KARYOTYPE INFORMED CONSENT

I-LAG-FOR-20 V1, 18/05/2024

CARIOTIPO X

Among the ethical standards required of medical professionals in Colombia by Law 23 of 1981 is the duty to adequately and timely inform all patients of the risks that may arise from the treatment that will be performed, requesting their consent in advance (article 15). and 16). Therefore, this written document seeks to inform you about the procedure or test to be performed, for which we request that you fill in the blank spaces in your own handwriting.

The Karyotype consists of analyzing the number and structure of the chromosomes present in the cell´s nucleus of the tissue to be cultured. The examination will only inform us of chromosomal anomalies and not other types of genetic or multifactorial diseases, such as innate metabolic diseases or monogenic diseases. Therefore, the normal result of this test, in cases of prenatal diagnosis, does not guarantee that the child will be born without morphological defects, mental retardation, blindness or deafness, among others.
This test only evaluates chromosomal pathology and even so, in some cases, some very small structural alterations such as certain microdeletions, duplications or inversions, among others, are not detected.
This test does not diagnose innate metabolic diseases, congenital blindness or deafness, or monogenic diseases such as Hemophilia or Cystic Fibrosis, among others.
Risks:
1. In 1-5% of cases, optimal cell growth is not obtained and for this reason it is not possible to analyze the sample obtained, having to repeat the procedure. This varies according to the type of sample and biological factors of each patient. In the case of prenatal diagnosis, at extreme gestational ages (from 12 to 14 weeks of gestation and from 26 to 36) this risk increases. When this is due to pre-analytical factors, the patient/institution must bear the costs of processing a new sample.
2. In approximately 1-2% of cases, the sample obtained may suffer from bacterial or fungal contamination and this would make its analysis difficult or impossible, requiring the sample to be taken again. When this is due to pre-analytical factors, the patient/institution must bear the costs of processing a new sample.
3. In some cases the findings of the cytogenetic study must be confirmed with other more precise ones such as molecular techniques and the procedure may even be required to be repeated. These will have an additional cost.
4. In some cases, results are obtained that must be confirmed by repeating the sample collection and a new analysis of the karyotype, having to pay its value again when it is due to causes beyond the control of the laboratory, such as low-proportion mosaics or maternal cell contamination.
5. Some low ratio mosaicism may not be detected.
Complications:
1. In prenatal diagnosis, approximately 1% of cases the sample obtained is contaminated with cells of maternal origin, which will give rise to a false result. This is especially common when the sample is bloody.
2. Highly hemolyzed samples do not develop efficient cell cultures, therefore it is possible to request a new sample for analysis.
3. Those generated during the taking of the blood sample, which are uncommon; but could include: dizziness, fainting, pain, minor bleeding or bruising, the latter generally resolve spontaneously in one to two weeks.
Alternatives: There are molecular biology tests complementary to karyotype studies such as FISH or microarrays; however, they are not a complete alternative to determine chromosomal aberrations such as translocations and inversions.
Benefits: The karyotype is a test that allows you to diagnose multiple diseases caused by chromosomal alterations, guiding your doctor on their diagnosis, defining follow-up and control and/or the need to order other more extensive tests.
TEST RESULTS: The test results will be sent to the health care provider when referred by a specific entity, if you are an individual, you will use your username and password to download the result from the web, present the result to your treating doctor for give proper management.
Genetix will not disclose personal information or test results to third parties unless required to do so by local, state, federal or national law.

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USE OF REMAINING INFORMATION AND SAMPLES: In accordance with best clinical laboratory practices and standards, leftover specimen (unless prohibited by law), as well as genetic information and other information learned from your tests, may be used by Genetix or others on its behalf for the purposes of quality control, laboratory operations, research studies, laboratory test development and laboratory improvement. All these uses will be in compliance with applicable laws. We may use your leftover sample and health information, including genetic information. Such uses may lead to the development of products, commercial services or scientific publications. You will not receive notice of specific uses and you will not receive any compensation for these uses. All such uses will be in accordance with applicable law.

You can revoke this consent whenever you wish, to do so you only have to request the revocation from the laboratory, which consists of signing the LAG-FOR-30 REVOCATION OF INFORMED CONSENT form.

Consent:
YES_____
I,_____ identified with citizenship card number _____ or I, _____as guardian of the patient noted above identified with citizenship card number _____, I DECLARE that I have read and understood what the test that I am going to undergo consists of. I authorize to the GENETIX CENTER to perform the KARYOTYPE test.

NO_____
I,_____ identified with citizenship card number _____ or I, _____as guardian of the patient noted above identified with citizenship card number _____, I DECLARE that I have read and understood what the test that I am going to undergo consists of. I do not authorize to the GENETIX CENTER to perform the KARYOTYPE test.
If you have marked NO, it is understood that you have refused to undergo the test. For this reason, it is important that you keep in mind the consequence of not performing the karyotype, which is not being able to determine chromosomal alterations and not being able to provide appropriate medical management in these cases, consult with your treating doctor.

Patient Name: _____
Document:_____
Signature date: _____

DATA PROTECTION

The information provided is protected in accordance with the personal data processing policy contemplated in Law 1266 of 2008, Law 1581 of 2012 and Law 1712 of 2014.