Elexes

18 EVIDENCE CHECKS

LDT Quality Readiness Checklist

Connect laboratory methods, quality records and change evidence.

Laboratory / assay: _____ Reviewer / date: _____

Tick when evidence is verified. Record your priority gap and next action below.

01 Define laboratory scope

- ☐ Record assay purpose, workflow and testing location.
- ☐ Confirm applicable laboratory and accreditation scope.
- ☐ Assign quality, technical and approval responsibilities.

02 Organize method evidence

- ☐ Index validation plans, results and review records.
- ☐ Link applicable performance criteria to evidence.
- ☐ Record gaps requiring qualified technical assessment.

03 Control the workflow

- ☐ Maintain specimen handling and acceptance procedures.
- ☐ Keep current methods and reporting procedures available.
- ☐ Retain relevant equipment and testing records.

04 Review quality controls

- ☐ Document control methods and acceptance criteria.
- ☐ Review applicable proficiency or alternative assessments.
- ☐ Record errors, corrective actions and follow-up.

05 Maintain personnel records

- ☐ Define roles, qualifications and assigned duties.
- ☐ Retain training and competency evidence as applicable.
- ☐ Keep director and authorized review records accessible.

06 Assess laboratory changes

- ☐ Record changes and affected methods or records.
- ☐ Define technical review and evidence-update needs.
- ☐ Retain approvals and implementation evidence.

Priority gap / evidence reference:

Action / owner / due date: