LABREFLEX™ AI GOVERNANCE & VALIDATION FRAMEWORK

CAP-Aligned Strategy Template for Clinical Laboratories

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Created by: LabReflex Podcast

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1. PURPOSE & SCOPE

Artificial Intelligence (AI), Machine Learning (ML), and algorithmic decision-support tools are increasingly embedded in laboratory instruments, middleware, and LIS applications. Most laboratories lack a formal governance and validation framework, despite regulatory expectations.

This document provides:

- A **5-Step AI Governance Strategy**, aligned with CAP principles
- Tools for **AI inventory, validation, monitoring, and documentation**
- **Copy/paste-ready templates** for immediate implementation

Applies to all clinical and anatomical labs.

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2. DEFINITIONS

AI / Artificial Intelligence: Algorithms assisting or automating lab functions.

High-Risk AI: Influences diagnostic results or autoverification.

Medium-Risk AI: Supports workflow/QC but does not release final results.

Low-Risk AI: Administrative automation.

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3. LABREFLEX™ 5-STEP AI GOVERNANCE STRATEGY

(CAP-Aligned)

STEP 1 — AI INVENTORY & DISCOVERY

3.1.1 List all AI tools in the lab

- ☐ Analyzer-embedded algorithms
- ☐ Digital pathology tools
- ☐ Middleware decision rules
- ☐ LIS interpretive algorithms
- ☐ Predictive analytics models
- ☐ Dictation/transcription AI
- ☐ Research/pilot tools

3.1.2 AI Inventory Table

Tool Name	Vendor	Version	Intended Use	Data Used	Risk Level	Owner	Notes
					Low/Med/High		

STEP 2 — RISK ASSESSMENT & PRIORITIZATION

3.2.1 Risk Scoring Criteria (Score 1–5)

- **Patient Safety Impact**
- **Transparency**
- **Validation Difficulty**
- **Bias Potential**
- **Clinical Dependence**

3.2.2 Risk Matrix

Tool	Safety	Transparency	Validation	Bias	Dependence	Total Score	Tier
							High/Med/Low

STEP 3 — VALIDATION OF AI TOOLS

3.3.1 Required Validation Elements

- Intended use
- Performance metrics (AUROC, accuracy, precision, recall)
- Method comparison (human vs AI)
- Error analysis
- Bias assessment

- Human-in-the-loop review rules
- Drift monitoring plan

3.3.2 Validation Template

AI System Name:
Version:
Validated By:
Dates:
Intended Use:
Performance Summary:
Drift Watch Items:
Approval:

STEP 4 — CONTINUOUS MONITORING & DRIFT DETECTION

3.4.1 Monitoring Requirements

- Monthly QC review
- Quarterly drift reports
- Vendor update tracking
- Override frequency monitoring
- Anomaly detection

3.4.2 Monitoring Log Template

Date	Version	Issue	Action Taken	Reviewer	Notes

STEP 5 — LABORATORY AI SAFETY & VALIDATION POLICY

(Copy/paste as official policy)

Policy Number:
Effective Date:
Approved By: Laboratory Director

Purpose

Ensure all AI-enabled tools meet CAP, CLIA, and local requirements.

Policy

1. All AI tools must be inventoried annually.
2. Medium/high-risk AI tools require formal validation.

3. Validation must include performance, bias, and drift.
4. Human-in-the-loop review is required for high-risk tools.
5. Monthly monitoring and documentation are mandatory.
6. Vendor updates must trigger re-evaluation.
7. Annual staff competency on AI tools is required.

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4. VENDOR AI DISCLOSURE FORM

Vendor:
Product:
Algorithm Type:
Version:
Training Data Source:
Limitations:
Bias Mitigation Strategy:
Update Frequency:
Regulatory Status:

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5. AI IMPLEMENTATION CHECKLIST

Before Go-Live

- ☐ Risk ranking completed
- ☐ Validation complete
- ☐ Staff trained
- ☐ LIS integration tested
- ☐ Override pathways defined

During Go-Live

- ☐ Shadow mode testing
- ☐ Daily QC checks
- ☐ Anomaly logs active

Post-Go-Live

- ☐ Monthly performance review
- ☐ Quarterly drift analysis
- ☐ Annual re-validation

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6. RISK TIERS

High Risk

- Bone marrow classifiers
- Urine culture prediction models
- Autoverification algorithms

Medium Risk

- QC anomaly detectors
- Middleware rule sets

Low Risk

- Scheduling AI
- Dictation/transcription

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7. CONTACT INFORMATION

For questions or implementation support:
LabReflex Podcast — contact your LabReflex representative.