Inspection report on compliance with HTA licensing standards
Inspection date: **02 July 2024**

Affinity Biomarker Labs

HTA licensing number 12689

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
Affinity Biomarker Labs	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 Affinity Biomarker Labs ('the establishment') had met the majority of the HTA's standards, four minor shortfalls were found against standards for Governance and quality systems. The shortfalls related to the standard operating procedure for responding to alarms, risk assessments and audits.

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
GQ1 All aspects of the establishments work are governed by documented policies and procedures as part of the overall governance process		
a) Ratified, documented and up-to-date policies and procedures are in place, covering all licensable activities.	The standard operating procedure (SOP) related to temperature monitoring did not provide sufficient detail on how to respond to alarms outside of normal working hours.	**Minor**

GQ2 There is a documented system of audit		
a) There is a documented schedule of audits covering licensable activities.	While the establishment had undertaken a range of vertical audits, it had not undertaken the horizontal or examination audits specified in the SOP related to audits.	**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's risk assessments did not cover all risks associated with licensed activities. For example, they did not include an assessment of the risks associated with: • Samples being stored after withdrawal of consent. • Samples being stored for a scheduled purpose beyond any maximum storage timeframes that may have been stipulated during the donor consent process. • Storing sample boxes 'loose' in freezers rather than in racks.	**Minor**
b) Risk assessments are reviewed regularly.	At the time of inspection, the establishment had not regularly reviewed risk assessments. There was therefore no assurance that the suite of risk assessments covered all current risks related to licensable activities.	**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.	C1(c)	The DI is advised to detail in the client agreements that clients are responsible for informing the establishment should a donor withdraw consent for the use or storage of their sample(s). This will provide an assurance that the client is aware of the need to inform the establishment should a donor withdraw consent.
2.	GQ1(a)	SOPs include a list of documents for reference. The DI is advised to consider adding the HTA's Codes of Practice A (Consent) and E (Research) to the reference list. In combination, Codes A and E aim to provide anyone undertaking activities relevant to this sector with a reference source which gives practical advice on the minimum steps necessary to comply with the relevant legislation.
3.	GQ3(b)	The DI is advised to ensure that all staff at the establishment have completed the training related to the use of human tissue. This will help provide assurance that they are aware of applicable regulatory expectations.
4.	GQ3(d)	The DI is advised to consider how best to formally document the quality assurance components in the expanded roles relevant staff members are currently undertaking; for example, in relation to audits and document control.
5.	T1(b)	Samples are recorded in client, project-specific spreadsheets. Since receiving its licence, the establishment has begun to store samples and the reliance on multiple client spreadsheets limits the ability of the establishment to have an overarching record of what is currently stored on site. The establishment has recently purchased a sample tracking system and the individual project spreadsheets are currently being uploaded into the system. After the new system has been

		implemented and appropriately validated, the DI is advised to use the overarching inventory to facilitate audits and oversight of sample storage.
6.	T1(c)	The establishment seeks assurance of recognised Research Ethics Committee approvals (where appropriate) and reviews example consent forms. The DI is advised to confirm and record the end dates of approvals and any limitations on the length of storage of relevant material. This will provide an assurance that material stored at the establishment has appropriate consent for its continued storage.
7.	T1(c)	The DI is advised to label freezers containing human material so that staff are aware of the necessity to maintain the quality, safety, and security of such material and prevent mix-ups with other tissues.
8.	PFE2(a)	The establishment has recently ordered custom-built racking to facilitate traceability of individual boxes within the freezers. The DI is advised to implement a process for tracking box location on individual freezer shelves once the racking is available.
9.	PFE2(c)	The DI is advised to add the temperature alarm set points to signs on the freezers so that staff are visually reminded of minimum and maximum temperatures.
10.	N/A	While contactable, the DI and quality manager primarily work remotely. The DI is advised to consider appointing Persons Designated (PDs) at the establishment to support day-to-day oversight of licensable activities.

Background

Affinity Biomarker Labs is a Contract Research Organisation (CRO) that provides a bespoke analytical service for biomarkers in a diverse range of human samples. In addition to undertaking biomarker analysis, the establishment offers the option for long term storage of cells

at -80°C. Samples are received from client projects and the depositing organisations take responsibility for donor consent. In addition to holding a HTA research sector licence, the establishment has recently been accredited to ISO15189:2012.

Affinity Biomarker Labs has been licensed by the HTA since 2019. This was the first inspection of the establishment since it was licensed. A site visit inspection of the establishment was undertaken in April 2019 as part of the licence application process. The establishment has moved premises since the licence was granted in 2019.

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

There are 47 standards in the Research sector, of which 38 were assessed. Standards C1(a), C1(b), C1(d), C1(e), C1(f), C2(a), C2(b), C2(c), and PFE2(b) could not be assessed as the establishment does not directly seek consent or store the deceased (standards published 3 April 2017).

Review of governance documentation

The assessment included a review of documentation relevant to the establishment's licensed activities. This included policies and procedural documents relating to licensed activities, client agreements, equipment maintenance records, risk assessments, arrangements for temperature monitoring for the storage units, staff training records, a review of the spreadsheets used for sample tracking, audits, and incidents.

Visual inspection

The site visit included a visual inspection of areas where samples are receipted into the establishment, and areas where samples are stored at either -20°C or -80°C.

Audit of records
During the visual inspection five samples were reviewed from record to location in storage. This included samples stored at -20°C and -80°C, and a review of all records associated with the respective sample including the client agreement and relevant consent documentation. While minor inconsistencies were identified these did not affect traceability and advice was provided.

In addition, ten internal audits were reviewed and discussed.

Meetings with establishment staff
The inspection included discussions with the DI, the Corporate Licence Holder contact, and other staff working under the licence.

Report sent to DI for factual accuracy: 26 July 2024

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

Final report issued: 26 July 2024

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: 28 October 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.