INFINITY IVD / CAPITAL PROJECT SERIES

Rapid Test Production Facility

Investor technical brief for lateral-flow manufacturing - from conjugate and membrane preparation through assembled, pouched and released rapid diagnostic tests.

INDICATIVE CAPEX

USD 1.8-5.5M

Excludes land, tax, duty and finance

DELIVERY

10-16 months

Design basis to validated pilot lot

ISSUE 01 / AUGUST 2026 / INDICATIVE

01 / CAPITAL DECISION

The facility in one investment view

A starting basis for localisation strategy, site screening, financing and formal feasibility commissioning.

CAPITAL BAND

USD 1.8-5.5M

Equipment + controlled environment + qualification

GROSS FOOTPRINT

1,000-2,500 m2

300-850 m2 controlled production

INSTALLED CAPACITY

5-60M tests/year

Tier, format and automation dependent

READINESS ROUTE

ISO 13485 / IVDR

WHO PQ support where applicable

A

Facility output

Lateral-flow rapid tests in cassette, strip or other validated configurations with labelled components, desiccant pouching and controlled finished-goods release.

B

Local value

Builds coating, conjugation, lamination, cutting, assembly, packaging, stability and lot-release capability rather than packaging imported finished tests.

C

Decision boundary

Analyte portfolio, membrane system, automation tier, humidity basis, packaging format and regulatory destination are fixed before equipment orders.

02 / DEFINE BEFORE DESIGN

The test portfolio determines the production system

Cassette geometry alone does not define a factory. Reagent chemistry, membrane behaviour, sample matrix and shelf-life target control the investment.

- Target analytes and intended-use settings: infectious disease, fertility, cardiac, toxicology, food or veterinary.
- Label system: colloidal gold, coloured latex, fluorescent particle or other validated reporter.
- Sample matrix, required sensitivity, test time, hook-effect and interference profile.
- Strip dimensions, cassette tooling, packaging barrier and target shelf life.
- Destination markets, product classification, languages and traceability rules.

Investor questions answered at Gate 1

- Which tests have bankable local and export demand?
- Which biological inputs remain import-dependent?
- What production yield is validated at target line speed?
- How much low-humidity area is actually required?
- Which products justify manual, semi-automatic or automatic assembly?
- What stability programme supports the target climate?

03 / PROCESS ARCHITECTURE

From labelled particles to released tests

01

Reagent & conjugate

Prepare buffers, labelled particles and conjugate systems under controlled time, pH and mixing conditions.

02

Pad preparation

Treat sample and conjugate pads; dispense reagent and dry to a defined residual-moisture state.

03

Membrane dispensing

Apply test/control lines with calibrated dispense volume, position and curing conditions.

04

Lamination & cutting

Assemble membrane, pads and backing card; slit to validated strip width with particulate control.

05

Cassette & pouch

Insert strips, close cassettes, add desiccant and seal barrier pouches with lot coding.

06

QC & release

Verify sensitivity, specificity, background, flow time, line intensity, seal integrity and stability.

CONTROL PRINCIPLE: LOT-TRACEABLE REAGENT PREPARATION + HUMIDITY-CONTROLLED MEMBRANE PROCESSING + VERIFIED POUCH SEAL

04 / FACILITY CONCEPT

Humidity control is a process utility

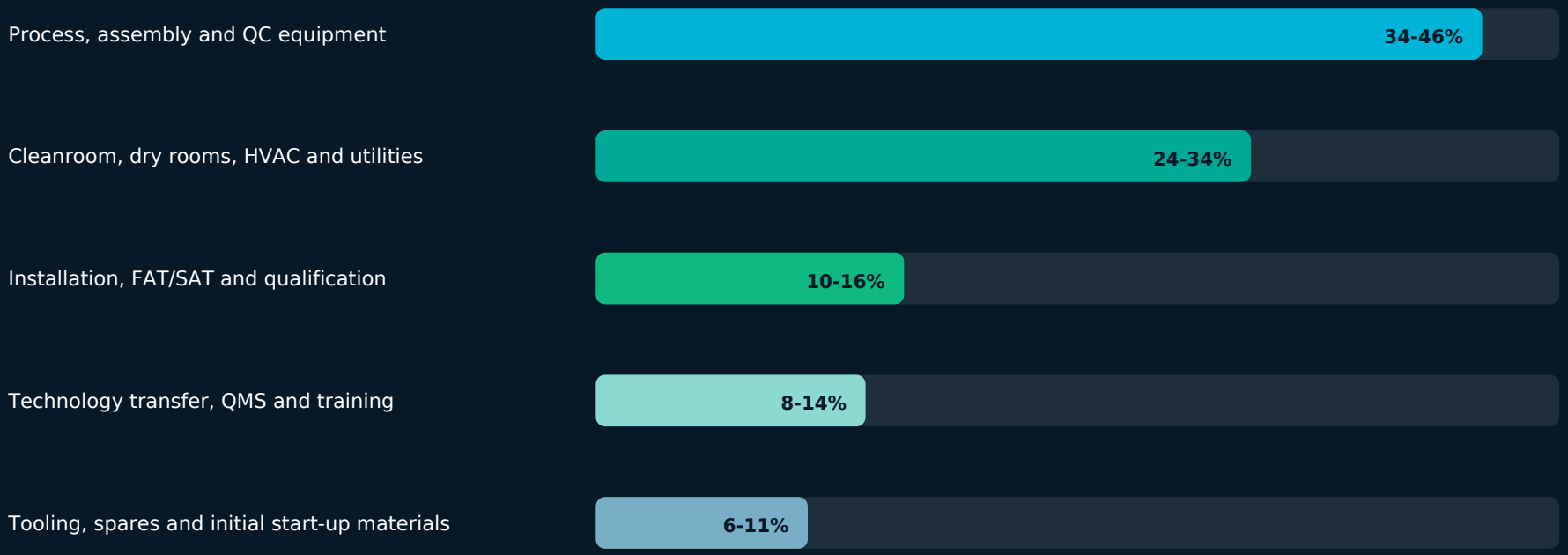
UNCLASSIFIED / CONTROLLED	Receiving, quarantine, component warehouse, carton packing, offices and technical rooms.
ISO 8 TYPICAL	Controlled reagent support, lamination, cutting, assembly and primary packaging as risk assessed.
LOW-HUMIDITY PROCESS	Membrane dispensing, drying, strip handling and pouching commonly require dedicated dry rooms, often at 30% RH or below where validated.
SEGREGATED QC	Wet chemistry, reader-based performance, microbiology where applicable, stability and packaging tests are separated from production.

Indicative footprint: 1,000-2,500 m2 gross, including 300-850 m2 controlled production. Final areas follow material/personnel flows, room data sheets, maintenance clearances, HVAC loads and local building requirements.

05 / CAPEX CONTROL

What the USD 1.8-5.5M band includes

The ranges below are an indicative allocation envelope, not a quotation. Final values follow URS, site survey and portfolio definition.



Excluded unless expressly contracted: land, financing, taxes, duty, off-site utility reinforcement, working capital, authority fees and client-side civil remediation.

06 / OUTPUT MODEL

Capacity depends on validated yield and product mix

TIER 1

5-15 million tests/year

Focused product mix; manual or semi-automated membrane handling and assembly; one to two shifts; modular packaging and QC capacity.

TIER 2

25-60 million tests/year

Automated lamination, cutting, cassette assembly, vision inspection and pouching; two shifts; higher dry-room and QC throughput.

Required calculation inputs

- Tests per strip/card and cassette format
- Validated line yield and scrap by process step
- Product changeover and cleaning time
- Shift pattern, planned maintenance and OEE
- Drying/curing dwell time and environmental recovery
- QC sampling, release lead time and stability inventory

07 / PROCUREMENT BOUNDARY

Vendor-neutral lateral-flow equipment architecture

A

Reagent preparation

Jacketed mixers, pH/conductivity control, filtration, balances and cold storage.

B

Dispensing & drying

Conjugate-pad systems, line dispensers, controlled drying cabinets or tunnels.

C

Lamination & cutting

Programmable laminators, card cutters, strip slitters and dust extraction.

D

Cassette assembly

Manual, semi-automatic or automatic insertion, closure and vision inspection.

E

Pouching & packing

Desiccant feed, foil pouch seal, leak test, coding, cartoning and reconciliation.

F

QC & stability

Readers, environmental chambers, imaging, flow-time and packaging test systems.

08 / SITE READINESS

Dry air, HVAC and packaging integrity are linked

POWER

Redundant supply, UPS for controls/QC and controlled generator transfer.

HVAC

Temperature stability, pressure cascade, filtration and recovery after access events.

DEHUMIDIFICATION

Dedicated low-dew-point system sized for infiltration, occupancy and process loads.

COMPRESSED AIR

Clean dry compressed air for automation, verified at points of use.

WATER

Potable/purified-water basis for buffer preparation and cleaning as required.

DATA & TRACEABILITY

Batch records, label control, vision data, calibration, backup and access

Feasibility output: utility gap assessment, room data sheets, humidity load basis, equipment load list 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, zoning, humidity basis, risk assessments and design review

02

FAT / SAT

Equipment acceptance, alarms, line functions and safety verification

03

IQ / OQ

Installation and operational qualification against approved protocols

04

Process validation

Dispense, drying, lamination, cutting, assembly and seal validation

05

QMS readiness

ISO 13485 procedures, records, training, audit and CAPA readiness

06

Technical dossier

IVDR/local registration and WHO PQ support where applicable

10 / PEOPLE AND KNOW-HOW

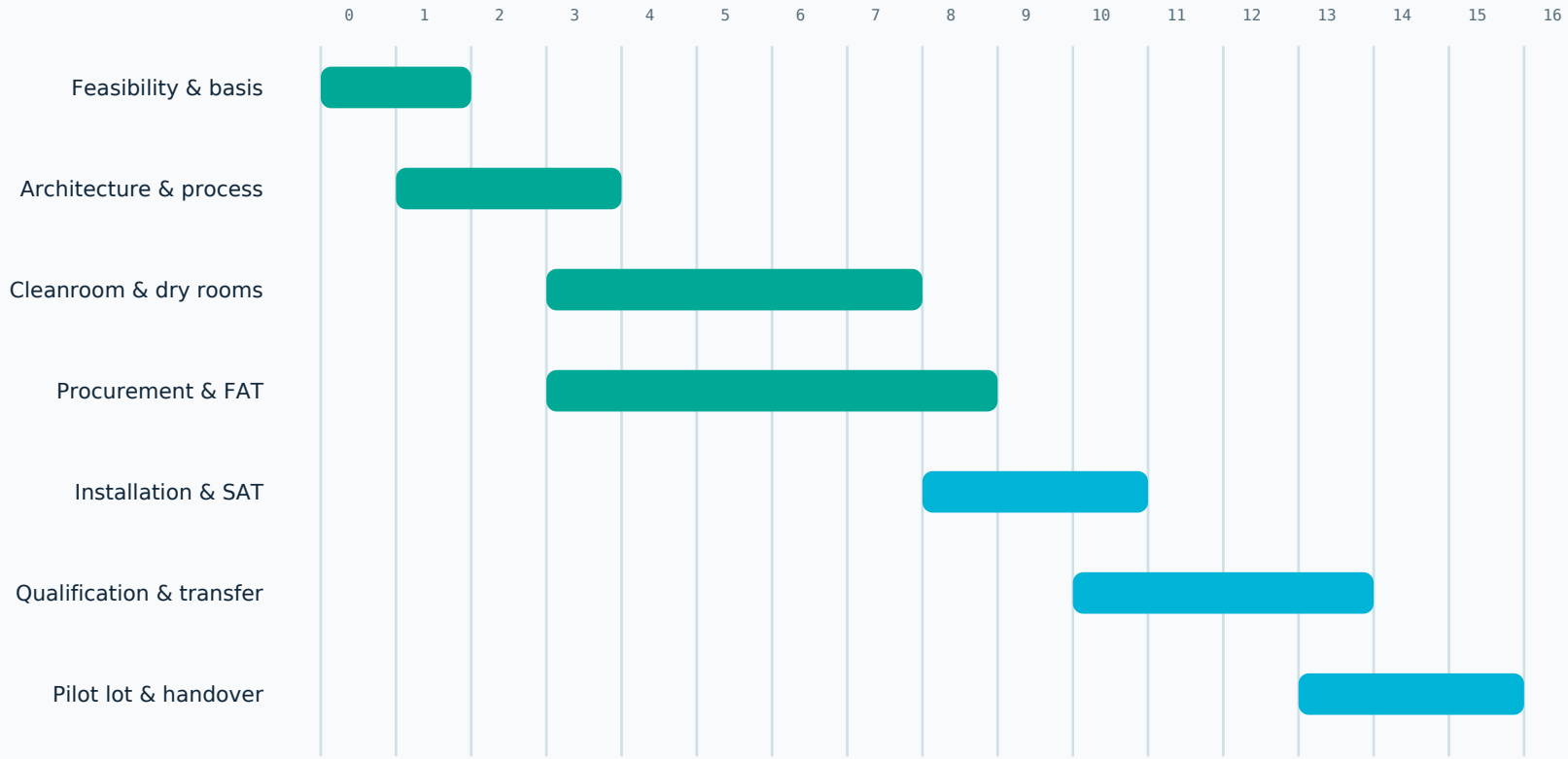
Indicative staffing: 28-75 FTE

Production	12-35 FTE	Reagent, dispensing, lamination, assembly and packaging
Quality control	5-12 FTE	Incoming, in-process, performance, seal and stability testing
QA & Regulatory	4-9 FTE	QMS, batch review, deviations, validation and dossiers
Warehouse & Planning	3-8 FTE	Status control, cold chain, inventory and scheduling
Engineering	2-7 FTE	HVAC/dry rooms, calibration, maintenance and automation

Transfer package: 6-10 weeks role-based training, controlled SOPs, equipment training, supervised engineering lots, competency records and three validation lots where scoped.

11 / EXECUTION

10-16 months from design basis to validated pilot lot



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

Conjugate aggregation	Qualified chemistry, pH/time control, mixing validation and release testing.
Membrane lot variability	Incoming qualification, supplier change control and lot-specific optimisation.
Dispense or line-position drift	Calibrated dispensers, vision checks, trending and preventive maintenance.
High background / weak signal	Controlled drying, conjugate release, blocking and analytical performance checks.
Moisture ingress	Low-humidity handling, desiccant control, seal validation and package integrity testing.
Capacity ahead of demand	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-, product- and market-specific investment decision.

- Country, city and intended site
- Target rapid-test portfolio
- Membrane/reagent ownership and transfer basis
- Annual demand and ramp assumptions
- Budget and financing source
- Building/land and utility evidence
- Target operational date
- Destination markets and regulatory route

REQUEST A FACILITY-SPECIFIC STUDY

Start the project feasibility gate.

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

infinityivd.com/start-project

CONFIDENTIALITY / NDA ROUTING AVAILABLE