Inspection report on compliance with HTA licensing standards
Inspection date: **14 June 2023**

Orchid Cellmark Ltd

HTA licensing number 12575

Licensed under the Human Tissue Act 2004

Licensed activities

Area	Storage of relevant material which has come from a human body for use for a scheduled purpose	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
Hub site **Orchid Cellmark Ltd**	Licensed	Not licensed
Satellite site **Cellmark Forensic Services**	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.

Orchid Cellmark 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(a)	The DI is advised to review and make any appropriate revisions to the information set out in the letter which is sent out to customers. The letter sets out the legal requirements for obtaining consent from a person related to the deceased; for example, lawful consent for removal of relevant material and lawful consent for DNA analysis purposes. As the consent requirements differ in their application, the DI is advised to ensure that the information provided to clients is optimally clear to support their understanding and decision-making.
2.	GQ5(a)	To assist staff and strengthen reporting, the DI is advised to review the procedure that sets out the management of adverse events and include the categories of adverse events that should be reported.
3.	GQ6(a)	The Identification Operations team (relationship testing) have in place an comprehensive risk assessment which covers sample receipt, storage, destruction and processing. To strengthen consistency in internal practices, the DI should consider developing a similar documented risk assessment for the Forensic Operations team, that deals with the identification of a living person or deceased for criminal justice purposes.

Background

Orchid Cellmark Ltd is a UK DNA and forensic testing company for a wide range of purposes, including criminal investigations, storing biological material from living and deceased people. This was the second inspection of the establishment; the most recent previous inspection took place in July 2017. The establishment is licensed to store relevant material from deceased people for the scheduled purpose of ‘Obtaining scientific or medical information about a living or deceased person which may be relevant to any other person (including a future person)’.

Since the previous inspection, there have been no significant changes to the licence arrangements or the activities carried out.

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, a virtual tour of the hub site using a mobile device was provided. The tour included the licensed storage areas at the hub site.

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, Laboratory Manager (Identity Operations team), Customer Services Manager, Submissions and Returns Manager.

Report sent to DI for factual accuracy: 4 July 2023

Report returned from DI: 4 July 2023 (no comments)

Final report issued: 5 July 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.