Amfira® PGT

AFFIX BARCODE LABEL — SIF HERE

SAMPLE INFORMATION FORM

Please complete sections below in English.

PATIENT INFORMATION

FIRST NAME	LAST NAME
DATE OF BIRTH	PATIENT GENETIC SEX
PHONE NUMBER	EMAIL
ADDRESS	
CITY / POST CODE / COUNTRY	

REFERRAL INFORMATION

CLINIC NAME	CLINIC ID
REFERRING HEALTHCARE PROVIDER	
PHONE NUMBER	FAX
EMAIL	
ADDRESS	
CITY / POST CODE / COUNTRY	

SPECIMEN INFORMATION

NUMBER OF BIOPSIED SAMPLES:	BLANK PROVIDED: ☐ YES ☐ NO

PARTNER/DONOR INFORMATION

FIRST NAME	LAST NAME
DATE OF BIRTH	GENETIC SEX

DONOR

☐ EGG ☐ SPERM ☐ N/A

CLINICAL AND TEST DETAILS

TEST INDICATIONS

TICK APPROPRIATE BOX

- ☐ ADVANCED MATERNAL AGE
- ☐ REPEATED FAILED IVF CYCLES
- ☐ RECURRENT PREGNANCY LOSS
- ☐ ANEUPLOIDY TESTING
- ☐ KNOWN STRUCTURAL REARRANGEMENT
  (Complete "structural rearrangement information" part below)

REQUESTED TEST

TICK ONLY ONE BOX BELOW

- ☐ PGT-A
- ☐ PGT-SR (includes PGT-A analysis)
  (Karyotype is required for evaluation, please complete structural rearrangement information)

STRUCTURAL REARRANGEMENT INFORMATION

(COMPLETE IF PGT-SR IS REQUESTED)

Amfira PGT-SR can detect structural rearrangements over 10Mb

MATERNAL STATUS

- ☐ NORMAL KARYOTYPE
- ☐ BALANCED CHROMOSOME REARRANGEMENT
- ☐ KARYOTYPE RESULT:
  (Attach karyotype report with SIF)

PATERNAL STATUS

- ☐ NORMAL KARYOTYPE
- ☐ BALANCED CHROMOSOME REARRANGEMENT
- ☐ KARYOTYPE RESULT:
  (Attach karyotype report with SIF)

FOR LABORATORY USE ONLY
F-OPR-01/05-V6-EN

ORDER NUMBER	LAB ID NUMBER	KIT LOT NUMBER
COMMENTS	DATE & TIME OF RECEIPT (DD/MM/YY HH:MM)	RECEIVED BY

MEDICOVER GENETICS
Neas Engomis 31, Nicosia, 2409 Cyprus
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Email: info.genetics@medicover.com

CAP ACCREDITED COLLEGE of AMERICAN PATHOLOGISTS
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PGT

SAMPLE INFORMATION FORM

PATIENT CONSENT

By placing my signature signing below I hereby:

1. Confirm that I have read, or have had read to me, the Patient Informed Consent which is attached to this page and that I understand it.
2. Declare that I have had the opportunity to receive counseling from my referring healthcare provider on the Amfira test and to discuss with the referring healthcare provider all aspects of the Amfira test and this form including the benefits, risks and limitations of the Amfira test, as well as the reasons for performing the test and availability of alternative testing options to my satisfaction.
3. Authorize my referring healthcare provider to perform embryo biopsy and provide the necessary embryo samples, and to submit this form and transport the samples to Medicover Genetics laboratories for the purposes of conducting the tests requested with this form.
4. Authorize Medicover Genetics to use the embryo samples for the purposes of conducting the tests requested with this form.
5. Authorize Medicover Genetics to communicate the results of the test to my referring healthcare provider.
6. Confirm that all the information on this form is true to the best of my knowledge.

Your test results and any unused biological material can help Medicover Genetics improve and further develop the quality, accuracy and effectiveness of diagnosis and help us expand the scope of genetic testing. For this reason, Medicover Genetics would like to use your anonymized, de-identified (i.e. after removing all the personal information from which you can be identified) test results and remaining biological material.

☐ For the above scope, I consent to the inclusion of my test results in Medicover Genetics' database, the coding, storing and using of biological material.

PATIENT/GUARDIAN SIGNATURE	DATE

HEALTHCARE PROVIDER ATTESTATION

I hereby certify and undertake that:

1. The patient has been informed that the laboratory will only perform the test requested on this form, has been duly and thoroughly counseled about the test, and has received all the advice necessary to provide their informed consent, including the benefits, risks, and limitations of the Amfira test.
2. I have answered all the patient's queries about the Amfira test.
3. This form has been completed according to the wishes and instructions of the patients.
4. I have obtained the patient's informed consent and have attested their signature.

HEALTHCARE PROVIDER SIGNATURE	DATE

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PATIENT INFORMED CONSENT

Amfira TEST

Amfira is a preimplantation genetic test to be used in combination with in vitro fertilization (IVF) treatments to identify embryos most suitable for transfer based on their chromosomal status. Chromosomal abnormalities are influenced by maternal age, may occur randomly in the embryo or be present and inherited by any of the parents as in the case of structural rearrangements. Embryos with chromosomal abnormalities (aneuploidies) may result in failed implantations, miscarriages, or the birth of a baby with cognitive or physical impairments. Amfira preimplantation genetic test (PGT) is based on a novel target capture enrichment technology that has been validated for its accuracy and precision.

SAMPLE COLLECTION

Your healthcare provider and embryology team will decide on your stimulation procedure, egg collection, fertilization and the day your embryos will be biopsied. During embryo biopsy, a few cells from your embryos will be removed, tubed and sent to Medicover Genetics for analysis and reporting of results. Highly trained embryologists can successfully perform embryo blastomere (Day 3) and blastocyst (Day 5 onwards) biopsies without damaging the embryos. Amfira has been validated for testing both blastomere and blastocyst-stage biopsies.

SAMPLE TRANSPORT

Transport of the biopsied embryo samples to the laboratory takes place after communication between your reproductive team and the testing laboratory. Depending on the location of the IVF clinic and the day of biopsy, transport method will be arranged in the proper temperature and container. Appropriate packaging material and paperwork will be applied to ensure correct, safe and fast delivery of the samples to our laboratory.

TESTING PROCESS

Genetic material (DNA) from the biopsied embryo samples will be extracted. Amfira uses an innovative technology called 'Target Capture Enrichment Technology' to detect the chromosomal status of the embryo. Sample Information Forms (SIFs) and biopsy worksheets should be completed in full by your reproductive team and delivered to the lab along with the biopsied samples. For PGT-SR, a karyotype report detailing the structural rearrangement is also required.

INTERPRETING RESULTS

The results are communicated directly to your reproductive team within 5-7 working days of sample arrival to the laboratory. Your reproductive team is responsible to understand the specific uses and limitations of the test, communicate this information to you and answer any questions you may have. Based on the reported results, your reproductive team will decide which embryo to transfer.

For PGT-A

EUPLOID: A chromosomally normal embryo, having in total 46 chromosomes – 22 pairs of autosomal (non-sex) chromosomes and 1 pair of sex chromosomes (XX or XY). Euploid embryos have the highest chance of resulting in a successful pregnancy.
In accordance with national laws our laboratory does not provide elective gender selection, unless it is for medical purposes. Gender is not reported unless a sex chromosome aneuploidy is detected.

MOSAIC: An embryo with the correct number of chromosomes in some of its cells, and an incorrect number of chromosomes in others. Mosaicism will be reported by our laboratory when the chromosomal change is over 50%, and only in cases where mosaicism is observed on the whole chromosome– partial chromosome mosaicism will not be reported. The chromosome affected determines how the embryo will develop. Mosaic embryos may be recommended for transfer by your reproductive team, if there are no euploid embryos, and depending on the mosaic chromosome. By implanting mosaic embryos, there is a risk of failed implantation or miscarriage, which your reproductive team is responsible for explaining to you if the decision to implant mosaic embryos is taken.

ANEUPLOID: An embryo with additional or fewer chromosomes than the correct number. Depending on whether the whole chromosome is affected or just a part of it (segmental aneuploidy), and which is the affected chromosome, embryo survival, implantation rate, chances of miscarriage and the health of the baby are determined. Aneuploid embryos are generally not recommended for transfer.

NO RESULT: No results will be issued when no DNA is present after the first stage of sample processing, due to limited material or degraded DNA. This could be because of poor sample quality, poor biopsy, or not tubing the biopsied cells. A rebiopsy of the specified sample may be recommended by your reproductive team.

NOT-INFORMATIVE RESULTS: Issued when the sample fails to pass analysis standards after test completion, due to poor sample quality. A rebiopsy of the specified sample may be recommended by your reproductive team.

For PGT-SR (includes PGT-A analysis)

PGT-SR is for **known carriers of structural rearrangements** (translocations) where karyotype reports have been submitted. PGT-A testing is included in all samples tested for PGT-SR. Results will be reported as for PGT-A (euploid, mosaic, aneuploid, no result, not-informative results) with the added clarification on whether the sample carries the structural rearrangement:

Euploid: For samples that are either euploid or carry a balanced form of the structural rearrangement tested for.

Aneuploid: For samples that carry an unbalanced form of the structural rearrangement tested for, with or without having additional aneuploidies.

DISCLOSURE

Medicover Genetics is a fully accredited state-of-the-art genetic testing laboratory. All necessary measures are taken to perform the testing reliably and under strict standards.
Amfira is highly accurate, however, there is a small possibility for false positive and false negative results due to technical and biological reasons. Although rare, these reasons include, but are not limited to: mislabeled samples, inaccurate clinical information, rare technical errors, or other rare events such as the presence of change(s) in a small percentage of cells (extremely low-level mosaicism) which may not be detectable by the resolution of the test. The analysis is specific only for the test ordered.
The results only reflect the DNA of the biopsied cells, and in some cases, due to technical or biological reasons, testing may not identify an aneuploidy even though one exists. For example, there may be differences in the genetic material of the Inner Cell Mass (which develops into the baby) and the trophectoderm (which develops into the placenta, and where cells are biopsied from). The accuracy of test results is also dependent upon the quality of the embryo, the correct practice of the biopsy procedure, the chromosomal status of the cells tubed, the level of mosaicism, and the patient's clinical diagnosis and karyotype in the case of structural rearrangements.
Amfira can detect selected male polyploidies (69XXY, 69XYY, 92XXXY) but cannot detect haploids. Amfira cannot differentiate between embryos that are chromosomally balanced for the structural rearrangement and euploid embryos. People who are balanced for a structural rearrangement are phenotypically healthy and do not display any characteristics associated with the unbalanced form of the structural rearrangement. Amfira can detect full chromosome aneuploidies and chromosomal rearrangements (partial deletions / duplications) larger than 10Mb. PGT-A cannot detect single gene disorders (i.e. b-thalassemia, cystic fibrosis), or Uniparental Disomy (UPD - two chromosome copies inherited from one parent and no copies of that chromosome inherited from the other). Amfira cannot ensure a successful pregnancy or a healthy baby, or completely eliminate the risk of miscarriage or birth of a baby with a chromosomal aneuploidy, physical or cognitive impairment.

QUALITY IMPROVEMENT

Please choose the relevant option on the consent form to grant us permission to anonymously use your remaining biological material to improve the quality, accuracy and effectiveness of Amfira.

Please make sure you read and understand the information on this document before signing and complete all relevant information accurately as incorrect information can lead to inaccurate test results. Please discuss any questions you may have with your healthcare provider. For additional information please visit our website at ***www.medicover-genetics.com.***

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PATIENT PRIVACY SUMMARY

This privacy notice provides a summary of how Medicover Genetics Limited collects and processes your personal data with this form. It is important that you read this privacy notice together with our full privacy policy which contains more detailed information about our data processing. A copy is available online at www.medicover-genetics.com

1. Important information and who we are

Medicover Genetics is responsible for processing the personal data collected on this form.

We have appointed a data protection officer (DPO). If you have any questions about this privacy notice or our data protection practices, please contact the DPO.

CONTACT DETAILS

Full name of legal entity: Medicover Genetics Limited (HE 418406)

Email address: dpo.cy@medicover.com

Postal address: 31 Neas Engomis Street, 2409 Engomi, Nicosia, Cyprus

Telephone number: + (357) 22266888

2. The data we collect about you

We collect, use, store and transfer personal data about you as follows:

- Identity Data.
- Contact Data.
- Sensitive data (medical/clinical data).

3. How we use your personal data

We will only use your personal data for the purpose for which we collected it. This includes the following:

- To register you as a new customer.
- To conduct your Amfira test and to process and deliver your results.
- To manage your relationship with us and to provide customer support, where applicable.
- To contact you or your referring healthcare provider on your results.
- To invoice the referring healthcare provider.

4. How we share your personal data

We share your personal data with your referring healthcare provider, so we can communicate the results of your test to them.

Medicover Genetics stores personal information on its database which is hosted by cloud service providers.

5. International transfers

We do not transfer, store or process your personal data outside the European Economic Area (EEA) unless you or your referring healthcare provider are located outside the EEA.

6. Your legal rights

Under certain circumstances, you have rights under data protection laws in relation to your personal data including the right to receive a copy of the personal data we hold about you, the right to erasure ('right to be forgotten'), the right to restriction of processing and the right to make a complaint at any time to the Office of the Commissioner for Personal Data Protection.

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