Blank space reserved for IGENOMIX use only

Request form for SAT test (sperm FISH analysis)

The fields marked with * are mandatory in order to perform the test

CLINICIAN INFORMATION

***Clinic:** _____

***Referring Clinician:** _____ Contact person: _____

E-mail or phone number:_____ ***Email for delivery of results:** _____

Address: _____

City: _____ County/Province/State: _____ ZIP/ Postal Code: _____

PATIENT INFORMATION

***MRN/Unique patient ID:** _____ If not available, please state NOT APPLICABLE

***Patient full name:** _____

***Date of birth:** _____ Email: _____

***Sex:** ☐ Male ☐ Female

*INDICATION FOR TEST

☐ Recurrent miscarriage (no. of miscarriages: ____) ☐ Chemotherapy/radiotherapy

☐ Implantation failures (no. of failures: ____) ☐ Male factor

☐ Previous pregnancy with chromosomal abnormality ☐ Abnormal karyotype

☐ Other: _____

SAMPLE INFORMATION

***Date of sample collection:** _____

***Origin of sample:** ☐ Ejaculate ☐ Testicle ☐ Epididymis

Type of sample: ☐ Fresh ☐ Frozen

ADDITIONAL INFORMATION

Semen analysis

Volume (ml):_____ Concentration (x10^6/ml):_____ Motility (%): A _____B _____C _____D _____

Comments: _____

Clinician authorisation

I certify that the patient and prescribing doctor's details given in this request form are accurate to the best of my knowledge and that I have requested the test indicated above based on my professional criteria. I have explained the limitations of this test and have answered any questions based on medical judgement. I understand that Igenomix may require further information and I agree to provide this information if necessary.

*Clincian's signature_____ Date:_____/_____/_____

Patient consent

By signing this application form, I voluntarily ask Igenomix to perform the test indicated above. I have read and received a copy of the informed consent included in these pages. I have also been adequately informed of the risks, benefits and limitations of this test.

*Patient's signature_____ Date:_____/_____/_____

SPERM ANEUPLOIDY TEST (SAT) - CONSENT FORM

DESCRIPTION, PURPOSE AND ADVANTAGES OF ANALYSIS

The SAT (Sperm Aneuploidy Test) to analyse the aneuploidies in sperm cells is a cytogenetic test that helps with male infertility counselling by analysing the incidence of sperm cells with numerical chromosomal alterations.

Every cell in the body contains chromosomes, which are organised structures made up of DNA and proteins. These chromosomes contain the information needed for growth and development. In humans there are 24 different types of chromosomes, twenty-two numbered from 1-22 and two sex chromosomes known as X and Y. Most cells contain a total of 46 chromosomes; 22 pairs plus an XX pair for females or an XY pair for males. The sperm and egg must each have 23 chromosomes in order to, after the egg is fertilised by the sperm, form an embryo with a total of 46 chromosomes. Aneuploidies are alterations in the correct number of chromosomes. If there is an aneuploidy in the sperm – for example one chromosome too many or too few – and this sperm fertilises an egg, this will produce an embryo with a chromosomal abnormality.

This test is requested for patients with an increased risk of chromosomal abnormalities in their sperm. This is generally the case in men with a normal karyotype in whom there is a suspicion that meiotic errors may have occurred during the creation of sperm (spermatogenesis), which may lead to an increase in sperm with chromosomal alterations. A greater incidence of chromosomal alterations has been identified in the sperm of patients with altered semen parameters, mainly with oligozoospermia (low sperm count), azoospermia (absence of sperm in the ejaculate), and in severe cases of teratozoospermia (sperm with abnormal morphology). This analysis is also recommended for couples who have experienced recurrent miscarriages, or recurrent implantation failures in assisted reproduction cycles. If chromosomal alterations are detected in sperm, there is an increased risk of miscarriages or births with chromosomal disorders. SAT analyses chromosomes 13, 18, 21, X and Y, alterations in which can lead to offspring with chromosomal disorders.

As a result of this analysis, the couple can find out the risk of transmission of chromosomal alterations of paternal origin to children in the event of pregnancy. Therefore, SAT results can help with the couple's reproductive counselling.

PROCEDURE, RISKS AND LIMITATIONS

SAT can be applied to ejaculate, epididymis and testicle samples. The sample obtained by ejaculation is collected in a sterile container and delivered to the Assisted Reproduction Clinic/Centre within a maximum of 2 hours. At the Clinic/Centre, the sperm sample (ejaculate, epididymis or testicle) is washed using a culture medium and sent to Igenomix at room temperature in a protected container in order to prevent any damage. If samples cannot be sent immediately, they can be stored at 4ºC until sending.
The fluorescent in situ hybridization (FISH) technique is used on sperm for genetic analysis. It is a cytogenetic analysis technique that marks specific chromosomes in the sperm with fluorescent DNA probes to determine if there is an increase in the incidence of sperm carrying numerical chromosomal alterations in the analysed sample. This test analyses the five most common chromosomes whose numerical alterations lead to offspring with genetic disorders (chromosomes 13, 18, 21, X and Y). The possibility of analysing other additional chromosomes must be requested by the doctor and assessed by the Igenomix staff before obtaining the sample.

To process the sample, the test application form must be completed correctly. If this is not the case, analysis may be suspended until the information required has been given to the laboratory.

Given the complexity of the genetic tests and the significant implications of the test results, the results obtained must be interpreted in conjunction with other clinical data, within the general context of a medical practice run by healthcare professionals. The results reports are strictly confidential.

The results of the test will be available within approximately 10 working days. A small percentage of samples may be delayed due to unforeseeable causes. Should this occur, the referring clinic will be notified.

There are no associated risks for the patient undergoing SAT.

The SAT test has the following limitations: (i) it does not evaluate numerical chromosomal alterations for all 24 chromosomes, only for the chromosomes included in the analysis; (ii) it cannot detect alterations for chromosome segments other than those labelled by the DNA probes used in the analysis; (iii) it does not analyse specific genes and cannot detect conditions caused by individual genetic mutations, such as sickle cell anaemia, cystic fibrosis or Tay-Sachs disease, among others; (iv) other limitations associated with poor sample quality, including absence of sperm or low concentrations and the presence of a high number of immature cells in the sample.

DATA PRIVACY, STORAGE AND SAMPLES USED FOR RESEARCH

Your privacy is a priority for the Igenomix Group ("**Igenomix**"). Your identity and all data referring to your personal information will be confidential and only Igenomix personnel will be permitted access to this information, along with the relevant authorities when required by the laws of the applicable jurisdiction. You will find further information on the Igenomix Privacy Policy, along with all your rights at www.igenomix.com, or this information may be provided to you upon request by sending an email to privacy@igenomix.com.

We would like to inform you that your personal data will only be processed to: (1) Fulfil the obligations arising from the provision of the services contracted by you; (2) Check and guarantee the quality of the services provided (internal audits, quality controls, laboratory validation studies); (3) For educational purposes, provided that it remains anonymous throughout and you cannot be identified during the analysis of the data, which will be removed from any publication; (4) For research purposes, scientific publications and presentations, provided that it remains anonymous throughout and you cannot be identified during the analysis of the data, which will be removed from any publication; (5) Personally address any doubts or suggestions made by the patient during the process and monitor the proper performance and resolution of the test, including the indefinite retention of your data, except where local laws of the applicable jurisdiction state otherwise; and (6) Contact you in the future to request an evaluation of the services received, send commercial communications (including 'cross-selling' and 'upselling') from associated

companies, and also to invite you to participate in market research and the development of new products.

You also declare that you understand and accept that you will not obtain, either now or in the future, any economic benefit for any research carried out, and that there is no intention to compensate you for the products developed from any research.

The sample will be analysed by Igenomix or an associated group selected by Igenomix on an international level. Igenomix reserves the right to carry out part or all of the analyses included in the test through Third Party Laboratories certified with recognised international quality standards, or failing this, they will be periodically assessed by Igenomix. Any results obtained in this way will be inspected by Igenomix and this circumstance will be indicated in the final report issued.

Samples and all associated data will be retained in the laboratory in accordance with the Igenomix's specimen retention policy which is in accordance with all the legal requirements.

Pursuant to the laws on the Protection of Personal Data[1], the requesting party must have the patient's consent to perform the diagnostic tests requested and to process their data. You may, at any time, exercise your rights regarding access, rectification, opposition, erasure, automated decisions, limitation, portability, by sending an email to privacy@igenomix.com, providing proof of the requesting party's identity.

HAVING READ AND UNDERSTOOD THE FOREGOING, I AM AWARE OF:

The indications, procedure, success rate, risks and complications of the proposed treatment, as well as the financial cost of said test.
The fact that medical staff are at my disposal to expand on any aspect of the information that is not sufficiently clear to me.
I have understood the explanations given to me in clear and simple language, and the clinician who saw me allowed me to make comments, clarifying any issues I raised and informing me that I may freely withdraw my consent at any time.

I am satisfied with the information received and I freely consent to my sperm sample being sent to the Igenomix facilities for the purpose of performing the SAT test. I also accept that the results of the test may be passed on to my medical specialist, so that he or she can provide me with suitable reproductive counselling in accordance with the results.

[1] **For non-US patients:** customers residing outside the United States under certain jurisdictions may at any time request to have their personal information deleted from our active databases, subject to the applicable laws and regulations in each jurisdiction. Although we can delete your personal information from our active databases, part or all of your personal information shall remain stored in back-up files for the purpose of complying with legal, regulatory or other requirements. Information that has already been coded and/or anonymised may not be recoverable or traceable for destruction, deletion or modification. If you wish to have your personal information removed from our active databases, please contact us at privacy@igenomix.com.