Part 8
Genetic Testing

Section 28

(1) Genetic testing consists of clinical and laboratory examinations; it is used to determine the contribution of variants in the human germline genome to the development of a disorder in a patient. Laboratory genetic testing means a laboratory analysis of human germline genome or its parts.

(2) Genetic laboratory testing may be performed only in laboratories whose professional competence has been assessed in accordance with the relevant harmonized standards[5] by an accrediting person.[6]

(3) Genetic testing in health care may be offered and/or performed only for the purposes of:

a) health services, namely:
   1. for preimplantation diagnosis within the framework of assisted reproduction,
   2. to diagnose genetic diseases and developmental defects,
   3. to determine the degree of predisposition to diseases and developmental defects,
   4. to determine asymptomaticcarriership of variants of the human germline genome causing illness or developmental defect,
   5. for targeted newborn screening in order to identify genetic diseases; for the purposes of genetic testing, targeted screening is deemed determining the proportion of changes in the human germline genome in the development of serious genetic diseases with the risk of early irreversible damage to the health of newborns,
   6. to optimize treatment.

b) biomedical research related to health and disorders.

(4) Genetic testing may be offered to the patient only

a) after providing information on its purpose, nature and impact on health, including the health of future generations and risks of unexpected findings for the patient and a genetically related person, and
b) based on his written consent or written consent of the patient's legal representative.

(5) For the purposes of genetic testing under this Act, persons genetically related to the patient are deemed related persons with medically significant genetic risk, namely relatives
a) in the direct line, i.e. grandparents, parents and their children, and
b) in the indirect line, where the level of risk is determined by the degree of relatedness and type of genetic disease.

(6) In the event that the results of genetic testing show a diagnostic conclusion, according to which expected impact on the health of the patient, including future generations, or the health of genetically related persons may be assumed, the provider shall recommend to the

[5] ČSN EN ISO 15189.2007 Medical laboratories - Special requirements for quality and competence
[6] Act No. 22/1997 Coll. on Technical Requirements for Products and on modification and amendments to certain acts, as amended.

patient and the genetically related person genetic counseling by a physician with specialized qualifications in the field of medical genetics, both before and after the testing.

Section 29

1) Genetic laboratory testing of biological material taken from a body of a deceased person for teaching, scientific and research purposes may only be performed, provided the deceased during his life or a person close to the deceased provided a demonstrable consent therewith. If the deceased during his lifetime expressed the prohibition of providing information about his health, such testing may not be performed; this does not apply if it is necessary to identify or verify relevant information on changes in the human germline genome of the deceased needed to secure health of genetically related persons.

2) The patient may not be offered or receive financial remuneration or another benefit for engagement in genetic testing pursuant to Section 28 paragraph 3 letter a). In case the patient rejects genetic testing, he must not be subject to any harm or psychological duress. The results of genetic tests must not be provided to third parties without the written consent of the patient. Sale or donation of genetic test results to third parties without the written consent of the patient, including the written consent of the genetically related affected persons, is prohibited. The results of genetic tests must not be used for any discrimination of the patient and genetically related persons.

3) Genetic laboratory testing of a human embryo or fetus, including determining its sex, must not be performed for reasons other than for the purposes of Section 28 paragraph 3 letter a) clauses 1 to 3 and clause 6. Laboratory genetic testing of a human embryo or fetus may be performed provided that a physician with specialized qualifications in the field of medical genetics provides genetic counseling for the mother, which after the end of laboratory genetic testing in a human embryo or fetus is followed by genetic counseling in order to interpret the results properly. Laboratory genetic testing of a human embryo or fetus is carried out only after the mother was informed and granted her written consent (Section 28 paragraph 4).

Section 30

(1) An intervention seeking to modify the human germline genome may be performed only in patients for preventive or therapeutic purposes, in the case of serious genetic diseases, while maintaining its natural biological integrity in germ cells. These interventions must not be performed if they could lead to changes in the genetic material of germ cells.

(2) Any procedure designed to create a human being who has the same human genome with another human being, living or dead, is prohibited.

(3) It is prohibited to transfer

a) the entire human genome into cells of another species and vice versa,
b) the human embryo into genital organs of another species.