

**NOTICE REGARDING THE PROCESSING OF PERSONAL, SPECIAL AND GENETIC DATA
AND THE USE OF BIOLOGICAL SAMPLES FOR NON-INVASIVE PRENATAL TESTING (NIPT)**

*Pursuant to art. 13 of Regulation (EU) 2016/679 and Decision No. 146 of the Data Protection Authority dated 5 June 2019
annex No. 4: "Requirements concerning the processing of genetic data" (Gen. Aut. No. 8/2016)*

Dear Madam,

We write to inform you that, pursuant to Regulation (EU) 2016/679 (GDPR) and Italian Legislative Decree No 196/2003 as amended by Legislative Decree No 101/2018, the data requested at the time of biological sampling for the purpose of genetic investigation, biochemical investigation and/or specialist examination, will be processed, i.e. used, in accordance with fundamental rights and freedoms, with particular reference to the confidentiality of information and the protection of personal data. The processing of personal data will therefore be based on the principles of fairness, lawfulness, legitimacy, indispensability and avoidance of excess in relation to the purposes for which it is collected. We would therefore ask you to read this notice carefully and fill in the attached form, by way of giving or denying your consent to the use of your genetic data and/or biological samples for the purposes indicated. The analysis of biological samples proposed to you during sampling and/or specialist examination will be carried out at the Laboratorio Unico Metropolitano of Azienda USL di Bologna or, in some cases, at an external laboratory formally designated as the Data Processor pursuant to art. 28 of the GDPR.

Definitions

The following definitions will help you understand this notice:

Genetic data: personal data relating to the hereditary or acquired genetic characteristics of a natural person, which provides unequivocal information about the physiology or health of that natural person, and which derives, in particular, from the analysis of a biological sample taken from the natural person concerned.

Genetic tests: analyses of DNA, RNA, chromosomes, metabolites and other genetic products, carried out to highlight alterations related to hereditary diseases. There are various types of genetic tests, whose purposes are, by way of example, to diagnose disease or to confirm a clinical suspicion in an individual who already has the disease (diagnostic tests), to identify, especially within a family, healthy carriers of a genetic disease (pre-symptomatic screening), to identify or rule out a genetic defect responsible for a disease whose symptoms are not present at birth but appear later in life (pre-clinical or pre-symptomatic tests), or to assess the extent to which an individual may be susceptible to complex, multifactorial diseases, i.e. diseases deriving from the interaction between genes and other risk factors (predictive or susceptibility tests), and lastly to assess individual response to specific drugs.

Biological sample: human biological samples, or human biomaterials, are defined as human biological tissues and fluids – blood, saliva, urine, cells, including all molecular fractions (proteins, RNA, DNA, etc.) derived from them, originating from healthy or diseased individuals. Biological samples can be taken by means of routine medical procedures or targeted interventions. They can give access to information contained in the human genome, with the implication that a "genetic profile" of the individual can be extracted from that material. The genetic information of each sample is linked with the medical history of the individual and can be connected with data relating to life-style.

Purposes

- A) Genetic data from the biological samples taken will be processed exclusively for the purposes of health protection, prevention, diagnosis and treatment, with particular reference to genetic pathologies and protecting your genetic identity, or the genetic identity of a third party belonging to the same genetic lineage as you, only with your consent and for the purpose of performing the institutional duties established by the law.

We would also like to inform you that your genetic data may be used for the following purpose:

- B) scientific and statistical evaluations aimed at verifying the continued performance of the non-invasive prenatal test currently in use and implementing other laboratory methods for performing the NIPT.

Processing methods and retention time

Biological samples will be taken and used, and the genetic data deriving from them will be processed lawfully, fairly and in a manner designed to prevent the violation of the rights, fundamental freedoms and dignity of the data subjects. We also inform you that the above data may be processed in hard-copy and/or electronic form, but always in such a way as to ensure that it remains secure and confidential. All of the above data and material will be retained for the time necessary to carry out the laboratory tests forming part of the diagnostic programme and for any subsequent diagnostic investigations, or to pursue the further purposes for which it is collected and subsequently used.

More specifically, the sample taken and the DNA extracted from it will be retained for up to 1 year for possible re-testing.

The data and samples will be processed only by expressly authorized personnel, and access to the IT systems and premises where they are stored will be controlled by means of appropriate security measures to minimize the risk of accidental disclosure and unlawful, unauthorized access to the them.

Any genetic data transferred to third parties outside Azienda USL di Bologna in electronic format will first be encrypted and in any event handled according to technical and organizational methods designed to guarantee an adequate level of security. These methods will also be used in relation to data and samples provided directly by the data subject or collected from third parties, including at the request of the data subject.

If you consent to the processing, the samples may be used for further scientific and statistical evaluations in NIPT diagnostics.

For the purposes of other research and if the samples are not anonymized, you will be contacted again to request additional specific consent to their use.

Consent to the processing of genetic data and the use of biological samples

The genetic data may be processed and the biological samples used only for the purposes set out in this notice, to which the data subject or their representative has given their prior written consent, using the attached form. Should the data subject refuse to provide their personal identification data for the purposes of diagnosis, treatment, rehabilitation and prevention, the health authority will inevitably be unable to provide the services requested.

In the case of minors, consent must be given by **both parents** or their representatives. Should it be necessary to process the genetic data in order to save your life or protect you from physical harm, consent may be requested from the subjects indicated in art. 82 paragraph 2, letter a) of the Privacy Code, i.e. not only from persons legally exercising parental responsibility (both parents pursuant to art. 316 of the civil code /tutor, etc.) but also from a close relative, family member, co-habiting partner or, in the absence thereof, the person in charge of the facility where the data subject is staying.

Data disclosure

In accordance with the requirements of the legislation in force, your personal and genetic data will not be disclosed, but it may be disclosed, exclusively for the purposes indicated above, to the following:

- personnel authorized to process it;
- public or private bodies or entities which by law, by virtue of their institutional purposes, regulations or EU legislation have the right or obligation to access it;
- the Judicial Authority and/or Public Security Authority in cases expressly established by the law.

It may become necessary to disclose genetic data, if doing so yields a tangible and direct benefit in terms of treatment, prevention or awareness of reproductive choices, including for members of the same genetic lineage as the data subject. This data may be disclosed to the latter, if they request it and the data subject has expressly consented to it, or has died and did not expressly indicate otherwise during their lifetime.

Rights of the data subject

The rights set down in articles 12 - 22 of Regulation (EU) 2016/679 – specifically the right to access your personal data, to get it corrected, updated or erased if it is incomplete, incorrect or was collected in breach of the law, and to object to the processing of it – will be upheld at all times. The data subject may exercise these rights in accordance with the forms and methods established by the authority's procedure for managing the personal data protection rights of data subjects, which can be viewed on its website: <https://www.ausl.bologna.it/privacy>

The data subject also has the right to:

- be informed of the results that can be obtained and of any unexpected information or other information that can be determined from the investigations carried out;
- limit the scope of disclosure the genetic data and identify the named individuals to whom health personnel can provide information about their health status.

Where there are grounds for doing so, the data subject can exercise the right to file a complaint with the Personal Data Protection Authority or with the supervisory authority of the EU Member State in which they habitually reside or work, or the place where the alleged infringement occurred, in accordance with the procedures set down in art. 77 of the Regulation.

Data controller

The data controller is Azienda USL di Bologna, with registered office at Via Castiglione n. 29 – 40124 – Bologna – telephone 051-6584910; certified email: protocollo@pec.ausl.bologna.it.

Data Protection Officer

The Data Protection Officer can be contacted by email at the following address: dpo@aosp.bologna.it – Certified email dpo@pec.aosp.bo.it.