Sample Retention and Disposal Schedule

Clinical, Research & Reference Sample Classes

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Process owner	Quality Assurance Manager, Nexa Diagnostics Laboratory
Applies to	All sample repositories: Clinical Testing, Biobank, R&D Chemistry, Environmental Monitoring
Regulatory scope	ISO 15189:2022, CLIA 42 CFR 493.1105, GLP OECD Principles, institutional biosafety committee (IBC) charter

Controlled Document

This schedule is the single authoritative reference for how long each sample class is held and how it is disposed of once retention expires. Local freezer logs, LIMS disposal flags, and department SOPs must not specify shorter or longer periods without a documented deviation approved under Section 6. Printed copies are uncontrolled after 24 hours.

1 Purpose and Scope

1.1 Purpose

This schedule defines how long each class of sample handled by Nexa Diagnostics Laboratory is retained after result reporting or study closeout, the regulatory or contractual basis for each retention period, and the approved method of disposal once that period has elapsed. It exists to satisfy three simultaneous obligations: (1) keep samples available long enough to support re-testing, audits, and adverse-finding investigations; (2) free freezer, shelf, and cold-room capacity on a predictable cycle; and (3) ensure that disposal of biological, chemical, and reference material is documented, witnessed, and traceable back to the authorising signature.

1.2 Scope

This document covers all sample material accessioned into the laboratory information management system (LIMS) under an Nexa sample ID, across the following repositories:

- **Clinical Testing** – patient specimens received for diagnostic assays (blood, serum, plasma, urine, tissue, swabs).
- **Biobank** – consented research specimens held under IRB protocol NX-IRB-118 for longitudinal studies.
- **R&D Chemistry** – reference standards, stability samples, and analytical method development material.
- **Environmental Monitoring** – water, air-particulate, and surface swab samples collected under the facility's environmental monitoring programme.

It does not cover primary reagents, calibrators, or QC material governed by *QMS-LAB-007 Reagent and Consumable Control*, nor electronic-only data retention, which is addressed in *QMS-IT-022 Records and Data Retention Policy*.

1.3 Regulatory Basis

Retention periods in Section 3 are set to the *longest* of the applicable regulatory, accreditation, and contractual minimums. Where two clauses conflict, the more conservative figure governs unless Quality Assurance documents a rationale for departure.

Governing References

- ISO 15189:2022 Clause 5.5.9 – retention of examined samples where re-examination may be needed.
- CLIA 42 CFR §493.1105 – record and specimen retention requirements for clinical laboratories.
- OECD Principles of Good Laboratory Practice (GLP), Section II.6 – retention of raw data, specimens, and reserve samples.
- Institutional Biosafety Committee (IBC) Charter, Art. 9 – disposal of biohazardous and consented human material.
- Sponsor contracts (R&D Chemistry) – retention terms per individual study agreement, recorded in LIMS field `contract_retention_override`.

2 Definitions and Sample Classes

2.1 Terms

Term	Definition
Retention clock start	The date on which the retention period begins counting, typically final result release, study closeout, or last amendment date.
Retention period	The minimum time a sample must remain in storage before it becomes eligible for disposal.
Disposal eligibility	The status assigned in LIMS once the retention period has elapsed and no legal hold or open investigation applies.
Legal hold	A flag preventing disposal of an otherwise eligible sample, placed by Quality Assurance, Legal, or the sponsor pending litigation, audit, or complaint investigation.
Witnessed disposal	Destruction performed with a second qualified staff member present who co-signs the disposal record in Section 5.
Chain of custody	The unbroken, dated record of everyone who accessed, moved, or acted on a sample from accession through disposal.

2.2 Sample Classes

Every sample accessioned into LIMS is assigned exactly one of the six classes below at intake; the class field is locked once testing begins and can only be changed by Quality Assurance with a documented reason.

Class A – Clinical Diagnostic

Patient blood, serum, plasma, urine, and tissue submitted for a reportable diagnostic result.

Class B – Biobank Consented

Research specimens held under active IRB consent for longitudinal or future-use studies.

Class C – Reference Standard

Certified reference material and calibration standards used across multiple studies.

Class D – Stability / R&D

Method development and stability-programme pulls tied to a sponsor study number.

Class E – Environmental

Water, air-particulate, and surface swabs from the facility monitoring programme.

Class F – Restricted / Hold

Any sample under legal hold, active complaint investigation, or sponsor audit – disposal suspended regardless of elapsed time.

3 Retention Matrix

3.1 Master Schedule by Sample Class

The table below is the controlled reference: LIMS disposal-eligibility flags are generated from these values nightly. Storage conditions describe the required state during the retention window, not the state at accession.

Sample class	Regulatory basis	Retention period	Storage condition	Clock start
A – Whole blood / serum (routine chemistry)	CLIA §493.1105(a)	7 days	2–8°C refrigerated	Result release
A – Whole blood / serum (immunology, send-out confirmatory)	CLIA §493.1105(a); ISO 15189 5.5.9	14 days	2–8°C refrigerated	Result release
A – Plasma (coagulation panel)	CLIA §493.1105(a)	7 days	−20°C frozen	Result release
A – Urine (routine urinalysis)	CLIA §493.1105(a)	24 hours	2–8°C refrigerated	Receipt
A – Tissue (histopathology block)	CAP Checklist ANP.12250; ISO 15189 5.5.9	10 years	Ambient, archival cabinet	Report sign-out
A – Tissue (histopathology slide)	CAP Checklist ANP.12250	10 years	Ambient, archival cabinet	Report sign-out
A – Positive microbiology culture	CLIA §493.1105(a)	7 days	35–37°C incubated, then discard	Final identification
B – Biobank plasma / DNA aliquot	IBC Charter Art. 9; IRB protocol NX-IRB-118	Duration of consent, max. 15 years	−80°C ultra-low freezer	Consent effective date
B – Biobank tissue block (research)	IBC Charter Art. 9	Duration of consent, max. 15 years	Ambient, archival cabinet	Consent effective date
C – Certified reference material (in-use vial)	ISO 17034; GLP OECD II.6	Manufacturer expiry or 5 years, whichever is sooner	Per certificate of analysis	Vial opening date
C – Reference standard reserve sample	GLP OECD II.6	5 years post study closeout	−20°C frozen, desiccated	Study closeout
D – Stability programme pull	Sponsor contract; GLP OECD II.6	Per study protocol, min. 2 years	As specified in stability protocol	Study closeout
D – Method development sample	Sponsor contract	1 year post final report	2–8°C refrigerated	Final report issue
E – Environmental water sample	EPA 40 CFR 141; internal EM programme SOP	90 days	2–8 °C refrigerated	Collection date
E – Environmental surface / air swab	Internal EM programme SOP	30 days	Ambient, sealed	Collection date
F – Any class under legal hold	Legal / Quality Assurance directive	Indefinite, until hold released	As per original class	Hold placement date

3.2 Reading the Matrix

- **Regulatory basis** lists every clause that constrains the period; where more than one applies, the period shown already reflects the longer of the two.
- **Clock start** is the LIMS-tracked timestamp, not the collection date, except where explicitly noted (environmental samples run from collection).
- A sample straddling two classes (e.g. a biobank specimen also used for a clinical confirmatory test) is retained under whichever class yields the longer period, and both class tags remain visible in LIMS.
- Class F overrides every other row for the duration of the hold; on release, the sample reverts to its original class and the clock resumes from the original start date, not the release date.

Common Deviation

The most frequent nonconformance found at internal audit is a Class A histopathology block discarded from a satellite storage cabinet before the 10-year mark because the local log used receipt date instead of report sign-out date as the clock start. Cabinet custodians must use the LIMS-generated eligibility date, never a manually calculated one.

4 Disposal Methods

4.1 Approved Disposal Routes

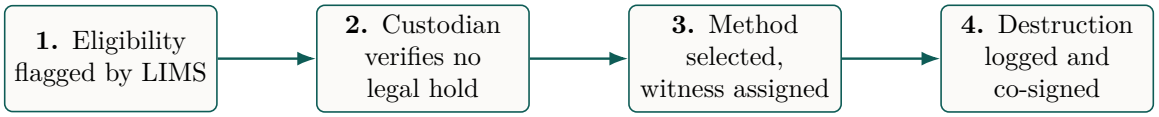
Disposal method is determined by material type, not by sample class alone – a Class A tissue block and a Class E water sample may both require autoclaving if bloodborne pathogens are suspected. Table 2 lists the routes approved for use at Nexa Diagnostics Laboratory.

Method	Applicable material	Vendor / route
Autoclave then landfill	Biohazardous solids: blood tubes, swabs, culture plates, used PPE	On-site autoclave, Unit 3
Medical waste incineration	Tissue blocks, slides beyond archival hold, pathological waste	Meridian Environmental Services (licensed carrier)
Chemical neutralisation	Reagent-contaminated stability and reference samples	On-site neutralisation bench, SOP QMS-CHEM-009
Sanitary sewer (treated)	Non-hazardous aqueous samples cleared by EHS	On-site, EHS sign-off required per batch
Secure shred / pulp	Paper chain-of-custody forms superseded by scanned record	On-site cross-cut shredder
Return to sponsor	Reference standards and stability samples where the sponsor contract requires return rather than destruction	Sponsor-nominated courier

Table 2: Approved disposal methods and routing.

4.2 Disposal Workflow

Every disposal follows the same four-step gate regardless of method; no sample leaves storage for destruction without all four steps recorded in LIMS.



4.3 Step Detail

1. **Eligibility flagged.** LIMS runs the nightly retention job against Section 3 and marks samples past their retention period as *disposal-eligible*. No manual flagging is permitted.
2. **Hold check.** The storage custodian queries the Legal Hold register before pulling any eligible sample. A sample under Class F is skipped and remains in place.
3. **Method and witness.** The custodian selects the method from Table 2 and books a second qualified staff member as witness; self-witnessed disposal is not accepted for Class A or Class B material.
4. **Record and co-sign.** Both parties complete the disposal record in Section 5, including sample ID, method, date, and quantity, then co-sign. The record is scanned into LIMS within 24 hours; the physical form is retained per Section 3's Class A record-retention line.

Batch Disposal

Environmental (Class E) samples may be disposed of in batches of up to 40 using a single disposal record listing all sample IDs, provided every sample in the batch shares the same method, date, and witness pair. All other classes require one record per sample.

5 Authorisation Record

5.1 Disposal Authorisation Log

Completed records are transcribed into LIMS; the extract below shows the required fields and a representative entry from the most recent quarterly batch.

Sample ID	Class	Method	Custodian	Witness	Date / sign-off
NX-CT-88213	A	Autoclave	R. Okafor	S. Bianchi	14 Jul 2026 ✓
NX-CT-88214	A	Autoclave	R. Okafor	S. Bianchi	14 Jul 2026 ✓
NX-BB-04471	B	Incineration	M. Haddad	L. Tran	22 Jul 2026 ✓
NX-EM-11029–068 (batch of 34)	E	Sanitary sewer	S. Bianchi	R. Okafor	29 Jul 2026 ✓
NX-RD-02290	D	Return to sponsor	L. Tran	– (courier receipt attached)	01 Aug 2026 ✓

5.2 Signature Block

The authorisation below applies to the disposal batch referenced in the log above and any subsequent batch executed under this version of the schedule.

Prepared by	Reviewed by	Approved by
Sofia Bianchi	Rahul Okafor	Elena Marchetti
Storage Operations Lead	Quality Systems Reviewer	Quality Assurance Manager
Date: _____	Date: _____	Date: _____

Escalation

Any disposal-eligible sample belonging to a study under active sponsor audit, or any Class A specimen tied to an open patient complaint, must be escalated to the Quality Assurance Manager *before* the custodian step in Section 4.2 – not deferred to the witness step. Escalations are logged in LIMS under incident type `RETENTION_HOLD_REQUEST`.

6 Revision History

Version	Date	Change	Author
1.0	03 Mar 2023	Initial release, Class A and Class C only.	E. Marchetti
2.0	19 Sep 2024	Added Class B (biobank) and Class E (environmental); introduced legal hold (Class F).	E. Marchetti
2.1	08 Jan 2025	Clarified clock-start rule for histopathology after external audit finding; see §3.2 warning.	R. Okafor
3.0	12 Sep 2025	Split Class D from Class C; added batch disposal provision for environmental samples.	S. Bianchi
3.1	12 Feb 2026	Updated CLIA citation formatting; added return-to-sponsor disposal route.	R. Okafor
3.2	04 Aug 2026	Added escalation pathway for samples under active sponsor audit or patient complaint (§5.2). Current version.	E. Marchetti

Next Review

Scheduled for 04 August 2026 + 24 months. Earlier review is triggered automatically by any change to CLIA §493.1105, ISO 15189 Clause 5.5.9, or the IBC Charter.