SUPRATECH

CONSENT FORM FOR PREIMPLANTATION GENETIC SCREENING

Supratech Micropath Laboratory & Research Institute Pvt. Ltd. (also known as Supratech) is a genetic testing laboratory specialized in preimplantation genetic screening and diagnosis. The lab conducts genetic testing on a small sample of your embryos to determine which embryo is chromosomally normal. Embryos with abnormal chromosome copy may cause failure of implantation, miscarriage, or lead to newborn with genetic disorder. In order for Supratech to provide your IVF center with genetic testing, we require you to read and sign this consent form.

Embryo Biopsy and PGS: The embryologist at your IVF lab will perform embryo biopsy to remove a single cell (Day 3 embryo) or few cells (Day 5 embryo) from each of your embryos. Embryo biopsy is performed using a medical laser or chemical methods to detach one or few cells from your embryos. The extracted cells will be prepared and shipped to Supratech for genetic testing. The embryos themselves will remain at your IVF clinic until testing is complete and embryo transfer can take place. Each biopsy samples will be analyzed using Next Generation Sequencing.

Next Generation Sequencing: (NGS): NGS is the latest technology available for preimplantation genetic screening and diagnosis. NGS is known for high accuracy in variety of genetic tests, while array CGH and FISH are reported to have significant error rates. Furthermore, indirect methods such as array CGH and FISH have a number of limitations that NGS does not have. For example, Array CGH and FISH rely on relatively low number of probes, and utilize fluorescence signal that are susceptible to signal saturation, and signal noise. These and other factors make aCGH and FISH prone to errors.

Please read and acknowledge the following items by initialing each:

- Patient Initial _____ Partner Initial _____ I request the following test:

  ☐ NGS-24™ (24 chromosome preimplantation genetic screening using Next Generation Sequencing)

- Patient Initial _____ Partner Initial _____
  I confirm my wish to have a small sample from each of my/our embryos biopsied for the purpose of identifying embryos without chromosomal abnormality.

- Patient Initial _____ Partner Initial _____
  I understand that all embryos may be at risk of having chromosomal abnormality.

- Patient Initial _____ Partner Initial _____
  I understand that PGS testing for aneuploidy does not eliminate the need for routineprenatal testing such as chronic villus sampling (CVS) or amniocentesis. The need forthese tests remains the same, whether or not I choose to have PGS screening.

- Patient Initial _____ Partner Initial _____
  I hereby confirm that this test is not intended by any means to be used for sex selection of the baby.

  I hereby confirm that I have been notified that the NGS-24TM provided by Supratech will never provide any details about the sex of the embryo. In cases where Sex chromosomal abnormalities are present, the Report may include a remark suggesting abnormal sex chromosomes but will in no way every suggest the nature of the abnormalities and the particular sex chromosome/s involved.

Patient's Full Name: _____ Age: _____

Partner's Full Name: _____

Address: _____

_____

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RISKS AND LIMITATIONS

Embryo Biopsy: The vast number of animal and human studies shows that microsurgery of the embryo does not seem to affect the normal development of the baby. The thousands of children born following an embryo biopsy since 1989 provide evidence of no deleterious effects as a result of the biopsy process. Despite this data, however, it is important to be aware that some rare, unrecognized potential risk does exist and can never be entirely ruled out.

Misdiagnosis: There is a chance of misdiagnosis with every sample analyzed. With embryo testing, it is possible for a chromosome anomaly to be present in a cell, yet not in other cells of the same embryo and vice-versa. This is a condition called mosaicism. A typical genetic test, on the other hand, involves obtaining many cells which are then cultured to divide into many, many more cells. Large amounts of chromosome/DNA sample are then tested over the course of a week or more. This is simply not possible in embryo testing. It is also important to understand that PGS represents the theoretical and practical limits of any medical diagnostic test. As in virtually any laboratory, including Supratech, diagnostic errors maybe encountered, even in the absence of mosaicism. We, unfortunately, are unable to eliminate risks completely but place the utmost importance on our goal of reducing the risk of misdiagnosis.

Genetic Defects: PGS will not detect conditions caused by single gene mutations, such as cystic fibrosis or Tay-Sachs disease. The general risk of having a baby with a birth defect or genetic condition, with or without IVF, is around 3 to 4 percent. PGS is not performed, nor is it able, to appreciably alter this background number. The purpose of PGS is, instead, to identify what are believed to be the best embryos for transfer to the womb to increase your chances of pregnancy and substantially reduce the chance of conceiving a baby with certain chromosomal abnormalities.

No Normal Embryos: There is a chance that your results may reveal that all embryos tested have chromosomal abnormalities and, therefore, are not suitable for transfer. It is also not always possible to transfer all embryos found to be genetically normal as some may not continue to develop normally or may cease to develop, all together, prior to transfer into the womb.

Patient Initial _____ Partner Initial _____

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OTHER RISKS AND LIMITATIONS

Technical Malfunctions: Any of the tests you may be choosing to have may fail in any individual case because of unforeseen technical malfunctions. It is not possible, therefore, to guarantee pregnancy after PGS for aneuploidy or even to promise that there will be benefits for any individual case.

Samples loss or damage due to transportation:
Supratech uses special courier (i.e. Blue Dart, FedEx, etc.) to ship embryo biopsies from the IVF centers to Supratech laboratory in specialized containers and may in some cases have their own staff transport biopsies for logistical and technical reasons. These small samples are designated for Genetic testing only, the actual embryos remain at the IVF clinic. There is a small chance these Samples may be delayed, damaged or lost during transportation because of weather, accident, human error, or any other reasons beyond the control of Supratech. Supratech is not responsible for any loss or damage of your sample during transportation.

Patient Initial _____ Partner Initial _____

Technical Malfunctions: Any of the tests you may be choosing to have may fail in any individual case because of unforeseen technical malfunctions. It is not possible, therefore, to guarantee pregnancy after PGD for aneuploidy or even to promise that there will be benefits for any individual case.

- Patient Initial _____ Partner Initial _____ I confirm that PGS and the risk of misdiagnosis were explained on _____ / _____ / _____ by Dr. _____.
- Patient Initial _____ Partner Initial _____ I confirm that I was given the opportunity to read about preimplantation genetic screening, and next generation sequencing listed on page 2 and page3, and I was given the chance to discuss all my concerns with my doctor, including but not limited to:
    - The purpose of PGS
    - How PGS is performed
    - Risks/limitations and benefits of PGS

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BENEFITS

Improved Chance of Pregnancy: PGS may help couples at higher risk for aneuploidy achieves ongoing pregnancies. Embryos with chromosomal abnormalities rarely develop into fetuses. Because only embryos found to be chromosomally normal are transferred to the womb, your chances for pregnancy are increased.

Improved Pregnancy Outcomes: PGS is able to identify most chromosomal abnormalities and allows only embryos found to be chromosomally normal to be transferred. PGS, therefore, has the potential to substantially reduce the chance of conceiving a baby with certain chromosomal abnormalities.

CONFIDENTIALITY

Your identity and all your personal details shall be kept confidentially, unless the law states otherwise. The Health Authorities shall have access to them to review your medical records. As part of their occupational duties, the personnel with access to your personal details shall be subject to permanent professional secrecy.

HAVING READ AND UNDERSTOOD THE INFORMATION ON THE PREVIOUS PAGE, I HAVE BEEN INFORMED ABOUT:

I/we consent to 24 chromosome-preimplantation genetic screening test by Supratech using next generation sequencing (NGS-24^{TM}).

Likewise, I accept that the PGS (Preimplantation genetic Screening) results will be made known to my gynecologist so that I can be suitably advised about my IVF treatment in accordance with these results.

_____ ____/____/_____
Patient's Signature Date (dd/mm/yyyy)

_____ ____/____/_____
Partner's Signature Date (dd/mm/yyyy)

My/our signature below means that I/we have read and understand this Supratech's Patient Consent Form. I/we confirm that I/we were provided the opportunity to discuss the content of this consent form with my/our doctor, legal advisors, family, and any other party whose advice or opinion may be relevant to my/our case. This Patient Consent Form is the only agreement between Supratech and me/us.

I/we here in confirm my/our wish to proceed with 24 chromosome-preimplantation genetic screening test using next generation sequencing (NGS-24^{TM}).

_____ _____/_____/_____
Patient's Signature Date (dd/mm/yyyy)

_____ _____/_____/_____
Partner's Signature Date (dd/mm/yyyy)