EMBRYOTEST PLUS™

Service Order and Client Information - Preimplantation Genetic Testing for Aneuploidy (PGT-A).

DATE: _____ /_____ /_____

PATIENT INFORMATION

	PATIENT	PARTNER
NAME(S)		
SURNAME		
DATE OF BIRTH		
SEX		
PHONE		

CLINIC INFORMATION

CLINIC NAME	
DOCTOR IN CHARGE	
LOCATION	

REQUESTED SERVICE: EMBRYOTEST PLUS™ (ETP) / PGT-A

ABOUT THE SERVICE

1. It offers a thorough analysis of the 46 chromosomes of the human embryos to detect possible gains or losses of genetic material (aneuploidies), including the sex chromosomes.
2. This test uses massively parallel sequencing for chromosome screening.
3. It allows the selection of those chromosomally normal embryos among all the evolutionary embryos of the patient, which increases the appropriate reproductive and evolutionary possibilities leading to a healthy child. However, this test does not guarantee it.
4. It is not a diagnostic test. The result must be interpreted by the doctor involved with this service for the patient's follow-up.
5. This test does not detect abnormalities caused by balanced translocation, inversion, ring, UPD, monogenic/polygenic disease, etc. Its use cannot exclude fetal mosaic chromosomal diseases either.
6. Potential causes of false positive or false negative results include mosaicism (mixtures of chromosomally normal and abnormal embryo cells) or chromosomal abnormality in either parent.
7. Embryonic sex identification can be false if the detected value is within the gray zone.
8. Semper Genomics (SG) is not responsible for the pregnancy success rate, embryo viability, receptivity in the patient, implantation, or any other risks related to assisted reproductive technology.
9. ETP scope is limited to reporting the qualitative findings of chromosomal gains or losses (aneuploidies) of the embryo biopsy analyzed by massively parallel sequencing.

Semper Genomics USA LLC
Santa Margarita 108, P3, C9-111
Insurgentes San Borja
Mexico City, 03100

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ABOUT THE SEMPER GENOMICS SERVICE

1. The client recognizes the herein as an Informed Consent so that SG as an involved third party can process their samples through ETP under their consent.
2. The EmbryoTest Plus™ service includes:
   a) Kit delivery (a box with 24 tubes of 0.2ul with 2.5ul 1X PBS buffer) for sampling (embryo biopsy).
   b) Sample collection by the logistics services of SG.
   c) DNA extraction and amplification regarding biopsies.
   d) Sample processing by Next-Generation Sequencing (NGS).
   e) Delivery of technical reports to the doctor in charge of the aneuploidies data found in each sample.
3. Samples are collected and relocated by the SG staff to the laboratory located at 108 Santa Margarita, floor 3, offices 9-11, Insurgentes San Borja, Benito Juárez. 0310, with an operation notice before COFEPRIS number 2309145056X00042.
4. Please reach your doctor to request the service.
5. Sample processing is conditional upon its quality inspection, determined by the SG technical staff under the criteria mentioned below.

SAMPLE EXCLUSION CRITERIA

1. Disagreement in the identification number and code of the samples with the recorded data in the Sample Collection, Transportation, and Handling Form for Embryo Test Plus ™.
2. Thawing of samples: it is requested that these remain frozen (-4°F) to keep the genetic material integrity before their collection. Centrifuge them before freezing if possible.
3. Sample absence: the microtube does not contain the sample.
4. In case of exclusion of one or all the samples, it will be notified to the doctor in charge in the Result Report.

SAMPLE LIMITATIONS AND RISKS

1. On the other hand, like any other analytical test, EmbryoTest Plus ™ has technical factors and limitations that can affect the results, such as:
   a) Sample degradation for inadequate storage or wrong handling (cold chain challenges).
   b) The test is limited to a qualitative analysis of the embryonic genome.
   c) The non-amplification of the genome for some intrinsic inhibitor of the sample.
2. Delivery time of the technical report is up to 15 working days from sample reception in the laboratory.
3. The technical report has an exclusively qualitative value. The digital file (*.PDF) will be sent via email to designated addresses in the Sample Collection, Transportation, and Handling Form for Embryo Test Plus ™ that is delivered with the sampling kit.
4. Semper Genomics will terminate the service in accordance with the results 72 hours after the file sending if no notification is received from the doctor in charge.

There are cases where the samples can be seen as "non-informative" and it may be for one of the following reasons: high amount of noise present when performing the sequencing data analysis, mainly due to low quality of the sample or PCR artifacts generated during whole genome amplification. Likewise, there are several factors that can generate artifacts during the PCR-based WGA, including a suboptimal biopsy, DNA degradation, incomplete cell lysis, cells in the apoptosis process, and the presence of PCR inhibitors in the culture medium.

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During the analysis, if there is noise present for reasons or a low number of readings, this impacts the interpretability and confidence of the results observed in the graphs. Therefore, that sample is "non-informative", and IT IS NOT RECOMMENDED TO TRANSFER THAT EMBRYO. It is suggested to repeat the analysis with a new biopsy.

This kind of test poses a risk of false positive/negative results. Such results commonly occur by biological reasons called "mosaicisms", present in approximately 5% of embryo biopsies. Mosaicism means that the embryo can have cells with different numbers of chromosomes (ploidy) both in the normal number (euploidy) and abnormal (aneuploidy). Other important factors that lead to false results are sample contamination, codification problems, rare genetics that interferes with the analysis, technical issues, and human error. Among all these factors, the chance of a false result that is not associated with mosaicism is about 2%.

DATA PRIVACY

Test results will be protected under strict privacy, and they can be provided by email only to the assigned people in the corresponding forms. The information privacy will be 90 calendar days from the results delivery. They will be eliminated after that date.

Filling instructions: The doctor in charge records the requested information in the form.

Name Date and conformed signature of the client	Name Date and signature of the partner

Name Date and conformed signature of the doctor in charge