


<div>REGIONE TOSCANA</div> 	LOGO AZIENDALE	cod. Az.	
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**Information within the meaning of Article 13 of Regulation (EU) 2016/679**  
**Regulation on the protection of natural persons with regard to the processing of personal data (GDPR)**

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**Processing of personal data for the performance of the test for the determination of the risk of aneuploidies of chromosomes 21, 18, 13 and sex chromosomes**  
**Through sequencing the cell-free foetal DNA in maternal plasma**

### **Purpose and legal basis of the processing of personal data**

The personal data will be processed for health protection purposes, as well as for administrative tasks related to this purpose.

The legal basis of the processing is represented by the art. 9 paragraph 2(g), art. 9 paragraph 2(h) and by art. 9 paragraph 3 of the GDPR; moreover, in reference to the processing necessary for reasons of substantial public interest within the meaning of the aforesaid art. 9 paragraph 2(g), art. 2-sexies sub-paragraph 2(t), (u), (aa) of Legislative Decree No. 30 June 2003 n.196 *Code on the protection of personal data* and (up to new regional provisions) sheets 21 and 24 of Annex B to the Regulation referred to in GDPR 12 February 2013 no. 6/R.

In any case, the test results will be transmitted to the facility that sent the sample.

the consent of the person concerned is not necessary for the processing of data for the aforesaid purposes.

Data processing is carried out in compliance with the requirements laid down by the authorisation of the Guarantor for the protection of personal data 8/2016 as amended by the decision of 13 December 2018 for the identification of the requirements of the general authorisations compatible with the GDPR.

The person concerned, if he/she so wishes, is required:

- to consent to the results of the test, in the case of high risk or with insufficient foetal fraction (FF), also being sent to their chosen Centre of Prenatal Diagnostics;
- to consent to the test results also being sent to the centre at which the combined test has been performed;
- to authorise the staff of SOD Diagnostica Genetica (Genetic Diagnostics Departmental Organisational Unit) at Careggi University Hospital and the Centre of Parental Diagnostics to contact them by telephone regarding the results of the test or for any follow ups

For these purposes the legal base is constituted by the consent of the person concerned, and therefore by art. 9 paragraph 2(a) of GDPR.


### **Types of data processed**

For the execution of the test, the following types of personal data will be processed ("any information relating to an identified or identifiable natural person; an identifiable natural person is one who can be identified, directly or indirectly, in particular by reference to an identifier such as a name, an identification number, location data, an online identifier or to one or more factors specific to the physical, physiological, genetic, mental, economic, cultural or social identity of that natural person":

- Genetic data ("personal data relating to hereditary or acquired genetic characteristics of a natural person that provide unique information on the physiology or on the health of such person and that result in particular from the analysis of a biological sample of the natural person in question");
- Health data ("personal data relating to mental or physical health of a person, including the provision of health care services, which reveal information relating to his/her health status").

### **Processing methods**

The biological sample taken, accompanied by an information document, is transmitted by the structure entrusted by the person concerned to the Genetic Diagnostics Departmental Organisational Unit of the Careggi University Hospital, which will perform the test.

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The test results will be transmitted, by telematic means compliant with the requirements of the aforesaid authorisation n. 8/2016, to the facility that sent the sample and, if consented to by the person concerned, to the Centre at which the combined test was performed. In the event of a high risk result and where consented to by the person concerned, the test results can also be transmitted to the indicated prenatal diagnosis centre. In any case, all the results will be available for pick up by the person concerned at the facility that sent the sample (i.e. the facility where the sample was taken).

If the person concerned consents, the telephone communications indicated above can be carried out by the chosen prenatal diagnosis centre and the Genetic Diagnostics Departmental Organisational Unit of the Careggi University Hospital.

The processing of the personal data of the person concerned will be carried out either by paper or with the use of electronic instruments, with the precautions and security measures provided for by the legislation currently in force.

#### **Exercise of rights by the person concerned**

The person concerned has the right to:

- Obtain, at any time, information on the use of the data regarding him/her;
- Access the personal data regarding him/her;
- Request rectification or integration;
- Request, in certain cases provided for by the regulations, the limitation of processing;
- Oppose to the processing of personal data regarding him/her;

To exercise the rights mentioned above, the person concerned may send request to the person responsible for the protection of personal data, whose contact data are reported below.

The person concerned also has the right to submit a complaint to the Guarantor for the protection of personal data.

#### **Data controller, data supervisor and person authorised to carry out processing**

The data controller is the company: \_\_\_\_\_, responsible for the person concerned and the relevant care process.

If it undertakes laboratory activities on behalf of other health care organisations, the Careggi University Hospital consequently carries out data processing on behalf of other data controllers and is empowered to that effect within the meaning of art. 28 of GDPR, from a legal act that identifies them as the Data supervisor.

The subjects who, in various ways, are involved in the processes of care and in the management and technical-administrative processes in support of the provision of the services, are persons authorised to carry out processing within the meaning of art. 29 of the GDPR for the specific field of competence and adequately trained in this sense.

#### **Contact data**

Data controller: .....

Legal representative: .....

Person responsible for the protection of personal data: .....

Inspection authority: The Guarantor for the protection of personal data [www.garanteprivacy.it](http://www.garanteprivacy.it), e-mail [garante@gpdp.it](mailto:garante@gpdp.it), switchboard tel. +39 06696771