plaintiff incorporates by reference the allegations contained in all preceding  
22 paragraphs of this complaint.

23          56.     Plaintiff brings this claim individually and on behalf of the members of the  
24 proposed Class against Defendant.

25          57.     Plaintiff and the Class conferred a benefit on Defendant in the form of monies  
26 paid to purchase Defendant’s defective Prequel tests.

27          58.     Defendant voluntarily accepted and retained this benefit.

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1 59. Because this benefit was obtained unlawfully, namely by selling and accepting  
2 compensation for medications unfit for the purpose in which they were sold, it would be unjust  
3 and inequitable for the Defendant to retain it without paying the value thereof.

4 **COUNT IV**  
5 **Fraud**

6 60. Plaintiff hereby incorporates by reference the allegations contained in all  
7 preceding paragraphs of this complaint.

8 61. Plaintiff brings this claim individually and on behalf of the members of the  
9 proposed Class against Defendant.

10 62. As discussed above, Defendant provided Plaintiff and Class members with  
11 materially false or misleading information about the Prequel tests manufactured, distributed, and  
12 sold by Defendant. Specifically, Defendant had knowledge of the fact that Prequel tests were  
13 highly inaccurate, often causing false positive results. Defendant nevertheless actively  
14 represented to consumers that the Prequel tests were fit for their intended purpose.

15 63. The misrepresentations and omissions of material fact made by Defendant, upon  
16 which Plaintiff and Class members reasonably and justifiably relied, were intended to induce and  
17 actually induced Plaintiff and Class members to purchase defective Prequel tests.

18 64. The fraudulent actions of Defendant caused damage to Plaintiff and Class  
19 members, who are entitled to damages and other legal and equitable relief as a result.

20 65. As a result of Defendant's willful and malicious conduct, punitive damages are  
21 warranted.

22 **COUNT V**  
23 **Fraudulent Omission**

24 66. Plaintiff incorporates by reference the allegations contained in all preceding  
25 paragraphs of this complaint.

26 67. Plaintiff brings this claim individually and on behalf of the members of the  
27 proposed Class against Defendant.  
28

1 68. As discussed above, Defendant failed to disclose that the Tests would frequently  
2 provide false positive results.

3 69. The false and misleading omissions were made with knowledge or their  
4 falsehood. Defendant is a national genetics laboratory that specializes in genetic testing and  
5 therefore knew the Tests would provide an unnecessarily high number of false positive results.  
6 Nonetheless, Defendant continued to sell its worthless Tests to unsuspecting consumers.

7 70. The false and misleading omissions were made by Defendant, upon which  
8 Plaintiff and members of the proposed Class reasonably and justifiably relied, and were intended  
9 to induce and actually induced Plaintiff and Class Members to purchase the tests.

10 71. The fraudulent actions of Defendant caused damage to Plaintiff and Class  
11 Members, who are entitled to damages and punitive damages.

12 **COUNT VI**  
13 **Violation of California’s Unfair Competition Law**  
**California Business and Professions Code § 17200 *et seq.***

14 72. Plaintiff hereby incorporates by reference the allegations contained in all  
15 preceding paragraphs of this complaint.

16 73. Plaintiff brings this claim individually and on behalf of the members of the  
17 California Subclass against Defendant.

18 74. By committing the acts and practices alleged herein, Defendant has violated  
19 California’s Unfair Competition Law (“UCL”), Cal. Bus. & Prof. Code §§ 17200, *et seq.*, as to  
20 the California Subclass, by engaging in unlawful, fraudulent, and unfair conduct.

21 75. Defendant has violated the UCL’s proscription against engaging in unlawful  
22 conduct as a result of its violations of the CLRA, FAL, and by committing fraud, unjust  
23 enrichment, and breaching express and implied warranties, as alleged herein.

24 76. Defendant’s acts and practices described above also violate the UCL’s  
25 proscription against engaging in fraudulent conduct. As more fully described above,  
26 Defendant’s misleading marketing, advertising, packaging, and labeling of the Tests is likely to  
27 deceive reasonable consumers.  
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1           77. Plaintiff and the other California Subclass members suffered a substantial injury  
2 by virtue of buying the Tests that they would not have purchased absent Defendant's unlawful,  
3 fraudulent, and unfair marketing, advertising, packaging, and omission about the accuracy of the  
4 Tests, or by virtue of paying an excessive premium price for the unlawfully, fraudulently, and  
5 unfairly marketed, advertised, packaged, and labeled Tests.

6           78. There is no benefit to consumers or competition from deceptively marketing and  
7 omitting material facts about the highly inaccurate nature of the Tests.

8           79. Plaintiff and the other California Subclass members had no way of reasonably  
9 knowing that the Tests they purchased were not as marketed, advertised, packaged, or labeled.  
10 Thus, they could not have reasonably avoided the injury each of them suffered.

11           80. The gravity of the consequences of Defendant's conduct as described above  
12 outweighs any justification, motive, or reason therefore, particularly considering the available  
13 legal alternatives which exist in the marketplace, and such conduct is immoral, unethical,  
14 unscrupulous, offends established public policy, or is substantially injurious to Plaintiff and the  
15 other members of the California Subclass.

16           81. Plaintiff, on behalf of herself and the California Subclass, seeks injunctive relief  
17 to require Defendant to: (1) provide notice to every class member that the NIPT test they  
18 purchased is not suited for its intended purpose; and (2) either provide a refund to Plaintiff and  
19 the California Subclass for their NIPT test in an amount to be determined at trial.

20           82. Defendant's conduct has caused substantial injury to Plaintiff, California Subclass  
21 Members, and the public. Defendant's conduct is ongoing and will continue absent a permanent  
22 injunction. Accordingly, Plaintiff seeks an order enjoining Defendant from committing such  
23 unlawful, unfair, and fraudulent business practices. Plaintiff further seeks an order granting  
24 restitution to Plaintiff and the California Subclass members in an amount to be proven at trial.  
25 Plaintiff further seeks an award of attorneys' fees and costs under Cal. Code Civ. Proc. § 1021.5.

26           83. Plaintiff and the general public lack an adequate remedy at law to remedy and/or  
27 mitigate the totality of the injuries and misconduct described herein.  
28

1 84. Absent injunctive relief, Defendant will continue to injure Plaintiff and the  
2 California Subclass members. Defendant’s conduct and omissions of material fact are ongoing.  
3 And, even if such conduct were to cease, it is behavior that is capable of repetition or  
4 reoccurrence by Defendant yet evades review.

5 85. In order to prevent injury to the general public, Plaintiff, in her individual  
6 capacity, seeks a public injunction requiring Defendant to stop advertising, and to instruct its  
7 resellers to stop advertising, any NIPT test, other than tests for Down Syndrome or Edwards  
8 Syndrome, as being highly accurate.

9  
10 **COUNT VII**  
**Violation of California’s False Advertising Law**  
**California Business and Professions Code § 17500, *et seq.***

11 86. Plaintiff incorporates by reference the allegations contained in all preceding  
12 paragraphs of this complaint.

13 87. Plaintiff brings this claim individually and on behalf of the members of the  
14 California Subclass against Defendant.

15 88. Defendant has engaged in false or misleading advertising in violation of  
16 California’s statutory False Advertising Law (“FAL”).

17 89. Defendant’s conduct as described herein is misleading, and/or has a capacity,  
18 likelihood or tendency to deceive reasonable consumers.

19 90. Defendant, with intent directly or indirectly to dispose of personal property or to  
20 perform services, or to induce the public to enter into any obligation relating thereto, makes,  
21 disseminates, has made or disseminated, causes to be made or disseminated, and/or has caused to  
22 be made or disseminated, before the public in California, in newspaper or other publication, or  
23 other advertising device, or by public outcry or by proclamation, or in any other manner or  
24 means, including over the internet, statements concerning that personal property or those  
25 services, and/or concerning any circumstance or matter of fact connected with the proposed  
26 performance or disposition thereof, which are untrue or misleading and which are known (or  
27 which by the exercise of reasonable care should be known) to be untrue or misleading.  
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1           91. Defendant made, disseminated, makes, disseminates, caused to be made or  
2 disseminated and/or causes to be made or disseminated any statements concerning the  
3 disposition of personal property or the performance of services, and/or concerning any  
4 circumstance or matter of fact connected with such statement as part of a plan or scheme with the  
5 intent not to sell that personal property or those services, professional or otherwise, as advertised.

6           92. With respect to omissions, Defendant at all relevant times had a duty to disclose  
7 the information in question because, *inter alia*: (a) Defendant had exclusive knowledge of  
8 material information that was not known to Plaintiff and the California Subclass; (b) Defendant  
9 concealed material information from Plaintiff and the California Subclass; and/or (c) Defendant  
10 made partial representations which were false and misleading absent the omitted information.

11           93. Defendant committed such violations of the FAL with actual knowledge that its  
12 advertising was misleading, or Defendant, in the exercise of reasonable care, should have known  
13 that its advertising was misleading.

14           94. Plaintiff and the California Subclass reasonably relied on Defendant's  
15 representations and/or omissions made in violation of the FAL.

16           95. As a direct and proximate result of Defendant's unfair, unlawful, and fraudulent  
17 conduct, Plaintiff and each member of the California Subclass suffered injury-in-fact and lost  
18 money.

19           96. But for Defendant's deceptive conduct and omissions of material facts, Plaintiff  
20 and the California Subclass would not have purchased the subject NIPT tests and/or would have  
21 purchased an appropriate NIPT test from one of Defendant's competitors instead.

22           97. Defendant should be ordered to disgorge or make restitution of all monies  
23 improperly accepted, received, or retained.

24           98. Defendant's conduct has caused substantial injury to Plaintiff, members of the  
25 California Subclass, and the public. Defendant's conduct is ongoing and will continue and recur  
26 absent a permanent injunction. Accordingly, Plaintiff seeks an order enjoining Defendant from  
27 committing such violations of the FAL. Plaintiff further seeks an order granting restitution to  
28

1 Plaintiff and the California Subclass in an amount to be proven at trial. Plaintiff further seeks an  
2 award of attorneys' fees and costs under Cal. Code Civ. Proc. § 1021.5.

3 99. Plaintiff, on behalf of herself and the California Subclass, seeks injunctive relief  
4 to require Defendant to: (1) provide notice to every class member that the NIPT test they  
5 purchased is not suited for its intended purpose; and (2) either provide a refund to Plaintiff and  
6 the California Subclass for their NIPT test in an amount to be determined at trial.

7 100. Absent injunctive relief, Defendant will continue to injure Plaintiff and the  
8 California Subclass members. Even if such conduct were to cease, it is behavior that is capable  
9 of repetition or reoccurrence by Defendant yet evades review.

10 101. In order to prevent injury to the general public, Plaintiff, in her individual  
11 capacity, seeks a public injunction requiring Defendant to stop advertising, and to instruct its  
12 resellers to stop advertising, any NIPT test, other than tests for Down Syndrome or Edwards  
13 Syndrome, as being highly accurate.

14 102. Plaintiff and the general public lack an adequate remedy at law to remedy and/or  
15 mitigate the totality of the injuries and misconduct described herein.

16 **COUNT VIII**  
17 **Violation of California's Consumers Legal Remedies Act**  
18 **California Civil Code § 1750 *et seq.***  
19 **(Injunctive Relief Only)**

20 103. Plaintiff incorporates by reference the allegations contained in all preceding  
21 paragraphs of this complaint.

22 104. Plaintiff brings this claim individually and on behalf of the members of the  
23 California Subclass against Defendant.

24 105. Defendant is a "person," as defined by California Civil Code § 1761(c).

25 106. Plaintiff and members of the California Subclass are "consumers," as defined by  
26 California Civil Code § 1761(d).

27 107. The NIPT tests purchased by the Plaintiff and the members of the California  
28 Subclass are "goods" as defined by California Civil Code § 1761(a).

1           108. The purchases by the Plaintiff and the members of the California Subclass  
2 constitute “transactions,” as defined by California Civil Code § 1761(e).

3           109. The unlawful methods, acts or practices alleged herein to have been undertaken  
4 by Defendant were all committed intentionally and knowingly. The unlawful methods, acts or  
5 practices alleged herein to have been undertaken by Defendant did not result from a *bona fide*  
6 error notwithstanding the use of reasonable procedures adopted to avoid such error.

7           110. With regard to this count of the pleading which alleges one or more violations of  
8 the CLRA, venue is proper in the state or federal court having jurisdiction over Santa Clara  
9 County, California (the county in which this action has been commenced) pursuant to Section  
10 1780(d) of the California Civil Code because, without limitation, Santa Clara County is a county  
11 in which Defendant is doing business and is the county in which a substantial portion of the  
12 events that gave rise to this cause of action occurred. A declaration establishing that this Court  
13 has proper venue for this count is attached hereto as **Exhibit 2**.

14           111. Defendant’s methods, acts and/or practices, including Defendant’s  
15 misrepresentations, omissions, active concealment, and/or failures to disclose, violated and  
16 continue to violate the CLRA in ways including, but not limited to, the following:

- 17           (a) Defendant misrepresented that its products had characteristics, benefits, or  
18 uses that they did not have (Cal. Civ. Code § 1770(a)(5));
- 19           (b) Defendant misrepresented that its products were of a particular standard,  
20 quality, grade, or of a particular style or model when the products were of  
21 another (Cal. Civ. Code § 1770(a)(7));
- 22           (c) Defendant advertised its products with an intent not to sell them as  
23 advertised (Cal. Civ. Code § 1770(a)(9)); and
- 24           (d) Defendant represented that its products were supplied in accordance with  
25 previous representations when they were not (Cal. Civ. Code  
26 § 1770(a)(16)).

27           112. Specifically, Defendant advertised and represented that these NIPT tests were  
28 suitable for the particular purpose when in fact the NIPT tests other than tests for Down  
Syndrome or Edwards Syndrome, were not as highly accurate as stated.

          113. With respect to omissions, Defendant at all relevant times had a duty to disclose

1 the information in question because, *inter alia*: (a) Defendant had exclusive knowledge of  
2 material information that was not known to Plaintiff and the California Subclass; (b) Defendant  
3 concealed material information from Plaintiff and the California Subclass; and/or (c) Defendant  
4 made partial representations which were false and misleading absent the omitted information.

5 114. Defendant's misrepresentations and nondisclosures deceive and have a tendency  
6 and ability to deceive the general public.

7 115. Defendant's misrepresentations and nondisclosures are material, in that a  
8 reasonable person would attach importance to the information and would be induced to act on  
9 the information in making purchase decisions. Indeed, the utility and value of Defendant's NIPT  
10 tests are significantly reduced, to the point of worthlessness, because these tests should not and  
11 cannot be used for their intended and advertised purpose.

12 116. As a direct and proximate result of Defendant's unfair, unlawful, and fraudulent  
13 conduct, Plaintiff and the California Subclass suffered injury-in-fact and lost money.

14 117. But for Defendant's deceptive conduct and omissions of material facts, Plaintiff  
15 and the California Subclass would not have purchased the subject NIPT tests and/or would have  
16 purchased an appropriate NIPT test from one of Defendant's competitors instead. Defendant's  
17 conduct as alleged herein caused substantial injury to Plaintiff, California Subclass Members,  
18 and the public. Defendant's conduct is ongoing and will continue and recur absent a permanent  
19 injunction. Accordingly, Plaintiff and the California Subclass seek an order enjoining Defendant  
20 from committing such practices.

21 118. If not enjoined by order of this Court, Defendant is free to resume its unlawful  
22 behavior and injure Plaintiff and consumers through the misconduct alleged herein once more.  
23 Defendant has a duty to speak truthfully or in a non-misleading manner.

24 119. Plaintiff will be harmed if, in the future, they are left to guess as to whether  
25 Defendant's representations are accurate and whether there are omissions of material facts  
26 regarding the features or specifications of the NIPT tests.

27 120. In order to prevent injury to the general public, Plaintiff, in their individual  
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1 capacities, seek a public injunction requiring Defendant to stop advertising, and to instruct its  
2 resellers to stop advertising, any NIPT test, other than tests for Down Syndrome or Edwards  
3 Syndrome, as being highly accurate.

4 121. The balance of the equities favors the entry of permanent injunctive relief against  
5 Defendant. Plaintiff and the general public will be irreparably harmed absent the entry of  
6 permanent injunctive relief against Defendant. Plaintiff and the general public lack an adequate  
7 remedy at law. A permanent injunction against Defendant is in the public interest. Defendant's  
8 unlawful behavior is capable of repetition or re-occurrence absent the entry of a permanent  
9 injunction.

10 **PRAYER FOR RELIEF**

11 WHEREFORE, Plaintiff, individually and on behalf of all others similarly situated, seeks  
12 judgment against Defendants, as follows:

- 13 (a) For an order certifying the nationwide Class under Rule 23 of the Federal Rules of  
14 Civil Procedure, naming Plaintiff as representative of the Class, and naming  
Plaintiff's attorneys as Class Counsel to represent the Class;
- 15 (b) For an order declaring the Defendants' conduct violates the statutes referenced  
16 herein;
- 17 (c) For an order finding in favor of Plaintiff and the Class on all counts asserted  
18 herein;
- 19 (d) For compensatory, statutory, and punitive damages in amounts to be determined  
20 by the Court and/or jury;
- 21 (e) For prejudgment interest on all amounts awarded;
- 22 (f) For an order of restitution and all other forms of equitable monetary relief;
- 23 (g) For injunctive relief as pleaded or as the Court may deem proper; and
- 24 (h) For an order awarding Plaintiff and the Class their reasonable attorneys' fees and  
25 expenses and costs of suit.

26 **DEMAND FOR TRIAL BY JURY**

27 Pursuant to Federal Rule of Civil Procedure 38(b), Plaintiff demands a trial by jury of any  
28 and all issues in this action so triable of right.

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Dated: February 3, 2022

Respectfully submitted,

**BURSOR & FISHER, P.A.**

By:           /s/ L. Timothy Fisher            
          L. Timothy Fisher

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January 20, 2022

**Via Fed Ex and Certified Mail - Return Receipt Requested**

Myriad Genetics, Inc.  
320 Wakara Way  
Salt Lake City, UT 84108

CT Corporation System  
1108 E South Union Ave  
Midvale, UT 84047

Re: *Demand Letter Pursuant to California Civil Code § 1782;  
U.C.C. §§ 2-313, 2-314; and all other applicable laws*

To Whom It May Concern:

This letter serves as a preliminary notice and demand for corrective action by Myriad Genetics, Inc. (“You” or “Defendant”) pursuant to numerous provisions of California law, including but not limited to subsections (a)(5), (7), and (9) of the Consumers Legal Remedies Act, Civil Code § 1770 and U.C.C. § 2-607(3)(A) concerning the breaches of warranty described herein on behalf of our client, Ashley Carroll, and all other similarly situated purchasers.

You have participated in the marketing and sale of the Prequel Prenatal Screen (the “Product”). Defendant markets and sells the Tests as genetic, prenatal screening tests for pregnant women that screen for various chromosomal and genetic conditions affecting a baby’s health. Defendant markets these tests as safe and accurate. However, these tests are incorrect about 85 percent of the time, subjecting expecting mothers to further diagnostic testing, genetic counseling, and the potential for erroneous termination of a viable pregnancy. Thus, the Product is unsuitable for its intended and advertised purpose, and Your representations are false and misleading.

Ms. Carroll purchased the Product based on the Product’s representations.

Ms. Carroll is acting on behalf of a class defined as all persons in the United States who purchased the Product. Ms. Carroll is also acting on behalf of a subclass of persons who purchased the Product in the State of California.

To cure these defects, we demand that you make full restitution to all purchasers of the Product of all money obtained from sales thereof.


We further demand that you preserve all documents and other evidence which refer or relate to any of the above-described practices including, but not limited to, the following:

1. All documents concerning the design, development, and/or testing of the Product;
2. All documents concerning the advertisement, labeling, marketing, or sale of the Product;
3. All documents concerning communications with purchasers of the Product, including but not limited to customer complaints; and
4. All documents concerning your total revenue derived from sales of the Product in California and the United States.
5. All communications with the FDA and other regulatory agencies about the Product.

If you contend that any statement in this letter is inaccurate in any respect, please provide us with your contentions and supporting documents immediately upon receipt of this letter.

Please contact me right away if you wish to discuss an appropriate way to remedy this matter. If I do not hear from you promptly, I will take that as an indication that you are not interested in doing so.

Very truly yours,



Joshua D. Arisohn



**CLRA Venue Declaration Pursuant to California Civil Code Section 1780(d)**

I, L. Timothy Fisher, declare as follows:

1. I am counsel for Plaintiff, and I am a partner at Bursor & Fisher, P.A.. I make this declaration to the best of my knowledge, information, and belief of the facts stated herein.

2. The complaint filed in this action is filed in the proper place for trial under California Civil Code Section 1780(d) because a substantial part of the events or omissions giving rise to these claims occurred in this District.

3. Plaintiff Ashley Carroll alleges that in or about July 2021, she purchased Defendant Myriad Genetics, Inc.'s ("Defendant") Prequel Test in California. *See* Compl. ¶ 8. Plaintiff further alleges that she purchased the Prequel Test because Defendant described the Prequel Test as accurate. Specifically, Defendant represented that the Prequel Test "has the lowest test failure rate in the industry, which translates to a lower chance of needing a repeat test or an unnecessary invasive diagnostic procedure." Defendant further represented that its Prequel Tests are "more accurate than maternal serum screening" and tells women that the Prequel Tests will "reduc[e] the chances you'll need an unnecessary invasive follow-up test." Plaintiff relied on Defendant's representations and warranties in deciding to purchase the Prequel Test. Accordingly, Defendant's representations and warranties were part of the basis of the bargain, in that she would not have purchased the Prequel Test on the same terms had she known the Test's representations about accuracy and trustworthiness were not true, or at least would have paid significantly less for the Prequel Test.

I declare under the penalty of perjury under the laws of the United States and the State of California that the foregoing is true and correct. Executed on February 3, 2022 in Walnut Creek, California.

/s/ L. Timothy Fisher  
L. Timothy Fisher