NABL ACCREDITED · NABL-M(EL)T-03030 · GCP/GLP

NIYAMIT HEALTH

DIAGNOSTIC & RESEARCH

Precision Diagnostics. Research Ready.

Clinical Trial & CRO Partner Brochure

Seeking long-term partnerships with CROs & pharma companies for clinical trial sample processing support

Dr. Priyanka Somwanshi | CEO & Founder | MBBS (KEM Mumbai), MD Pathology | 3+ Yrs CRO Experience

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About Niyamit Health

Who We Are

Niyamit Health Diagnostic & Research is a NABL-accredited laboratory founded by Dr. Priyanka Somwanshi — an MD Pathologist (MBBS, KEM Hospital Mumbai; MD Pathology, VIMS & RC Whitefield, Bengaluru) with over 15 years of experience.

Built with a research-oriented approach — focused on Oncology, Metabolic Disorders, Gastroenterology, and Infectious Disease. Workflows and documentation aligned to research-grade requirements from day one.

Dr. Priyanka brings 3+ years of personal CRO experience as an Authorized Signatory. Currently NABL M(EL)T accredited — processes already aligned to full NABL. ISO 15189 actively on roadmap.

15+
Years of Experience

NABL
Accredited Laboratory

3+
Years CRO Experience (Dr. Priyanka)

200/hr
Test Processing Capacity

Why Choose Niyamit for Your CRO Needs

CRO-Trained Leadership

Dr. Priyanka has 3+ years direct CRO experience as an Authorized Signatory — she understands your protocols, timelines, and audit expectations from the inside.

Research-Oriented by Design

Built for clinical research, not routine diagnostics. Workflows, infrastructure, and documentation are aligned to research-grade requirements from day one.

Therapeutic Area Focus

Oncology · Metabolic Disorders · Gastroenterology · Infectious Disease. Research background directly aligned to these trial-heavy areas.

NABL Accredited + Roadmap

Current: NABL-M(EL)T-03030 (valid June 2028). Processes already aligned to full NABL. ISO 15189 accreditation on roadmap — actively progressing.

Full Cold Chain + COC

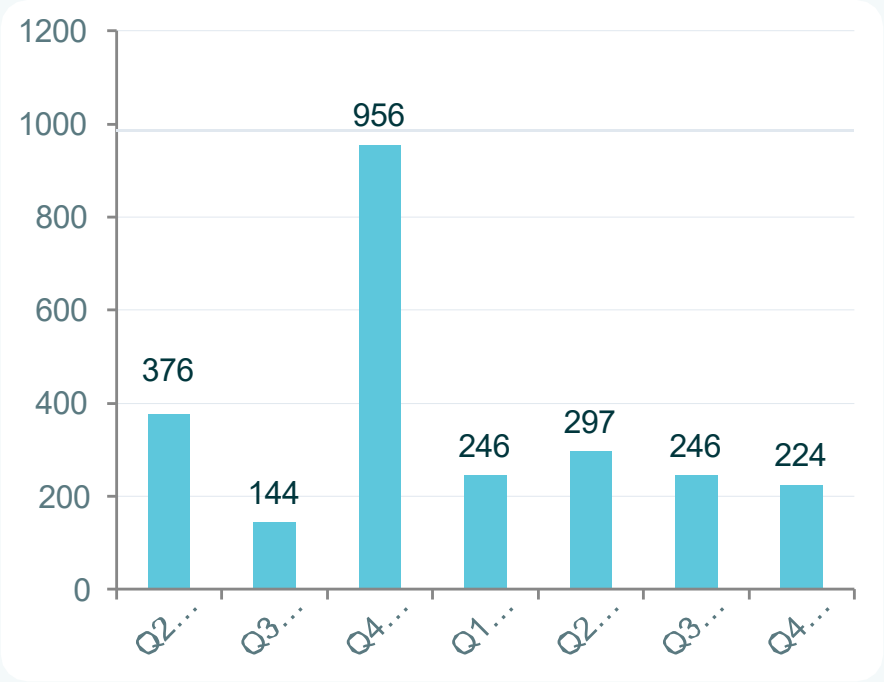
LiveHealth (Crelio) LIS. Barcode tracking. Cold chain with 15-minute temperature logs. Full chain of custody from collection to archiving.

GCP & GLP Compliant

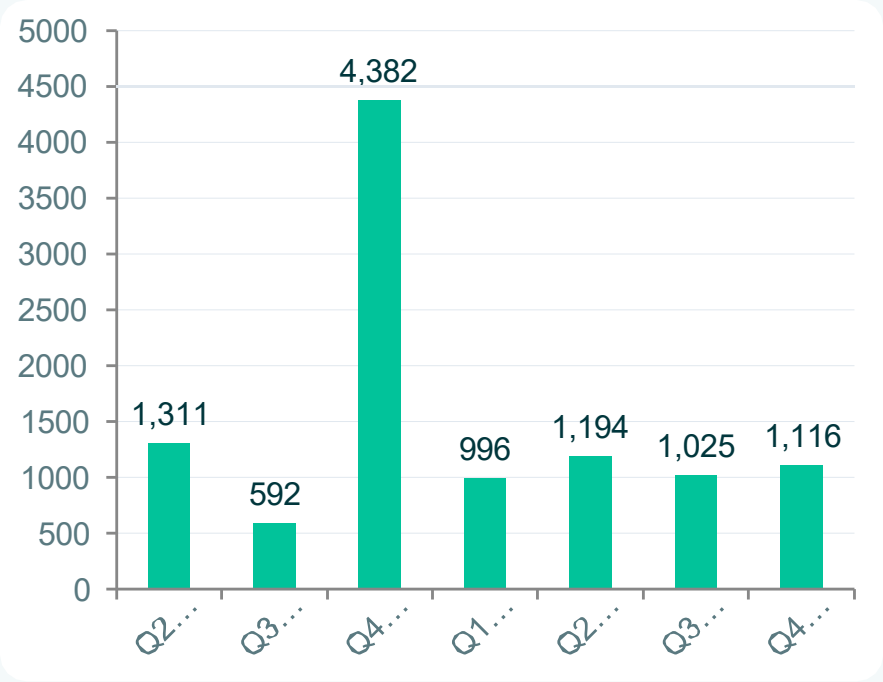
Documented GCP/GLP compliance. Audit-experienced across NABL, CAP, GCC, and pre-qualification CRO audits. Records always audit-ready.

Our Scale: Patient & Test Volume

Patients Served per Quarter



Tests Conducted per Quarter



**Q1 FY2024-25 (Apr–Jun 2024): lab in setup phase — data not captured. Q4 FY2025-26 (Jan–Mar 2026) ongoing.*

CRO-Specific Capabilities

CORE DIAGNOSTIC SERVICES

- Hematology (CBC, Peripheral Smear)
- Biochemistry (Metabolic, Liver, Kidney panels)
- Serology & Immunology
- Clinical Pathology (Urine, Body Fluids)
- Cytology — FNAC & Gynae Cytology
- Histopathology & Biopsy Processing

CRO & RESEARCH CAPABILITIES

- GCP & GLP-compliant reporting
- Protocol-customized workflows per CRO
- Chain of custody — collection to archiving
- Cold chain with 15-min temperature logs
- Home collection & multi-location pickup
- Dry-run / mock sample runs on request
- Co-development of lab manuals & SOPs
- Flexible TAT — minimum 4 hrs post-receipt

Process-Oriented Operations

01 Collection

Home collection & multi-location pickup. Barcode labelling at point of collection. Chain of custody initiated.

02 Transport

Cold chain maintained throughout. Temperature logs every 15 minutes. Active logistics network across Bangalore.

03 Accessioning

Barcode-based registration on LiveHealth (Crelio) LIS. Real-time logging with full audit trail from first entry.

04 Testing

Fully automated analyzers. ~200 tests/hour capacity. Daily internal QC + EQAS external benchmarking.

05 Reporting

Minimum 4-hour TAT post-receipt. Protocol-adapted templates. Encrypted transfer or API integration available.

06 Archiving

Record retention per GCP/GLP/NABL guidelines. All logs — calibration, QC, EQAS — available for audit at any time.

Infrastructure & Technology

Lab Infrastructure

- LIS: LiveHealth by Crelio Health
- ~200 tests/hour processing capacity
- 100% automation — pre/analytical/post
- Bidirectionally interfaced analyzers
- Barcode-based sample tracking
- Cold chain — 15-min temperature logs
- Temperature-monitored sample storage
- Backup power — zero downtime
- HIPAA-compliant, role-based LIS access
- Encrypted result transfers & API-ready

LiveHealth (Crelio) LIS

Real-time logging, full audit trails, role-based access, encrypted result delivery.

Cold Chain Protocol

Temperature logs every 15 minutes. Cold chain from collection point to storage.

~200 Tests/Hour Capacity

Minimum 4-hour TAT post sample receipt. STAT processing available on request.

API Integration

System can integrate directly with CRO platforms for seamless data exchange.

Quality, Compliance & Audit Experience

NABL Accreditation

NABL-M(EL)T-03030

Valid: Jun 2025 – Jun 2028

Accredited under NABL 128 criteria. Processes aligned across all phases. EQAS participation via RML and other national schemes.

GCP & GLP Compliance

Good Clinical / Lab Practice

Active & documented

Documented adherence to GCP and GLP standards. All SOPs, checklists, and documentation maintained audit-ready at all times.

Regulatory Compliance

BMW · KPME · Karnataka Reg.

All current & valid

Karnataka Private Medical Establishment registered. BMW management authorized. All records available for site inspections.

Audit Experience

- **NABL**
- **CAP**
- **GCC**
- **Pre-qualification CRO Audits**

Zero patient complaints · No major technical breakdowns · Consistently audit-ready

Turnaround Time (TAT) & Reporting

TAT by Test Category

Test Category	Routine	Urgent
Hematology (CBC, ESR)	4–6 hrs	1–2 hrs
Biochemistry Panels	6–8 hrs	2–4 hrs
Serology / Immunology	Same day	4–6 hrs
Clinical Pathology	4–6 hrs	2 hrs
Histopathology / Biopsy	3–5 days	24–48 hrs
Cytology (FNAC)	2–3 days	Same day

Trial Visit Window Scenarios

Scenario	Typical Tests	Sample Count	TAT Achievable
Screening Visit	CBC, Biochem, Serology, Urine	8–15	6–8 hrs same day
Day 1 Dosing Visit	CBC, Biochem, Coagulation, LFT	10–20	4–6 hrs (STAT)
Follow-up Visit	CBC, Biochem, UA, Serology	6–12	4–6 hrs
Safety Monitoring	CBC, Metabolic Panel, LFT, RFT	8–15	6 hrs / 2 hrs STAT

** STAT available on request. All TATs from sample receipt. Custom windows agreed in study-specific MOU.*

Reporting Standards

Protocol-Adapted Templates

Report formats customized to match each CRO's protocol requirements.

Daily Reporting Logs

Logs shared daily for trial visibility and CRO coordination.

Encrypted Transfer / API

Results via encrypted channels or API integration with CRO platforms.

STAT Capability

Priority processing available for time-critical or urgent trial samples.

Regulatory Readiness & Data Security

Audit Readiness

- Prepared for NABL, CAP, GCC & CRO pre-qualification visits
- Record retention policies aligned to guidelines
- Instrument calibration logs — maintained & accessible
- QC logs and EQAS reports readily available
- Staff competency records and training documentation
- SOPs and checklists for every testing phase
- Audit trail via LIS — every entry timestamped

Data & Confidentiality

HIPAA-Compliant LIS

Role-based access. Patient data protected at all system levels.

Encrypted Result Transfer

Results via encrypted channels. API integration with CRO platforms.

Full Audit Trail

Every entry and modification logged with timestamp in LiveHealth LIS.

All records and documentation available on-site for regulatory inspection at any time.

Our Team & Point of Contact



Dr. Priyanka Somwanshi

CEO & Founder · MBBS, MD Pathology

MBBS — KEM Hospital, Mumbai (MUHS Nashik, 2007)
MD Pathology — VIMS & RC Whitefield, Bengaluru (RGUHS, 2014)
3+ yrs CRO Experience as Authorized Signatory · 15+ yrs Diagnostics

Our Team for CRO Engagements

Dedicated SPOC

Single Point of Contact per CRO client. Fast response and coordination.

Clinical Lab Scientists

Competency-certified, experienced in trial-related workflows.

Lab Technicians

Skilled in sample handling, processing, and pre-analytical QC.

Quality Manager

Daily QC oversight, EQAS participation, and audit documentation.

Research Work & Academic Expertise

Completed Research Projects

COMPLETED

AI-based Ki-67 Scoring in Sarcomas

Application of AI to automate Ki-67 proliferation index scoring in sarcoma histopathology — demonstrating capability in computational pathology and research-grade sample analysis.

COMPLETED

AI-based Gleason Scoring in Prostate Carcinoma

AI models applied to standardize Gleason grading in prostate cancer pathology — advancing AI-driven diagnostic accuracy in oncological research workflows.

COMPLETED

HER-2/neu Detection in Gastroesophageal Adenocarcinomas

Histopathological study of upper GI endoscopic biopsies with special emphasis on detection of HER-2/neu in gastroesophageal adenocarcinomas — clinically relevant for targeted therapy eligibility.

Special Expertise

Clinical Pathology

Specialized in body fluid analysis, urine pathology, and clinical specimen handling.

FNAC Expertise

Fine Needle Aspiration Cytology — key for clinical trials involving tissue sampling.

Audit Preparation

Deep experience in NABL, CAP, GCC, and pre-qualification CRO audit preparation.

Clinical Sample Handling

Specialized protocols for research-grade handling and processing of human samples.

Location Advantage & Clinical Network

Strategically located in Whitefield, Bangalore — the city's most active corridor for clinical trials, research hospitals, and technology enterprises.

Nearby Hospitals

- Manipal Hospital Whitefield
- Vydehi Hospital
- Sri Sathya Sai Hospital
- Cloudnine Hospital
- Medicover Hospitals
- Devi Eye Hospital
- Lions Airport City Hospital
- Laxmi Nursing Home
- Dino Hospital

Nearby Tech Parks

- ITPL – International Tech Park
- Brigade Tech Park
- Prestige Tech Park
- Bagmane Tech Park
- Sigma Tech Park

Trial-Heavy Zones

- Vydehi Hospital
- Manipal Hospital Whitefield
- Sri Sathya Sai Hospital
- Bangalore pharma & biotech cluster
- Easy access to all major CRO offices

Hospital Network: Medicover · Devi Eye Hospital · Dino Hospital · Lions Airport City Hospital · Laxmi Nursing Home

Our Facility





Reception & Waiting Area



Erba XL 200



Lab — Hematology · Biochemistry · Serology Stations



Erba H560 (Hematology) & EC90 Analyzers

Our Partnership Intent

What We're Looking For

Clinical Trial Sample Processing

Seeking CRO partners who need a reliable, research-oriented lab for sample testing, processing, and reporting.

Long-Term Partnerships

Interested in sustained relationships with CROs and pharma companies — not just project-by-project engagements.

Protocol Co-Development

Open to co-developing lab manuals and SOPs tailored to your trial protocols from the ground up.

Pilot / Dry-Run Engagements

Happy to begin with a mock run or pilot phase — giving your team confidence before committing to a full study.

What We Bring to the Table

- ✓ NABL-accredited, GCP/GLP-compliant lab
- ✓ Leadership with 3+ yrs direct CRO experience
- ✓ Research-oriented — not a routine diagnostic lab
- ✓ Fully automated, LiveHealth LIS integrated
- ✓ Cold chain with 15-min temperature logging
- ✓ NABL, CAP, GCC & pre-qual CRO audit experience
- ✓ Active research in AI-based pathology scoring
- ✓ Whitefield — Bangalore's clinical trial corridor
- ✓ Transparent, flexible, and fast communication

Additional Capabilities & Flexibility

1 Dry-Run Capability

Mock sample run before trial initiation — de-risking the workflow before Day 1.

4 Home & Multi-Site Collection

Home collection plus active logistics across Bangalore for multi-location pickup.

5 AI-Assisted Pathology

Completed research in AI-based Ki-67, Gleason scoring & HER-2/neu — future-ready for AI-integrated workflows.

2 Co-Developed Lab Manuals

Collaborate to develop SOPs and lab manuals specific to your trial protocol.

3 Scalable Volumes

Infrastructure to scale volumes across trial phases with uniform quality standards.

6 Fast Communication

Rapid issue resolution. Daily coordination touchpoints available for CRO project managers.

Documents Available for CRO Review

All the following documents are maintained, current, and available for inspection at any time — including pre-qualification CRO audits and regulatory site visits.

Q — Quality Manual

Full QMS documentation — policies, objectives, and scope of the quality management system.

S — QMS Records

Complete quality management system records including procedures, work instructions, and forms.

E — Equipment Maintenance

IQ, OQ, PQ documentation for all instruments plus calibration logs and service records.

X — EQAS Data

External Quality Assurance Scheme participation records — RML and other national schemes.

N — NC, CAPA & Risk Mitigation

Non-conformance records, Corrective/Preventive Actions, and Risk Management documentation.

V — Vendor Qualification

Supplier qualification, evaluation, and approval records for all reagents and consumables.

K — Stock Maintenance

Inventory management records including reagent tracking, expiry monitoring, and stock logs.

M — Sample Stability Data

Validated sample stability data for all specimen types and storage conditions.

T — Staff Training Records

Competency assessments, training logs, and certification records for all lab personnel.

L — LIS Verification (IQ/OQ/PQ)

LiveHealth LIS installation, operational, and performance qualification documentation.

D — Daily Logs

Day-to-day QC logs, instrument run records, and operational checklists — all timestamped.

+ — And Many More…

SOPs, procedure manuals, audit trail reports, chain of custody records, and more available on request.

Let's Partner

Think of us as your diagnostic backbone — precise, professional, and research-ready.

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