LabSentra

Connecting Every Sample. Empowering Every Decision.

USER MANUAL

Quality Manager

Owners of the quality management system (ISO 15189): documents, nonconformities, CAPA, audits, EQA, QC review and competency.

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About this manual

This manual is for the **Quality Manager** role in LabSentra. It explains the screens you will use and the exact buttons to press, in the order you meet them in a working day.

Screens show only what your role is allowed to do. If a button described here is missing, your laboratory may have configured things differently – ask your administrator.

Your day at a glance

1. Review QC, lockouts and Sigma metrics
2. Manage nonconformities and CAPA to closure
3. Control documents and acknowledgements
4. Plan audits, track EQA and risks
5. Prepare the management review pack

Your menu

Menu group	Items you will see
Operations	Overview, Patients, Clinicians & clients, Orders, Samples, Worklists, Results & Verification
Output	Reports, Deliveries, Notifications
Workbenches	Haematology, Chemistry, Coagulation, Urinalysis, Immunology & Serology, Parasitology, Microbiology, Molecular, Histopathology, Cytology, Blood Bank
Analytics	Control Tower, Metric explorer, Benchmarks, Dashboards, Scheduled reports, Data exports, Anomalies, Forecasts, Benchmarking, Branches, Lab Twin
AI	AI Copilot
Quality	Quality dashboard, Documents, Nonconformities, Risk register, Audits, EQA, Competency & training, Environment, QC, Sigma metrics, Management review
Inventory	Movements & stock take
Equipment	Equipment register, Due list, Equipment KPIs
Settings	Administration, Test Catalogue, Integrations, Voice, Audit Log

Signing in for the first time

Your laboratory administrator invites you by e-mail. LabSentra never asks for your password by e-mail or phone.

1. Open the invitation e-mail and follow the link. You arrive at **Welcome to LabSentra**.
2. Enter your full name (optional), a **New password** of at least 12 characters, and **Confirm password**.
3. Select **Activate account**. If the page says the link is invalid or has expired, ask your administrator for a new invitation.

Everyday sign-in

1. Go to **labsentra.com** and choose **Sign in**.

2. Enter your e-mail and password and select **Sign in**. You land on your start page.

Forgotten password

1. On the sign-in page choose **Forgot password?**, enter your e-mail and select **Send reset link**.
2. Open the e-mail, choose **Set a new password**, enter it twice (at least 12 characters) and select **Update password**.

Two-step verification (required for your role)

Your role can sign or view sensitive clinical data, so LabSentra asks for a 6-digit code from an authenticator app (Google Authenticator, Microsoft Authenticator or similar) in addition to your password.

1. The first time, the **Two-step verification** screen shows a QR code. Scan it with your authenticator app (or use **Can't scan? Enter this key:**).
2. Type the 6-digit code from the app and select **Verify**.
3. On later sign-ins you are asked: **Enter the code from your authenticator app.**

> **Note.** You can check or change your authenticator under **Profile → Two-step verification**. The status shows **Verified (AAL2)** once you have entered a code in this session. If you lose your phone, ask your administrator to reset your access.

Finding your way around

Element	What it does
Sidebar	Groups of modules. You only see items your role is allowed to use (see "Your menu"). Long groups can be collapsed.
Branch selector	Choose **All branches** or one branch (shown as *code · name*). Lists, queues and dashboards follow this choice.
Organisation selector	Shown only if you work for more than one laboratory. Changing it resets the branch.
Go to… (Ctrl/Cmd + K)	Command palette: type a module name to jump straight to it.
Scan or type barcode / ID	Scan a specimen, order or patient barcode (or type the number) and press Enter to open it. "Not found" means no match in your branch.
Notifications bell	Unread count and the latest 8 alerts. Click one to open the record; **Mark shown as read** clears them.
Account menu	**Profile** and **Sign out**.

Your profile

- **Personal details** – full name, phone, professional title and registration number. Select **Save changes**. Your title appears beside your e-signature on reports.
- **Change password** – at least 12 characters.
- **My notifications** – mute or unmute categories you can receive (some safety-critical categories cannot be muted).
- **Two-step verification** – add or remove your authenticator.

> **Tip.** Sign out when you leave a shared workstation: Account menu → **Sign out**.

Signatures, reasons and statuses

LabSentra protects patient safety and the audit trail. Some actions need more than a click:

Marked in this manual	What happens on screen
(reason)	You must type why. The reason is stored in the audit trail.
(confirm)	A confirmation dialog asks you to check before continuing.
(e-signature)	The **Electronic signature** dialog asks you to re-enter your **Password** and choose **Sign**. It shows what you are signing and records it in the audit trail. A wrong password shows “Password incorrect”.

- Every change is recorded with who, when, what and why – it cannot be edited or deleted.
- Turnaround (TAT) chips: **red** = breached, **amber** = 30 minutes or less left, **green** = on time.
- Result flags: **H/L** outside the reference interval, **HH/LL** critical, **DELTA** big change from the last result, **AMR** outside the measuring range, **NO REF** no reference interval.
- Colour is never the only signal – every status also has a word or icon.

Quality control (QC)

Open **QC** (Quality). Tabs: Enter QC, Levey-Jennings, Lockouts, Materials, Lots, Targets, Westgard rules.

1. Run QC before patient samples and after calibration, maintenance or reagent lot change.
2. In **Enter QC**, pick the analyser, material and level, enter the value and select **Record QC** (Enter submits).
3. LabSentra applies the Westgard rules and shows **accepted**, **warning** or **rejected** with the z-score and any rule broken (1-3s, 2-2s, R-4s, 4-1s, 10x reject; 1-2s warns).
4. Check trends on the **Levey-Jennings** chart (mean, ±1/2/3 SD; green, amber, red points).

> **Important.** When QC is rejected and patient locking is on, the “QC rejected” dialog tells you patient results are locked. Bench cells show **QC locked** and verification is blocked until a reviewer releases the lockout.

Set-up (materials, lots, targets and rules) is under the other tabs: **New …** / **Create …** / **Save changes**. The option “Lock patient results when QC is rejected” is set per rule set.

Releasing a QC lockout

1. Open **Lockouts** and choose **Review & release**.
2. Describe the corrective action (at least 10 characters) – what was wrong and what you did.
3. Select **Sign & release** (e-signature). Consider whether patient results since the last good QC need re-testing.

Reports and deliveries

- **Reports** lists preliminary, final, amended and corrected reports. Open one to see every version and the PDF.

- Report PDFs carry a QR code so anyone can check authenticity at labsentra.com/verify.
- **Deliveries** tracks e-mail, SMS, portal and interface delivery: queued, sending, sent, delivered, acknowledged, failed, retrying, dead letter.

Quality management (ISO 15189)

Raising a nonconformity (everyone)

Choose **Raise NC** in the top bar (or Quality → Nonconformities) whenever something goes wrong: a complaint, error, near miss, equipment failure or unmet requirement. Describe what happened and its severity (low / medium / high / critical). Raising issues is expected and protects patients.

Reading controlled documents

When a procedure is issued or revised, the **Quality dashboard** lists it under pending acknowledgements. Open it, read it and choose **I have read and understood v{n}**.

Managing nonconformities and CAPA

1. Open the NC → investigate and **Save investigation** (root cause). **Draft root cause with AI** can suggest a starting point – review it before **Apply to investigation**.
2. **Add CAPA** for each corrective or preventive action, with owner and due date. Owners finish with **Complete** → **Mark complete**.
3. **Verify effectiveness** → **Sign & record** (e-signature; the verifier must differ from the owner).
4. **Close (sign)** → **Sign & close** (e-signature; needs a root cause and completed CAPAs). **Cancel NC** needs a reason.

Statuses: open → investigating → CAPA in progress → pending closure → closed (or cancelled).

Documents

Draft → **Submit for approval** → **Approve & sign** → **Sign & approve** (e-signature). You cannot approve your own document. **Reject** and **Retire** need a reason.

Audits, EQA, risks and review

- **Audits**: **Plan audit** → **Add finding** (can raise an NC) → **Move to {status}**: planned → in progress → report issued → closed. An audit cannot close while its NCs are open.
- **EQA**: **New scheme** → **New round** → **Submit results** → **Record evaluation**.
- **Risk register**: **New risk** scored as likelihood × severity; open / mitigating / accepted / closed.
- **Management review**: **Generate pack** collects KPIs, NCs, audits, EQA and risks for the review meeting; **Print / Save as PDF**.

Competency & training

Open **Competency & training**. Record an assessment with **Sign & record** (e-signature); add or edit training records. Status shows current, expiring or expired. Expired competency can block a person from entering or signing results for that test.

Analytics and AI

- **Overview** / **Control Tower**: live volumes, pending verification, TAT breached and at risk, criticals, by department and branch. Refreshes every 60 seconds; **Full screen** for a wall display.

- **Metric explorer**: pick a metric, filter, **View records**, **Export CSV** or **Save to dashboard**.
- **Dashboards**: **New dashboard** → **Add tile** → **Save layout**.
- **Scheduled reports**: **New schedule** sends a report automatically; **Run now** for an instant copy.
- **Forecasts** are statistical projections of volume; **Benchmarks** compare against targets; **Data exports** → **Download CSV**.
- **Anomalies**: unusual patterns in volumes, TAT or results. **Explain with AI**, then **Acknowledge**, **Re-open** or **Dismiss** (reason).
- **AI Copilot**: ask questions about your lab's operations in plain language and choose **Ask**.

> **Note.** All AI output is labelled “AI-generated — requires professional review”. Rate it **Helpful** / **Not helpful**; for commentary choose **Adopt** or **Reject** (reason). AI never releases results.

Lab Twin simulates staffing, analyser and workload changes so you can compare scenarios before you make them.

Administration

Users and roles

1. **Administration → Users** → **Invite user**: e-mail, name, role and optional branch → **Send invitation**.
2. **Assign** adds another role; **Revoke role** (reason) removes one.
3. **Deactivate** (reason) the day someone leaves; **Reactivate** if they return.

- **Roles** lists system and custom roles with their permissions (read-only).
- **Competency privileges**: **Grant privilege** → **Grant** lets a person perform specific tests; **Revoke** (reason).

AI tab: switch AI features on or off, set limits and review usage and evaluation. If AI is switched off, AI buttons are hidden for everyone.

Audit log

- **Audit Log** shows every action: who, when, what changed, the reason and the before/after state. Filter by date, user, record type or action.
- **Verify integrity** checks the tamper-evident hash chain: “Chain intact — {n} events verified”, or the sequence where it is broken (report this immediately).

Practising in the free demo

- A free demo lab contains synthetic patients at every stage. The yellow bar shows the days left.
- Use **View as** (“Try the app as…”) to switch to your role and practise exactly what you will see.
- In the demo, printing, PDFs and branding are removed, and SMS, e-mail, claims, mobile money and portal invites are not really sent.
- Same-person checks are relaxed so one person can play every role. In your live lab they apply in full.

Getting help

- Your first contact is your laboratory manager or system administrator – they can reset access, change your role and fix configuration.
- If something looks wrong in a result or report, do not work around it: raise a nonconformity (**Raise NC** in the top bar) so it is investigated.
- Product support and training: **labsentra.com/contact**.

> **Note.** This manual describes LabSentra as configured by default. Your laboratory may have switched some features off, added custom roles or changed who issues reports (scientist or clinical authoriser) – your administrator can confirm.