



MEDIBRIDGE LABCORE • TRIAL RUN SOP
UNIFIED DIGITAL ECOSYSTEM

TRIAL RUN SOP · CLIENT TRIAL PLAN

MediBridge LabCore on your own laboratory: a 14-day parallel run

This plan runs MediBridge LabCore beside your existing laboratory system on one branch or department for 14 days. Your existing system stays the system of record and keeps releasing every report. LabCore takes the same samples, receives results from your analyzers through MediBridge Connect, and is compared with your existing system every day. At the end, your laboratory and ClinexGen decide go, conditional go or no-go on evidence from your own work.

Where	How long	System of record	Decision
One branch or department, named in A1	14 days in parallel, after Stages 1 and 2	Your existing system, throughout the trial	Go, conditional go or no-go, signed by both sides
Stage 1 Pre-trial audit and instrument mapping Before day 1	Stage 2 Trial workspace and historical data Before day 1	Stage 3 14-day parallel run Days 1–14	Stage 4 Go / no-go and handover After day 14
		Part B Functional walkthrough 81 checks · about 7 h 20 min	LOG Issue log Every Fail, until closed

Ground rules for the trial

- Your existing system remains the **system of record**. Every report to a patient or clinician comes from it.
- No LabCore report is released** to patients or clinicians during the trial. Trial reports carry a “Trial report, not for clinical use” header and disclaimer.
- Critical values are still phoned under your existing procedure. LabCore records the same call, with read-back, for comparison.
- Historical data is a **masked sample only**, loaded with your written approval.
- No reference range, critical limit or calculated-test text ships pre-filled: **your pathologists approve every clinical master**.

Reading this plan

Part A is the plan, for your trial owner and the ClinexGen trial lead. **Part B** is the checklist your users mark on the trial workspace. The **issue log** on the last page collects every Fail until it is closed.

Pass LabCore did what the Expected result says.

Fail It did something else. Write what you saw and copy it to the issue log.

Skip Not run on purpose, because that module or interface is out of scope for this trial. Write the reason.

In this document

- A1** Purpose and scope · **A2** Before day 1: prerequisites
- A3** Roles and RACI · **A4** The four stages
- A5** Day-by-day plan · **A6** Test scenarios
- A7** Data handling and privacy (DPDP Act, 2023)
- A8** Success and exit criteria · **A9** Issues and escalation
- A10** Go / no-go decision and sign-off
- B** Functional walkthrough: 81 checks in 16 groups · **LOG** Issue log

Trial details

Laboratory _____

Branch or department _____

Client trial owner _____

ClinexGen trial lead _____

Day 1 date _____

Workspace address _____

ClinexGen gives the trial owner the workspace address, served over HTTPS, at Stage 2.

PART A · THE TRIAL PLAN

A1 Purpose and scope

What the trial proves, where, for how long, and what it leaves out.

The trial proves, on your own samples, analyzers and staff, that LabCore keeps every sample, result and decision in one traceable place. It is the third step of the buying sequence: a live demo on your workflow, fit and gap, **this trial on your data**, the proposal, then rollout, branch by branch.

WHAT THE TRIAL PROVES

- Analyzer results reach LabCore through MediBridge Connect with no re-typing, and agree with your existing system value for value, or the difference is explained.
- Every tube is traceable by barcode from collection to storage, and a rejected sample plans its own recollection.
- The rules your pathologists approve hold an unsafe result before release: ranges and flags, delta checks, auto-verification, QC blocks and two-step sign-off.
- Critical values are flagged, escalated through your duty roster and closed with a read-back.
- Trial reports are digitally signed, verifiable by QR code and audited end to end.
- TAT by stage (median and 90th percentile) can be measured on your own data, beside your existing system's figures.

ITEM	FOR THIS TRIAL
Branch or department	One branch, or one department of a larger laboratory
Sections and benches	
Analyzers	Those listed in the instrument map (Stage 1), connected through MediBridge Connect
Duration	14 days of parallel running (days 1–14), after Stages 1 and 2 are signed off. Stage 4 follows day 14
Modules exercised	Patients, Orders, Specimens, Instruments, Results, Quality control, Reporting & delivery, Notifications, Billing, Analytics and Audit, plus any module named at fit and gap
System of record	Your existing system, for every report released during the trial

OUT OF SCOPE FOR THIS TRIAL

ITEM	HOW IT IS HANDLED
ABDM / ABHA live linking	Needs your HIP registration and ABDM sandbox validation first. The screens can be shown; no live ABHA verification or linking runs. Part B marks it Skip
Blood centre (M22)	Only for blood centres licensed under the Drugs and Cosmetics Act, 1940 and Rules, 1945, following NBTC guidelines, and only if named in scope at Stage 1
Reports to patients and clinicians	None released from LabCore. Messages go to test numbers and test addresses only
Full historical migration	Only a masked sample is loaded, as a dry run. The production migration is planned in the proposal
Other branches, sections and specialty benches	Not tested in this trial; added at rollout, branch by branch
Real payments	Trial bills use a test price list with made-up test values. No live gateway collections
Commercial terms and service levels	Set out in the proposal, not in this plan

A2 Before day 1: prerequisites

Tick each item when it is in place. Stage 2 cannot close while any item is open.

YOUR LABORATORY PROVIDES

#	PREREQUISITE	DETAIL	READY
C1	Named trial owner	One person who runs the trial day to day, keeps the issue log and signs each stage gate	☐
C2	Trial users	Named front office, phlebotomy, reception, technologist, section head, pathologist and lab manager users. One account per person, never shared	☐
C3	Bench PCs and browsers	A current browser on every bench PC in the trial, and on any tablet or phone used for collection	☐
C4	Barcode printers and scanners	Label printers for Code 128 labels; scanners at collection, reception and each bench	☐

#	PREREQUISITE	DETAIL	READY
C5	Analyzer access	For each analyzer in scope: make, model, interface type and connection point, and the analyzer vendor's support where the interface needs it	☐
C6	Masters	Test menu, panels and packages, a test price list (test values only), report formats, branches and collection centres; reference ranges, critical limits and calculated-test text approved by your pathologists	☐
C7	Signing authorities and duty roster	Named pathologists with the dates of their signing authority; the duty roster for critical-value escalation	☐
C8	Masked historical sample	An extract from your current system, masked before it leaves you, with your written approval	☐
C9	Contacts and test addresses	HIS and billing contacts where those links are in scope; a test mobile number and a test e-mail address for messages	☐

CLINEXGEN PROVIDES

#	PREREQUISITE	DETAIL	READY
G1	Trial workspace	Served over HTTPS, set up where agreed with your IT; the address goes to your trial owner	☐
G2	Accounts	One account per named trial user, with the role agreed in A3; multi-factor sign-in for pathologists and administrators	☐
G3	Configured masters	Loaded through the Setup wizard and CSV or Excel import with a dry-run preview, from the masters you provide (C6)	☐
G4	MediBridge Connect	Configured for each analyzer in the instrument map, with its test and flag maps	☐
G5	Trial report template	Your report format, with a "Trial report, not for clinical use" header and disclaimer	☐
G6	Trial team	A named ClinexGen trial lead and delivery / interface engineer, and the support desk contact for the trial	☐

A3 Roles and RACI

Who does what. Write each name in before Stage 1 starts.

ROLE	NAME	RESPONSIBLE FOR
Client sponsor	_____	Owens the decision and the written approvals; chairs the go / no-go
Client trial owner	_____	Runs the trial day to day; signs each gate; keeps the issue log
Laboratory manager	_____	Workload, staffing and duty roster; leads the volume test day
Pathologist (signing authority)	_____	Approves clinical masters and rules; validates trial results
Section heads	_____	Daily result comparison; interface sign-off with client IT
Client IT	_____	Network, bench PCs, printers, analyzer links; interface sign-off
ClinexGen trial lead	_____	Plans and reports the trial; daily review; issue triage
ClinexGen delivery / interface engineer	_____	Workspace, masters, MediBridge Connect, migration dry run, fixes
ClinexGen support desk	ClinexGen	Open items after handover; service levels as in your proposal

ACTIVITY	Your laboratory						ClinexGen		
	Sponsor	Trial owner	Lab manager	Pathologist	Section heads	IT	Trial lead	Engineer	Support desk
Fit and gap; instrument map (Stage 1)	I	A	C	C	R	R	R	R	–
Approve ranges, limits, rules and calculated-test text	I	C	C	A/R	C	–	C	C	–
Trial workspace, accounts and masters (Stage 2)	–	A	I	C	C	C	C	R	–
Masked sample: written approval and extract	A	R	I	–	–	R	C	C	–
Migration dry run, reconciliation and spot check	–	A	C	–	R	C	C	R	–
Analyzer interface sign-off	–	I	I	–	A/R	R	C	R	–

ACTIVITY	Your laboratory						ClinexGen		
	Sponsor	Trial owner	Lab manager	Pathologist	Section heads	IT	Trial lead	Engineer	Support desk
Daily result comparison and review (Stage 3)	I	A	C	C	R	–	R	C	–
Critical values during the trial	–	I	C	A	R	–	I	–	–
Issue logging, triage and fixes	I	A	C	C	R	C	R	R	I
Volume test day	I	A	R	C	R	C	R	C	–
Go / no-go decision and sign-off (Stage 4)	A	R	C	C	C	C	R	C	I
Support handover	I	A	C	–	–	C	R	C	R

R responsible: does the work · A accountable: signs it off · C consulted · I informed · – not involved.

A4 The four stages

Each stage ends at a gate your trial owner signs before the next one starts.

Stage 1 Pre-trial audit and instrument mapping Before day 1

ACTIVITY	WHO	EVIDENCE AT THE GATE
Fit and gap on your test menu and panels, current report formats, branches and collection centres, and HIS and billing contacts	Trial lead, trial owner, section heads	Signed fit-and-gap sheet, with anything not covered marked
Instrument map: each analyzer in scope by make and model, section, and interface type through MediBridge Connect (ASTM E1381 / E1394 over serial or TCP, or HL7 v2); host query or results only	Engineer, client IT, section heads	Instrument map (form below)
Test and flag maps for each analyzer, with dilutions and reruns; how each analyzer reports to LabCore during the run without disturbing your existing interface	Engineer, section heads	Maps approved by the section head
Clinical masters: reference ranges (by age, sex, pregnancy, fasting and analyzer), critical limits, calculated-test text, and delta-check, auto-verification, reflex and Westgard rules	Your pathologists approve; engineer loads	Signed approval of every clinical master. Nothing ships pre-filled
Signing authorities with their dates, and the duty roster per branch for critical-value escalation (defaults +15 and +30 minutes, set per branch)	Lab manager, pathologists	Names, dates and roster on file
Identity rule for samples registered during the parallel run (A7)	Sponsor, trial owner	Written decision

Analyzer (make and model)	Section	Interface: ASTM serial / ASTM TCP / HL7 v2	Host query?	Test and flag maps approved	Signed off by IT and section head (Stage 2)

Gate 1. Fit and gap, instrument map, test and flag maps and every clinical master signed; signing authorities and duty roster named; identity rule decided.

Stage 2 Trial workspace and historical data Before day 1

ACTIVITY	WHO	EVIDENCE AT THE GATE
Trial workspace served over HTTPS; accounts for the named users; Setup wizard steps 1–10: organisation, branches, departments, benches, number series, users and roles, signing authorities and duty roster, catalogue, settings, go-live readiness	Engineer, client IT	Workspace address; every trial user has signed in
Masters imported from CSV or Excel, each with a dry-run preview and diff before it is saved	Engineer; trial owner reviews	Masters match the approved sheets

ACTIVITY	WHO	EVIDENCE AT THE GATE
Historical data: a masked sample only, with your written approval, loaded on the Data migration screen as a dry run first	Engineer, trial owner	Written approval; masking done before the file left you
Reconciliation report against your source totals, then a spot check of _____ records the trial owner chooses	Engineer, section head	Report and spot check signed
Interface sign-off: each analyzer tested with QC material and retained samples of known value, then signed off by client IT and the section head before any results are compared	Engineer, client IT, section heads	Sign-off for every analyzer on the instrument map
Training for each user on their own screens (F2 save, F4 search, F8 verify, F9 validate, Ctrl+K)	Trial lead	Attendance list

Gate 2. Workspace live over HTTPS; masters imported; masked sample reconciled and spot-checked; every analyzer interface signed off by IT and the section head; Part B group 0 marked.

Stage 3 14-day parallel run on one branch or department Days 1–14

- Your existing system **remains the system of record**. Every report to patients and clinicians comes from it.
- LabCore reports are trial reports, marked “Trial report, not for clinical use”, and are **not released to patients or clinicians**.
- Critical values are phoned under your existing procedure; the same call is recorded in LabCore with read-back, so the two can be compared.

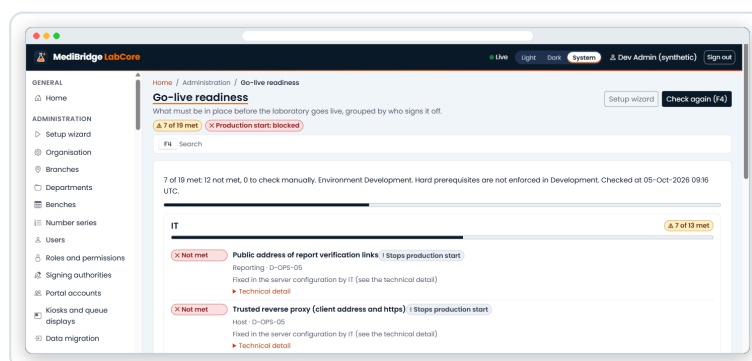
COMPARED EVERY DAY	HOW	WHO
Results	Value, unit and flag for every sample in scope, LabCore against your existing system, on the daily comparison sheet. Each difference is explained: mapping, range, rounding, or an entry error in either system	Section heads, trial lead
Flags and holds	Delta-check, auto-verification and missing-range holds, each decided by a named user	Technologists, pathologist
TAT by stage	Median and 90th percentile per stage from LabCore, beside your existing system's figures where it records them	Lab manager, trial lead
Critical values	Each one flagged, escalated at the configured minutes and closed with read-back	Section heads, pathologist
QC (Westgard)	Each rejected run blocked verification until a corrective action was recorded; look-back checked	Section heads
Rejections	Each has a reason, a recollection with a new barcode, and the collector told	Reception, lab manager
Issues	Logged with a severity and triaged at the daily review (A9)	Trial owner, trial lead

Volume test. On one normal working day between days 6 and 10, the full workload of the branch or department runs through LabCore in parallel. The lab manager records queues on the Live lab board, TAT by stage, and any value lost or doubled.

Gate 3. All 14 days run; comparison sheets signed daily; Part B marked; evidence collected for every success criterion in A8.

Stage 4 Go / no-go, production sign-off and support handover After day 14

- Readiness check** on the Go-live readiness screen: what must be in place before go-live, grouped by who signs it off.
- Success criteria** (A8) reviewed one by one, with the issue log.
- Decision:** go, conditional go or no-go (A10), signed by your laboratory and ClinexGen.
- Production sign-off:** the go-live plan for this branch or department, then branch by branch, as your proposal sets out.
- Support handover:** open items, the issue log, contacts, interface maps and configuration notes pass to the ClinexGen support desk.
- Service levels are as set out in your proposal.**
- Trial data:** deleted with written confirmation, or carried into go-live if you sign for it (A7).



Go-live readiness. Product screen, synthetic sample data.

A5 Day-by-day plan

The length of the pre-trial stages is agreed at Stage 1. The 14 days start only when Gate 2 is signed.

DAYS	STAGE	WHAT HAPPENS	LEAD	OUTPUT
Pre-trial	1	Fit and gap; instrument map; test and flag maps; clinical masters approved; signing authorities and duty roster named; identity rule decided	Trial lead, trial owner	Gate 1 signed
Pre-trial	2	Workspace over HTTPS; Setup wizard; masters imported with dry runs; masked-sample migration dry run, reconciliation and spot check; interface sign-off; training; Part B group 0 (about 40 min)	Engineer, client IT	Gate 2 signed
Day 1	3	Kick-off with every trial user; the parallel run starts with the first shift; first samples registered, collected, received, analysed and verified; first comparison sheet	Trial owner, trial lead	First comparison sheet; issue log opened
Days 2–5	3	Full routine on every bench in scope; daily comparison and review; first QC runs, holds and rejections handled; Part B groups 1–9, the workflow (44 checks, about 3 h 50 min)	Section heads	Daily sheets; groups 1–9 marked
Days 6–10	3	Volume test on one normal working day; Part B groups 10–15 (31 checks, about 2 h 50 min); mid-trial review with the sponsor	Lab manager, trial lead	Volume-day record; review notes
Days 11–14	3	Steady running; open issues retested; TAT by stage compiled; evidence gathered for each success criterion; readiness check started	Trial owner, trial lead	Evidence pack for A8
Go / no-go	4	Readiness check; decision meeting; signatures; support handover; trial data deleted or carried	Client sponsor	Signed decision (A10)

A6 Test scenarios

Mapped to what LabCore does differently. Run on TRIAL patients and samples; the Part B checks hold the detail.

#	SCENARIO	EXPECTED RESULT	PASS CRITERION	PART B
S1	Sample to report. Register, collect, transport, receive, analyse through MediBridge Connect, verify, validate, release and deliver one TRIAL order	One record follows the sample; every hand-off is a scan; the signed trial report reaches the test channel	Every step recorded with who and when	Groups B1–B9
S2	Rejection and recollection. Reject a tube at reception with a reason	A recollection is planned with a new barcode and the collector is told	Every rejection has a reason and a recollection	B4 . 2
S3	Delta-check hold. Result a patient far from their last released value	Held out of batch verification, with the trace stored	No held result released without a named user's decision	B6 . 3
S4	QC failure and look-back. Run a control that breaks a Westgard rule	Verification blocked until a corrective action is recorded; look-back lists results since the last accepted run	Every rejected run blocked verification; look-back produced	B10 . 1–B10 . 3
S5	Critical value. Result a value beyond its critical limit and leave it unacknowledged	Banner and alert at once; Level 1 at +15 min and Level 2 at +30 min (per-branch defaults, or your minutes); closed with read-back	Every critical value closed with who, role, how, when and read-back	B11 . 1–B11 . 4
S6	Reflex test. Result a value that meets a reflex rule, then rerun it	The next test is added to the same sample once, billed per rule	Added once only, after a rerun too	B6 . 6
S7	Amendment. Amend a released result	A new version with the AMENDED watermark; the earlier version kept; calculated tests recalculated	No released result overwritten	B12 . 2–B12 . 3
S8	QR verification. Scan the QR code on a signed trial report	The verification page asks for date of birth or a one-time code, then confirms the report	Every sampled report verifies	B8 . 4
S9	Role restriction. An administrator, and a user without signing authority, try to validate	Both refused; only a dated signing authority can validate	Every attempt outside the role refused	B7 . 2–B7 . 3, B14 . 1
S10	Audit trail. Open the audit trail of a TRIAL sample	Every view, print, change, release, export and sign-in, in the hash-chained audit trail	Every sampled action found, with who and when	B14 . 5
S11	Interface robustness. Send an unmatched result, re-send a delivered one, run QC material	Unmatched value queued; no value doubled; controls go to quality control	No value lost or doubled	B5 . 3–B5 . 4

#	SCENARIO	EXPECTED RESULT	PASS CRITERION	PART B
S12	Message privacy. Send a report by SMS, WhatsApp and e-mail; try a sensitive test	A secure link, never the PDF; sensitive tests not sent by message	No PDF and no sensitive test sent by message	B9.1–B9.2

A7 Data handling and privacy

Under India's Digital Personal Data Protection Act, 2023 (DPDP Act).

- **You are the data fiduciary.** ClinexGen processes trial data on your behalf, only for the trial.
- **Historical records:** a masked sample only, loaded with your written approval. Masking is done before the file leaves you.
- **Samples in the parallel run** are registered the way you decide in writing at Stage 1: pseudonymised and keyed to your existing laboratory number, or with full identity under your written approval.
- **Access** is limited to named trial users, each with their own account and role. Pathologists and administrators sign in with a second factor.
- In LabCore, names, phone numbers, e-mail and address are encrypted field by field; sensitive tests (such as HIV and genetic results) are identity-coded except for named roles; every view, print and export is audited.
- **Messages** go to test numbers and test addresses only. No report reaches a patient or clinician from the trial workspace.
- **After the go / no-go,** trial data is either deleted, with ClinexGen confirming the deletion in writing, or carried into go-live if you sign for it. The choice is recorded in A10.

A8 Success and exit criteria

Measured on the trial records. Every criterion met supports a go; see A10 for conditional go.

#	CRITERION	PASS CRITERION	MET?
1	Result agreement	100% of compared results (value, unit and flag) match your existing system, or the difference is explained and accepted by the section head	☐ Yes ☐ No
2	No transcription	Zero manual transcription of results from interfaced analyzers: every interfaced value arrives through MediBridge Connect	☐ Yes ☐ No
3	Interfaces validated	Every analyzer interface in scope signed off by IT and the section head before comparison started	☐ Yes ☐ No
4	Critical values	100% of critical values in LabCore closed with who, role, how, when and read-back, escalated at the configured minutes	☐ Yes ☐ No
5	QC rules	QC rules fire as configured: every rejected run blocked verification until a corrective action was recorded	☐ Yes ☐ No
6	Holds and sign-off	Every held result decided by a named user; every trial report verified, then validated by a dated signing authority	☐ Yes ☐ No
7	Traceability	Every trial sample has a complete scan trail from collection to reception; every rejection has a recollection	☐ Yes ☐ No
8	TAT by stage	Median and 90th percentile reported for every stage over the 14 days, beside your existing system's figures where it records them	☐ Yes ☐ No
9	Reports	Every trial report signed; every sampled QR verification works; no trial report released to a patient or clinician	☐ Yes ☐ No
10	Audit trail	Every sampled view, print, change and release found in the audit trail	☐ Yes ☐ No
11	Migration dry run	Reconciliation report equals the source totals; every spot-checked record matches	☐ Yes ☐ No
12	Volume day	A normal working day run in parallel, with no value lost or doubled	☐ Yes ☐ No
13	Part B	Every check marked Pass or Skip with a reason; any Fail is closed or is a named open item (A10)	☐ Yes ☐ No

Exit: pause the trial on the affected bench, and the trial owner and trial lead decide the next step, if a severity 1 issue touches result integrity or patient identity, trial data is handled outside this plan, or an interface disturbs your existing system's work. The trial resumes only when both sign the issue log.

A9 Issues and escalation

Every Fail in Part B and every problem seen in the run goes on the issue log.

SEVERITY	EXAMPLES	HANDLED BY	WHAT HAPPENS
1 · Critical	A wrong value or wrong patient on a result; a value lost or doubled; access outside a role; an interface disturbing your existing system	Trial owner and trial lead at once; engineer fixes	Pause the affected part (A8); fix, retest; both sign before resuming
2 · Major	A workflow step cannot be completed, or needs a workaround	Trial lead at the daily review; engineer fixes	Fixed and retested in the trial, or a named open item at go / no-go
3 · Minor	Layout, wording or report format; a slow screen with a workaround	Trial lead; engineer	Scheduled fix; does not block a go
4 · Change request	Something outside the agreed scope	Trial lead with the client sponsor	Recorded for the proposal

Path of an issue. Any trial user logs it, the trial owner sets the severity, the trial lead triages it at the daily review, the engineer fixes it, the user who raised it retests it, and the trial owner closes it. Response times are not part of this plan; after go-live, service levels are as set out in your proposal.

A10 Go / no-go decision and sign-off

Taken at Stage 4, on the success criteria (A8), the Part B results and the issue log.

Go

Every success criterion met and the readiness check passed. Go-live proceeds as planned.

Conditional go

Criteria met except named open items, each with an owner and a date. Go-live proceeds when they close.

No-go

A criterion not met with no agreed fix. Findings and next steps are recorded; trial data is handled as below.

#	OPEN ITEM (CONDITIONAL GO)	OWNER	DUE DATE
1			
2			
3			
4			

DECISION ☐ Go ☐ Conditional go ☐ No-go

TRIAL DATA ☐ Deleted, ClinexGen to confirm in writing ☐ Carried into go-live, as signed below

FOR YOUR LABORATORY

Client sponsor · name, signature, date

Client trial owner · name, signature, date

Pathologist (signing authority) · name, signature, date

FOR CLINEXGEN PRIVATE LIMITED

ClinexGen trial lead · name, signature, date

Authorised signatory · name, signature, date

Handover received by the support desk · date

PART B · FUNCTIONAL WALKTHROUGH

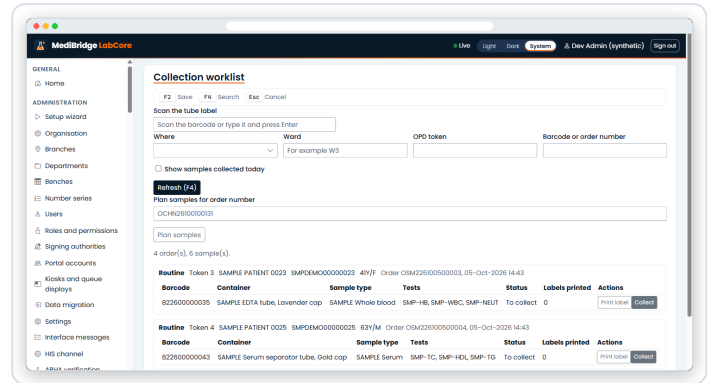
B Functional walkthrough

81 step-by-step checks on the trial workspace. Mark each one Pass, Fail or Skip.

Run Part B on **TRIAL patients and samples**: made-up names, the test mobile number and the test e-mail address, with QC material or retained samples where a check needs a real analyzer run. Never amend, message or release a real patient's result for a check.

Screen names are those of the trial build. If one differs, note it once. Times are working estimates for one pass. Group 0 runs at Stage 2, groups 1–9 on days 2–5, and groups 10–15 on days 6–10 (A5).

A check marked “Only if ... in scope” is Skip when that module or interface is not part of this trial. Copy every Fail to the issue log with its check number.



Collection worklist. Product screen, synthetic sample data.

GROUP	AREA	WHO	CHECKS	MINUTES	WHEN
B0	Set-up, import and readiness	Administrator · ClinexGen engineer	6	40	Stage 2
B1	Register	Front office	6	30	Days 2–5
B2	Collect	Phlebotomist	4	20	Days 2–5
B3	Transport	Collection centre · Reception	3	15	Days 2–5
B4	Receive	Reception	4	25	Days 2–5
B5	Analyse, through MediBridge Connect	Technologist · ClinexGen engineer	5	35	Days 2–5
B6	Verify	Technologist	8	40	Days 2–5
B7	Validate	Pathologist	4	20	Days 2–5
B8	Release	Pathologist · Technologist	4	20	Days 2–5
B9	Deliver	Front office · ClinexGen engineer	6	25	Days 2–5
B10	Quality control	Technologist · Section head	5	30	Days 6–10
B11	Critical values	Technologist · Pathologist · Lab manager	5	45	Days 6–10
B12	Reports and amendments	Pathologist · Section head	5	20	Days 6–10
B13	Billing with tax	Front office · Accounts	6	25	Days 6–10
B14	Security and audit	Administrator · Trial owner	6	30	Days 6–10
B15	Insight and TAT	Lab manager	4	20	Days 6–10
Total			81	440	about 7 h 20 min

#	WHO	CHECK	EXPECTED RESULT	PASS	FAIL	SKIP
B0 Set-up, import and readiness Administrator · ClinexGen engineer · 6 checks · about 40 min						
B0.1	Administrator	Open the trial workspace address and sign in; then sign in as a pathologist	The address is HTTPS; administrator and pathologist are asked for a second factor	☐	☐	☐
B0.2	Administrator	Open the Setup wizard and step through 1 to 10 for the trial branch	Each step saved: benches, number series, users and roles, signing authorities, duty roster	☐	☐	☐
B0.3	Engineer	Import the test catalogue from CSV or Excel	A dry-run preview and diff appear before anything is saved	☐	☐	☐
B0.4	Pathologist	Open the reference ranges and critical limits of three trial tests	Only the values your pathologists approved; nothing pre-filled	☐	☐	☐
B0.5	Engineer	On Data migration, run the masked sample as a dry run, then load it	The reconciliation report equals the source totals; the spot check matches	☐	☐	☐
B0.6	Administrator	Open Go-live readiness	Items grouped by who signs them off, each shown as met or not met	☐	☐	☐

#	WHO	CHECK	EXPECTED RESULT	PASS	FAIL	SKIP
B1 Register Front office · 6 checks · about 30 min						
B1.1	Front office	Search TRIAL Patient One by a spelling variant (Lakshmi / Laxmi) and by mobile	Found by phonetic search; a duplicate warning before a second record is made	☐	☐	☐
B1.2	Front office	Register a new TRIAL patient with an estimated age, a category (e.g. VIP) and consent	UHID issued, or taken from your HIS where it is in scope; consent recorded	☐	☐	☐
B1.3	Front office	Order a package and a single test by name, code or alias; mark one STAT	The package expands to its panels and tests; the STAT due time is shown	☐	☐	☐
B1.4	Front office	Order the same test again; then a test inside its retest interval	Duplicate-order warning; retest-interval stop	☐	☐	☐
B1.5	Front office	Open the order's per-item timeline	Shows where each test is, without a call to the bench	☐	☐	☐
B1.6	Front office + second user	Merge two TRIAL duplicate records	The merge waits for the second user's approval	☐	☐	☐
B2 Collect Phlebotomist · 4 checks · about 20 min						
B2.1	Phlebotomist	On the Collection worklist, plan samples for the TRIAL order	Tubes split automatically by container and sample type	☐	☐	☐
B2.2	Phlebotomist	Print the labels	12-digit check-digit barcodes on Code 128 labels, from your label template	☐	☐	☐
B2.3	Phlebotomist	Scan each tube as it is collected	Collection time and collector recorded; status moves on from To collect	☐	☐	☐
B2.4	Phlebotomist	Only if the phlebotomy app is in scope: collect a home visit offline, then reconnect	OTP check-in, barcode scan, tube photo and cool-box temperature sync	☐	☐	☐
B3 Transport Collection centre · Reception · 3 checks · about 15 min						
B3.1	Collection centre	Create a manifest for the trial box, with the box temperature at dispatch	The manifest lists every tube and the dispatch temperature	☐	☐	☐
B3.2	Reception	Record the box's arrival with its temperature	Arrival temperature on the manifest; a custody event for each tube	☐	☐	☐
B3.3	Reception	Open the chain-of-custody trail for one tube	Every scan from collection to arrival, with who and when	☐	☐	☐
B4 Receive Reception · 4 checks · about 25 min						
B4.1	Reception	Scan-to-receive one tube, then a whole rack	Container, stability, volume and labelling checked on receipt	☐	☐	☐
B4.2	Reception	Reject one TRIAL tube with a reason (e.g. insufficient volume)	A recollection is planned with a new barcode, at no charge, and the collector is told	☐	☐	☐
B4.3	Reception	Store an aliquot in a rack position; find it again by scan	Position found by scan; the retention rule is shown	☐	☐	☐
B4.4	Reception + second user	Register a sample on a pre-printed downtime ID; a second person re-types the result blind	Not released until the blind re-typing is done	☐	☐	☐
B5 Analyse, through MediBridge Connect Technologist · ClinexGen engineer · 5 checks · about 35 min						
B5.1	Technologist	Load a barcoded TRIAL sample on a bidirectional analyzer	Host query downloads the order; results reach the Worklist with no typing	☐	☐	☐
B5.2	Technologist	Compare one sample's results with the analyzer's printout	Values, units and flags match; histograms and scattergrams shown where sent	☐	☐	☐
B5.3	Engineer	Send a result for an unregistered barcode; re-send one already delivered	The unmatched value waits in a queue; no value doubled; both on Interface messages	☐	☐	☐
B5.4	Technologist	Run QC material on the analyzer	Control results go to quality control, never to a patient	☐	☐	☐

#	WHO	CHECK	EXPECTED RESULT	PASS	FAIL	SKIP
B5.5	Engineer	Leave one analyzer idle beyond the silence limit set for it	An alert is raised	☐	☐	☐
B6 Verify Technologist · 8 checks · about 40 min						
B6.1	Technologist	Open the Worklist	STAT first, then overdue, urgent and routine; updates as results arrive	☐	☐	☐
B6.2	Technologist	Enter a manual result by keyboard (Enter to move on, F2 to save)	Range for age and sex applied; the flag shown as text as well as colour	☐	☐	☐
B6.3	Technologist	Result a TRIAL patient far from their last released value	Held out of batch verification, with the delta-check trace stored	☐	☐	☐
B6.4	Technologist	Result a test that has no approved range for this patient	Held until someone decides	☐	☐	☐
B6.5	Technologist	Let a normal result run through auto-verification	Per-check trace: QC validity, analyzer flags, serum indices, delta check, holds	☐	☐	☐
B6.6	Technologist	Result a value that meets a reflex rule; then rerun it	The next test is added to the same sample once only, and billed per rule	☐	☐	☐
B6.7	Technologist	Check a calculated test (e.g. eGFR CKD-EPI 2021 or LDL)	Calculated from the approved formula, with your approved text	☐	☐	☐
B6.8	Technologist	Verify a batch with F8 on the Verification queue	Verified results move to the Validation queue; held results stay behind	☐	☐	☐
B7 Validate Pathologist · 4 checks · about 20 min						
B7.1	Pathologist	On the Validation queue, validate a verified result (F9)	Validation recorded under the pathologist's dated signing authority	☐	☐	☐
B7.2	Technologist	Try to validate a result without a signing authority	Refused	☐	☐	☐
B7.3	Administrator	End a TRIAL user's signing authority yesterday; that user tries to validate	Refused once the authority has lapsed	☐	☐	☐
B7.4	Pathologist	Only if competency blocking is switched on: a TRIAL user with expired competency tries to validate	Blocked	☐	☐	☐
B8 Release Pathologist · Technologist · 4 checks · about 20 min						
B8.1	Pathologist	Validate the last test of a group	The report is released automatically, with the trial header and disclaimer	☐	☐	☐
B8.2	Pathologist	Validate a group with one test still pending	Partial report marked "result to follow", with the PARTIAL watermark	☐	☐	☐
B8.3	Technologist	Open the released report	PDF/A signed with the laboratory's certificate; signatories with qualification and registration number	☐	☐	☐
B8.4	Trial owner	Scan the report's QR code with a phone	The verification page asks for date of birth or a one-time code, then confirms the report	☐	☐	☐
B9 Deliver Front office · ClinexGen engineer · 6 checks · about 25 min						
B9.1	Front office	Send a TRIAL report by SMS, WhatsApp and e-mail to the test number and address	Each message carries a secure link, never the PDF	☐	☐	☐
B9.2	Front office	Try to send a sensitive test (e.g. HIV) by message	Not sent by message	☐	☐	☐
B9.3	Front office	Print the TRIAL report	Prints the signed report	☐	☐	☐
B9.4	Trial owner	Only if portals are in scope: open the report on the patient or doctor portal	Shown with its integrity check; the doctor signs in by OTP	☐	☐	☐
B9.5	Engineer	Only if your HIS is in scope: send the result to your HIS test system through MediBridge Connect	One ORU^R01 with LOINC, UCUM, flags and the signed PDF; no duplicate	☐	☐	☐
B9.6	Any	ABHA verification and linking	Skip: out of scope until your HIP registration and ABDM sandbox validation are done	☐	☐	☐

#	WHO	CHECK	EXPECTED RESULT	PASS	FAIL	SKIP
B10 Quality control Technologist · Section head · 5 checks · about 30 min						
B10.1	Technologist	Run a control that breaks a Westgard rule (e.g. 1-3s)	Run rejected; verification blocked for that test and analyzer	☐	☐	☐
B10.2	Section head	Record the corrective action	Verification unblocked only after the action is recorded	☐	☐	☐
B10.3	Section head	Open the look-back for the failed run	Lists the results released since the last accepted run	☐	☐	☐
B10.4	Section head	Open the Levey-Jennings chart for the test	Chart with the month's mean, SD and CV%	☐	☐	☐
B10.5	Section head	Enter an unacceptable result in a TRIAL EQAS round	A CAPA opens automatically	☐	☐	☐
B11 Critical values Technologist · Pathologist · Lab manager · 5 checks · about 45 min						
B11.1	Technologist	Result a TRIAL sample beyond its critical limit	A banner on every screen and an audible alert; listed on Critical values	☐	☐	☐
B11.2	Technologist	Leave it unacknowledged for the Level 1 time (default +15 min)	Escalates to the senior technologist on the Duty roster	☐	☐	☐
B11.3	Technologist	Leave it for the Level 2 time (default +30 min)	Escalates to the pathologist and lab manager, with SMS backup	☐	☐	☐
B11.4	Senior technologist	Close the call	Records who was told, their role, how, when and a confirmed read-back	☐	☐	☐
B11.5	Lab manager	Open the call-time indicators	Median, 90th percentile and longest call time	☐	☐	☐
B12 Reports and amendments Pathologist · Section head · 5 checks · about 20 min						
B12.1	Section head	Open the report template of the trial department	Versioned header, footer and disclaimer; signatories listed	☐	☐	☐
B12.2	Pathologist	Amend a released TRIAL result	A new version with the AMENDED watermark; the earlier version is kept	☐	☐	☐
B12.3	Pathologist	Amend an input of a calculated test	The calculated test is recalculated automatically	☐	☐	☐
B12.4	Pathologist	Open the cumulative view for a TRIAL patient	The last five values, with the trend	☐	☐	☐
B12.5	Front office	Download a stored report	Its integrity is checked on download	☐	☐	☐
B13 Billing with tax Front office · Accounts · 6 checks · about 25 min						
B13.1	Front office	Bill a TRIAL order on the test price list (test values, not rates)	Tax per line by SAC code; number from the gapless bill series	☐	☐	☐
B13.2	Front office	Cancel one test and refund it	The refund needs approval; credit note from its own gapless series	☐	☐	☐
B13.3	Front office	Close the cash session	Day-end report for the session	☐	☐	☐
B13.4	Accounts	Bill a TRIAL B2B client	Posted to the client's ledger, with ageing and credit limit	☐	☐	☐
B13.5	Accounts	Export the tax register and the Tally export for a trial day	Both files produced	☐	☐	☐
B13.6	Front office	Only if the payment hold is switched on: release an unpaid OPD order	Report held until the bill is paid	☐	☐	☐
B14 Security and audit Administrator · Trial owner · 6 checks · about 30 min						
B14.1	Administrator	Try to verify or validate a result	Refused: administrators never hold result permissions	☐	☐	☐
B14.2	Technologist	Open the work of a department outside the role's scope	Refused	☐	☐	☐
B14.3	Front office	Open a sensitive TRIAL result (e.g. HIV) without the named role	The patient's identity is coded	☐	☐	☐

#	WHO	CHECK	EXPECTED RESULT	PASS	FAIL	SKIP
B14.4	Pathologist	Use break-glass access on that result	Access is time-boxed and an alert is raised	☐	☐	☐
B14.5	Trial owner	Open the audit trail of one TRIAL sample	Every view, print, change, release, export and sign-in, with who and when	☐	☐	☐
B14.6	Administrator	Log a TRIAL data-principal request (access or correction)	A due date is set; it escalates if the date passes	☐	☐	☐
B15 Insight and TAT Lab manager · 4 checks · about 20 min						
B15.1	Lab manager	Open the Live lab board in TV mode	Queues, overdue samples and open critical calls; refreshes on its own	☐	☐	☐
B15.2	Lab manager	Open TAT by stage for the trial days	Median and 90th percentile for each stage, with breaches by test	☐	☐	☐
B15.3	Lab manager	Open the quality indicators	Rejection rate, TAT compliance, critical call time, amended reports	☐	☐	☐
B15.4	Lab manager	Export one report to Excel and PDF; schedule it to a test address	Both exports produced; the scheduled e-mail arrives	☐	☐	☐

Results Part B results

Count the marks per group. Every Fail goes to the issue log; the totals feed success criterion 13 (A8).

GROUP	AREA	CHECKS	PASS	FAIL	SKIP	MARKED BY	DATE
B0	Set-up, import and readiness	6					
B1	Register	6					
B2	Collect	4					
B3	Transport	3					
B4	Receive	4					
B5	Analyse, through MediBridge Connect	5					
B6	Verify	8					
B7	Validate	4					
B8	Release	4					
B9	Deliver	6					
B10	Quality control	5					
B11	Critical values	5					
B12	Reports and amendments	5					
B13	Billing with tax	6					
B14	Security and audit	6					
B15	Insight and TAT	4					
Total		81					

LOG Issue log

Every Fail in Part B and every problem seen in the run, with its severity (A9). Kept by the client trial owner.

CHECK / DAY	SEVERITY	WHAT HAPPENED	OWNER	DUE	CLOSED

Client trial owner · signature, date

ClinexGen trial lead · signature, date

Handed to the support desk · date

Prepared by Clinexgen Private Limited, Gemini Square (Parsn Manere), B Wing, 8th Floor, 602 Anna Salai, Chennai 600006 · info@clinexgen.com · +91 7338 786 196 · www.clinexgen.com. MediBridge LabCore is designed to support NABL / ISO 15189:2022 workflows; this trial does not certify or accredit your laboratory, and no certification is claimed. Commercial terms and service levels are set out in your proposal.