Inspection report on compliance with HTA licensing standards
Inspection date: **23 February 2023**

Mologic Ltd

HTA licensing number 12647

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
Mologic Ltd	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 Mologic Ltd ('the establishment') had met the majority of the HTA's standards, four minor shortfalls were found against standards for Consent, Governance and quality systems, and Traceability. The shortfalls related to ongoing competency assessment for consent training, Standard Operating Procedures, internal audits, and traceability of samples in storage.

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
C2 Staff involved in seeking consent receive training and support in the essential requirements of taking consent		
c) Competency is assessed and maintained.	There was no documentary evidence that competency in consent-seeking is assessed and maintained.	**Minor**

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 document 'G007 – Use and Maintenance of Sub-Ambient Temperature Storage Equipment' did not provide information on how to access or use the remote monitoring systems, or how to respond to alarms in or out of hours. The document also does not contain details on when and how material should be transferred to contingency storage.	**Minor**

GQ2 There is a documented system of audit		
a) There is a documented schedule of audits covering licensable activities.	There is no documented schedule of audits for HTA licensable activities.	**Minor**

T1 A coding and records system facilitates the traceability of bodies and human tissue, ensuring a robust audit trail		
c) An audit trail is maintained, which includes details of: when and where the bodies or tissue were acquired and received; the consent obtained; all sample storage locations; the uses to which any material was put; when and where the material was transferred, and to whom.	The sample log did not provide sufficient details to maintain full traceability. This was evidenced for one sample that was included in the HTA's traceability audit, which had been split into two different storage locations following receipt. There were no details on how and why the sample was divided for storage or what happened to the samples prior to their disposal.	**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(a)	The DI is advised to review ‘G007 – Use and Maintenance of Sub-Ambient Temperature Storage Equipment’ to ensure that minimum and maximum temperatures, and target temperature ranges, for storage units reflect those in use and good practice.
2.	GQ2(a)	The DI is advised to consider implementing a schedule of procedural horizontal audits in addition to the vertical audits of records and specimens currently undertaken. This may help to ensure that SOPs accurately reflect the practices being carried out.
3.	GQ4(b)	The paper sample record indicates the freezer used for storage but not the location within the freezer, which is recorded in the paper location map displayed on the freezer doors. The DI is advised to review the frequency of scanning the paper sample record and freezer maps to limit the risk of losing this information should the paper sample records or freezer map be lost or damaged between back-ups.
4.	PFE3(a)	The establishment has made the decision to not maintain its freezers under a preventative maintenance contract. The DI is advised to document this decision and any steps that have been undertaken to mitigate any associated risks.

Background

Mologic Ltd is a biotechnology company involved in innovation and development of *in vitro* diagnostic products, and also undertakes contract research work. The establishment recruits staff as healthy volunteers who may donate urine, blood and tissue swabs for research and performance assessment purposes. Human tissue may also be purchased from third party tissue providers or acquired from research tissue banks.

Mologic Ltd has been licensed by the HTA since 2016. This was the second inspection of the establishment; the most recent previous inspection took place in June 2018.

The current DI is the second DI to have been appointed since the last inspection.

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 46 were assessed. Standard PFE2(b) could not be assessed as the establishment does not 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, agreements with suppliers, equipment records, risk assessments, arrangements for temperature monitoring for the storage units, staff training records, a review of the physical sample log sheets used to record and track relevant material, and audits.

Visual inspection

No site visit was undertaken as part of this inspection. However, the establishment provided photographs of the storage facility that allowed an assessment of security around the storage units and the signage on the individual units.

Audit of records

Three recent internal audits were reviewed as part of the inspection. This was in addition to a review of examples of the paper based sample log sheets and freezer maps, and consent records for three donor collections covering a collection of saliva, peripheral venous blood, and a vaginal swab.

Meetings with establishment staff
The inspection included discussions with the DI and other staff working under the licence. This included the Facilities Manager, the Biosafety Officer, representatives from Regulatory Affairs, the Quality Manager, the Clinical Trials Manager and a Principle Investigator working under the licence.

Report sent to DI for factual accuracy: 21 March 2023

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

Final report issued: 5 April 2023

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: 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.