



Score the Risk. Treat It in Order.

Every identified risk is scored, treated, and recorded in the Risk Register (F-QM-009-A-V0).

INFOGRAPHIC IG-10
Source: LAB-QM-009
Version V0 — DRAFT

THE MATRIX — §5.4 (SEVERITY × LIKELIHOOD)

	LOW LIKELIHOOD (RARE / UNLIKELY)	MEDIUM (POSSIBLE)	HIGH (PROBABLE / FREQUENT)
HIGH SEVERITY (CRITICAL / SEVERE)	Medium	High	Critical
MEDIUM SEVERITY (MODERATE IMPACT)	Low	Medium	High
LOW SEVERITY (MINOR / NEGLECTIBLE)	Low	Low	Medium

CRITICAL / HIGH — UNACCEPTABLE: immediate intervention, preventive barriers, and notification of the Pathologist and Hospital Director.

MEDIUM — TOLERABLE WITH ACTIVE CONTROLS: action plan required, with a defined monitoring frequency.

LOW — ACCEPTABLE: routine monitoring under standard operating procedures.

SIX RISK DOMAINS — §5.2

- 1 · Organizational & Governance** — staffing levels, competency gaps, delegation, resource constraints.
- 2 · Pre-Examination & Phlebotomy** — patient misidentification, labeling errors, hemolysis, uncentrifuged delays, transport problems.
- 3 · Analytical & Equipment** — analyzer breakdowns, expired reagents, calibration drift, water quality, IQC/EQA failures.
- 4 · Post-Analytical & LIS** — transcription errors, delayed critical-value reporting, amended reports.
- 5 · Biosafety & Environmental** — sharps injuries, spills, laboratory-acquired infections, chemical and electrical hazards, typhoon/flood disruption.
- 6 · External & Referral** — referral delays (Samar Provincial Hospital), specimen transit integrity, utility outages, supply-chain interruptions.

RE-ASSESS IMMEDIATELY WHEN (§5.3): new equipment or methods are commissioned · workflow, facility, or LIS changes · occurrence or near-miss trends · CAPA findings · audit nonconformities.

1 · Elimination

2 · Engineering controls

3 · Administrative controls

4 · PPE (last line)

TREAT IN THIS ORDER (§5.5): eliminate the hazard first; then engineering controls (e.g. biosafety cabinet, centrifuge safety buckets); then administrative controls (e.g. two-identifier verification, SOPs, dual verification); PPE is the last line. Each plan names a responsible person, steps, target date, and budget in F-QM-009-A-V0. After controls, **RE-SCORE:** if the residual risk is still unacceptable, add controls — or **SUSPEND THE ACTIVITY** until the Pathologist and Hospital Director authorize otherwise.