IN THE UNITED STATES DISTRICT COURT
FOR THE DISTRICT OF NEW JERSEY

ADRIAN ANDERSON, AMANDA MALKIN, and MAUREEN EWING individually and on behalf of all others similarly situated, Plaintiffs, v. GENOMIC PREDICTION, INC. and GENOMIC PREDICTION CLINICAL LABORATORY Defendants.	Case No. **CLASS ACTION COMPLAINT** DEMAND FOR JURY TRIAL

Plaintiffs Adrian Anderson, Amanda Malkin, and Maureen Ewing ("Plaintiffs"), 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 Genomic Prediction, Inc. and Genomic Prediction Clinical Laboratory ("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 its 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. In addition to making misrepresentations as detailed herein, there are circumstances in which non-disclosure or concealment may constitute actionable fraud, and the facts set forth below demonstrate that in marketing to Plaintiffs and Class members, Defendants made partial representations while suppressing material facts. 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 each 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, from 368,502 in 2021 to 389,993 in 2022.

6. The demand for IVF is growing, thus providing economic opportunity 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.

10. Defendants market its PGT-A testing product, LifeView, directly to individual consumers.

11. Defendants also market its PGT-A testing product to clinics and clinicians.

12. Individual consumers going through the IVF process must decide whether to purchase PGT-A testing prior to the testing being performed.

13. If PGT-A testing is purchased by individual consumers as an add-on to the IVF process from Defendants, the IVF clinic performs a biopsy and sends a small number of cells from the embryo to Defendants' laboratory.

14. Defendants perform PGT-A testing on its testing product LifeView and provides results to the customer and their clinic.

15. 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.

16. PGT-A testing is marketed and sold by Defendants to people pursuing IVF as the most advanced genetic screening available, increasing pregnancy rates, lowering miscarriage rates, reducing the number of cycles of IVF needed, reducing the number of wasted transfers, increasing the chance of success, increasing the chance of a healthy child, leading to more euploid embryos and more embryos available for transfer, and increasing the chances of a successful pregnancy. Defendants also market and sell their PGT-A testing as 98 to 99% accurate with a lower false positive and false negative rate. Based on these material representations and the material omissions that underlay them as detailed below, Plaintiffs and Class members choose to purchase PGT-A testing from Defendants as an add-on to their IVF treatment.

17. PGT-A testing does occur as part of the IVF process until after it is purchased from Defendants by the Plaintiffs and Class members.

18. The above representations by Defendants are false and/or 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 advertised or disclosed.

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

20. Insurance companies have independently determined that there is insufficient basis to support the use of PGT-A. Thus, a PGT-A test 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.

21. 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]

22. Likewise, another large health insurance company, Aetna, states that PGT-A tests are "experimental, investigational, or unproven."[2]

23. 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.

24. Embryos that are assigned an "abnormal" or "aneuploid" testing result (*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.

25. Despite scientific research and studies showing insufficient evidence of efficacy, the use of PGT-A 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.

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

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[1] United Healthcare Commercial and Individual Exchange Medical Policy, Preimplantation Genetic Testing and Related Services, effective date July 1, 2025.
[2] *See* https://www.aetna.com/cpb/medical/data/300_399/0358.html.

27. Defendants have known for years that there is insufficient evidence of efficacy of PGT-A, and that PGT-A does not improve pregnancy rates, lower miscarriage rates, reduce the number of cycles of IVF needed, reduce the number of wasted transfers, increase the chance of success of a healthy child, lead to more euploid embryos and more embryos available for transfer. Despite that, Defendants have continued to aggressively promote PGT-A tests to vulnerable and unsuspecting consumers.

28. Defendants have known for years that their PGT-A tests are not 98-99% accurate and have a lower false positive rate and false negative rate.

29. Defendants have acted to mislead customers 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 tests.

30. Plaintiffs and Class members 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.

31. 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

32. Plaintiff Adrian Anderson is a resident of Cincinnati, Ohio and received fertility treatment fertility in San Diego, California.

33. Plaintiff Amanda Malkin is a resident of Boca Raton, Florida and received fertility treatment in Boca Raton, Florida.

34. Plaintiff Maureen Ewing is a resident of Doylestown, Pennsylvania and received fertility treatment in Fort Washington, Pennsylvania.

35. Defendant Genomic Prediction, Inc. is a company incorporated in Delaware with its headquarters at 700 Grand Avenue, Unit 1, Hackettstown, NJ 07840.

36. Genomic Prediction, Inc. performs PGT-A testing utilizing its LifeView product through Genomic Prediction Clinical Laboratory, Inc.

37. Defendant Genomic Prediction Clinical Laboratory, Inc. is a company incorporated in Delaware with its location at 700 Grand Avenue, Unit 1, Hackettstown, NJ 07840.

38. Defendants market, advertise, and promote the sale of their PGT-A testing in New Jersey and throughout the United States.

JURISDICTION AND VENUE

39. This Court has subject matter jurisdiction over this action pursuant to the Class Action Fairness Act, 28 U.S.C. Section 1332(d)(3)(B) and (D) 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) some Plaintiffs and Class members and Defendants are residents of different states.

40. This Court has supplemental jurisdiction over Plaintiffs' state law claims pursuant to 28 U.S.C. § 1367.

41. 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 New Jersey. 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 New Jersey. Defendants have engaged, and continue to engage, in substantial and continuous business practices in the State of New Jersey and across the country.

42. Venue is proper in this District pursuant to 28 U.S.C. § 1391(b)(2) because a substantial part of the events or omissions giving rise to the claims occurred in the State of New Jersey, including within this District.

SUBSTANTIVE ALLEGATIONS

A. Background Concerning IVF

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

44. 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.

45. 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 she is 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.

46. 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.

47. The extracted eggs are then fertilized with sperm in a laboratory to create embryos.

48. If a PGT-A test 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.

49. If a PGT-A test product is purchased from Defendants, then 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.

50. 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.

51. The biopsy is sent to Defendants' laboratory for a PGT-A test to be performed.

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

53. Test results are then provided by Defendants to the IVF clinic and the IVF patient.

54. If Plaintiffs and Class members were aware of the true efficacy and accuracy rates of PGT-A testing, they would have forgone such testing.

55. 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.

56. 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.

57. 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.

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

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

60. Defendants' PGT-A tests sold to Plaintiffs and Class members has substantial ramifications including, without limitation, the costs that are paid for such testing, and the additional costs of related procedures.

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

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

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

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

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

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

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

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

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

70. In selling PGT-A to consumers, Defendants represent that their PGT-A testing (a) is the most advanced genetic screening available; (b) increases pregnancy rates; (c) lowers miscarriage rates; (d) reduces the number of cycles of IVF needed; (e) reduces the number of wasted transfers; (f) increases your chance of success and a healthy child; (g) leads to more euploid embryos and more embryos available for transfer; (h) increases chances of a successful pregnancy; (i) has a lower false positive rate and false negative rate; and (j) is 98-99% accurate.

71. These representations are false and misleading, and Plaintiffs and Class members would not have purchased PGT-A testing from Defendants had they known the truth about PGT-testing, which Defendants misrepresented and materially omitted. Defendants further made these misrepresentations while suppressing material facts as set forth in detail below.

B. History of PGT-A

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

73. 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.[3]

74. 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.

75. 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.

76. In fact, as of 2025, there have been no randomized, properly structured, non-commercial trials conducted to support the basis of Defendant's marketing.

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

78. This method, described as PGS 1.0, became increasingly popular despite that researchers in 2005 were still unable to demonstrate outcome benefits.[4]

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

[4] 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 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.

79. 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.[5]

80. 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.[6]

81. The same outcome was found in a review of the available research, when it was determined in 2009 that prevalent chromosome instability in all early human cleavage stage embryos provides a biological basis for the failure of cleavage stage PGS in improving birth rates per embryo transferred.[7]

82. Due to the lack of expected benefit from aneuploidy screening, in November 2010, Nathan Treff and a team released a study indicating that they had developed a whole genome amplification and single nucleotide polymorphism (SNP) microarray protocol for accurate single cell 24 chromosome aneuploidy screening, a new diagnostic tool in the IVF arena.[8]

83. It was noted that extensive preclinical validation and accuracy of assessment of the technology was needed, including performance of prospective, randomized and blinded

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[5] 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).
[6] *Id*.
[7] Vanneste, E., et al., *What next for preimplantation genetic screening? High mitotic chromosome instability rate provides the biological basis for the low success rate.* Human Reproduction, Vol. 24, Issue 11 (2009).
[8] Treff, N., et al., *Accurate single cell 24 chromosome aneuploidy screening using whole genome amplification and single nucleotide polymorphism microarrays.* Fertility and Sterility, Vol. 94, No. 6, November 2010.

nonselection trials investigating the clinical positive and negative probative value for reproductive potential as well as randomized clinic trials of SNP microarray-based aneuploidy screening.[9]

84. According to the authors, the results of these trials would be critical when considering whether to use this or any new comprehensive screening technology in a clinical setting.[10]

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.[11]

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.[12]

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.[13]

88. The authors cautioned that new approaches in the application of PGS should be carefully evaluated before introduction into clinical practice.[14]

89. In a 2013 paired randomized clinical trial on 116 patients, scientists sought to evaluate if cleavage[15] or blastocyst stage embryo biopsy affects reproductive competence.[16]

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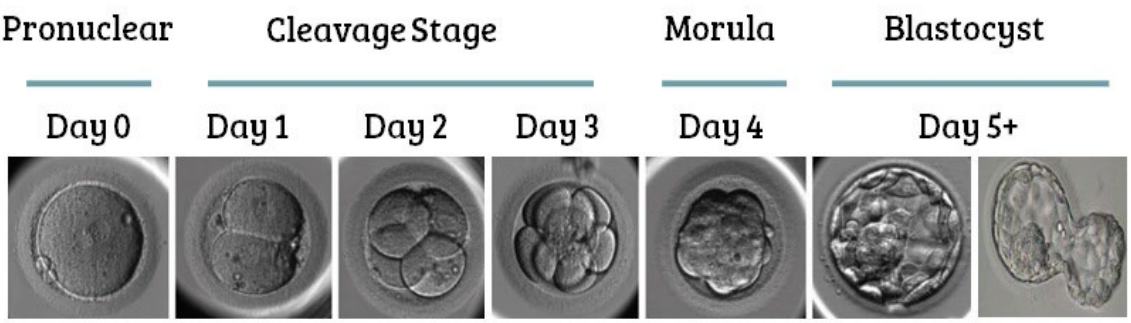
[9] *Id.*
[10] *Id.*
[11] Mastenbroek, S. *Preimplantation genetic screening: a systemic review and meta-analysis of RCTs*. Human Reproduction Update, Vol.17, No.4, 454-466 (2011).
[12] *Id.*
[13] *Id*.
[14] *Id.*
[15] Cleavage stage refers to embryos at day 2-3 while blastocyst refers to embryos at day 5-6.
[16] 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.



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.[17]

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.[18]

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.

[17] *Id.*
[18] *Id.*

97. The embryonic cells form the inner cell mass ("ICM") of the blastocyst, 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 test 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, whether PGS 2.0 provides the information claimed,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, however, did not happen.

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

105. In a 2016 study, researchers tested embryos that had previously been tested and deemed aneuploid.[19] 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.[20]

106. 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%.[21]

107. 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.[22]

108. Based upon their findings, the authors urged careful reassessment of PGS considering its increasing use.[23]

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[19] 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.
[20] *Id*.
[21] *Id.*
[22] *Id*.
[23] *Id*.

109. 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.[24]

110. In yet another study in 2016, researchers re-biopsied 37 embryos determined to be "abnormal" and found that 33% of embryos originally reported to be "aneuploid" were found to be "euploid" upon repeat assessment.[25] This study further demonstrated PGS testing's inability to accurately differentiate between euploidy and aneuploidy of any given embryo.

111. 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.[26]

112. The findings suggested that it may be biologically impossible to accurately assess an embryo's viability with a single trophectoderm biopsy at blastocyst stage.[27]

113. 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.

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[24] 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.
[25] 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).
[26] 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.
[27] *Id.*

114. 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.

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

116. 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.

117. PGDIS was cofounded by Yuri Verlinsky, who created a genetic testing company, Reproductive Genetic Innovations, Inc. ("RGI"), and Santiago Munne, who also co-founded the genetic testing companies, Reprogenetics and Recombine and worked as the Chief Scientific Officer of CooperGenomics in 2016 and 2017.

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

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

120. Research conducted the following year in 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.[28]

121. 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

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

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.[29]

122. Instead of undertaking randomized and properly structured studies regarding the accuracy and efficiency of PGT-A testing, Defendant Genomic Predictions, Inc. was incorporated on May 1, 2017 to release to market a variation of PGT-A which screens embryos with claimed higher sensitivity and accuracy, lower cost, and an easier protocol than existing tests.[30]

123. At the time of incorporation, Defendant had not conducted the extensive preclinical validation and accuracy of assessment of their technology, including performance of prospective, randomized and blinded nonselection trials investigating the clinical positive and negative probative value for reproductive potential as well as randomized clinic trials of SNP microarray-based aneuploidy screening as discussed in their earlier 2011 research.[31]

124. Prior to selling PGT-A tests to the public, Defendant never confirmed that its PGT-A tests provide the information it markets the test can provide.

125. 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.[32] The author estimated that the proportion of normal embryos that are discarded based upon faulty results may be as high as

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[29] *Id*.
[30] https://www.njeda.gov/genomic-prediction-moves-to-ccit-cites-array-of-resources-and-ideal-location-as-factors/ (last visited August 18, 2025).
[31] *Id.*
[32] Paulson, R., *Preimplantation genetic screening: what is the clinical efficiency?* Fert. Ster. Vo. 108 No. 2, August 2017.

40%. The author noted that this would lead to an overall decrease in the cumulative pregnancy rate achievable.[33]

126. 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.[34]

127. The author commented, "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."[35] The author called for registered, randomized, properly structured, non-commercial trials before clinical application of a technology that can lead to such devastating consequences like viable embryo destruction.

128. 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."[36]

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

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[33] *Id.*
[34] 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.
[35] *Id.*
[36] 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.

130. Notably, research which purported to demonstrate the value of PGT-A in 2018 by looking at the pregnancy outcomes from more than 1,800 IVF cycles with the use of PGT-A testing with SNP stated that a limitation of the 2018 study was that it was not randomized.[37]

131. In addition, the researchers stated that "the data presented in this study are not sufficient to demonstrate the absolute impact of SNP-based PGT-A on IVF outcomes".[38]

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.[39]

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.[40]

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 improve IVF outcomes."[41]

135. The co-founder, chief science office, and clinical laboratory director of Defendants, Nathan Treff, published research in 2019 which he indicated validated concurrent preimplantation genetic testing for aneuploidy. However, the research was only based upon 48 rebiopsies. [42]

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[37] Simon, A., et.al., *Pregnancy outcomes from more than 1,800 in vitro fertilization cycles with the use of 24-chromosome single-nucleotide polymorphism-based preimplantation genetic testing for aneuploidy.* Fertility and Sterility. Vol. 110, Issue 1. July 2018.
[38] *Id.*
[39] 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.
[40] *Id.*
[41] Orvieto, R., *Preimplantation genetic testing for aneuploidy (PGT-A- finally revealed*. Journal of Assisted Reproduction and Genetics (2020) 37-669-672.
[42] Treff, Nathan, et al., *Validation of concurrent preimplantation genetic testing for polygenic and monogenic disorders, structural rearrangements, and whole and segmental chromosome aneuploidy with a single universal platform.* European Journal of Medical Genetics. 62 (2019).

136. Further, the researchers stated in support of their findings that "PGT has been successfully used to reduce miscarriage and increase success rates following IVF" and that this was due to PGT-A being validated by several randomized control trials.[43]

137. However, in support of this statement, the researchers cited to research conducted in 2013 comparing the transfer of one tested embryo to two non-tested embryos which revealed similar ongoing pregnancy rates and thus, did not prove the success of PGT-A.[44]

138. Further, the researchers cited to studies conducted in 2012 and 2013 which were performed on a small number of good prognosis patients with testing which differs from the type of PGT-A testing performed by Defendants and thus, cannot be used to support Defendants' claims.[45] The study by Yang in 2012 was conducted utilizing array comparative genomic hybridization and the study by Scott in 2013 was conducted with quantitative Polymerase Chain Reaction–based Comprehensive Chromosome Screening.[46]

139. In 2020, Dr. Richard Paulson cautioned about PGT-A being actively marketed as a mature technology by overstating its benefits and underestimating its losses.[47]

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[43] *Id.*
[44] *Id.* citing Forman, Eric, et al., *In vitro fertilization with single euploid blastocyst transfer: a randomized controlled trial.* Fertility and Sterility. Vol. 100, Issue 1 (2013).
[45] *Id.* citing Scott, R.T., et al., *Blastocyst biopsy with comprehensive chromosome screening and fresh embryo transfer significantly increases in vitro fertilization implantation and delivery rates: a randomized control trial.* Fertility and Sterility. Vol and Yang, Z., et al., *Selection of single blastocysts for fresh transfer via standard morphology assessment alone and with array CGH for good prognosis IVF patients: results from a randomized pilot study.* Mol. Cytogenet. 5, 24 (2012).
[46] *Id.*
[47] 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).

140. 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.[48]

141. The American College of Obstetricians and Gynecologists' (ACOG) Committee Opinion release in March 2020 raised similar concerns. Notably, ACOG noted that the three randomized control studies on the clinical effectiveness of PGT-A that reported higher pregnancy rates in younger patients with no previous failed IVF attempts were small studies with substantial limitations.[49]

142. ACOG also determined that a randomized control study which found women aged 38 to 41 had higher birth rates and lower miscarriage rates after PGT-A was problematic because 32% of the patients in the PGT-A group did not have an embryo to transfer.[50]

143. ACOG cited to ASRM's 2018 determination that "there is insufficient evidence to recommend the routine use of preimplantation genetic testing-aneuploidy in all infertile women" and concluded that the ideal genetic platform to analyze all chromosomes had not yet been established.[51]

144. ACOG also stated that worldwide randomized controlled trials were needed to determine, which patient cohorts, if any, may benefit from PGT-A and that, in concordance with

[48] *Id.*
[49] Committee on Genetics of the American College of Obstetricians and Gynecologists. *ACOG Committee Opinion – Preimplantation Genetic Testing*. Number 799. March 2020.
[50] *Id.*
[51] *Id.*

ASRM, there was insufficient evidence to recommend routine use of PGT-A in all infertile women.[52]

145. In conclusion, ACOG determined future research was necessary to establish the overall clinical utility for PGT-A, the subset of patients that may benefit from PGT-A, the clinical significance of mosaicism, and the residual risk for aneuploidy in PGT-A screened embryos.[53]

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

147. 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.[54]

148. These findings suggested that patient educational materials concerning PGT-A may not always be comprehensible or clear to all patients. Lack of 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.[55]

149. Additional research in 2020 also continued to show that live birth rates for PGT-A should be calculated per cycle, instead of per transfer.[56] The authors of the 2020 study found that

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[52] *Id.*
[53] *Id*.
[54] 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).
[55] Yang, H., et al., *Preimplantation genetic testing for aneuploidy: Challenges in clinical practice*, Human Genomics, article 69 (2022).
[56] 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).

PGT-A resulted in a lower chance of live birth in all age groups compared to transfer of embryos without PGT-A.[57]

150. A study released in June 2021, compared PGT-A utilizing next-generation sequencing (NGS) with PGT-A utilizing single-nucleotide polymorphism array analysis (SNP).[58]

151. SNP is the type of PGT-A testing utilized by the Defendants.

152. The study revealed a higher spontaneous abortion rate with SNP than NGS and a lower live birth rate with SNP than NGS.[59]

153. 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.[60]

154. 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."[61]

155. 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."[62]

156. The authors of the study concluded:

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[57] *Id*.
[58] Xiao, M., et al., *Next-Generation Sequencing Is More Efficient at Detecting Mosaic Embryos and Improving Pregnancy Outcomes than Single-Nucleotide Polymorphism Array Analysis.* The Journal of Molecular Diagnostics. Vol. 23, Issue 6, pp. 710-718 (June 2021).
[59] *Id.*
[60] Yan, J., et al., *Live Birth with or without Preimplantation Genetic Testing for Aneuploidy*, N. Engl. J. Med. 385;22, November 25, 2021.
[61] *Id.*
[62] *Id*. at 2054.

a. Trophectoderm biopsy may be harmful;[63]

b. No benefit for PGT-A regardless of age on cumulative live-birth rate;[64] and

c. No benefit for PGT-A for ongoing pregnancy and live birth rates after first frozen embryo transfer.[65]

157. 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 thus unsuitable for transfer, that ultimately will 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. Whether PGT-A improves live birth outcomes has yet to be proven.[66]

158. Despite these findings, Defendants continued to advertise and 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.

159. Despite these findings, Defendants continued to advertise and misrepresent material information that PGT-A could provide to patients that was and is not supported by science.

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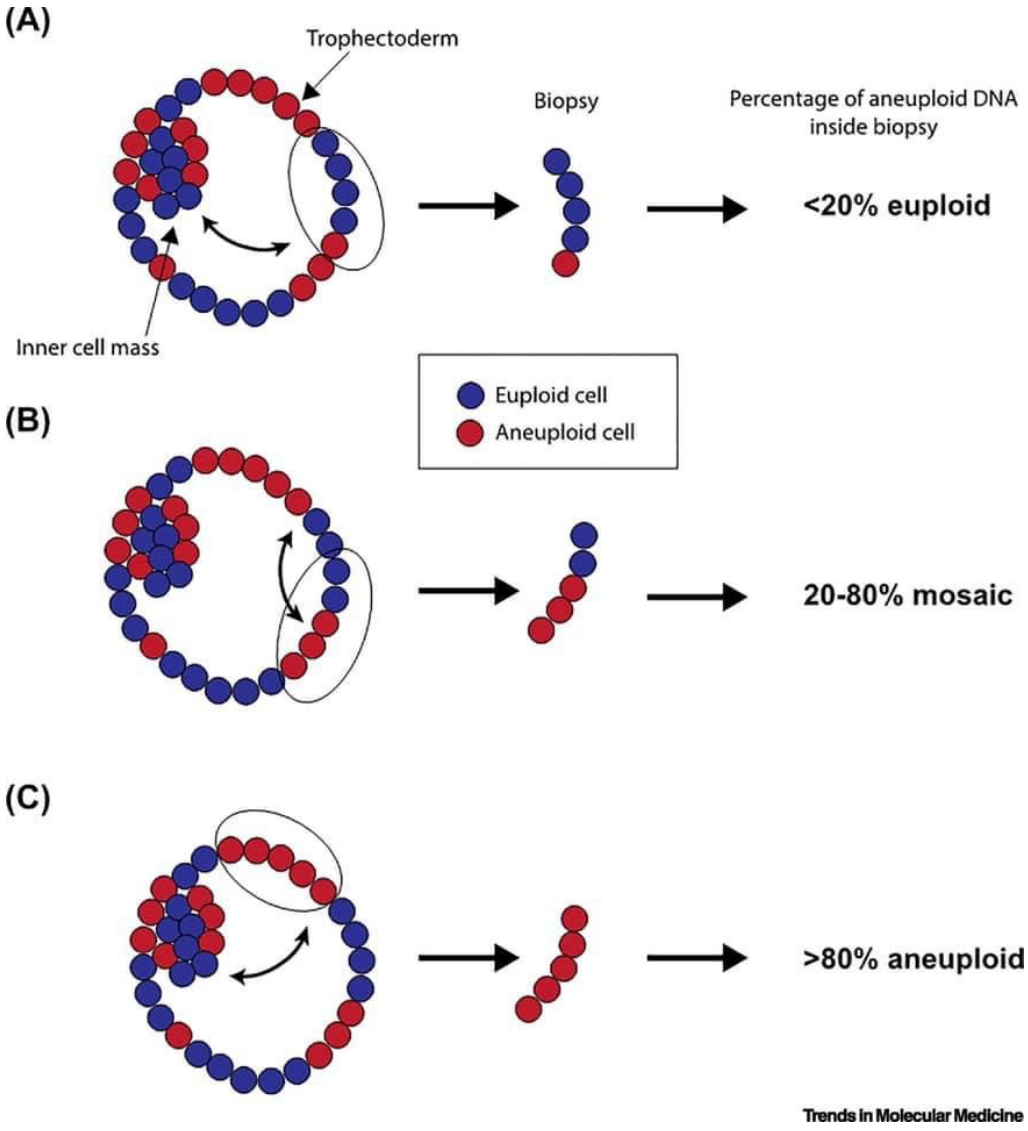
[63] *Id*., at 2056.
[64] *Id.*
[65] *Id*.
[66] Burks, C., et al., *The Technological Advances in Embryo Selection and Genetic Testing: A Look Back at the Evolution of Aneuploidy Screening and the Prospects of Non-Invasive PGT*, Reprod. Med. 2021, 2, 26-34.

160. 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.[67]

161. 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.

162. 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:[68]

[67] Coorens, et al., *Inherent mosaicism and extensive mutation of human placentas*. Nature 592, 80-85 (2021).
[68] 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).



163. 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.[69]

[69] 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).

164. Also in 2022, a retrospective cohort study was published comparing cumulative live birth rates between embryo transfers with or without PGT-A.[70] 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.[71]

165. 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."[72]

166. 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."[73]

167. Defendants, however, continued to advertise and market PGT-A based upon live birth rates per embryo transfer thereby excluding from analysis any IVF cycles without transferable embryos. As a result, Defendants artificially and materially inflated and misrepresented the utility of PGT-A on increasing pregnancy rates, increasing the chance of success, increasing the chances of a healthy child, and increasing the chances of a successful pregnancy.

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[70] 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.
[71] *Id*.
[72] *Id*.
[73] *Id*.

168. Another article published in Human Genomics called for regulatory oversight, recognizing that PGT-A had regrettably become a routine add-on for IVF 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.[74]

169. 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.[75]

[74] Yang, H., et al., *Preimplantation genetic testing for aneuploidy: challenges in clinical practice*, Human Genomics (2022)16.69.
[75] 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.

170. The researchers noted that the euploid rate suggested that chaotic abnormal results on PGT-A have "reduced predictive value."[76]

171. 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%.[77]

172. 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.[78]

173. Based upon his findings, Dr. Casper raised concerns that PGT-A caused irreparable harm to patients with diminished ovary reserve who lost their only chance to have a baby from their cycle of IVF.[79]

174. 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.[80]

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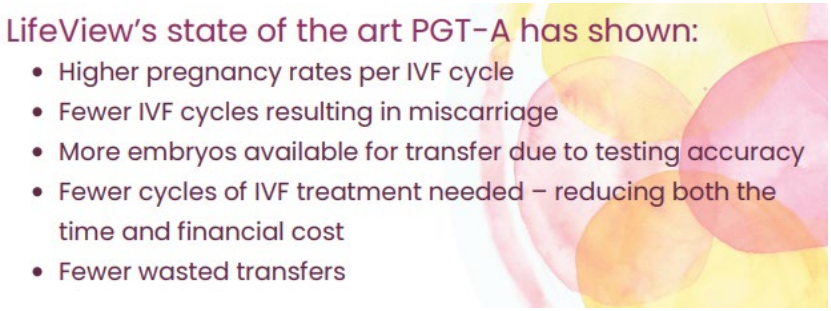
[76] *Id.*
[77] Lim, Joshua, et al., *Corcordance of Repeat Biopsy Results Among Embryos with 6 or More Aneuploidies*. Fertility and Sterility. Vol. 120, Issue 4. October 2023.
[78] Casper, R. *PGT-A in patients with a single blastocyst.* Journal of Assisted Reproduction and Genetics, v. 40, p. 1227 (2023).
[79] *Id*.
[80] Lundin, K., et al., *Good Practice Recommendations on Add-Ons in Reproductive Medicine*. Human Reproduction. Vol, 38, Issue 11. November 2023.

175. 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 embryos.

176. Then 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."[81]

177. Patients with unexplained recurrent implantation failure are precisely the type of vulnerable and unsuspecting consumers that Defendants are targeting and marketing to with its misleading statements that PGT-A reduces miscarriage rates and increases the chances of a live birth. [82]



178. The authors of the October 2023 retrospective cohort study also 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";

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;

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[81] 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.

[82] https://irp.cdn-website.com/ab108d98/files/uploaded/PGT-A_flyer.pdf (last visited August 18, 2025).

c. Trials targeting older women found no improvement in the cumulative live birth rate after PGT-A.

d. PGT-A should be applied with caution.[83]

179. Again, researchers determined that high quality randomized clinical trials are needed to find patients with indications that would benefit from PGT-A.[84]

180. Defendants have not conducted such studies.

181. Defendants have not conducted any studies to establish that its tests provide the material information it claims to provide.

182. Instead, Defendants have continued to falsely and misleadingly market and advertise the purported capabilities of PGT-A as described herein without a valid and proven scientific basis to support and validate its claims.

183. 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).[85]

184. Defendants omitted this material fact in its advertising and marketing materials, including those received, reviewed, and relied upon by Plaintiffs and Class Members.

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[83] 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.

[84] *Id.*

[85] 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.

185. 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.[86]

186. 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.[87]

187. In support of the importance of acknowledging the risks associated with PGT-A, the authors cited to the Human Fertilisation & Embryology Authority ("HFEA"), which is the United Kingdom's government's independent regulator of fertility treatment and research involving human embryos.[88]

188. 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.[89]

189. 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."[90]

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[86] *Id.*
[87] 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.
[88] *Id*.
[89] https://www.hfea.gov.uk/treatments/explore-all-treatments/frequently-asked-questions-about-pre-implantation-genetic-testing-for-aneuploidy-pgt-a/ (last visited September 26, 2024).
[90] *Id.*

190. Further, the HFEA cautions that PGT-A can cause damage to the embryo thereby preventing it from developing once transferred to the womb, and that PGT-A has the possibility of misdiagnosis.[91]

191. 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.[92]

192. 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".[93]

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[91] *Id.*

[92] https://www.hfea.gov.uk/treatments/treatment-add-ons/pre-implantation-genetic-testing-for-aneuploidy-pgt-a/ (last visited September 26, 2024).

[93] 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.

193. 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 detected in the PGT-A testing.[94]

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

195. 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.[95]

196. In 2023, prenatal testing determined that out of 250 pregnancies, only 3 had the same mosaic abnormality as the PGT-A testing result.[96]

197. In May 2024 and then in September 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.[97]

198. ASRM noted that despite early single-center studies reporting higher birth rates after PGT-A in the primary embryo transfer of favorable-prognosis patients, two recent,

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[94] 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

[95] 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.

[96] 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.

[97] 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.

multicenter, randomized control trials concluded that overall pregnancy outcomes in frozen embryo transfers were similar between conventional IVF and PGT-A.[98]

199. According to ASRM, there have been few well-designed studies providing high-quality evidence regarding IVF pregnancy outcomes in select populations with PGT-A.[99]

200. This position was supported by Dr. Viville and Dr. Aboulghar who reviewed the studies supporting PGT-A testing and determined that all the studies were based upon criterion which implied the exclusion of a large number of attempts.[100]

201. The doctors noted the several studies, on the other hand, concluded that overall pregnancy outcomes per one cycle were similar between PGT-A and conventional IVF and that PGT-A is actually associated with lower live birth rates.[101]

202. ASRM also indicated that the value of PGT-A to lower the risk of miscarriage is unclear.[102]

203. ASRM concluded that the studies had important limitations and questions remained about appropriate patient selection and testing platforms.[103]

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[98] *Id.*
[99] *Id.*
[100] Viville, S. and Aboulghar, M., *PGT-A: what's it for, what's wrong?* Journal of Assisted Reproduction and Genetics. Vol. 42, pp. 63-69 (2025).
[101] *Id. citing* Viotti M, Victor AR, Barnes FL, Zouves CG, Besser AG, Grifo JA, et al. *Using outcome data from one thousand mosaic embryo transfers to formulate an embryo ranking system for clinical use.* Fertility Sterilility. 2021;115:1212–24; Viotti M, Greco E, Grifo JA, Madjunkov M, Librach C, Cetinkaya M, et al. *Chromosomal, gestational, and neonatal outcomes of embryos classified as a mosaic by preimplantation genetic testing for aneuploidy.* Fertility Sterilility. 2023;120:957–66; Cornelisse S, Zagers M, Kostova E, Fleischer K, van Wely M, Mastenbroek S. Preimplantation genetic testing for aneuploidies (abnormal number of chromosomes) in in vitro fertilisation. Cochrane Database Syst Rev. 2020;9:CD005291.
[102] *Id.*
[103] *Id.*

204. Defendants omitted these material facts in its advertising materials.

205. 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.[104]

206. However, these studies have not been conducted.

207. Thus, based upon the research available, ASRM concluded, as it had in 2018, that PGT-A in all infertile patients undergoing IVF cannot be recommended.[105]

208. Still, Defendants continue to promote widespread use and sale of its PGT-A product.

209. Following the 2024 committee opinion by ASRM and SART, 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.[106]

210. Specifically, the 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.[107]

211. Despite the lack of supporting research and scientific basis as well as the recommendations of ASRM and SART, Defendants have continued to aggressively market and

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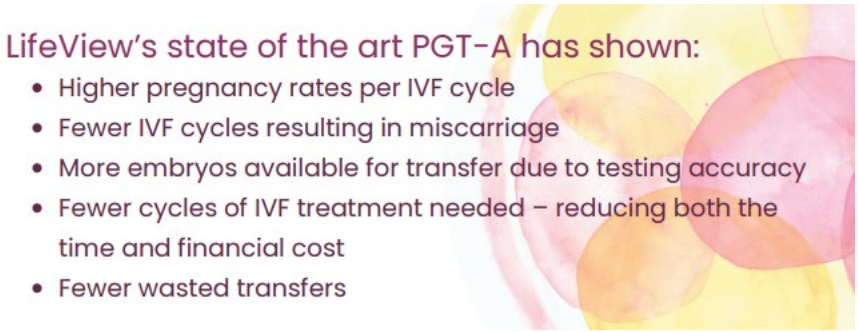
[104] *Id.*
[105] *Id.*
[106] Tikhonov, A., et al., *Re-Examination of PGT-A Detected Genetic Pathology in Compartments of Human Blastocysts: A Series of 23 Cases*. Journal of Clinical Medicine. 2024; 13(11):3289. https://doi.org/10.3390/jcm13113289.
[107] *Id.*

promote PGT-A as having benefits, capabilities and properties that it does not have and has omitted the disclosure of material and relevant information to consumers.

212. Despite the lack of supporting research and scientific basis as well as 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 while suppressing material facts and omitting material and relevant information from consumers.[108]



213. 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.

214. Plaintiffs and Class members could not have known that Defendants' representations were false as Defendants are the expert in the field in which they operate.

C. Defendants Have Utilized False And Misleading Statements To Increase Sales Of PGT-A

215. 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.

[108] https://irp.cdn-website.com/ab108d98/files/uploaded/PGT-A_flyer.pdf (last visited August 22, 2025).

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

217. Defendants' false and misleading statements concerning its PGT-A, include, without limitation, the following:

a. Defendants' PGT-A testing is the most advanced genetic screening available;

b. Defendants' PGT-A testing is 98-99% accurate;

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

d. Defendants' PGT-A testing lowers miscarriage rates;

e. Defendants' PGT-A testing reduces the number of cycles of IVF needed;

f. Defendants' PGT-A testing reduces the number of wasted transfers;

g. Defendants' PGT-A testing increases the chance of success;

h. Defendants' PGT-A testing increases the chance of a healthy child;

i. Defendants' PGT-A testing leads to more euploid embryos and embryos available for transfer;

j. Defendants' PGT-A testing increases the chance of a successful pregnancy;

k. and

l. Defendants' PGT-A testing has a lower false positive and false negative rate.

218. In making these claims to sell, promote and market its PGT-A testing, Defendants provided no valid studies, clinical validation or support for its claims.

219. The only validation that Defendants have provided is published research in 2019 based upon the results of only 48 rebiopsies. [109]

220. The research made no findings regarding clinical validation to determine whether the testing results were accurately represented in live births or healthy babies. Rather, it simply determined whether the rebiopsy result matched the prior result.[110]

221. Further, Defendants suppressed material facts and concealed and omitted material information from consumers, including, without limitation:

a. By failing to disclose an accurate assessment of the state of scientific study and knowledge concerning PGT-A, of which Defendants are aware;

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.

222. 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.

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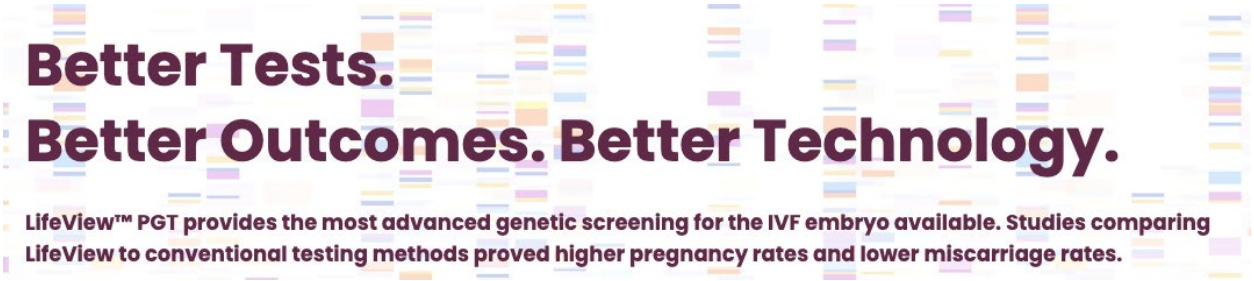
[109] Treff, Nathan, et al., *Validation of concurrent preimplantation genetic testing for polygenic and monogenic disorders, structural rearrangements, and whole and segmental chromosome aneuploidy with a single universal platform.* European Journal of Medical Genetics. 62 (2019).
[110] *Id.*

1. Defendants Falsely State That Their PGT-A Testing Is The Most Advanced Genetic Screening Available

223. Defendants' PGT-A flyer for clinics and patients claims that their PGT-A testing is better with better outcomes.[111]

224. Defendants' website claims their PGT provides the most advanced genetic screening available.[112]



225. Defendants even provide a graph showing how their outcomes are better over two other common PGT laboratories.[113]

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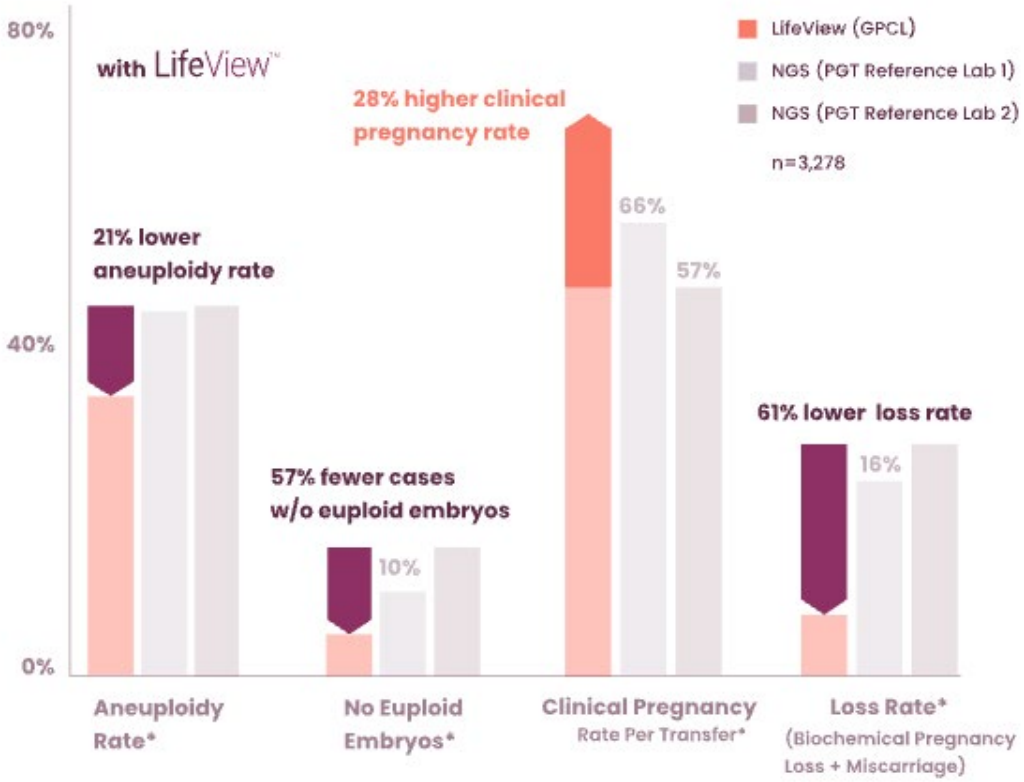
[111] https://irp.cdn-website.com/ab108d98/files/uploaded/PGT-A_flyer.pdf (last visited August 18, 2025).
[112] https://www.lifeview.com/platform (last visited August 18, 2025).
[113] https://www.lifeview.com/platform (last visited August 18, 2025).

BETTER OUTCOMES

LifeView vs Next-Generation Sequencing

Below is a graph of three different labs that perform preimplantation genetic testing (PGT) on IVF embryos. The orange bar represents Genomic Prediction's Clinical Laboratory where LifeView is used. The other two bars in the graph represent two other commonly used PGT laboratories.



226. Defendants know this statement is false and misleading as there is no valid and scientifically supportable evidence to show that Defendants' PGT-A is a better test or the most advanced genetic screening available.

227. The only comparison of PGT-A results between laboratories that has been conducted was of 4 national laboratories in 2023.[114]

228. 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.[115] Thus, it is unknown whether Defendants' PGT-A testing was included.

229. Further, multiple studies have determined that next generation sequencing is more efficient and has improved outcomes compared to SNP array analysis, which is the type of PGT-A platform utilized by Defendants for testing.[116]

2. Defendants Falsely State That Their PGT-A Testing Is 98-99% Accurate

230. Defendants' PGT-A flyer for clinics and patients claim that their PGT-A testing is 98-99% accurate.[117]

- It has an accuracy rate of 98-99%.

231. Also in its consent form, Defendants misleadingly state that their PGT-A testing has a diagnostic accuracy of 98 to 99%.[118]

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[114] 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).
[115] *Id.*
[116] Xia, M., et al., *Next-Generation Sequencing is More Efficient at Detecting Mosaic Embryos and Improving Pregnancy Outcomes than Single-Nucleotide Polymorphism Array Analysis. Journal of Molecular Diagnostics,* Vol. 23, Issue 6. (June 2021); Niu, W., et al., *Improved clinical outcomes of preimplantation genetic testing for aneuploidy using MALBAC-NGS compared with MDA-SNP array. BMC Pregnancy and Childbirth,* 20, 388 (2020).
[117] https://irp.cdn-website.com/ab108d98/files/uploaded/PGT-A_flyer.pdf (last visited August 18, 2025).
[118] Genomic Prediction Informed Consent for Preimplantation Genetic Testing.

Accuracy:
The diagnostic accuracy of PGT-A is 98-99%.

232. Not only do Defendants fail to provide support for this assertion but it is 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.[119]

233. Another scientific study suggested a potential false positive PGT-A rate of almost 55% and an intra-embryo discrepancy of almost 50%.[120]

234. The only non-selection study performed was on a testing assay which differs from the one utilized by Defendants and specifically stated that validation needs to be performed on each assay.[121]

235. Defendants improperly rely on research which specifically states that it does not apply to other assays.[122]

236. Defendants' assay has never been properly validated to determine its accuracy, but this fact has been suppressed by Defendants and not disclosed to clinics, doctors, Plaintiffs and Class members.

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[119] 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.

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

[121] 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.

[122] *Id.*

237. In fact, multiple studies have determined that next generation sequencing is more efficient and has improved outcomes compared to SNP array analysis, which is the type of PGT-A platform utilized by Defendants for testing.[123]

238. Only Defendants have knowledge of whether its testing platform has been validated and materially omitted this information from clinics, doctors, Plaintiffs and Class members.

239. Rather, Defendants improperly rely on research which specifically states that it does not apply to other assays such as the one utilized by Defendants for its PGT-A testing.[124]

3. Defendants Falsely State That Its' PGT-A Testing Increases Pregnancy Rates

240. Defendants' website misleadingly states that its PGT-A testing increases pregnancy rates.[125]

> **LifeView™ PGT provides the most advanced genetic screening for the IVF embryo available. Studies comparing LifeView to conventional testing methods proved higher pregnancy rates and lower miscarriage rates.**

241. Defendants also claims in its flyer, provided to clinics and patients, that their PGT-A testing has proven higher pregnancy rates.[126]

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[123] Xia, M., et al., *Next-Generation Sequencing is More Efficient at Detecting Mosaic Embryos and Improving Pregnancy Outcomes than Single-Nucleotide Polymorphism Array Analysis. Journal of Molecular Diagnostics,* Vol. 23, Issue 6. (June 2021); Niu, W., et al., *Improved clinical outcomes of preimplantation genetic testing for aneuploidy using MALBAC-NGS compared with MDA-SNP array. BMC Pregnancy and Childbirth,* 20, 388 (2020).
[124] *Id.*
[125] https://www.lifeview.com/platform (last visited September 8, 2025).
[126] https://irp.cdn-website.com/ab108d98/files/uploaded/PGT-A_flyer.pdf (last visited August 18, 2025).

LifeView's state of the art PGT-A has been proven to show:

- Higher pregnancy rates per IVF cycle

242. Published scientific results, however, 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.[127]

243. Defendants' false and misleading claim also contradicts scientific research that PGT-A use in older patients may instead reduce pregnancy and live birth chances.[128]

244. Further, 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."[129]

245. Researchers looking across age groups have further found no benefit for PGT-A regardless of age on cumulative live-birth rate.[130]

246. Defendants' false and misleading statements promoting the use of PGT-A are also in direct contradiction to the ASRM which has concluded that PGT-A has showed no improvement in live birth rates.[131]

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[127] 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).
[128] Gleicher, N, Orvieto, R. *Is the hypothesis of preimplantation genetic screening (PGS) still supportable? A review*. Journal of Ovarian Research (2017) 10:21.
[129] 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.
[130] Yan, J., et al., *Live Birth with or without Preimplantation Genetic Testing for Aneuploidy*, N. Engl. J. Med. 385;22, November 25, 2021.
[131] Practice Committee of the American Society for Reproductive Medicine and the Genetic Counseling Professional Group. *Clinical management of mosaic results from preimplantation*

247. Finally, there are no studies to show Defendants' PGT-A testing platform has proven higher pregnancy rates over conventional testing methods. [132]

248. Defendants have conducted no studies to prove its PGT-A testing product increases pregnancy rates and so it boasts unproven claims.

4. Defendants Falsely State That Its' PGT-A Testing Lowers Miscarriage Rates

249. Defendants falsely claim in its advertising materials and statements to clinics, doctors and consumers that its PGT-A decreases the chance of miscarriage and lowers loss rate by 61% over two other "commonly used PGT laboratories.[133]

genetic testing for aneuploidy of blastocysts: a committee opinion. Fertility and Sterility. Vol. 120, No. 5. November 2023.

[132] Xia, M., et al., *Next-Generation Sequencing is More Efficient at Detecting Mosaic Embryos and Improving Pregnancy Outcomes than Single-Nucleotide Polymorphism Array Analysis. Journal of Molecular Diagnostics,* Vol. 23, Issue 6. (June 2021); Niu, W., et al., *Improved clinical outcomes of preimplantation genetic testing for aneuploidy using MALBAC-NGS compared with MDA-SNP array. BMC Pregnancy and Childbirth,* 20, 388 (2020).

[133] https://www.lifeview.com/platform (last visited September 8, 2025).

250. Defendants know these statements and material omissions are false and misleading in light of the scientific research that there is no clear evidence resulting from valid scientific studies to show that PGT-A decreases the chance of miscarriage.[134]

251. In fact, 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.[135]

[134] 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. *See also* 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.

[135] 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.

252. ACOG has also determined that a randomized control study which found women aged 38 to 41 had higher birth rates and lower miscarriage rates after PGT-A was problematic because 32% of the patients in the PGT-A group did not have an embryo to transfer.[136]

5. Defendants Falsely State That Its PGT-A Testing Reduces the Number of Cycles of IVF Needed and Results in Fewer Wasted Transfers

253. Defendants' flyer makes misleading claims that its PGT-A testing results in fewer cycles of IVF needed, thereby reducing time and cost, and fewer wasted transfers.[137]

254. However, Defendants know these claims are false and misleading as there is no valid scientific research to support this false and misleading statement, and in fact, research shows that utilizing PGT-A does not decrease time to pregnancy or result in fewer wasted transfers.[138]

255. Research has 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.[139]

6. Defendants Falsely State That Its PGT-A Testing Increases the Chance of Success and the Chance of Successful Pregnancy

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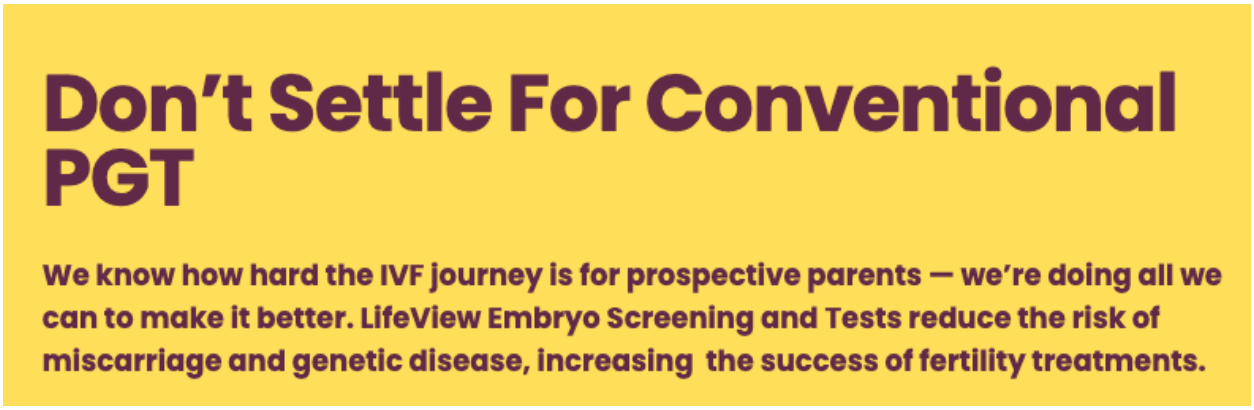
[136]Committee on Genetics of the American College of Obstetricians and Gynecologists. *ACOG Committee Opinion – Preimplantation Genetic Testing*. Number 799. March 2020.
[137] https://irp.cdn-website.com/ab108d98/files/uploaded/PGT-A_flyer.pdf (last visited September 8, 2025).
[138] Palmer, M., et al., *Preimplantation Genetic Testing For Aneuploidy and Time to Pregnancy*. Fertility and Sterility. Vol. 114, Issue 3. September 2020.
[139] Casper, R. *PGT-A in patients with a single blastocyst.* Journal of Assisted Reproduction and Genetics, v. 40, p. 1227 (2023).

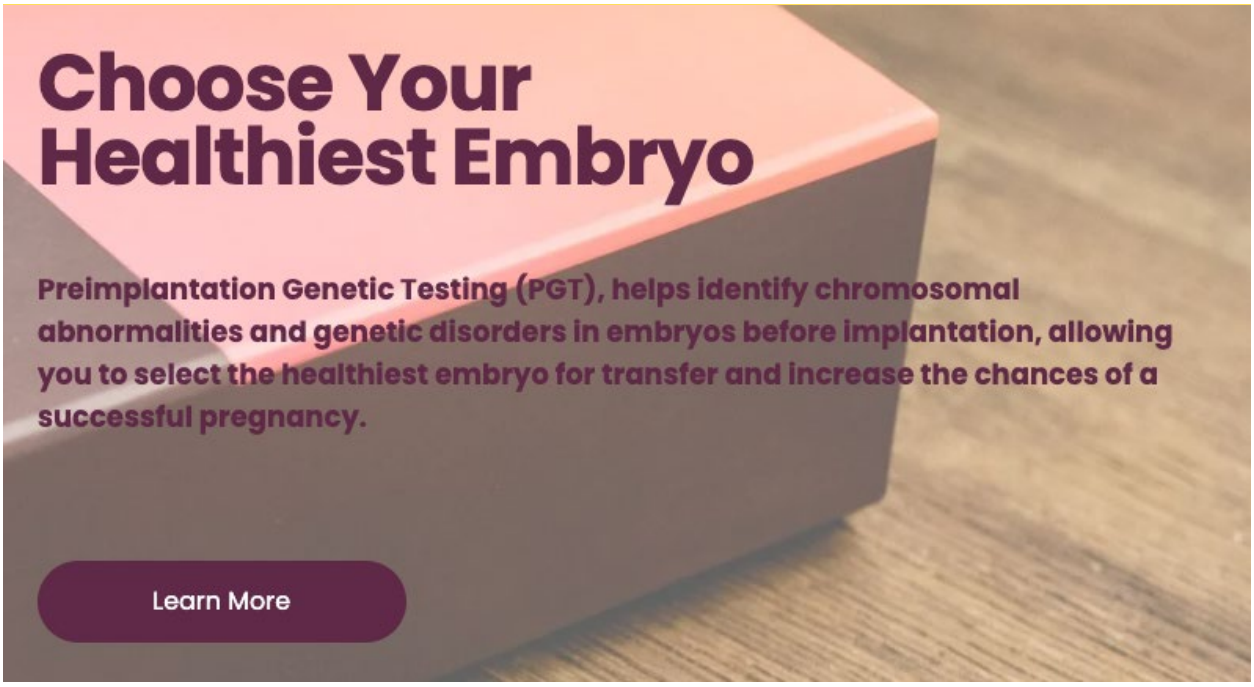
256. Defendants' website falsely claims their PGT-A testing increases the chance of successful fertility treatments over "conventional PGT".[140]



257. Notably, to support their claims, Defendants issued research in 2021 implying their testing is more accurate than other platforms. However, the research was limited to testing where parental DNA was also available and it only applied to labeling of embryos, not clinical outcomes.[141]

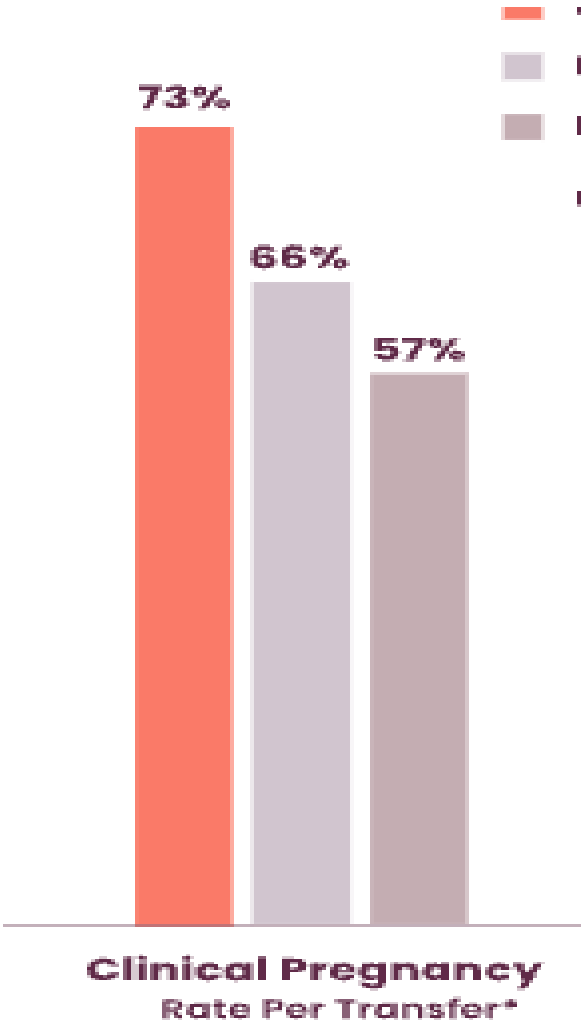
[140] https://www.lifeview.com/ (last visited September 8, 2025).
[141] Marin, Diego, et al., Accurate Genomic Prediction of Mosaicism Through Cell Division Origin oof Aneuploidy Analysis in the Preimplantation Embryo. Fertility and Sterility. Vol. 116, Issue 3. (September 2021).

258. Defendants' website also falsely claims their PGT-A testing increases the chance of a successful pregnancy.[142]



259. Further, Defendants' website falsely claims an increase in clinical pregnancy over two other testing laboratories.[143]

[142] https://www.lifeview.com/patients (last visited September 8, 2025).
[143] https://lifeview.com/platform (last visited September 8, 2025).



260. Defendants conducted no studies to prove its PGT-A testing increases IVF success and so it boasts unproven claims. Again, Defendants suppressed this material fact from clinics, physicians, Plaintiffs and Class members while at the same time making the misrepresentations set forth herein.

261. Defendants make knowingly false statements and omits material information from clinics, physicians and consumers, as there is no valid and scientifically supportable evidence to show that PGT-A improves the success of IVF, and in light of all the studies described above. [144]

262. Researchers looking across age groups have further found no benefit for PGT-A regardless of age on cumulative live-birth rate.[145]

263. Defendants' false and misleading statements promoting the use of PGT-A are also in direct contradiction to the ASRM which has concluded that PGT-A has showed no improvement in live birth rates.[146]

264. In fact, research in 2016 had already shown that PGT-A *decreased* live birth rates when compared to IVF without testing.[147]

7. Defendants Falsely State That Its PGT-A Testing Increases the Chance Of A Healthy Child

265. Defendants' website misleadingly claims that its PGT-A testing increases the chance of a healthy child.[148]

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[144] 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).

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

[146] 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.

[147] 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.

[148] https://lifeview.com/platform (last visited September 8, 2025).

266. Defendants know these representations are false and misleading to consumers, and omits 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 similar between conventional IVF and PGT-A.[149]

[149]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.

267. Research has 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.[150]

268. Further, it has been determined that PGT-A testing cannot accurately predict the inner cell mass.[151]

8. Defendants Falsely State That Its PGT-A Testing Leads to More Euploid Embryos and Embryos Available for Transfer

269. Defendants' website misleadingly claims there are more embryos available for transfer with their PGT-A.

270. This claim is false, deceptive, and misleading as research has proven that trophectoderm biopsy cannot predict the inner cell mass.[152]

271. Further, research has determined that PGT-A does not change the embryo.[153]

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

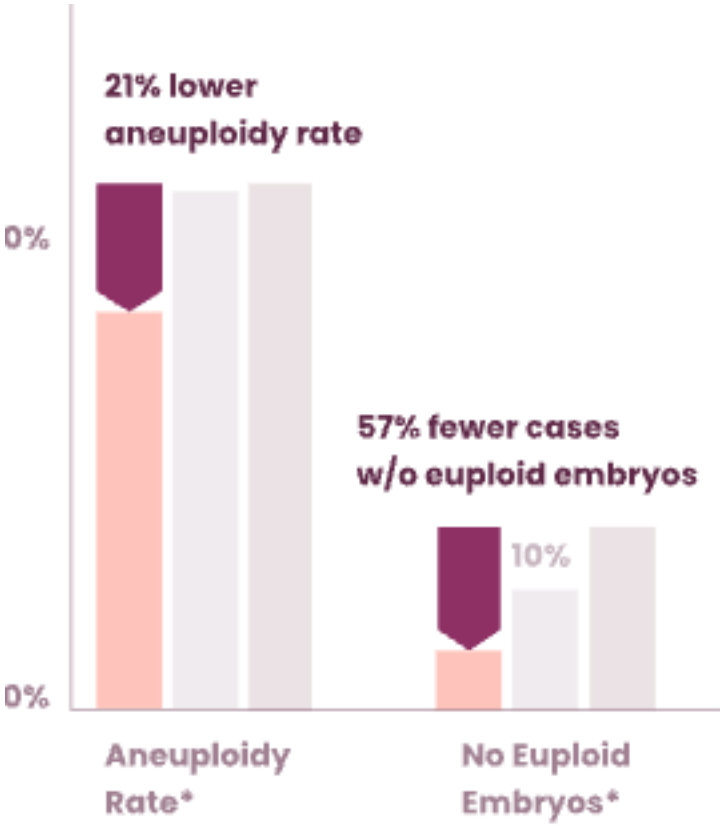
[151] Gleicher, N., et al., Preimplantation Genetic Testing for Aneuploid – a Castle built on sand. Trends in Molecular Medicine, Opinion I Special Issue: Reproductive and Sexual Health, Vol. 27, Issue 8, pp 731-742 (August 2021).

[152] 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).

[153] 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

272. Despite research to the contrary, Defendants simply published their own review of the data implying that because other testing platforms incorrectly determined that embryos were mosaic, their testing platform is somehow better because they do not provide mosaic results.[154]

273. Defendants also misleadingly claim their testing leads to a 21% less aneuploidy rate and 57% fewer cases with no euploid embryos.[155]



[154] Treff, N. and Marin, D., *The "mosaic" embryo: misconceptions and misinterpretations in preimplantation genetic testing for aneuploidy.* Fertility and Sterility. Vol. 116, Issue 5, pp. 1205-1211 (November 2021).
[155] https://www.lifeview.com/platform (last visited September 8, 2025).

274. However, the only comparison of PGT-A results between laboratories that has been conducted was of 4 national laboratories in 2023.[156]

275. 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.[157] Thus, it is unknown whether Defendants' PGT-A testing was included.

276. Further, multiple studies have determined that next generation sequencing is more efficient and has improved outcomes compared to SNP array analysis, which is the type of PGT-A platform utilized by Defendants for testing.[158]

277. Thus, the claim made by Defendants that its PGT-A testing leads to more euploid embryos and embryos for transfer is misleading and false.

278. In addition, this claim is impossible given the inner cell mass predictability and is unvalidated by the research.

9. Defendants Falsely State That Its PGT-A Testing Has Lower False Positive and False Negative Rate

279. Defendants' website claims their testing has improved accuracy.[159]

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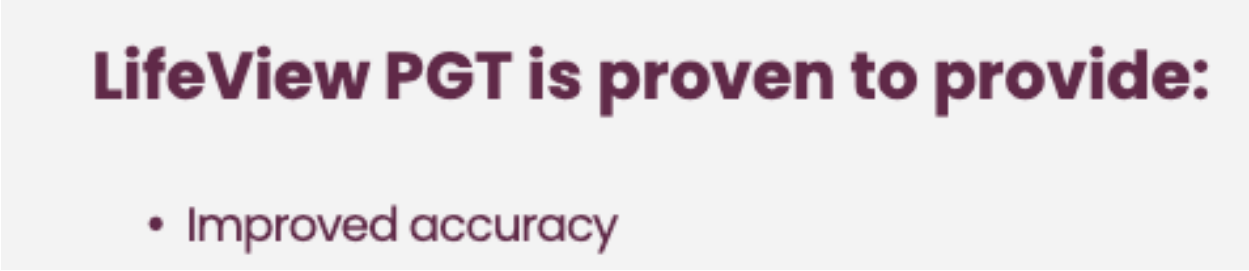
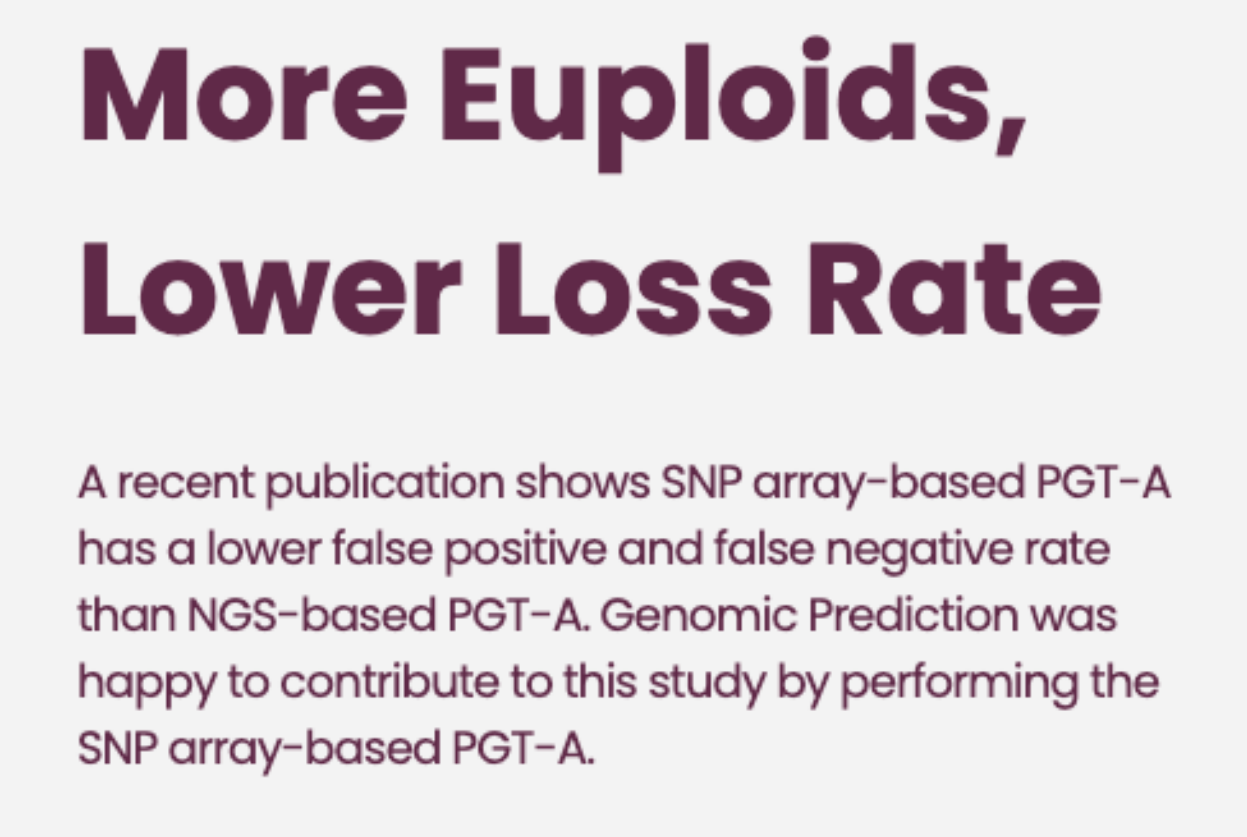
[156] Bardos, J., et.al. *Reproductive genetics laboratory may impact euploid blastocyst and live birth rates: A comparison of 4 national laboratories' PGT-A results from vitrified donor oocytes*. Fert. Ster. 119(1) pp. 23-35 (Ja.n 2023).
[157] *Id.*
[158] Xia, M., et al., *Next-Generation Sequencing is More Efficient at Detecting Mosaic Embryos and Improving Pregnancy Outcomes than Single-Nucleotide Polymorphism Array Analysis. Journal of Molecular Diagnostics,* Vol. 23, Issue 6. (June 2021); Niu, W., et al., *Improved clinical outcomes of preimplantation genetic testing for aneuploidy using MALBAC-NGS compared with MDA-SNP array. BMC Pregnancy and Childbirth,* 20, 388 (2020).
[159] https://lifeview.com (last visited September 8, 2025).



280. Defendants also falsely claim their testing has a lower false positive and false negative rate than NGS based PGT-A testing.[160]



281. Defendants know these claims are false and misleading.

[160] https://lifeview.com/platform (last visited September 8, 2025).

282. There are no valid, independent, and properly conducted scientific research supporting that their testing is more accurate or has a lower false positive and false negative rate.

283. Defendants published their own review of data agreeing there are "controversies over the efficacy of PGT-A" and that "better methods are needed with fewer false positives".

284. However, this research does not prove that Defendants' testing is more accurate or has a lower false positive rate than other testing platforms.[161]

285. Rather, multiple studies have determined that next generation sequencing is more efficient and has improved outcomes compared to SNP array analysis, which is the type of PGT-A platform utilized by Defendants for testing.[162]

D. Defendants' Additional Material Omissions

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

287. Defendants fail to inform clinics, physicians and consumers concerning the numerous scientific studies and opinions of professional organizations detailed above.

288. Defendants inform consumers that a PGT-A biopsy is taken from the trophectoderm but does not inform consumers that science shows that the inner cell mass is more effective in self-

[161] Treff, N. and Marin, D., *The "mosaic" embryo: misconceptions and misinterpretations in preimplantation genetic testing for aneuploidy.* Fertility and Sterility. Vol. 116, Issue 5, pp. 1205-1211 (November 2021).

[162] Xia, M., et al., *Next-Generation Sequencing is More Efficient at Detecting Mosaic Embryos and Improving Pregnancy Outcomes than Single-Nucleotide Polymorphism Array Analysis. Journal of Molecular Diagnostics,* Vol. 23, Issue 6. (June 2021); Niu, W., et al., *Improved clinical outcomes of preimplantation genetic testing for aneuploidy using MALBAC-NGS compared with MDA-SNP array. BMC Pregnancy and Childbirth,* 20, 388 (2020).

correcting than the trophectoderm. Chromosomal abnormal embryos may self-correct downstream, which renders earlier biopsy results irrelevant, but Defendants omit this from consumers.

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

290. 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, but Defendants omit this from consumers.

291. Instead, the co-founder of Defendants released research, not available to consumers, which implies that "mosaic" embryos are simply misclassified by PGT-A.[163]

292. 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.

293. Defendants also omit to inform consumers concerning the false positives and false negatives that occur with PGT-A, and the actual rates of false positives and false negatives shown through scientific study. Rather, they market their PGT-A testing has a lower false positive and false negative rate than other testing.[164]

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[163] Treff, N. and Marin, D., *The "mosaic" embryo: misconceptions and misinterpretations in preimplantation genetic testing for aneuploidy.* Fertility and Sterility. Vol. 116, Issue 5, pp. 1205-1211 (November 2021).
[164] https://www.lifeview.com/platform (last visited August 22, 2025).

> A recent publication shows SNP array-based PGT-A has a lower false positive and false negative rate than NGS-based PGT-A. Genomic Prediction was happy to contribute to this study by performing the SNP array-based PGT-A.

294. Scientific research, by the co-founder of Defendants, 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.[165]

295. Another scientific study suggested a potential false positive PGT-A rate of almost 55% and an intra-embryo discrepancy of almost 50%.[166]

E. PGT-A Has Enriched Defendants

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

297. The global preimplantation genetic testing market was estimated to be worth $0.7 billion in 2023 and is poised to reach $1.2 billion by 2028.

298. The PGT-A segment is expected to dominate the global preimplantation genetic testing market within the next several years.

299. The use of PGT-A now encompasses an estimated 40% of IVF cycles in the United States.

300. Despite all the scientific literature concerning PGT-A set forth above, Defendants have continued to advertise and market their PGT-A to clinics, physicians and consumers as the

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[165] 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.

[166] 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.

most advanced genetic screening available, increasing pregnancy rates, lowering miscarriage rates, reducing the number of cycles of IVF needed, reducing the number of wasted transfers, increasing the chance of success, increasing the chance of a healthy child, leading to more euploid embryos and more embryos available for transfer, and increasing the chances of a successful pregnancy. Defendants also market and sell their PGT-A testing as 98 to 99% accurate with a lower false positive and false negative rate.

301. Each of these claims are false and misleading, unsupported by scientific evidence, and made while Defendant omitted and withheld material information.

F. Plaintiffs' Experiences With Defendants' PGT-A

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

303. 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 misstatements and omissions detailed above. Each separate misstatement and omission by Defendants separately and independently gives rise to the causes of action alleged below.

304. 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.

305. Plaintiffs and Class members could not have known of the scientific literature that Defendants are charged to be an expert in.

1. Plaintiff Adrian Anderson's Purchase of a PGT-A Test

306. Adrian Anderson purchased PGT-A testing from Defendants based upon Defendants' false and misleading statements and omissions of material information, including that its PGT-A testing is the most advanced genetic screening available, increases pregnancy rates, increases the likelihood of implantation, lowers miscarriage rates, reduces the number of cycles of IVF needed, reduces the number of wasted transfers, increases the chance of success, increases the chance of a healthy child, leads to more euploid embryos and more embryos available for transfer, increase the chances of a successful pregnancy, and is 98 to 99% accurate with a lower false positive and false negative rate.

307. Prior to purchasing PGT-A testing from Defendants, Plaintiff Anderson was provided with Defendants' patient flyer on or about February 4, 2021 which stated that Defendants' PGT-A testing product decreases the risk of implantation failure, decreases the risk of miscarriage, and decreases the time to conceive. [167]

308. Plaintiff Anderson viewed Defendants' website on or about June 2021, which at that time stated that Defendants' PGT-A testing is the most advanced genetic screening for IVF, increases the chance of a healthy baby, increases the normal pregnancy rate per cycle (almost twice), increases the chance of successful pregnancy, increases the likelihood of implantation, lowers the miscarriage rate, has fewer false positives and false negatives than other testing platforms, and leads to more embryos available for transfer.[168]

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[167] https://web.archive.org/web/20210226101309/https://assets-global.website-files.com/5f47aef619bbf2fb7d26071a/6001a97d27c7a9329bf4c140_%E2%93%96-PGTA-Bifold.pdf (last visited September 22, 2025).

[168] https://web.archive.org/web/20210622104434/https://www.lifeview.com/ and https://web.archive.org/web/20210622103206/https://www.lifeview.com/faq#how-accurate-are-the-results (last visited September 22, 2025).

PGT-A (A for Aneuploidy).

Previously known as PGS, testing to determine whether chromosome count is normal. By combining copy number and genotyping data, LifeView provides the most accurate, highest resolution prediction of chromosomal abnormalities in IVF than older testing methods (NGS).

LifeView's fewer false positives means more embryos available for transfer. LifeView's fewer false negatives means embryos that are transferred will implant with higher likelihood, and miscarryless frequently. We have shown significantly better outcomes on these three metrics than other labs: less than half the normal miscarriage rate, and almost twice the normal pregnancy rate per cycle. [7]

309. Plaintiff Anderson signed Defendants' consent form to purchase testing on July 7, 2021, which stated that the purpose of PGT-A testing is to identify which embryos have a higher chance of implantation and a successful pregnancy outcome; that aneuploidy is associated with increased risk of implantation failure, miscarriage or the birth of a child with medical problems, birth defects and intellectual disability; and that testing has a diagnostic accuracy of 98 to 99%.

310. Relying on the claims viewed on Defendant's website and in Defendant's brochure and consent form, which collectively led to Plaintiff Anderson's purchase of Defendant's PGT-A testing, biopsies were collected from her embryos on July 12, 2021 and provided to Defendants on July 15, 2021.

311. Test results were delivered by Defendants to Plaintiff Anderson on July 20, 2021. The results report falsely and misleadingly claimed a diagnostic accuracy rate of 98.6%.

312. Plaintiff Anderson relied upon Defendants' false and misleading misrepresentations and omissions and paid approximately $3,590 plus additional costs for her

PGT-A testing, which she would not have purchased absent Defendants' false and misleading misrepresentations and omissions.

2. Plaintiff Amanda Malkin's Purchase of a PGT-A Test

313. Amanda Malkin purchased PGT-A testing from Defendants based upon Defendants' false and misleading statements and omissions of material information, including that its PGT-A testing is the most advanced genetic screening available, increases pregnancy rates, lowers miscarriage rates, reduces the number of cycles of IVF needed, reduces the number of wasted transfers, increases the chance of success, increases the chance of a healthy child, leads to more euploid embryos and more embryos available for transfer, increase the chances of a successful pregnancy, and is 98 to 99% accurate with a lower false positive and false negative rate.

314. Prior to purchasing PGT-A testing from Defendants, on or about October 2023, Plaintiff Malkin was provided with Defendants' patient flyer which stated that Defendants' PGT-A testing was better than other tests and yielded better outcomes, is 98 to 99% accurate, has higher pregnancy rates, results in fewer cycles of IVF thereby reducing the time and financial costs, and results in fewer wasted transfers.

315. Prior to purchasing PGT-A testing, on or about October 2023, Plaintiff Malkin viewed Defendants' website which stated that Defendants' PGT-A testing is the most advanced testing available, increases pregnancy rates, lowers miscarriage rates, increases the chance of success, increases the chance of successful pregnancy, lead to more available embryos for transfer, and has a lower false positive and false negative rate than other testing platforms.[169]

[169] https://web.archive.org/web/20230806041200/https://lifeview.com/tests_pgta.html

316. Plaintiff Malkin signed Defendants' consent form to purchase testing on or about October 17, 2023, which stated that the purpose of PGT-A testing is to identify which embryos have a higher chance of implantation and a successful pregnancy outcome; that aneuploidy is associated with increased risk of implantation failure, miscarriage or the birth of a child with medical problems, birth defects and intellectual disability; and that testing has a diagnostic accuracy of 98 to 99%.

317. Following the viewing of the website, the brochure and the consent form which led to Plaintiff Malkin's purchase of PGT-A testing from Defendants, biopsies were collected from her embryos in October 2023 and provided to Defendants on October 31, 2023.

318. Test results were delivered by Defendants to Plaintiff Malkin on November 14, 2023. The results report listed a diagnostic accuracy rate of 98.6%.

319. Plaintiff Malkin relied upon Defendants' false and misleading misrepresentations and omissions and paid approximately $8,400 plus additional costs for her PGT-A testing, which she would not have purchased absent Defendants' false and misleading misrepresentations and omissions.

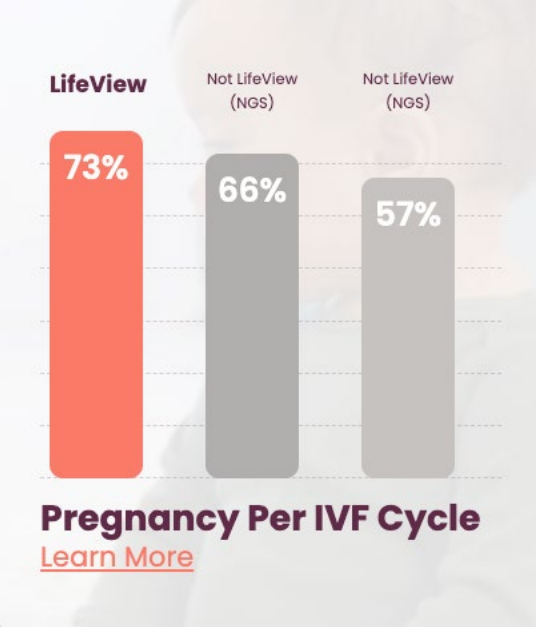
3. Plaintiff Maureen Ewing's Purchase of a PGT-A Test

320. Maureen Ewing purchased PGT-A testing from Defendants based upon Defendants' false and misleading statements and omissions of material information, including that its PGT-A testing is the most advanced genetic screening available, increases pregnancy rates, lowers miscarriage rates, reduces the number of cycles of IVF needed, reduces the number of wasted transfers, increases the chance of success, increases the chance of a healthy child, leads to

more euploid embryos and more embryos available for transfer, increase the chances of a successful pregnancy, and is 98 to 99% accurate with a lower false positive and false negative rate.

321. Prior to purchasing PGT-A testing from Defendants, on or about January 2022, Plaintiff Ewing was provided with Defendants' patient flyer which stated that Defendants' PGT-A testing was better than other tests and yielded better outcomes, is 98 to 99% accurate, has higher pregnancy rates, results in fewer cycles of IVF thereby reducing the time and financial costs, and results in fewer wasted transfers.

322. On or about January 2022, Plaintiff Ewing viewed Defendants' website which at that time stated that Defendants' PGT-A testing is the most advanced embryo genetic testing available, increases pregnancy rates, increases the chance of successful pregnancy and healthy babies, leads to more available embryos for transfer, and has lower false positives.[170]



[170] https://web.archive.org/web/20220120223339/https://www.lifeview.com/ and https://web.archive.org/web/20220202155033/https://www.lifeview.com/lifeview (last visited October 3, 2025)

323. Plaintiff Ewing signed Defendants' consent form to purchase testing on February 24, 2022, which stated that the purpose of PGT-A testing is to identify which embryos have a higher chance of implantation and a successful pregnancy outcome; that aneuploidy is associated with increased risk of implantation failure, miscarriage or the birth of a child with medical problems, birth defects and intellectual disability; and that testing has a diagnostic accuracy of 98 to 99%.

324. Following the viewing of the website, the brochure and the consent form which led to Plaintiff Ewing's purchase of PGT-A testing from Defendants, biopsies were collected from her embryos and provided to Defendants on March 28, 2022 and June 16, 2022.

325. Test results were delivered by Defendants to Plaintiff Ewing following the analysis of her embryo biopsies that were received on March 28, 2022 and June 16, 2022. The results reports listed a diagnostic accuracy rate of 98.6%.

326. Plaintiff Ewing relied upon Defendants' false and misleading misrepresentations and omissions and paid approximately $8,962.68 plus additional costs for her PGT-A testing, which she would not have purchased absent Defendants' false and misleading misrepresentations and omissions.

CLASS ALLEGATIONS

327. 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").

328. In addition, Plaintiff Anderson 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").

329. In addition, Plaintiff Malkin 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").

330. In addition, Plaintiff Ewing brings this lawsuit on behalf of a class of all residents of the State of Pennsylvania who purchased PGT-A testing from Defendants (the "Pennsylvania Class").

331. The Nationwide Class and each state-wide Class defined above are referred to collectively herein as the "Class."

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

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

334. **Numerosity**. Each defined Class is so numerous that the joinder of all Class members 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.

335. **Common Questions Predominate**. This action involves common questions of law and fact to each Class because each member's claim derives from Defendants' false, deceptive,

and misleading statements and omissions as alleged above. Common questions of law and fact include but are not limited to:

- Defendants' misstatements and omissions to Class members regarding PGT-A;
- 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;
- Whether a reasonable consumer would rely upon Defendants' misstatements and omissions concerning PGT-A;
- Defendants' knowledge of its 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; and
- Whether Defendants were unjustly enriched as a result of its conduct.

These 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.

336. **Typicality**. Plaintiffs' claims are typical of the claims of other Class members they seek to 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 Defendant's misrepresentations and omissions and they all suffered economic damages as a result.

337. **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.

338. **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.

339. 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.

340. **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

341. All Nationwide Class members have a nexus with New Jersey such that New Jersey law should apply to all of them. In the alternative, if the Court finds that New Jersey law, including all of the New Jersey law causes of action alleged below, does not apply to Plaintiffs and all Class members residing outside of New Jersey for any reason, then Plaintiffs and Class members residing outside of California assert their claims under the laws of their respective states of residence.

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

342. Plaintiffs incorporate by reference all preceding allegations.

343. 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."

344. 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.

345. Defendants have in the course of its 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.

346. 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 Class members and the general public.

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

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

349. Pursuant to Business and Professions Code §§ 17200 and 17203, Plaintiff and 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.

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

351. Plaintiff and 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.

352. 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.

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

354. The gravity of harm resulting from Defendants' unfair conduct outweighs any potential utility. The practice of falsely and deceptively 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.

355. Plaintiff and the Class 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.

356. Through its unfair conduct, Defendants acquired money that Plaintiffs and the Class members once had ownership of.

357. Plaintiffs and the 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 its unfair practices.

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

358. Plaintiff incorporates by reference all preceding allegations.

359. 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 violated the UCL.

360. 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.

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

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

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

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

364. Plaintiff incorporates by reference all preceding allegations.

365. Plaintiff Anderson 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.

366. Defendants are a "person" as defined by Civil Code §§ 1761(c) and 1770 and has provided "services" as defined by Civil Code §§ 1761(b) and 1770.

367. 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.

368. Defendants' acts and practices violated the Consumers Legal Remedies Act because they failed to disclose information that was material to Plaintiff and 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-described 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.

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

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

371. 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 not to mislead consumers through its advertising, marketing, and promotion of PGT-A.

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

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

374. Plaintiff and the 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.

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

376. Plaintiffs accordingly are entitled to statutory relief, equitable relief, reasonable attorneys' fees and costs, declaratory relief, and a permanent injunction enjoining Defendants from continuing its continued unlawful, fraudulent, and deceptive activity.

377. Pursuant to Civil Code § 1782(a), on July 12, 2024, Plaintiff, individually and on behalf of the Class, sent a letter Defendants to notify it of its CLRA violations and afford it the opportunity to correct its business practices and rectify the harm it 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 Class Members seek money damages under CLRA.

COUNT IV
Violations of Florida Deceptive and Unfair Trade Practices Act,
Fla. Stat. § 501.201, *et seq*.
(On behalf of Amanda Malkin and the Florida Class)

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

379. Plaintiff Malkin is a "consumer" within the meaning of Fla. Stat. § 501.203.

380. 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.

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

382. 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.

383. 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).

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

385. 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.

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

387. 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.

388. 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.

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

COUNT V
Violations of Pennsylvania Unfair Trade Practices and Consumer Protection Law 73 Pa. Stat. Ann. §§201-1, *et seq*. ("UTPCPL")
(On behalf of Maureen Ewing and the Pennsylvania Class)

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

391. Plaintiff brings this action individually and on behalf of the members of the Pennsylvania Subclass.

392. The Pennsylvania Unfair Trade Practices and Consumer Protection Law ("UTPCPL") was created to protect Pennsylvania consumers from fraudulent or deceptive business practices.

393. Defendants have knowingly engaged in deceptive, unconscionable, unfair, false, fraudulent and misleading commercial practices, including misleading omissions of material fact, in connection with the marketing, promotion and sale of its PGT-A testing.

394. Plaintiff and Pennsylvania Class members justifiably relied on Defendants' unlawful conduct in purchasing Defendants' PGT-A testing and suffered ascertainable losses of money or property as the result of the act or practice declared unlawful by 73 Pa. Stat. Ann. §§201-1, et seq.

395. Plaintiffs and Pennsylvania Class members acted as reasonable consumers would have acted under the circumstances and would not have purchased PGT-A testing had they known the truth.

396. Accordingly, pursuant to the aforementioned statutes, Plaintiff and Pennsylvania Class members are entitled to recover their actual damages, which can be calculated with a reasonable degree of certainty using sufficiently definitive and objective evidence.

397. In addition, given the nature of Defendants' conduct, Plaintiff and Pennsylvania Class members are entitled to recover all available statutory, exemplary, treble, and/or punitive damages, costs of suit, and attorneys' fees based on the amount of time reasonable expended and equitable relief necessary, and all such other relief as the Court deems proper.

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

398. Plaintiffs incorporate by reference all preceding allegations.

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

400. 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*.

401. Defendants breached the implied warranty of merchantability in connection with the sale of PGT-A. While Defendants advertise, market, and promote that its PGT-A testing is substantiated, accurate and reliable, it is not, rendering it unsuitable for use.

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

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

404. 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.

405. Plaintiffs provided pre-suit notice to Defendants on April 15, 2025.

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

406. Plaintiffs incorporate by reference all preceding allegations.

407. By operation of law, Defendants, as the sellers and providers of PGT-A testing, warranted to Plaintiffs and the Class members through its statements that PGT-A was usable for its ordinary and intended use.

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

409. 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*.

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

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

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

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

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

415. 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.

416. Plaintiffs provided pre-suit notice to Defendants on April 15, 2025.

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

417. Plaintiffs incorporate by reference all preceding allegations.

418. By advertising and selling PGT-A testing, Defendants made promises and affirmations of fact about PGT-A testing through its marketing and advertising statements, patient flyer, Consent Form, test results, and as further set forth above.

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

420. Defendants purport, through its marketing and advertising, patient flyer, consent forms, statements, and test results that its PGT-A testing is accurate and reliable, among other things as detailed here.

421. Despite Defendants' express warranties about accuracy and reliability, its PGT-A testing is not accurate or reliable and does not provide the information claimed to provide.

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

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

424. 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.

425. Plaintiffs provided pre-suit notice to Defendants on April 15, 2025.

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

426. Plaintiffs incorporate by reference all preceding allegations.

427. 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 the most advanced genetic screening available;

b. Defendants' PGT-A testing is 98-99% accurate;

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

d. Defendants' PGT-A testing lowers miscarriage rates;

e. Defendants' PGT-A testing reduces the number of cycles of IVF needed;

f. Defendants' PGT-A testing reduces the number of wasted transfers;

g. Defendants' PGT-A testing increases the chance of success;

h. Defendants' PGT-A testing increases the chance of a healthy child;

i. Defendants' PGT-A testing leads to more euploid embryos and embryos available for transfer;

j. Defendants' PGT-A testing increases the chance of a successful pregnancy;

k. and

l. Defendants' PGT-A testing has a lower false positive and false negative rate.

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

429. Defendants knew or should have known that its misrepresentations and omissions were false and misleading and intended for consumers to rely on.

430. Plaintiff 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.

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

432. 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.

433. 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 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.

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

COUNT X
Fraud by Concealment/Omission
(On behalf of Plaintiffs and Class Members)

435. Plaintiffs incorporate by reference all preceding allegations.

436. Defendants provide that it wants to be part of prospective parents' journey and increase their "chances of success and a healthy child".[171]

[171] https://www.lifeview.com/patients and www.lifeview.com/why_choose.html (last visited September 22, 2025).

437. Having assumed this role as a trusted partner on the path to building a family and helping clients achieve their dreams of starting a healthy family, Defendants owed a duty to disclose material facts that rendered its representations misleading and false.

438. However, Defendants intentionally suppressed and concealed material facts about its 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.

439. Defendants omitted the material fact that it had never conducted the validation studies necessary to substantiate its claims of accuracy and efficacy**.**

440. By affirmatively advertising its PGT-A testing as '98-99% accurate,' 'reducing miscarriage,' and 'increasing the chance of healthy pregnancy,' Defendants created the false impression that these claims were supported by rigorous scientific validation, when in truth no such validation exists.

441. Only Defendants possess knowledge of whether its assay has ever been validated to support these claims, and patients could not reasonably discover this fact on their own.

442. Defendants' concealment of the absence of validation studies constitutes fraud by omission because it rendered Defendants' partial representations misleading, suppressed facts within its exclusive knowledge, and affirmatively misled Plaintiffs into purchasing PGT-A testing.

443. Instead of conducting the necessary studies to validate its PGT-A testing to support its claims to sell the test, Defendants provided research in 2019 based upon the results of only 48 rebiopsies. [172]

[172] Treff, Nathan, et al., *Validation of concurrent preimplantation genetic testing for polygenic and monogenic disorders, structural rearrangements, and whole and segmental chromosome aneuploidy with a single universal platform.* European Journal of Medical Genetics. 62 (2019).

444. Research which made no findings regarding clinical validation to determine whether the testing results were accurately represented in live births or healthy babies. Rather, it simply determined whether the rebiopsy result matched the prior result.[173]

445. Defendants then relied upon research which specifically states that it does not apply to other assays such as the one utilized by Defendant for its PGT-A testing to claim that its testing is 98 to 99% accurate.[174]

446. In addition, Defendants rely upon research which both ACOG and ASRM have raised concerns about due to their limitations and insufficiency.[175]

447. As a "world's leading expert" that specializes in preimplantation genetic testing, only Defendants have exclusive knowledge of the limitations and insufficiency of these studies and why they are not applicable to the claims being made by Defendants to sell its PGT-A testing.

448. However, Defendants actively omit and conceal this information from the Plaintiffs and Class members.

449. Defendants provide partial representations that are misleading without disclosure.

450. 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.

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

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[173] *Id.*

[174] 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.

[175] Committee on Genetics of the American College of Obstetricians and Gynecologists. *ACOG Committee Opinion – Preimplantation Genetic Testing*. Number 799. March 2020.

452. Defendants were aware of the scientific studies and research concerning PGT-A, as well the limitations of same, including from major medical associations such as ASRM and ACOG.

453. Defendants had a duty to disclose the truth about PGT-A because Defendant actively concealed material information about PGT-A testing and any validation data.

454. The only validation study that Defendants have disclosed is their own published research in 2019 based upon the results of only 48 rebiopsies. [176]

455. The research made no findings regarding clinical validation to determine whether the testing results were accurately represented in live births or healthy babies. Rather, it simply determined whether the rebiopsy result matched the prior result.[177]

456. Defendants had a duty to disclose the truth about PGT-A because, through Defendants' advertising, marketing, website statements, consent form, and other 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.

457. 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.

458. 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

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[176] Treff, Nathan, et al., *Validation of concurrent preimplantation genetic testing for polygenic and monogenic disorders, structural rearrangements, and whole and segmental chromosome aneuploidy with a single universal platform.* European Journal of Medical Genetics. 62 (2019).
[177] *Id.*

Defendants, including advertisements, websites, brochures, or promotional materials, indicated or disclosed the full truth about PGT-A testing as detailed herein.

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

460. 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.

461. 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.

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

463. 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.

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

464. Plaintiffs incorporate by reference all preceding allegations.

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

466. Defendants created and implemented a scheme to market for PGT-A testing to increase sales through numerous false and misleading statements and material omissions as set forth above.

467. As a result, Defendants have been unjustly enriched at Plaintiffs and Class Members' expense by retaining the benefits derived from the sale of PGT-A testing, despite not providing Plaintiffs with fair compensation.

468. Plaintiffs and Class Members conferred a benefit on Defendant in the form of payment for PGT-A testing and associated costs.

469. Defendants knowingly accepted and retained this benefit under circumstances that make it unjust for Defendants to retain the benefit without compensating Plaintiffs and Class members.

470. These benefits were the result of Defendants acting in its pecuniary interest at the expense of its consumers.

471. 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 as a result of its wrongful conduct.

472. As a result, Defendants should be required to make restitution to Plaintiffs and Class members in an amount according to proof at trial.

PRAYER FOR RELIEF

WHEREFORE, Plaintiffs, individually and on behalf of the Classes defined above, respectfully request that the Court:

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

b. Award Plaintiffs and the Classes defined above all compensatory, statutory, restitution, and 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.

l. Plaintiffs reserve the right to seek all remedies available at law or equity, including any remedies that may become available upon further order of the Court.

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: March 19, 2026

Respectfully submitted,

/s/Russell D. Paul

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