



Something Went Wrong?

Report it the same shift. Contain it now. Then fix the cause so it cannot happen again.

INFOGRAPHIC IG-07
Source: LAB-QM-010 · LAB-QM-011
Version V0 — DRAFT

REPORTING IS SAFE (§5.1): occurrence reporting exists to find system weaknesses, not to punish. Staff who report genuine errors, faults, or near-misses **SHALL NOT FACE DISCIPLINARY RETALIATION**. Willful misconduct is handled separately under LAB-QM-006 — it never blocks a report.

1 · CLASSIFY IT — QM-010 §5.2

MINOR

No impact on patient safety, result accuracy, or compliance — e.g. a minor delay caught before any clinical impact; a transient, non-systemic error.

MAJOR

Actual — or high-risk potential — impact on patient care, diagnosis, result integrity, or staff safety: an erroneous report issued, a mislabeled specimen tested, a critical value not notified.

SENTINEL EVENT

Death, permanent harm, or severe temporary harm. **Escalate immediately** to the Hospital Director and Pathologist for hospital-wide review (§5.5).

2 · REPORT & CONTAIN — §5.3–§5.4

- Report on **F-QM-010-A-V0** as soon as possible **during the same shift — no later than 24 hours** after discovery.
- Active risk to a patient, or a wrong result already released? **Phone the CMT/LQM or attending physician immediately.**
- **Halt** affected testing; **quarantine** suspect analyzers, reagents, or supplies.
- **Withhold or recall** questionable results; if a wrong result was released, issue an **amended report**.
- Sharps injury or exposure? **Immediate medical evaluation and prophylaxis.**
- Log the occurrence in the **master log** of F-QM-010-A-V0.

DEVIATIONS (§5.6): a planned deviation needs a written justification in advance and the **PATHOLOGIST'S WRITTEN AUTHORIZATION** — valid for one batch/event only. An emergency deviation is documented and submitted to the Pathologist **WITHIN 24 HOURS**.

3 · WHAT HAPPENS NEXT — §5.5 + QM-011

- **Minor, isolated, corrected on the spot** → closed locally in F-QM-010-A-V0.
- **Major, recurring, or systemic** → formal **CAPA** on F-QM-011-A-V0, with root-cause analysis:
- **5 Whys** — straightforward, single-factor problems.
- **Fishbone** — complex/systemic: Personnel · Equipment · Materials · Methods · Measurement · Environment.
- Plans touching analytical procedure, interpretation, or patient safety need the **Pathologist's written approval**; budget/admin plans need the **Hospital Director's**.
- **Effectiveness is checked after 30–90 days** of monitoring. Not effective? The CAPA re-opens for deeper analysis.
- Occurrences are trended **monthly**; CAPAs are trend-reviewed **quarterly** (QM-011 §5.7).