INFINITY IVD / CAPITAL PROJECT SERIES

Turnkey Diagnostic Laboratory

Investor technical brief for patient reception, sample accessioning, pre-analytics, core laboratory automation, molecular diagnostics, microbiology, cold chain, LIS integration, quality readiness and controlled operational handover.

INDICATIVE CAPEX

USD 0.8-4.5M

Excludes land, tax, duty and finance

DELIVERY

6-12 months

Design basis to qualified operation

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01 / CAPITAL DECISION

The laboratory in one investment view

Preliminary ranges for service planning, financing, equipment strategy and formal feasibility commissioning.

CAPITAL BAND

USD 0.8-4.5M

Equipment + fit-out + digital + qualification

GROSS FOOTPRINT

350-1,800 m2

Department mix and risk dependent

DELIVERY

6-12 months

Approved design basis to OQ

CAPACITY

500-6,000/day

Samples; mix and shifts dependent

A

Hospital laboratory

Routine chemistry, immunoassay, haematology, coagulation, urinalysis and selected molecular testing.

B

Central laboratory

Higher automation, broader menu, referral logistics, microbiology and integrated molecular departments.

C

Boundary

Range excludes land, finance, tax, import duty, working capital and off-site utility reinforcement unless contracted.

02 / CLINICAL MODEL

The test menu—not the equipment catalogue—sets the design basis

Population, referral structure, daily and peak arrivals, turnaround targets and clinical criticality are frozen before platform selection.

CHEMISTRY & IMMUNOASSAY

Routine and specialty chemistry, hormones, infectious serology and cardiac markers.

HAEMATOLOGY

CBC, morphology support, ESR and reticulocyte workflows sized to peak arrivals.

COAGULATION

Routine PT/APTT through specialised haemostasis depending on referral scope.

MOLECULAR DIAGNOSTICS

Separated reagent, extraction and amplification zones with contamination control.

MICROBIOLOGY

Biosafety cabinet work, culture, incubation, identification and susceptibility testing.

URINALYSIS & SPECIAL TESTS

Automated urinalysis plus electrophoresis, allergy or reference testing where justified.

03 / OPERATING FLOW

Every handoff is designed for identity, speed and traceability

01

Register & collect

Positive patient identification, order entry, labels and collection instructions.

02

Transport & receive

Defined packaging, route, time/temperature limits and rejection criteria.

03

Accession & sort

Barcode scan, prioritisation, centrifugation, decapping and aliquoting.

04

Analyse

Discipline-specific systems with calibration, QC and reflex-testing rules.

05

Validate & report

Technical/autoverification, clinical review, LIS release and critical-result escalation.

06

Retain & dispose

Defined sample retention, cold storage, waste segregation and complete genealogy.

04 / ARCHITECTURE

Patient, specimen, staff and waste routes do not compete

PUBLIC

Reception, waiting and phlebotomy remain outside technical circulation.

ACCESSIONING

One controlled sample handoff feeds pre-analytics and priority routing.

CORE LAB

Open, observable analytical floor with service clearances and expansion lanes.

PCR SUITE

Reagent, extraction and amplification rooms follow a one-way clean-to-dirty logic.

MICROBIOLOGY

BSC work, incubation and decontamination are segregated by biological risk.

SUPPORT

Cold chain, wash-up, waste, stores, staff, IT and utilities have dedicated access.

Routine laboratories usually use controlled, risk-based rooms rather than a pharmaceutical cleanroom. PCR and microbiology controls are process-specific; final pressure relationships, biosafety level and containment follow the approved menu and national rules.

05 / THROUGHPUT

Capacity is modelled around the busiest hour

Nominal analyser speed is discounted for loading, reruns, maintenance, QC, calibration, reflex testing and sample-mix variability.

TIER 1

500-1,500 samples/day; modular pre-analytics; one shift plus emergency cover.

TIER 2

2,000-3,500 samples/day; consolidated platforms, redundancy and extended operating hours.

TIER 3

4,000-6,000 samples/day; automated track, referral logistics and multi-shift operation.

PEAK FACTOR

Hourly arrivals, inpatient/outpatient mix and emergency STAT workload drive buffers.

OEE BASIS

Validated uptime, planned maintenance, reagent loading and rerun rates are explicit.

EXPANSION

Reserved utility, bench, track and cold-storage capacity protects later growth.

06 / PROCUREMENT

A vendor-neutral analytical and operational ecosystem

01

Pre-analytics

Sorters, centrifuges, decappers, aliquoters, sample archive and track options.

02

Core systems

Chemistry, immunoassay, haematology, coagulation and urinalysis platforms.

03

Molecular

Extraction, PCR/RT-qPCR, clean cabinets, cold chain and contamination controls.

04

Microbiology

BSCs, incubators, autoclave interface, identification and susceptibility systems.

05

Support

Refrigerators, freezers, water, gases, UPS, furniture and safety equipment.

06

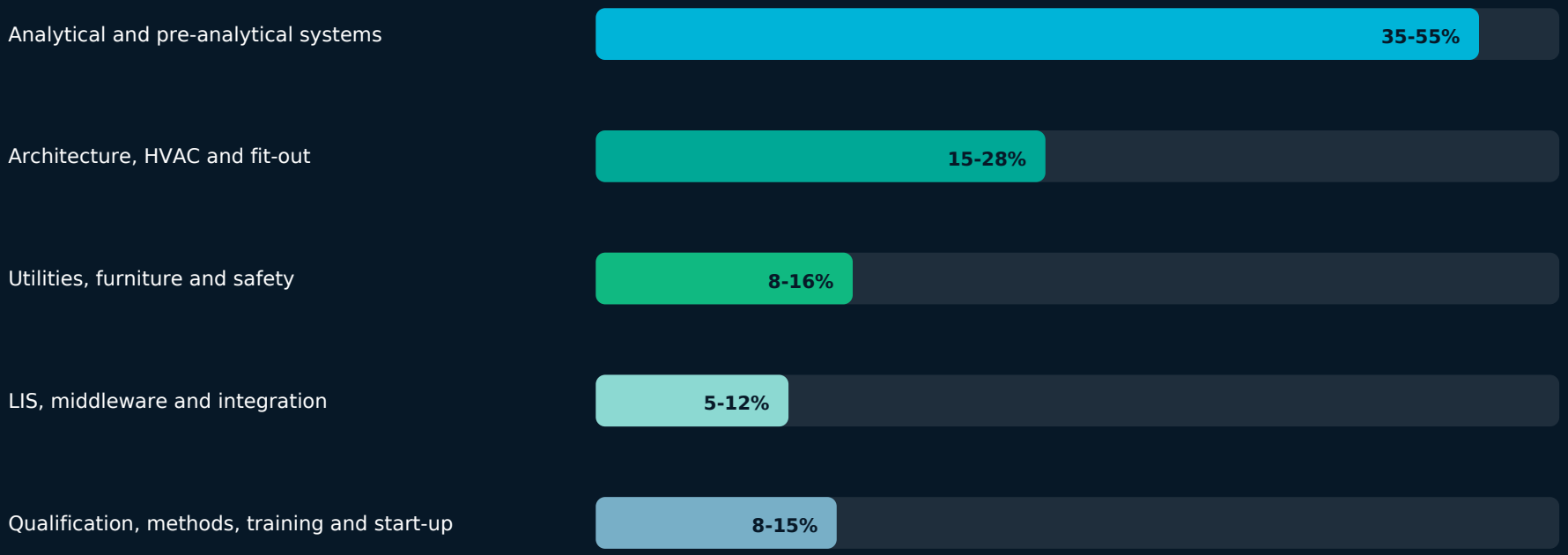
Digital

LIS, middleware, analyser interfaces, autoverification, cybersecurity and backup.

07 / CAPEX CONTROL

What the USD 0.8-4.5M band includes

Final allocation follows menu, automation, redundancy, service model, site condition and supplier quotations.



The lower band assumes a compact routine laboratory in an adaptable building. The upper band includes multi-discipline reference scope, greater automation, redundancy, molecular/microbiology suites and expanded digital integration.

08 / SITE READINESS

Power, water, HVAC and data continuity protect every result

01

Electrical

Conditioned supply, UPS for analysers/IT and generator coverage for critical loads.

02

Water

Analyser-grade or purified water sized by platform, regeneration and peak demand.

03

HVAC

Temperature, humidity, filtration, pressure and heat-load control by department.

04

Gases & air

CO2, compressed air or specialty gases only where the selected methods require.

05

Cold chain

Mapped 2-8C, frozen and ultra-low storage with alarm and backup strategy.

06

Waste & drainage

Infectious, chemical, sharps and liquid waste routes matched to local regulation.

09 / ISO 15189 PATHWAY

Accreditation readiness begins before installation

The laboratory is configured for documented competence; accreditation is decided by the independent national accreditation body.

METHOD VERIFICATION

Precision, bias/comparison, reportable range, reference intervals and uncertainty.

QUALITY CONTROL

Internal QC rules, lot change, calibration, Westgard strategy and corrective action.

EQA / PT

Programme selection, submission, review, investigation and improvement.

EQUIPMENT LIFECYCLE

URS, IQ/OQ, calibration, maintenance, service and downtime control.

DATA INTEGRITY

User roles, audit trail, interface validation, backup, recovery and cybersecurity.

COMPETENCY

Role profiles, training, observation, authorisation and periodic reassessment.

10 / CONNECTIVITY

The digital chain is part of the laboratory—not an afterthought

01

Order entry

Hospital, clinic, outreach and manual orders share controlled identifiers.

02

Instrument interfaces

Bidirectional orders/results reduce transcription and routing errors.

03

Middleware

Rules manage reruns, reflexes, autoverification and delta checks.

04

Critical results

Escalation, acknowledgement and audit evidence are configured by policy.

05

Dashboards

Turnaround, QC, workload, rejection and analyser utilisation support management.

06

Continuity

Offline procedures, resilient servers, backup and validated recovery protect service.

11 / PEOPLE

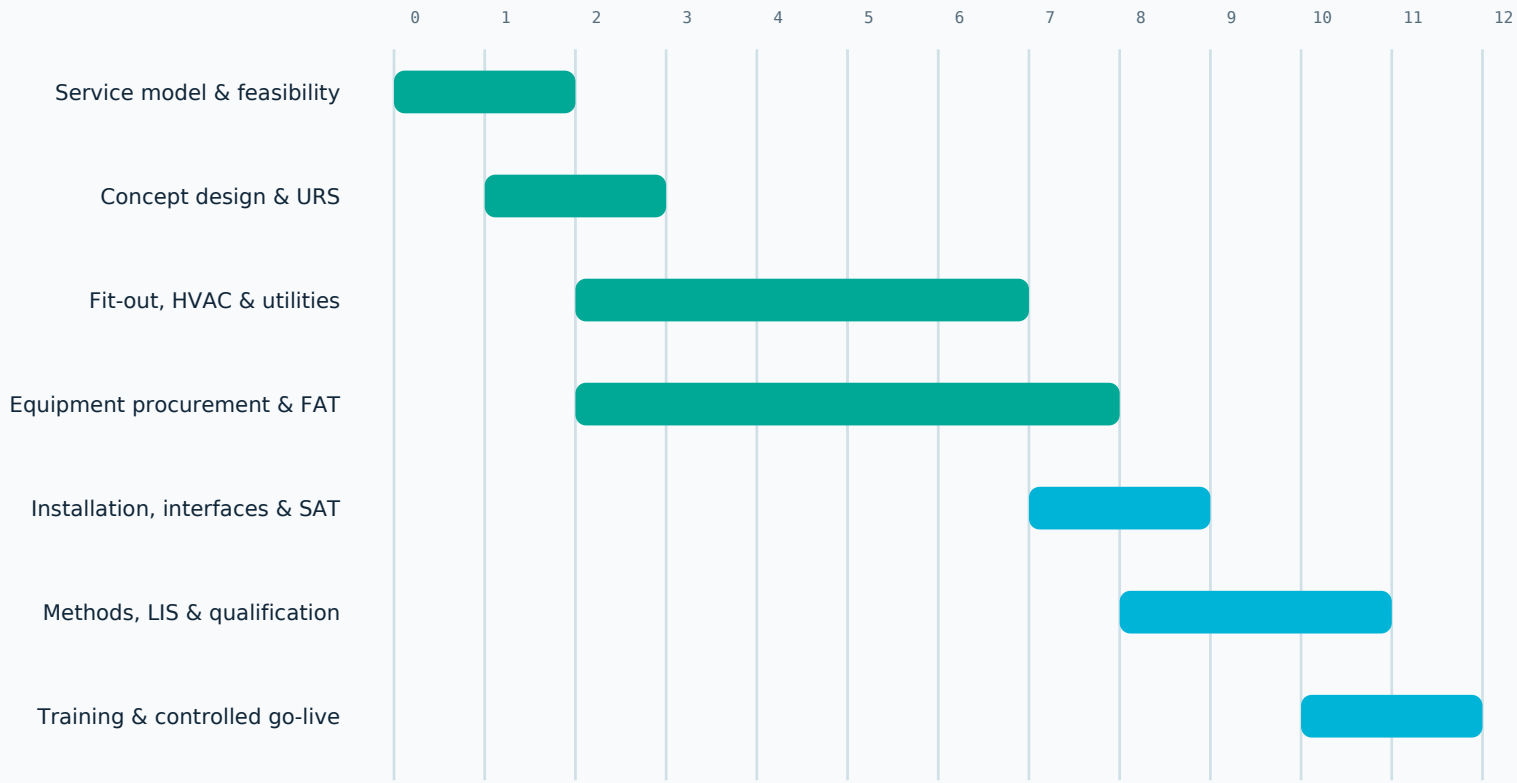
Indicative staffing: 18-80 FTE

Reception / phlebotomy	4-18 FTE	Patient identity, collection, routing and service desk
Core laboratory	6-26 FTE	Chemistry, immunoassay, haematology, coagulation and urinalysis
Molecular / microbiology	3-16 FTE	Extraction, PCR, culture, identification and biosafety
Quality / clinical oversight	2-7 FTE	Medical validation, QMS, QC, EQA and accreditation
IT / engineering	1-5 FTE	LIS, interfaces, utilities, calibration and maintenance

Training package: 4-10 weeks covering platforms, methods, biosafety, quality, LIS, critical-result workflows, maintenance and supervised go-live. Final staffing follows operating hours, menu and local professional rules.

12 / EXECUTION

6-12 months from design basis to controlled go-live



MONTH 0 = APPROVED SERVICE MODEL, SITE, MENU, CAPACITY AND DESIGN BASIS. LICENSING / ACCREDITATION REVIEW IS AUTHORITY-DEPENDENT.

13 / INVESTMENT RISK

Failure modes that must be designed out

Laboratory performance is controlled across identity, analytical quality, capacity, utilities and data—not by analyser procurement alone.

IDENTITY ERROR

Positive identification, barcode controls, rejection rules and complete chain of custody.

CARRYOVER / CONTAMINATION

Zoning, cleaning, PCR separation, BSC practice and environmental controls.

QC OR CALIBRATION FAILURE

Rules, lockouts, trend review, lot-change verification and escalation.

TURNAROUND BOTTLENECK

Peak-hour modelling, buffers, redundancy, STAT routing and workload dashboards.

POWER / COLD-CHAIN LOSS

UPS, generator, alarms, mapping, excursion response and business continuity.

INTERFACE / DATA FAILURE

Validated interfaces, audit trails, access control, backup and manual fallback.

14 / OUTPUTS

What the client receives before operational handover

01

Feasibility package

Demand, menu, capacity tiers, CAPEX/OPEX boundary and risk register.

02

Design package

Department schedule, concept layout, flows, room data and utility basis.

03

Procurement package

Equipment URS, comparison, scope matrix, FAT/SAT and lifecycle assumptions.

04

Quality package

Method verification, QC/EQA, equipment, biosafety and document framework.

05

Digital package

LIS architecture, interfaces, rules, cybersecurity and continuity plan.

06

Handover package

Training, supervised go-live, open-item closure and performance review.

15 / NEXT DECISION

Commission the diagnostic laboratory feasibility study

This document is an indicative engineering envelope. The feasibility gate converts it into a country-, menu-, capacity- and site-specific investment case.

- Country, city and intended site
- Population and referral network
- Daily and peak sample volume
- Test menu and turnaround targets
- Operating hours and staffing baseline
- Existing equipment / LIS / building
- Accreditation and licensing target
- Budget, financing and launch date

REQUEST A FACILITY-SPECIFIC STUDY

Start the laboratory feasibility gate.

Receive a service model, workload forecast, department schedule, zoning concept, equipment boundary, CAPEX/OPEX estimate, delivery programme, licensing pathway and operational risk register.

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