INFORMED CONSENT FOR POSTNATAL aCGH ANALYSIS

PATIENT IDENTIFICATION

Medical record # .....

Mr./Ms. .....
(NAME AND SURNAME)

Residing in ....., and with ID/Passport number .....

TEST REQUEST

Dr. ..... , voluntarily requests qGenomics (Quantitative Genomic Medicine Laboratories, SL) to perform a comparative genomic hybridization test on arrays (aCGH) using DNA obtained from a biological sample from Mr./Ms. ..... , in order to determine if he/she harbours any copy number variation (gain or loss) of genetic material in his/her chromosomes that, according to current knowledge, could explain the observed phenotype.

I DECLARE

That Dr. .....
(NAME AND SURNAME OF MEDICAL GENETICIST OR GENETIC COUNSELOR)

has informed me about the risks, limitations and expected results of the aCGH test.

1. The aCGH tests require obtaining a blood sample, which implies a low risk to health. It may be necessary to obtain more samples if the laboratory identifies an alteration, or if the sample suffers any deterioration during the shipment or processing.

2. The aCGH tests use research products (DNA microarrays) to identify gains and / or losses of genetic material. The use of DNA chips allows us to obtain the same information as classical cytogenetic

tests (karyotype) in relation to gains and / or losses of genetic material, but with a higher resolution. The aCGH tests are considered research studies, because there have not been enough studies to have the absolute certainty that a normal result means that there is no alteration. For this reason, aCGH tests may require the use of other genetic reference tests to obtain conclusive results.

3. In case that we identify a gain or loss of genetic material, it may be necessary to perform this same test on other members of the family in order to determine if the variant found is inherited or if it is only present in the sample we are analyzing. In addition, it may be necessary to make other types of confirmatory tests. In case that no samples from relatives are available and the other eventually necessary validation tests can not be performed , the result of the analysis might be inconclusive.

4. As with any other genetic test, the results of this study may be relevant to other members of your family.

5. The correct interpretation of the results of the test depends on the clinical diagnosis of the patient and / or the family medical history , as well as the family relationships reported are true from the biological point of view. Genetic testing in other family members may reveal that true biological relationships are not consistent with those reported. For example, cases of non-paternity can be detected, which means that the real father of the child is other than the one reported.

6. CGH arrays can not detect chromosomal alterations in which the dosage of DNA is not altered (such as balanced rearrangements: reciprocal translocations, Robertsonian translocations, inversions and balanced insertions), variants that affect regions not interrogated by the array, or that have a smaller size than the resolution of the array. In addition, the array can not detect point mutations, alterations in methylation, uniparental disomies or mosaicism lower than 20-30%.

7. The aCGH tests are totally voluntary. If you do not want to undergo this test, medical care will not be adversely affected and you will receive all the care you need. The results of the aCGH tests could identify a cause of the symptoms and could be used to provide you a better medical care.

8. The interpretation of genetic tests is not a trivial task, the methodology to follow can be complicated and the results can have serious implications that will require adequate genetic counseling. Thus, the results of this test will only be reported to a specialist. The results are confidential and will only be provided to another professional or authorized persons under my written consent.

9. It is the responsibility of the physician to know the usefulness and specific limitations of the test that he / she is requesting, as well as to inform the patient of these limitations. The results of the tests and patient information will be kept confidential and under no circumstances will be transferred to third parties without my express written consent.

CONTRIBUTE TO IMPROVING PEOPLE'S QUALITY OF LIFE

Quantitative Genomic Medicine Laboratories, SL (qGenomics) has pioneered the application of new technologies to the diagnosis of genetic diseases, and collaborates in research and development projects with Universities, research centers and public hospitals in our country. In compliance with current regulations we keep the biological samples (or their derivatives) received for future validations and / or investigations, maintaining complete anonymity about the origin of each sample. You (or the authorized person) have the right not to consent to the use of your sample for research purposes, without detriment to the diagnostic tests or the elaboration of the results ordered to qGenomics. You (or an authorized person) may at any time decline the consent granted by contacting qGenomics. You decline to claim any rights over the research products that may be developed from the use of your samples.

If you authorize the use of the genetic material for research purposes, check this box ☐

THE PATIENT

I have been explained and I have understood the risks, benefits and limitations of genetic testing. I have read and will receive a copy of this informed consent.

In .....
(PLACE AND DATE)

.....

Signed by: PATIENT

.....

Signature of the father, mother or legal representative

PHYSICIAN or GENETIC COUNSELOR

I have communicated the risks, benefits and limitations of the genetic tests to the patient, father, mother or legal representative. I have reviewed the form in the presence of the patient, father, mother or legal representative. I accept responsibility for genetic counseling before and after the genetic test.

In ..... (PLACE AND DATE)

Signed by PHYSICIAN or GENETIC COUNSELOR
Certification number:
Name & Surname

In accordance with the provisions in force regarding the protection of personal data, and in particular by Organic Law 15/1999 on Personal Data Protection (LOPD), QUANTITATIVE GENOMIC MEDICINE LABORATORIES, S.L. is obliged, in relation to the personal data to which might have access to for the provision of contracted services, to: i) Treat the data only according to the instructions of the client; (ii) not apply or use data for purposes other than those contained in this undertaking; (iii) not to communicate the data to third parties, even for its preservation; iv) implement the security measures that are applicable, in order to preserve the integrity, confidentiality and availability of data; and v) destroying or returning the data to the client, as well as any support or document in which any data that has been subject to the treatment can be recorded once the service is finished.

We also inform you that the data you provide during the provision of contracted services will be stored in files under responsibility of Quantitative Genomic Medicine Laboratories, SL, in order to maintain, renew, extend or modify, where appropriate, the business relationship that mediates between the parties or the part that you represent, which expressly includes the commercial promotion of our products and services. You may exercise your rights of access, cancellation, rectification or opposition by contacting Quantitative Genomic Medicine Laboratories, S.L., C / Joan XXIII, 10, Esplugues del Llobregat, or by e-mail to info@qgenomics.com.