CooperSurgical®

Preimplantation Genetic Testing
Patient Consent Form

BACKGROUND

Individuals typically have 23 pairs of chromosomes (46 total) – one chromosome in each pair from the egg and one from the sperm. Chromosome abnormalities can occur spontaneously during maturation of the egg or sperm, or during the process of embryo division after fertilization. Any alteration to the number or structure of chromosomes, or to single genes within those chromosomes, may lead to implantation failure, miscarriage, or the birth of a child with a genetic or genetically-influenced condition. Genetic testing of embyros prior to transfer and implantation is known as "preimplantation genetic testing" or "PGT". PGT can only be performed in conjunction with *in vitro* fertilization (IVF) and must be ordered by a healthcare provider (referred to as "HCP"). PGT is an optional genetic test that can be performed on cells (referred to as "Sample") taken from the outer layer of an embryo (also known as a "trophectoderm biopsy"). PGT is a screening test that can provide information about the genetic status of biopsied cells. Results of PGT testing often represent the genetic status of the remaining embryo, but this is not always the case. For this reason, PGT is not a substitute for routine prenatal testing ordered by your HCP post-implantation. You should review and understand not only the benefits but also the limitations of PGT. If you would like to review references/ support for certain statements or claims made in this Patient Consent Form, please visit www.coopersurgical.com.

TESTING PROCEDURE

Preimplantation Genetic Testing (referred to as "Tests") and certain services will be provided by CooperSurgical, Inc. and/or one or more of its affiliate laboratories, InVitro Ltd and/or CooperGenomics Inc. (all of which shall be referred to herein as "CooperSurgical"). Testing on a Sample is a multi-step procedure that involves both your IVF center and the CooperSurgical testing laboratory. The potential risks, benefits, and limitations of these optional Tests should be discussed with your HCP and a genetic counselor. CooperSurgical is providing the Test but your HCP (and your genetic counselor in some cases) is responsible for understanding, and helping you understand, the results of any Test. The HCP will then determine, with you, how and whether to use the outcome of the Test to help make decisions about your embryo(s). All decisions regarding your embryo(s) should be between you and your HCP.

GENERAL RISKS, BENEFITS & LIMITATIONS

- Spontaneous pregnancy during treatment would invalidate the results of any preimplantation genetic testing.
- Favorable Test results do not guarantee that a child will be born without any birth defect(s) or genetic disorder(s).
- All Tests have an inherent risk of discovering additional results not related to the indication of the ordered Test (incidental findings). We will only report results for the Tests ordered by your HCP.
- All Tests have an inherent risk of error or misdiagnosis. It is strongly recommended that if you become pregnant with an embryo tested by us, that post-implantation diagnostic prenatal testing be performed to test the genetic status of the fetus.
- Preimplantation genetic testing does not guarantee a healthy pregnancy or reduce all protential risk factors.
- DNA contamination present in the Sample received from the IVF laboratory may interfere with PGT testing and invalidate the results of these Tests.
- This form does not provide all of the information that may be necessary and/or important for you to understand your Test results. Therefore, you should consult with your HCP to discuss and understand your Test results to determine whether or how you will use your Test results in your family planning decisions. Tests should be analyzed and discussed with your HCP.
- Clinical interpretation provided in the Test results will be current as of the date such Test results are provided. Clinical interpretation of Test results can change over time with emerging data, changes in professional organization guidelines and/or for other reasons. CooperSurgical is under no obligation to update Test results in response to these changes or to inform you of these changes even if it might affect such previously provided Test results.
- CooperSurgical is not responsible for the biopsy process or for the IVF center's failure to perform biopsy, Sample preparation and labeling.
- CooperSurgical uses proprietary technology in order to amplify the DNA in the Sample in preparation for testing. Because the testing service you have requested includes this proprietary amplification, any raw data that has been generated may not be transferred by you or on your behalf to a third party for further or additional testing or analysis. Furthermore, Sample(s) received and/or processed by CooperSurgical may not be suitable or available for testing at other laboratories.
- CooperSurgical sends test results to the parties you authorize us to send the results to, and as otherwise required by law.
- The selection of embryos for transfer is the decision of, and at the discretion of, you and your HCP. The Test results provided to your HCP are intended as a guide.

SAMPLE TRANSPORT AND RELATED RISKS

- Samples will be shipped by your IVF center.
- Loss, delays or damage of Samples can occur during shipping and may result in the inability to perform the Test(s) or report Test results.
- Transport issues may impact CooperSurgical's ability to perform the requested Test(s) so we may reject Sample(s) that do not meet our standards.
- CooperSurgical is not responsible for the errors above or any associated costs.

SAMPLE ANALYSIS

- Once we have received your Sample(s), the DNA is isolated from the cells, purified, and amplified to perform the Test(s). It is possible that technical problems during these steps may prevent the Test(s) from being performed.
- Only those Tests that have been ordered by your HCP and for which you have provided your informed consent will be performed and reported in the manner requested by your HCP.
- The initial biopsied cells are destroyed during the testing process and cannot be returned to your IVF center.
- If Samples are received by the laboratory with no paperwork or Test instructions on file, the DNA will undergo a Sample stabilization process to ensure Sample stability. Testing will not proceed until CooperSurgical has received all necessary documents.
- If we do not receive follow-up testing instructions and the necessary documents from an authorized provider within 60 days of receiving Samples, the Samples may be destroyed.

DATA AND SAMPLE RETENTION

CooperSurgical may store your Test data and Sample to:

- conduct retesting or additional testing provided such testing is necessary and required to demonstrate the integrity of the Sample tested or to resolve the analysis of a Test with a previously indeterminate result
- perform additional PGT testing ordered by your HCP
- perform quality management and ensure continuous development of testing processes necessary for the provision of healthcare services
- ensure compliance with quality assurance standards and applicable laws
- support research and development activities (R&D)

Your de-identified Test data and Sample may be used and stored by CooperSurgical for supporting R&D activities including the creation of new testing methods, tools or innovations (if you are not a US or Canadian patient, you need to consent to this below). De-identified data refers to information that has been processed to remove specific identifiers such as names, dates of birth and contact details that could reasonably be used to identify you. Once de-identified, the data no longer contains Protected Health Information (referred to as "PHI") and cannot be used to identify you. Your Test data and Sample will be de-identified prior to conducting any R&D activities. Your Test data and Sample will not be used in any identifiable fashion for research purposes without your consent. Because all of your PHI will be removed from the Test data and Sample, you will be given no notice or compensation if your Test data or Sample is used to support the creation of new testing methods, tools or innovations. You further disclaim all ownership and acknowledge that you have no rights to any commercial discoveries or related proceeds which may arise from such activities.

CooperSurgical's use and storage of your Test data and Samples shall at all times be in accordance with the requirements and retention periods set forth in applicable laws and regulations.

PGT-A (Including Genetic PN Check) (Preimplantation Genetic Testing for Aneuploidies)

TEST PURPOSE

The purpose of PGT-A is to evaluate embryo biopsies to help inform whether the embryo might have an abnormal number of chromosomes or other detectable chromosome abnormality. PGT-A does not screen for other genetic conditions or diseases.

TECHNOLOGY

Testing is performed via a next-generation sequencing (NGS) technology. This technology evaluates the amount of chromosomal material present and is capable of identifying regions of missing or extra material larger than 5 megabases (Mb).

PGT-A CAN DETECT:

- Whole chromosome aneuploidies (an entire extra or missing chromosome)
- Some forms of segmental aneuploidy (extra or missing segments of chromosomes)
- Haploidy (single set of chromosomes) and some forms of polyploidy (more than two sets of chromosomes) - Genetic PN Check
- Mosaicism (a Sample that includes a number of cells with one chromosome makeup while the remaining cells in the same Sample have a different chromosome makeup) - is reported as instructed by your HCP

PGT-A CANNOT DETECT:

- Balanced chromosome rearrangements (i.e. translocations or inversions where the chromosomal material has moved from its original location, but does not differ in the amount of material present)
- Alterations smaller than 5 Mb, including small insertions or deletions
- Point mutations associated with single-gene disorders
- Some forms of polyploidy

PGT-COMPLETE℠ (parentage testing)

PGT-Complete includes origin of aneuploidy testing which provides information on parental origin of aneuploidy for meiotic whole chromosome aneuploidies as well as meiotic segmental aneuploidies of 10Mb or larger. It does not determine parental origin for mosaic aneuploidies or for segmental aneuploidies smaller than 10Mb. Origin of aneuploidy information is not reported for Samples found to be euploid by PGT-A.

- The parentage confirmation evaluates the inheritance of the embryo biopsy in comparison to provided parental samples. This assessment is intended to support protocols performed by your IVF clinic, including witnessing/electronic witnessing and embryo biopsy procedures.
- Parental origin of aneuploidy and parentage testing are only performed when requested by your HCP. Parental samples and consent are required for test completion.
- In countries where confirmation of embryo parentage is not permitted, only origin of aneuploidy is reported.

SELECT SYNDROME SCREEN℠

The purpose of Select Syndrome Screen is to assess for specific gains or losses of genetic material that are associated with specific phenotypes. These are also referred to as microdeletion or microduplication syndromes. Select Syndrome Screen is designed and validated to detect specific microduplication/microdeletion regions that may be below the detection size of five (5) megabases (Mb) available in standard PGT-A testing but above the detection size of two (2) Mb.

Select Syndrome Screen tests for only the following, and not for any other conditions or diseases:

Microdeletion/Microduplication	Location
1p36 deletion syndrome	1p36
2q33.1 deletion syndrome	2q33.1
Angelman / Prader-Willi syndrome	15q11.2-q13.1
Cri du chat syndrome	5p15
DiGeorge syndrome (22q11.2 deletion syndrome / Velo-Cardio-Facial syndrome)	22q11.2
Jacobsen syndrome	11q23-qter
Langer-Giedion syndrome	8q23.2–q24.1
Potocki-Lupski / Smith-Magenis syndrome	17p11.2
Wolf-Hirschhorn syndrome	4p16.3

BENEFITS & LIMITATIONS OF PGT-A AND PGT-COMPLETE

- PGT-A is not 100% accurate. Our NGS technology has an accuracy of >99%. The accuracy of PGT-A testing is further limited to the Sample tested by PGT-A.
- Because the Sample is only a very small sample of the entire embryo, it is possible that the chromosome complement identified via PGT-A will differ from the overall chromosome complement in other section(s) of the embryo.
- It is possible that all embryos tested will be identified as abnormal. There is a small chance that some embryos may not yield a result.
- The PGT-Complete parentage assessment may supplement but does not replace IVF laboratory witnessing techniques.
- PGT-Complete is not meant to be used as a replacement for diagnostic parentage testing.

BENEFITS & LIMITATIONS OF SELECT SYNDROME SCREEN

- Select Syndrome Screen is not 100% accurate. Select Syndrome Screen has an accuracy of >99%. The accuracy of Select Syndrome Screen testing is further limited to the the Sample tested by Select Syndrome Screen.
- A chromosome microdeletion or microduplication may be present at a size lower than the resolution of the standard PGT-A test. Improved microdeletion/microduplication detection provides information about the specific additional disorders listed in the chart provided under Select Syndrome Screen prior to embryo transfer.
- Select Syndrome Screen only assesses for the microdeletion/microduplication syndromes indicated. Syndromes involving microdeletions and/or microduplications on other chromosomes or other locations of chromosomes will not be detected.
- The resolution of Select Syndrome Screen is 2 Mb. Gains or losses less than 2 Mb within the indicated microdeletion/microduplication regions might not be detected.
- As the resolution of CooperSurgical PGT-A is 5 Mb, some microdeletion/microduplication abnormalities might be detected by both the PGT-A and Select Syndrome Screen technologies.
- Large deletions/duplications involving the microdeletion/microduplication location and significant other locations of the same chromosome will be reported by the PGT-A technology and not Select Syndrome Screen.
- Mosaic reporting is not available for locations included on Select Syndrome Screen.
- Origin of aneuploidy will not be reported for microdeletions or microduplications identified by Select Syndrome Screen.

PGT-M (Preimplantation Genetic Testing for Monogenic/Single-Gene Defects and PGT-SR (Preimplantation Genetic Testing for Chromosomal Structural Rearrangements)

TEST PURPOSE

The purpose of PGT-M is to identify embryos that may contain single-gene (monogenic) disorders related to mutations previously identified in one or both parents. The purpose of PGT-SR is to identify embryos that may contain unbalanced structural rearrangements associated with known parental rearrangements.

TECHNOLOGY

PGT-M may be performed by linkage-based analysis alone, or linkage analysis combined with direct mutation testing. If the Sample is found to be free of the single-gene disorder, it is concluded that the embryo it was derived from is also free of the single-gene disorder. A genetic mutation report identifying the mutation is required before testing can be performed.

PGT-SR is typically performed via next-generation sequencing (NGS) to determine if a balanced amount of genetic material (DNA) is present. A subset of gene disorders or chromosome rearrangements may not be detectable via NGS. A karyotype identifying the structural rearrangement is required before testing can be performed.

BENEFITS & LIMITATIONS OF PGT-M and PGT-SR

- PGT-M and PGT-SR are not 100% accurate. CooperSurgical's PGT-M and PGT-SR technologies have an accuracy of >99%. The accuracy of PGT-M and PGT-SR testing is further limited to the Sample tested by PGT-M and PGT-SR.
- It is possible that all embryos tested will be determined to have a mutation or chromosome rearrangement. There is a small chance that some embryos may not yield a result.
- PGT-M and PGT-SR will only be performed for the single-gene disorder(s) or chromosome rearrangements that were ordered by your HCP.
- PGT-M and PGT-SR are not available or appropriate for all identified genetic mutations or structural rearrangements. CooperSurgical may decline to perform the PGT-M or PGT-SR Tests ordered by your HCP.

CONFIDENTIALITY AND DATA TRANSFER

If you are outside the United States, your data may be transferred to the United States, which may not offer the same level of data protection as certain other countries/regions such as the UK/EEA. Where such transfer occurs, CooperSurgical implements appropriate safeguards, such as Standard Contractual Clauses approved by the European Commission. CooperSurgical will only use or disclose your information and results as permitted or required under CooperSurgical's Privacy Policy, which is attached to this consent form and can be found here: https://www.coopersurgical.com/data-privacy-policy/

GENETIC COUNSELING AND FOLLOW UP

- A trained and certified genetic counselor is available through CooperSurgical (additional charges may apply).
- We may contact you throughout the course of any resulting pregnancy and afterward to ask about outcomes. Any information received shall remain confidential except to the extent that regulatory bodies may inspect these records and/or the legal system may require disclosure.

FINANCIAL CONSIDERATIONS

In consideration of the services rendered, you agree to pay all charges not covered by your insurance company or any applicable health benefit including, but not limited to, deductibles, co-payments, coinsurance, and non-covered services. You understand that it is your personal responsibility to pay for all charges for services rendered irrespective of any disputes or disagreements between you and your insurance company. We are entitled to payment in the event a Test is started but is canceled or not performed.

TEST SELECTION:

☐ **I hereby consent to the performance of all of the following Tests ordered by my HCP: PGT-A (Including Genetic PN Check), Select Syndrome Screen, PGT-Complete (parentage testing), PGT-M and PGT-SR**

OR

☐ **I hereby consent to the performance of only the following Test(s) ordered by my HCP (check all that apply):**
PGT-A (Including Genetic PN Check) ☐ **Select Syndrome Screen** ☐ **PGT-Complete (parentage testing)** ☐ **PGT-M** ☐ **PGT-SR** ☐

FOR PATIENTS IN THE US OR CANADA:

By affixing my signature at the bottom of the page (PATIENT SIGNATURE), I hereby consent to the following:

- I am either (1) at least 18 years of age; or (2) I am legally recognized as an 'emancipated minor' by the state in which I reside.
- I have read this Patient Consent Form and any appendices relevant to the ordered Test(s) and agree to the contents and hereby authorize all of the activities described herein.
- I have read and agree to the financial considerations and have been given the opportunity to ask my HCP and CooperSurgical questions concerning the payment terms outlined.
- I agree that my Sample will be stored for an additional 5 years following the initial 60-day testing period to conduct the activities outlined in this consent. If I have authorized a PGT-M test to be performed, I agree that my genomic DNA will be stored for an additional 10 years.
- I have been given an opportunity to ask questions about the Testing and the contents of this consent form. If I think of additional questions, I may contact my HCP or genetic counselor.

☐ Check box to opt in for text message communications. Message & data rates may apply. You may opt out at any time.

FOR PATIENTS OUTSIDE THE US OR CANADA:

Please mark below to indicate whether or not you are willing for your Test data and Sample to be used in a secure, de-identified form for supporting research and development activities. CooperSurgical will not condition its performance of services on your decision to provide consent.

☐ Opt in: I agree to the use of my Test data and Sample in a secure, de-identified form for supporting research and development activities.

Please note that you have the right to withdraw your consent at any time by contacting us at dpo@cooperco.com. This will not affect the lawfulness of any processing up to the point at which consent is withdrawn.

By affixing my signature at the bottom of the page (PATIENT SIGNATURE), I hereby consent to the following:

- I am at least 18 years of age.
- I have read this Patient Consent Form and any appendices relevant to the ordered Test(s) and agree to the contents and hereby authorize all of the activities described herein.
- I have been given an opportunity to ask questions about the Tests and the contents of this form. If I think of additional questions, I may contact my authorized HCP or genetic counselor.
- I understand that processing of personal data will be carried out under Article 9 (2) (h) of Regulation (EU) 2016/679 (General Data Protection Regulation) in accordance with CooperSurgical's Privacy Policy, which can be found at: https://www.coopergenomics.com/gdpr-privacy-practices/ or in hard copy at the clinic with this consent form. The Privacy Policy explains how my data is protected, the rights I have under data protection law, and how I can raise any questions or complaints with CooperSurgical or the relevant data protection authority.

PATIENT SIGNATURE (ALL PATIENTS)*:

Patient 1 Signature _____ Print Name _____ Date ____/____/_____
Month / Day / Year

Patient 2 (Partner) Signature _____ Print Name _____ Date ____/____/_____
Month / Day / Year

**Patient and Partner names must match the names provided in the Test Requisition Form.*