The truth about Third-party QC

Patient results drive 70% of clinical decisions, yet most QC failures are not caught by the controls that come in the reagent box. That gap is why accreditation bodies have moved from "suggesting" to expecting true third-party controls.

Why regulators now point to third-party QC

- **ISO 15189:2012, Section 5.6.2.2** states: *"Use of independent third-party control materials should be considered, either instead of, or in addition to, any control materials supplied by the reagent or instrument manufacturer."*
- **ISO 15189:2022, Section 7.3.7.2** requires you to select, accept, and manage QC materials based on stability, homogeneity and commutability, with risk analysis driving frequency and limits. The IFCC implementation guidance for 2022 specifically anchors these requirements in sections 7.3.7.2 and 6.6.
- **US CLIA – 42 CFR §493.1256** obliges every lab to have control procedures that monitor accuracy and precision of the complete analytic process, and when calibration material is used as a control, it must be from a different lot than the calibrator. This is the regulatory basis for independence from manufacturer materials.
- **EU IVDR Article 5(5)** – as of 26 May 2024, health-institution labs using laboratory-developed tests must have a QMS and demonstrate EN ISO 15189 compliance. EN ISO 15189:2022 is now referenced in the EU Official Journal, making independent QC part of the IVDR conformity pathway in Europe, including Greece under ESYD accreditation.

In short: you are not legally forced to buy a specific brand, but you are required to prove unbiased error detection — and auditors interpret that as third-party QC.

What manufacturer controls miss

First-party controls are often made from the same raw material as the calibrator, so they are optimized to pass on that system. Independent studies show the consequence:

- A 2014 PTH assay recall affected 19 labs in Lombardy, Italy. The manufacturer controls did not detect a 13-45% positive shift, risking up to 40,000 inaccurate results. The authors concluded the shift "could have been prevented by third-party control materials independent from the calibrator materials."

Similar cases for thyroglobulin and ALT have been documented where only third-party material flagged lot-to-lot bias or wash-step interference.

Introducing SERAQUAL 365 – built for the standard, not for the analyzer

SERAQUAL 365 was designed specifically to meet the independence criteria above:

- **True third-party matrix:** not designed or optimized for any single instrument, kit or method, so it mirrors patient samples and reveals reagent or system drift
- **365-day stability program:** long shelf life and lot continuity reduce crossover studies and support year-round trending
- **Clinical-range coverage:** multi-analyte levels placed at medical decision points, not just manufacturer ranges
- **SERAQUAL software:** daily Levey-Jennings, Westgard rules, peer-group comparison, measurement uncertainty tracking, and automatic documentation for ISO 15189 7.3.7 and CLIA §493.1256(g) records

Labs using SERAQUAL 365 report fewer false rejections, faster root-cause analysis during audits, and a single control set across chemistry, immunoassay and special proteins — which cuts inventory and training time.