|  |  |
| --- | --- |
| HTA master file document: | Section 9 – audit report |
|  | Type d – traceability audit (reverse) |
| Laboratory: |  |
| Person designate: |  |

|  |  |
| --- | --- |
| Lead auditor: |  |
| Audit date: |  |

|  |  |  |  |  |
| --- | --- | --- | --- | --- |
|  | Sample ID number | Date collected | Does storage location match database?  (Y/N) | Non-conformance details |
| 1 |  |  |  |  |
| 2 |  |  |  |  |
| 3 |  |  |  |  |
| 4 |  |  |  |  |
| 5 |  |  |  |  |
| 6 |  |  |  |  |
| 7 |  |  |  |  |
| 8 |  |  |  |  |
| 9 |  |  |  |  |
| 10 |  |  |  |  |

|  |  |  |  |
| --- | --- | --- | --- |
| Corrective action | | | |
| Target date: |  | Owner: |  |
| Details: |  | | |

|  |  |  |  |
| --- | --- | --- | --- |
| Follow up | | | |
| Details: |  | | |
| Audit Closed Date: |  | Audit Closed by: |  |

Type d - traceability audit (reverse)

Choose 10 samples from storage and record the following:

Sample ID number: identifier for the sample as stated on the tube/container

Date collected: date sample received into archive

Does storage location match database?: Is the physical storage location traceable back to the database? E.g. if Sample 01 is in Box A – grid A1 does the database state the same?

Non-conformance: Record details of any non-conformance (e.g. location the sample is stored in does not match the database, identifiers do not match).

Corrective action: Decide on any corrective action to be implemented in light of any non-conformance found (e.g. new login procedure, database changes). Assign a date and person responsible for this action.

Follow-up: Enter details of follow up on audit (e.g. corrective actions completed). When all corrective actions have been completed the audit is closed.

Note: Corrective action and follow up must not be done by the same person.

Audits, corrective actions and follow-up will be checked on a random basis by the Research Governance Ethics and Integrity (REGI) Office.