Amfira®
PGT

Preimplantation genetic testing to optimize IVF success

MEDICOVER GENETICS

WHAT IS **Amfira**?

Amfira is a **preimplantation genetic test** (PGT) that can determine whether an embryo created through in vitro fertilization (IVF) is chromosomally normal (euploid). Choosing to implant a euploid embryo can increase the chances of achieving pregnancy and live birth, and potentially reduce the number of IVF cycles and time needed to achieve pregnancy.

CLINICAL UTILITY

Chromosomal aneuploidy in embryos negatively impacts implantation rates and is the primary cause of miscarriage, accounting for approximately 50% of pregnancy losses[1,2]. While the risk for whole autosomal chromosome aneuploidies increases with advanced maternal age, the risk for segmental aneuploidies and mosaicism is the same for women of all ages.

PGT cannot correct embryos with a chromosomal aneuploidy; however, identifying and choosing to implant euploid embryos can:

- increase the chances of achieving implantation, pregnancy and live birth
- lower miscarriage rate
- lead to safer pregnancies, with fewer maternal and perinatal complications by promoting single embryo transfer
- achieve a pregnancy earlier compared to cycles without PGT

Studies demonstrate that robust, reliable and fast chromosomal assessment of embryos, in addition to morphological grading, can result in **improved assessment of embryo ploidy** and higher implantation potential. Contrary to previous technologies, the recent introduction of Next Generation Sequencing (NGS) for PGT has shown **improved efficiency** and **precision**.

With Amfira PGT, you can take informed decisions based on accurate and reliable information that will benefit your patients by increasing their chances to achieve pregnancy.

WHO IS **Amfira** FOR?

- Any individual or couple going through IVF
- Any individual or couple with a history of unsuccessful fertility treatments
- Women who have experienced at least one miscarriage
- Individuals with structural chromosomal rearrangements
- Women who have experienced a previous pregnancy with a chromosomal aneuploidy
- Women over 35 years old going through IVF

1. *Silver RM., and Branch D. W. "Sporadic and Recurrent Pregnancy Loss." Handbook of Clinical Obstetrics, pp. 41–46, 2007*

2. *Essers R. et al. "Prevalence of chromosomal alterations in first-trimester spontaneous pregnancy loss". Nature Medicine, Vol. 29, 2023*

Amfira PANELS

PGT-A: PGT FOR ANEUPLOIDIES

For everyone going through IVF.

PGT-A identifies embryos that are euploid and have the highest potential for resulting in a live birth.

- Testing of all 23 chromosomal pairs
- Detection of segmental changes down to 10Mb
- Detection of mosaic changes up to 50%

PGT-SR: PGT FOR STRUCTURAL REARRANGEMENTS

For people who have been diagnosed with a balanced chromosomal rearrangement (translocation) and are at a higher risk of having:

implantation failures	recurrent pregnancy loss	a child with a chromosomal disorder

PGT-SR identifies embryos that are euploid or balanced for the translocation, and have better prospects of leading to a pregnancy with lower risk of miscarriage.

- Testing of all 23 chromosomal pairs
- Detection of segmental changes down to 10Mb
- Detection of mosaic changes up to 50%

WHY RECOMMEND **Amfira** TO MY PATIENTS?

As a targeted test, Amfira is designed to overcome the limitations of whole genome analysis by avoiding problematic regions that can affect the accuracy of the results. It provides a very high-read depth compared to whole genome analysis increasing the statistical confidence of the results. Due to the robust technological design, which includes in-solution hybridization and the use of very long probes, superior enrichment uniformity and high levels of multiplexing are achieved.

SENSITIVITY	
Whole Chromosome Aneuploidy	100% (95% CI: 95 - 100%)
Segmental Aneuploidy	100% (95% CI: 63 - 100%)
Whole Chromosome Mosaicism >50%	91.7% (95% CI: 62 - 99.8%)
Selected Male Polyploidies	100% (95% CI: 50 - 100%)

SPECIFICITY	
Whole Chromosome Aneuploidy	100% (95% CI: 96 - 100%)
Segmental Aneuploidy	
Whole Chromosome Mosaicism >50%	
Selected Male Polyploidies	

*The above are internal data which can be found in the Amfira White Paper (2021). Biopsied embryos, at **blastomere** and **blastocyst** stage, with selected male polyploidies, whole chromosome and small segmental aneuploidies were tested. Confirmation was established using an orthogonal method such as array Comparative Genomic Hybridization (aCGH) or Whole Genome Sequencing (WGS).*
Please visit our website for access to the Amfira White Paper (2021).

TECHNOLOGICAL ADVANTAGES

TARGETED TECHNOLOGY

Amfira is built on a novel, **Target Capture Enrichment Technology** which utilizes Next Generation Sequencing, and has been thoroughly validated for its accuracy and precision.

NOVEL BIOINFORMATICS

Innovative bioinformatic pipelines analyze the sequencing data produced from each sample, increasing the sensitivity and specificity of Amfira.

DETECTION OF SELECTED MALE POLYPLOIDIES

Amfira can detect **69XXY**, **69XYY** and **92XXXY** male polyploidies.

HIGH RESOLUTION

Amfira can detect segmental changes as small as **10Mb**.

BENEFITS OF **Amfira**

FAST
Results in 5-7 working days

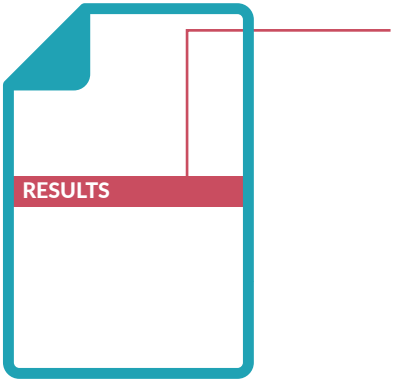
VALUABLE
Identifies chromosomally normal embryos

INFORMATIVE
Screens all chromosomal pairs

RELIABLE
Robust technological platform for accurate results

WHAT WILL THE **REPORT** TELL ME?

Amfira PGT analyzes all **23 chromosomal pairs** of an embryo, and reports whether the sample tested is euploid, aneuploid or mosaic.



EUPLOID

An embryo which is chromosomally normal, having a total of 46 chromosomes.
Euploid embryos have the best chance to result in pregnancy and livebirth.

ANEUPLOID

An embryo with additional or fewer than 46 chromosomes.

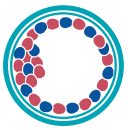
- Whole chromosome aneuploidy: an entire chromosome is either missing (monosomy - 1 copy) or is extra (trisomy - 3 copies).
- Segmental aneuploidy: part of a chromosome is missing (deletion), or is extra (duplication).
  The development of the embryo, its survival, implantation potential, miscarriage risk and whether a baby with a chromosomal abnormality is born, depend on whether the aneuploidy is whole or segmental, and on the affected chromosome.

MOSAIC

An embryo which has 46 chromosomes in some of its cells, and fewer or more chromosomes in other cells.
Mosaicism is a biological limitation that cannot be overcome with any current technology. Mosaic embryos may still result in a viable pregnancy. The development of the embryo and the health of the baby depend on whether the fetus shares the same mosaic cell lineage as the trophectoderm, on the chromosome affected by mosaicism, and on the mosaicism level.

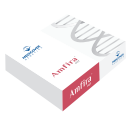

EUPLOID


ANEUPLOID


MOSAIC

HOW TO ADMINISTER **Amfira** PGT?

Evaluate patients' personal and clinical history



Recommend Amfira PGT during the IVF cycle

Perform embryo biopsy on the optimal day

Send biopsy samples to **Medicover Genetics**

The sample will be analyzed at **Medicover Genetics** laboratories

Results will be sent to you within 5-7 working days from sample receipt

MORE **QUESTIONS**?

If you have additional questions or concerns, please contact us at **info.genetics@medicover.com**

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