



New Method? Verify First.

Method verification — no patient testing until the Pathologist approves (LAB-QM-ANA-003 Figure 1).

THE RULE: patient testing commences **ONLY AFTER THE PATHOLOGIST'S FORMAL APPROVAL**. If the claims are not reproduced, patient testing shall not commence — the method undergoes comprehensive validation.

1 · THE STUDIES

- Trigger: a **new, modified, or relocated** test method is proposed for clinical use.
- First, **define acceptance criteria** from the manufacturer's performance claims.
- **Repeatability** (within-run precision) and **between-day reproducibility**.
- **Accuracy** verified against a validated comparative method.
- **Linearity** verified across the analytical measurement range.
- Manufacturer **reference intervals verified** before adoption.

2 · THE DECISION

- Decision: **do the studies confirm the manufacturer's performance claims are reproduced?**
- Compile the comprehensive **Method Verification and Validation Report**.
- Prepare the **validation summary dossier** for Pathologist review and sign-off.

3 · APPROVAL — THEN PATIENTS

- The **Pathologist signs** the formal approval report.
- **Train staff and verify competency** on the new method.
- Only then does **patient testing commence**.

New / changed method



Set acceptance criteria



Precision · accuracy ·
linearity



Report + dossier



Pathologist signs →
testing starts