Evaluation report on compliance with HTA licensing standards

Report date: 18 August 2025



QuantuMDx HTA licensing number 12701

Licensed under the Human Tissue Act 2004

Licensed activities

QuantuMDx, Lugano Building (NE1 2JQ)

 Storage of relevant material which has come from a human body for use for a scheduled purpose **Evaluation summary**

At the HTA's request, the establishment submitted a self-assessment for evaluation

of compliance against the HTA's licensing standards.

Evaluated self-assessments are intended to be proportionate and risk-based. They are one of several tools that the HTA uses to maintain regulatory oversight. The

regulatory framework places responsibility for compliance with those undertaking

regulated activities. Designated Individuals are responsible for the accuracy of self-

assessments.

As part of this process, the Designated Individual (DI) reported the establishment

(HTA licensing number 12701) was substantially compliant with HTA's licensing standards. Based on the assurances provided, the HTA takes overall compliance to

be satisfactory.

The HTA cannot provide any guarantees or endorsements of licensed

establishments, or their activities, based on self-assessments.

The frequency and format of future assessments of compliance will be determined

by the HTA according to evaluated risk.

Final report issued: 19 August 2025