



BUSINESS PLAN · INDIA

Specialty / Molecular Diagnostics Lab

Where a result can be correct and useless, the report must say which it is

DIAGNOSTIC LABS & IMAGING

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August 2026

This document is confidential and prepared for planning purposes. All financial figures are illustrative model assumptions for an Indian MSME context and must be validated against live quotes, local rates and professional advice before any investment or borrowing decision.

1. Executive Summary

This plan sets out a **Specialty / Molecular Diagnostics Lab** in India — oncology molecular and solid-tumour profiling, infectious-disease PCR, inherited-disease and clinical exome testing, prenatal and reproductive genetics, cytogenetics and flow cytometry, plus reference testing and pharmaceutical trial support, running roughly 268,000 tests a year by Year 3.

This plan inherits the diagnostics anchor's rules from `pathology-lab` and confronts a problem the routine laboratory never has. **A haemoglobin is either right or wrong. A genomic result can be entirely right and completely useless — and the laboratory is paid identically either way.**

□ **A MOLECULAR OR GENETIC TEST CAN RETURN A RESULT THAT IS ACCURATE, EXPENSIVE, AND CLINICALLY USELESS. A variant of uncertain significance; a carrier status with no available intervention; a pharmacogenomic panel no prescriber will read; a tumour marker whose matched therapy is unavailable or unaffordable in India. The laboratory is paid the same for all of them, THE REFERRING CLINICIAN FREQUENTLY CANNOT INTERPRET THEM, and the patient receives a document that generates anxiety, cascade testing, and occasionally irreversible decisions — on a finding that meant nothing. The commercial gradient is the worst in this vertical: THE BROADEST PANELS ARE THE MOST PROFITABLE AND SYSTEMATICALLY THE LEAST ACTIONABLE, because breadth adds variants far faster than it adds answers. So this laboratory STATES ACTIONABILITY ON THE REPORT ITSELF — printing "NO CLINICAL ACTION IS INDICATED BY THIS RESULT" where that is true — and REFUSES TO RUN PANELS WHOSE ACTIONABLE YIELD FALLS BELOW A PUBLISHED THRESHOLD: 8,200 declined in Year 3 at ₹3.42 crore forgone. WHERE A RESULT CAN BE CORRECT AND USELESS, THE REPORT MUST SAY WHICH IT IS — AND THE LABORATORY MUST DECLINE THE TEST NOBODY CAN ACT ON.**

□ **AND A VARIANT OF UNCERTAIN SIGNIFICANCE IS NOT A FINDING, IT IS AN ABSENCE OF ONE. So the VUS RATE IS PUBLISHED PER PANEL, 892 VARIANTS WERE RE-CLASSIFIED as evidence changed with 100% OF AFFECTED PATIENTS RE-CONTACTED, and NIL variants of uncertain significance are reported in language a patient could read as a diagnosis.**

□ **AND CONSENT FOR HERITABLE INFORMATION IS NOT THE PATIENT'S ALONE. A result implicates parents, siblings and children who never consented and may not wish to know — so that is stated plainly BEFORE the sample is taken, with pre- and post-test GENETIC COUNSELLING on 100% of heritable testing and NIL tests run without it. 46 requests for foetal sex were refused and reported under PCPNDT.**

This plan models an operator requiring **₹32.00 crore** (₹14.60 crore investor + ₹11.20 crore term loan + ₹3.80 crore promoter + ₹2.40 crore working capital), moving from **₹9.00 crore revenue and a ₹5.85 crore loss** to **₹58.00 crore revenue and ₹6.38 crore profit** by Year 3 — *an 11.0% net margin and 26.6% return on capital. (Molecular diagnostics — figures illustrative.)*

2. Business Description, Vision & Legal Structure

Concept: A genomics laboratory that tells you when the answer does not help.

Vision: To make actionability a printed field rather than an assumption.

Mission: Say on the report whether anything can be done about the result; decline the panel whose yield does not justify it; publish the uncertainty rate and re-contact when the evidence moves; counsel before and after; and never let a family's information be taken without saying whose it is.

Legal structure

- **Private Limited** — recommended. Accreditation, institutional and pharmaceutical contracts, heavy equipment finance and outside capital all assume it.
- **Clinical geneticist as laboratory director** — **reporting is a clinical act here, not a technical one, and the sign-out must sit with somebody who can be asked why.**
- **Test-approval committee independent of commercial** — **because the panels a salesperson would most like to sell are the ones with the least behind them.**

Regulatory anchor: the Clinical Establishments Act 2010 and state rules where adopted; NABL accreditation under ISO 15189, with **laboratory-developed tests requiring in-house validation because most molecular assays in India are LDTs rather than approved kits** — **which means the laboratory itself certifies the assay it profits from;** the **PCPNDT Act 1994, which applies to any prenatal or cell-free DNA work capable of revealing foetal sex, with registration, record and reporting duties;** the Drugs and Cosmetics Act and CDSCO for imported kits, reagents and companion diagnostics; the Digital Personal Data Protection Act 2023, under which **genomic data is sensitive personal data that is inherently identifying, cannot be truly anonymised, and implicates relatives who are not data principals;** ICMR's National Ethical Guidelines for Biomedical and Health Research on consent, incidental findings and return of results, which are **guidelines rather than statute;** the Assisted Reproductive Technology and Surrogacy Acts where preimplantation testing arises; biosafety and Bio-Medical Waste Rules; NMC conduct regulations on referral commissions, binding on the doctor who receives; GST; and EPF/ESI and POSH. **The decisive structural fact is that NOTHING REQUIRES A LABORATORY TO STATE WHETHER A RESULT IS ACTIONABLE, and nothing prevents it selling a panel whose yield it has never measured.**

3. Promoter & Ownership

Led by a promoter with molecular pathology, genomics or specialty laboratory background, with a clinical geneticist as director. Three competences decide outcomes. *Assay validation and bioinformatics*, because most of what this laboratory sells is a test it designed and certified itself. *Clinical interpretation capacity*, since the constraint is curators and counsellors rather than sequencers. And *the willingness to decline a profitable panel*, which is where this plan's proposition sits and which forgoes the fastest-growing revenue in the category. Ownership, equity & investor terms are editable inputs; **the test-approval committee is independent of commercial, holds authority to refuse a panel on yield, and no employee's pay is linked to panel breadth or test value.**

4. Market Analysis — India

The fastest-growing segment of diagnostics, selling results faster than medicine can use them.

Demand drivers

- **Oncology precision medicine** requiring molecular profiling before therapy selection.
- **Falling sequencing cost** putting exomes within reach of middle-income households.
- **Infectious-disease molecular testing** normalised at scale since the pandemic.
- **Reproductive genetics** — carrier screening, NIPT and preimplantation testing.
- **Rare-disease diagnosis**, where a genomic answer can end a decade of investigation.

- **Pharmaceutical trial support** requiring accredited central-laboratory capability.

Market sizing (illustrative framing)

Layer	Definition	Indicative scale
TAM	Indian molecular and genetic diagnostics	Growing faster than any other diagnostics segment
SAM	Tests whose actionable yield clears a published threshold	Materially smaller than what the market will buy
SOM (Yr 1-3)	Tests reported	₹9cr → ₹58cr; 268,000 tests; 6-day median turnaround

Revenue mix and share (Year 3)

Stream	Share	Gross margin — and whether anybody can act on it
Oncology molecular & solid-tumour profiling	30.0%	68.0% — actionable only if the matched therapy is reachable
Infectious-disease molecular (PCR, TB, HIV, HCV)	22.0%	72.0% — the most actionable testing in the book
Inherited disease & clinical exome	17.0%	62.0% — high VUS rate; counselling-intensive
Prenatal & reproductive genetics	14.0%	66.0% — PCPNDT-bound; decisions are irreversible
Cytogenetics, FISH & flow cytometry	10.0%	70.0% — established, interpretable, unfashionable
Reference testing & pharma trial support	7.0%	58.0% — B2B; no patient, no counselling burden

The second row is the quiet correction to this whole category's story: **INFECTIOUS-DISEASE MOLECULAR TESTING CARRIES THE HIGHEST MARGIN IN THE BOOK AND IS ALSO BY A LONG DISTANCE THE MOST ACTIONABLE THING WE DO.** A drug-resistance profile on a tuberculosis isolate changes a regimen next week, for a patient who will actually receive it, at a cost the system can bear. It is unglamorous, it does not appear in the category's marketing, and it is the strongest business in the table. The first row is the harder one: oncology profiling is genuinely transformative when the matched therapy is available and affordable, and produces an expensive, correct, unusable result when it is not — a distinction that depends on the patient's circumstances rather than on the assay, and one this laboratory therefore has to state case by case rather than in a brochure.

Constraints

- **Curation and counselling capacity**, which limits volume long before sequencers do.
- **Clinician interpretive capability**, which the laboratory cannot supply by report alone.
- **Reagent import cost and currency** on closed-system platforms.
- **Competitor breadth** — bigger panels sell better and are easier to market.

5. Competition & Position

Competitor type	Strength	Weakness this plan exploits
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National genomics laboratories	Scale, menu breadth, brand, clinician networks, capital	Panel breadth sold as value; yield never measured or published
Hospital molecular laboratories	Clinician proximity, tumour boards, immediate context	Limited menu; validation depth variable
International send-out laboratories	Menu depth, established assays, research pedigree	Cost, turnaround, no counselling in the patient's language
Routine labs adding molecular menus	Existing referral base and collection reach	LDT validation and variant curation are not routine-lab skills
This plan	Actionability printed, low-yield panels declined, VUS rate published, counselling mandatory	Declines the fastest-growing revenue; 246 referrers lost

The positioning is unusually difficult to sell because it consists largely of saying no to things the customer has already decided he wants. A clinician who has read about a 500-gene panel is not pleased to be told our threshold declines it for his indication, and a patient who has saved for an exome does not want a conversation about what it probably will not find. What replaces enthusiasm is a set of published numbers: actionable yield by panel, VUS rate by panel, and the count of tests we declined. The clinicians who stay are those who have had to explain a variant of uncertain significance to a frightened family and do not wish to do it again unnecessarily — and there are fewer of them than there are clinicians, which is why 246 referrers stopped and why the first two years lose money.

The cost of the honest position is stated in rupees rather than implied. Refusing panels whose actionable yield falls below the published threshold cost ₹3.42 crore of Year-3 revenue — the largest item, and it is the fastest-growing revenue line in the category. Paying no referral commission, per the vertical anchor, cost ₹1.68 crore of profit with 246 referrers gone. Pre- and post-test genetic counselling on all heritable testing cost ₹1.24 crore. Variant re-classification and patient re-contact cost ₹86 lakh. Total ₹6.20 crore against ₹6.38 crore of profit — so an operator with the same sequencers and the same menu running trade-standard practice would earn ₹12.58 crore.

6. Correct, Expensive and Useless

This is the finding, and it is invisible in every quality system ever built.

The result	Analytically correct?	Can anybody act on it?
Variant of uncertain significance	Yes	No — by definition
Carrier status, no intervention available	Yes	Reproductive planning only
Pharmacogenomic panel, prescriber will not read it	Yes	No
Tumour marker, matched therapy unaffordable here	Yes	No — and the family now knows that
Incidental finding unrelated to the question asked	Yes	Sometimes. Often only harm.
What every quality system measures	Column two. Never column three.	

The last row is the whole problem. Accreditation, proficiency testing, internal quality control, turnaround measurement and error rates all interrogate the second column — was the answer right? — and NOT ONE OF

THEM ASKS THE THIRD. A laboratory can therefore be flawlessly accurate, fully accredited, top of every EQA scheme, and still be producing documents that help nobody, at ₹40,000 each, at increasing volume, with every metric it reports improving. The fourth row is the one that keeps clinical geneticists awake: a correct tumour profile identifying a target whose therapy costs more per month than the family earns in a year is not a neutral non-event — it converts a manageable prognosis into a specific, named, unaffordable hope, and the laboratory that produced it has done real harm while performing perfectly. And the commercial gradient runs directly at it: **BREADTH ADDS VARIANTS FAR FASTER THAN IT ADDS ANSWERS**, so the broadest panels carry the best margins and the worst yield, and a salesperson describing a 500-gene panel as "more comprehensive" is telling the literal truth.

So the third column is measured, printed and acted on. **EVERY REPORT CARRIES AN ACTIONABILITY STATEMENT**, and where it is true the report says plainly "NO CLINICAL ACTION IS INDICATED BY THIS RESULT" — a sentence no laboratory in this market prints, and the single most useful thing most of these documents could contain. **ACTIONABLE YIELD IS MEASURED PER PANEL PER INDICATION AND PUBLISHED**, and **A PANEL WHOSE YIELD FALLS BELOW THE PUBLISHED THRESHOLD FOR THAT INDICATION IS DECLINED** — 8,200 in Year 3 — with a narrower, higher-yield alternative proposed rather than a bare refusal. **WHERE A MATCHED THERAPY EXISTS BUT IS UNAVAILABLE OR UNAFFORDABLE IN INDIA, THAT IS STATED IN THE PRE-TEST CONVERSATION RATHER THAN DISCOVERED IN THE REPORT**, so a family chooses whether to know. The test-approval committee sits outside commercial and can refuse a panel outright. Cost ₹3.42 crore. **WHERE A RESULT CAN BE CORRECT AND USELESS, THE REPORT MUST SAY WHICH IT IS — AND THE LABORATORY MUST DECLINE THE TEST NOBODY CAN ACT ON.**

7. Uncertainty, Family and the Assay You Certified Yourself

Four further rules, the first of which is the commonest result in genomic medicine.

□ **A VARIANT OF UNCERTAIN SIGNIFICANCE IS NOT A FINDING — IT IS AN ABSENCE OF ONE, DESCRIBED IN TECHNICAL LANGUAGE THAT SOUNDS LIKE A DIAGNOSIS.** Patients read "variant detected" and hear "something is wrong with me"; some pursue surveillance, surgery or reproductive decisions on the strength of it. So the **VUS RATE IS PUBLISHED PER PANEL** — which discourages broad panels precisely as it should, since breadth and VUS rate move together — **NIL VARIANTS OF UNCERTAIN SIGNIFICANCE ARE REPORTED IN LANGUAGE A PATIENT COULD READ AS A DIAGNOSIS**, and **892 VARIANTS WERE RE-CLASSIFIED** as evidence changed with **100% OF AFFECTED PATIENTS RE-CONTACTED**. Re-contact is the expensive half and the part almost nobody does: a variant reclassified from uncertain to benign three years later is good news that never reaches the person still worrying about it unless somebody goes looking for them.

□ **AND CONSENT FOR HERITABLE INFORMATION IS NOT THE PATIENT'S ALONE.** A pathogenic variant in one person is simultaneously information about parents, siblings and children who never consented, may not want to know, and in some cases will be told by a family member without any counselling at all. So **THE FAMILY IMPLICATION IS STATED PLAINLY BEFORE THE SAMPLE IS TAKEN** rather than in a consent form afterwards, **PRE- AND POST-TEST GENETIC COUNSELLING IS PROVIDED ON 100% OF HERITABLE TESTING** with **NIL tests run without pre-test counselling**, and the patient decides in advance about incidental findings. Twenty-two counsellors for 268,000 tests is a heavy cost and is the binding constraint on volume, which is the correct constraint for this business to have.

□ **AND MOST MOLECULAR ASSAYS IN INDIA ARE LABORATORY-DEVELOPED TESTS — WHICH MEANS THE LABORATORY CERTIFIES THE ASSAY IT PROFITS FROM.** There is no approved kit, no external body that has

assessed the claim, and no independent check that the sensitivity stated on the report is the sensitivity achieved. So **VALIDATION DATA IS PUBLISHED PER ASSAY** — sensitivity, specificity, limit of detection and the population it was validated in — **EQA PARTICIPATION AND RESULTS ARE PUBLISHED INCLUDING FAILURES** per the vertical anchor, and **RAW DATA IS RETURNED TO THE PATIENT ON REQUEST** at 100%, because a person's sequence is not our proprietary asset.

□ **AND PCPNDT REACHES ANY TEST CAPABLE OF REVEALING FOETAL SEX, INCLUDING CELL-FREE DNA.** Registration is current, records are maintained, and **46 REQUESTS FOR FOETAL SEX WERE REFUSED AND REPORTED** in Year 3 — because per the pharmacy anchor's logic, the request is the only measurable thing, and a laboratory recording none has stopped counting rather than stopped receiving them.

8. Operations Plan (approve, run, curate, counsel)

Test approval

- **Actionable yield measured per panel per indication** and published.
- **Panels below the published threshold declined**, with a narrower alternative proposed.
- **Test-approval committee independent of commercial**, able to refuse a panel outright.
- **Nil employee pay linked to panel breadth or test value.**

Analysis and curation

- **Validation data published per assay** — sensitivity, specificity, limit of detection, validation population.
- **VUS rate published per panel**; nil VUS reported in diagnosis-like language.
- **Variants re-classified as evidence changes**; 100% of affected patients re-contacted.
- **EQA participation and results published**, failures included, per the vertical anchor.

The patient conversation

- **Family implication stated before the sample is taken**, not in a form afterwards.
- **Pre- and post-test genetic counselling on 100% of heritable testing.**
- **Therapy availability and affordability discussed pre-test** for oncology profiling.
- **Incidental-findings preference recorded in advance** by the patient.

Reporting and compliance

- **Actionability statement on every report**, including "no clinical action is indicated".
- **Raw data returned to the patient on request**; nil proprietary lock on a person's sequence.
- **PCPNDT registration current; foetal-sex requests refused and reported.**
- **Nil referral commission**, published per the vertical anchor.

The operational hinge is an oncologist requesting a 500-gene tumour panel for a patient whose disease has three approved matched therapies in India, two of which the family cannot afford — where our published threshold for that indication permits a 52-gene panel that will find everything actionable at a third of the price. The oncologist is not wrong to want more; he is treating a specific patient and would rather have the information than not. So **THE BROADER PANEL IS DECLINED WITH THE NARROWER ONE PROPOSED AND THE YIELD DATA ATTACHED**, and the pre-test conversation covers what a finding would mean if the therapy is out of reach — because a family that learns of an unaffordable target after the fact has been given a specific,

named hope it cannot act on. The system refuses rather than warns: a panel below threshold for a stated indication cannot be ordered without a recorded clinical override, and **OVERRIDES ARE COUNTED, PUBLISHED AND REVIEWED BY THE TEST-APPROVAL COMMITTEE.**

9. Accreditation, PCPNDT & Operating Compliance (India)

- **Clinical Establishments Act 2010** and state rules where adopted; NABL accreditation under ISO 15189.
- **Laboratory-developed tests** — most molecular assays in India are LDTs requiring in-house validation, which means the laboratory itself certifies the assay it profits from, with no external body assessing the claim.
- **PCPNDT Act 1994** — applies to any prenatal or cell-free DNA work capable of revealing foetal sex, with registration, record and reporting duties.
- **Drugs and Cosmetics Act and CDSCO** for imported kits, reagents and companion diagnostics.
- **Digital Personal Data Protection Act 2023** — genomic data is sensitive personal data that is inherently identifying, cannot be truly anonymised, and implicates relatives who are not data principals at all.
- **ICMR National Ethical Guidelines** on consent, incidental findings and return of results — **guidelines rather than statute.**
- **ART and Surrogacy Acts** where preimplantation testing arises; biosafety and Bio-Medical Waste Rules.
- **NMC conduct regulations, GST, EPF/ESI and POSH.** Nothing requires a laboratory to state whether a result is actionable, and nothing prevents it selling a panel whose yield it has never measured.

10. Organisation & Manpower Plan

Function	Yr 1	Yr 3	Notes
Promoter / managing director	1	1	Owns the yield threshold
Laboratory scientists & technologists	34	96	Wet lab across six platforms
Bioinformatics & pipeline	8	24	Assay validation is published per test
Genetic counsellors	5	22	Pre- and post-test; the binding constraint on volume
Clinical geneticists & molecular pathologists	6	18	Sign-out is a clinical act; named on the report
Variant curation, re-classification & recontact	4	14	892 re-classified; 100% re-contacted
Quality, EQA & validation	4	12	Publishes failures, per the vertical anchor
Technology, LIMS & variant database	4	12	Raw data returned on request
Admin, finance, clinician education & corporate	10	27	Education, not referral commission
Total	76	226	Counselling, curation and genetics at 24%

Twenty-two genetic counsellors is the line that most distinguishes this laboratory and the one a financial reviewer will question first, because counselling generates almost no revenue and is the binding constraint on how many heritable tests can be run. That constraint is deliberate and is the correct one for this business to have: a laboratory whose throughput is limited by sequencers rather than by explanation capacity is producing reports faster than anybody can absorb them. Fourteen people on variant curation and re-contact exist to do the thing the category almost universally omits — going back to find a patient whose variant has

been reclassified, years later, usually with good news. No employee's pay is linked to panel breadth or test value, which matters more here than anywhere else in the vertical, since breadth is the single easiest way to increase a bill.

11. Implementation Timeline & Milestones

Phase	Window	Milestones
Formation & laboratory build	Month 0-10	Incorporation, biosafety build, sequencers commissioned, LIMS live
Assay validation & publication	Month 5-14	LDT validation data published per assay; EQA enrolled
Yield thresholds & test approval	Month 8-16	Actionable yield measured per indication; committee constituted
Counselling service	Month 10-20	Pre- and post-test counselling on all heritable testing
Curation & re-contact programme	Month 16-28	Re-classification pipeline; first patient re-contacts completed
Scale & publication	Month 26-36	268,000 tests; VUS rates and declined-panel counts published

Training and competence

- **Declining a panel to a clinician** with yield data rather than policy.
- **Explaining a VUS** to a frightened family without either alarming or dismissing.
- **The affordability conversation** before an oncology profile, not after it.
- **Re-contact practice** — reaching a patient years later about a reclassified variant.

12. Financial Plan (Illustrative)

All figures are illustrative model assumptions, not forecasts or guarantees. They exist to show the drivers of a molecular diagnostics P&L and how the actionability, curation and counselling disciplines move them. Every input is editable. **The defining economics are a 67.1% gross margin against ₹4.64 crore of depreciation and a heavy interpretive payroll — and the fact that the panels this laboratory declines are the fastest-growing revenue in its own category.**

12.1 Project cost & funding

Item	₹ lakh	Notes
Sequencers, PCR platforms, flow cytometry & cytogenetics	1,344	Imported, closed-system reagents
Laboratory build-out, biosafety & clean areas	576	Contamination control is existential in PCR
Bioinformatics infrastructure, LIMS & variant database	448	Carries re-classification and re-contact
Working capital — reagents & institutional receivables	384	Pharma and institutional terms are long
Genetic counselling service build & clinician education	256	The binding constraint, funded deliberately

Validation, accreditation & assay development	128	LDTs must be validated in-house and published
Licences, deposits & pre-operative	64	Registration, PCPNDT, CDSCO import
Total project cost	3,200	₹1,460L investor + ₹1,120L term loan + ₹380L promoter + ₹240L WC

12.2 Operating metrics

Metric	Yr 1	Yr 2	Yr 3
ACTIONABILITY STATED ON EVERY REPORT, including "NO CLINICAL ACTION IS INDICATED BY THIS RESULT" where true / panels REFUSED because actionable yield falls below the published threshold / narrower alternative proposed / revenue forgone (₹cr)	100% / 1,840 / 74% / 0.68	100% / 4,600 / 82% / 1.86	100% / 8,200 / 89% / 3.42
VUS RATE PUBLISHED PER PANEL / variants RE-CLASSIFIED as evidence changed / affected patients RE-CONTACTED / VUS reported in language a patient could read as a diagnosis	100% / 214 / 100% / NIL	100% / 486 / 100% / NIL	100% / 892 / 100% / NIL
PRE- AND POST-TEST GENETIC COUNSELLING on heritable testing / tests run WITHOUT pre-test counselling / family-implication statement made BEFORE the sample is taken / incidental-findings preference recorded in advance	100% / NIL / 100% / 100%	100% / NIL / 100% / 100%	100% / NIL / 100% / 100%
ASSAY VALIDATION DATA PUBLISHED PER LDT (sensitivity, specificity, LOD, validation population) / EQA participation / EQA results published INCLUDING FAILURES / raw data returned to the patient on request	100% / 100% / 100% / 100%	100% / 100% / 100% / 100%	100% / 100% / 100% / 100%
REFERRAL COMMISSION paid (vertical anchor) / policy published / referrers who stopped / PCPNDT: foetal-sex requests REFUSED AND REPORTED / registration current	NIL / 100% / 86 / 12 / 100%	NIL / 100% / 168 / 28 / 100%	NIL / 100% / 246 / 46 / 100%
Tests reported / turnaround median (90th percentile) / employee pay linked to panel breadth or test value / reference & pharma share of revenue	42k / 9d (21d) / NIL / 7.0%	128k / 7d (16d) / NIL / 7.0%	268k / 6d (12d) / NIL / 7.0%

Row one contains the sentence this plan exists to print: "no clinical action is indicated by this result", on 100% of reports where it is true. No laboratory in this market prints it, and it is the single most useful thing most of these documents could contain. The 8,200 declined panels are the cost, and the 89% given a narrower alternative are why the referrer usually stays. Row two's re-contact figure is the expensive half and the part almost nobody does — a variant reclassified from uncertain to benign three years later is good news that never reaches the person still worrying about it unless somebody goes looking. Row four publishes validation data for assays we certified ourselves, which is the only external check that exists on a laboratory-developed test. Row five applies the pharmacy anchor's logic to PCPNDT: 46 refusals recorded, because a laboratory recording none has stopped counting rather than stopped receiving them.

12.3 Revenue build

Stream	Yr 1 (₹L)	Yr 2 (₹L)	Yr 3 (₹L)	Gross margin
Oncology molecular & solid-tumour profiling	270	840	1,740	68.0%
Infectious-disease molecular (PCR, TB, HIV, HCV)	198	616	1,276	72.0%

Inherited disease & clinical exome	153	476	986	62.0%
Prenatal & reproductive genetics	126	392	812	66.0%
Cytogenetics, FISH & flow cytometry	90	280	580	70.0%
Reference testing & pharma trial support	63	196	406	58.0%
Total revenue	900	2,800	5,800	67.1% blended

12.4 P&L summary

Line	Yr 1 (₹L)	Yr 2 (₹L)	Yr 3 (₹L)
Revenue	900	2,800	5,800
Cost of testing — reagents, flow cells, consumables & send-outs	(296)	(922)	(1,909)
Gross profit	604	1,878	3,891
Laboratory scientists, bioinformatics & technologists	(386)	(638)	(986)
Clinical geneticists, pathologists & genetic counsellors	(218)	(348)	(522)
Premises, utilities, cold chain & biosafety	(148)	(206)	(290)
Variant curation, re-classification & re-contact	(86)	(142)	(232)
Technology, LIMS, variant database & reporting	(118)	(168)	(232)
Clinician education — NO referral commission	(68)	(96)	(116)
Admin, legal, compliance & other	(96)	(142)	(198)
EBITDA	(516)	138	1,315
Depreciation & amortisation	(232)	(348)	(464)
Finance cost	(86)	(128)	(174)
Other income — pharma trial milestones and platform placement terms <i>(disclosed)</i>	54	112	174
PBT	(780)	(226)	851
Tax	195	57	(213)
PAT	(585)	(169)	638
Net margin	(65.0%)	(6.0%)	11.0%
ROCE	(23.4%)	(6.6%)	26.6%

The interpretive payroll — geneticists, pathologists, counsellors and curators at ₹7.54 crore combined — is 13.0% of revenue and is what this laboratory is actually selling, since the sequencing itself is a commodity available to anyone with ₹13 crore. Variant curation and re-contact at ₹2.32 crore is spent almost entirely on work that generates no invoice, and clinician education at ₹1.16 crore is 2.0% of revenue against a referral-commission spend of nil. Other income of ₹1.74 crore is pharmaceutical trial milestones and platform placement terms, disclosed as a line because placement arrangements tie a laboratory to a manufacturer's reagents and can quietly shape which assays it offers. Commitments of ₹6.20 crore against ₹6.38 crore of profit mean an operator with the same sequencers and the same menu running trade-standard practice would

earn ₹12.58 crore.

12.5 Break-even & sensitivity

Scenario	Yr 3 revenue	Yr 3 PAT	Comment
Base	₹58.0cr	₹6.38cr	As modelled, 11.0% net
Trade-standard practice	₹67.2cr	₹12.58cr	No yield threshold, commission paid, no re-contact
Broad panels sold without a yield threshold	₹61.4cr	₹7.72cr	The fastest-growing revenue in the category
Oncology volume doubles	₹75.4cr	₹12.40cr	Operating leverage against fixed platforms
Reagent & sequencing cost +15%	₹58.0cr	₹4.24cr	Closed systems, imported, currency-exposed
A published EQA failure on a major assay	₹52.2cr	₹3.46cr	The cost of having published in the first place

13. Funding Requirement & Bankability

Source	₹ lakh	Terms (indicative)
Investor equity	1,460	Platform build; yield-threshold and counselling covenants
Term loan / equipment finance	1,120	Sequencers and build-out; 6–7 years, asset-backed
Promoter contribution	380	Cash and clinical leadership
Working capital facility	240	Reagents and institutional receivables
Total	3,200	Illustrative structure

An investor should read counselling capacity, reagent cost exposure and the declined-panel count, and should understand that the third of those is a deliberate ceiling on revenue rather than a failure to convert. Counselling capacity is the binding constraint on heritable volume and cannot be relieved by buying another sequencer — 22 counsellors is what 268,000 tests requires, and scaling means recruiting a scarce profession. Reagent cost is the sharpest operating sensitivity: a 15% rise takes profit from ₹6.38 crore to ₹4.24 crore, and closed imported systems leave no substitution option once installed. The EQA-failure scenario at ₹3.46 crore is the price of publishing validation and quality data — a price this plan accepts deliberately, because on a laboratory-developed test that publication is the only external check that exists. The yield threshold deserves a covenant precisely because removing it would add ₹1.34 crore of profit within two quarters and would be invisible to every patient and most clinicians.

- **Use of funds** — 42% sequencing and analytical platforms, 18% laboratory build-out and biosafety, 14% bioinformatics and LIMS, 12% working capital, 8% counselling service and education, 4% validation and accreditation, 2% licences.
- **Repayment** — equipment finance over six to seven years; working capital revolving against institutional receivables.
- **Investor exit** — sale to a national diagnostics chain, a global genomics group or a hospital network; or promoter buyback. **Yield-threshold, counselling and raw-data commitments survive change of control.**

14. Risk Analysis & Mitigation

Risk	Impact	Mitigation
Correct, expensive and useless	A molecular or genetic test can return a result that is ACCURATE, EXPENSIVE AND CLINICALLY USELESS — a variant of uncertain significance, a carrier status with no intervention, a pharmacogenomic panel no prescriber will read, A TUMOUR MARKER WHOSE MATCHED THERAPY IS UNAVAILABLE OR UNAFFORDABLE IN INDIA. The laboratory is PAID THE SAME FOR ALL OF THEM, the referring clinician FREQUENTLY CANNOT INTERPRET THEM, and the patient receives a document that generates ANXIETY, CASCADE TESTING AND OCCASIONALLY IRREVERSIBLE DECISIONS. And ACCREDITATION, PROFICIENCY TESTING, IQC, TURNAROUND AND ERROR RATES ALL INTERROGATE WHETHER THE ANSWER WAS RIGHT AND NOT ONE OF THEM ASKS WHETHER ANYBODY CAN ACT ON IT — so a laboratory can be flawlessly accurate, fully accredited, top of every EQA scheme, AND STILL BE PRODUCING DOCUMENTS THAT HELP NOBODY, AT ₹40,000 EACH, AT INCREASING VOLUME, WITH EVERY METRIC IT REPORTS IMPROVING. A correct tumour profile naming a target whose therapy costs more per month than the family earns in a year IS NOT A NEUTRAL NON-EVENT — IT CONVERTS A MANAGEABLE PROGNOSIS INTO A SPECIFIC, NAMED, UNAFFORDABLE HOPE, AND THE LABORATORY HAS DONE REAL HARM WHILE PERFORMING PERFECTLY. And the gradient runs at it: BREADTH ADDS VARIANTS FAR FASTER THAN IT ADDS ANSWERS, so the broadest panels carry the best margins and the worst yield	MEASURE, PRINT AND ACT ON THE THIRD COLUMN. EVERY REPORT CARRIES AN ACTIONABILITY STATEMENT, and where true it says plainly "NO CLINICAL ACTION IS INDICATED BY THIS RESULT" — A SENTENCE NO LABORATORY IN THIS MARKET PRINTS AND THE SINGLE MOST USEFUL THING MOST OF THESE DOCUMENTS COULD CONTAIN. ACTIONABLE YIELD MEASURED PER PANEL PER INDICATION AND PUBLISHED, with any panel below the published threshold DECLINED (8,200 in Yr3) and A NARROWER, HIGHER-YIELD ALTERNATIVE PROPOSED in 89% of cases rather than a bare refusal. WHERE A MATCHED THERAPY EXISTS BUT IS UNAVAILABLE OR UNAFFORDABLE IN INDIA, THAT IS STATED IN THE PRE-TEST CONVERSATION RATHER THAN DISCOVERED IN THE REPORT, SO A FAMILY CHOOSES WHETHER TO KNOW. Test-approval committee OUTSIDE COMMERCIAL; NIL pay linked to panel breadth (₹3.42cr). GENERAL RULE: WHERE A RESULT CAN BE CORRECT AND USELESS, THE REPORT MUST SAY WHICH IT IS — AND THE LABORATORY MUST DECLINE THE TEST NOBODY CAN ACT ON
The 500-gene request	An oncologist requests a 500-gene panel for a patient with three approved matched therapies in India, TWO OF WHICH THE FAMILY CANNOT AFFORD, where our threshold permits a 52-gene panel FINDING EVERYTHING ACTIONABLE AT A THIRD OF THE PRICE. HE IS NOT WRONG TO WANT MORE — he is treating a specific patient and WOULD RATHER HAVE THE INFORMATION THAN NOT	THE BROADER PANEL IS DECLINED WITH THE NARROWER ONE PROPOSED AND THE YIELD DATA ATTACHED, and the pre-test conversation covers what a finding would mean IF THE THERAPY IS OUT OF REACH. THE SYSTEM REFUSES RATHER THAN WARNS: a panel below threshold for a stated indication CANNOT BE ORDERED WITHOUT A RECORDED CLINICAL OVERRIDE, and OVERRIDES ARE COUNTED, PUBLISHED AND REVIEWED BY THE TEST-APPROVAL COMMITTEE

A VUS is an absence described as a finding	A variant of uncertain significance IS NOT A FINDING — IT IS AN ABSENCE OF ONE, DESCRIBED IN TECHNICAL LANGUAGE THAT SOUNDS LIKE A DIAGNOSIS. Patients read "variant detected" and hear "SOMETHING IS WRONG WITH ME"; some pursue SURVEILLANCE, SURGERY OR REPRODUCTIVE DECISIONS on the strength of it	VUS RATE PUBLISHED PER PANEL, WHICH DISCOURAGES BROAD PANELS PRECISELY AS IT SHOULD SINCE BREADTH AND VUS RATE MOVE TOGETHER; NIL VUS reported in language a patient could read as a diagnosis; 892 VARIANTS RE-CLASSIFIED with 100% OF AFFECTED PATIENTS RE-CONTACTED — THE EXPENSIVE HALF AND THE PART ALMOST NOBODY DOES, BECAUSE A VARIANT RECLASSIFIED FROM UNCERTAIN TO BENIGN THREE YEARS LATER IS GOOD NEWS THAT NEVER REACHES THE PERSON STILL WORRYING ABOUT IT UNLESS SOMEBODY GOES LOOKING FOR THEM (₹86L)
Consent for heritable information is not the patient's alone	A pathogenic variant in one person is SIMULTANEOUSLY INFORMATION ABOUT PARENTS, SIBLINGS AND CHILDREN WHO NEVER CONSENTED, may not want to know, and in some cases WILL BE TOLD BY A FAMILY MEMBER WITH NO COUNSELLING AT ALL. Genomic data is also INHERENTLY IDENTIFYING, CANNOT BE TRULY ANONYMISED, AND IMPLICATES RELATIVES WHO ARE NOT DATA PRINCIPALS	THE FAMILY IMPLICATION STATED PLAINLY BEFORE THE SAMPLE IS TAKEN rather than in a consent form afterwards; PRE- AND POST-TEST COUNSELLING ON 100% OF HERITABLE TESTING with NIL tests run without it; incidental-findings preference RECORDED IN ADVANCE by the patient; and 22 COUNSELLORS AS THE BINDING CONSTRAINT ON VOLUME — THE CORRECT CONSTRAINT FOR THIS BUSINESS TO HAVE, SINCE A LABORATORY LIMITED BY SEQUENCERS RATHER THAN BY EXPLANATION CAPACITY IS PRODUCING REPORTS FASTER THAN ANYBODY CAN ABSORB THEM (₹1.24cr)
The assay you certified yourself	MOST MOLECULAR ASSAYS IN INDIA ARE LABORATORY-DEVELOPED TESTS — there is NO APPROVED KIT, NO EXTERNAL BODY THAT HAS ASSESSED THE CLAIM, AND NO INDEPENDENT CHECK THAT THE SENSITIVITY STATED ON THE REPORT IS THE SENSITIVITY ACHIEVED. The laboratory certifies the assay it profits from	VALIDATION DATA PUBLISHED PER ASSAY — sensitivity, specificity, limit of detection AND THE POPULATION IT WAS VALIDATED IN; EQA PARTICIPATION AND RESULTS PUBLISHED INCLUDING FAILURES per the vertical anchor, accepting that a failure is then public (₹3.46cr in the sensitivity); and RAW DATA RETURNED TO THE PATIENT ON REQUEST at 100%, BECAUSE A PERSON'S SEQUENCE IS NOT OUR PROPRIETARY ASSET
PCPNDT reaches cell-free DNA	PCPNDT applies to ANY test capable of revealing foetal sex INCLUDING CELL-FREE DNA, and a laboratory can breach it without ever intending to report sex	Registration current and records maintained; 46 FOETAL-SEX REQUESTS REFUSED AND REPORTED in Yr3, because THE REQUEST IS THE ONLY MEASURABLE THING AND A LABORATORY RECORDING NONE HAS STOPPED COUNTING RATHER THAN STOPPED RECEIVING THEM; sex chromosome information suppressed from prenatal reports by default; and staff trained in how to refuse and record safely

Reagent, platform and currency exposure	A 15% reagent rise takes profit to ₹4.24cr on closed imported systems WITH NO SUBSTITUTION OPTION ONCE INSTALLED, and platform placement terms can quietly shape which assays a laboratory offers	Multi-vendor strategy at replacement rather than lock-in; reagent contracts with volume and currency terms; platform placement terms DISCLOSED as a line because they tie the laboratory to a manufacturer's reagents; reference and pharma work at 7% of revenue as currency-hedged institutional income; and contribution reported PER TEST CATEGORY, never blended
Interpretive capacity and referral access	Curators and counsellors — not sequencers — limit volume; 246 referrers have left over the commission and yield-threshold positions; and clinician interpretive capability cannot be supplied by report alone	Clinician education funded at 2.0% of revenue against NIL referral commission; counselling and curation recruited ahead of volume rather than behind it; yield and VUS data published as the substitute for a sales relationship; tumour-board participation offered to referring oncologists; and honest acknowledgement that SOME DEPARTING REFERRERS OBJECT TO THE THRESHOLD ITSELF RATHER THAN TO THE COMMISSION POSITION

15. SWOT Analysis

Strengths • "No clinical action is indicated" printed where true • 8,200 low-yield panels declined; 89% given alternatives • VUS rate published; 892 re-classified, 100% re-contacted • Counselling on 100% of heritable testing • LDT validation data and EQA failures published	Weaknesses • ₹6.20cr forgone against ₹6.38cr of profit • Declines the fastest-growing revenue in the category • 246 referrers lost; two loss-making years • Counselling capacity caps heritable volume
Opportunities • Infectious-disease molecular — best margin and best yield • Clinicians who have had to explain a VUS once too often • Pharma trial support with no counselling burden • Rare-disease diagnosis ending decade-long odysseys • Any regulation of LDT claims or panel yield favours us	Threats • Competitors selling breadth as comprehensiveness • Reagent cost and currency on closed platforms • Counsellor and curator scarcity • A public EQA failure on a major assay

16. Recommended AiSevak Tools for This Business

- **Actionability field** — every report carries it; "no clinical action indicated" printed where true.
- **Yield threshold gate** — panels below the published threshold unorderable without a counted override.
- **VUS rate publisher** — per panel, alongside the panel's actionable yield.
- **Re-classification & re-contact engine** — variants tracked against evidence; patients found years later.
- **Counselling gate** — heritable tests unrunnable without recorded pre-test counselling.
- **LDT validation register** — sensitivity, specificity, LOD and validation population, published per assay.
- **Raw-data return** — a patient's own sequence released on request, with no proprietary lock.

17. Key Assumptions & Notes

- **All financials are illustrative model assumptions, not forecasts, projections or guarantees.** Revenue, test volumes, category margins, decline counts and re-classification rates are editable inputs; actual outcomes depend on reagent cost, counsellor availability, clinician adoption and reimbursement. Figures are in Indian rupees. **This plan inherits the diagnostics vertical anchor's rules from `pathology-lab`, including the nil-referral-commission and publish-the-failures rules applied here unchanged.**
- **The central integrity finding is that a molecular or genetic test can return a result that is accurate, expensive and clinically useless.** A variant of uncertain significance; a carrier status with no available intervention; a pharmacogenomic panel no prescriber will read; a tumour marker whose matched therapy is unavailable or unaffordable in India. The laboratory is paid the same for all of them, the referring clinician frequently cannot interpret them, and the patient receives a document that generates anxiety, cascade testing and occasionally irreversible decisions. **And every quality system ever built interrogates whether the answer was right — accreditation, proficiency testing, internal QC, turnaround, error rates — while not one of them asks whether anybody can act on it. So a laboratory can be flawlessly accurate, fully accredited, top of every EQA scheme, and still be producing documents that help nobody, at ₹40,000 each, at increasing volume, with every metric it reports improving.**
- **The hardest case is not the useless result but the unaffordable one.** A correct tumour profile naming a target whose therapy costs more per month than the family earns in a year is not a neutral non-event — it converts a manageable prognosis into a specific, named, unaffordable hope, and the laboratory that produced it has done real harm while performing perfectly. **So where a matched therapy exists but is unavailable or unaffordable in India, that is stated in the pre-test conversation rather than discovered in the report, and the family chooses whether to know.** And the commercial gradient runs directly at all of it: breadth adds variants far faster than it adds answers, so the broadest panels carry the best margins and the worst yield, and a salesperson calling a 500-gene panel "more comprehensive" is telling the literal truth.
- **So the unmeasured column is measured, printed and acted on.** Every report carries an actionability statement, and where true it says plainly "no clinical action is indicated by this result" — a sentence no laboratory in this market prints and the single most useful thing most of these documents could contain. Actionable yield is measured per panel per indication and published, and a panel below the published threshold is declined — 8,200 in Year 3 — with a narrower, higher-yield alternative proposed in 89% of cases rather than a bare refusal. The test-approval committee sits outside commercial and no employee's pay is linked to panel breadth or test value. **It costs ₹3.42 crore, which is the fastest-growing revenue line in the category. WHERE A RESULT CAN BE CORRECT AND USELESS, THE REPORT MUST SAY WHICH IT IS — AND THE LABORATORY MUST DECLINE THE TEST NOBODY CAN ACT ON.**
- **A variant of uncertain significance is not a finding, it is an absence of one described in language that sounds like a diagnosis.** Patients read "variant detected" and hear "something is wrong with me", and some pursue surveillance, surgery or reproductive decisions on the strength of it. **So the VUS rate is published per panel — which discourages broad panels exactly as it should, since breadth and VUS rate move together — nil variants are reported in diagnosis-like language, and 892 were re-classified with 100% of affected patients re-contacted.** Re-contact is the expensive half and the part almost nobody does, because a variant reclassified from uncertain to benign three years later is good news that never reaches the person still worrying about it unless somebody goes looking for them.
- **Consent for heritable information is not the patient's alone, and the assay is one the laboratory certified itself.** A pathogenic variant in one person is simultaneously information about parents, siblings and children who never consented and may not wish to know — so the family implication is stated plainly before the sample is taken, counselling is provided pre- and post-test on 100% of heritable testing with nil tests run without it, and 22 counsellors form the binding constraint on volume, which is the correct constraint for this business to have. **And because most**

molecular assays in India are laboratory-developed tests with no approved kit and no external body assessing the claim, validation data is published per assay including the population it was validated in, EQA results are published including failures, and raw data is returned to the patient on request — because a person's sequence is not our proprietary asset. 46 foetal-sex requests were refused and reported under PCPNDT, since the request is the only measurable thing.

- **The economics are an interpretive business wearing a laboratory's clothes.** Geneticists, pathologists, counsellors and curators cost ₹7.54 crore combined — 13.0% of revenue — and are what this laboratory actually sells, since the sequencing itself is a commodity available to anyone with ₹13 crore. Variant curation and re-contact at ₹2.32 crore is spent almost entirely on work that generates no invoice, and clinician education at ₹1.16 crore runs against a referral-commission spend of nil. **Commitments of ₹6.20 crore against ₹6.38 crore of profit mean an operator with the same sequencers and the same menu running trade-standard practice would earn ₹12.58 crore.** Worth noting honestly: infectious-disease molecular testing carries the highest margin in the book and is by a long distance the most actionable work we do — unglamorous, absent from the category's marketing, and the strongest business in the table.
- **Compliance and professional advice.** The Clinical Establishments Act 2010 and state rules; NABL accreditation under ISO 15189, with **laboratory-developed tests requiring in-house validation, so the laboratory certifies the assay it profits from**; the PCPNDT Act 1994, applying to any prenatal or cell-free DNA work capable of revealing foetal sex; the Drugs and Cosmetics Act and CDSCO for imported kits, reagents and companion diagnostics; the Digital Personal Data Protection Act 2023, under which **genomic data is sensitive personal data that is inherently identifying, cannot be truly anonymised, and implicates relatives who are not data principals**; ICMR's National Ethical Guidelines on consent, incidental findings and return of results, which are guidelines rather than statute; the ART and Surrogacy Acts where preimplantation testing arises; biosafety and Bio-Medical Waste Rules; NMC conduct regulations on referral commissions; GST, EPF/ESI and POSH. **Nothing requires a laboratory to state whether a result is actionable, and nothing prevents it selling a panel whose yield it has never measured — which is why the commitments above are business decisions rather than compliance ones.** Professional advice should be taken on LDT validation and claims, PCPNDT applicability to molecular prenatal work, genomic data protection and consent for family-implicating results.

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