Licence application assessment report on compliance with HTA licensing standards
Licence assessment date: **6 May 2020**

QuantuMDx

Proposed HTA licensing number 12701

Application for a licence under the Human Tissue Act 2004 (HT Act)

Activities applied to be licensed

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: Lugano Building	Applied to be licensed	Not applied to be licensed
Satellite site: Infectious Diseases Facility, Newcastle University	Applied to be licensed	Not applied to be licensed

Summary of assessment findings

The HTA found the proposed Designated Individual (DI) and the proposed Licence Holder (LH) to be suitable in accordance with the requirements of the legislation.

Although the HTA found that QuantuMDx (the 'establishment') had met the majority of the HTA's standards, two minor shortfalls were found against Governance and Quality systems 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 assessment.

Minor Shortfall

Standard	**Assessment findings**	**Level of shortfall**
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.	Current risk assessments do not cover the following risks: • storing or using human tissue after consent withdrawal; • sample mix-up or loss of traceability; • incorrect disposal.	**Minor**

Standard	Assessment findings	Level of shortfall
PFE2 There are appropriate facilities for the storage of bodies and human tissue		
c) Storage conditions are monitored, recorded and acted on when required.	Neither continuous nor continual temperature monitoring is currently performed for the -80ºC freezer at the satellite site although the proposed DI has confirmed that any alarms are acted on by university staff when temperature excursions are detected outside the set range. As there is currently no Person Designated (PD) at the satellite site, the proposed DI does not have sufficient oversight of storage conditions.	**Minor**

Advice

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

Number	Standard	Advice
1.	C1(c)	An import agreement with a third party was reviewed during the assessment. Although the consent provisions of the HT Act do not apply to imported material, it is good practice for there to be mechanisms in place to provide assurance that the tissue has been obtained with valid consent. The proposed DI is advised to include this in future agreements for imported tissue for research.
2.	GQ1(a)	For 'healthy volunteer' donations from employees, the proposed DI is advised to define and document donation thresholds and monitor donation quantities to ensure that donors do not donate excessively.

3.	T1(c)	The proposed DI is advised to include the name of the consent seeker and the date consent was sought to the current 'Employee Sample Consent Form' (QTEM-356). This will improve traceability of samples.
4.	PFE2(c)	Storage conditions are monitored by a continual web-based temperature recording system. On review of the temperature readouts, several traces have been annotated for quality assurance purposes. The proposed DI is advised to annotate all temperature deviations outside the set levels to provide assurance that deviations are being monitored.

Background

QuantuMDx is a biotechnology company that designs and develops molecular *in vitro* devices for the point of care diagnosis of infectious diseases.
The hub site is based at the Lugano Building, Newcastle upon Tyne.
The satellite site is based in the laboratory and ancillary rooms in the Infectious Diseases Facility at Newcastle University.

Description of activities undertaken during visit

The HTA's regulatory requirements are set out in Appendix 1. The Regulation Manager covered the following areas during a desk-based assessment.

Standards assessed against

A total of 46 HTA licensing standards were covered during the assessment (standards published 3 April 2017). Standard PFE2(b) was not applicable.

Review of governance documentation

Policies and procedural documents relating to all licensable activities including standard operating procedures, risk assessments and those pertaining to traceability systems were assessed. Documents detailing the plans for staff training, adverse events, incident management, governance meetings and audits were also reviewed.

Visual inspection

No site visit was undertaken as part of the licence application assessment.

Meetings with establishment staff
The assessment included a meeting with the proposed DI and PDs.

Report sent to proposed DI for factual accuracy: 28 May 2020

Report returned from proposed DI: 1 June 2020

Final report issued: 8 June 2020

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 July 2020

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 site visit 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, and;
- 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, or;
   - 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 site visit.

   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 site visit inspection;
- a request for information that shows completion of actions;
- monitoring of the action plan completion, or;
- follow up at next routine site visit inspection.

After an assessment of the proposed action plan establishments will be notified of the follow-up approach the HTA will take.