

Inspection report on compliance with HTA licensing standards  
Inspection date: **28 June 2023**



**LGC Genomics Ltd**  
HTA licensing number 12600

Licensed under the Human Tissue Act 2004

**Licensed activities**

<b>Area</b>	<b>Storage of relevant material which has come from a human body for use for a scheduled purpose</b>	<b>Removal from the body of a deceased person (otherwise than in the course of an anatomical examination or post-mortem examination) of relevant material of which the body consists or which it contains, for use for a scheduled purpose other than transplantation</b>
<b>Hub site</b> <b>LGC Genomics Ltd - Hoddesdon</b>	Licensed	Not licensed
<b>Satellite site</b> <b>LGC Genomics Ltd - Oxford</b>	Licensed	Not licensed

**Summary of inspection findings**

The HTA found the Designated Individual (DI) and the Licence Holder (LH) to be suitable in accordance with the requirements of the legislation.

LGC Genomics Ltd ('the establishment') was found to have met all HTA standards.

The HTA has assessed the establishment as suitable to be licensed for the activities specified.

**Compliance with HTA standards**

All applicable HTA standards have been assessed as fully met.

## Advice

The HTA advises the DI to consider the following to further improve practices:

Number	Standard	Advice
1.	C1(d)	The DI is advised to review the documents that are used to support consent-seeking and to revise them accordingly to ensure that staff donors are clear about how their consent can be withdrawn.
2.	C2(a)	The DI is advised to integrate regular training that addresses the requirements of the HT Act and the HTA's Codes of Practice into the existing training arrangements. This will help to ensure that staff members responsible for managing relevant material maintain awareness and understanding of the legislation and regulatory expectations.

## Background

LGC Genomics Ltd provides genotyping services for national and international customers for a number of different purposes. As part of this service provision, the establishment receives and stores tissues and/or cells from its customers and undertakes DNA extraction prior to genotyping.

Since the previous inspection, the establishment has been granted satellite licence.

## Description of inspection activities undertaken

The HTA's regulatory requirements are set out in Appendix 1. The inspection team covered the following areas during the inspection:

*Standards assessed against during inspection*

All 47 HTA licensing standards were covered during the inspection (standards published 3 April 2017).

*Review of governance documentation*

A review of the key documents was carried out including: policies and procedural documents relating to licensed activities, contracts for servicing of equipment and records of servicing, audits, risk assessments, reported incidents, meeting minutes, temperature monitoring for the storage units, and staff training records.

*Visual inspection*

A site visit inspection was not carried out; however, hub site floor plans and some pictures of storage were made available.

*Audit of records*

There were no sample audits carried out. A number of audits carried out by the establishment staff, which included audits covering processes and traceability of specimens, were reviewed.

*Meetings with establishment staff*

Roundtable discussions took place with the DI, Quality Manager, Extraction Team Leader and Laboratory Service Manager.

**Report sent to DI for factual accuracy: 7 July 2023**

**Report returned from DI: No factual accuracy or request for redaction comments were made by the DI**

**Final report issued: 1 August 2023**

## **Appendix 1: The HTA's regulatory requirements**

Prior to the grant of a licence, the HTA must assure itself that the DI is a suitable person to supervise the activity authorised by the licence and that the premises are suitable for the activity.

The statutory duties of the DI are set down in Section 18 of the Human Tissue Act 2004. They are to secure that:

- the other persons to whom the licence applies are suitable persons to participate in the carrying-on of the licensed activity;
- suitable practices are used in the course of carrying on that activity; and
- the conditions of the licence are complied with.

Its programme of inspections to assess compliance with HTA licensing standards is one of the assurance mechanisms used by the HTA.

The HTA developed its licensing standards with input from its stakeholders. They are designed to ensure the safe and ethical use of human tissue and the dignified and respectful treatment of the deceased. They are grouped under four headings:

- consent
- governance and quality systems
- traceability
- premises facilities and equipment.

This is an exception-based report: only those standards that have been assessed as not met are included. Where the HTA determines that there has been a shortfall against a standard, the level of the shortfall is classified as 'Critical', 'Major' or 'Minor' (see Appendix 2: Classification of the level of shortfall). Where HTA standards are fully met, but the HTA has identified an area of practice that could be further improved, advice is provided.

HTA inspection reports are published on the HTA's website.

## **Appendix 2: Classification of the level of shortfall**

Where the HTA determines that a licensing standard is not met, the improvements required will be stated and the level of the shortfall will be classified as 'Critical', 'Major' or 'Minor'. Where the HTA is not presented with evidence that an establishment meets the requirements of an expected standard, it works on the premise that a lack of evidence indicates a shortfall.

The action an establishment will be required to make following the identification of a shortfall is based on the HTA's assessment of risk of harm and/or a breach of the Human Tissue Act 2004 (HT Act) or associated Directions.

### **1. Critical shortfall:**

A shortfall which poses a significant risk to human safety and/or dignity or is a breach of the HT Act or associated Directions  
*or*

A combination of several major shortfalls, none of which is critical on its own, but which together could constitute a critical shortfall and should be explained and reported as such.

A critical shortfall may result in one or more of the following:

- A notice of proposal being issued to revoke the licence
- Some or all of the licensable activity at the establishment ceasing with immediate effect until a corrective action plan is developed, agreed by the HTA and implemented.
- A notice of suspension of licensable activities
- Additional conditions being proposed
- Directions being issued requiring specific action to be taken straightaway

### **2. Major shortfall:**

A non-critical shortfall that:

- poses a risk to human safety and/or dignity, or
- indicates a failure to carry out satisfactory procedures, or
- indicates a breach of the relevant Codes of Practice, the HT Act and other relevant professional and statutory guidelines, or

- has the potential to become a critical shortfall unless addressed

*or*

A combination of several minor shortfalls, none of which is major on its own, but which, together, could constitute a major shortfall and should be explained and reported as such.

In response to a major shortfall, an establishment is expected to implement corrective and preventative actions within 1-2 months of the issue of the final inspection report. Major shortfalls pose a higher level of risk and therefore a shorter deadline is given, compared to minor shortfalls, to ensure the level of risk is reduced in an appropriate timeframe.

### **3. Minor shortfall:**

A shortfall which cannot be classified as either critical or major, but which indicates a departure from expected standards.

This category of shortfall requires the development of a corrective action plan, the results of which will usually be assessed by the HTA either by desk based review or at the time of the next inspection.

In response to a minor shortfall, an establishment is expected to implement corrective and preventative actions within 3-4 months of the issue of the final inspection report.

### **Follow up actions**

A template corrective and preventative action plan will be sent as a separate Word document with the final inspection report.

Establishments must complete this template and return it to the HTA within 14 days of the issue of the final report.

Based on the level of the shortfall, the HTA will consider the most suitable type of follow-up of the completion of the corrective and preventative action plan. This may include a combination of

- a follow-up inspection
- a request for information that shows completion of actions
- monitoring of the action plan completion
- follow up at next routine inspection.

After an assessment of the proposed action plan establishments will be notified of the follow-up approach the HTA will take.