INFINITY IVD / CAPITAL PROJECT SERIES

Blood Grouping Gel-Card Production

Investor technical brief for controlled gel preparation, reagent-cell processing, microcolumn filling, foil sealing, immunohaematology quality control and released finished cards.

INDICATIVE CAPEX

USD 3.2-8.5M

Excludes land, tax, duty and finance

DELIVERY

14-22 months

Design basis to validated pilot batches

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01 / CAPITAL DECISION

The facility in one investment view

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

CAPITAL BAND

USD 3.2-8.5M

Equipment + controlled environment + qualification

GROSS FOOTPRINT

1,500-3,500 m2

450-1,100 m2 controlled production

INSTALLED CAPACITY

3-25M cards/year

Portfolio, card format and shifts dependent

READINESS ROUTE

ISO 13485 / IVDR

Biological-material controls included

A

Facility output

Gel cards, qualified antisera or reagent-cell systems and finished immunohaematology kits produced under lot-controlled conditions.

B

Local value

Creates formulation, filling, sealing, biological QC, cold-chain and stability capability instead of importing finished cards.

C

Decision boundary

Portfolio, biological inputs, card configuration, automation tier and market route are fixed before machinery procurement.

02 / DEFINE BEFORE DESIGN

The portfolio determines biology, tooling and capacity

The factory is configured around assay families, reagent ownership, cell-panel strategy, cold-chain exposure and target registrations.

- ABO and Rh typing, antiglobulin and compatibility-testing portfolio to be localised.
- Card geometry, microcolumn count, gel matrix, foil system and analyser compatibility.
- Antisera source, reagent-cell preparation, donor qualification and traceability boundary.
- Manual, semi-automated or automated filling, sealing, inspection and packing tier.
- Shelf-life target, transport climate, 2-8 C controls and stability inventory requirement.

Gate 1 investor decisions

- Which card families have bankable demand?
- Which biological inputs are local or imported?
- Is cell-panel production inside the project boundary?
- Which analysers and centrifugation profiles must be matched?
- What cold-chain resilience is required?
- Which IVDR/local classification route applies?

03 / PROCESS ARCHITECTURE

From gel formulation to released cards

01

Gel preparation

Controlled mixing, hydration, pH, density, viscosity and vacuum degassing.

02

Biological reagents

Antisera or reagent-cell preparation, qualification, standardisation and cold holding.

03

Microcolumn filling

Precision fill-volume control with bubble, carryover and column-uniformity prevention.

04

Foil sealing

Alignment, heat-seal profile, closure integrity and evaporation control.

05

Performance QC

Centrifugation, incubation, reaction grading, specificity and non-specific agglutination checks.

06

Pack and release

Labelling, reconciliation, cold-chain staging, stability and batch disposition.

CONTROL PRINCIPLE: BIOLOGICAL TRACEABILITY + GEL UNIFORMITY + MICROCOLUMN FILL ACCURACY + VERIFIED SEAL INTEGRITY

04 / FACILITY CONCEPT

Segregate biology, open filling and packaging

UNCLASSIFIED / CONTROLLED

Receiving, quarantine, released warehouse, secondary packing, offices and technical rooms.

ISO 8 TYPICAL

Controlled gel preparation, card production and primary packaging where product risk assessment requires.

ISO 7 LOCAL PROTECTION

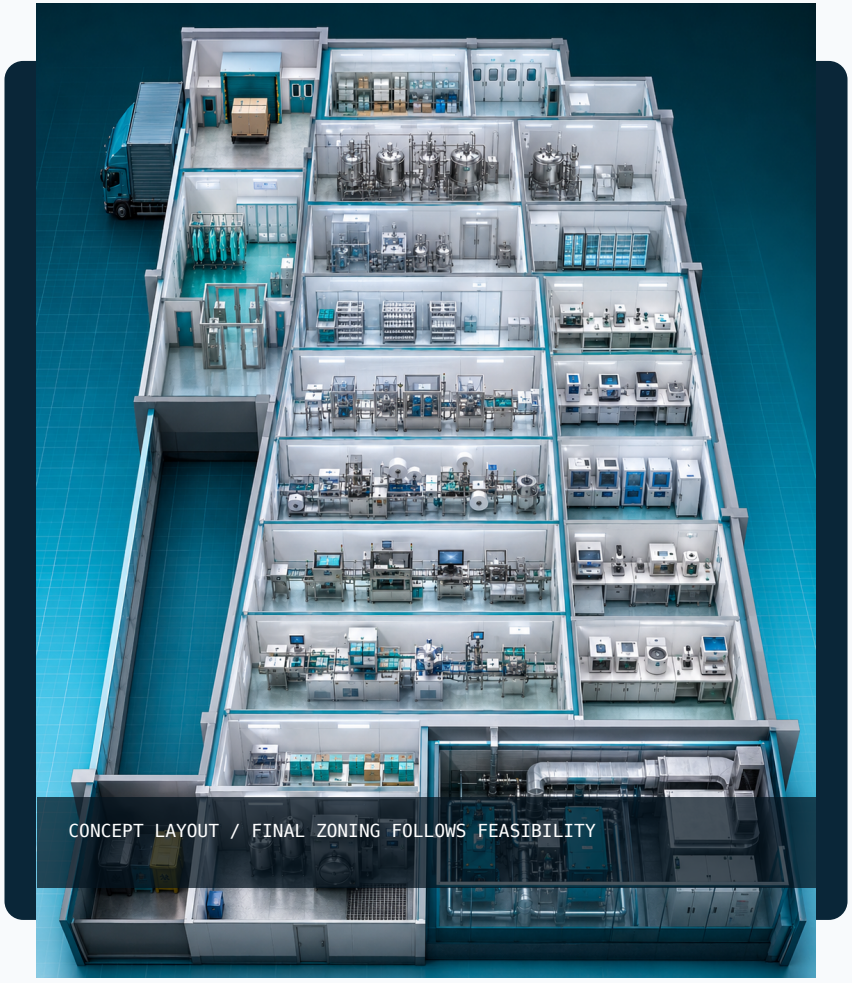
Local protection over open microcolumn filling or other exposed operations where validated.

SEGREGATED BIOLOGICAL SUITE

Reagent-cell and antisera work separated from plastics, packaging and microbiology activities.

COLD CHAIN

Mapped 2-8 C rooms and controlled transfer routes for biological inputs, intermediates and finished goods.

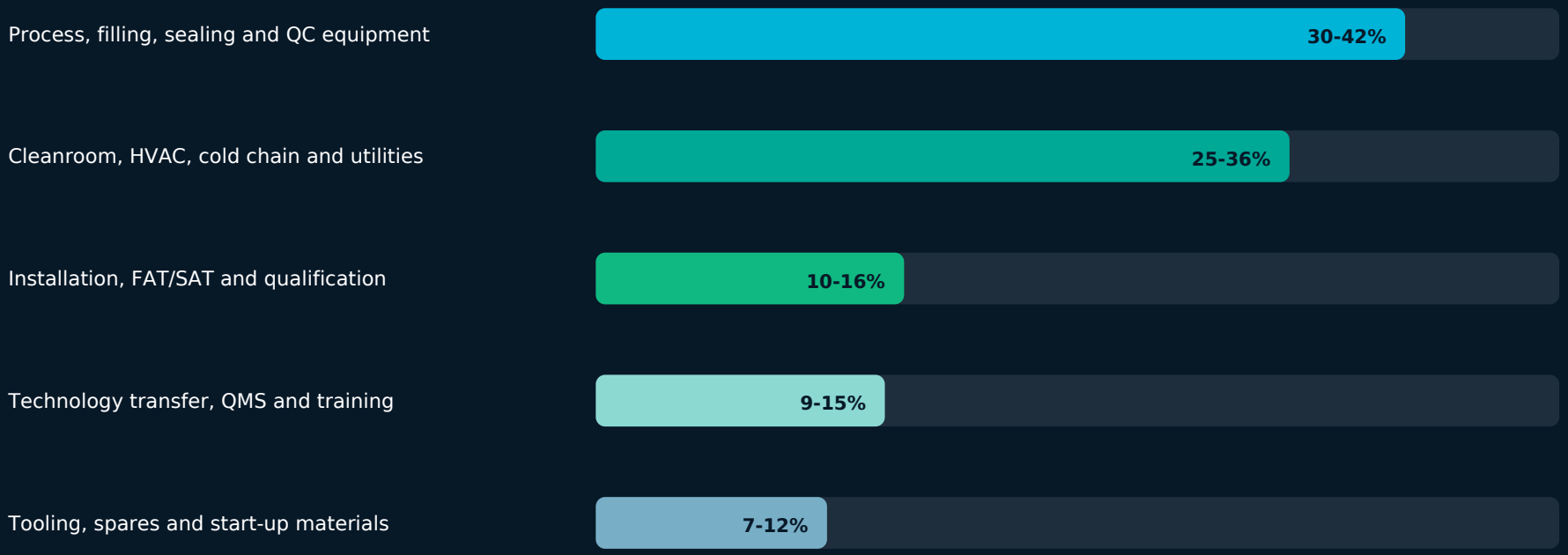


Indicative footprint: 1,500-3,500 m2 gross, including 450-1,100 m2 controlled production. Final areas follow room data sheets, biological flows, equipment service access and local requirements.

05 / CAPEX CONTROL

What the USD 3.2-8.5M band includes

Indicative allocation envelope only. Final values follow URS, site survey, portfolio definition and supplier quotations.



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

06 / OUTPUT MODEL

Capacity follows card configuration and validated yield

TIER 1

3-8 million cards/year

Focused portfolio; modular gel preparation, filling and sealing; one to two shifts; selected biological reagent capability.

TIER 2

12-25 million cards/year

Higher automation, parallel filling/sealing, expanded biological QC and cold-chain capacity; two shifts.

Required calculation inputs

- Microcolumns per card and portfolio mix
- Validated fill and seal cycle time
- Yield, leak-reject and rework assumptions
- Biological reagent batch size and release time
- Changeover, cleaning and line-clearance time
- QC sampling, stability stock and cold-storage dwell

07 / PROCUREMENT BOUNDARY

Vendor-neutral gel-card equipment architecture

A

Gel system

Jacketed mixing, vacuum degassing, pH, density, viscosity and filtration controls.

B

Biological preparation

Cell processing, microscopy, centrifugation, incubators and mapped cold storage.

C

Card components

Qualified supplied cards or injection moulding, component inspection and controlled staging.

D

Fill and seal

Precision microcolumn filling, foil alignment, heat sealing and parameter recording.

E

Inspection and pack

Leak, vision, coding, labelling, reconciliation, cartoning and cold-chain staging.

F

QC and stability

Immunohaematology analysers, centrifuges, incubators and stability chambers.

08 / SITE READINESS

Cold chain and HVAC protect process consistency

POWER

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

HVAC

Temperature, pressure cascade, filtration and recovery matched to room risk.

PURIFIED WATER

Defined quality and capacity for gel/reagent preparation and validated cleaning.

COMPRESSED AIR

Clean, dry process air verified at points of use.

COLD CHAIN

Mapped 2-8 C storage, alarm escalation, backup and qualified transport

WASTE & DATA

Biological waste route, batch genealogy, access control, calibration and

Feasibility output: utility gap assessment, room data sheets, cold-chain load basis, equipment load list and owner-versus-EPC responsibility matrix.

09 / VALIDATION ROUTE

Facility readiness and product authorisation are separate

Infinity structures the QMS, qualification and dossier work in scope. Certification and market authorisation remain decisions of independent competent bodies.

01

Design qualification

URS, zoning, biological flow, cold-chain and risk review

02

FAT / SAT

Equipment functions, alarms, fill/seal and safety verification

03

IQ / OQ

Installation and operation against approved protocols

04

Process validation

Gel, fill volume, seal, reaction performance and cleaning

05

QMS readiness

ISO 13485 records, competency, audit and CAPA readiness

06

Technical dossier

IVDR classification-specific and local registration support

10 / PEOPLE AND KNOW-HOW

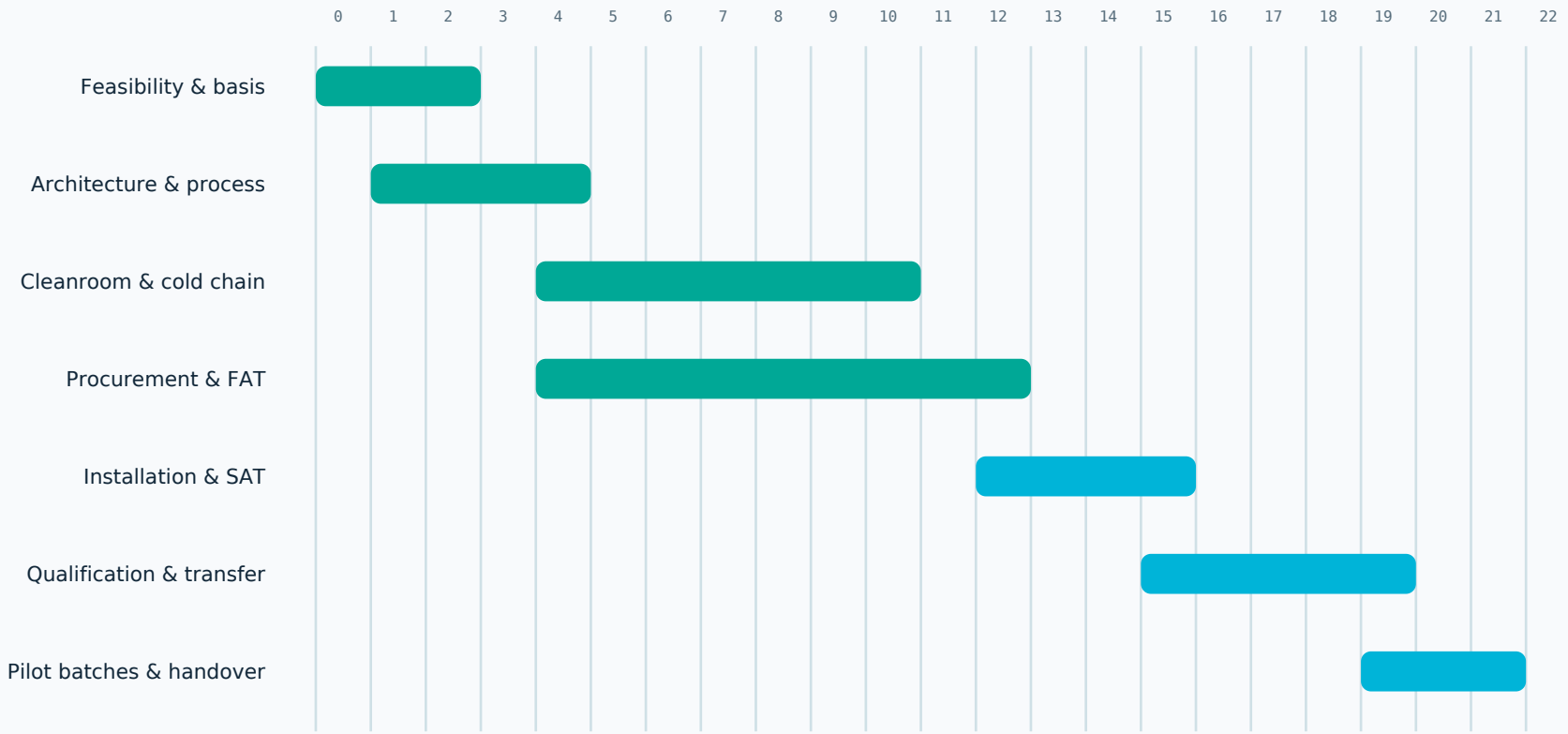
Indicative staffing: 35-85 FTE

Production	14-35 FTE	Gel, biological reagents, filling, sealing and packaging
Quality control	7-16 FTE	Biological, physical, reaction, seal and stability testing
QA & Regulatory	5-10 FTE	QMS, batch review, validation, vigilance and dossiers
Warehouse & Planning	3-8 FTE	Status control, cold chain, inventory and scheduling
Engineering	3-9 FTE	HVAC, cold rooms, calibration, maintenance and automation

Transfer package: 8-16 weeks role-based training, SOPs, equipment training, supervised comparability work, competency records and validation batches where scoped.

11 / EXECUTION

14-22 months from design basis to validated pilot batches



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

12 / INVESTMENT RISK

Failure modes that must be designed out

Gel density or viscosity drift	Defined formulation controls, in-process checks, calibrated mixing and batch trending.
Air bubbles or fill-volume variation	Vacuum degassing, validated dispense settings, vision checks and reject limits.
Reagent-cell potency drift	Qualified inputs, standardisation, cold-chain alarms and performance trending.
Seal leakage and evaporation	Foil alignment, heat-seal validation, leak testing and stability monitoring.
Non-specific agglutination	Raw-material controls, reaction panel testing and investigation criteria.
Traceability failure	Donor/material genealogy, status segregation, reconciliation and electronic batch records.

13 / AREA PROGRAMME

Controlled areas are sized by process risk and throughput

ROOM / FUNCTION	INDICATIVE AREA	ENVIRONMENT	DESIGN BASIS
Gel preparation and degassing	70-160 m2	ISO 8 typical	Mixing, filtration, vacuum, hold vessels
Antisera / reagent-cell suite	90-220 m2	Segregated ISO 8	Biological processing, microscopy, cold hold
Card staging and filling	100-240 m2	ISO 8 + ISO 7 local	Open filling, bubble and fill-volume control
Foil sealing and inspection	90-210 m2	ISO 8 typical	Seal parameters, vision and leak testing
Immunohaematology QC	120-260 m2	Controlled laboratory	Reaction panels, analysers, centrifuges
Cold stores and stability	80-180 m2	Mapped 2-8 C	Inputs, WIP, finished goods and samples
Primary / secondary packing	100-260 m2	Controlled / unclassified	Label control, reconciliation, cartoning

Area bands exclude offices, utilities, circulation and future expansion. Final room schedule is issued after portfolio, batch size, equipment clearances, personnel flow and local code review.

14 / LOT RELEASE

Every card lot needs physical, biological and packaging evidence

The release strategy links raw materials, gel properties, reaction performance and package integrity to a traceable batch decision.

INCOMING

Cards, foil, gel inputs, antisera, cells

Identity, status, CoA review, sampling

GEL IPC

pH, density, viscosity, appearance

Defined limits before filling release

FILLING IPC

Volume, bubbles, column uniformity

Start, interval and end-of-run checks

SEAL IPC

Alignment, temperature, pressure, dwell

Parameter record + leak sample

REACTION QC

Positive/negative panel and grading

Manual and analyser comparability

STABILITY

Real-time and accelerated programme

Trend, shelf-life and transport support

15 / SCOPE CLARITY

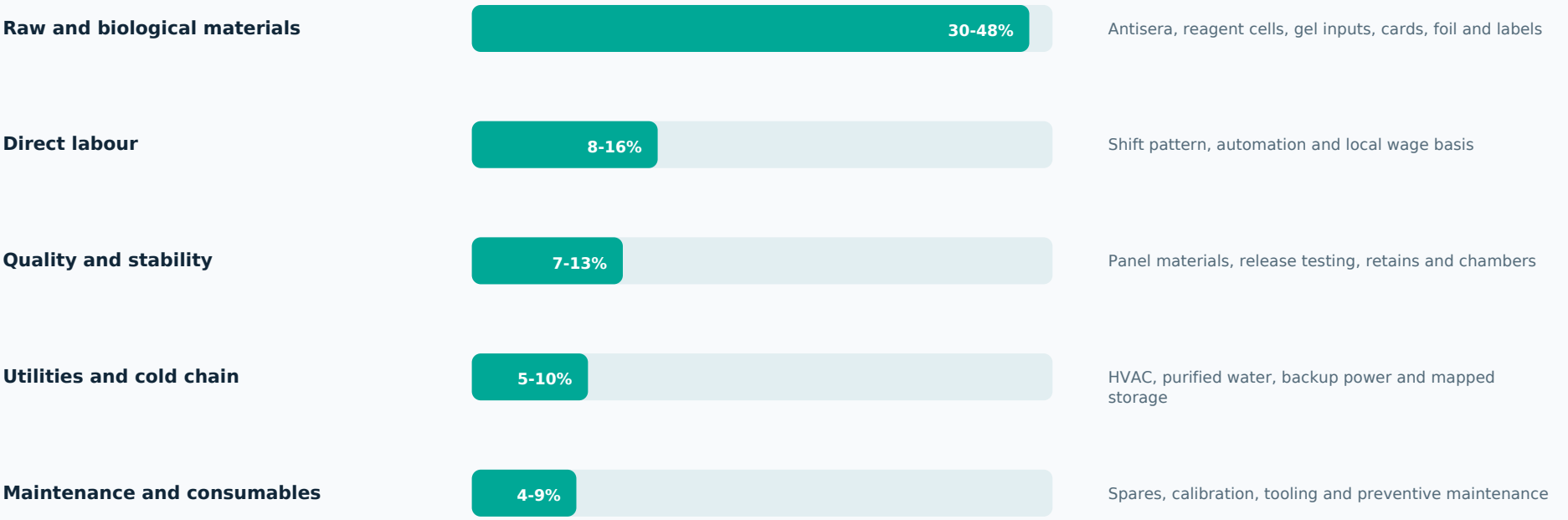
Included, optional and client-side boundaries

PACKAGE	BOUNDARY	QUALIFIER
Gel mixing, filtration and vacuum degassing	CORE EPC	Batch size fixed at feasibility
Microcolumn filling and foil sealing line	CORE EPC	Automation tier follows capacity
Card injection mould and moulding machine	OPTION	May use qualified purchased cards
Reagent-cell preparation equipment	OPTION / CORE	Depends on biological transfer boundary
BG-SA analyser, centrifuges and incubators	CORE QC	Configuration follows intended card system
Cold rooms and stability chambers	CORE EPC	Mapped storage and alarm integration
Building shell and off-site utility upgrade	CLIENT / OPTION	Confirmed by site survey
Initial biological materials and consumables	START-UP LOT	Volume fixed in transfer plan

16 / ECONOMIC MODEL

Unit economics are driven by utilisation and biological inputs

No return is guaranteed. A site-specific model is issued at feasibility using verified local prices, financing and market assumptions.



Feasibility model outputs: cost per released card, gross margin by portfolio, break-even utilisation, working-capital requirement, sensitivity to imported biology and indicative payback range.

17 / DELIVERABLES

The handover is a controlled operating system, not machinery alone

The contracted scope is converted into an indexed engineering, quality and transfer dossier suitable for client ownership and audit readiness.

ENGINEERING

- Design basis and URS
- Process flow and zoning
- Room data sheets
- Utility and equipment loads

QUALIFICATION

- DQ / FAT / SAT
- IQ / OQ protocols
- Calibration register
- Process-validation plan

QUALITY

- Quality manual and SOP set
- Batch and QC records
- Deviation / CAPA system
- Supplier qualification

TRANSFER

- Formulation and work instructions
- Training and competency
- Comparability protocol
- Supervised pilot batches

18 / INVESTOR INPUTS

What must be known before a binding offer

MARKET

Product families, annual demand, tender structure, local-content target, export markets

SITE

Land/building drawings, utilities, logistics, environmental and permitting constraints

TECHNOLOGY

Card design, gel/reagent ownership, analyser compatibility, transfer rights

REGULATORY

Classification, destination markets, clinical/performance evidence and local authority route

FINANCE

Budget, funding source, duty/tax assumptions, working capital and target return criteria

SCHEDULE

Target first batch, decision gates, procurement constraints and client approval periods

The feasibility gate converts these inputs into a site-specific CAPEX/OPEX model, room schedule, equipment register, regulatory plan, delivery programme and risk register.

19 / NEXT DECISION

Commission the blood grouping facility feasibility study

This 20-page brief is an indicative engineering envelope. The feasibility gate produces the location-, portfolio- and market-specific investment case.

- Country, city and intended site
- Target gel-card portfolio
- Biological-input and IP boundary
- Annual demand and ramp assumptions
- Budget and financing source
- Building 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

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