Molecular Test Production

PCR and RT-qPCR reagent and kit production from oligonucleotide control through validated finished kits.

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

- Indicative CAPEX: USD 2.4–6.8M
- Delivery: 12–18 months from approved design basis to validated pilot batch.
- Capacity: Tier 1: 1–3M tests/year; Tier 2: 5–12M tests/year; two shifts, product mix and lyophilisation cycle dependent.

Process flow

Preliminary basis for zoning, equipment and validation.

- Controlled receipt and segregation of primers, probes, enzymes and master-mix inputs
- Primer/probe dilution and identity control
- Master-mix formulation under temperature control
- Aliquoting or lyophilisation where selected
- Component kitting, labelling and controlled cold storage
- Analytical performance, stability and batch-release programme

Facility & clean environment

1,200–2,800 m² gross; 350–900 m² controlled production, typically ISO 8 with ISO 7 formulation/filling zones where risk assessment requires.

ISO 8 background is typical for reagent preparation support; ISO 7 local zones may be specified for exposed formulation/filling. Pre- and post-amplification QC rooms are physically separated to control amplicon contamination.

- Redundant power, 18–25°C temperature control, humidity control where lyophilised formats are handled, monitored 2–8°C and frozen storage, purified water where formulation requires, segregated QC airflow and data backup.

Equipment architecture

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

- Calibrated liquid handling and cold-chain systems
- PCR/RT-qPCR QC platforms and extraction systems
- Automated or semi-automated filling, capping and labelling
- Lyophiliser and moisture-control equipment when freeze-dried format is selected
- Environmental monitoring and temperature mapping

Capacity & programme

Tier 1: 1–3M tests/year; Tier 2: 5–12M tests/year; two shifts, product mix and lyophilisation cycle dependent.

12–18 months from approved design basis to validated pilot batch.

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

Quality & regulatory route

ISO 13485 QMS readiness; IVDR technical-documentation and local registration pathway.
Typical facility/QMS readiness: 9–15 months; product registration is authority-dependent.

- Approval decisions remain with the competent independent authority.

Critical risks & staffing

Indicative 22–55 FTE across production, molecular QC, QA, regulatory, warehouse, maintenance and supervision; 6–12 weeks role-based training plus supervised pilot batches.

- Primer/probe mix-up or degradation
- Enzyme activity loss through temperature excursion
- Cross-contamination and false-positive QC signals
- Fill-volume drift
- Stability failure across transport conditions

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.

- Türkiye — molecular diagnostics production portfolio
- Germany — PCR production technology programme, client confidential
- United States — PCR localisation programme, client confidential