Standard Operating Procedure

Reagent Handling, Labeling & Cold-Chain Storage Control

Document No.	Revision	Effective Date	Review Cycle
SOP-QC-014	4.0	15 June 2026	24 months
Department	**Site**	**Owner**	**Status**
Quality Assurance	Nexa Biosciences – Meridian Campus	L. Fontaine, QA Manager	✔ Approved for Use

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1 Purpose and Scope

1.1 Purpose

This Standard Operating Procedure (SOP) defines the controlled process for receiving, labeling, storing, and monitoring laboratory reagents at Nexa Biosciences, including temperature-sensitive and light-sensitive materials. The objective is to prevent reagent degradation, cross-contamination, and traceability gaps that could invalidate downstream analytical or cell-based assay results.

1.2 Scope

This procedure applies to all reagents, buffers, standards, and consumable chemical stocks received into the Meridian Campus wet-lab suites (Rooms 2A, 2B, and 3C), including:

- Commercially sourced reagents requiring 2–8 °C, -20 °C, or -80 °C storage.
- In-house prepared buffers and working solutions assigned an internal lot number.
- Reference standards used for analytical method qualification and QC release testing.

This SOP does **not** cover controlled substances (see SOP-QC-021, *Controlled Substance Custody*) or biological samples under chain-of-custody (see SOP-QC-009).

1.3 Regulatory Basis

This procedure is written to satisfy the storage-and-handling expectations of ISO/IEC 17025:2017 §6.4 and the internal Nexa Quality Manual QM-01, and is cross-referenced during annual internal audits [1].

> Deviations from any numbered step in Section 4 must be logged per SOP-QC-002 (*Deviation and CAPA Reporting*) before the affected reagent lot is released for use.

2 Roles and Responsibilities

Role	Responsibility
Laboratory Technician	Executes receiving, labeling, and storage steps; records lot data in the reagent log within 1 hour of receipt.
Laboratory Supervisor	Verifies weekly cold-chain logs; co-signs storage-excursion investigations; approves reagent disposal requests.
QA Reviewer	Audits reagent log entries monthly; confirms this SOP is followed during internal inspections; initiates CAPA for repeat deviations.
Document Control Officer	Maintains the master copy of this SOP; distributes controlled revisions; retires superseded versions per Section 6.

3 Materials and Equipment

Item	ID / Model	Function
Calibrated refrigerator (2–8 °C)	COLD-04	Short-term reagent storage
Chest freezer (-20 °C)	FRZ-11	Working-stock storage
Ultra-low freezer (-80 °C)	ULT-02	Long-term standard storage
Continuous temperature logger	LOG-TEMP-06	15-min interval monitoring, alarms to QA
Barcode label printer	PRN-BC-3	Internal lot-number labeling
Reagent Receiving Log (Form QF-014-A)	–	Chain-of-custody record on receipt

Never place a reagent into ULT-02 without confirming the logger battery indicator reads green. A dead logger battery was the root cause of a 6-hour undetected excursion in deviation DEV-2025-118.

4 Procedure

4.1 Receiving and Inspection

Step 1

Confirm the shipment matches the packing slip: catalog number, lot number, quantity, and expiration date. Reject and quarantine any shipment with a damaged cold-pack or a temperature-indicator strip showing excursion.

Step 2

Record the reagent name, supplier lot number, receipt date, and assigned internal lot number (format `NXB-YYYY-####`) in Form QF-014-A within 1 hour of receipt.

Step 3

Print and affix an internal barcode label to every individual container. The label must include the internal lot number, receipt date, and assigned storage condition.

4.2 Storage Assignment

Step 4

Consult the Safety Data Sheet (SDS) storage recommendation and assign the reagent to COLD-04, FRZ-11, or ULT-02 accordingly. Light-sensitive reagents are additionally wrapped in amber sleeves before placement.

Step 5

Place the reagent in the shelf position designated for its category on the storage map posted inside each unit door. First-in-first-out (FIFO) rotation applies within each category.

4.3 Ongoing Monitoring

Step 6

Verify the continuous logger reading against the unit's independent thermometer at the start of each shift and initial Form QF-014-B. Investigate any deviation of more than 2 °C from setpoint immediately.

Step 7

Review the weekly logger export every Monday. Flag any excursion event exceeding 30 minutes to the Laboratory Supervisor for disposition of the affected lots.

A confirmed excursion of more than 2 hours at 2–8 °C, or any duration above -65 °C for ULT-02 contents, requires immediate quarantine of the affected lot and notification of the QA Reviewer before any further use.

5 Quality Control and Deviation Handling

5.1 Acceptance Criteria

- Storage unit temperature remains within the validated range at every twice-daily check, with no unexplained gap greater than 8 hours between logged readings.
- 100% of received containers carry a legible internal barcode label before first use.

- Monthly QA audit finds zero reagents past expiration still present in active storage.

5.2 Deviation Response

Any step in Section 4 that cannot be completed as written (e.g., logger malfunction, mislabeled shipment, unit door left ajar) is a deviation and must be recorded per SOP-QC-002 within 24 hours. The table below summarizes disposition by severity.

Severity	Example	Disposition
Minor	Label printed but placement delayed >1h	Correct and note in log; no lot impact.
Major	Excursion 30 min–2h within 2–8 °C range	Supervisor reviews stability data before release.
Critical	Excursion >2h, or any ULT-02 door-open alarm >15 min	Quarantine lot; QA-led CAPA per SOP-QC-002.

6 Revision History and Approval

6.1 Revision History

Rev.	Date	Description of Change	Author
1.0	2022-03-11	Initial release.	R. Okafor
2.0	2023-07-19	Added ULT-02 procedure; introduced Form QF-014-B.	R. Okafor
3.0	2024-11-04	Revised excursion thresholds after DEV-2024-071 CAPA.	L. Fontaine
4.0	2026-06-15	Added critical-severity quarantine trigger; clarified FIFO rotation mapping.	L. Fontaine

6.2 Approval Signatures

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Next scheduled review: **15 June 2028**. Direct questions regarding this SOP to the Document Control Office at `qms@nexabiosciences.example`.

References

[1] International Organization for Standardization. ISO/IEC 17025:2017 – General requirements for the competence of testing and calibration laboratories. Technical report, International Organization for Standardization, Geneva, Switzerland, 2017.