Form A

Guidelines and informed consent **epigene**

Enter here the barcode **epigene**	Write the name of the **professional** or **company** (reference code) with which you test

What should I do to get tested?

The procedure for performing the epigenetic analysis is:

- → Apply 2 (two) adhesive labels that do not bear the initials "M, S or I, II, III, IV" on forms A and B, in the appropriate box.
- → Fill out form A (present document) in all its parts - front and back
- → Fill out form B (self-assessment form) in all its parts - front and back
- → Perform the sampling procedure ("**How to perform the salivary sample collection**")
- → Apply the adhesive labels bearing the initials "M, S or I, II, III, IV" on the salivary collection tubes according to instructions below.
- → Insert the samples (with adhesive labels applied) in the plastic bag and send everything (including forms A and B) to our laboratory (see address on the next page and/or printed on the padded envelope for shipping).

How to perform the salivary sample collection

The patient who wants to undergo the epigenetic test must perform the saliva sampling autonomously at set times of the day (see below depending on the test). Cleaning of the oral cavity can be done with simple running water and this condition of oral hygiene must be maintained for <u>at least</u> thirty minutes. At the end of the thirty minutes, without having eaten (do not chew gum or eat food), smoked or drunk in these thirty minutes prior to the sampling, the patient can proceed with the collection of saliva. Avoid lipstick or any type of cream or lip balm that is spread around the sides of the mouth and lips. Do not collect the sample if blood is present.

Procedure for saliva collection:

1. When sampling, fill the tubes using the sterile straw. Fill at least half of the tube (1ml).
   ATTENTION: The straws are used exclusively to direct the saliva inside the tube. Saliva can anyway be introduced into the tube without a straw. This small device is intended to reduce the dispersion of saliva beyond the test tube.
   ATTENTION: Never rinse your mouth before collecting the sample (at the latest 30 minutes before). <u>Don't consider the bubbles</u> in the assessment of the amount of saliva (1 ml). Gently tap the bottom of the tube to pop part of the bubbles that are formed, in order to better evaluate the overall quantity of saliva collected. Repeat the operation until the collection is complete (1 ml).
2. Close the individual tubes.
3. Apply the adhesive label with the appropriate code based on the sampling time and the type of analysis:

epigene WELLNESS, LONGEVITY (n°2 tubes/samples)
8.00 am (1° collection) apply label “M”
6.00 pm (2° collection) apply lable “S”
<u>Warning WELLNESS test</u>: You must make the first withdrawal (8:00 am) on an empty stomach.

epigene INFLAMMAGING (n°2 tubes/samples)
8.00 am (1° collection) apply label “M”
6.00 pm (2° collection) apply lable “S”

epigene CRONO (n°4 tubes/samples)
8.00 am (1° collection) apply label “I”
12.00 am (2° collection) apply label “II”
6.00 pm (3° collection) apply label “III”
12.00 pm (4° collection) apply label “IV”

epigene OVERTRAINING, OVERTRAINING^{plus} (n°2 tubes/samples)
30 minutes <u>before</u> starting physical activity (1 sample) apply the "M" label
30 minutes after completing physical activity (1 sample) apply the "S" label
<u>Attention</u>: The evaluation of the overtraining test must be carried out in the day of greatest load / effort during the athletic training course

4. Store the sample at 4°C (common refrigerator) to keep it 100% stable. Out of the refrigerator the sample remains however perfectly stable for 14 days.
5. Ship the sample at room temperature.

Shipping address

NEXT Genomics Srl
Via delle Robinie 22
50019 Sesto Fiorentino (FI)

INFORMATION ON THE TREATMENT OF PERSONAL DATA AND SENSITIVE DATA

Disclosure Art. 13 EU Regulation no. 679/2016

Dear Patient,
We wish to inform you that Article 13 of EU Regulation no. 679/2016 the (General Data Protection Regulation) regulates the processing by an individual, a company or an organization of personal data relating to individuals in the EU. According to the indicated legislation, data processing will be based on principles of correctness, lawfulness, transparency and protection of your privacy and your rights. Abiding by Article 13 of EU Regulation no. 679/2016, therefore, we inform you of the following:

Data processor
NEXT Genomics S.r.l. based in via Madonna del Piano, 6 a Sesto Fiorentino (Firenze) CAP 50019, Telephone +39 055 4574605 e-mail info@nextgenomics.it.

Purpose of the processing
The data processing is aimed solely at the correct and complete execution of the test requested by you; as well as the performance of related activities or administrative procedures related to the execution of the test itself. The personal and fiscal data will be used for the billing. The biological data will be used for the elaboration of the report requested by you and, anonymously, for scientific research and statistical processing. The biological data will be analysed anonymously, using an alpha-numeric code that will mark the samples for carrying out the analyses. Provided you express your consent at the bottom of this document, the electronic identification data will be used for communication purposes and commercial services offered by our company. As for the genetic data, please note that the requesting Owner / Professional will process this data in accordance with the Authorization for the processing of genetic data issued by the Privacy Guarantor on 22 February 2007 and published in the G.U. No. 65 of March 19, 2007.

Processing methods
The personal data collected are subjected to both paper and electronic processing and / or automated in compliance with the provisions of art. 32 of the GDPR 2016/679 regarding security measures, carried out by specifically authorised persons and in compliance with the provisions of art. 29 GDPR 2016/679.

Data disclosure
The Data Controller does not disclose personal and sensitive data to the outside world. Biological data are totally anonymous; clinical data can be used exclusively for the internal evaluation of the statistics associated with the pathologies treated, for the generation of algorithms and for scientific publications (in no way will it be possible to trace identification of the subject).

Data retention period
In compliance with the principles of lawfulness, purpose limitation and data minimization, pursuant to art. 5 GDPR 2016/679, the Data Controller and the Reference Professional will keep and process the personal data provided for the time necessary to fulfil the purposes mentioned above and for a further period strictly aimed at carrying out the procedures conservation required by current legislation. All bioinformatics data will be kept for at least 10 years.

Transfer of data abroad
Personal data may be transferred to countries of the European Union and to third countries with respect to the European Union in the context of the purposes referred to in paragraph 2 of article 26 of Directive 95/46/EC. In this case, the Owner/Professional ensures from now on that the data transfer outside the EU will take place in compliance with the applicable legal provisions.

Delivery of the test results
The results must be delivered directly to the person concerned or to their Professional of reference. If you decide to have them delivered to a third party, this request should be specified in the self-assessment form (form B).

Rights of the interested party
You may, at any time, request explanations and clarifications relating to this information, and exercise your rights towards the Data Controller, pursuant to Article 13 of EU Regulation no. 679/2016. The interested party has, pursuant to articles 15 to 22 of EU Regulation n. 2016/679, the right to:
a) ask for confirmation of the existence or otherwise of their personal data;
b) obtain information on the purposes of the processing, the categories of personal data, recipients or categories of recipients to whom the personal data have been or will be disclosed and, when possible, the retention period;
c) obtain the rectification and cancellation of data;
d) obtain the limitation of the processing;
e) obtain data portability, i.e. receive them from a data controller, in a structured format, commonly used and readable by an automatic device, and transmit them to another data controller without hindrance;
f) oppose an automated decision-making process relating to natural persons, including profiling.
g) withdraw consent at any time without prejudice
the lawfulness of the processing based on the consent given before the revocation;
h) lodge a complaint with the Personal Data Protection Authority.
You can exercise your rights at any time by sending a registered letter with return receipt to NEXT Genomics S.r.l. via Madonna del Piano, 6 - 50019 Sesto Fiorentino (FI).

Consequences of failure to communicate data
The processing of data (including sensitive data) is necessary and indispensable for the purposes of the execution of the services requested pursuant to art. 6 paragraph 1 letter a) EU Regulation. Any refusal on your part to provide the data necessary or useful for the purpose of execution of the services themselves and in any case, any opposition to the treatment of their own personal or sensitive data, makes it impossible to execute what is requested. The electronic identification data are optional.

INFORMED CONSENT

Treatment of personal and sensitive data

The undersigned _____

place of birth _____ date of birth _____

Tax code _____ resident in _____

street/square _____ Post code _____

Having acquired the information provided by the Data Controller, pursuant to art. 13 EU Regulation n. 679/2016, read and understood the contents of the information note of which they have received a copy, and aware, in particular, that the treatment will also concern data suitable for revealing the state of health and genetic data included among sensitive data (art 9 EU Regulation).

DECLARES to have been informed explicitly, exhaustively and with understandable language, regarding the test which they have consciously decided to undergo;

CONFIRMS to have been informed about the type and purpose of the tests and their validity scientific and to be free from any conditioning or coercion;

THEREFORE GIVES THEIR CONSENT TO THE PROCESSING OF PERSONAL AND SENSITIVE DATA for the purposes and according to the methods indicated in the aforementioned information, aware that the failure to provide data will inevitably imply the impossibility of providing the requested service.

- ☐ YOU AGREE to receive commercial and / or promotional communication and e-mails on our products or services.
- ☐ YOU DO NOT AGREE to receive commercial and / or promotional communication and e-mails about our products or services.

Date _____ Place _____

Signature _____

INFORMED CONSENT

to perform the salivary / epigenetic analysis

The undersigned _____

DECLARES
to have been expressly informed explicitly, comprehensively that the tests salivary/epigenetics provide a service of investigation on the levels of some biological markers (e.g. hormones, inflammatory cytokines) that are in saliva samples collected at different times of the day. The salivary/epigenetic test is informative only where the absolute quantities of specific markers involved in the patient's state of health are analysed. The ranges related to each individual marker should never be considered diagnostic, but indicative of the values observed within the reference population. It is important to understand that in the case of salivary/epigenetic tests it is never a diagnosis of disease.

AGREE
to take the biological material for the purpose of this test, declaring at the same time to have decided in full freedom and autonomy to undergo this examination.

DECLARES
a) to have also been informed that the biological sample taken will be analysed at NEXT Genomics S.r.l. who commits to using it by respecting the current legislation on the subject. They consent, therefore, to the extrapolation of data by the above company;
b) to have been informed that the biological samples will be destroyed following the execution of the analysis.

O Agrees O Does not consent

to the use of biological and clinical data in a totally anonymous form exclusively for the internal evaluation of the statistics associated with the pathologies treated, for the generation of algorithms and for scientific publications (in no way will it be possible to trace the identification of the subject).

O Authorise O Does not authorise

that the report is also sent to the doctor/professional/company who requested it.

Date _____ Place _____

Signature _____