Inspection report on compliance with HTA licensing standards
Inspection date: **15 October 2024**

Sera Laboratories International Ltd t/a BioIVT

HTA licensing number 12699

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 Sera Laboratories International Ltd t/a BioIVT	Licensed	Not licensed
Satellite site Clinical Trials Laboratory Services (CTLS) Limited	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.Although the HTA found that Sera Laboratories International Ltd t/a BioIVT ('the establishment') had met the majority of the HTA's standards, three minor shortfalls were found against standards for Consent, Governance and quality systems and Premises facilities and equipment. The shortfalls related to consent procedures, complaints management and risk assessment.

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 inspection.

Compliance with HTA standards

Minor Shortfalls

Standard	Inspection findings	Level of shortfall
C1 Consent is obtained in accordance with the requirements of the Human Tissue Act 2004 (HT Act) and as set out in the code of practice		
a) Consent procedures are documented and these, along with any associated documents, comply with the HT Act and the HTA's Codes of Practice	The consent form and the subject information sheet used by the establishment state that donor information will be removed after 10 years but do not specify the duration for which samples will be stored or used. The establishment indicated that they may use the samples for longer than 10 years. *The establishment submitted sufficient evidence to address this shortfall before the report was finalised.*	**Minor**

GQ1 All aspects of the establishments work are governed by documented policies and procedures as part of the overall governance process		
e) There is a system for managing complaints	The establishment does not have a documented complaints policy in place to manage complaints relevant to HTA-licensed activities *The establishment submitted sufficient evidence to address this shortfall before the report was finalised.*	**Minor**

GQ6 Risk assessments of the establishment's practices and processes are completed regularly, recorded and monitored		
a) There are documented risk assessments for all practices and processes requiring compliance with the HT Act and the HTA's Codes of Practice.	The establishment had some risk assessments in place; however, they did not comprehensively cover all practices and processes related to licensed activities. *The establishment submitted sufficient evidence to address this shortfall before the report was finalised.*	**Minor**

The HTA requires the DI to submit a completed corrective and preventative action (CAPA) plan setting out how the shortfalls will be addressed, within 14 days of receipt of the final report (refer to Appendix 2 for recommended timeframes within which to complete actions). The HTA will then inform the establishment of the evidence required to demonstrate that the actions agreed in the plan have been completed.

Advice

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

Number	Standard	Advice
1.	GQ1(b)	At the time of the inspection, it was observed that some documents had not been approved within the two-year review timeline specified by the internal policy, with several documents still in the approval process. The DI is advised to review and update governance documents in alignment with the establishment's internal policy.
2.	PFE2(c)	The DI is advised to display the defined temperature range for storage on refrigerators where relevant materials are kept. Displaying the defined temperature range for storage on refrigerators is beneficial for other users as it ensures clear and immediate access to important information. This practice can support the maintenance of proper storage conditions, thereby preserving the integrity and viability of the stored materials.
3.	PFE2(c)	The 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

Sera Laboratories International Ltd t/a BioIVT is licensed for the storage of relevant material which has come from a human body for use in a scheduled purpose, under the Human Tissue Act 2004 (HT Act). The establishment is a biological research company that supplies specimens.

Sera Laboratories International Ltd t/a BioIVT has been licensed by the HTA since December 2019. This was the second inspection of the establishment - the hub site was previously inspected in March 2020 and satellite site was inspected in August 2021. Since the previous inspections, the establishment has appointed a new Corporate Licence Holder contact (CLHc) and DI.

Description of inspection activities undertaken

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

Standards assessed against during inspection

There are 47 standards in the Research sector, of which 46 were assessed. Standard PFE2(b) could not be assessed as the establishment does not store bodies or body parts (standards published 3 April 2017).

Review of governance documentation

The assessment involved a comprehensive review of the establishment's documentation related to its licensed activities. This included examining policies and procedures, supplier agreements, equipment maintenance logs, temperature monitoring protocols for storage units, and staff training records. Additionally, the review covered sample tracking systems, including databases, as well as audits and incident reports.

Visual inspection

No site visit was undertaken as part of this inspection. The establishment provided images of the storage facilities that allowed for assessment of security measures and the signage on the individual units.

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
The inspection included discussions with the DI, PDs and other staff working under the licence. This included the Quality Assurance Manager.

Report sent to DI for factual accuracy: 5 November 2024

Report returned from DI: 22 November 2024

Final report issued: 25 November 2024

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.