Blood Grouping Gel Card Production

Gel-card, antisera and screening-cell production for controlled immunohaematology testing.

Preliminary engineering range; excludes land, finance cost, taxes and import duty. Final scope and price are confirmed at the feasibility gate.

- Indicative CAPEX: USD 3.2–8.5M
- Delivery: 14–22 months to validated pilot batches, excluding authority review.
- Capacity: Tier 1: 3–8M cards/year; Tier 2: 12–25M cards/year; two shifts, card configuration and reagent portfolio dependent.

Process flow

Preliminary basis for zoning, equipment and validation.

- Gel preparation, degassing and viscosity control
- Antisera or reagent-cell preparation and qualification
- Microcolumn card filling
- Foil alignment, sealing and leak inspection
- Cell-panel standardisation and cold storage
- Centrifugation/reaction performance and stability release

Facility & clean environment

1,500–3,500 m² gross; 450–1,100 m² controlled reagent, cell and card production areas, typically ISO 8 with ISO 7 local filling protection.

ISO 8 is typical for controlled card production; ISO 7 local protection may be used over open filling. Cell/reagent preparation is segregated from plastics, packaging and microbiology testing.

- Purified water, controlled 2–8°C storage, backup power, clean compressed air, controlled HVAC, biological-waste management and temperature-mapped logistics.

Equipment architecture

Vendor-neutral equipment classes; final URS is issued at feasibility.

- Gel mixing and vacuum-degassing systems
- Precision microcolumn filling and foil sealing
- Card injection moulding or qualified component supply
- Immunohaematology analysers, incubators and centrifuges
- Cell processing, microscopy and cold-chain systems

Capacity & programme

Tier 1: 3–8M cards/year; Tier 2: 12–25M cards/year; two shifts, card configuration and reagent portfolio dependent.

14–22 months to validated pilot batches, excluding authority review.

- Capacity assumes stated shifts, qualified inputs, maintenance and validated yield.

Quality & regulatory route

ISO 13485 QMS readiness, IVDR classification-specific technical documentation, biological-material controls and local registration. Facility/QMS readiness typically 12–18 months.

- Approval decisions remain with the competent independent authority.

Critical risks & staffing

Indicative 35–85 FTE including immunohaematology specialists, biological QC, QA and engineering; 8–16 weeks training plus supervised comparability and stability work.

- Gel density or column variation
- Reagent-cell potency drift
- Seal leakage and evaporation
- Non-specific agglutination
- Biological material traceability failure

Feasibility gate

Operating economics are issued as a sensitivity model using local labour, utilities, materials, yield, utilisation and financing assumptions; they are not a guaranteed return.

Provide country, site, portfolio, capacity, budget, financing and target date.

- Egypt — gel-card production programme, in progress
- Türkiye — gel-card production portfolio
- Azerbaijan — blood-grouping localisation scope