Inspection report on compliance with HTA licensing standards
Inspection date: **1 February 2024**

Labcorp Early Development Laboratories Ltd

HTA licensing number 12494

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
Labcorp Early Development Laboratories Ltd **Harrogate (Hub)**	Licensed	Not licensed
Labcorp Early Development Laboratories Ltd **Shardlow (Satellite)**	Licensed	Not licensed

Labcorp Early Development Laboratories Ltd **Eye (Satellite)**	Licensed	Not licensed
Labcorp Early Development Laboratories Ltd **Huntingdon (Satellite)**	Licensed	Not licensed
Labcorp Early Development Laboratories Ltd **York (Satellite)**	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.

The HTA has assessed the establishment as suitable to be licensed for the activities specified.

Advice

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

Number	Standard	Advice
1.	C2(a)	Due to recent re-structuring, the establishment did not have a formalised consent-seeker training provider to train and observe new staff in seeking consent. A training provider has been agreed informally and the DI is advised to formalise this agreement to ensure effective training and support of new staff in the consent-seeking process.
2.	C2(b)	Reviewed records demonstrated a consent-seeker was observed seeking and obtaining consent from donors as part of their initial training. Records of the observations were not signed-off by the trainer at the time of observations. The DI is advised to ensure records demonstrating staff consent training are completed and documented at the time of activity.
3.	C2(c)	Consent training, once completed, is not reassessed. The DI is advised to consider implementing consent-seeker reassessments to provide assurance that current standards, legislative changes, new policies and practices in regard to consent are understood and maintained in practice.
4.	GQ6(a)	Some departments within the establishment use paper based records which, in the event of loss, may result in the loss/destruction of relevant material samples held under the licence. Mitigating actions to prevent the loss of records have been taken at an establishment-wide level. However, the DI is advised to formally identify and document the risks inherent with the keeping of paperbased records as part of their licensed activites, and the steps taken to mitigate the potential risks, within the HTA risk assessment.

Background

Labcorp Early Development Laboratories Ltd provides drug development services to the pharmaceutical industry for studies that require storage and use of human tissue.

Labcorp Early Development Laboratories Ltd has been licensed by the HTA since 2007. This was the second inspection of the establishment; the most recent previous inspection took place in August 2014.

Since the previous inspection, there has been significant change to the organisational structure of the establishment but licensable activities remain the same. In addition, a new Corporate Licence Holder contact has been agreed.

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

46 out of 47 HTA licensing standards were covered during the assessment (standards published 3 April 2017). One standard was not applicable as the establishment does not store bodies or body parts [standard PFE2(b)]. All other standards were assessed.

Review of governance documentation

The inspection included a review of documentation relevant to the establishment's licensable activities. This included policies and procedural documents, audits, adverse event reporting, training requirements, temperature monitoring of the relevant material storage areas, calibration certificates, contingency plans and a review of the HTA tissue tracking databases used to record and track relevant material.

Visual inspection

No site visit was undertaken as part of this inspection. However, the establishment provided photographs of critical storage areas at the hub and satellite sites.

Audit of records

Samples relating to projects were reviewed on the tissue traceability databases along with corresponding consent documentation, transport records and material transfer agreements.

Meetings with establishment staff

The inspection included virtual meetings with the following staff: the Designated Individual (DI), Persons Designated (PD), the named Corporate Licence Holder representative, members of the Quality Assurance team, consent seekers and site security. The meetings covered: consent, quality management, traceability, and premises, facilities and equipment.

Report sent to DI for factual accuracy: 14 February 2024

Report returned from DI: 26 February 2024

Final report issued: 27 February 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.