

**Eurofins Genomics Europe DTC - Population Genetics Products & Services Limited**

Proposed HTA licensing number 12801

Application to be licensed under the Human Tissue Act 2004

**Activities**

<b>Premises/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>
Eurofins Genomics Europe DTC - Population Genetics Products & Services Limited Milton Keynes	Application made	Application not made

**Summary of findings**

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

Although the HTA found that Eurofins Genomics Europe DTC - Population Genetics Products & Services Limited ('the establishment') had met the majority of the HTA's standards, one minor shortfall was found against standards for Premises, facilities and equipment.

The HTA has assessed the establishment as suitable to be licensed for the activities specified, subject to corrective and preventative actions being implemented to meet the shortfalls identified during the assessment.

## Compliance with HTA standards

Standard	Assessment findings	Level of shortfall
<b>PFE2 There are appropriate facilities for the storage of bodies and human tissue</b>		
d) There are documented contingency plans in place in case of failure in storage area.	<p>The establishment did not have a documented contingency plan in place for the storage area.</p> <p><i>The establishment submitted sufficient evidence to address this shortfall before the report was finalised.</i></p>	Minor

## Advice

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

Number	Standard	Advice
1.	GQ1(b)	While the establishment reviews its SOPs every year, the current practice is not to circulate SOPs to staff if no changes have been made. The proposed DI is advised to consider distributing the reviewed SOPs to staff even if no changes are made, to ensure ongoing awareness and compliance
2.	PFE2(c)	The proposed DI is advised to display the defined temperature range for storage on fridges and freezers where relevant material is stored. This would provide staff with ready access to important information, supporting the maintenance of storage conditions to preserve the integrity and viability of the stored material.
3.	PFE2(c)	The proposed DI is advised to implement a process to regularly test and periodically manually challenge fridges and freezers temperature alarms to provide an assurance that they are operating as expected

## **Background**

Eurofins Genomics Europe DTC - Population Genetics Products & Services Limited provides Genotyping, NGS and Proteomics services for customers for a number of different purposes. As part of this service provision the establishment may at times receive and store human cells for fractionation to serum/plasma or DNA extraction prior to production.

## **Description of activities undertaken**

The HTA's regulatory requirements are set out in Appendix 1. The Regulation Manager covered the following areas during a desk based assessment and site visit:

### *Standards assessed*

There are 47 standards in the Research sector, of which 40 were assessed (standards published 3 April 2017). Standards C1(d)(e) and (f) and Standards C2(a)(b) and (c) were not applicable because the establishment will not be seeking consent. Standard PFE2(b) could not be assessed as the establishment does not intend to store bodies or body parts.

### *Review of governance documentation*

A review of policies and procedural documents relating to licensable activities, records of servicing, audit procedures, risk assessments, incident reporting, temperature monitoring for the storage units and staff training records was carried out.

### *Visual inspection*

An inspection of the storage areas was undertaken at the time of the licence application assessment visit. The facility was accessible by access card only and had appropriate temperature monitoring in place

### *Meetings with establishment staff*

A roundtable discussion was carried out with the proposed Designated Individual (DI) and a member of staff taking on the role of Person Designated (PD)

**Report sent to proposed DI for factual accuracy: 2 June 2025**

**Report returned from proposed DI: 3 June 2025**

**Final report issued: 3 June 2025**

### **Completion of corrective and preventative actions (CAPA) plan**

Based on information provided, the HTA is satisfied that the establishment has completed the agreed actions in the CAPA plan and in doing so has taken sufficient action to correct all shortfalls addressed in the Inspection Report.

**Date: 23 May 2025**

## **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, and;
- 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, or;
- 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 site visit.

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, or;
- 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.