FOR CLINIC TEAMS · PRINT AND USE TODAY

POCT connectivity and quality readiness, checklist-ready.

A practical, vendor-neutral checklist for any clinic preparing for inspection or a connectivity project. Work through the six sections, tick what you can already evidence, and you will see exactly where the gaps are before an assessor does.

6
SECTIONS, FROM DEVICES TO GOVERNANCE

1
LINE OF EVIDENCE BESIDE EVERY ITEM

Use anywhere
USEFUL WITH OR WITHOUT A PLATFORM

How to use this: print it, or work through it as a team. Each item names the evidence an assessor tends to ask for. If you can point to that evidence today, tick the box. If you cannot, you have found a task worth doing before your next inspection or go-live.

Devices, quality and the people who run them.

Sections one to three cover where results come from, how you prove those results are sound, and how you show the person who produced them was competent to do so.

01 Devices & connectivity

Every analyser accounted for, and every result reaching the record the same way each time.

- [ ] **A live inventory of every analyser**
  You know each device, its site, its firmware and who owns it. A missing device is a missing audit trail. `EVIDENCE: device register with make, model, serial, location and service dates.`

- [ ] **Results reach the record without re-keying**
  Values move from analyser to record by connection, not by hand. Manual entry is where a digit gets transposed. `EVIDENCE: interface configuration, or a documented and controlled manual-entry procedure.`

- [ ] **Every result is traceable to its device and run**
  Any result can be traced back to the instrument, operator and timestamp that produced it. `EVIDENCE: result records carrying device ID, operator ID and date-time.`

- [ ] **Interfaces and mappings are documented**
  The way each device talks to your systems is written down, including units and reference ranges, so nothing depends on one person's memory. `EVIDENCE: interface specification and unit/reference-range mapping table.`

- [ ] **A plan for when a connection drops**
  You know what happens to a result if the link is down, and how it is reconciled once restored. `EVIDENCE: downtime and reconciliation procedure with a recovery owner.`

02 Quality control & Westgard

Controls run to a schedule, evaluated against defined rules, kept separate from patient results.

- [ ] **QC runs to a defined schedule and range**
  Each test has documented control levels, frequency, and target means and limits, not a schedule that lives in someone's head. `EVIDENCE: QC schedule and target/limit table per analyte.`

- [ ] **QC is charted and rule-checked**
  Controls are plotted on Levey-Jennings charts and evaluated against defined multi-rules, so a shift or trend is caught early. `EVIDENCE: Levey-Jennings charts with Westgard multi-rule flags.`

- [ ] **A failed control stops patient testing**
  When QC fails, testing pauses until the cause is resolved, rather than results being released while a control is out. `EVIDENCE: lockout or hold procedure, with QC-failure events and their resolution.`

- [ ] **QC records are kept separate from patient results**
  Control data is clearly distinct from patient data, so QC can be reviewed as its own evidence stream. `EVIDENCE: QC log or dataset held apart from the patient record.`

- [ ] **External quality assessment is enrolled and reviewed**
  Where a scheme exists for your tests, you take part and act on the returns. `EVIDENCE: EQA enrolment, recent reports, and documented actions on outliers.`

03 Operator competency

Only trained, in-date operators test, and you can prove it for any name on any date.

- [ ] **Every operator is trained and signed off**
  Each person who tests has documented training and an initial competency sign-off before they run patients. EVIDENCE: training records and initial competency assessments.

- [ ] **Competency is reassessed on a cycle**
  Sign-off is not once and forever: competency is refreshed on a defined schedule with live expiry visibility. EVIDENCE: reassessment schedule and current expiry dates per operator.

- [ ] **You can show who was competent on a given day**
  For any past date, you can name who was authorised to run each test. Inspections often ask exactly this. EVIDENCE: a competency matrix mapping operators to tests over time.

Records, reporting and the governance around it.

Sections four to six cover what you can evidence after the fact, how results leave the building, and the standing documents that hold the whole service together.

04 Audit & records

A durable, attributable record of who did what, that survives scrutiny after the event.

- [ ] **Every action is attributable to a named user**
  Logins, edits, reviews and releases are tied to the authenticated person who made them, not a shared account. `EVIDENCE: access log and per-user activity trail.`

- [ ] **Records cannot be silently altered**
  Changes are versioned or otherwise tamper-evident, so an edit after the fact is visible rather than hidden. `EVIDENCE: change history, version records, or a tamper-evident audit trail.`

- [ ] **Retention and disposal are defined**
  You know how long each record type is kept and how it is disposed of, in line with your obligations. `EVIDENCE: retention schedule by record type, and disposal log.`

- [ ] **You can produce evidence on request, quickly**
  When an assessor or complaint asks for a specific record, you can retrieve it without a folder hunt. `EVIDENCE: a retrieval that returns the record, its QC context and its audit trail together.`

05 Reporting & delivery

Nothing leaves the building until a clinician has reviewed it, and every report is complete.

- [ ] **A clinician reviews and signs before release**
  No result reaches a patient or referrer until a clinician has reviewed and authorised it. `EVIDENCE: a mandatory review-and-sign step recorded before each release.`

- [ ] **Reports are complete and consistently formatted**
  Reports carry patient identity, result, units, reference ranges and the authoriser, every time. `EVIDENCE: a report template and a completeness check before send.`

- [ ] **Delivery is tracked and secure**
  You can show a report was sent, to whom, and by a secure route appropriate to the content. `EVIDENCE: delivery log with recipient, channel and timestamp.`

- [ ] **Critical and abnormal results have a pathway**
  There is a defined route for flagging results that need urgent clinician attention, so nothing sits unseen. `EVIDENCE: escalation procedure and a record of critical-result handling.`

06 Governance: SOPs, CAPA, GDPR

The standing documents and duties that hold the service together between inspections.

- [ ] **SOPs are current, versioned and signed off**
  Each procedure has an owner, a version and a review date, and staff can find the current one. `EVIDENCE: SOP register with versions, owners and per-site sign-off.`

- [ ] **Issues become logged, tracked actions**

Non-conformances and complaints are captured, actioned and closed, with the loop documented. EVIDENCE: a CAPA register showing issues from raised to resolved.

- [ ] **Data protection is documented and enforced**

  Personal data is handled under a defined policy with role-based access, encryption and a lawful basis. EVIDENCE: data-protection policy, access-control records and processing basis.

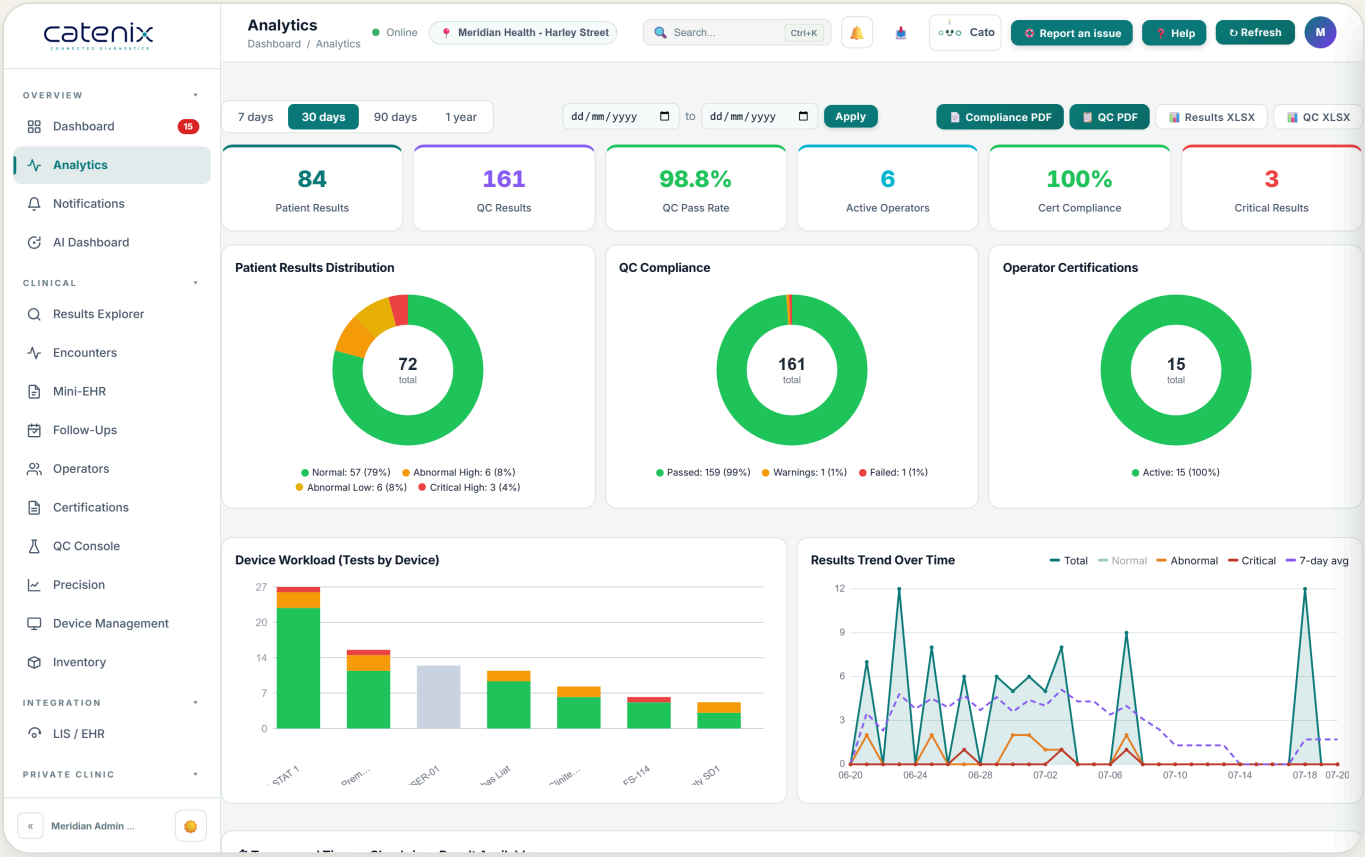
- [ ] **You can meet a data-subject request**

  There is a route to find, export or erase an individual's data within the required timeframe. EVIDENCE: a subject-access procedure and a recent completed request.

IF TICKING THOSE BOXES FELT LIKE WORK

How Catenix helps you tick these boxes, by design.

The checklist stands on its own. But most of what it asks for is evidence that has to be created and kept by hand: a spreadsheet of QC, a folder of competency records, a log of who signed what. Catenix connects every analyser to one audited record and builds that evidence as a by-product of running the clinic, so the answers already exist when someone asks.



One view of results, QC compliance, operator certification and turnaround, without a spreadsheet.

- **Devices and results, connected**
  A small on-site gateway captures results automatically over HL7, POCT1-A2 and ASTM, with protocol support across around 51 analyser families. Every result is traceable to device, operator and time.
- **Competency that populates itself**
  Operators are auto-discovered from device traffic where devices transmit operator ID, matched to certifications, with live expiry alerts and a who-can-cover-what matrix.
- **Review-and-sign before release**
- **QC evidence that builds itself**
  Controls are captured, kept separate from patient results, plotted on Levey-Jennings charts and checked against Westgard multi-rules, with a lockout after failed QC.
- **A tamper-evident audit trail**
  Every login, edit, review and report release is recorded against the authenticated actor, hash-chained and labelled to 21 CFR Part 11 and ISO 15189:2022 expectations.
- **Governance in the same system**

No report leaves the building until a clinician reviews and signs, and reports carry a signed completeness manifest for tamper-evidence.

SOP version control with per-site sign-off, an auditor-ready CAPA register, GDPR-aligned handling with role-based access, and a route for data-subject requests.

See your evidence build itself.

Bring your analyser list. We will show results landing in the record, QC charting itself, and the audit trail filling in, live, in a 30-minute walkthrough.

Book a demo →

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