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UNITED STATES DISTRICT COURT
SOUTHERN DISTRICT OF CALIFORNIA

DEJANNE JOHNSON, EVE EPSTEIN-ORTIZ, and SANDRA GAMLIN, individually and on behalf of others similarly situated,

Plaintiffs,

vs.

LUMINARY GENETICS f/k/a NEXTGEN GENETICS, LLC, and LUMINARY LIFE SCIENCES, and DOES 1 through 50, inclusive,

Defendants.

CASE NO.: '25CV1629 WQHBLM

CLASS ACTION COMPLAINT FOR:

1. **VIOLATIONS OF FLORIDA DECEPTIVE AND UNFAIR TRADE PRACTICES ACT, FLA. STAT. § 501.201, *ET SEQ*.**
2. **VIOLATIONS OF CALIFORNIA UNFAIR COMPETITION LAW,**

3. **CAL. BUS. & PROF. CODE §§ 17200, *ET SEQ.* (UNFAIR AND FRAUDULENT PRONGS)**
4. **VIOLATIONS OF CALIFORNIA UNFAIR COMPETITION LAW,**
5. **CAL. BUS. & PROF. CODE §§ 17200, *ET SEQ.* (UNLAWFUL PRONG)**
6. **VIOLATIONS OF CALIFORNIA CONSUMER LEGAL REMEDIES ACT, CAL. CIV. CODE § 1750, *ET SEQ.***
7. **VIOLATIONS OF VIRGINIA CONSUMER PROTECTION ACT (VCPA), VA. CODE. ANN. § 59.1-196, *ET SEQ.***
8. **BREACH OF IMPLIED WARRANTY OF MERCHANTABILITY**
9. **BREACH OF IMPLIED WARRANTY OF USABILITY**
10. **FRAUD**
11. **FRAUD BY CONCEALMENT**
12. **BREACH OF EXPRESS WARRANTY**
13. **UNJUST ENRICHMENT**

DEMAND FOR JURY TRIAL

Plaintiffs, DeJanne Johnson, Eve Epstein-Ortiz, and Sandra Gamlin, individually and on behalf of all others similarly situated, through their undersigned attorneys, allege as follows based upon personal knowledge as to the individual allegations pertaining to each of them, and the investigation of their counsel, against Defendants, Luminary Genetics LLC, formerly known as NextGen Genetics LLC, and Luminary Life Sciences ("Defendants").

NATURE OF THE ACTION

1. Plaintiffs bring this class action lawsuit to recover economic losses suffered by Plaintiffs and Class members (defined below) as a result of the false, deceptive, unfair, and misleading advertising marketing, and promotion of Defendants' preimplantation genetic testing for aneuploidy ("PGT-A" or "PGT-A testing"). Plaintiffs and Class members each spent thousands of dollars for PGT-A based on Defendants' material misrepresentations and omissions.

2. Plaintiffs file this lawsuit to remedy Defendants' unfair and deceptive business practices arising from Defendants' marketing and sale of PGT-A testing as a proven, accurate, and reliable method to decrease the chance of miscarriage and increase the chance of giving birth to a healthy baby when science does not support this. Defendants' misleading statements and omissions as described in detail below are false and misleading to any reasonable consumer because PGT-A is unproven, inaccurate, and unreliable.

INTRODUCTION

3. According to the World Health Organization in April 2023, one in six people worldwide experience infertility. One-third of the people in the United States have sought or know someone who has sought fertility treatments or assisted reproductive technology ("ART") to assist them in becoming pregnant.

4. According to the United States Centers for Disease Control ("CDC"), as of 2021, approximately 2.3% of all infants born in the United States every year are conceived using ART, and that percentage is growing.

5. According to The American Society of Reproductive Medicine ("ASRM") in 2022, the number of babies in America born from *in vitro* fertilization ("IVF") increased from 89,208 in 2021 to 91,771 in 2022, indicating that 2.5% of all births in the United States are a result of successful ART cycles. The total number of IVF cycles performed increased by over 6% from 2021, going from 368,502 in

2021 to 389,993 in 2022.

6. The demand for IVF is growing, thus providing economic opportunities for investors wishing to take advantage of this increasing market.

7. There are now approximately 450 fertility clinics in the United States performing IVF and a huge majority of these procedures are not covered by insurance, as many states do not mandate insurance for IVF.

8. The IVF process begins with medication taken by women to stimulate the follicles to create several mature eggs for collection. Once the eggs are retrieved from the ovaries, they are then fertilized by the fertility clinic with sperm to create embryos. If the embryos reach the blastocyst stage, they are then ready for implantation to see if they will result in a pregnancy.

9. PGT-A testing is marketed and sold by Defendants as an add-on to the IVF process and purports to screen embryos for chromosomal abnormalities. With respect to PGT-A conducted by Defendants, IVF clinics perform a biopsy and send a small number of cells from the embryo to Defendants who perform the PGT-A testing and provide results to the customer and their clinic. The results purport to determine which embryos are "euploid" or best suited for implantation and which embryos are "aneuploid" or abnormal and not suited for implantation.

10. PGT-A testing is marketed by Defendants to people pursuing IVF as increasing the chance of a healthy and successful pregnancy, increasing implantation rates, increasing live birth rates, benefiting every couple especially those of advanced maternal age, reducing the number of abnormal embryos for cryopreservation, decreasing the rate of miscarriage, and being superior to all others' testing. Defendants also market their PGT-A testing as being 98% accurate. Based on these material representations and the material omissions that underlay them as detailed below, Plaintiffs and Class members purchased PGT-A testing from Defendants.

11. The above representations by Defendants are false and misleading and deceptive based upon the omission of material information. Studies show that when looking at clinic pregnancy, miscarriage, or live-birth rates, there is no difference between cycles utilizing PGT-A and cycles not utilizing PGT-A. Studies also show the accuracy rating for PGT-A is significantly lower than 98% accurate.

12. Defendants' false and misleading statements have severe consequences, including causing ascertainable economic losses in the thousands of dollars suffered by Plaintiffs and Class members.

13. Insurance companies have independently determined that there is insufficient basis to support the use of PGT-A. Thus, PGT-A testing is rarely covered by insurance and is primarily sold to consumers as an additional out-of-pocket expense in addition to the expensive cost of IVF.

14. For example, the largest health insurance company in America, United Healthcare, has noted that PGT-A is unproven and not medically necessary due to "insufficient evidence of efficacy." United Healthcare further states with respect to PGT-A that "[t]here is insufficient evidence to support the use of PGT for aneuploidy screening at this time."[1]

15. Likewise, another large health insurance company, Aetna, states that PGT-A testing is "experimental, investigational, or unproven."[2]

16. As detailed below, these conclusions by United Healthcare, Aetna, and other insurance companies are in line with conclusions reached by major professional health organizations in the area of women's health.

17. Embryos that are assigned an "abnormal" or "aneuploid" testing result

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[1] United Healthcare Commercial and Individual Exchange Medical Policy, Preimplantation Genetic Testing and Related Services, effective date May 1, 2025.

[2] *See* https://www.aetna.com/cpb/medical/data/300_399/0358.html (last visited May 15, 2025).

(*i.e.*, embryos that are designated as having an abnormal number of chromosomes) by Defendants are typically not transferred and are often discarded due to customers being told that "abnormal" embryos as determined by Defendants' PGT-A testing are unsuitable for transfer.

18. Despite scientific research and studies showing insufficient evidence of efficacy, the use of PGT-A testing has spiked in recent years due to Defendants' marketing and advertising. For example, from 2014 to 2021, the use of PGT-A testing increased from being utilized in 13% of IVF cycles to approximately 40% of IVF cycles.

19. The PGT-A testing industry now generates an estimated revenue of between $300 million to $400 million dollars per year.

20. Defendants have known for years that there is insufficient evidence of efficacy of PGT-A testing, and that PGT-A testing does not improve pregnancy rates, reduce the rate of miscarriage, increase the success of in vitro fertilization, decrease the time and cost of IVF, and increase the chances of a healthy baby. Despite that, they have continued to aggressively promote PGT-A testing to vulnerable and unsuspecting consumers.

21. Defendants have known for years that their PGT-A testing is not 98% accurate.

22. Defendants have acted to mislead patients with their false and deceptive marketing and advertising statements, and material omissions, in exchange for the opportunity to reap millions of dollars in profit each year from selling PGT-A testing as an add-on to IVF treatment.

23. Plaintiffs and Class members who have purchased PGT-A testing have relied on Defendants' false and deceptive marketing and advertising statements, and material omissions, in purchasing PGT-A testing, and have suffered economic losses as a direct result.

24. Plaintiffs and Class members have relied on Defendants' false and deceptive statements that their PGT-A testing improves pregnancy rates, increases implantation rates, increases delivery rates, increases the chance of a healthy baby, benefits every couple, especially individuals of advanced maternal age, increases the success of IVF, provides more viable embryos, decreases the time and cost of IVF, decreases the rate of miscarriage, and is superior to all others' testing.

25. Plaintiffs and Class members would not have purchased PGT-A testing from Defendants had they known the truth as detailed below, and seek all available damages, equitable relief, and other remedies from Defendants as alleged herein.

PARTIES

26. Plaintiff Eve Epstein-Ortiz is a resident of Saint Petersburg, Florida and received fertility treatment in Tampa, Florida.

27. Plaintiff DeJanne Johnson is a resident of San Diego, California and received fertility treatment in San Diego, California.

28. Plaintiff Sandra Gamlin is a resident of Norfolk, Virginia and received fertility treatment in Richmond, Virginia.

29. NextGen Genetics LLC was headquartered at 2338 Walsh Ave., Ste. B, Santa Clara, California 95051. In October of 2023, NextGen Genetics became Luminary Genetics and joined the Luminary Life Sciences family.[3]

30. Defendant Luminary Genetics LLC (hereinafter "Luminary") is headquartered at 2338 Walsh Ave., Ste. B, Santa Clara, California 95051.

31. Luminary is a wholly owned subsidiary of Luminary Life Sciences.

32. Defendant Luminary Life Sciences (hereinafter "Luminary LS") is also

[3] https://www.prnewswire.com/news-releases/NextGen-genetics-joins-the-luminary-life-sciences-family-to-launch-luminary-genetics-301954163.html (last visited May 15, 2025).

headquartered at 2338 Walsh Ave., Ste. B, Santa Clara, California 95051.

33. Since being acquired by Luminary LS, NextGen Genetics has served no separate existence or function outside of the corporate interests of Luminary, as evidenced by the companies' respective sharing of facilities, tools, employees, and offices. This sharing of services, assets, and personnel have resulted in an excessive comingling that far exceeds any norms that characterize an affiliated but separate company relationship. Since the 2023 acquisition, Luminary has dominated and controlled NextGen Genetics in all respects, including marketing of its PGT-A testing and decision-making.

34. Prior to October of 2023, NextGen Genetics promoted itself as a leading provider of genetic testing services, including PGT-A, for the reproductive health industry.

35. Luminary LS promotes itself as "an expanding suite of life science services that [includes] precision fertility and prenatal vitamins, donor gamete and surrogacy services, medical devices, and cryogenic storage solutions. The Luminary portfolio [brings] the next generation of scientific advancements that elevate patient care by delivering superior ancillary support at all stages of the reproductive health journey."[4]

36. With the acquisition of NextGen Genetics, Luminary LS renamed the entity Luminary Genetics and maintained the corporate leadership that was in place at NextGen Genetics, including CEO Cengiz Cinnioglu, Ph.D. who was NextGen Genetics founder and General Manager, Amy Jordan who was NextGen Genetics Director of Reproductive Genetics and Mae Hoover, Director of Operations at

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[4] https://www.luminarylifesciences.com/news/NextGen-genetics-joins-the-luminary-life-sciences-family-to-launch-luminary-genetics (last visited May 15, 2025).

NextGen Genetics.

37. All three leaders at NextGen Genetics now hold same or similar positions at Luminary.

38. Luminary LS promotes its portfolio that includes Luminary Genetics, as "setting new standards in reproductive health services by offering a wide range of specialized solutions, including precision fertility and prenatal vitamins, donor gamete and surrogacy services, medical devices, and genetic testing services."[5]

39. Luminary LS and Luminary do not maintain separateness when it comes to PGT-A testing and the marketing, promotion, and sale of testing.

40. NextGen Genetics is now Luminary.

41. Defendants collectively market, promote, advertise and sell PGT-A testing in California and throughout the United States.

JURISDICTION AND VENUE

42. This Court has subject matter jurisdiction over this action pursuant to the Class Action Fairness Act, 28 U.S.C. Section 1332(d)(2)(A) because: (i) there are 100 or more class members; (ii) there is an aggregate amount in controversy exceeding $5,000,000, exclusive of interest and costs; and (iii) Plaintiffs and Defendants are citizens of different states.

43. This Court has supplemental jurisdiction over any state law claims pursuant to 28 U.S.C. Section 1367.

44. The injuries, damages and/or harm upon which this action is based occurred or arose out of activities engaged in by Defendants within, affecting, and emanating from, the state of California. Defendants regularly conduct and/or solicit business in, engage in other persistent courses of conduct in, and/or derive substantial revenue from services provided to persons in the state of California and

[5] https://www.luminarylifesciences.com/services (last visited February 15, 2025).

across the country. Defendants have engaged, and continue to engage, in substantial and continuous business practices in the state of California and across the country.

45. Venue is proper in this District pursuant to ; because a substantial part of the events or omissions giving rise to the claims occurred in the state of California including within this District. Defendants are also headquartered in this District of California.

SUBSTANTIVE ALLEGATIONS

A. Background Concerning IVF

46. IVF is a process of fertilization where an egg is combined with sperm in vitro ("in glass").

47. To prepare for egg retrieval, certain drugs and hormone therapies are taken orally and by injection over several weeks to stabilize the uterine lining, stimulate the ovaries into producing follicles, and stop the ovary follicles from releasing eggs. The injections often result in bruising, swelling, and discomfort. The drugs and hormones often also trigger side effects including fatigue, nausea, headaches, allergic reactions, and blood clots, as well as negative emotions and mood swings.

48. After eggs are determined to be ready for retrieval, an ovulation trigger injection is performed. The patient then proceeds to an operating room for egg retrieval, where they are sedated or placed under general anesthesia and undergoes insertion of a needle through the vaginal wall and into each follicle in the ovary to drain the follicles of their fluid. The fluid in the follicle is then extracted into a test tube and studied under a microscope to look for eggs.

49. Residual pain from the egg retrieval procedure can last for several days. Some patients suffer significant side effects such as ovarian hyperstimulation syndrome that causes the ovaries to painfully swell and can lead to hospitalization.

50. The extracted eggs are then fertilized with sperm in a laboratory to

create embryos.

51. If PGT-A testing is not performed on the embryos, after the fertilized egg (zygote) undergoes embryo culture for 2-6 days, it may then be transferred by catheter into the uterus with the intention of establishing a successful pregnancy.

52. If PGT-A testing is performed, a biopsy is taken from the trophectoderm component of the embryo (meaning the outer layer of the blastocyst) after the embryo reaches the blastocyst stage of development.

53. During the biopsy, the embryologist creates a hole in the embryo's zona pellucida which allows for the removal of five to ten cells from the trophectoderm component of the embryo.

54. For those who purchase PGT-A testing from Defendants, the removed cells are then sent to Defendants' laboratory in California for PGT-A testing.

55. All United States genetic testing purchased by Defendants is completed in their California laboratory.

56. Meanwhile, the embryos are frozen and stored with the IVF clinic while PGT-A testing is performed.

57. Embryos are fragile and vulnerable to damage from biopsy and the freezing and thawing process necessary for PGT-A testing to be performed.[6]

58. For this reason, experts caution that performing additional biopsies for PGT-A testing, which requires thawing and refreezing the embryo, can cause additional damage to the embryo and negatively affect IVF outcomes.[7] It can also

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[6] Aluko, A., et al., *Multiple cryopreservation – warming cycles, coupled with blastocyst biopsy, negatively affect IVF outcomes.* Reproductive Biomedicine Online. Vol. 42, Issue 3. March 2021.

[7] *Id.*

result in a reduced chance of pregnancy.[8]

59. As a result, if Plaintiffs and other Class Members were aware of the true ineffectiveness and inaccuracy rates of PGT-A testing, they would forego such testing.

60. Defendants are aware of the lengths to which individuals undergoing IVF go to create embryos, their emotional and financial investment in assuring the viability of their embryos, and their expectations that any genetic testing should not be sold in a misleading and deceptive manner.

61. In some cases, additional procedures with additional costs may be purchased by those undergoing IVF, including (a) intracytoplasmic sperm injection ("ICSI") to increase the chance for fertilization; (b) assisted hatching of embryos to potentially increase the chance of embryo attachment ("implantation"); and (c) cryopreservation (freezing) of eggs or embryos.

62. Embryos are precious and irreplaceable. Human eggs, also known as oocytes, are a limited resource. A woman has about one million eggs at birth and this supply diminishes at a rate of about 1,000 eggs per month as part of the natural aging process.

63. The loss of oocytes from the ovaries continues in the absence of menstrual cycles, and even during pregnancy, nursing, or taking of oral contraceptives.

64. Egg quality, too, diminishes with time, with miscarriages and chromosomal abnormalities occurring more frequently for older women than for younger women.

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[8] Bradley, Cara. *Impact of multiple blastocyst biopsy and vitrification – warming procedures on pregnancy outcomes.* Fertility and Sterility. Vol. 108, Issue 6. December 2021.

65. PGT-A testing sold to Plaintiffs and Class members by Defendants has substantial ramifications including the costs that are paid for such testing.

66. Defendants promote PGT-A testing as an add-on to the IVF process and strongly encourage individuals to purchase PGT-A testing to determine which embryos are suitable to transfer.

67. PGT-A testing can and does result in unnecessary loss of embryos.

68. PGT-A testing can and does result in embryos that could result in live births not being transferred.

69. PGT-A testing can and does result in embryos that could result in live births being discarded.

70. PGT-A testing can and does result in additional egg retrievals.

71. PGT-A testing can and does provide false positives and false negatives.

72. PGT-A testing can and does result in important decisions being made during IVF based upon inaccurate information.

73. PGT-A testing can and does result in embryos being unable to be transferred.

74. Inaccurate PGT-A testing can and does result in healthy babies being born from embryos deemed "abnormal" and "unsuitable for transfer".

75. In selling PGT-A to consumers, Defendants represent that their PGT-A testing is 98% accurate, increases the chance of a healthy and successful pregnancy, increases implantation rates, increases live birth rates, benefits every couple especially those of advanced maternal age, reduces the number of abnormal embryos for cryopreservation, decreases the rate of miscarriage, and is superior to all others' testing.[9]

76. These representations are false, and Plaintiffs and Class members

[9] https://www.luminarygenetics.com/pgt-a-video (last visited May 15, 2025).

would not have purchased PGT-A testing from Defendants had they known the truth about PGT-testing, which Defendants misrepresented and materially omitted.

B. History of PGT-A.

77. Preimplantation genetic testing was pioneered by Yuri Verlinsky and his colleagues beginning in the late 1980s.

78. In 1996, the hypothesis was first proposed that preimplantation genetic screening ("PGS") that eliminated aneuploid embryos prior to transfer would improve implantation rates of remaining embryos in IVF, increase pregnancy and live birth rates, and reduce miscarriages.[10]

79. In reaching this hypothesis, the authors made at least five assumptions: (a) most IVF cycles fail because of aneuploid embryos; (b) their elimination prior to embryo transfer will improve IVF outcomes; (c) a single trophectoderm biopsy ("TEB") at blastocyst stage is representative of the whole trophectoderm ("TE"); (d) TE ploidy reliably represents the inner cell mass ("ICM"); and (e) ploidy does not self-correct downstream from blastocyst stage.

80. Based upon these assumptions, PGS began to be marketed as an add-on to IVF treatments, with promises of improved outcomes and reduced miscarriage rates.

81. Initially, PGS was proposed by polar body biopsy, and eventually, technology was implemented to a more invasive cleavage state embryo biopsy.

82. This method, described as PGS 1.0, became increasingly popular despite that researchers in 2005 were still unable to demonstrate outcome benefits.[11]

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[10] Verlinsky, Y. and Kuliev, A., *Preimplantation diagnosis of common aneuploidies in infertile couples of advanced maternal age*. Hum. Reprod. 1996, 11:2076-7.

[11] Staessen C, Platteau P, Van Assche E, Miciels A, Tournaye H, Camus M, Devroey P, Liebaers I, van Steirteghem A. *Comparison of blastocyst transfer with and without preimplantation genetic diagnosis for aneuploidy screening in women of*

83. In 2008, a randomized clinical trial sought to study one of the above-stated hypotheses: whether the effect of PGS on live births rates differs in women of advanced maternal age with variable risks for embryonic aneuploidy, and weighed these effects against the results obtained after IVF without PGS.[12]

84. The authors of this study concluded that PGS had no clinical benefit over standard IVF in women of advanced maternal age regardless of their risk for embryonic aneuploidy.[13]

85. In 2011, researchers conducted a meta-analysis of randomized control trials on the effect of PGS on the probability of live birth after IVF.[14]

86. The authors of this meta-analysis found that there is no evidence of a beneficial effect of PGS as currently applied on the live birth rate after IVF.[15]

87. In addition, the authors determined that PGS significantly lowers the live birth rate for women of advanced maternal age. The authors noted that technical drawbacks underlined the inefficiency of PGS.[16]

88. The authors cautioned that new approaches in the application of PGS

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advanced maternal age: a prospective randomized controlled trial. Hum Reprod. 2005;19:2849–58. 16. Platteau P, Staessen C, Michiels A, Van Steirteghem A, Liebaers I, Devroey P. *Preimplantation genetic diagnosis for eneuploidy screening in women older than 37 years. Fertil Steril*. 2005;84:319–24. 17. Platteau P, Staessen C, Michiels A, Van Steirteghem A, Liebaers I, Devroey P. *Preimplantation genetic diagnosis for aneuploidy screening in patients with unexplained recurrent miscarriages*. Fertil Steril. 2005;83:393–7.

[12] Twisk, M., Mastenbroek, S., et al. *No beneficial effect of preimplantation genetic screening in women of advanced maternal age with a high risk for embryonic aneuploidy*. Human Reproduction, Vol,23, No. 12 pp. 2813-2817 (2008).

[13] *Id*.

[14] Mastenbroek, S. *Preimplantation genetic screening: a systemic review and meta-analysis of RCTs*. Human Reproduction Update, Vol.17, No.4, 454-466 (2011).

[15] *Id*.

[16] *Id*.

should be carefully evaluated before introduction into clinical practice.[17]

89. In a 2013 paired randomized clinical trial on 116 patients, scientists sought to evaluate if cleavage[18] or blastocyst stage embryo biopsy affects reproductive competence.[19]

90. Until this time, most biopsies for PGS were performed at the cleavage stage of embryogenesis, whereas less than one percent (1%) were being performed on blastocyst stage.

91. The authors concluded that cleavage-stage biopsy markedly reduced embryonic reproductive potential.[20]

92. They further concluded that until laboratories demonstrated safety by applying a similar powerful study design, there remained insufficient evidence that biopsy at the blastocyst stage could be safely performed without impacting the reproductive potential of human embryos.[21]

93. Soon thereafter, however, the PGS testing labs began trophectoderm biopsy at the blastocyst stage without conducting further appropriate studies.

94. To perform PGT-A, DNA must be obtained from embryos for analysis.

95. The approach most widely adopted in practice today to obtain DNA is by performing a biopsy from a blastocyst 5 to 6 days after conception.

96. The blastocyst is made up of embryonic cells and extraembryonic cells.

97. The embryonic cells form the inner cell mass ("ICM") of the blastocyst,

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[17] *Id*.
[18] Cleavage stage refers to embryos at day 2-3 while blastocyst refers to embryos at day 5-6.
[19] Scott, R., et al. *Cleavage-stage biopsy significantly impairs human embryonic implantation potential while blastocyst biopsy does not: a randomized and paired clinical trial*, Fertility and Sterility Vol. 100, No. 3, September 2013 0015-0282
[20] *Id*.
[21] *Id*.

which will lead to the development of the fetus, and the extraembryonic cells form the trophectoderm of the blastocyst which will form the placenta.

98. The biopsy is taken from the trophectoderm which is made up of extraembryonic cell lineage cells. This extraembryonic cell DNA is then analyzed to determine if the embryo contains a normal or abnormal number of chromosomes.

99. For PGS testing results, the number of chromosomes detected from the biopsied cells, taken from the trophectoderm, are interpreted to be representative of the entire embryo including the inner cell mass.

100. Laboratories performing preimplantation genetic testing proclaim that if testing results show a normal number of chromosomes in the biopsy, then the embryo should be considered euploidy (the word comes from the Greek word eu, which means true or even), which means it has a higher chance of successful implantation and live birth. In contrast, if testing shows an abnormal number of chromosomes in the biopsy, then the embryo should be considered aneuploid.

101. The trophectoderm biopsy at blastocyst stage, referred to as PGS 2.0, was considered by PGS proponents as more accurate than PGS 1.0, and quickly replaced the earlier method.

102. There were, however, no properly conducted studies to assess PGS 2.0 accuracy and whether the new method increased implantation and reduced miscarriage rates.

103. When embryo biopsy moved from cleavage to blastocyst stage, and selected chromosome investigations went to full chromosomal analyses with a newly developed diagnostic platform for conducting PGS 2.0, the assumption was that PGS would finally show its effectiveness. This did not happen.

104. Thus, genetic laboratories questioned whether other platforms could more accurately determine embryo ploidy.

105. In 2015, as laboratories began to question the effectiveness of PGS,

Defendants began promoting PGS as one of its "pioneering tests to help reproductive health professionals and treat their patients."

106. In a 2016 study, researchers tested embryos that had previously been tested and deemed aneuploid.[22] Six out of eleven embryos upon retesting were determined to be either definitively normal or mosaic with the potential to be normal, thus offering a chance for pregnancy if transferred.[23]

107. The authors of this 2016 study concluded that while the study was small, it suggested a potential false positive rate of almost 55% and an intra-embryo discrepancy of almost 50%.[24]

108. Further, of the eleven embryos originally deemed abnormal, eight patients decided to undergo a transfer, and five of those eight transfers resulted in the delivery of healthy newborns.[25]

109. Based upon their findings, the authors urged careful reassessment of PGS considering its increasing use.[26]

110. In another 2016 study, researchers analyzed assisted reproductive technology in the United States from 2011 to 2012 and found that overall PGS was associated with a decreased live birth rate when compared to IVF without PGS.[27]

111. In yet another study in 2016, researchers re-biopsied 37 embryos determined to be "abnormal" and found that 33% of embryos originally reported to

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[22] Gleicher, N. et al., *Accuracy of preimplantation genetic screening (PGS) is compromised by degree of mosaicism of human embryos*, Reproductive Biology and Endocrinology (2016) 14:54.

[23] *Id*.

[24] *Id*.

[25] *Id*.

[26] *Id*.

[27] Kushnir, VA, et. al, *Effectiveness of in vitro fertilization with preimplantation genetic screening: a reanalysis of Unites States assisted reproductive technology data 2011-2012*. Fert Steril, 2016; 106(1): 75-9.

be "aneuploid" were found to be "euploid" upon repeat assessment.[28] This study further demonstrated PGS testing's inability to accurately differentiate between euploidy and aneuploidy of any given embryo.

112. Furthermore, in 2016, researchers in a mouse study found that mosaic embryos were able to self-correct and that aneuploid cells were progressively depleted from the blastocyst stage on.[29]

113. The findings suggested that it may be biologically impossible to accurately assess an embryo's viability with a single trophectoderm biopsy at blastocyst stage.[30]

114. By this time, proponents of PGS, were aware of the above scientific literature that a problem existed with the results of PGS and that there was a problem with strictly defining embryos as either euploid or aneuploid, with the known resulting consequences of delivering aneuploid test results to patients.

115. Defendants, however, did not incorporate this knowledge into their marketing and advertising, to inform their customers about the issues inherent in PGS testing.

116. Despite the mounting research as of 2016, the Preimplantation Genetic Diagnosis International Society ("PGDIS") published practice guidance for PGS on its website for the first time in July 2016.

117. At the same time, the PGDIS announced a name change from PGS to PGT-A. Notably, this change replaced the term "screening" with the term "testing."

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[28] Tortoriello D., et al., *Reanalysis of human blastocysts with different molecular genetic screening platforms reveals significant discordance in ploidy status*. Fert Steril, 2016; 106(1).

[29] Bolton, H., et. al., *Mouse model of chromosome mosaicism reveals lineage-specific depletion of aneuploid cells and normal development potential*. *Nat Commun* **7**, 11165 (2016). https://doi.org/10.1038/ncomms11165.

[30] *Id.*

118. PGDIS is heavily influenced by and comprised of influential members of the genetic testing industry and has its headquarters located at a genetic testing laboratory.

119. PGDIS was cofounded by Yuri Verlinsky, who created Reproductive Genetic Innovations, LLC, ("RGI"), a genetic testing company, and Santiago Munne, who co-founded Reprogenetics and Recombine and was the Chief Scientific Officer ("CSO") of CooperGenomics, another genetic testing company, in 2016 and 2017.

120. In fact, PGDIS has its headquarters at the same location as RGI, another genetic testing laboratory that markets and sells PGT-A.

121. The PGDIS guidelines contained no references to scientific literature and were published without being subject to peer review.

122. Research conducted the following year, 2017, shed even more light on the issues with PGS testing, now known as PGT-A. Specifically, the authors conducted a review of 455 publications related to testing, and concluded that all five assumptions made in 1996 are scientifically unsupportable and the hypotheses of PGS were discredited.[31]

123. The authors of the 2017 review urged testing for the purpose of research and acknowledged that not one properly analyzed study had been able to demonstrate clinical outcome benefits and, indeed, increasing evidence suggested that at least in unfavorable patient populations (i.e., older patients) who were considered the best candidates for the test, testing may instead reduce pregnancy and live birth chances.[32]

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[31] Gleicher, N, Orvieto, R. *Is the hypothesis of preimplantation genetic screening (PGS) still supportable? A review*. Journal of Ovarian Research (2017) 10:21.
[32] *Id*.

124. Instead of undertaking randomized and properly structured studies, Defendants continued to falsely promote and tout the benefits of PGS testing and PGT-A testing to IVF patients without appropriate validation or scientific support.

125. Thereafter, PGT-A testing proponents pivoted yet again, and suggested that aneuploid embryos would now be divided into two diagnostic categories, mosaic and aneuploid. However, the thresholds of classification for euploid, mosaic, and aneuploid embryos were not based on appropriate peer reviewed scientific research.

126. In another study in 2017, a researcher sought to analyze the clinical reliability of PGT-A results and the resulting loss of what may be viable embryos.[33] The author estimated that the proportion of normal embryos that are discarded based upon faulty results may be as high as 40%. The author noted that this would lead to an overall decrease in the cumulative pregnancy rate achievable.[34]

127. In 2018, an abstract titled *The Emperor Still Looks Naked* was published in Reproductive Biomedicine criticizing PGS/PGT-A as a novel technology that has seen widespread implementation without scientific support.[35]

128. The author's commentary stated, "I have been appalled at the implementation into clinical practice of novel technology without the appropriate underpinning science. Saddest of all is the peddling, not infrequently for substantial pecuniary gain, of these unproven techniques to vulnerable people – older age women, or those with repeated IVF failure or recurrent miscarriage – as miracle treatments that will change their blighted lives."[36] The author called for registered,

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[33] Paulson, R., *Preimplantation genetic screening: what is the clinical efficiency?* Fert. Ster. Vo. 108 No. 2, August 2017.

[34] *Id.*

[35] Braude P. *The Emperor Still Looks Naked*. Reprod Biomed Online. 2018 Aug;37(2):133-135. doi: 10.1016/j.rbmo.2018.06.018. PMID: 30075840.

[36] *Id.*

randomized, properly structured, non-commercial trials before clinical application of a technology that can lead to such devastating consequences like viable embryo destruction.

129. Subsequently, no such study was conducted.

130. In 2018, the American Society for Reproductive Medicine ("ASRM") and the Society for Assisted Reproductive Technology ("SART") issued a committee opinion on PGS/PGT-A, concluding that "the value of PGS/PGT-A as a screening test for IVF patients has yet to be determined."[37]

131. Defendants, however, materially omitted to inform their customers and potential customers of this important pronouncement by the leading organization for reproductive medicine.

132. In 2019, Santiago Munne, conducted a randomized controlled trial to evaluate the benefit of PGT-A for embryo selection in frozen-thawed embryo transfer.[38]

133. Mr. Munne and his fellow researchers found that PGT-A did not improve overall pregnancy outcomes, did not improve live birth rates, and did not reduce miscarriage rates.[39]

134. Commentary published following this study included the following: "Considering all presented evidence, it is difficult to understand what further argument can be made for the continuous routing clinical utilization of PGT-A to

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[37] Penzias, A. et.al. *The use of preimplantation genetic testing for aneuploidy (PGT-A): A committee opinion.* Fertility and Sterility, Vol. 109, No. 3, March 2018.

[38] Munne, S., et. al., *Preimplantation genetic testing for aneuploidy versus morphology as selection criteria for single frozen-thawed embryo transfer in good-prognosis patients: a multicenter randomized clinical trial*. Fertility and Sterility, Vol. 112, No. 6, December 2019.

[39] *Id.*

improve IVF outcomes."[40]

135. However, NextGen was created in 2019 and started to falsely promote and tout the benefits of its PGT-A testing to IVF patients without appropriate validation or scientific support.

136. In 2020, Dr. Richard Paulson cautioned about PGT-A being actively marketed as a mature technology by overstating its benefits and underestimating its losses.[41]

137. Dr. Paulson noted that the marketing of PGT-A as accurate, having minimal errors, and applicable to IVF patients generally was not supported with evidence-based science and that the losses of potential implantations are evident. Dr. Paulson called for scientific scrutiny of the available PGT-A data.[42]

138. In addition, an assessment was done of IVF and PGT patient education materials, which also raised concerns.

139. The United States Centers for Disease Control and Prevention ("CDC") requires that patient education materials be written at or below a fifth-grade reading level, but researchers found that among the educational materials examined, none met the CDC standard.[43]

140. These findings suggested that patient educational materials concerning PGT-A may not always be comprehensible or clear to all patients. Lack of

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[40] Orvieto, R., *Preimplantation genetic testing for aneuploidy (PGT-A- finally revealed*. Journal of Assisted Reproduction and Genetics (2020) 37-669-672.

[41] Paulson, R. *Hidden in plain sight: the overstated benefits and underestimated losses of potential implantations associated with advertised PGT-A success rates***.** Human Reproduction, Vol. 35, Issue 3, p. 490-493 (March 2020).

[42] *Id*.

[43] Early, M., et al., *Literary assessment of preimplantation genetic patient education materials exceed national reading levels*, Journal of Assisted Reproduction and Genetics, Vol.37, p. 1913-1922, (2020).

appropriate educational materials that present information about PGT-A in an accessible, unbiased, and comprehensible manner have the potential to lead to disparities in the use of PGT-A because patient educational materials have exceeded the average literacy skills of U.S. residents.[44]

141. Additional research in 2020 also continued to show that live birth rates for PGT-A should be calculated per cycle, instead of per transfer.[45] The authors of the 2020 study found that PGT-A resulted in a lower chance of live birth in all age groups compared to transfer of embryos without PGT-A.[46]

142. In November 2021, the preeminent New England Journal of Medicine published the results of a randomized controlled trial to assess whether PGT-A improves the cumulative live-birth rate as compared with conventional IVF.[47]

143. The authors concluded that "conventional IVF treatment was noninferior to PGT-A and resulted in a higher cumulative live-birth rate in women with a good prognosis for a live birth."[48]

144. The authors also noted that "the results of trophectoderm biopsy may not totally represent the genetic composition of the inner cell mass of the blastocyst that is the precursor to the embryo, and subsequent cell division may also eliminate a genetically abnormal cell line."[49]

145. The authors of the study concluded:

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[44] Yang, H., et al., *Preimplantation genetic testing for aneuploidy: Challenges in clinical practice*, Human Genomics, article 69 (2022).

[45] Doody, K. *Live Birth Rate Following PGT Results in Lower Live Birth Rate Compared to Untested Embryos Transferred at Day 5/6.* Fertility and Sterility. Vol. 114, Issue 3, Supplement E419 (September 2020).

[46] *Id*.

[47] Yan, J., et al., *Live Birth with or without Preimplantation Genetic Testing for Aneuploidy*, N. Engl. J. Med. 385;22, November 25, 2021.

[48] *Id*.

[49] *Id*. at 2054.

A. Trophectoderm biopsy may be harmful;[50]

B. No benefit for PGT-A regardless of age on cumulative live-birth rate;[51] and

C. No benefit for PGT-A for ongoing pregnancy and live birth rates after first frozen embryo transfer.[52]

146. Also in 2021, researchers reviewed the literature on PGT-A as a precursor to the possibility of advancing technology to a non-invasive test for aneuploidy. In their analysis, the authors recognized:

A. That it is possible for normal embryos to be misdiagnosed as mosaic and deemed unsuitable for transfer, that ultimately would self-correct and lead to a live birth;

B. Studies do not support the use of PGT-A for all couples who undergo IVF, even in women on the older end of the age spectrum (35-40), who theoretically have the most to gain;

C. Improved live birth rates with PGT-A have not been consistently reported; and

D. It has yet to be proven whether PGT-A improves live birth outcomes.[53]

147. Despite all of these findings, NextGen continued to advertise, market, and affirmatively misrepresent non-existent benefits of PGT-A that are not supported by science to vulnerable consumers, while at the same time omitting material information concerning the efficacy of PGT-A.

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[50] *Id.*, at 2056.
[51] *Id.*
[52] *Id.*
[53] Burks, C., et al., *The Technological Advances in Embryo Selection and Genetic Testing: A Look Back at the Evolution of Aneuploidy Screening and the Prospects of Non-Invasive PGT*, Reprod. Med. 2021, 2, 26-34.

148. Another study in 2021 also reconfirmed a known observation that term placentas, which are what the trophectoderm becomes, are inherently mosaic, characterized by a substantial number of chromosomal abnormalities, even if the fetus is completely euploid.[54]

149. The results of the 2021 study conflict with and further undermine Defendants' position in promulgating PGT-A that a trophectoderm biopsy at blastocyst stage can adequately predict the entire embryo and what will develop from the inner cell mass.

150. For this reason, where the trophectoderm biopsy is taken from may alter the results of PGT-A such that the test does not accurately predict the entire trophectoderm or the inner cell mass, as shown in the following illustration:[55]

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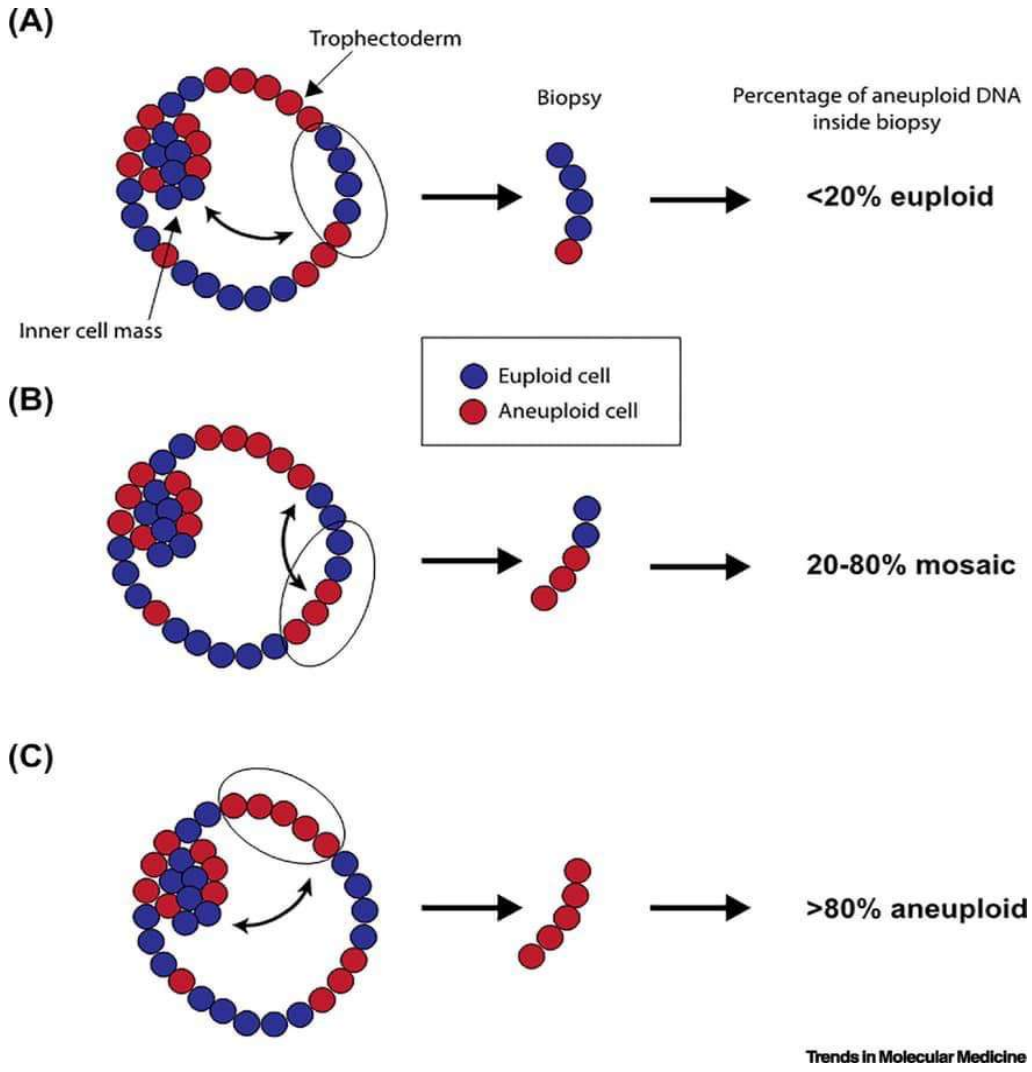
[54] Coorens, et al., *Inherent mosaicism and extensive mutation of human placentas*. Nature 592, 80-85 (2021).

[55] Gleicher, N., et al., *Preimplantation Genetic Testing for Aneuploid – a Castle built on sand*. Trends in Molecular Medicine, Opinion I Special Issue: Reproductive and Sexual Health, Vol. 27, Issue 8, pp 731-742 (August 2021).



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151. In March 2022, an opinion based upon a review of the recent scientific literature was published in Human Reproduction, urging that PGT-A be restricted to only research protocols.[57]

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[56] https://www.vitrolifegroup.com/en/what-we-offer/module-holder/genetic-services (last visited February 19, 2025).

[57] Gleicher, N., et al., *We have reached a dead end for preimplantation genetic testing for aneuploidy*, Human Reproduction, Vol. 37, No. 12, pp. 273002734 (2022).

152. Also in 2022, a retrospective cohort study was published comparing cumulative live birth rates between embryo transfers with or without PGT-A.[58] The authors noted that an improvement in cumulative live birth rates with PGT-A utilization, calculated per cycle start, cannot be assumed because simply testing embryos for aneuploidy does not increase the number of euploid embryos, nor does it decrease the number of aneuploid embryos.[59]

153. The authors concluded that there is no clear improvement to cumulative live birth rates with PGT-A. In fact, "amongst the youngest patients (age <35), not only does there appear to be no benefit to PGT-A, but there appears to be a considerable reduction in cumulative live birth rates per cycle start."[60]

154. The authors further recognized calls for reevaluation or even repeal of widespread PGT-A usage and concluded with an advocation for "responsible innovation supported by high-quality data, which is not the case for PGT-A."[61]

155. Defendants, however, have continued to advertise and market PGT-A based upon live birth rates per embryo transfer thereby excluding from analysis any IVF cycles without transferrable embryos. As a result, Defendants artificially and materially inflates and misrepresents the utility of PGT-A on increasing the chance of implantation, increasing the likelihood of a successful pregnancy, and reducing the time and costs of having a healthy baby.

156. Another article published in Human Genomics called for regulatory oversight, recognizing that PGT-A had regrettably become a routine add-on for IVF

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[58] Kucherov, A. et al. *PGT-A is associated with reduced cumulative live birth rate in first reported IVF stimulation cycles age ≤; an analysis of 133,494 autologous cycles reported by SART CORS*, Journal of Assisted Reproduction and Genetics (2023) 40:137-149.

[59] *Id.*

[60] *Id.*

[61] *Id.*

to improve clinical outcomes, and noted the following:

A. There are significant knowledge gaps in PGT-A;

B. PGT-A is a screening tool, not a diagnostic test;

C. Mosaicism is much higher in the blastocyst stage from PGT-A than recognized by industry;

D. Mosaic embryos may not accurately represent future fetal viability;

E. PGT-A has not been validated;

F. High false positive rates are extremely concerning;

G. Use in particular age groups is uncertain;

H. Routine use of PGT-A should not be recommended;

I. Evidence-based data are needed to evaluate the risks and benefits for patients; and

J. Industry self-regulation has shown to be insufficient.[62]

157. As further proof of the concern raised by the authors in Human Genomics regarding the high false positive rates, a re-biopsy and repeat of PGT-A testing on fifty-eight embryos that were originally determined to be chaotically abnormal concluded that twenty-two of the embryos had a euploid result.[63]

158. The researchers noted that the euploid rate suggested that chaotic

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[62] Yang, H., et al. *Preimplantation genetic testing for aneuploidy: challenges in clinical practice*, Human Genomics (2022)16.69.

[63] Rabkina, L., et al. *Concordance of Chromosomes Within Re-Biopsy Samples of Embryos Following Initial Chaotic Results.* Fertility and Sterility, Vol. 118, Issue 4. October 2022.

abnormal results on PGT-A have "reduced predictive value."[64]

159. These findings were further supported a year later when researchers re-biopsied sixty-four embryos reported as "chaotic", which they defined as an embryo with a PGT-A result of more than six chromosome aneuploidies and found concordance of only 67%.[65]

160. Then in April 2023, Dr. Robert Casper determined that when the research data utilized all IVF cycles, and not just the ones where there was a transferrable embryo following PGT-A, there was actually a threefold increase in live birth rates for the group that did not have PGT-A testing performed, and a reduction in live birth rates for the group where PGT-A was utilized.[66]

161. Based upon his findings, Dr. Casper raised concerns that PGT-A caused irreparable harm to patients with diminished ovary reserves who lost their only chance to have a baby from their cycle of IVF.[67]

162. Then in September of 2023, the European Society of Human Reproduction and Embryology ("ESHRE") add-ons working group released its good practice recommendations on add-ons in reproductive medicine in September of 2023 in which it was determined that PGT-A was not currently recommended for routine clinical use.[68]

163. In support of this recommendation, ESHRE noted that random control test studies did not report benefits on live birth rates and caused disposal of viable

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[64] *Id.*

[65] Lim, Joshua, et al. *Corcordance of Repeat Biopsy Results Among Embryos with 6 or More Aneuploidies*. Fertility and Sterility. Vol. 120, Issue 4. October 2023.

[66] Casper, R. *PGT-A in patients with a single blastocyst.* Journal of Assisted Reproduction and Genetics, v. 40, p. 1227 (2023).

[67] *Id.*

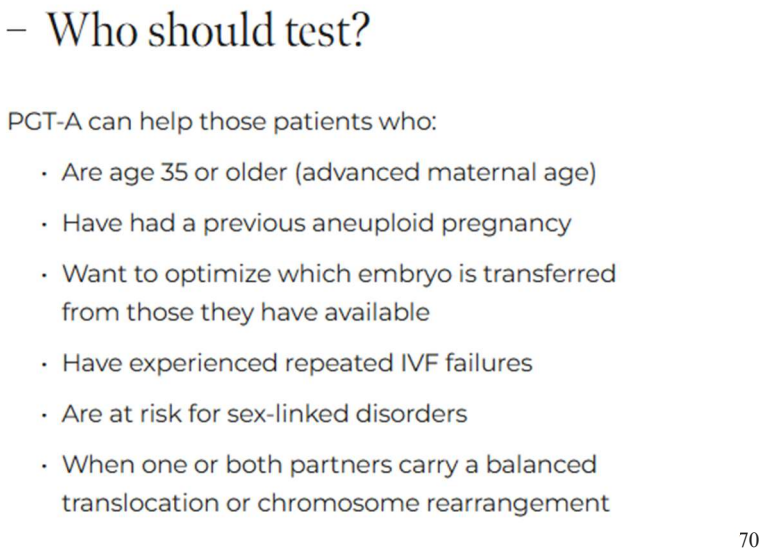
[68] Lundin, K., et al, *Good Practice Recommendations on Add-Ons in Reproductive Medicine*. Human Reproduction. Vol, 38, Issue 11. November 2023.

embryos.

164. The following month in October 2023, it was recognized in the scientific literature that "there is currently insufficient evidence to prove the effectiveness of PGT-A in patients with unexplained recurrent implantation failure."[69]

165. Patients with unexplained recurrent implantation failure are precisely the type of vulnerable and unsuspecting consumers that Defendants are targeting and marketing to with their misleading statements that PGT-A reduces miscarriage rates and increases the chances of a live birth.

166. For example, Defendants' marketing includes the following:



[70]

167. The authors of the October 2023 retrospective cohort study noted:

A. The ineffectiveness of PGT-A may be due to the high mosaicism and unavoidable false-positive results from trophectoderm biopsies, "which led to much waste of viable embryos";

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[69] Lui, Y., et al., *Preimplantation Genetic Testing for Aneuploidy Could Not Improve Cumulative Live Birth Rate Among 705 Couples with Unexplained Recurrent Implantation Failure*, The Application of Clinical Genetics 2024:17 1-13.

[70] https://www.luminarygenetics.com/pgt-a-link (last visited May 13, 2025).

B. The effectiveness of PGT-A in ≥38-year-old group is significantly undermined by low egg retrieval, high aneuploidy and mosaicism rate, resulting in a lot of women with no embryos to transfer;

C. Trials targeting older women found no improvement in the cumulative live birth rate after PGT-A.[71]

168. Again, researchers determined that high quality randomized clinical trials are needed to find patients with indications that would benefit from PGT-A.

169. Defendants have not conducted such studies but instead have continued to falsely and misleadingly market and advertise the purported benefits of PGT-A as described herein, without a scientific basis.

170. At this same time, Defendant NextGen was acquired by Luminary Life Sciences and began operating as Luminary Genetics, touting it was a "leading provider of genetic testing services for the reproductive health industry…" and delivering "unparalleled precision and expertise to give patients peace of mind…"[72]

171. In November 2023, ASRM again stated emphatically and clearly that the "*value of preimplantation genetic testing for aneuploidy (PGT-A) as a universal screening test for all patients undergoing in vitro fertilization (IVF) has not been established*." (emphasis added).[73]

172. Defendants have omitted to include this material fact in their advertising and marketing materials.

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[71] *Id.*

[72] https://www.prnewswire.com/news-releases/NextGen-genetics-joins-the-luminary-life-sciences-family-to-launch-luminary-genetics-301954163.html (last visited May 13, 2025).

[73] Practice Committee of the American Society for Reproductive Medicine and the Genetic Counseling Professional Group. *Clinical management of mosaic results from preimplantation genetic testing for aneuploidy of blastocysts: a committee opinion*. Fertility and Sterility. Vol. 120, No. 5. November 2023.

173. ASRM further noted that two randomized controlled trials have been conducted which showed no benefit of PGT-A in improving live birth rates, particularly in women less than 38 years of age.[74]

174. An article published in March of 2024 noted that it was imperative to acknowledge the inherent risks associated with PGT-A, including the potential for misdiagnosis and the risk of embryo damage during biopsy.[75]

175. In support of the importance of acknowledging the risks associated with PGT-A, the authors cited to the Human Fertilization & Embryology Authority ("HFEA"), which is the United Kingdom's government's independent regulator of fertility treatment and research involving human embryos.[76]

176. The HFEA states that there is limited evidence to show that PGT-A improves the chances of having a baby for women over 37, individuals with a history of or chromosomal problems, and those with several miscarriages or failed IVF attempts.[77]

177. For this reason, the HFEA cautions that "Until larger trials have been run and we have more evidence, there's no guarantee that PGT-A can improve your chances of a successful pregnancy."[78]

178. Further, the HFEA cautions that PGT-A can cause damage to the embryo thereby preventing it from developing once transferred to the womb, and

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[74] *Id.*

[75] Gudapati, S. Advancements and Applications of Preimplantation Genetic Testing in In Vitro Fertilization: A Comprehensive Review. Cureus 16(3): e57357, doi: 10.7759/cureus.57357. March 2024.

[76] *Id.*

[77] https://www.hfea.gov.uk/treatments/explore-all-treatments/frequently-asked-questions-about-pre-implantation-genetic-testing-for-aneuploidy-pgt-a/ (last visited May 15, 2025).

[78] *Id.*

that PGT-A has the possibility of misdiagnosis.[79]

179. In looking at the evidence for PGT-A, the HFEA also noted the following:

A. There is no evidence from randomized controlled trials that PGT-A carried out at the blastocyst stage on day 5 or 6 is effective at improving your chances of having a baby for most patients undergoing IVF.

B. PGT-A may decrease the chance of having a baby as it often reduces the number of embryos available for transfer.

C. Although current PGT-A techniques are mostly very accurate, the test may give the wrong result.

D. If a test result is not accurate, healthy embryos may be discarded.

E. Embryos can continue to develop successfully after a few cells have been removed, however, removing cells from the embryo may damage it and prevent it from successfully developing.[80]

180. Further research conducted in 2024 supported HFEA's position that PGT-A testing may give the wrong result. A re-biopsy and PGT-A testing of 69 embryos previously determined as abnormal with a result of more than five abnormal chromosomes revealed that 24.6 percent of those embryos were in fact euploid or "normal".[81]

181. In addition, a review of 552 pregnancies of mosaic embryo transfers found that only 7 of the 552 pregnancies revealed the mosaicism that had been

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[79] *Id.*

[80] https://www.hfea.gov.uk/treatments/treatment-add-ons/pre-implantation-genetic-testing-for-aneuploidy-pgt-a/ (last visited May 15, 2025).

[81] Bago, A. et al, *Chaotic blastocysts in preimplantation genetic testing for aneuploidies: prevalence, characterization and re-biopsy results.* Human Reproduction, Vol. 39, Issue Supplement_1. July 2024.

detected in the PGT-A testing.[82]

182. This agreed with prior studies where prenatal testing determined that the pregnancy did not have the same mosaic result as the PGT-A testing.

183. In 2021, research revealed no instances of mosaicism in pregnancies or newborns born from 282 embryos deemed "low-grade mosaic", and 131 embryos deemed "medium-grade mosaic" by PGT-A testing.[83]

184. Also in 2023, prenatal testing determined that out of 250 pregnancies, only 3 had the same mosaic abnormality as the PGT-A testing result.[84]

185. In 2024, researchers determined that nearly all blastocyst and fetal tissue contain some level of mosaicism.[85]

186. Also in 2024, ASRM and SART issued another committee opinion to replace their prior committee opinion of the same name published in 2018 and discussed above. ASRM and SART reiterated that the value of PGT-A as a universal screening test for all patients undergoing IVF had not been demonstrated.[86]

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[82] Spinella, F, et al., Chromosomal, gestational, and neonatal outcomes of mosaic embryos: analysis of 3074 cases from the international registry of mosaic embryo, *Human Reproduction*, Volume 39, Issue Supplement_1. July 2024.

[83] Capalbo, A., et al, *Mosaic human preimplantation embryos and their developmental potential in a prospective, non-selection clinical trial.* Am. J. Hum. Genet. Vol. 108, Issue 2. December 2021.

[84] Viotti, M, et. al., *Chromosomal, gestational, and neonatal outcomes of embryos classified as a mosaic by preimplantation genetic testing for aneuploidy.* Fertility and Sterility. Vol. 120, Issue 5. November 2023.

[85]Zhai, F., et.al., *Human Embryos Harbor Complex Mosaicism With Broad Presence of Aneuploid Cells During Early Development*. Cell Discovery 10, 98. (September 2024) https://doi.org/10.1038/s41421-024-00719-3.

[86] Practice Committee of the American Society for Reproductive Medicine and the Society for Assisted Reproductive Technology, *The use of preimplantation genetic testing for aneuploidy: a committee opinion.* Fertility and Sterility. Vol. 122, Issue 3. September 2024.

187. ASRM further noted that two recent, multicenter, randomized control trials concluded that overall pregnancy outcomes in frozen embryo transfers were similar between conventional IVF and PGT-A.[87]

188. Defendants omitted to include this material fact in their advertising and marketing materials.

189. ASRM stated that the value of PGT-A to lower the risk of clinical miscarriage was unclear and raised concerns about the studies and trials performed. ASRM cautioned that large, prospective, well-controlled studies in a more inclusive patient population are needed.[88]

190. ASRM concluded, as it had in 2018, that PGT-A in all infertile patients undergoing IVF cannot be recommended.[89]

191. Still the Defendants continue to promote widespread use of PGT-A.

192. Following the 2024 committee opinion by ASRM and SART in, researchers re-examined the PGT-A results of embryos that were determined to be abnormal by PGT-A testing and again found a low rate of concordance between the initial PGT-A testing result and PGT-A testing result of the re-biopsy.[90]

193. Specifically, researchers found that the re-biopsy was concordant with only 47.7% of the PGT-A testing results. They also found that 15.8% of the re-biopsies revealed a partially concordant result and 36.8% revealed totally discordant results.[91]

194. Despite the lack of supporting research and scientific basis as well as

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[87] *Id.*
[88] *Id.*
[89] *Id.*
[90] Tikhonov, A., et al., *Re-Examination of PGT-A Detected Genetic Pathology in Compartments of Human Blastocysts: A Series of 23 Cases*. Journal of Clinical Medicine. 2024; 13(11):3289. https://doi.org/10.3390/jcm13113289.
[91] *Id.*

the recommendations of ASRM and SART, Defendants have continued to aggressively market and promote PGT-A as having benefits and properties that it does not have and have omitted the disclosure of material and relevant information to consumers.

195. As of 2025, there have been no randomized, properly structured, non-commercial trials to support the basis of Defendants' sale of PGT-A.

196. There are only two non-selection studies showing the efficacy and accuracy of PGT-A.

197. The first was performed on single nucleotide polymorphism microarray-based PGT-A, which is not the same PGT-A assay utilized by Defendants.[92]

198. The second was performed on next-generation sequencing PGT-A but noted that the results were only to be applied to that targeted PGT-A assay, which differs from the one utilized by Defendant, and that validation needs to be performed on each assay.[93]

199. Plaintiffs and Class members have relied on Defendants' material misstatements and omissions to their detriment by purchasing an expensive test that they would not have purchased if the facts had been disclosed at the time of sale.

C. Defendants Have Utilized False and Misleading Statements to Increase Sales of PGT-A.

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[92] Scott Jr., R.T., et.al., *Comprehensive chromosome screening is highly predictive of the reproductive potential of human embryos: a prospective, blinded, nonselection study*. Fertility and Sterility, Vol. 97, Issue 1. April 2012).

[93] Tiegs, A.W., et.al., *A multicenter, prospective, blinded, nonselection study evaluating the predictive value of an aneuploid diagnosis using a targeted next-generation sequencing–based preimplantation genetic testing for aneuploidy assay and impact of biopsy.* Fertility and Sterility, Vol. 115, Issue 3. March 2021.

200. As a result of Defendants' aggressive advertising and marketing, PGT-A testing is now purchased by consumers as an add-on in an estimated 40% of IVF cycles in the United States.

201. Despite the increase in PGT-A testing use, live birth rates among individuals undergoing IVF have declined.

202. Defendants' false and misleading statements include, without limitation, the following:

A. Defendants' PGT-A testing is 98% accurate;

B. Defendants' PGT-A testing increases chances of a healthy and successful pregnancy;

C. Defendants' PGT-A testing increases live birth rates;

D. Defendants' PGT-A testing increases implantation rates;

E. Defendant's PGT-A testing increases live birth rates;

F. Defendants' PGT-A testing benefits every couple, especially individuals of advanced maternal age;

G. Defendant's PGT-A reduces cryopreservation for abnormal embryos;

H. Defendants' PGT-A testing decreases the rate of miscarriage; and

I. Defendants' PGT-A testing is superior to all others.

203. Furthermore, in making the above statements, Defendants have concealed and omitted material information from consumers, including, without limitation:

A. By failing to provide an accurate assessment of the state of scientific study and knowledge concerning PGT-A;

B. By failing to disclose that the value of PGT-A as a screening test for IVF patients has not been demonstrated by science;

C. By failing to have the above statements supported by properly designed research studies;

D. By failing to tell consumers that PGT-A is experimental;

E. By failing to tell consumers that PGT-A is unproven;

F. By failing to tell consumers that PGT-A results have a substantial degree of inaccuracy; and

G. By failing to tell consumers that PGT-A has a substantial degree of unreliability.

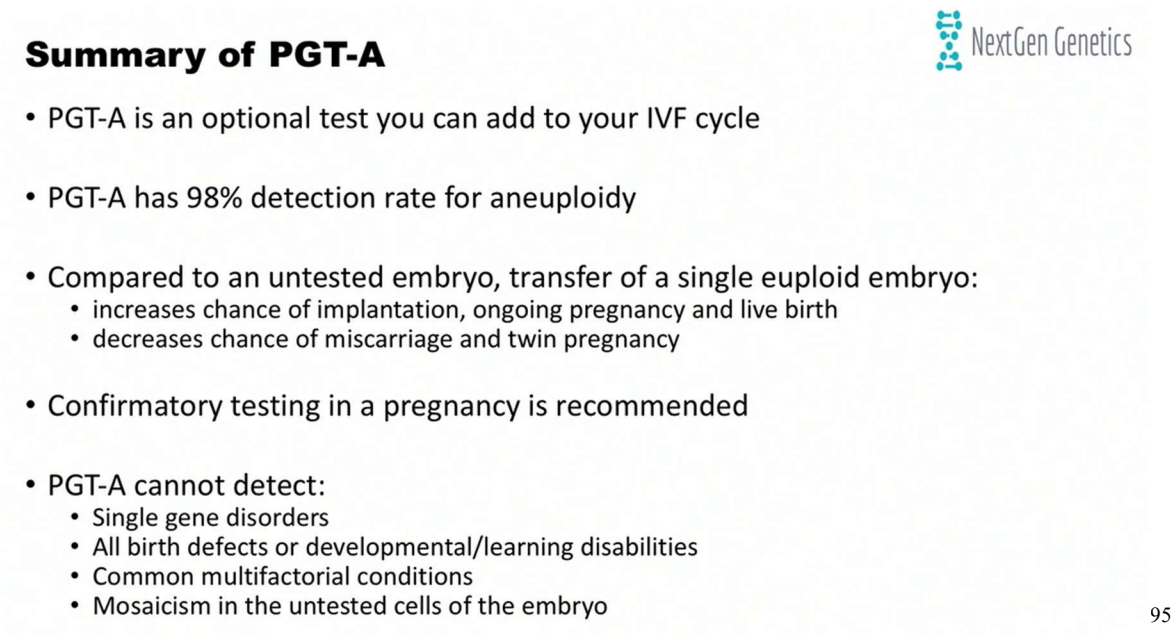
204. Defendants' false and misleading advertising and marketing statements, which include the following, have played a key role in driving up the use of PGT-A testing in the United States.

1. Defendants Falsely State That Their PGT-A Testing Is 98% Accurate.

205. Defendants repeatedly misrepresent that its PGT-A testing is 98% accurate. In a video on the Luminary website describing PGT-A, NextGen states: "The likelihood of a misdiagnosis, specifically a normal PGT-A result leading to a fetus found to have aneuploidy on a confirmatory test such amniocentesis is typically less than 1%."[94]

206. In its video promoting PGT-A, Defendants assure consumers that there is a small chance of misdiagnosis of a tested embryo:

[94] https://www.luminarygenetics.com/pgt-a-video at 25.30 (last visited May 13, 2025).



207. This is also a misrepresentation made by Defendants in its Informed Consent Form in which Defendants claim that their results are 98% accurate.

> Misdiagnosis Due to Test Error: PGT though very reliable, is not a perfect technology and limitations have been described in both PGT technologies and techniques, therefore, 100% accuracy is not guaranteed, expected or possible. There remains an empirically determined 2% chance of a misdiagnosis, either by a false negative or a false positive result. A false negative result will indicate an embryo has a normal number of chromosomes when it contains a chromosomal abnormality. A false positive result will indicate an embryo is aneuploid when it is actually chromosomally normal.

208. Not only do Defendants fail to provide support for their assertions, but the assertions are belied by the scientific literature which has found concordance rates of reanalysis with original PGT-A results as 93.8% for euploid results, 81.4% for aneuploid results and 42.6% for mosaic aneuploid results, and also found that PGT-A is unproven, as described above.[96]

209. Another scientific study suggested a potential false positive PGT-A

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[95] *Id.*

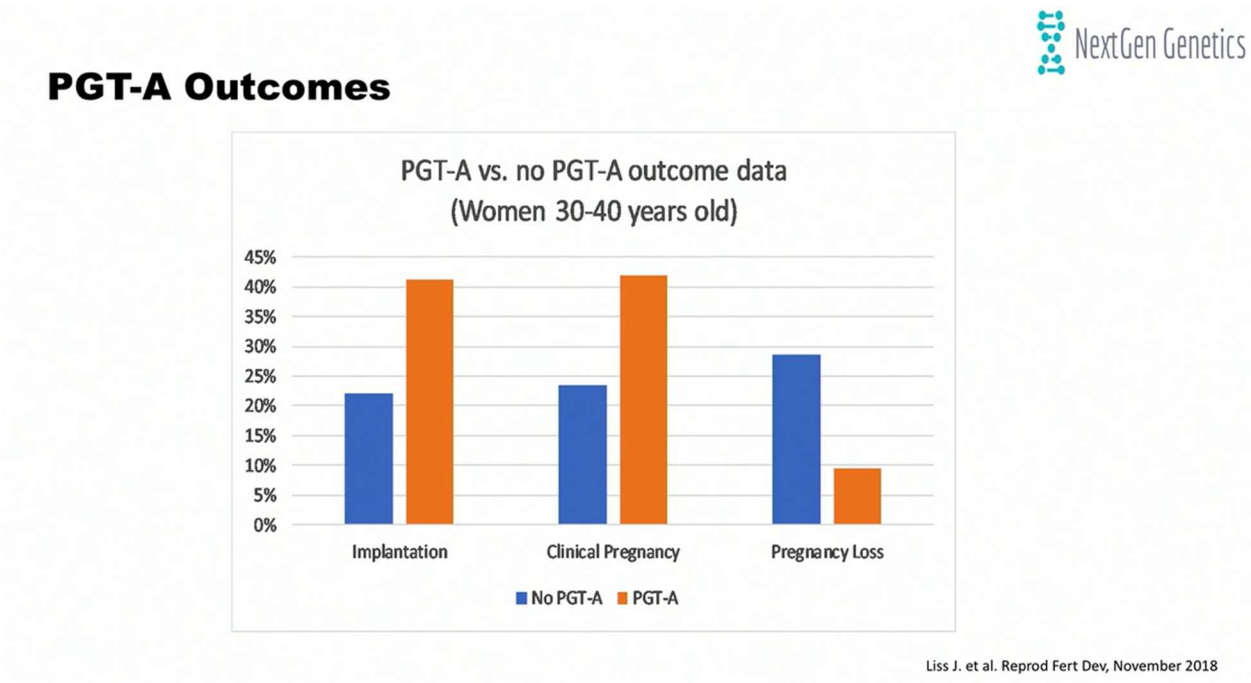
[96] Marin, D., et al., *Preimplantation genetic testing for aneuploidy: A review of published blastocyst reanalysis concordance data.* Prenatal Diagnosis. Vol. 4, Issue 5. Pp. 545-553. April 2021.

rate of almost 55% and an intra-embryo discrepancy of almost 50%.

210. And with no properly conducted studies in support, Defendants continue to promote their PGT-A and PGT-A Plus testing with 98% accuracy.

2. Defendants Falsely State That Their PGT-A Testing Increases The Chance of a Healthy And Successful Pregnancy, Increases Live Birth Rates, And Increases Implantation Rates

211. Defendants claim that their PGT-A testing improves implantation rates and pregnancy rates over IVF without PGT-A based on data from 2018 despite NextGen not being created until 2019.[97]



212. These claims are also made in Defendants' sales video which provides the following summary of benefits related to Defendants' PGT-A: increased implantation rates, increased on going pregnancy rates, and increased live birth rates.[98]

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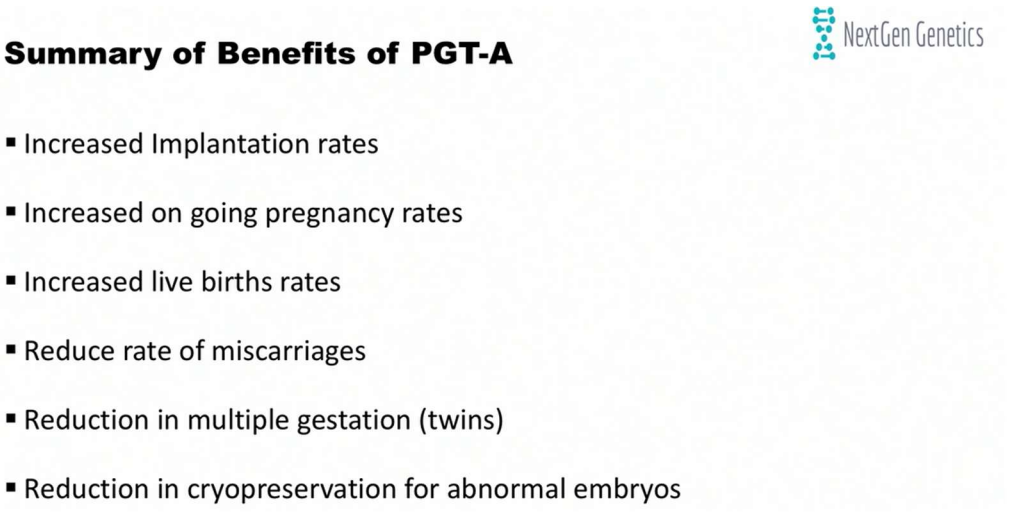
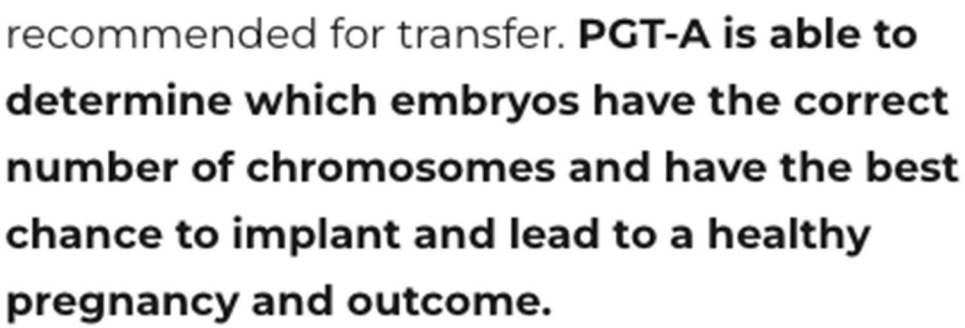
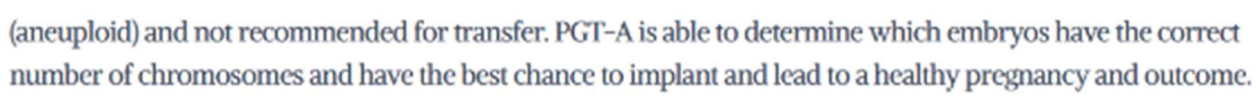
[97] https://www.luminarygenetics.com/pgt-a-video (last visited May 13, 2025).
[98] *Id.*



213. And are included on their website.[99]



214. These claims were also made on NextGen's website before becoming Luminary.[100]



215. Defendants know these representations are false and misleading to consumers, and that they omit material relevant information, as no valid scientific research has concluded this to be accurate. In fact, ASRM has repeatedly noted that trials concluded that overall pregnancy outcomes in frozen embryo transfers were

[99] https://www.luminarygenetics.com/pgt-a-link (last visited May 15, 2025).
[100] https://www.nextgengenetics.com/pgt-a-link (last visited May 15, 2025).

similar between conventional IVF and PGT-A.[101]

216. Research has further shown that there is a threefold increase in live birth rates for those that did not have PGT-A testing performed and a reduction in live birth rates for the group where PGT-A was utilized.[102]

217. Further, it has been determined that PGT-A testing cannot accurately predict the inner cell mass.[103]

3. Defendants Falsely State That Its PGT-A Benefits Every Couple and Especially Individuals of Advanced Maternal Age.

218. Defendants falsely and misleading promote on their website that nearly every patient benefits from PGT-A.[104]

219. Further, Defendants advertise that their PGT-A testing is especially beneficial to patients of advanced maternal age, which Defendants identify as 35 years of age or older.[105]

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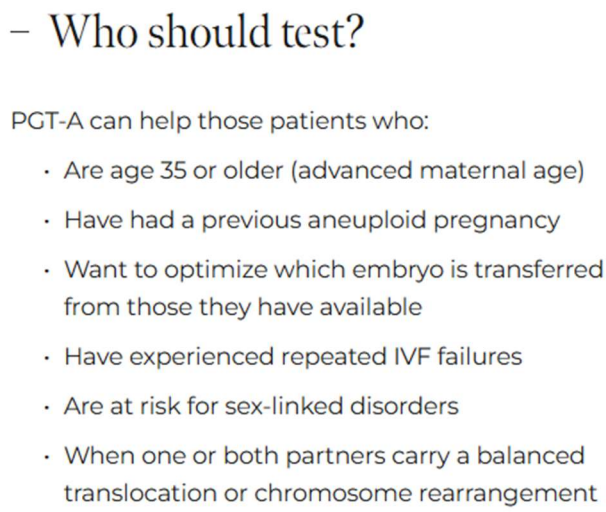
[101] Practice Committee of the American Society for Reproductive Medicine and the Genetic Counseling Professional Group. *Clinical management of mosaic results from preimplantation genetic testing for aneuploidy of blastocysts: a committee opinion*. Fertility and Sterility. Vol. 120, No. 5. November 2023.

[102] Casper, R. *PGT-A in patients with a single blastocyst.* Journal of Assisted Reproduction and Genetics, v. 40, p. 1227 (2023)

[103] Gleicher, N., et al., *Preimplantation Genetic Testing for Aneuploid – a castle built on sand.* Trends in Molecular Medicine, Opinion I Special Issue: Reproductive and Sexual Health, Vol. 27, Issue 8, pp 731-742 (August 2021).

[104] https://luminarygenetics.com (last visited May 15, 2025).

[105] https://www.luminarygenetics.com/pgt-a-link (last visited May 15, 2025).



220. These claims contradict scientific research.

221. Researchers have found no benefit for PGT-A regardless of age on cumulative live-birth rate.[106]

222. Specifically, published scientific results have reported no benefit of PGT-A to live birth rates for women under 35 and unchanged ongoing embryo implantation rates of ~50% for PGT-A and non-PGT-A. [107]

223. Furthermore, scientists have found that "amongst the youngest patients (age <35), not only does there appear to be no benefit to PGT-A, but there appears to be a considerable reduction in cumulative birth rate per cycle start." [108]

224. Defendants' statements promoting the use of PGT-A for patients 35

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[106] Yan, J., et al., *Live Birth with or without Preimplantation Genetic Testing for Aneuploidy*, N. Engl. J. Med. 385;22, November 25, 2021.

[107] Paulson, R. *Hidden in plain sight: the overstated benefits and underestimated losses of potential implantations associated with advertised PGT-A success rates.* Human Reproduction, Vol. 35, Issue 3, p. 490-493 (March 2020).

[108] Kucherov, A., et al., *PGT-A is associated with reduced cumulative live birth rate in first reported IVF stimulation cycles age ≤; an analysis of 133,494 autologous cycles reported by SART CORS*, Journal of Assisted Reproduction and Genetics (2023) 40:137-149.

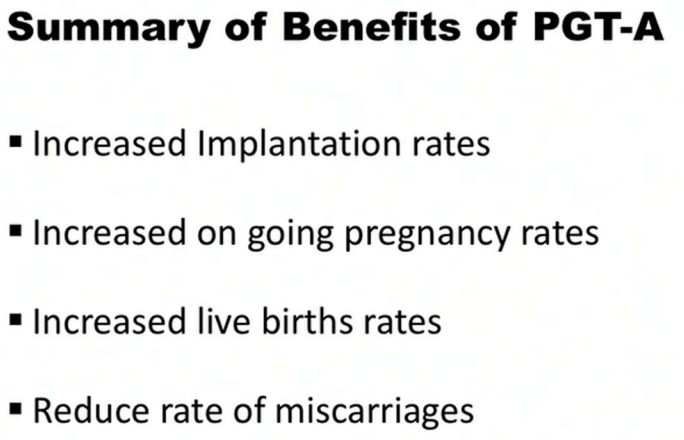
years of age or older are also in direct contradiction to ASRM which has agreed that PGT-A has showed no improvement in live birth rates, particularly in women less than 38 years of age.[109]

225. Further, Defendants' claim contradicts evidence that PGT-A use in older patients may reduce pregnancy and live birth chances.[110]

226. Despite all the scientific research, Defendants have chosen to falsely promote the benefits of PGT-A testing to all IVF patients, specifically those the older patient population.

4. Defendants Falsely State that Their PGT-A Testing Decreases the Chance of Miscarriage.

227. Throughout its website, Defendants make false and misleading statements that its PGT-A decreases the chances of miscarriage. [111]



228. Defendants know this statement is false and misleading to consumers

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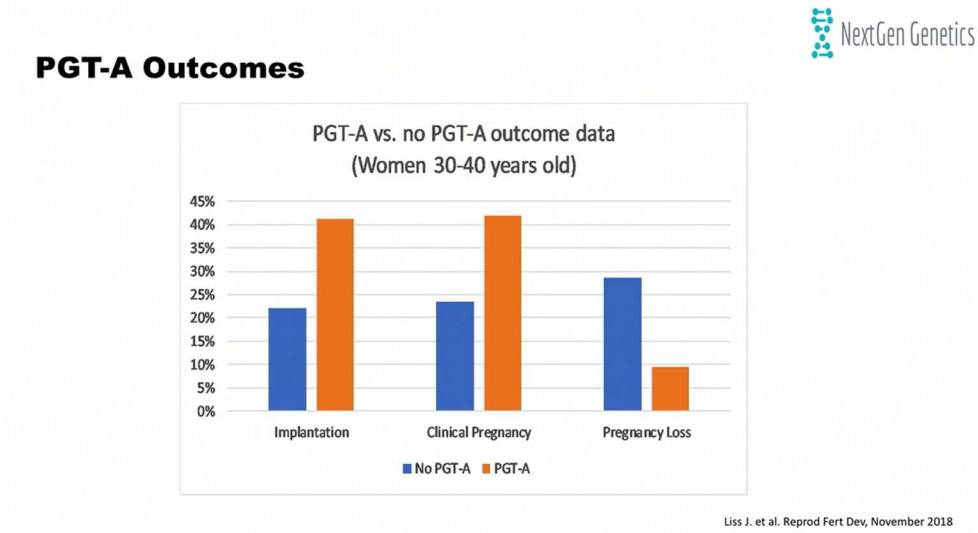
[109] Practice Committee of the American Society for Reproductive Medicine and the Genetic Counseling Professional Group. *Clinical management of mosaic results from preimplantation genetic testing for aneuploidy of blastocysts: a committee opinion*. Fertility and Sterility. Vol. 120, No. 5. November 2023.

[110] Gleicher, N, Orvieto, R. *Is the hypothesis of preimplantation genetic screening (PGS) still supportable? A review*. Journal of Ovarian Research (2017) 10:21.

[111] https://www.luminarygenetics.com/pgt-a-video (last visited May 13, 2025).

as there is no evidence to show that PGT-A decreases the chance of miscarriage, nor does it do so twice as much or more in women over 38 as claimed in the chart.[112]



229. A randomized controlled trial to evaluate the benefit of PGT-A for embryo selection in frozen-thawed embryo transfer found that PGT-A did not reduce miscarriage rates.[113]

230. Thus, there is no valid scientific proof for Defendants' claim that its PGT-A reduces miscarriage rates.

5. Defendants Falsely State that Their PGT-A Testing Reduces Abnormal Embryos.

231. In its sales video, Defendants claim that their testing reduces the number of abnormal embryos to be frozen.[114]

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[112] https://www.luminarygenetics.com/pgt-a-video (last visited May 13, 2025).
[113] Munne, S., et al., *Preimplantation genetic testing for aneuploidy versus morphology as selection criteria for single frozen-thawed embryo transfer in good-prognosis patients: a multicenter randomized clinical trial*. Fertility and Sterility, Vol. 112, No. 6, December 2019.
[114] https://www.luminarygenetics.com/pgt-a-video (last visited May 13, 2025).

- Reduction in cryopreservation for abnormal embryos

232. Defendants are well-aware that they are advertising, marketing, and selling their product to vulnerable consumers undergoing IVF, however, Defendants have utilized this false, deceptive, and misleading claim to sell their testing.

233. Research has proven that trophectoderm biopsy cannot predict the inner cell mass.[115]

234. Further, research has determined that PGT-A does not change the embryo.[116] In other words, an embryo will be euploid or aneuploid regardless of whether it undergoes PGT-A. PGT-A only purports to test for whether an embryo is normal or abnormal.

235. Therefore, it is impossible for Defendants' PGT-A testing to result in less abnormal embryos for cryopreservation.

6. Defendants Falsely State That Their PGT-A Testing Is Superior To Others.

236. Defendants market their PGT-A testing as superior to competing IVF laboratories.[117]

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[115] Gleicher, N., et al., *Preimplantation Genetic Testing for Aneuploid – a Castle built on sand.* Trends in Molecular Medicine, Opinion I Special Issue: Reproductive and Sexual Health, Vol. 27, Issue 8, pp 731-742 (August 2021). *See also* Xu, Jian, et.al., *Biopsy vs comprehensive embryo/blastocyst analysis: a closer look at embryonic chromosome evaluation.* Human Reproduction Open. Volume 2025, Issue 2 (March 2025).

[116] Lamb, B., et al., *Pre-implantation genetic testing: decisional factors to accept or decline among in vitro fertilization patient*. Journal of Assisted Reproduction and Genetics, Vol. 35, pp. 1605- 1612 (2018) 37-669-672

[117] https://www.luminarygenetics.com/pgt-a-link (last visited May 15, 2025).

PGT-A Link™ brings enhanced testing to the market that can help improve a patient's chance of a successful pregnancy.

237. The same claim was made on NextGen's website before becoming Luminary.[118]

> Current PGT-A technology has limitations in reporting haploidy and polyploidy that PGT-A Link solves. PGT-A Link brings enhanced testing to the market that can help improve a patient's chance of a successful pregnancy. The service also confirms that embryos are genetically related to one another, reassuring patients that their embryos underwent testing without error

238. To date, there are only two random control studies that have been conducted thus far on testing assays and neither were conducted on Defendants' assay.[119]

239. As such, Defendants claim that its PGT-A testing is superior to others is false and misleading.

240. In addition, the only comparison of PGT-A results between laboratories that has been conducted was of 4 national laboratories in 2023.[120]

241. The comparison revealed statistical significance in findings of euploid, mosaicism and aneuploid rates between the 4 laboratories but did not reveal which laboratories had been included in the study.[121]

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[118] https://www.nextgengenetics.com/pgt-a-link (last visited March 7, 2024).
[119] Tiegs, A.W., et.al., *A multicenter, prospective, blinded, nonselection study evaluating the predictive value of an aneuploid diagnosis using a targeted next-generation sequencing–based preimplantation genetic testing for aneuploidy assay and impact of biopsy.* Fertility and Sterility, Vol. 115, Issue 3. March 2021.
[120] Bardos, J., et.al. *Reproductive genetics laboratory may impact euploid blastocyst and live birth rates: A comparison of 4 national laboratories' PGT-A results from vitrified donor oocytes*. Fert. Ster. 119(1) pp. 23-35 (Ja.n 2023).
[121] *Id.*

242. Thus, it is unknown whether Defendants' PGT-A testing was included and there is no evidence upon which Defendants can claim their testing is superior.

7. Defendants' Misrepresentations In Their Uniform Patient Consent Form Signed By All Customers.

243. Defendants provide a Preimplantation Genetic Testing (PGT-A) for Aneuploidy Consent Form ("Consent Form") that all customers are asked to sign prior to obtaining their PGT-A testing.

244. The Consent Form states on the top of Page 1 that it is issued by Defendant NextGen Genetics.

245. The Consent Form directs consumers to watch the sales video discussed hereinabove which includes false statements and misrepresentations that Plaintiffs and Class Members are intended to view and rely upon to purchase PGT-A.

> **Informational Video:** Nextgen Genetics offers a pre-test PGT-A video information session with visual aids to describe the process, benefits, and risks of PGT-A. This video is available to view at https://nextgengenetics.com/pgt-a-mos-p/ and the password is ngg2338b. Any further questions before undergoing PGT-A should be addressed by a genetic counselor specializing in PGT-A.

246. In addition, the Consent Form falsely states that Defendants' PGT-A testing is 98% accurate:

> Misdiagnosis Due to Test Error: PGT though very reliable, is not a perfect technology and limitations have been described in both PGT technologies and techniques, therefore, 100% accuracy is not guaranteed, expected or possible. There remains an empirically determined 2% chance of a misdiagnosis, either by a false negative or a false positive result. A false negative result will indicate an embryo has a normal number of chromosomes when it contains a chromosomal abnormality. A false positive result will indicate an embryo is aneuploid when it is actually chromosomally normal.

247. The Consent Form simply mirrors and continues the misleading and false marketing, promotion, and advertising discussed above.

D. Defendants' Additional Material Omissions.

248. As detailed above, Defendants aggressively market PGT-A with misleading and unsupported statements while omitting material information from consumers prior to their payment for PGT-A.

249. There is no valid, independent, and properly conducted scientific research to support the idea that conducting a biopsy of an embryo does not harm implantation. However, biopsying an embryo is a prerequisite for PGT-A testing and this material fact is not disclosed by Defendants to unsuspecting and vulnerably consumers.

250. Defendants omit to inform consumers that damage to embryos caused by biopsy may be the reason for unsuccessful IVF outcomes following PGT-A.[122]

251. Defendants have also failed to inform consumers concerning the numerous scientific studies and opinions of professional organizations detailed above.

252. A tiny number of trophectoderm cells taken from one location at blastocyst—the method used by PGT-A—cannot reliably reflect whether an entire embryo is aneuploid, or will remain so, but Defendants omit this information from its marketing statements and documents intended to be reviewed by consumers in deciding whether to purchase PGT-A.[123]

253. Science has shown that the inner cell mass is more effective in self-correcting than the trophectoderm. Chromosomal abnormal embryos may self-correct downstream, which renders earlier biopsy results irrelevant, but Defendants omit this from consumers.[124]

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[122] Alteri, Alessandra. *Obstetrick neonatal and child health outcomes following embryo biopsy for preimplantation genetic testing. Human Reproduction Update*, Vol. 29, Issue 3. pp. 291-306 (2023).

[123] 8 Gleicher, N., et al., *Preimplantation Genetic Testing for Aneuploid – a Castle built on sand.* Trends in Molecular Medicine, Opinion I Special Issue: Reproductive and Sexual Health, Vol. 27, Issue 8, pp 731-742 (August 2021).

[124] Burks, C., et al., *The Technological Advances in Embryo Selection and Genetic Testing: A Look Back at the Evolution of Aneuploidy Screening and the Prospects of Non-Invasive PGT*, Reprod. Med. 2021, 2, 26-34

254. The trophectoderm – from which the placenta develops – has been known to contain aneuploid cells even in chromosomally normal pregnancies, which means that the fetus, arising from the inner cell mass, remains chromosomally normal. Defendants omit this from consumers.[125]

255. Because of the complexity introduced by mosaicism when testing an extremely small sample of cells that may or may not represent the whole embryo, there is a substantial probability that an embryo may be misdiagnosed, and the test results inaccurate. In fact, research has shown that all blastocysts exhibit mosaicism.[126] However, Defendants omit this from consumers.

256. Further, with respect to self-correction that occurs in human embryos, Defendants fail to inform consumers that biopsy at the blastocyst stage may not accurately reflect the final chromosomal outcome of embryos.

257. Defendants also omit to inform consumers concerning the false positives and false negatives that occur with PGT-A testing, and the actual rates of false positives and false negatives based on scientific research and study.

258. Scientific research has found concordance rates of reanalysis with original PGT-A results as 93.8% for euploid results, 81.4% for aneuploid results, and 42.6% for mosaic aneuploid results.[127]

259. Another scientific study suggested a potentially positive PGT-A rate of

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[125] Bolton, H., et. al., *Mouse model of chromosome mosaicism reveals lineage-specific depletion of aneuploid cells and normal development potential*. Nat Commun 7, 11165 (2016). https://doi.org/10.1038/ncomms11165.

[126] Zhai, F., et.al., *Human embryos harbor complex mosaicism with broad presence of aneuploid cells during early development. Cell Discov 10, 98 (2024)* https://doi.org/10.1038/s41421-024-00719-3

[127] *Marin, D., et al., Preimplantation genetic testing for aneuploidy: A review of published blastocyst reanalysis concordance data.* Prenatal Diagnosis. Vol. 4, Issue 5. Pp. 545-553. April 2021.

almost 55% and an intra-embryo discrepancy of almost 50% ???.[128]

260. Instead of informing consumers how errors with PGT-A testing can severely impact consumers, Defendants advises consumers against the transfer of embryos determined to be "abnormal."

E. PGT-A Has Enriched Defendants

261. The average cost of PGT-A is $5,000 per IVF cycle and is an "add-on" expense to IVF not usually covered by insurance.

262. Despite all of the scientific literature concerning PGT-A set forth above, Defendants have continued to advertise and market PGT-A to consumers as 98% accurate, increasing the chance of a healthy and successful pregnancy, increasing implantation rates, increasing live birth rates, benefiting every couple especially those of advanced maternal age, reducing the number of abnormal embryos for cryopreservation, decreasing the rate of miscarriage, and being superior to all others' testing. Each of these claims is false and misleading as described with specificity above, unsupported by scientific evidence, and made while Defendants omitted and withheld material information, again, as described above in detail.

263. Plaintiffs and Class members were harmed by paying for an unproven and unreliable test sold utilizing false statements and omissions.

264. Plaintiffs and Class members were injured at the time of sale and would not have purchased PGT-A from Defendants had they been told the truth at the time of sale concerning the body of scientific knowledge about PGT-A and each of the detailed misstatements and omissions detailed above. Each separate misstatement and omission by Defendants separately and independently give rise to the causes of

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[128] Gleicher, N., et al., *Accuracy of preimplantation genetic screening (PGS) is compromised by degree of mosaicism of huma embryos*, Reproductive Biology and Endocriniology (2016) 14:54.

action alleged below.

265. Plaintiffs and Class members suffered direct economic losses as a result of their purchase of PGT-A testing from Defendants, including but not limited to the out-of-pocket payments that each paid to Defendants for their PGT-A testing as well as additional costs associated with their PGT-A testing.

F. Eve Epstein-Ortiz's Purchase of PGT-A Testing

266. Plaintiff Epstein-Ortiz purchased PGT-A testing from Defendants in April 2023 in Tampa, Florida based upon Defendants' false and misleading statements, including that PGT-A is 98% accurate, increases the chance of a healthy and successful pregnancy, increases implantation rates, increases live birth rates, benefits every couple especially those of advanced maternal age, reduces the number of abnormal embryos for cryopreservation, decreases the rate of miscarriage, and is superior to all others' testing.

267. Plaintiff Epstein-Ortiz received and relied upon Defendants' website, materials, consent form, and videos in purchasing PGT-A from Defendants.

268. Plaintiff Epstein-Ortiz purchased Defendants' PGT-A testing based upon Defendants' omissions of material information including but not limited to that PGT-A is an unproven science and that the test had not been validated.

269. Plaintiff Epstein-Ortiz relied upon Defendants' false and misleading misrepresentations and omissions and paid approximately $1,800 plus additional costs for PGT-A testing, which she would not have purchased absent Defendants' false and misleading misrepresentations and omissions.

G. DeJanne Johnson's Purchase of PGT-A Testing

270. Plaintiff DeJanne Johnson purchased PGT-A testing from Defendants in June 2022 in San Diego, California based upon Defendants' false and misleading statements, including that PGT-A is 98% accurate, increases the chance of a

healthy and successful pregnancy, increases implantation rates, increases live birth rates, benefits every couple especially those of advanced maternal age, reduces the number of abnormal embryos for cryopreservation, decreases the rate of miscarriage, and is superior to all others' testing.

271. Plaintiff DeJanne Johnson received and relied upon Defendants' website, materials, consent form, and videos in purchasing PGT-A from Defendants.

272. Plaintiff DeJanne Johnson purchased Defendants' PGT-A testing based upon Defendants' omissions of material information including but not limited to that PGT-A is an unproven science and that the test had not been validated.

273. Plaintiff DeJanne Johnson relied upon Defendants' false and misleading misrepresentations and omissions and paid approximately $4,250 plus additional costs for PGT-A testing, which she would not have purchased absent Defendants' false and misleading misrepresentations and omissions.

H. Sandra Gamlin's Purchase of PGT-A Testing

274. Plaintiff Sandra Gamlin purchased PGT-A testing from Defendants in or around April 2024 in Richmond,Virginia based upon Defendants' false and misleading statements, including that PGT-A is 98% accurate, increases the chance of a healthy and successful pregnancy, increases implantation rates, increases live birth rates, benefits every couple especially those of advanced maternal age, reduces the number of abnormal embryos for cryopreservation, decreases the rate of miscarriage, and is superior to all others' testing.

275. Plaintiff Sandra Gamlin received and relied upon Defendants' website, materials, consent form, and videos in purchasing PGT-A from Defendants.

276. Plaintiff Sandra Gamlin purchased Defendants' PGT-A testing based upon Defendants' omissions of material information including but not limited to that PGT-A is an unproven science and that the test had not been validated.

277. Plaintiff Sandra Gamlin relied upon Defendants' false and misleading misrepresentations and omissions and paid approximately $1,000 plus additional costs for PGT-A testing, which she would not have purchased absent the false and misleading misrepresentations and omissions.

CLASS ALLEGATIONS

278. Plaintiffs bring this lawsuit individually, and pursuant to Rule 23(a), (b)(2), and (b)(3) of the Federal Rules of Civil Procedure, for economic losses, injunctive relief, and declaratory relief on behalf of all persons in the United States who have purchased PGT-A testing from Defendants (the "Nationwide Class").

279. Plaintiff Epstein-Ortiz brings this lawsuit on behalf of a class of all residents of the State of Florida who purchased PGT-A testing from Defendants (the "Florida Class").

280. Plaintiff Johnson brings this lawsuit on behalf of a class of all residents of the State of California who purchased PGT-A testing from Defendants (the "California Class").

281. Plaintiff Gamlin brings this lawsuit on behalf of a class of all residents of the State of Virginia who purchased PGT-A testing from Defendants (the "Virginia Class").

282. The Nationwide Class and the individual states Classes defined above are referred to collectively herein as the "Class."

283. Excluded from each Class are Defendants, their affiliates, employees, officers, and directors, and the Judge(s) assigned to this case.

284. Plaintiffs reserve the right to modify, change, or amend the Class definitions set forth above based on discovery and further investigation.

285. **Numerosity**. Each defined Class defined is so numerous that the joinder of all Class member is impracticable and the disposition of their claims in a class action rather than in individual actions will benefit the parties and the courts.

Plaintiffs do not presently know the exact size of each Class but this information is in Defendants' possession and will be obtained in discovery.

286. **Common Questions Exist and Predominate**. This action involves common questions of law and fact to each Class member because each member's claim derives from Defendants' false, deceptive, and misleading statements and omissions as alleged above. Such questions in common include but are not limited to:

- Whether Defendants made misstatements and omissions to Class members regarding PGT-A testing;
- Whether a reasonable consumer would consider the misstatements and omissions to be material;
- Whether a reasonable consumer would be misled by Defendants' advertising and marketing regarding PGT-A testing;
- Whether a reasonable consumer would rely upon the misstatements and omissions regarding PGT-A testing;
- Whether Defendants had knowledge of their misstatements and omissions;
- The date of Defendants' knowledge;
- Whether each of the alleged advertising misstatements described in detail above was false or misleading;
- Whether Defendants' conduct violates each of the laws set forth in the causes of action below;
- Whether Plaintiffs and the Class were harmed at the point of sale by Defendants' conduct;
- Whether Defendants violated express and/or implied promises or warranties concerning the sale of PGT-A testing; and
- Whether Defendants was unjustly enriched as a result of their conduct.

The common questions of law and fact predominate over individual questions,

as proof of a common or single set of facts will establish the right of each member of the Class to recover.

287. **Typicality**. Plaintiffs' claims are typical of the claims of other members of the Class(es) they represent because, among other things, all such claims arise out of the same unlawful course of conduct by Defendants as alleged herein. Plaintiffs and Class members each purchased PGT-A based on Defendants' misrepresentations and omissions and they all suffered economic damages as a result.

288. **Adequacy of Representation**. Plaintiffs will fairly and adequately protect the interests of all Class members. Plaintiffs have no interests in conflict with the interests of Class members. Plaintiffs have retained highly competent and experienced class action attorneys to represent their interests and those of the Class. By prevailing on their own claims, Plaintiffs will establish Defendants' liability to all Class members. Plaintiffs and their counsel have the necessary financial resources to adequately and vigorously litigate this class action and Plaintiffs and their counsel are aware of their fiduciary responsibilities to the Class members and will diligently discharge those duties.

289. **Superiority**. There is no plain, speedy, or adequate remedy other than by maintenance of this class action. The prosecution of individual remedies by Class members will tend to establish inconsistent standards of conduct for Defendants and result in the impairment of Class members' rights and the disposition of their interests through actions to which they were not parties. Class action treatment will permit a large number of similarly situated persons to prosecute their common claims in a single forum simultaneously, efficiently, and without the unnecessary duplication of effort and expense that numerous individual actions would engender. Furthermore, an important public interest will be served by addressing the matter as a class action.

290. Plaintiffs are unaware of any difficulties that are likely to be encountered in the management of this action that would preclude its maintenance as a class action.

291. **Injunctive Relief**. Class certification is also appropriate under Rule 23(b)(2) of the Federal Rules of Civil Procedure because Defendants acted and refused to act on grounds generally applicable to the class, making appropriate final injunctive relief with respect to the Class as a whole.

CAUSES OF ACTION

COUNT I
Violations of Florida Deceptive and Unfair Trade Practices Act, Fla. Stat. § 501.201, *et seq*.
(On behalf of Epstein-Ortiz and the Florida Class)

292. Plaintiffs adopt and incorporate the above paragraphs as if set forth fully here .

293. Plaintiff Epstein-Ortiz is a "consumer" within the meaning of Fla. Stat. § 501.203.

294. Defendants are engaged in "trade" and "commerce" within the meaning of Fla. Stat. § 501.203 as they market, promote, and sell PGT-A testing for sale to consumers within the State of Florida.

295. Defendants' representations were material to a reasonable consumer and likely to affect consumer decisions and conduct.

296. Defendants used and employed deceptive and unfair methods of competition and unfair or deceptive acts, practices, and or representations in the conduct of trade or commerce.

297. Defendants' acts and practices offend public policy as established by statute. Defendants' acts and practices violate the Federal Trade Commission Act, which provides that "unfair or deceptive acts or practices in or affecting commerce

. . . are . . . declared unlawful." 15 U.S.C. Sec. 45(a)(1). An act or practice is "unfair" if it "causes or is likely to cause substantial injury to consumers which is not reasonably avoidable by consumers themselves and not outweighed by countervailing benefits to consumers or to competition." 15 U.S.C. § 45(n).

298. Defendants' acts and practices are fraudulent, willful, knowing, or intentional, immoral, unethical, oppressive, and unscrupulous.

299. Defendants' conduct is substantially injurious to consumers. Such conduct has, and continues to cause, substantial economic injury to consumers because consumers would not have paid for Defendants' PGT-A testing but for Defendants' false and misleading representations, omissions, and promotion as detailed throughout this Complaint.

300. Consumers have thus paid unnecessarily for testing and such injury is not outweighed by any countervailing benefits to consumers or competition.

301. No benefit to consumers or competition results from Defendants' conduct. Since consumers reasonably rely on Defendants' representations of its services, consumers could not have reasonably avoided such injury.

302. The foregoing unfair and deceptive practices directly, foreseeably, and proximately caused Plaintiff and the Florida Class to suffer an ascertainable loss when they paid for PGT-A testing based on Defendants' false and misleading material statements and omissions.

303. Plaintiff and the Florida Class are entitled to recover damages and other appropriate relief pursuant to Fla. Stat. § 501.211 and 501.2105.

COUNT II

Violations of California Unfair Competition Law, Cal. Bus. & Prof. Code §§ 17200, *et seq*. (Unfair and Fraudulent Prongs) (On behalf of Johnson and the California Class)

304. Plaintiffs adopt and incorporate the above paragraphs as if set forth

fully here.

305. California Business & Professions Code § 17200 ("UCL") prohibits acts of "unfair competition," including any "unlawful, unfair or fraudulent business act or practice" and "unfair, deceptive, untrue or misleading advertising."

306. The acts and practices of Defendants as alleged herein constitute "unfair" business acts and practices under the UCL in that Defendants' conduct is unconscionable, immoral, deceptive, unfair, illegal, unethical, oppressive, and/or unscrupulous. Further, the gravity of Defendants' conduct outweighs any conceivable benefit of such conduct.

307. Defendants have in the course of their business, and in the course of trade or commerce, undertaken and engaged in unfair business acts and practices under the UCL by making misleading statements and omitting material information regarding the accuracy and reliability of PGT-A, and making the additional false and misleading statements and omissions alleged herein.

308. These acts also constitute "fraudulent" business acts and practices under the UCL in that Defendants' conduct is false, misleading, and has a tendency to deceive California Class members and the general public.

309. Plaintiff and the California Class members have suffered injury in fact and have lost money as a result of Defendants' fraudulent business acts or practices.

310. The above-described unfair business acts or practices present a threat and likelihood of harm and deception to Plaintiff and California Class members in that Defendants have systematically perpetrated the unfair conduct upon members of the public by engaging in the conduct described herein.

311. Pursuant to Business and Professions Code §§ 17200 and 17203, Plaintiff and California Class members seek an order providing restitution and disgorgement of all profits relating to the above-described unfair business acts or practices, and injunctive and declaratory relief as may be appropriate.

312. Because of their reliance on Defendants' misleading statements and omissions concerning Defendants' PGT-A testing, Plaintiff and California Class members suffered an ascertainable loss of money, property, and/or value, and were harmed and suffered actual damages.

313. Plaintiff and California Class members are reasonable consumers who, based on Defendants' public misleading statements and omissions as alleged herein, did not expect that Defendants' PGT-A would not be consistent with those statements.

314. Defendants' conduct in concealing and failing to disclose the inaccuracy and unreliability of PGT-A testing is unfair in violation of the UCL, because it is immoral, unethical, unscrupulous, oppressive, and substantially injurious.

315. Defendants acted in an immoral, unethical, unscrupulous, outrageous, oppressive, and substantially injurious manner.

316. The gravity of harm resulting from Defendants' unfair conduct outweighs any potential utility. The practice of falsely marketing PGT-A as accurate and reliable to consumers harms the public at large and is part of a common and uniform course of wrongful conduct.

317. Plaintiff and the California Class members suffered injury in fact, including direct economic losses, as a direct result of Defendants' unfair acts. Absent Defendants' conduct, Plaintiff would not have bought PGT-A from Defendants.

318. Through their unfair conduct, Defendants acquired money that Plaintiff and the California Class members once had ownership of.

319. Plaintiff and the California Class members accordingly seek appropriate relief under the UCL, including (a) restitution in full, and (b) such orders or judgments as may be necessary to enjoin Defendants from continuing their unfair practices.

COUNT III
Violations of California Unfair Competition Law,
Cal. Bus. & Prof. Code §§ 17200, *et seq*. (Unlawful Prong)
(On behalf of Johnson and the California Class)

320. Plaintiffs incorporate by reference all preceding allegations.

321. The UCL prohibits any "unlawful, unfair, or fraudulent business act or practice and unfair, deceptive, untrue or misleading advertising." Cal. Bus. & Prof. Code § 17200 ("UCL"). By engaging in business practices which are also illegal, Defendants have violated the UCL.

322. Defendants' "unlawful" acts and practices include breach of the implied warranty of merchantability, breach of the implied warranty of usability, fraud-based omissions, and unjust enrichment.

323. More specifically, Defendants breached applicable warranties in connection with the marketing and sale of Defendants' PGT-A testing. Defendants marketed and sold PGT-A testing to Plaintiff and the California Class members, knowing that PGT-A testing was unproven, inaccurate, and unreliable.

324. Plaintiff and the California Class members conferred tangible and material economic benefits upon Defendants by purchasing PGT-A. Plaintiff and the California Class members would not have purchased PGT-A from Defendants had they known that it was unproven, inaccurate, and unreliable.

325. Defendants reaped unjust profits, revenue, and benefits by virtue of their UCL violations. Plaintiff and California Class members seek restitutionary disgorgement of these unjust profits and revenues.

COUNT IV
Violations of California Consumer Legal Remedies Act,
Cal. Civ. Code § 1750, *et seq*.
(On behalf of Johnson and the California Class)

326. Plaintiffs incorporate by reference all preceding allegations.

327. Plaintiff Johnson is a consumer as defined by Civil Code §§ 1761(d) and 1770 and have engaged in "transaction[s]" as defined by Civil Code §§ 1761(e) and 1770.

328. Defendants are "person[s]" as defined by Civil Code §§ 1761(c) and 1770 and has provided "services" as defined by Civil Code §§ 1761(b) and 1770.

329. Defendants' acts and practices as detailed herein, violated Civil Code § 1770 by the following:

a. (2) Misrepresenting the source, sponsorship, approval, or certification of goods or services;

b. (5) Representing that services have approval, characteristics, uses, benefits, or qualities that they do not have;

c. (7) Representing that services are of a particular standard, quality, or grade; and

d. (9) Advertising services with intent not to sell them as advertised.

330. Defendants' acts and practices violated the Consumers Legal Remedies Act because they failed to disclose information that was material to Plaintiff and California Class members' relevant transactions, for example:

a. By failing to provide an accurate assessment of the state of scientific study and knowledge concerning PGT-A;

b. By failing to disclose that the value of PGT-A as a screening test for IVF patients has not been demonstrated by science;

c. By failing to have the above statements supported by properly designed research studies;

d. By failing to tell consumers that PGT-A is experimental;

e. By failing to tell consumers that PGT-A is unproven;

f. By failing to tell consumers that PGT-A results have a substantial degree of inaccuracy; and

g. By failing to tell consumers that PGT-A has a substantial degree of unreliability.

331. Defendants had ample means and opportunities to alert Plaintiffs and California Class members that PGT-A was not supported by science as claimed by Defendants' advertising, marketing, and promotional materials.

332. Despite these opportunities, Defendants failed to disclose information that was material to Plaintiff and California Class members. Had such disclosures been made, Plaintiff and California Class members would not have purchased PGT-A and relied on the results.

333. Defendants had a duty to accurately disclose the validity of PGT-A, the unsupported claims that they were making to consumers, and to accurately disclose the current state of science regarding PGT-A. Defendants had a duty to, through its advertising, marketing, and promotion of PGT-A, not mislead consumers.

334. Defendants had superior knowledge of the relevant facts and science as compared to Plaintiffs and Class members, yet actively concealed and misled consumers concerning the truth about PGT-A.

335. As a direct and proximate result of Defendants' deceptive acts and practices in violation of the Consumers Legal Remedies Act, Plaintiff and the California Class members have suffered actual damages.

336. Plaintiff and the California Class members would not have purchased PGT-A had they been told the truth by Defendants. In the meantime, Defendants generated more revenue than they otherwise would have, unjustly enriching themselves.

337. Plaintiff and the California Class members were harmed, and Defendants' misleading statements and omissions were a substantial factor in causing this harm in the form of economic losses.

338. Plaintiffs accordingly are entitled to statutory relief, equitable relief,

reasonable attorneys' fees and costs, declaratory relief, and a permanent injunction enjoining Defendants from their continued unlawful, fraudulent, and deceitful activity.

339. Pursuant to Civil Code § 1782(a), on July 3, 2024, Plaintiffs, individually and on behalf of the Class, sent a letter to all three Defendants to notify them of their CLRA violations and afford them the opportunity to correct their business practices and rectify the harm they caused. The correspondence was mailed via first class certified mail with return receipt requested. Defendants failed to correct the acts and practices detailed herein within 30 days. Therefore, Plaintiff and the California Class Members seek money damages under CLRA.

COUNT V
Violations of Virginia Consumer Protection Act (VCPA)
Va. Code Ann. § 59.1-196, *et seq*.
(On behalf of Gamlin and the Virginia Class)

340. Plaintiffs adopt and incorporate the above paragraphs as if set forth fully here.

341. Defendants are engaged in "consumer transaction" within the meaning of § 59.1-198 as they advertise and sell PGT-A testing to be used by consumers.

342. Defendants misrepresented that PGT-A testing had certain benefits;

343. Plaintiff and Class Members relied on those misrepresentations in purchasing PGT-A testing from Defendants.

344. Plaintiff and the Virginia Class are entitled to recover damages and other appropriate relief pursuant to § 59.1-204-206.

COUNT VI
Breach of the Implied Warranty of Merchantability
(On behalf of Plaintiffs and the Class)

345. Plaintiffs adopt and incorporate the above paragraphs as if set forth fully herein.

346. By operation of law, Defendants, as the provider and seller of their PGT-A testing, impliedly warranted to Plaintiffs and the Class that Defendants' PGT-A was of merchantable quality and fit for its ordinary and intended use.

347. Such implied warranty of merchantability, contained in U.C.C. § 2-314, has been codified in each state. *See, e.g.*, Ala. Code §§ 7-2-314, *et seq.*; Alaska Stat. §§ 45.02.314, *et seq.*; Ariz. Rev. Stat. Ann. §§ 47-2314, *et seq.*; Ark. Code Ann. §§ 4-2-314, *et seq.*; Cal. Com. Code §§ 2314, *et seq.*; Colo. Rev. Stat. §§ 4-2-314, *et seq.*; Conn. Gen. Stat. Ann. §§ 42a-2-314, *et seq.*; Del. Code Ann. tit. 6, §§ 2-314, *et seq.*; D.C. Code Ann. §§ 28:2-314, *et seq.*; Fla. Stat. Ann. §§ 672.314, *et seq.*; O.C.G.A. §§ 11-2-314, *et seq.*; Haw. Rev. Stat. §§ 490:2-314, *et seq.*; Idaho Code §§ 28-2-314, *et seq.*; Ill. Comp. Stat. Ann. Ch. 810, 5/2-314, *et seq.*; Ind. Code Ann. §§ 26-1-2-314, *et seq.*; Iowa Code Ann. §§ 554.2314, *et seq.*; Kan. Stat. Ann. §§ 84-2-314, *et seq.*; Ky. Rev. Stat. Ann. §§ 355.2-314, *et seq.*; La. Civ. Code Ann. art. 2520, *et seq.*; Me. Rev. Stat. Ann. tit. 11, §§ 2-314, *et seq.*; Md. Code Ann., Com. Law §§ 2-314, *et seq.*; Mass. Gen. Laws Ann. Ch. 106, §§ 2-314, *et seq.*; Mich. Comp. Laws Ann. §§ 440.2314, *et seq.*; Minn. Stat. Ann. §§ 336.2-314, *et seq.*; Miss. Code Ann. §§ 75-2-314, *et seq.*; Mo. Rev. Stat. §§ 400.2-314, *et seq.*; Mont. Code Ann. §§ 30-2-314, *et seq.*; Neb. Rev. Stat. §§ 2-314, *et seq.*; Nev. Rev. Stat. §§ 104.2314, *et seq.*; N.H. Rev. Stat. Ann. §§ 382-A:2-314, *et seq.*; N.J. Stat. Ann. §§ 12A:2-314, *et seq.*; N.M. Stat. Ann. § 55-2-314, *et seq.*; N.Y. U.C.C. Law §§ 2-314, *et seq.*; N.C. Gen. Stat. Ann. §§ 25-2-314, *et seq.*; N.D. Cent. Code §§ 41-02-31, *et seq.*; Ohio Rev. Code Ann. §§ 1302.27, *et seq.*; Okla. Stat. tit. 12A, §§ 2-314, *et seq.*; Or. Rev. Stat. §§ 72.3140, *et seq.*; 13 Pa. Stat. Ann. §§ 2314, *et seq.*; R.I. Gen. Laws §§ 6A-2-314, *et seq.*; S.C. Code Ann. §§ 36-2-314, *et seq.*; S.D. Codified Laws §§ 57A-2-314, *et seq.*; Tenn. Code Ann. §§ 47-2-314, *et seq.*; Tex. Bus. & Com. Code §§ 2.314, *et seq.*; Utah Code Ann. §§ 70A-2-314, *et seq.*; Va. Code Ann. §§ 8.2-314, *et seq.*; Vt. Stat. Ann. tit. 9A, §§ 2-314, *et seq.*; Wash. Rev. Code §§ 62A.2-314, *et*

seq.; W. Va. Code §§ 46-2-314, *et seq*.; Wis. Stat. Ann. §§ 402.314, *et seq*.; and Wyo. Stat. Ann. §§ 34.1-2-314, *et seq*.

348. Defendants breached the implied warranty of merchantability in connection with the sale of PGT-A. While Defendants advertises, markets, and promotes that their PGT-A testing is accurate and reliable, it is not, rendering it unsuitable for use.

349. Had Plaintiffs and the Class known that Defendants' PGT-A was unproven, inaccurate, and unreliable, they would not have purchased it.

350. To the extent privity may be required, Plaintiff and the Class can establish privity with Defendants because Plaintiffs purchased PGT-A from Defendants.

351. Plaintiffs and the Class may also establish privity as the intended third-party beneficiaries of agreements between Defendants and the Plaintiff's and Class Members' IVF clinics. The agreements between Defendants and Plaintiffs' and Class members' IVF clinics to use Defendants' PGT-A testing were designed and intended for the benefit of Plaintiff and Class members to make decisions about their embryos and fertility treatment. Defendants understood that Plaintiffs and Class members would require that their PGT-A testing provide reliable and accurate information regarding their embryos and Defendants delivered their PGT-A tests to Plaintiffs and Class members understanding the need to meet these requirements.

352. As a direct and proximate result of Defendants' breach of the implied warranty of merchantability, Plaintiffs and the Class have sustained damages in an amount to be determined at trial.

COUNT VII
Breach of the Implied Warranty of Usability
(On behalf of Plaintiffs and the Class)

353. Plaintiffs adopt and incorporate the above paragraphs as if set forth

fully here.

354. By operation of law, Defendants, as the seller and provider of PGT-A testing, warranted to Plaintiffs and the Class through their statements that PGT-A was usable for its ordinary and intended use.

355. Such implied warranty arises under U.C.C. § 2-314(3) as adopted in each state.

356. Such implied warranty of usability, contained in U.C.C. § 2-314, has been codified in each state. *See, e.g.*, Ala. Code §§ 7-2-314, *et seq.*; Alaska Stat. §§ 45.02.314, *et seq.*; Ariz. Rev. Stat. Ann. §§ 47-2314, *et seq.*; Ark. Code Ann. §§ 4-2-314, *et seq.*; Cal. Com. Code §§ 2314, *et seq.*; Colo. Rev. Stat. §§ 4-2-314, *et seq.*; Conn. Gen. Stat. Ann. §§ 42a-2-314, *et seq.*; Del. Code Ann. tit. 6, §§ 2-314, *et seq.*; D.C. Code Ann. §§ 28:2-314, *et seq.*; Fla. Stat. Ann. §§ 672.314, *et seq.*; O.C.G.A. §§ 11-2-314, *et seq.*; Haw. Rev. Stat. §§ 490:2-314, *et seq.*; Idaho Code §§ 28-2-314, *et seq.*; Ill. Comp. Stat. Ann. Ch. 810, 5/2-314, *et seq.*; Ind. Code Ann. §§ 26-1-2-314, *et seq.*; Iowa Code Ann. §§ 554.2314, *et seq.*; Kan. Stat. Ann. §§ 84-2-314, *et seq.*; Ky. Rev. Stat. Ann. §§ 355.2-314, *et seq.*; La. Civ. Code Ann. art. 2520, *et seq.*; Me. Rev. Stat. Ann. tit. 11, §§ 2-314, *et seq.*; Md. Code Ann., Com. Law §§ 2-314, *et seq.*; Mass. Gen. Laws Ann. Ch. 106, §§ 2-314, *et seq.*; Mich. Comp. Laws Ann. §§ 440.2314, *et seq.*; Minn. Stat. Ann. §§ 336.2-314, *et seq.*; Miss. Code Ann. §§ 75-2-314, *et seq.*; Mo. Rev. Stat. §§ 400.2-314, *et seq.*; Mont. Code Ann. §§ 30-2-314, *et seq.*; Neb. Rev. Stat. §§ 2-314, *et seq.*; Nev. Rev. Stat. §§ 104.2314, *et seq.*; N.H. Rev. Stat. Ann. §§ 382-A:2-314, *et seq.*; N.J. Stat. Ann. §§ 12A:2-314, *et seq.*; N.M. Stat. Ann. § 55-2-314, *et seq.*; N.Y. U.C.C. Law §§ 2-314, *et seq.*; N.C. Gen. Stat. Ann. §§ 25-2-314, *et seq.*; N.D. Cent. Code §§ 41-02-31, *et seq.*; Ohio Rev. Code Ann. §§ 1302.27, *et seq.*; Okla. Stat. tit. 12A, §§ 2-314, *et seq.*; Or. Rev. Stat. §§ 72.3140, *et seq.*; 13 Pa. Stat. Ann. §§ 2314, *et seq.*; R.I. Gen. Laws §§ 6A-2-314, *et seq.*; S.C. Code Ann. §§ 36-2-314, *et seq.*; S.D. Codified Laws §§ 57A-2-314, *et*

seq.; Tenn. Code Ann. §§ 47-2-314, *et seq*.; Tex. Bus. & Com. Code §§ 2.314, *et seq*.; Utah Code Ann. §§ 70A-2-314, *et seq*.; Va. Code Ann. §§ 8.2-314, *et seq*.; Vt. Stat. Ann. tit. 9A, §§ 2-314, *et seq*.; Wash. Rev. Code §§ 62A.2-314, *et seq*.; W. Va. Code §§ 46-2-314, *et seq*.; Wis. Stat. Ann. §§ 402.314, *et seq*.; and Wyo. Stat. Ann. §§ 34.1-2-314, *et seq*.

357. Defendants, by its advertising, marketing, and sale of PGT-A to Plaintiffs and the Class, impliedly warrant that its product is usable.

358. Defendants breached the implied warranty of usability in connection with its sale of PGT-A as it contained defects and suffered from issues that were not readily apparent to consumers.

359. Defendants knew or should have known that PGT-A is unproven and does not produce accurate or reliable results to such an extent that it is unusable.

360. To the extent privity may be required, Plaintiffs and the Class can establish privity with Defendants as they purchased PGT-A from Defendants.

361. Plaintiffs and the Class may also establish privity as the intended third-party beneficiaries of agreements between Defendants and the Plaintiffs' and Class Members' IVF clinics. The agreements between Defendants and Plaintiffs' and Class members' IVF clinics to use Defendants' PGT-A testing were designed and intended for the benefit of Plaintiff and Class members to make decisions about their embryos and fertility treatment. Defendants understood that Plaintiffs and Class members would require that their PGT-A testing provide reliable and accurate information regarding their embryos and Defendants delivered its PGT-A to Plaintiffs and Class members understanding the need to meet these requirements.

362. Had Plaintiffs and Class members known that they would not be able to use the results of Defendants' PGT-A testing, they would not have purchased it or would have paid significantly less for it.

363. As a direct and proximate result of Defendants' breach of the implied

warranty of usability, Plaintiffs and the Class have sustained damages in an amount to be determined at trial.

COUNT VIII
Fraud
(On behalf of Plaintiffs and Class Members)

364. Plaintiffs adopt and incorporate the above paragraphs as if set forth fully here.

365. Defendants created and implemented a scheme to market its PGT-A to increase sales through false and misleading statements and material omissions, including, for example, that:

a. Defendants' PGT-A testing is 98% accurate;

b. Defendants' PGT-A testing increases chances of a healthy and successful pregnancy;

c. Defendants' PGT-A testing increases implantation rates;

d. Defendant's PGT-A testing increases live birth rates;

e. Defendants' PGT-A testing benefits every couple, especially individuals of advanced maternal age;

f. Defendant's PGT-A reduces cryopreservation for abnormal embryos;

g. Defendants' PGT-A testing decreases the rate of miscarriage; and

h. Defendants' PGT-A testing is superior to all others.

366. Defendants' conduct was fraudulent and deceptive because its misrepresentations and omissions were likely to, and did, deceive consumers, including Plaintiffs and the Classes.

367. Defendants knew or should have known that their misrepresentations

and omissions were false and misleading and intended for consumers to rely on.

368. Plaintiffs and the Class members have been injured because they paid for PGT-A and suffered economic losses based upon the material misrepresentations and omissions of Defendants.

369. Defendants' false statements and omissions induced Plaintiffs and Class members to purchase Defendants' PGT-A.

370. Defendants' advertising, marketing, and promotion of PGT-A fraudulently concealed the truth about PGT-A as alleged herein. Accordingly, Plaintiffs and the Class could not have known that they were subject to deceptive and misleading marketing and promotion.

371. Absent Defendants' conduct, Plaintiffs and Class members would not have purchased PGT-A from Defendants and are entitled to a full refund of the purchase price and additional associated costs and economic losses. In the alternative, Plaintiffs and Class members are entitled to the difference in value between the unproven and unreliable test Plaintiffs and Class members purchased and the test Defendants advertised.

372. As a result of Defendants' false and deceptive conduct, Plaintiffs and Class members are entitled to monetary, compensatory, treble, and punitive damages, injunctive relief, restitution, and disgorgement of all moneys obtained by means of Defendants' unlawful conduct, interest, and attorneys' fees and costs.

COUNT IX
Fraud by Concealment
(On behalf of Plaintiffs and Class Members)

373. Plaintiffs adopt and incorporate the above paragraphs as if set forth fully here.

374. Defendants intentionally suppressed and concealed material facts about their PGT-A testing as alleged herein. Defendants knew about the problems and

issues with PGT-A, that it was unproven, inaccurate, and unreliable, as well as the status of scientific knowledge concerning PGT-A but failed to disclose these material facts to Plaintiffs and Class members.

375. Plaintiffs and Class members had no reasonable means of knowing that Defendants' representations concerning PGT-A were materially incomplete, false, or misleading, or that Defendants had failed to disclose relevant material facts about PGT-A. Plaintiffs and Class members did not and reasonably could not have discovered Defendants' deceit before they purchased PGT-A from Defendants.

376. Had Plaintiffs and Class members known the truth, and of the material facts that Defendants omitted to disclose to them, they would not have purchased PGT-A from Defendants and incurred economic costs.

377. Defendants had a duty to disclose the truth because the facts that Defendants chose not to disclose are material and Defendants possessed knowledge of these facts that unsuspecting and vulnerable consumers did not have.

378. Defendants were aware of the scientific studies and research concerning PGT-A as Defendants reviewed the research and publications concerning PGT-A, including from major medical associations such as ASRM.

379. Defendants had a duty to disclose the truth about PGT-A because, through Defendants' advertising, marketing, website statements, patient materials, consent form, and other written statements made to consumers, Defendants made partial representations regarding PGT-A including purported representations concerning its reliability and accuracy, but failed to disclose facts that would have materially qualified those partial representations.

380. Having volunteered purportedly scientific and research-based information relating to PGT-A to Plaintiffs and Class members, Defendants had a duty to disclose the whole truth about PGT-A and its unproven, inaccurate, and unreliable nature.

381. Each Plaintiff and Class member was exposed to Defendants' representations prior to and immediately after purchase. Each Plaintiff and Class member saw the same generalized representations as detailed herein, that were repeated by Defendants throughout their promotional materials. None of the informational sources that Plaintiffs and Class members were provided by Defendants, including advertisements, websites, brochures, or promotional materials, indicated the full truth about PGT-A testing as detailed herein.

382. Defendants concealed the truth to sell more PGT-A testing and to avoid the public finding out the truth about PGT-A.

383. The facts that Defendants suppressed and omitted were material, and Plaintiffs and Class members were unaware of them at the time of purchase. Had the facts been disclosed, Plaintiffs and Class members would not have purchased PGT-A and incurred the associated economic costs by which they were damaged.

384. When deciding whether to purchase PGT-A, Plaintiffs and Class members reasonably relied to their detriment on Defendants' material misrepresentations and omissions as detailed herein.

385. Plaintiffs and Class members sustained damages in the form of economic costs as a direct and proximate result of Defendants' deceit and fraudulent concealment.

386. Defendants' fraudulent concealment was malicious, oppressive, deliberate, intended to defraud Plaintiffs and Class members, and intended to enrich Defendants, and has been in reckless disregard of Plaintiffs' and Class members' rights, interests, and well-being. Defendants' conduct warrants an assessment of punitive damages in an amount sufficient to deter such conduct, to be determined according to proof at trial.

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COUNT X
Breach of Express Warranty
(On behalf of Plaintiffs and the Class)

387. Plaintiffs adopt and incorporate the above paragraphs as if set forth fully here.

388. By advertising and selling PGT-A testing, Defendants made promises and affirmations of fact about PGT-A testing through its marketing and advertising, consent form and test results.

389. These promises and affirmations constitute an express warranty under U.C.C. § 2-313 and became the basis for the purchase of PGT-A testing by Plaintiffs and Class members from Defendants.

390. Defendants purport, through their marketing and advertising, consent form and test results that its PGT-A testing is accurate and reliable, among other things as detailed here.

391. Despite Defendants' express warranties about accuracy and reliability, its PGT-A testing is not accurate or reliable.

392. Defendants' PGT-A testing is therefore not what Defendants represented it to be.

393. Accordingly, Defendants breached express warranties about PGT-A because its PGT-A testing does not conform to Defendants' affirmations and promises that the testing is accurate and reliable.

394. As a direct and proximate result of Defendants' breach of express warranty, Plaintiffs and the Class have sustained damages in an amount to be determined at trial.

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COUNT XI
Unjust Enrichment
(On behalf of Plaintiffs and Class Members)

395. Plaintiffs adopt and incorporate the above paragraphs as if set forth fully here.

396. Plaintiffs plead this claim in the alternative to their other claims to the extent there is no adequate remedy at law.

397. Defendants created and implemented a scheme to market for PGT-A testing to increase sales through numerous false and misleading statements and material omissions.

398. As a result, Defendants have been unjustly enriched.

399. Defendants received a measurable benefit at the expense of Plaintiffs and Class members in the form of payment for PGT-A testing.

400. Defendants accepted monetary benefits from Plaintiffs and Class members at the detriment of Plaintiffs and Class members.

401. These benefits were the result of Defendants acting in their pecuniary interest at the expense of their consumers.

402. There is no justification for Defendants' enrichment. It would be inequitable, unconscionable, and unjust for Defendants to be permitted to retain benefits because the benefits were procured because of their wrongful conduct.

403. Plaintiffs and Class members are entitled to full restitution of the benefits that Defendants unjustly received and/or any amounts necessary to return Plaintiffs and Class members to the position they occupied prior to purchasing PGT-A from Defendants.

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PRAYER FOR RELIEF

WHEREFORE, Plaintiffs, individually and on behalf of the Class, respectfully request that the Court:

a. Determine that Defendants are liable for the violations set forth above;

b. Award Plaintiffs and the Class all compensatory, statutory, restitution, and punitive damages as provided by law;

c. Grant appropriate equitable relief, including, without limitation, an order requiring Defendants to adequately disclose the true nature of PGT-A testing;

d. Certify each Class as defined herein, designating Plaintiffs as Class representatives, and appointing the undersigned counsel as Class Counsel;

e. Declare that Defendants are financially responsible for notifying the Class members of the pendency of this action;

f. Require that Defendants disgorge amounts wrongfully obtained for PGT-A testing and award injunctive relief as permitted by law or equity, including enjoining Defendants from engaging in misleading and deceptive practices going forward;

g. Schedule a trial by jury in this action on all claims so triable;

h. Award Plaintiffs' reasonable attorneys' fees, costs, and expenses, as provided by law;

i. Award Plaintiffs and Class members trebled, statutory, and/or punitive damages as authorized by law;

j. Award pre-judgment and post-judgment interest on any amounts awarded, as provided by law; and

k. Grant such further relief that the Court deems appropriate.

DEMAND FOR JURY TRIAL

Pursuant to Federal Rule of Civil Procedure 38(b), Plaintiffs request a trial by jury of all issues triable as of right.

DATED: June 26, 2025

/s/ Karen Barth Menzies

Karen Barth Menzies
Justice Law Collaborative, LLC
6701 Center Drive West, #1400
Los Angeles, California 90045
Telephone: (310) 363-0030
karen@justicelc.com

Counsel for Plaintiffs, DeJanne Johnson, Eve Epstein-Ortiz, and Sandra Gamlin

JS 44 (Rev. 03/24)

CIVIL COVER SHEET

The JS 44 civil cover sheet and the information contained herein neither replace nor supplement the filing and service of pleadings or other papers as required by law, except as provided by local rules of court. This form, approved by the Judicial Conference of the United States in September 1974, is required for the use of the Clerk of Court for the purpose of initiating the civil docket sheet. *(SEE INSTRUCTIONS ON NE T PAGE OF THIS FORM.)*

I. (a) PLAINTIFFS

DeJanne Johnson, Eve Epstein-Ortiz, and Sandra Gamlin

(b) County of Residence of First Listed Plaintiff San Diego
(E CEPT IN U.S. PLAINTIFF CASES)

(c) Attorneys *(Firm Name, Address, and Telephone Number)*

See attached.

DEFENDANTS

Luminary Genetics f/k/a NextGen Genetics, LLC, and Luminary Life Sciences

County of Residence of First Listed Defendant Santa Clara
(IN U.S. PLAINTIFF CASES ONL)

NOTE: IN LAND CONDEMNATION CASES, USE THE LOCATION OF THE TRACT OF LAND INVOLVED.

Attorneys *(If Known)*

'25CV1629 WQHBLM

II. BASIS OF JURISDICTION *(Place an in One Box Only)*

- ☐ 1 U.S. Government Plaintiff
- ☐ 3 Federal Question *(U.S. Government Not a Party)*
- ☐ 2 U.S. Government Defendant
- ☒ 4 Diversity *(Indicate Citizenship of Parties in Item III)*

III. CITIZENSHIP OF PRINCIPAL PARTIES *(Place an in One Box for Plaintiff and One Box for Defendant)*
(For Diversity Cases Only)

	PTF	DEF		PTF	DEF
Citizen of This State	☐ 1	☐ 1	Incorporated *or* Principal Place of Business In This State	☐ 4	☒ 4
Citizen of Another State	☒ 2	☐ 2	Incorporated *and* Principal Place of Business In Another State	☐ 5	☐ 5
Citizen or Subject of a Foreign Country	☐ 3	☐ 3	Foreign Nation	☐ 6	☐ 6

IV. NATURE OF SUIT *(Place an in One Box Only)* Click here for: Nature of Suit Code Descriptions.

CONTRACT	TORTS		FORFEITURE/PENALTY	BANKRUPTCY	OTHER STATUTES
☐ 110 Insurance	PERSONAL INJURY	PERSONAL INJURY	☐ 625 Drug Related Seizure of Property 21 USC 881	☐ 422 Appeal 28 USC 158	☐ 375 False Claims Act
☐ 120 Marine	☐ 310 Airplane	☐ 365 Personal Injury - Product Liability	☐ 690 Other	☐ 423 Withdrawal 28 USC 157	☐ 376 Qui Tam (31 USC 3729(a))
☐ 130 Miller Act	☐ 315 Airplane Product Liability	☐ 367 Health Care/ Pharmaceutical Personal Injury Product Liability		INTELLECTUAL PROPERTY RIGHTS	☐ 400 State Reapportionment
☐ 140 Negotiable Instrument	☐ 320 Assault, Libel & Slander	☐ 368 Asbestos Personal Injury Product Liability		☐ 820 Copyrights	☐ 410 Antitrust
☐ 150 Recovery of Overpayment & Enforcement of Judgment	☐ 330 Federal Employers' Liability	PERSONAL PROPERTY	LABOR	☐ 830 Patent	☐ 430 Banks and Banking
☐ 151 Medicare Act	☐ 340 Marine	☐ 370 Other Fraud	☐ 710 Fair Labor Standards Act	☐ 835 Patent - Abbreviated New Drug Application	☐ 450 Commerce
☐ 152 Recovery of Defaulted Student Loans (Excludes Veterans)	☐ 345 Marine Product Liability	☐ 371 Truth in Lending	☐ 720 Labor/Management Relations	☐ 840 Trademark	☐ 460 Deportation
☐ 153 Recovery of Overpayment of Veteran's Benefits	☐ 350 Motor Vehicle	☐ 380 Other Personal Property Damage	☐ 740 Railway Labor Act	☐ 880 Defend Trade Secrets Act of 2016	☐ 470 Racketeer Influenced and Corrupt Organizations
☐ 160 Stockholders' Suits	☐ 355 Motor Vehicle Product Liability	☐ 385 Property Damage Product Liability	☐ 751 Family and Medical Leave Act	SOCIAL SECURITY	☐ 480 Consumer Credit (15 USC 1681 or 1692)
☐ 190 Other Contract	☐ 360 Other Personal Injury		☐ 790 Other Labor Litigation	☐ 861 HIA (1395ff)	☐ 485 Telephone Consumer Protection Act
☐ 195 Contract Product Liability	☐ 362 Personal Injury - Medical Malpractice		☐ 791 Employee Retirement Income Security Act	☐ 862 Black Lung (923)	☐ 490 Cable/Sat TV
☐ 196 Franchise				☐ 863 DIWC/DIWW (405(g))	☐ 850 Securities/Commodities/ Exchange
				☐ 864 SSID Title XVI	☒ 890 Other Statutory Actions
				☐ 865 RSI (405(g))	☐ 891 Agricultural Acts
					☐ 893 Environmental Matters
				FEDERAL TAX SUITS	☐ 895 Freedom of Information Act
				☐ 870 Taxes (U.S. Plaintiff or Defendant)	☐ 896 Arbitration
				☐ 871 IRS—Third Party 26 USC 7609	☐ 899 Administrative Procedure Act/Review or Appeal of Agency Decision
					☐ 950 Constitutionality of State Statutes

REAL PROPERTY	CIVIL RIGHTS	PRISONER PETITIONS	IMMIGRATION
☐ 210 Land Condemnation	☐ 440 Other Civil Rights	Habeas Corpus:	☐ 462 Naturalization Application
☐ 220 Foreclosure	☐ 441 Voting	☐ 463 Alien Detainee	☐ 465 Other Immigration Actions
☐ 230 Rent Lease & Ejectment	☐ 442 Employment	☐ 510 Motions to Vacate Sentence	
☐ 240 Torts to Land	☐ 443 Housing/ Accommodations	☐ 530 General	
☐ 245 Tort Product Liability	☐ 445 Amer. w/Disabilities - Employment	☐ 535 Death Penalty	
☐ 290 All Other Real Property	☐ 446 Amer. w/Disabilities - Other	Other:	
	☐ 448 Education	☐ 540 Mandamus & Other	
		☐ 550 Civil Rights	
		☐ 555 Prison Condition	
		☐ 560 Civil Detainee - Conditions of Confinement	

V. ORIGIN *(Place an in One Box Only)*

- ☒ 1 Original Proceeding
- ☐ 2 Removed from State Court
- ☐ 3 Remanded from Appellate Court
- ☐ 4 Reinstated or Reopened
- ☐ 5 Transferred from Another District *(specify)*
- ☐ 6 Multidistrict Litigation - Transfer
- ☐ 8 Multidistrict Litigation - Direct File

VI. CAUSE OF ACTION

Cite the U.S. Civil Statute under which you are filing ***(Do not cite jurisdictional statutes unless diversity)***:
28 U.S.C. Section 1332(d)(2)(A); 28 U.S.C. Section 1367; 28 U.S.C. § 1391(b)(2)

Brief description of cause:
False, deceptive, unfair and misleading advertising marketing, and promotion of Defendants' preimplantation genetic testing for aneuploidy (PGT-A)

VII. REQUESTED IN COMPLAINT:

☒ CHECK IF THIS IS A **CLASS ACTION** UNDER RULE 23, F.R.Cv.P.

DEMAND $ >$5,000,000.00

CHECK YES only if demanded in complaint:
JURY DEMAND: ☒ Yes ☐ No

VIII. RELATED CASE(S) IF ANY *(See instructions):*

JUDGE _____ DOCKET NUMBER _____

DATE
Jun 26, 2025

SIGNATURE OF ATTORNEY OF RECORD
/s/Karen Barth Menzies

FOR OFFICE USE ONLY

RECEIPT # _____ AMOUNT _____ APPLYING IFP _____ JUDGE _____ MAG. JUDGE _____

Attachment to Civil Cover Sheet

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