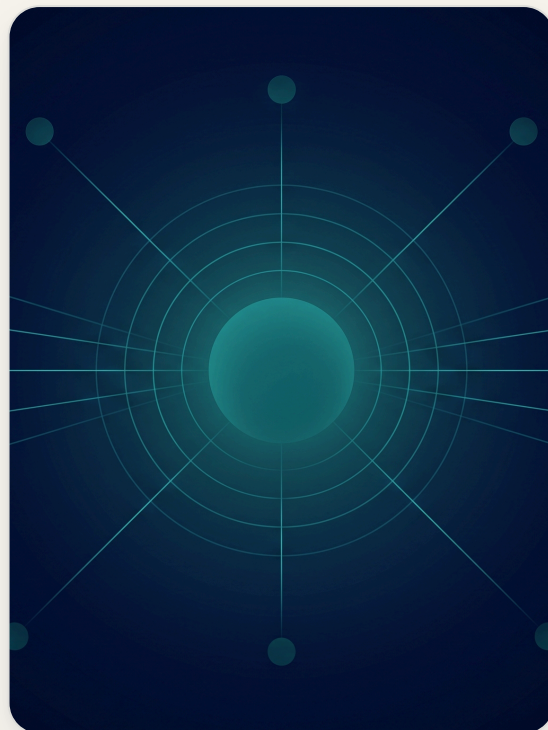


FOR PRIVATE, SPECIALTY & SATELLITE LABS

Lab-grade governance, *without the full LIS.*

Near-patient and decentralised testing has to meet ISO 15189-grade expectations: rule-checked QC, competent operators, method verification and an audit trail an assessor can follow. Standing up a full LIS to carry that governance is heavy, slow and priced for a hospital.

Catenix delivers the governance layer as cloud software: connectivity, Westgard QC, precision studies, CAPA, document control and a tamper-evident audit trail, live in days rather than a deployment project.



THE GOVERNANCE LAYER, ON ONE THREAD

01 CONNECT

Every analyser

An on-site gateway captures results automatically over HL7, POCT1-A2 and ASTM, with protocol support across around 51 device families. Forwarded onward to your LIS, EHR or FHIR when you want it.

02 ASSURE

QC that self-builds

Control runs are captured, kept separate from patient results, and rule-checked against Westgard multi-rules on Levey-Jennings charts. A lockout engine stops a device after failed QC.

03 VERIFY

Method verification

Precision and verification studies aligned with EP15, EP05 and EP09 approaches, built from your wired QC data, producing a print-ready validation report.

04 PROVE

Evidence, ready

CAPA register, document control with per-site sign-off, and a tamper-evident audit trail. The evidence an assessor asks for already exists.

ISO 15189

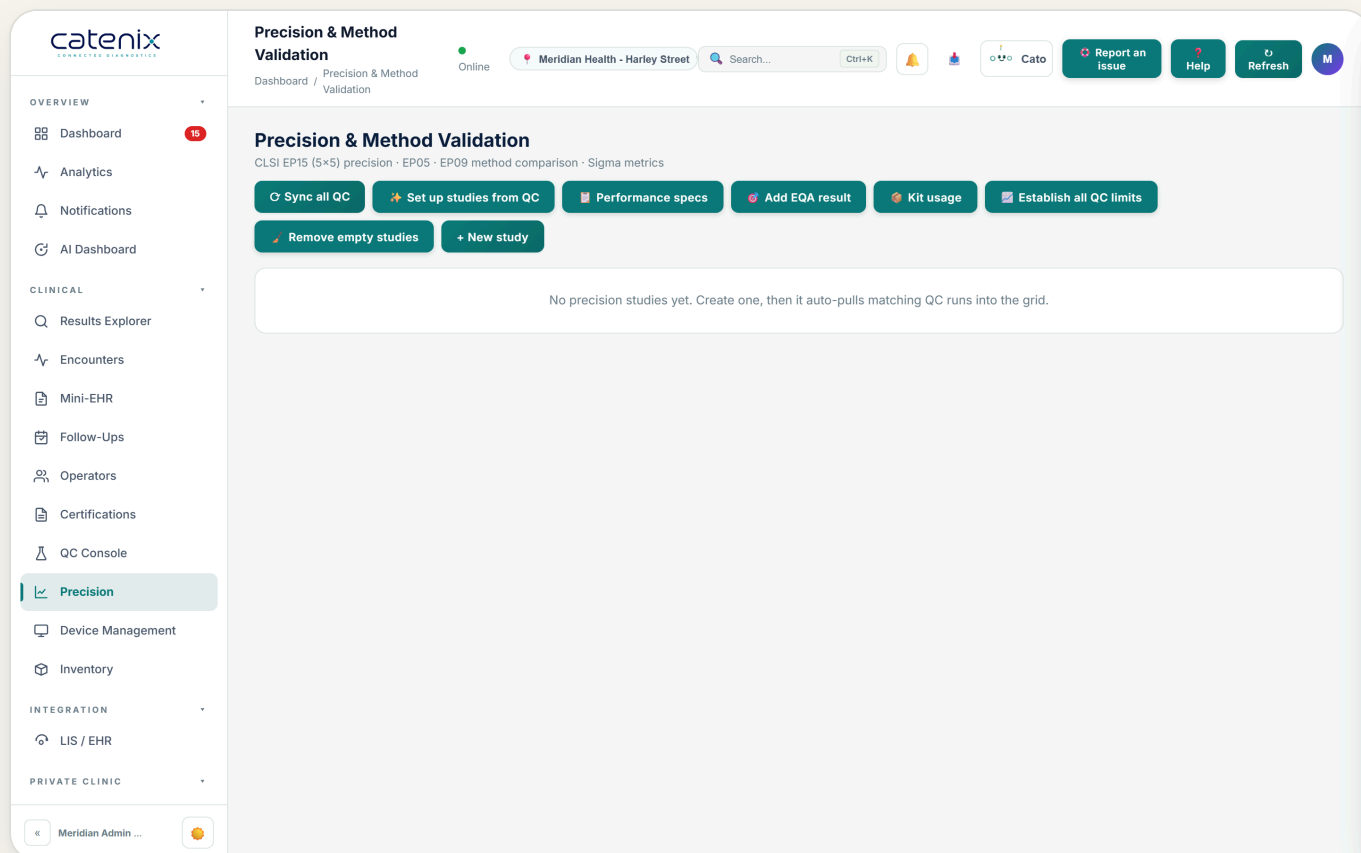
Days, not quarters

1 record

Catenix does not interpret clinical results and provides no clinical decision support. Interpretation, validation and authorisation stay with your clinicians, exactly where accreditation expects them.

CATENIX.COM

Verification studies, built from *your wired data*.



Precision and method-verification studies aligned with EP15, EP05 and EP09 approaches, producing a print-ready validation report from the QC data your analysers already send.

- Westgard multi-rules on Levey-Jennings**
 Control runs are rule-checked against Westgard multi-rules on Levey-Jennings charts with a CUSUM overlay. QC is kept separate from patient results.
- CAPA register, auditor-ready**
 ISO 15189-aligned quality workflows: log corrective and preventive actions and keep an auditor-ready CAPA register in the same system that caught the issue.
- Tamper-evident audit and QC receipts**
 Every login, edit, review and release is recorded against the authenticated actor. QC receipts are tamper-evident and independently verifiable offline: no login, no trust in us required.
- Precision and verification studio**
 Precision and method-verification studies aligned with EP15, EP05 and EP09 approaches, producing a print-ready validation report.
- Document control with per-site sign-off**
 SOP version control with per-site sign-off tracking, so each satellite site reads and acknowledges the current version.
- Analyte and test library**
 A managed analyte and test library keeps units, reference ranges and codes consistent across every site and every analyser.

ALSO ON THE SAME THREAD

OPERATOR COMPETENCY

LOCKOUT ENGINE

MULTI-SITE NETWORK

HL7 • POCT1-A2 • ASTM

FHIR R4 ONWARD

SIGNED VALIDATION REPORTS

Operator competency populates itself from analyser telemetry where devices transmit operator identity, with live expiry alerts and a cover matrix. Data is encrypted in transit and at rest, with database-enforced tenant isolation on a least-privilege app account: defence in depth.

Book a walkthrough of the quality and verification tooling.

Bring your analyser list and your QC targets. We will show a verification study and an audit trail building themselves, live, in a 30-minute walkthrough.

Book a demo
→

catenix.com/contact

Catenix provides ISO 15189-aligned quality workflows; it does not make a lab accredited or certified. Product and company names mentioned are the trademarks of their respective owners; reference is for identification only.

CONTACT@CATENIX.COM