INFINITY IVD / CAPITAL PROJECT SERIES

Molecular Test Production Facility

Investor technical brief for PCR and RT-qPCR reagent and kit manufacturing - from oligonucleotide control through validated finished kits.

INDICATIVE CAPEX

USD 2.4-6.8M

Excludes land, tax, duty and finance

DELIVERY

12-18 months

Design basis to validated pilot batch

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01 / CAPITAL DECISION

The facility in one investment view

A defensible starting basis for site screening, financing discussion and feasibility commissioning.

CAPITAL BAND
USD 2.4-6.8M
Equipment + cleanroom + qualification

GROSS FOOTPRINT
1,200-2,800 m2
350-900 m2 controlled production

INSTALLED CAPACITY
1-12M tests/year
Tier and product-mix dependent

READINESS ROUTE
ISO 13485 / IVDR
Authority decision remains independent

A
Facility output

Liquid or freeze-dried PCR and RT-qPCR reagent kits, controls, labelled components and validated finished configurations for a defined diagnostic portfolio.

B
Local value

Reduces dependency on finished-kit imports while building formulation, filling, molecular QC, stability and batch-release capability in-country.

C
Decision boundary

Portfolio, format, annual demand, site utilities, registration strategy and make-versus-buy scope are fixed before equipment procurement.

02 / DEFINE BEFORE DESIGN

Portfolio architecture drives the factory

A PCR facility is not a generic line. Product format, panel complexity and cold-chain strategy determine zoning, equipment and validation effort.

- Target applications: respiratory, transplant monitoring, antimicrobial resistance, veterinary, food or plant health.
- Format: liquid master mix, component kit or lyophilised reaction format.
- Configuration: singleplex, multiplex, qualitative or quantitative.
- Pack sizes, controls, extraction compatibility and instrument channel mapping.
- Destination markets, classification, language and traceability requirements.

Investor questions answered at Gate 1

- What annual addressable demand is bankable?
- Which products justify local formulation versus imported bulk?
- What validated batch size balances cost and expiry risk?
- Which claims and markets define the evidence package?
- What capacity is required at one and two shifts?
- Which inputs remain dependent on international suppliers?

03 / PROCESS ARCHITECTURE

From controlled inputs to released kits

01

Receipt & quarantine

Primers, probes, enzymes, buffers, controls and packaging are status-labelled and segregated.

02

Oligo preparation

Identity, concentration and controlled dilution are performed with mix-up prevention.

03

Master-mix formulation

Temperature-controlled formulation with calibrated gravimetric or volumetric control.

04

Aliquot or lyophilise

Automated/semi-automated filling; optional freeze-drying and residual-moisture control.

05

Kit assembly

Controls, reaction components, IFU and labels are reconciled into saleable configurations.

06

QC & release

Performance, fill volume, identity, contamination, stability and documentation are reviewed.

CONTROL PRINCIPLE: UNI-DIRECTIONAL MATERIAL STATUS + PHYSICAL PRE/POST-AMPLIFICATION SEPARATION

04 / FACILITY CONCEPT

Clean environment by process risk - not by habit

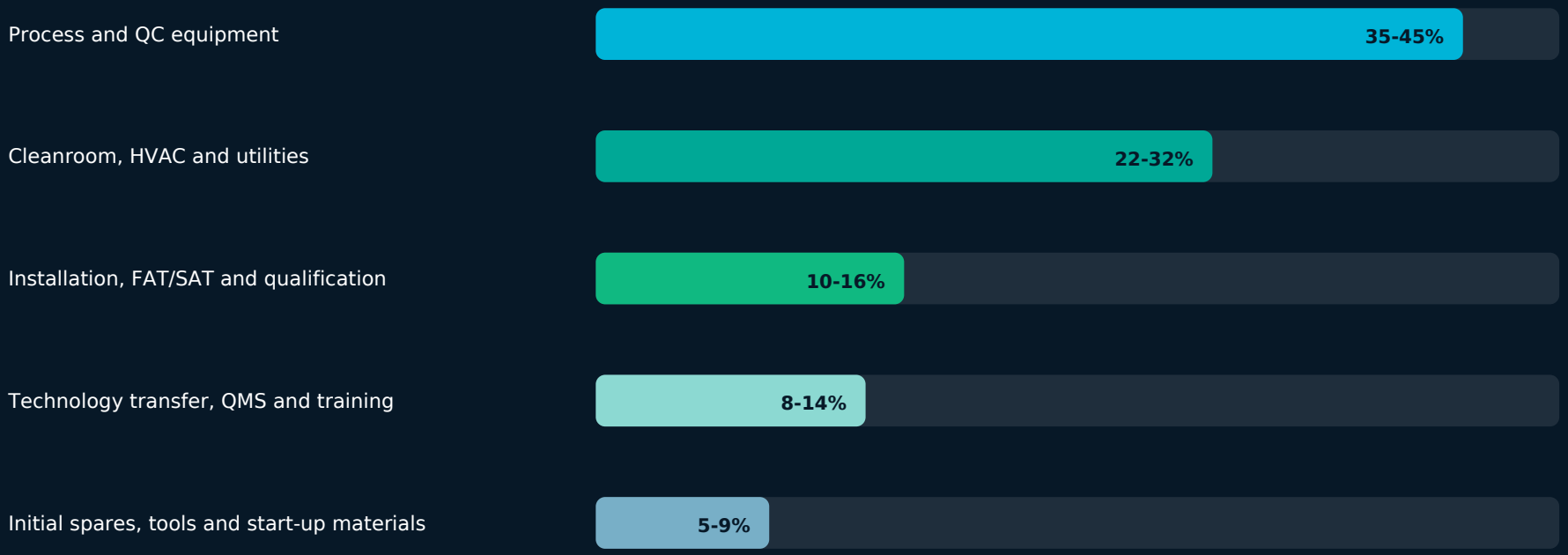
UNCLASSIFIED / CONTROLLED	Receiving, quarantine, packaging warehouse, offices and technical rooms.
ISO 8 TYPICAL	Preparation support, kitting and controlled production where exposed-product risk is limited.
ISO 7 LOCAL ZONES	Open formulation/filling protection where the documented contamination-control assessment requires it.
SEGREGATED QC	Reagent preparation, extraction and amplification rooms separated to prevent amplicon contamination.

Indicative footprint: 1,200-2,800 m2 gross, including 350-900 m2 controlled production. Final areas are established through room data sheets, personnel/material flows, equipment maintenance clearances and local building-code requirements.

05 / CAPEX CONTROL

What the USD 2.4-6.8M band includes

Percentages below are an indicative allocation envelope, not a quotation. Final values are issued after URS and site survey.



Excluded unless expressly added: land, finance cost, tax, import duty, major off-site utility reinforcement, commercial working capital, authority fees and client-side civil remediation.

06 / OUTPUT MODEL

Capacity is validated output - not nameplate speed

TIER 1

1-3 million tests/year

Semi-automated or focused automated filling; selected product portfolio; one to two shifts; liquid format or limited lyophilisation; modular QC capacity.

TIER 2

5-12 million tests/year

Higher automation, parallel formulation/filling, expanded cold storage and QC throughput; two shifts; product-mix and lyophilisation-cycle dependent.

Required calculation inputs

- Validated batch size and batch frequency
- Tests per kit and pack-size mix
- Liquid versus freeze-dried cycle time
- Planned shifts, changeovers and maintenance
- Target yield, QC sampling and release lead time
- Demand ramp, expiry exposure and safety stock

07 / PROCUREMENT BOUNDARY

Vendor-neutral equipment architecture

A

Materials & cold chain

Monitored 2-8 C, frozen storage, quarantine, dispensing and temperature mapping.

B

Formulation

Calibrated balances, cold blocks, mixers, liquid handling and controlled transfer.

C

Filling & closure

Automated/semi-automated aliquoting, capping, label and in-process fill checks.

D

Lyophilisation option

Lyophiliser, loading protection, moisture control and residual-moisture verification.

E

Molecular QC

Extraction, PCR/RT-qPCR, plate handling, contamination control and data systems.

F

Packaging & traceability

Kit assembly, label reconciliation, coding, vision checks and secondary packing.

08 / SITE READINESS

Utilities are part of process capability

POWER

Redundant supply, UPS for critical QC/data systems and controlled generator transfer.

HVAC

18-25 C process basis, pressure cascade, filtration and humidity control where formats require.

COLD CHAIN

Mapped 2-8 C and frozen storage with alarms, backup power and excursion response.

WATER

Potable/purified-water strategy defined by formulation and cleaning requirements.

DATA

Access control, audit-ready records, backup, equipment interfaces and

WASTE

Chemical, biological and packaging waste segregation with compliant

Feasibility deliverable: site utility gap assessment, load list, room data sheets, redundancy philosophy and owner-versus-EPC responsibility matrix.

09 / VALIDATION ROUTE

Facility readiness and product authorisation are separate

Infinity structures the contracted QMS, qualification and technical-documentation work. Certification and market authorisation remain decisions of independent competent bodies.

01

Design qualification

URS, layouts, risk assessments and design review

02

FAT / SAT

Documented equipment acceptance before and after installation

03

IQ / OQ

Installation and operational qualification against approved protocols

04

Process validation

Pilot and validation lots, methods, cleaning and hold-time controls

05

QMS readiness

ISO 13485 procedures, records, training and internal audit

06

Technical dossier

IVDR/local registration evidence architecture and submission support

10 / PEOPLE AND KNOW-HOW

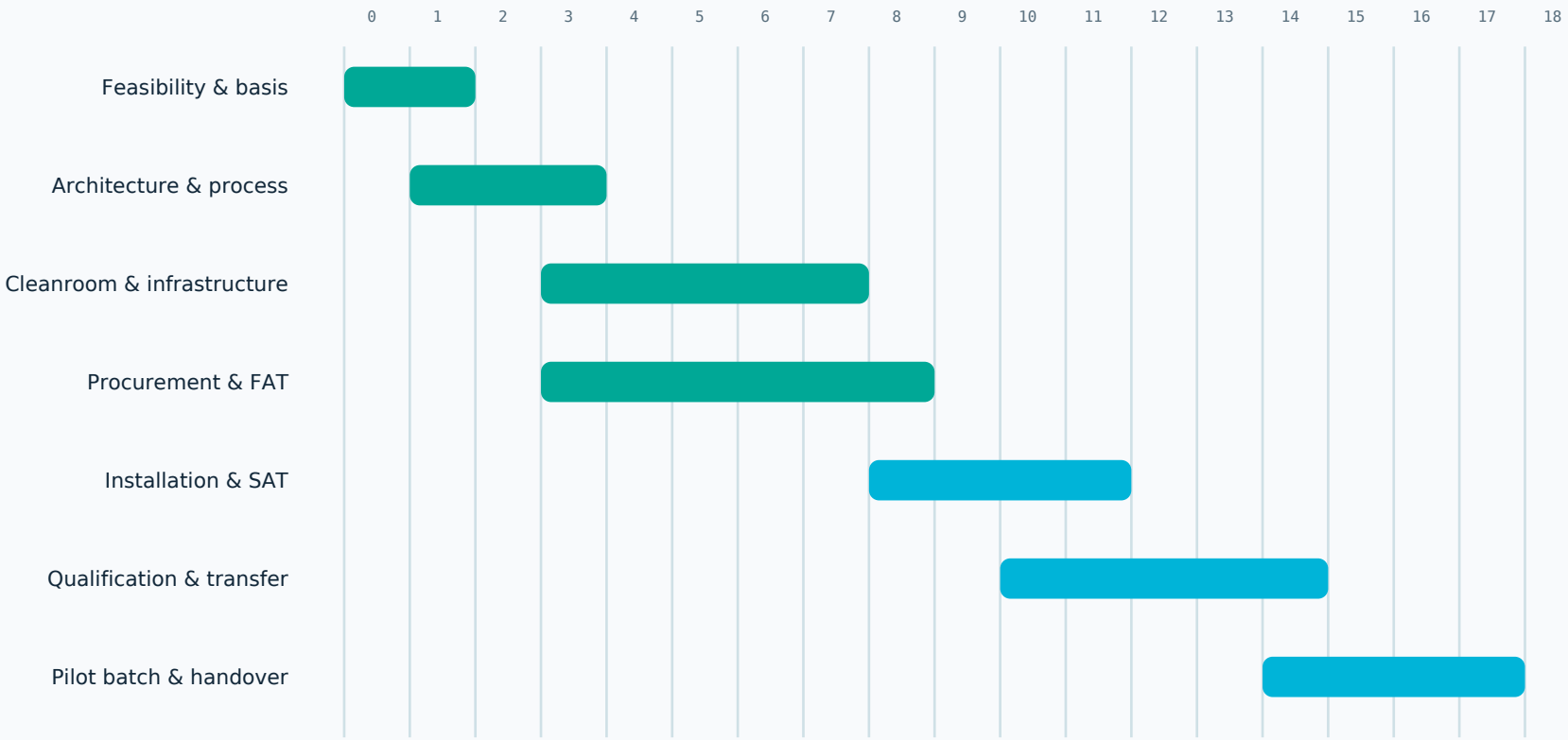
Indicative staffing: 22-55 FTE

Production	8-20 FTE	Formulation, filling, kitting and line supervision
Molecular QC	4-10 FTE	Incoming, in-process, performance and release testing
QA & Regulatory	3-8 FTE	QMS, batch review, deviations, validation and dossiers
Warehouse & Planning	3-7 FTE	Status control, cold chain, inventory and scheduling
Engineering	2-6 FTE	Utilities, calibration, maintenance and automation

Transfer package: 6-12 weeks role-based training, approved SOPs, equipment training, supervised pilot batches, competency records and controlled handover of process know-how.

11 / EXECUTION

12-18 months from design basis to validated pilot batch



MONTH 0 = APPROVED DESIGN BASIS. PERMITS, CUSTOMS AND CLIENT APPROVAL DELAYS ARE OUTSIDE THE BASE PROGRAMME UNLESS CONTRACTED.

12 / INVESTMENT RISK

Failure modes that must be designed out

Primer/probe mix-up	Barcode/status control, segregation, independent reconciliation and identity testing.
Enzyme activity loss	Qualified cold chain, alarmed storage, excursion assessment and supplier controls.
Amplicon contamination	Physical workflow separation, pressure strategy, cleaning and environmental controls.
Fill-volume drift	Calibrated liquid handling, in-process checks, trending and preventive maintenance.
Stability failure	Defined transport profile, real-time/accelerated programme and packaging qualification.
Demand below capacity	Phased automation, portfolio prioritisation and financing tied to validated demand.

13 / NEXT DECISION

Inputs required for a bankable feasibility package

This brief is a preliminary engineering envelope. The feasibility gate converts it into a site-, market- and portfolio-specific investment decision.

- Country, city and intended site
- Target product list and formats
- Annual demand and ramp assumptions
- Budget band and financing source
- Building/land status and utility evidence
- Target operational date
- Destination markets and regulatory strategy
- Client-supplied equipment or infrastructure

REQUEST A FACILITY-SPECIFIC STUDY

Start the project feasibility gate.

Submit the project location, portfolio, site condition, target capacity, budget and schedule through the secure project desk.

infinityivd.com/start-project

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