

THE LEGAL REGIME REGULATING HUMAN DNA SAMPLES IN TANZANIA

Human DNA refers to those genes inherited from each biological parent that contains instructions for development, growth and reproduction.

Under the Human DNA Regulation Act, 2009 of the laws of Tanzania (“Human DNA Act”), samples of Human DNA are collected and analysed for various purposes, *inter alia*, to establish parentage, kinship, criminal investigation, research in population genetics, medical, pharmaceutical, chemical and nutrition assessments.

These samples are collected by sampling officers and analysed at either the Human DNA Laboratory at the Government Chemist Laboratory Authority or other designated and licenced laboratories for Human DNA testing.

The analysis of Human DNA samples is required to be initiated by the requesting officer on behalf of the sample source (a person from whom a Human DNA sample is collected) by a written application to either the Human DNA Laboratory or to a designated and licenced laboratory for Human DNA testing.

A requesting officer can be any of the following:-

- a) The court where the subject matter is in dispute between the parties;
- b) Advocates, Social Welfare Officers and Community Development Officers;
- c) Police Officer of or above the rank of Inspector;
- d) Research institutions that are mandated to research Human DNA;
- e) District Commissioner in case of mass disaster; and
- f) Medical practitioner for medical cases.

Licencing Procedures

Human DNA testing is regulated by the Government Chemist Laboratory Authority, vide the authority vested in it under the Government Chemistry Laboratory Authority Act, 2011 of the laws of Tanzania.

Accordingly, the Human DNA Act provides for the establishment of a regulator of human DNA services within the Government Chemist Laboratory Authority. This office is regulated by the Chief Government Chemist who is responsible for overseeing and regulating the administration of human DNA services in accordance with the provision of the underlying legislation.

Therefore, any person or entity who desires to provide human DNA testing services in Tanzania is required by section 17 of the Human DNA Act, to apply for a licence to operate a Human DNA laboratory to the Chief Government Chemist. This licence is valid for twelve (12) months from the date of issuance and may be renewed. The licence is non-transferable, and in the event of a transfer of control of a licensee to a third party, prior written notice must be given to the Chief Government Chemist to determine if the change of control may require a separate licence.

After issuing the licence, the Minister responsible for health shall by notice published in the Government Gazette establish a designated laboratory to carry out the functions of collecting and analyzing samples for Human DNA.

In addition to the above, if there are several premises/laboratories in respect of which Human DNA testing is conducted by a licensee, these laboratories shall be required to be issued with separate licenses, meaning that, the licensee will make separate applications in respect of each laboratory designated for Human DNA testing.

In the event there are several pieces of equipment and devices to be used and stored in Tanzania, then, the importer will be required to register the equipment and the premises/laboratories used to store the equipment with the Tanzania Medicine and Medical Devices Authority (hereinafter referred to as “TMDA”).

Transportation, exportation and storage of the Human DNA Sample

The Human DNA Act is silent on the exportation and storage of Human DNA test samples outside Tanzania. However, it requires a sampling officer of a designated Human DNA laboratory before collecting any Human DNA samples from the sample source, to obtain verbal and written consent from the sample source on the use of the samples collected from him.

Accordingly, the sampling officer is first required to verbally inform the sample source or his representative (in case of a minor or a person of unsound mind) of his rights and assurance.

Thereafter, the sampling officer is required to issue the sample source with a **Rights and Assurance Form** which shall contain information on the sample source’s consent and rights in respect of the use of his samples for Human DNA testing. It shall be considered as the sample source’s consent to the Human DNA testing once the signing of the Rights and Assurance Form by the sample source or his representative is done.

Furthermore, the law requires the sampling officer to transport (if it were locally) the samples through appropriate and safe means while taking into account the nature, sensitivity and urgency of the genetic information to be used for Human DNA. In this regard, the sampling officer in charge of transporting the samples is required to fill out a prescribed form issued by the designated Human DNA laboratory at every stage of the transportation of the samples.

Confidentiality and Data Protection

It should be noted further the data confidentiality, storage and security of personal health information have been established in previous policies and laws, including the Health Information System Guidelines, May 2019 (hereinafter referred to as the “**HISG**”). Thus, clients’ records are confidential information and shall not be passed to unauthorized persons without the prior written approval of the client.

Concerning samples for Human DNA testing, the Human DNA Act imposes several restrictions on the disclosure of a sample source’s DNA tests to unauthorized third parties.

In conclusion, an entity may provide Human DNA sampling services (including the advertisement of the same) provided they apply for and obtain a licence to operate a Human DNA laboratory from the Chief Government Chemist.

Essentially, the entity is required to meet the relevant qualifications for the licence, including but not limited to, registering a company in Tanzania, obtaining appropriate premises and equipment for DNA testing and sampling, having in place qualified staff and a Director of the laboratory with the relevant qualifications and credentials and having in place a laboratory that meets the standards of Human DNA testing.

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Note: This is not a legal opinion and the contents hereof are not meant to be relied upon by any recipient unless our written consent is sought and explicitly obtained in writing.