Inspection report on compliance with HTA licensing standards
Inspection date: **05-06 December 2022**

Eurofins Forensic Science Ltd

HTA licensing number 12425

Licensed under the Human Tissue Act 2004

Licensed activities

The table below shows the activities this establishment is licensed for and the activities currently undertaken at the establishment.

Area	Making of a post-mortem examination	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	Storage of the body of a deceased person or relevant material which has come from a human body for use for a scheduled purpose
Hub site **Eurofins Forensic Services Ltd Toxicology Laboratory**	Not licensed	Not licensed	Licensed
Pathology lab			*Carried out*
Satellite site **Birchwood Park**	Not licensed	Not licensed	Licensed
Pathology Lab (satellite site)			*Carried out*
Satellite site **Calder Park**	Not licensed	Not licensed	Licensed

Pathology Lab (satellite site)			*Carried out*

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 Eurofins Forensic Services Ltd ('the establishment') had met the majority of the HTA's standards, four major and eight minor shortfalls were found against standards for Governance and quality systems, Traceability and 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 inspection.

Compliance with HTA standards

Major shortfalls

Standard	Inspection findings	Level of shortfall
GQ2 There is a documented system of audit		
c) Regular audits are carried out of tissue being stored so that staff are fully aware of what is held and why and to enable timely disposal of tissue where consent has not been given for continued retention	The establishment do not undertake regular tissue traceability audits of post mortem (PM) examination samples received at all sites under the licence. A number of discrepancies were identified by the inspection team when conducting the traceability audits. *See standard T2(a) for further detail.*	**Major**
GQ5 There are systems to ensure that all untoward incidents are investigated promptly		

a) Staff know how to identify and report incidents, including those that must be reported to the HTA	Staff at all sites inspected undertaking licensed activities are not aware of what incidents should be reported to the Human Tissue Authority (HTA). The inspection team found a small number of incidents that should have been reported to the HTA. *See advice item 2.*	**Major**
T2 Disposal of tissue is carried out in an appropriate manner and in line with the HTA's codes of practice.		
a) Tissue is disposed of as soon as reasonably possible once it is no longer needed, such as when the coroner's or police authority over its retention ends or the consented post-mortem examination process is complete	During the inspection, tissue traceability audits were conducted. The inspection team identified four cases where there were discrepancies: • For one case the date of birth on paperwork received was not transcribed to the laboratory information management system (LIMS); • For two cases the number of samples stated on the paperwork did not match the number of samples scanned into LIMS; and • For one case the correction of an error on the admission paperwork was not in line with the record management procedure.	**Major**
PFE2 There are appropriate facilities for the storage of bodies and human tissue.		
e) Fridge and freezer units are alarmed and the alarms are tested regularly to ensure that they trigger when temperatures go out of upper or lower set range	The establishment do not manually challenge the fridge and freezer alarms to ensure that the alarms trigger at the appropriate upper and lower temperatures.	**Major**

Minor Shortfalls

Standard	**Inspection findings**	**Level of shortfall**
GQ1 All aspects of the establishment's work are governed by documented policies and procedures		

a) Documented policies and SOPs cover all mortuary/laboratory procedures relevant to the licensed activity, take account of relevant Health and Safety legislation and guidance and, where applicable, reflect guidance from RCPath.	Not all Standard Operating Procedures (SOPs) include all practices that are undertaken by staff. These include, but are not limited to, SOPs detailing the process for: • Return of samples and confirmation of receipt; and • Querying discrepancies found on paperwork.	**Minor**
GQ2 There is a documented system of audit		
a) There is a documented schedule of audits	The establishment does not include vertical audits against applicable HTA standards in the audit schedule.	**Minor**
GQ3 Staff are appropriately qualified and trained in techniques relevant to their work and demonstrate competence in key tasks		
a) All staff who are involved in mortuary duties are appropriately trained/qualified or supervised	Although training records and competency assessments are in place, the newest member of the submissions staff does not appear to have been signed off on the initial competency assessment for procedures or have signed the initial training documents.	**Minor**
c) Staff are assessed as competent for the tasks they perform	One long term member of the submissions staff has not completed their annual review competency assessment.	**Minor**
GQ6 Risk assessments of the establishment's practices and processes are completed regularly, recorded and monitored		
a) All procedures related to the licensed activities (as outlined in standard GQ1) are risk assessed on a regular basis	Not all procedures relating to licensed activities have been risk assessed. For example: • Disposal or retention of an organ or tissue against the express wishes of the family; and • Loss of an organ or tissue	**Minor**
T1 A coding and records system facilitates traceability of bodies and human tissue, ensuring a robust audit trail		

g) Organs or tissue taken during post-mortem examination are fully traceable, including blocks and slides (including police holdings).	There is no procedure in place to confirm the receipt of samples returned to the coroner service if this is conducted by a courier other than the establishment's contracted courier.	**Minor**
h) There are documented procedures for transportation of bodies and tissue anywhere outside the mortuary, (such as to the lab or another establishment), including record-keeping requirements	There is no documented procedure in the business case plan for how coroner's samples would be transferred to the contingency storage sites.	**Minor**
PFE2 There are appropriate facilities for the storage of bodies and human tissue.		
b) There is sufficient capacity for storage of bodies, organs and tissue samples, which takes into account predicated peaks of activity	Due to staff shortages the number of returned samples to the coroner's service has been limited. The inspection team found that the freezer used to store the samples for return was full. However; a new staff member has been appointed and the establishment have an action plan to ensure all outstanding return of samples is completed.	**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 practice:

Number	Standard	Advice
1.	GQ3g	The DI is advised to put in place an induction package for any staff who are required to visit and work at a different site under the licence, which includes the site's policies and procedures.

2.	GQ5a	The DI is advised to roll out to all staff undertaking licensed activities the HTA awareness presentation and to incorporate this as part of the annual review of procedures. This will provide assurance that those staff that are not routinely working with HTA samples are aware of the categories that are reportable to the HTA.
3.	T2d	The DI is advised to receive a copy of the incineration paperwork to attach to the container record in LIMS to complete the procedure of disposal of samples, and to be assured that the third party contractor has complied with the terms of the contract.
4.	PFE1c	The inspection team found that two of the weekly activities to be carried out by the contracted cleaning service had not been completed for a number of months. The DI is advised to put in place a procedure for ensuring that all cleaning activities have been completed.
5.	PFE2d	The DI is advised to ensure that the schedule for defrosting freezers is maintained to ensure the effective working temperatures of the units.
6.	PFE2f	There is a procedure in place at the satellite sites that temperatures are checked on the service providers webpage on a daily basis. The DI is advised to implement a similar procedure at the hub site. The DI is also advised to conduct trend analysis on the fridge and freezer temperatures to assure themselves that the units are working effectively.

Background

Eurofins Forensic Services Ltd (EFS Ltd) is licensed for the storage of bodies of the deceased and relevant material for use for scheduled purposes.

EFS Ltd has been licensed by the HTA since 2008. This was the third inspection of the establishment; the most recent previous inspection took place in August 2018.

Since the previous inspection, the establishment has moved to a new primary laboratory premises.

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

51 out of 72 standards were assessed. Standards C1a – g, C2a – d, GQ1b, GQ1c, T1a, T1d – f, PFE2a, PFE2g, PFE2h and PFE3b were not assessed as the standards were not applicable.

Review of governance documentation

The inspection included a review of the establishment's governance documentation relating to licensed activities. This included policies and procedural documents relating to licensed activities, cleaning records for the laboratory, records servicing of equipment, ventilation reports, audits, risk assessments, meeting minutes, temperature monitoring for the storage units, reported incidents and staff training records.

Visual inspection

The inspection included a visual inspection of the laboratories conducting licensed activities.

Audit of records

Audits of traceability were conducted for Coroner's samples from eight post mortem examination cases. Four discrepancies found.

Meetings with establishment staff

Staff carrying out processes under the licence were interviewed including the DI, quality manager and histology manager.

Materials held for the police

Under section 39 of the HT Act, relevant material held for criminal justice purposes is outside the scope of HTA regulation and is not subject to the licensing requirements for storage. Any information provided by the establishment in relation to police holdings have been shared with the Home Office, but do not appear in the report as they are outside the scope of the HT Act.

Report sent to DI for factual accuracy: 11 January 2023

Report returned from DI: 25 January 2023

Final report issued: 30 January 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: 17 April 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 both the draft and 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.