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This document outlines the opportunity, requirements, and execution plan for a microRNA-based forensic assay. Its purpose is to help the team align on four critical fronts: (1) the scientific landscape we’re operating in, (2) the legal constraints we must overcome, (3) the market conditions that determine scale, and (4) the cost, timeline, and data needed to reach admissibility in court.

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## Key Questions This Document Aims to Answer

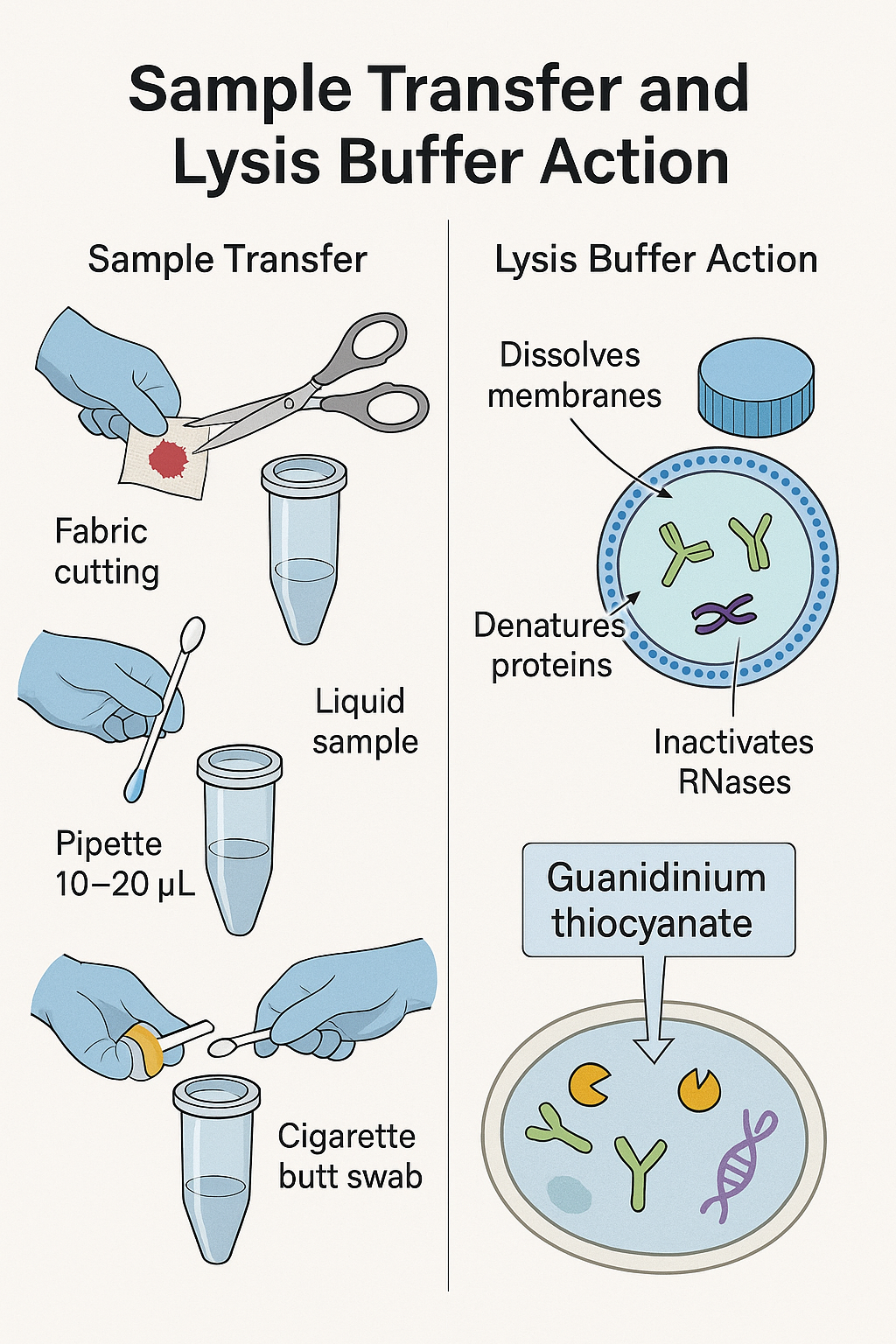
1. **Technical**: Can microRNA reliably identify body fluids where current methods fail?
2. **Legal**: What validation will courts require, and how long will it take?
3. **Financial**: Is there a venture-scale opportunity here, or should we pursue alternative funding?
4. **Strategic**: Should we position as a replacement or complement to existing tests?
5. **Practical**: What will it actually cost and how long will it take to bring this to market?

**Section 1: Background of the problem space**

**Current Forensic Evidence Collection**

When a forensic team arrives at a crime scene, their first priority is creating an unbroken record of every sample that might reach a courtroom. This written log, known as the chain of custody, documents who collected each piece of evidence, records the time of each transfer and tracks where each item travels throughout the investigative process. Courts require this continuous documentation to ensure no tampering or contamination occurred before testing begins. Likewise, any software we develop with our assay will need to keep this in mind.

Once the scene is properly documented, investigators open sterile evidence collection kits. These contain swabs designed to absorb biological samples, along with disposable scissors that are used to cut pieces of stained fabric, such as bloodied jeans. The challenge facing investigators is that biological materials degrade rapidly under real-world conditions. Messenger RNA, for instance, breaks down within hours at room temperature, making immediate preservation critical for successful analysis.

Cold-chain shipping provides the ideal solution for sample preservation but is a formidable logistic challenge at crime scenes. Refrigerated sample transport is expensive, requires specialized equipment, and moreover, is bound by a limited capacity. Even in coastal cities with abundant resources, it is not feasible to refrigerate all samples. Therefore, investigators must triage evidence and decide which merit this premium handling.

To guide these decisions, officers perform presumptive chemical assays on scene. Take note of this term, as it these assays we will either compliment or eliminate. These rapid tests indicate whether a stain contains biomarkers associated with blood, saliva, or semen, though they cannot provide definitive identification.

The inherent limitation of presumptive tests resembles that of preliminary drug screening. They serve as low-confidence indicators that suggest, but cannot prove, the presence of target substances. This uncertainty means presumptive results alone cannot are not admissible in court as evidence without additional laboratory confirmation.

Consider the standard blood detection method, known as the Kastle-Meyer test, that leverages hemoglobin’s peroxidase-like activity. In this test, investigators apply reduced colorless reagent (phenolphthalein) to a swab sample, followed by H₂O₂. If blood is present, these reagents will oxidize the substrate and cause the swab to turn bright pink.

While this **non-destructive** test can detect less than a microliter of blood, it suffers from significant false positive rates. Rust, plant peroxidases, certain cleaning products, and oxidized copper surfaces all produce identical color changes, necessitating DNA analysis before any sample can serve as courtroom evidence.

Saliva detection relies on α-amylase, an enzyme present in saliva at concentrations several thousand times higher than in other body fluids. The Phadebas Press Test employs filter paper embedded with dye-linked starch molecules. When saliva contacts the paper, α-amylase cleaves the starch, releasing blue dye that creates a visible spot within minutes. However, feces, **certain foods,** and **other amylase-containing materials** can generate false positives, again requiring laboratory verification.

**SEX-CRIME PRESUMPTIVE ASSAYS: Most relevant!**

Lastly, and of most interest to our startup, are forensics tests relevant to semen. This has the highest social value, as there majority of forensic backlog cases are from sexual assault evidence. There is upward of 90,000 to 400,000 kits waiting to be tested. A rapid, reliable assay would speed up the justice process for these victims and their families.

The first test most U.S. laboratories run is the **acid-phosphatase spot assay**. Acid phosphatase concentrations in semen are hundreds to thousands of times higher than in other body fluids, a fact noted in current National Institute of Justice training materials. This relevant physiology is that the **prostate epithelium secretes large quantities of the enzyme directly into prostatic fluid,** and in turn makes up part the ejaculate volume. Like the Kastle–Meyer test for blood, this is a colorimetric assay and produces a colored product.

A document with text on it

AI-generated content may be incorrect.A 2024 state protocol directs analysts to “examine with an alternate light source, **test areas of interest with the Acid Phosphatase test**, then decide on DNA or further work-ups”. Another 2024 SOP entitled Screening Test for Semen (Acid Phosphatase/Brentamine Test) describes the reaction chemistry, limitations, and report wording and lists the AP test as purpose “to perform a screening test for the presence of semen in forensic samples” [CT.gov](https://portal.ct.gov/dmv/-/media/despp-beta/pdf/scientific-services/sop/dna/fb/fb-12/fb-sop-12-screening-test-for-semen-2272-10.pdf). These documents confirm that the AP spot test remains the routine, first-pass assay because it costs only cents per swab and yields a visible purple color in under a minute. It is **quick, cheap, and not specific.**

Please See attached document for further info on assay workflow

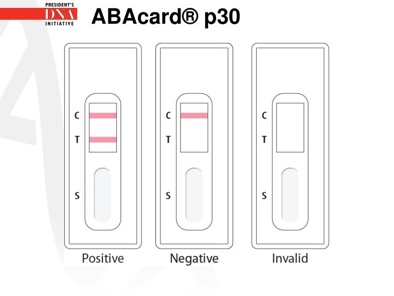
**A screenshot of a document

AI-generated content may be incorrect.**Despite its speed and price, the acid phosphatase test misses evidence in three common situations.

1. **Low-enzyme stains**—vasectomized or severely oligospermic donors contribute less enzyme, so partial crime-scene swabs often fall below the 30-second threshold for reactivity. A comparative biochemical study showed activity falling in the order normal > oligospermic > vasectomized > azoospermic.
2. **Environmental decay**—heat, humidity, or laundering denature the enzyme and thus cause a rapid decline in activity.
3. **Cross-reactivity**—contraceptive creams and vaginal secretions are common causes are false positives, reports one [state police forensic units](https://www.nj.gov/njsp/division/investigations/forensic-serology.shtml?utm_source=chatgpt.com). And oddly, one study out of a forensics unit in India found cross reactivity in amongst saliva, ear-wax, sweat and some plant juices.

**What is the ‘Gold standard?’ presumptive test for semen?**

To refine screening, crime labs employ two more robust assays. Take careful note that while these assays are more robust than acid phosphatase, they have the same failure nodes that microRNA can overcome. Moreover, both are over 25 years old. If you suspect science has improved in the past quarter century, you should suspect that we can develop a better technical solution.

The presumptive gold-standard for semen screening now consists of two lateral-flow strips that superseded the old acid-phosphatase spot. The first, **ABAcard p30**, targets prostate-specific antigen; a [National Institute of Justice](https://nij.ojp.gov/nij-hosted-online-training-courses/laboratory-orientation-and-testing-body-fluids-and-tissues/testing-body-fluids-tissues/semen/screening-and-identification-tests?utm_source=chatgpt.com) document from June 2023 still describes it as 'the currently accepted method of choice for identification of semen in all circumstances.' This kit reached the market in the late 1990s and became routine in U.S. laboratories during the early-2000s. The second, **RSID-Semen™**, targets semenogelin and was released in 2007.

A close-up of a test

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RSID Internal study is on the left. Observe that target analyte concentration is increasing from 1 to 9, yet peaks and falls after sample 6.

**How the gold standard kits work**

The two assays behave identically. They differ only in which biomarker their antibodies recognize. They share the same architecture, which is diagramed below. Depicted is a a sample pad, a conjugate pad, a nitrocellulose membrane with a test line and a control line, and a final absorbent wick. A lateral-flow semen strip contains **one mobile antibody species and two immobilized antibody species**.

A screenshot of a computer

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* **Mobile antibody + nanoparticle (conjugate-pad)**  
  Mouse monoclonal IgG is covalently attached to a gold nanoparticle. This antibody is specific for an epitope of the forensic biomarker and will refer to its target as **Epitope A (PSA/semenogelin). This moves with the fluid front, regardless of whether the analyte is present.**
* **Immobilized antibody #1 – the test line**  
  A second antibody say goat or rabbit IgG that recognizes **Epitope B** on the same antigen, is immobilized across the nitrocellulose membrane at the test line. When the gold-antibody–antigen complex reaches this stripe, the capture antibody grabs the antigen’s free epitope and anchors the entire complex. Thousands of gold particles accumulate, producing the colored test bar. Take note that the color is produced by accumulation of the gold nanoparticle, not by the analyte itself.
* **Immobilized antibody #2 – the control line**  
  Farther downstream, another embedded set of antibodies is designed to binds the constant-region (Fc) of any gold-labeled probe that was not caught at the test line, proving that the conjugate was active and that capillary flow traversed the full strip.

Given this assay design, what do you expect would occur when there is a high condition of target analyte? What would you observe visually on the strip and why? Ask yourself: in capillary flow, what moves faster—a small unbound protein or a bulky gold-antibody-protein complex?

In high analyte conditions, every antibody at the conjugate pad saturates with antigen, leaving no free binding sites. Meanwhile, excess free protein rushes ahead and saturates the test line. Since the gold nanoparticle creates the visible signal—not the protein itself—excess of the target protein blocking the binding sites at the test line prevents sandwich formation.

**In cases with high concentrations of the sample, there is the test line will appear blank.** This false negative in the present of high concentrations is known as the hook effect. Other causes of false negatives, The 2024 Connecticut p30 assay SOP flags as a cause of false negatives—and when PSA degrades in hot, wet environments; undiluted adult urine or breast milk can also give weak positives.[CT.gov](https://portal.ct.gov/dmv/-/media/despp-beta/pdf/scientific-services/sop/dna/fb/fb-15/fb-sop-15-ria-for-semen-2275-11.pdf)

A pink card with black text

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**Chemical differences, distinct false-positive profiles, shared weak points**

Although PSA and semenogelin strips use the same lateral flow assay design, the proteins they detect behave differently in biological contexts, resulting in distinct assay characteristics. PSA is known to circulate at low levels outside of semen in fluids such as breast milk, urine, and some vaginal secretions. As a result, PSA-based tests are expected to show broader cross-reactivity and a higher likelihood of false positives. In contrast, semenogelin is produced exclusively in the seminal vesicles and is believed to be specific to seminal fluid, making it theoretically less prone to cross-reactivity with other body fluids.

In a 2024 study titled A Comparative Analysis of Accuracy and Sensitivity in Semen Presumptive Testing, Heather Rogers tested three commercial kits—ABAcard P30 (PSA), Seratec PSA, and RSID Semen (semenogelin)—against a range of real-world substrates. While PSA-based strips did produce false positives with female urine, the **semenogelin-based RSID™ strip also returned unexpected positives.** As Rogers writes, there were

“…false positives occurring to some degree with all methods. RSID Semen, Seratec PSA, and ABAcard P30 all had issues detecting semen in a 1:10,000 dilution. Additionally, RSID Semen could not detect semen when it was mixed with dirt. There was an issue of non-specificity with all three of the test kits with various absorbent hygiene products. RSID Semen, Seratec PSA, and ABAcard P30 all had several false positive test results with tampons, menstrual pads with blood, and diapers with urine samples. Additionally, ABAcard P30 had false positive test results with female urine samples”.

The below figure is from her paper.

A graph of test results

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A second study by Melanie Chang (2011) further complicates the specificity claims around RSID™. In testing under various extraction conditions, she found that “RSID – Semen gave positive results with female urine and vaginal samples,” and noted that the test produced “a false positive result with PBS and a failed test with ultrapure autoclaved water.” These findings suggest that both buffer composition and biological contaminants can interfere with RSID’s reliability, despite its intended specificity.

Taken together, these theses indicate that while PSA and semenogelin differ in origin, neither yields a truly fluid-specific presumptive result under field-relevant conditions. Both proteins are liable for environmental degradation, false positives, and false negatives. This reinforces the need for a next-generation confirmatory assay—such as one based on tissue-specific microRNAs—that is robust to mixed matrices, environmentally stable, and chemically agnostic to buffer conditions.

**SUMMARY**

In summary, there are consistent limitations that persist across all presumptive body fluid assays. They generate false positives, miss degraded or dilute samples, and produce variable results depending on environmental conditions and operator technique. This systematic weakness in current methodology creates a clear market opportunity for more reliable field-deployable technologies that can withstand environmental stress while avoiding cross-reactivity pitfalls.

**COSTS OF THESE AFORMENTIONED ASSAYS**

|  |  |  |  |  |
| --- | --- | --- | --- | --- |
| Product | Tests | Price | Price per Test | Source |
| **ABAcard P30™** (PSA) | 25 tests | $346.80 | ≈ $13.90 | ([Fisher Scientific](https://www.fishersci.com/shop/products/abacard-p30-semen-test-25t-kit-1/NC1699451?utm_source=chatgpt.com)) |
| **Seratec PSA SemiQuant™** (PSA) | 40 tests | $185.00 | ≈ $4.60 | ([serological.com](https://serological.com/forensic-dna-testing/facility-items/r564-seratec-psa-semiquant-165/?utm_source=chatgpt.com)) |
| **RSID™ Semen – Universal Buffer kit** (semenogelin) | 25 tests | $267.60 | ≈ $10.70 | [(Fisher Scientific)](https://www.fishersci.com/shop/products/rsid-semen-kit-w-universl-buf/NC0396091?utm_source=chatgpt.com) |
| RSID™ Semen Field kit (5-pack) | 5 tests | $95.00 | ≈ $19.00 | [(store.ifi-test.com)](https://store.ifi-test.com/product/fluid-id/rsid-semen-field-kit-5-packs-kit-complete-kit-for-use-in-field/?utm_source=chatgpt.com) |
| **Seratec PAM™ duplex** (semen + saliva)† | 40 tests | $300.00 | ≈ $7.50 | [(serological.com)](https://serological.com/forensic-dna-testing/facility-items/r615pam/?utm_source=chatgpt.com) |

**SECTION 3: MicroRNA**

MicroRNAs (miRNAs) are short, 19-25 nt, non-coding RNA molecules that regulate gene expression and travel through the body inside ribonucleoprotein complexes and extracellular vesicles. These complexes shield the molecules from nucleases, heat, and UV light, which explains their remarkable persistence on clothing, soil, and aged evidence. Studies that compared matched samples show miRNAs remain detectable after conditions that erase most mRNA signals and severely fragment DNA

**Core forensic capabilities**

MicroRNAs represent an emerging frontier in forensic science with significant potential to enhance investigative capabilities beyond traditional analytic method. These small, non-coding RNA molecules, typically 19-25 nucleotides in length, offer unique advantages due to their remarkable stability and tissue-specific expression patterns. This includes body fluid identification and better estimates of time of death (Post mortem interval)

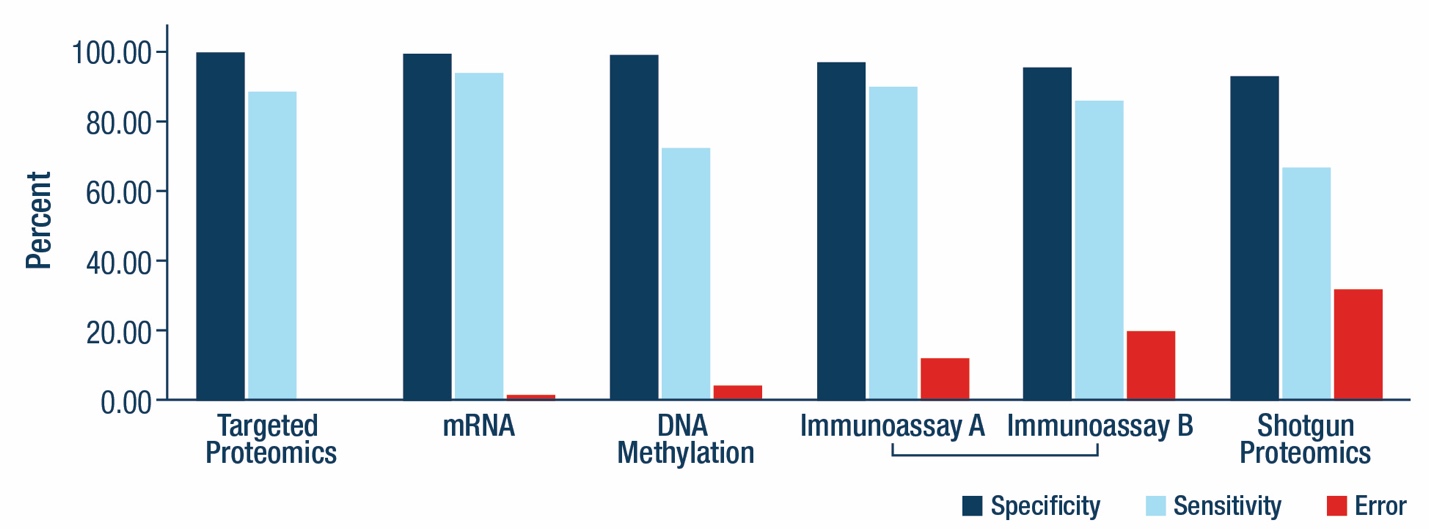
For investigators, microRNA analysis dramatically enhances the ability to reconstruct crime scenes and establish accurate narratives of events. Consider a sexual assault investigation where multiple individuals had consensual contact with the victim prior to the assault. Traditional DNA analysis might identify multiple contributors but cannot distinguish between biological fluids deposited during consensual versus non-consensual contact. MicroRNA profiling can identify whether detected sample originates from saliva, semen, or skin cells, allowing investigators to differentiate between a shared drink and sexual assault.

Different microRNAs break down at predictable, tissue-specific rates. Some remain stable for months (miR-16), while others degrade within days (miR-10b). By measuring the ratio of stable to unstable markers, forensic scientists can estimate post-mortem intervals with unprecedented precision. In cases where bodies are discovered weeks or months after death, traditional decomposition-based timing methods often provide only broad estimates. MicroRNA analysis can narrow these windows significantly. For instance, in a case where a missing person's remains are discovered, establishing whether death occurred shortly after disappearance or weeks later can completely redirect an investigation, potentially excluding or implicating suspects based on their alibis during the refined timeframe.

Please see below relevant studies

|  |  |
| --- | --- |
| **Hyperlinked study** | **Finding** |
| |  |  | | --- | --- | |  | [**mRNA and microRNA stability validation of blood samples under different environmental conditions**. Forensic Sci Int Genet 2021. *DOI 10.1016/j.fsigen.2021.102567*](https://pubmed.ncbi.nlm.nih.gov/34403952/) | | Blood-specific miR-451a and miR-16 stayed detectable after 90 °C heat shocks, UV irradiation, and 28 days at 80 % RH, while matched mRNAs dropped below detection within 24 h. |
| [**The stability and persistence of blood and semen mRNA and miRNA targets for body fluid identification in environmentally challenged and laundered samples**. Legal Medicine 2019. *PubMed 30959396*](https://pubmed.ncbi.nlm.nih.gov/30959396/) | Six-month trial of 37 °C heat, tropical humidity, direct sunlight, and machine-laundering: miRNA markers for blood and semen remained amplifiable for the full 6 months; all mRNA targets disappeared after ≤30 days. |
| [**Forensic stability evaluation of selected miRNA and mRNA markers in blood-stained samples under different conditions**. Forensic Sci Int Genet 2024. *PubMed 39094222*](https://pubmed.ncbi.nlm.nih.gov/39094222/) | miR-451a, miR-144-3p, and miR-888-5p survived 12 weeks of freeze–thaw cycling, 60 °C dry heat, and outdoor weathering; corresponding mRNAs lost >90 % signal. |
| [**Estimation of the post-mortem interval using microRNA in the bones**. J Forensic & Legal Med 2020. *DOI 10.1016/j.jflm.2020.102049*](https://pubmed.ncbi.nlm.nih.gov/32861958/) | let-7e and miR-16 remained quantifiable in patella bone for **up to 2 years** post-mortem, providing a molecular clock after extensive decomposition. |
| [**Distinct spectrum of microRNA expression in forensically relevant body fluids and probabilistic discriminant approach**. Sci Rep 2019. *DOI 10.1038/s41598-019-50796-8*](https://www.nature.com/articles/s41598-019-50796-8?utm_source=chatgpt.com) | Core fluid markers (e.g., miR-451a, miR-888-5p) still classified samples with >95 % accuracy after 8 weeks of UV exposure and 37 °C/80 % RH incubation on porous substrates. |
| [**Best of both: A simultaneous analysis of mRNA and miRNA markers for body fluid identification**. Forensic Sci Int Genet 2022. *DOI 10.1016/j.fsigen.2022.102709*](https://www.sciencedirect.com/science/article/pii/S1872497322000485?utm_source=chatgpt.com) | After 30 days of alternating sun/rain outdoor cycles, miRNA markers showed ≥95 % detection while mRNA signals fell below 40 %, confirming the benefit of hybrid panels for degraded evidence. |
| [**Differentiation of five forensically relevant body fluids using an 18-miRNA panel under environmental stress**. Forensic Sci Int Genet 2024. *PubMed 39076047*](https://pubmed.ncbi.nlm.nih.gov/39076047/) | The 18-marker panel retained ≥96 % classification accuracy after 6 weeks at 60 °C, 80 % RH, and continuous UV exposure. |

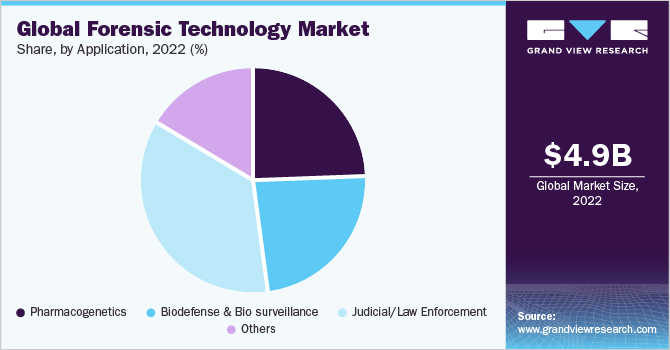
The NIJ article *“Direct Comparison of Body Fluid Identification Technologies”* (published Nov 21 2024) reports the first NIJ-funded head-to-head evaluation of six body-fluid tests: two traditional immunoassays, DNA-methylation PCR, mRNA RT-qPCR, shotgun proteomics, and targeted proteomics.



**Source:** National Institute of Justice - [Direct Comparison of Body Fluid Identification Technologies](https://nij.ojp.gov/topics/articles/direct-comparison-body-fluid-identification-technologies)

**MARKET OPPORUTTINIY**

The U.S. forensic system is straining under the weight of a substantial evidence-processing backlog. According to the Bureau of Justice Statistics, publicly funded crime laboratories received approximately 3.3 million forensic service requests in 2020, yet concluded the year with over 710,000 cases still unresolved after 30 days. [At the BJS-reported average cost of $620 per case,](https://bjs.ojp.gov/document/pffcl20.pdf) this backlog represents roughly $440 million in stranded forensic work annually—an unmet need that creates a natural entry point for new technology. **If a microRNA assay were able to unlock just 10 percent of this degraded-evidence segment, it would generate approximately $44 million in new U.S. billings each year.**

This opportunity sits within a growing global market[. The forensic technology sector was valued at $5.51 billion in 2023 and is projected to grow to $10.65 billion by 2030, reflecting a compound annual growth rate (CAGR) of 9.9 percent](https://www.grandviewresearch.com/industry-analysis/forensic-technology-market). Within this market, consumable kits and reagents account for approximately 67 percent of all revenue, underscoring a structural bias toward recurring-purchase assay platforms over one-time instrumentation sales. This consumables-heavy dynamic creates favorable conditions for platforms like microRNA cartridges that drive high-margin, repeatable sales through laboratory workflows.

Importantly, crime laboratories and public agencies have already demonstrated a willingness to pay premium prices for tools that deliver speed and certainty in forensic outcomes. In the case of Rapid DNA instruments, for example, agencies such as the [Florida Sheriffs Association have invested roughly $250,000 per unit](https://flsheriffs.org/blog/entry/public-safety-tip-what-you-need-to-know-about-rapid-dna/?utm_source=chatgpt.com), with consumables priced at over $100 per cartridge—more than ten times the cost of standard STR reagents. Similarly, ABAcard p30 strips for semen detection are widely adopted despite costing over ten times more than legacy acid phosphatase tests. In both cases, the premium is justified by either courtroom admissibility or turnaround time, illustrating the high value placed on decisiveness and reliability in forensic contexts. A microRNA assay priced between $80 and $100 per use would occupy a commercially viable middle ground: offering novel evidentiary capabilities at a price point aligned with existing spending patterns.

The funding environment further supports innovation in this space. The U.S. National Institute of Justice (NIJ) consistently allocates between $12 and $14 million annually to support forensic science research and development. [In fiscal year 2024, the NIJ awarded $13.6 million across 24](https://nij.ojp.gov/funding/nij-awards-14m-support-forensic-science-research?utm_source=chatgpt.com) projects focused specifically on method validation, prototype development, and inter-laboratory studies. This funding stream can be used to offset the cost of critical early-stage activities, including multi-site validation studies under ISO 17025, the generation of error-rate reference datasets required for Daubert admissibility, and the piloting of field-ready qPCR cartridges in state laboratories**. By leveraging NIJ support, our startup can reduce capital intensity and significantly de-risk the pathway to courtroom acceptance.**

Downstream market validation comes from recent M&A activity. Once a specialized forensic assay demonstrates courtroom viability and generates recurring kit sales, it becomes a prime acquisition target for large life sciences firms seeking to expand their footprint in forensic genomics. [In January 2023, QIAGEN acquired Verogen—a spinout from Illumina focused on forensic next-generation sequencing—for $150 million in cash](https://www.nasdaq.com/articles/qiagen-completes-acquisition-of-verogen?utm_source=chatgpt.com). Verogen’s flagship products include ForenSeq kits, which enable simultaneous analysis of thousands of STRs and SNPs, and GEDmatch PRO, a database used in investigative genetic genealogy. At the time of acquisition, Verogen was projected to generate $20 million in revenue for 2023, implying a deal multiple of approximately 7.5× sales.

Together, these factors create a compelling case for investment. The U.S. backlog alone offers an immediate, underserved demand signal. The global market for forensic technology is growing quickly and structurally favors consumable-driven models. Public funding is available to subsidize validation, reducing execution risk. And once product-market fit is achieved, the acquisition pathway is well established and supports attractive exit multiples. **In sum, the development of a microRNA-based forensic assay is well aligned with both unmet need and proven commercial dynamics, positioning it as a high-upside opportunity within a defensible and expanding market segment**

**Implicit question:** Your technology is new, perhaps promising, but has failed to reproduce,

## Overcoming the Reproducibility Barrier: Lessons from Forensic History

Investors and forensic decision-makers naturally question the reproducibility of emerging technologies—particularly when early results, however promising, have not yet demonstrated consistent performance across laboratories. This concern is valid. However, it is not disqualifying. In fact, history suggests that reproducibility challenges are a predictable phase in the life cycle of transformative forensic technologies. Those who anticipate and strategically navigate this phase often emerge as long-term market leaders.

The path of microRNA assays today closely parallels the early trajectories of DNA profiling and PCR—two technologies that now define modern molecular forensics.

When Alec Jeffreys introduced DNA fingerprinting in 1985, the method faced widespread reproducibility issues. Laboratories used different restriction enzymes, gel conditions, and probe sequences, making cross-institutional comparisons nearly impossible. Acceptance by the courts and forensic community required years of coordinated standardization. This culminated in the formation of the [Technical Working Group on DNA Analysis Methods (TWGDAM) in](https://www.swgdam.org/about-us?utm_source=chatgpt.com) 1988, which established consensus protocols, mandated inter-lab proficiency testing, and eventually standardized the CODIS core loci. What began as a fragmented field matured into a global gold standard.

PCR experienced a similar trajectory. First described by Kary Mullis in 1985, early PCR reactions were notoriously difficult to reproduce. Amplification results varied widely, contamination was common, and many researchers dismissed the method as unreliable. PCR’s transition into a trusted forensic mainstay required a series of strategic advances: the development of stable, commercially available reagents; introduction of hot-start polymerases; buffer optimization; and the articulation of good laboratory practices designed specifically for PCR workflows. These efforts transformed PCR from a fragile research tool into a foundational method in life sciences.

Currently, the microRNA field lacks shared extraction protocols, reference materials, amplification conditions, and marker panels. Detection methods vary widely—from qPCR to sequencing to microarray—each with distinct sensitivity profiles. As with early DNA methods, inconsistency stems not from flawed science but from the absence of coordinated infrastructure. That gap represents both a risk and an opportunity.

Once reproducibility is established, the first successful platform often captures dominant market share, as Promega did with STR kits by investing early in validation and interoperability. Against this backdrop, a microRNA startup has three viable strategic pathways, each aligned to different capital profiles and exit timelines:

**1. Establish the Standard (High Capital, High Defensibility)**

This approach treats reproducibility as the main strategic focus. It involves leading the charge on standardization through ISO 17025-aligned validation, multi-lab reproducibility trials, reference dataset creation, and active engagement with forensic working groups. This is likely capital-intensive and on the span of 5–7 years, but this strategy positions the company as the default platform in an emerging modality. It converts scientific friction into long-term defensibility, potentially leading to exclusive procurement contracts, kit mandates, or acquisition by a major life sciences player.

**Pursue Tactical Niches (Moderate Capital, Near-Term Revenue)**

Alternatively, the company can target less-regulated domains where reproducibility standards are lighter but technical need is high. Use cases include military forensics, disaster victim identification (DVI), or research-use-only contexts. This pathway enables revenue generation while building scientific credibility. Successful forensic firms such as [InnoGenomics](https://innogenomics.com/products/innotyper-21/) and [DNA Solutions](https://www.dnasolutionsusa.com/services/forensic_mass_disaster) began with this approach, using it to fund development and eventually expand into court-admissible applications.

**Position as Complementary, Not Competitive (Low Barrier, Unique Value)**

The third strategy avoids head-to-head comparison with established tools. Instead, it positions microRNA as an orthogonal solution—particularly for body fluid identification in degraded samples where STR profiling, or presumptive chemical assays, fail This approach addresses a well-documented forensic gap without triggering direct challenges to existing workflows or admissibility precedents. By solving a problem that current tools cannot, the technology can be introduced earlier and with less resistance, especially if paired with conventional DNA evidence in a hybrid workflow.

**What do we need to do to get into a courtroom?**

The **Daubert standard** stems from the 1993 Supreme Court decision *Daubert v. Merrell Dow Pharmaceuticals* and governs the admissibility of expert testimony under Federal Rule of Evidence 702. It places the judge in the role of *gatekeeper*, requiring that any scientific method offered in court must be both **reliable** and **relevant**.

To determine reliability, courts consider five core factors:

1. **Testability** — Can the method be empirically tested and falsified?
2. **Peer Review** — Has it been published and subjected to scientific scrutiny?
3. **Known Error Rate** — Are accuracy and precision statistically quantified?
4. **Standards and Controls** — Does the method follow a validated protocol?
5. **General Acceptance** — Is the method recognized by experts in the relevant scientific community?

Judges evaluate methodology not just the expert’s qualifications to determine if the evidence is scientifically sound. Somestates still uses a simpler standard, known as Frye, where scientific evidence is admissible once the underlying methodology is “generally accepted” within its field. No error-rate calculation or peer-review proof is required.

As of May 2025, California, New York, Pennsylvania, Washington, Illinois, Minnesota, and a handful of smaller jurisdictions still apply Frye for state cases, while their federal counterparts follow Daubert.

**Sample costs**

Samples can also be sourced from Partner crime-labs (future validation) or the red cross.

|  |  |  |
| --- | --- | --- |
| **Fluid** | **Vendor & catalog code** | **Unit price\*** |
| Whole blood (10 mL, K2-EDTA) | Innovative Research — IWB1K2E10MLC | **$98** |
| Saliva (single donor, ≥1 mL) | Lee Bio 991-05-M-1 | **$76.88** |
| Semen (pooled donors, 1 mL) | Lee Bio 991-04-P-1 | **$77.49** |
| Vaginal fluid (100 µL, single donor) | Innovative Research — IRHUSVF100UL | **$728.00** |
| Menstrual blood (≥1 mL, single donor) | Lee Bio 991-15-S-1 | **$245.00** |

**Stakeholder list**

|  |  |  |
| --- | --- | --- |
| **Stakeholder** | **Primary need / pain point** | **How the assay addresses it** |
| State & local crime laboratories (e.g., Texas DPS, NY State Police Forensic Sci. Center) | Low-complexity workflow, ISO 17025-ready validation package, compatibility with existing thermocyclers | Provide turnkey kit, SOP, QC chart, and developmental-validation data for rapid scope addition |
| Federal labs (FBI, ATF, USACIL) | Early-adopter innovations that set national practice, data for policy briefs | Supply multi-site data package; invite participation in method-development round-robin |
| Prosecutors & district attorneys | Clear, reliable evidence that survives Daubert, helps establish activity level (what body fluid, where) | Publish peer-reviewed error-rate tables, ANSI/ASB standard citation, expert-witness bench book |
| Public defenders & innocence-project lawyers | Transparent method, accessible discovery files for independent review | Make raw validation data and assay software open for defense replication; offer low-cost proficiency tests |
| Kit vendors & diagnostics OEMs (Thermo Fisher, Qiagen, Promega) | Proven market demand, defensible IP, clear standards moat | License the marker panel and locked dataset; co-brand under ANSI/ASB standard to secure reagent exclusivity |
| Grant funders (NIJ Forensic Science R&D) | High-impact technology that closes critical evidence gaps | Frame proposal around documented STR failure cases and projected cost-savings per investigation |
| Accreditation bodies (ANAB, A2LA) | Robust validation dossiers to approve scope expansions | Deliver complete developmental- and internal-validation templates aligned to ISO 17025 § 7.2 |

**SUPPLEMENTAL SECTION : How Did RSID get validated? Can we copy their study design?**

Forensic testimony in U.S. courts follows Frye or Daubert standards. Neither standard requires a single peer-reviewed “developmental validation”; they require that the method be generally accepted (Frye) or have reliable scientific grounding (Daubert). Once a crime laboratory completes its own internal validation—often guided by SWGDAM or ASB standards—the strip’s results can be introduced. Labs began adopting RSID-Semen soon after the 2006–2007 studies; published case reports using semenogelin strips appear in the literature before 2010, indicating courtroom use well ahead of the 2017 update.

**Timeline of validation work**

* **2006 – manufacturer “Rev. B” developmental-validation report.** Independent Forensics published a 70-page internal study titled Developmental Validation Studies of RSID-Semen that documented sensitivity, species specificity, substrate effects, temperature stability, and the high-dose hook phenomenon. [seidden.com](https://www.seidden.com/Develp_Validation_RSID_Semen_03_22_06.pdf?utm_source=chatgpt.com)
* **2007 – first peer-reviewed comparison with ABAcard.** Pang et al. evaluated RSID-Semen alongside a PSA strip and showed that the new test detected semenogelin in samples where sperm were absent. [ScienceDirect](https://www.sciencedirect.com/science/article/abs/pii/S037907380600524X?utm_source=chatgpt.com)[PubMed](https://pubmed.ncbi.nlm.nih.gov/16949235/?utm_source=chatgpt.com)
* **2011–2012 – Journal of Forensic Sciences developmental-validation article.** Old et al. reported < 2.5 nL detection limits, no cross-reactivity, and performance on casework-like samples. [PubMed](https://pubmed.ncbi.nlm.nih.gov/22211796/?utm_source=chatgpt.com)[ResearchGate](https://www.researchgate.net/publication/51974933_Developmental_Validation_of_RSID_TM-Semen_A_Lateral_Flow_Immunochromatographic_Strip_Test_for_the_Forensic_Detection_of_Human_Semen?utm_source=chatgpt.com)
* **2017 – updated manufacturer validation (“Rev. D”).** This later study expanded the stress tests (laundering, UV, detergents) but was not the first validation. [ifi-test.com](https://www.ifi-test.com/documents/RSID_Semen_Validation.pdf?utm_source=chatgpt.com)

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**PITCH SETUP**

This project seeks to design, validate, and operationalize a forensic assay using microRNA (miRNA) expression profiles to identify biological fluids left at crime scenes. Our core objective is to demonstrate that miRNA-based fluid identification is scientifically reliable but also legally admissible under the Daubert standard and scalable for routine deployment in forensic laboratories.

Our co-founders met while working on an RNA therapeutics team at a major U.S. pharmaceutical company. Their shared obsession with RNA, and bringing drugs to patients, formed the genesis of this startup. They had been working on RNA's biggest unsolved problem: current RNA therapies distribute throughout the body indiscriminately, causing off-target effects and limiting therapeutic potential. Their research, along with mounting public evidence, showed that microRNAs could solve this problem.

MicroRNAs are small, non-coding RNA molecules that regulate gene expression by silencing specific messenger RNAs. Each cell type expresses a distinct combination of these microRNAs, creating a unique molecular fingerprint that reveals a cell's tissue of origin, physiological state, and developmental stage. We can exploit these fingerprints by engineering therapeutic RNAs with artificial binding sites that match specific microRNA patterns. This creates biological logic gates that can be used to create next generation therapeutics for patients.

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When the company disbanded its U.S. RNA division during global restructuring, our co-founders faced barriers to continuing their work. The U.S. political and investment climate has grown increasingly hostile toward RNA science, and despite mRNA vaccines' success, public skepticism and regulatory uncertainty make investors wary of RNA platforms. Moreover, creating viable therapeutic platforms requires navigating a high-capital, long-horizon development cycle. And while such work holds clear value to human health, its risk and cost often render it invisible to investors focused on short-term returns

Therefore, the capital and political realities prompted us to seek alternative markets where RNA technology could generate reliable revenue while still advancing the state of the art. We turned to forensic science, where many core assays have remained unchanged for over two decades. This field offered a rare alignment of technical need, a viable addressable market, and social impact.

When investigators find biological evidence at a crime scene, a stain on clothing, a swab from an assault victim, dried material on a weapon, they must answer two separate questions: whose is it, and what is it? DNA tells you who, but not what. It can match a suspect to a sample, but it cannot distinguish whether that sample was blood, semen, or saliva. This distinction is crucial because the type of fluid reveals the nature of the activity.

Consider a sexual assault case where the suspect admits prior consensual contact with the victim. His DNA will be present regardless. But is it saliva from conversation? Skin cells from physical contact? Or semen from assault? The fluid type establishes the activity and therefore is evidence of the crime. Yet current presumptive tests, based on 1990s protein chemistry, fail on degraded samples and produce false positives inadmissible in court.

Today’s presumptive tests for body fluids are chemical color reactions that suffer from false positives, degrade rapidly, and cannot be used once samples have aged. MicroRNAs offer a precise molecular alternative. Because their expression patterns are tissue-specific and remain detectable even in degraded material, they can identify the source of biological fluids with greater accuracy and longer post-event viability. Better forensic assays directly prevent violent crimes by linking perpetrators earlier in their offending cycle, before further escalation to the next victim.

The market opportunity for microRNA-based body fluid identification is substantial and immediate. [The forensic technology sector was valued at $5.51 billion in 2023 and is projected to grow to $10.65 billion by 2030, reflecting a compound annual growth rate (CAGR) of 9.9 percent](https://www.grandviewresearch.com/industry-analysis/forensic-technology-market). Within this market, consumable kits and reagents account for approximately 67 percent of all revenue, underscoring a structural bias toward recurring-purchase assay platforms over one-time instrumentation sales. This consumables-heavy dynamic creates favorable conditions for platforms like microRNA cartridges that drive high-margin, repeatable sales through laboratory workflows.

According to the Bureau of Justice Statistics, publicly funded crime laboratories received approximately 3.3 million forensic service requests in 2020, yet concluded the year with over 710,000 cases still unresolved after 30 days. At the Bureau of Justice Statistics-reported average cost of $620 per case. this backlog represents roughly $440 million in stranded forensic work annually. This is an unmet need that creates a natural entry point for new technology. **If a microRNA assay were able to unlock just 10 percent of this degraded-evidence segment, it would generate approximately $44 million in new U.S. billings each year.**

The funding environment further supports innovation in this space. The U.S. National Institute of Justice (NIJ) consistently allocates between $12 and $14 million annually to support forensic science research and development. **By leveraging NIJ support, our startup can reduce capital intensity and significantly de-risk the pathway to courtroom acceptance.**

This established funding pathway enables us to leverage initial ACX support into substantially larger NIJ grants for expanded validation and field deployment.

Downstream market validation comes from recent M&A activity. Once a specialized forensic assay demonstrates courtroom viability and generates recurring kit sales, it becomes a prime acquisition target for large life sciences firms seeking to expand their footprint in forensic genomics. [In January 2023, QIAGEN acquired Verogen—a spinout from Illumina focused on forensic next-generation sequencing—for $150 million in cash](https://www.nasdaq.com/articles/qiagen-completes-acquisition-of-verogen?utm_source=chatgpt.com). Verogen’s flagship products include ForenSeq kits, which enable simultaneous analysis of thousands of STRs and SNPs, and GEDmatch PRO, a database used in investigative genetic genealogy. At the time of acquisition, Verogen was projected to generate $20 million in revenue for 2023, implying a deal multiple of approximately 7.5× sales.

Together, these factors create a compelling case for investment. The U.S. backlog alone offers an immediate, underserved demand signal. The global market for forensic technology is growing quickly and structurally favors consumable-driven models. Public funding is available to subsidize validation, reducing execution risk. And once product-market fit is achieved, the acquisition pathway is well established and supports attractive exit multiples. In sum, the development of a microRNA-based forensic assay is well aligned with both unmet need and proven commercial dynamics, positioning it as a high-upside opportunity within a defensible and expanding market segment

Our hypothesis is that miRNA markers, due to their tissue-specific expression and post-mortem stability, can enable a reliable molecular signature for each body fluid. Our project will execute the foundational steps required to transition this technique from academic literature into a deployable, court-validated forensic product.

The path from validation to market adoption is well-established. Unlike medical devices requiring FDA approval, forensic tests operate under enforcement discretion, needing only to meet evidentiary standards. Recent market validation comes from QIAGEN's $150 million acquisition of Verogen at 7.5 times revenue, demonstrating strong exit multiples for validated forensic technologies. More importantly, similar technologies like RSID-Semen achieved nationwide court admissibility through systematic validation between 2006 and 2017, providing a proven roadmap we can accelerate.

We are requesting $57k for our initial pilot study, to get groundwork data needed for NIJ grants.

uster**55,957**

Our co-founders met while developing RNA therapeutics at a major pharmaceutical company. They were solving RNA therapy's biggest problem: current treatments distribute indiscriminately throughout the body, causing severe off-target effects. Their solution used microRNAs—small RNA molecules that create unique molecular fingerprints in each cell type. By engineering therapeutic RNAs with artificial microRNA binding sites, they could create biological logic gates: drugs that activate only in cancer cells while remaining dormant in healthy tissue.

When the company shuttered its RNA division, they faced reality. Developing RNA therapeutics requires $200-500M—impossible without clinical proof. The U.S. investment climate has turned hostile toward RNA platforms despite mRNA vaccine success. But they realized the same microRNA signatures that enable drug targeting also solve critical forensic problems.

Forensic science relies on presumptive tests unchanged since the 1990s. When investigators find biological evidence, they must answer: whose is it, and what is it? DNA identifies WHO but not WHAT. This distinction matters—in sexual assault cases where suspects admit prior contact, proving the fluid is semen versus saliva determines guilt. Current protein-based tests fail on degraded samples and produce false positives inadmissible in court.

MicroRNAs solve this. Each body fluid has distinct microRNA patterns—blood expresses miR-451a, semen contains miR-888-5p. These signatures survive six months after proteins degrade, enabling definitive identification of previously untestable evidence. This capability transforms investigations and prevents crimes—studies show the average rapist commits 5.8 assaults before identification.

The market opportunity is immediate. The forensic technology sector, valued at $5.51B growing at 9.9% annually, derives 67% of revenue from consumable tests. U.S. labs face 710,900 backlogged cases worth $440M at $620 per case. Labs already pay $14 per test for methods with 15% error rates, establishing price acceptance for superior technology at $80-100. Capturing 10% of degraded evidence generates $44M annually.

The funding pathway is clear. This $50K grant enables preliminary validation for NIJ grants averaging $500K. NIJ allocated $13.6M across 24 forensic projects in 2024. Unlike FDA-regulated therapeutics, forensic tests need only Daubert standards—documented error rates and peer review. RSID-Semen achieved nationwide admissibility following this path from 2006-2017. Recent validation: QIAGEN acquired Verogen for $150M at 7.5x revenue.

Critically, forensics funds our return to therapeutics. Every body fluid signature identified for courtrooms maps tissue-targeting sequences for drugs. Every optimization for degraded evidence improves our RNA platform. The projected $10-40M annual revenue eliminates dilutive fundraising while advancing toward programmable cancer therapeutics—our ultimate goal.

We're not abandoning our therapeutic vision but strategically sequencing it. Build the technology through forensics, generate revenue, prove the platform works, then return to therapeutics with credibility and capital. The path to programmable cancer drugs runs through the crime lab.

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Key elements of their voice:

* "Our co-founders met while working on an RNA therapeutics team"
* "Their shared obsession with RNA"
* Specific technical details about the market
* The narrative about the company shuttering
* Their specific phrasing about forensics and the market opportunity

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