Rapid Test Production

Lateral-flow manufacturing from conjugate and membrane preparation through automated assembly and packaged test release.

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

- Indicative CAPEX: USD 1.8–5.5M
- Delivery: 10–16 months from design basis to validated pilot lot.
- Capacity: Tier 1: 5–15M tests/year; Tier 2: 25–60M tests/year; two shifts, strip format and automation dependent.

Process flow

Preliminary basis for zoning, equipment and validation.

- Gold conjugate or labelled-particle preparation
- Conjugate-pad treatment and controlled drying
- Membrane line dispensing and curing
- Card lamination, strip cutting and cassette assembly
- Desiccant pouching, sealing and secondary packing
- Sensitivity, specificity, flow-time, stability and lot-release testing

Facility & clean environment

1,000–2,500 m² gross; 300–850 m² controlled production, commonly ISO 8 with tightly controlled low-humidity membrane and assembly rooms.

ISO 8 controlled production is typical; humidity-critical coating, drying and assembly rooms are engineered separately, often at ≤30% RH depending on membrane and reagent system.

- Stable HVAC with low-humidity capability, clean dry compressed air, redundant power, controlled reagent cold storage, purified water for buffers and calibrated environmental monitoring.

Equipment architecture

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

- Precision line dispensers and drying systems
- Programmable cutters and laminators
- Cassette assembly and vision-inspection systems
- Flow-pack or foil-pouch packaging lines
- Environmental chambers and reader-based QC systems

Capacity & programme

Tier 1: 5–15M tests/year; Tier 2: 25–60M tests/year; two shifts, strip format and automation dependent.

10–16 months from design basis to validated pilot lot.

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

Quality & regulatory route

ISO 13485 QMS readiness; IVDR/local IVD registration and WHO PQ preparation where applicable. Typical facility/QMS readiness: 8–14 months.

- Approval decisions remain with the competent independent authority.

Critical risks & staffing

Indicative 28–75 FTE depending on automation and shifts; 6–10 weeks production/QC training and three supervised validation lots.

- Conjugate aggregation or weak release
- Membrane lot variability
- Line-position and dispense-volume drift
- High background or hook effect
- Moisture ingress and accelerated stability 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.

- Nigeria — rapid-test production and technology-transfer programme
- Azerbaijan — rapid-test localisation programme
- Romania — rapid-test production programme, client confidential