LG-MG-FR-007	INFORMED CONSENT AND TEST REQUEST FORM FOR CHROMOSOMAL ANOMALIES (PGT-A AND PGT-SR)

Female	**Name-Surname**				**BARCODE**
	Date of Birth				
	Phone				
	E-Mail Address				
	Type of Sample		**Sampling Date - Time**		
Male	**Name-Surname**				**BARCODE**
	Date of Birth				
	Phone				
	E-Mail Address				
Address Details					
Doctor Information	**Name-Surname**				**Stamp/Signature**
	Institution				
	Phone				
	E-Mail Address				
Clinical Information and Family History					
Requested Test Information					

GENERAL INFORMATION ABOUT THE APPLICATION

This application is the examination of fertilized embryos by genetic methods before implantation through “In Vitro Fertilization (IVF)”. This method makes it possible to detect numerical and structural anomalies of chromosomes in cells taken from embryos by biopsy and to distinguish chromosomally healthy or abnormal embryos.

Aneuploidy is defined by the fact that one or more chromosomes or chromosomal regions are less or more than the normal number.

Preimplantation Genetic Test-Aneuploidy (PGT-A; Aneuploidy) is the process of screening the embryos of the expectant parents for chromosomal aneuploidies, whose chromosome formation is known to be normal or who do not have any information about the abnormal chromosome formation.

Preimplantation Genetic Test-Structural Rearrangements (PGT-SR) applications are the process of screening embryos for such rearrangement and other possible chromosomal aneuploidies in cases where there is balanced or unbalanced chromosomal rearrangement in the expectant mother and/or father.

With PGT-A and PGT-SR methods, it is aimed to increase the success of implantation (attachment to the inner surface of the uterus after transfer of the embryo) in IVF applications, to shorten the time to obtain pregnancy and to reduce the risk of miscarriage due to fetal aneuploidy.

PGT-A and PGT-SR are mostly applied to cells taken by biopsy from embryos that have arrived on the 5th day following fertilization.

NGS* (“Next Generation Sequencing”) method is used in PGT-A and PGT-SR tests.

LIMITATIONS

- PGT-A and PGT-SR processes in embryos are limited to the chromosomal regions scanned within the detection capacity and do not include other possible genetic diseases such as single gene diseases. For this reason, our institution cannot be held responsible for direct and indirect damages that may occur in the event of a possible single gene disease in the embryo.
- The results may be affected by procedures performed during biopsy collection, barcoding errors during the sending of samples, failure to use appropriate biopsy transfer solutions. In addition, situations such as the inability to obtain informative results after genetic testing or the results being below the reliability limit may be encountered.

- These tests do not provide information about single gene diseases, multifactorial diseases, microdeletion syndromes, ploidy disorders (triploidy, tetraploidy, etc.) and balanced chromosomal changes (translocation, inversion). Under these conditions, the precision of the results should be confirmed by one of the invasive (interventional) prenatal diagnostic techniques (CVS, amniocentesis, cordocentesis) during pregnancy. Our institution cannot be held responsible for direct and indirect damages arising from situations that arise in this way and fall outside the limits of the test power.
- In the application of PGT (PGT-SR) for translocation, the resolution limits of the NGS method should be considered. In particular, fractures in the end regions of the chromosomes called telomeres and small losses and gains below the resolution limits may not be detected by this method. In the case of such small chromosomal segments, it is necessary to test the fetus with one of the invasive prenatal diagnostic methods. Prenatal diagnosis should be made using both karyotyping and microarray methods. Our institution cannot be held responsible for direct and indirect damages arising from situations beyond the detection limits of prenatal diagnostic tests used for these purposes.
- With these tests, disorders known as Uniparental Disomy (UPD) ** cannot be detected. Our institution cannot be held responsible for direct and indirect damages arising from situations where UPD cannot be detected.
- The probability of misdiagnosis with PGT-A is around[1] 0.7-1% per embryo, and the reliability of the test is 99%. It should be taken into account that testing the embryo biopsy taken may not provide information about the whole embryo and may not detect possible aneuploidies that may occur after the biopsy. Therefore, if there is any finding indicating fetal involvement, testing the fetus with one of the invasive prenatal diagnostic methods should be considered.
- Loss and gains below the resolution limit of the chitin used and mosaics*** below 25% cannot be detected. It should be taken into account that the rate of mosaicism may vary depending on the number of cells taken and the embryonic region where the biopsy is taken. In addition, since the biopsy procedure is performed from the outer cell mass (trophoblast) of the embryo, the results obtained may be incompatible between the inner cell mass (embryoblast). For this reason, as stated in international guidelines, the results of the test should be confirmed by prenatal diagnostic techniques (CVS, amniocentesis and cordocentesis).
- Although it has been reported in the literature that a healthy pregnancy can be achieved after the transfer of low-grade mosaic embryos, genetic counseling is recommended in cases of mosaic embryo transfer [2-3].
- Couples need to abstain or be protected to avoid the risk of an unplanned pregnancy during PGT-supported IVF application. Our institution cannot be held responsible for direct and indirect damages arising from pregnancy that may occur before or after embryo transfer if the patient has a child.
- Since the test is a screening test, it is necessary to test the fetus with one of the invasive prenatal diagnostic methods in case of any finding indicating fetal effect in case of pregnancy.
- The responsibility for the accuracy and suitability of the test results performed outside our center in PGT-A and PGT-SR procedures belongs to the applicant parent and the said centers.
- Embryo biopsy samples delivered to our laboratory and not processed will be stored for a maximum of 3 years after they reach our laboratory and will be destroyed at the end of the period.

* NGS is a high-capacity sequencing method applied to determine part of the nucleotide sequence of an individual's genome. This method determines the changes in the number of copies of chromosomes depending on the differences in the number of readings compared to the reference genome set.

** Uniparental disomy is when two copies of a chromosome or chromosome fragment come from one parent and no copies come from the other parent.

*** Mosaicism is defined as the coexistence of two or more cell lines with different chromosome structures. Mosaicism occurs during mitosis divisions that the embryo undergoes. In other divisions following the first division, it is the case that the chromosomes cannot be evenly distributed to the cells, but cells containing an abnormal number of chromosomes are formed. Mosaicism, that is, abnormal cells, can be found in other cells of an embryo that is chromosomally “normal” without biopsy, or vice versa; “norma”cells can be found in the unanalyzed part of an embryo that is “abnormal”. Therefore, if there is mosaicism in the embryo, this may cause misdiagnosis.

EVALUATION OF THE RESULTS

Suitable for transfer: Identifies embryos in which a chromosomal aneuploidy is not detected within the detection limit of this test.

Not suitable for transfer: Identifies embryos in which one or more chromosomal aneuploids remain within the detection limit of this test and whose transfer is not recommended by international guidelines.

Genetic counseling is recommended: It defines the results that genetic counseling should be given to the parent and/or the following physician about the condition in embryos with mosaic chromosomal aneuploidy or in which the results cannot be clearly evaluated.

Failure to obtain results: These are results that are at a low level of reliability and are not sufficiently informative.

INCORRECT DIAGNOSIS CASES

PGT-A and PGT-SR have a 0.7-11% risk of misdiagnosis. “False positives” are among the most important causes of errors. “False positives” means abnormal detection of normal embryos. In addition, there is a possibility that abnormal embryos are detected as “normal”, that is, there is a possibility of “false negatives”

A second important cause is contamination. Contamination means that maternal, paternal or foreign DNA molecules mix with the DNA of the sample to be analyzed before or during the procedure and affect the results. To prevent contamination; culture conditions, embryo biopsy process and all laboratory procedures should be carried out under highly sterile conditions to prevent possible foreign genetic material that may come from outside.

Our institution cannot be held responsible for direct and indirect damages caused by faulty diagnoses, including false positivity or false negativity, due to the technical and biological limitations of the tests in terms of diagnosis.

COST AND CONFIDENTIALITY

In accordance with the provisions of the "Tıbbi Laboratuvar Hizmetleri ve İleri Teknoloji Tıbbi Laboratuvar Uygulamaları Hakkında Yönetmelik" in force, the service breakdown and unit prices for the services provided for the examinations are arranged in detail and a copy is given to the parent upon request.

In accordance with the provisions of the relevant legislation, test takers have the right to request that their personal information, health conditions, diagnosis and treatment information, as well as their visits during diagnosis and treatment, be kept confidential. Such information may only be shared with legal authorities if necessary.

Persons in charge of providing health services may only access the health data of the person concerned, provided that it is limited to the requirement of the health service to be provided.

Our institution cannot be held responsible for direct and indirect damages caused by patients who share limited/incomplete health data due to incomplete data sharing.

CERTIFICATION

In accordance with the provisions of the "Biyoloji ve Tıbbın Uygulaması Bakımından İnsan Hakları ve Haysiyetinin Korunması Sözleşmesi [4]" and the "Tıbbi Laboratuvar Hizmetleri ve İleri Teknoloji Tıbbi Laboratuvar Uygulamaları Hakkında Yönetmelik[5]" in force, genetic examination is not performed for the purpose of gender determination only without medical indication at each step of PGT procedures from the beginning to the end. In cases other than gender-related diseases, gender is not specified in preimplantation genetic test reports.

CONSENT TO STORAGE AND USE

Consent of Storage	**Consent to Use**
DNA samples may need to be used for additional genetic testing in the future. DNA samples of the obtained embryo biopsies are kept for 5 years.	Test results are an important resource for researchers to investigate genetic diseases and improve their diagnosis and treatment. In this case, personal data is anonymized and/or encrypted. After anonymization, the rights regarding the data and material will belong to Acıbadem Maslak Genetic Diagnosis Center. Accordingly, I consent to the storage and use of my test results in the database for scientific purposes, to improve and facilitate the identification of diseases and to provide statistical information.
□ **I accept.** □ **I do not accept, my samples should be destroyed when legal obligations are eliminated.**	□ **I accept.** □ **I do not accept, it should be kept only for the purpose of being used for additional processes approved by me.**

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CONSENT

By signing this request form, I consent to the PGT-A/PGT-SR test being performed voluntarily. I have received comprehensive information on the indication, procedure, chance of success, limitations and results of the proposed test, as well as the duration and cost of this test. The applications to be performed, their duration, possible consequences and complications, risks, and consequences were explained in detail. In the event that this information is not sufficiently understood by me, I know that the experts are ready to explain all aspects of the relevant issues.

All genetic data are processed, recorded and stored by you within the scope of personal consent for the purposes specified in this document. I have been informed about my rights as the relevant person within the scope of Article 11 of the Kişisel Sağlık Verileri Hakkında Yönetmelik[6] that my data obtained and processed by Acıbadem in line with the purposes specified in the relevant legislation and this document can be shared with the companies included in the Acıbadem Group, all kinds of judicial authorities, their authorized representatives, domestic and foreign institutions from which you receive consultancy, regulatory and supervisory institutions, business partners and other third parties with whom they cooperate in order to realize or improve the services offered, including official authorities; in the physical archives and/or information systems of Acıbadem, both in the digital environment and in the physical environment.

I have read a copy of the informed consent, understand and accept that no result has been committed to me by the application of the said tests, that these tests have limitations and that I cannot impose any defects and liability on those who perform the test due to direct and indirect damages incurred in these cases. We authorize this practice to be carried out without any pressure and direction, completely of my own free will, and we request this practice to be carried out. We consent this practice to be carried out voluntarily.

I know that I can withdraw this permission partially or completely at any time without giving any reason, provided that I convey it in writing and signed, and that I have the right not to receive information about the test results.

We have read, understood and fully accepted all the above-mentioned stages.

Please, write "I have read, I understand and I accept" in your handwriting in this field.

Wife (Name-Surname/Signature/Date)	Husband (Name-Surname/Signature/Date)	Witness (Name-Surname/Signature/Date)	Physician (Name-Surname/Signature/Date)

Report Delivery Preference: All genetic data is personal and cannot be shared with third parties. In our center, only your physician who made the test request is informed by e-mail. If you give your consent, your final report may be sent to the physician or physicians who make the request and follow you clinically, to you or to another person you authorize. For this, you need to indicate your authorization request in your handwriting.

Authorization to Receive Information on the Result:

REFERENCES

1. Greco E. et al,. Preimplantation Genetic Testing: Where We Are Today. Int J Mol Sci. 2020 Jun 19;21(12):4381.
2. Gleicher N. et al,. International Do No Harm Group in IVF (IDNHG-IVF). The 2019 PGDIS position statement on the transfer of mosaic embryos within a context of new information on PGT-A. Reprod Biol Endocrinol. 2020 May 29;18(1):57.
3. Leigh D. et al,. PGDIS position statement on the transfer of mosaic embryos 2021. Reprod Biomed Online. 2022 Jul;45(1):19-25.
4. In accordance with Law No. 5013 "Biyoloji ve Tıbbın Uygulaması Bakımından İnsan Hakları ve Haysiyetinin Korunması Sözleşmesi"
5. Dated October 24, 2025 and numbered 33057 **"**Tıbbi Laboratuvar Hizmetleri ve İleri Teknoloji Tıbbi Laboratuvar Uygulamaları Hakkında Yönetmelik"
6. Dated June 21, 2019 and numbered 30808 "Kişisel Sağlık Verileri Hakkında Yönetmelik"

Adress: Özel Acıbadem Maslak Hospital Genetic Diagnosis Center, Darrüssafaka Mahallesi Büyükdere Caddesi No:198 Sarıyer/Istanbul
web: www.acibademgenetik.com.tr ● **e-mail:** genetik@acibadem.com.tr ● **Tel:** (0216) 544 38 38