

Rapid Urine Diagnostic for Drug-Facilitated Assault Detection

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A. INTRODUCTION

Drug-facilitated sexual assault (DFSA) involves the covert administration of agents like GHB, ketamine, and benzodiazepines to impair memory and resistance [1].

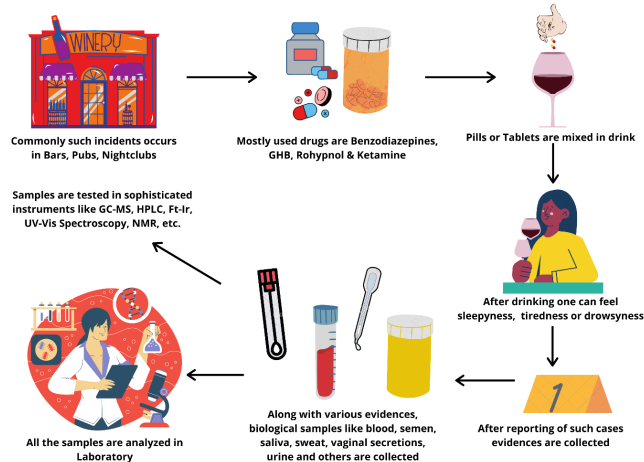


Figure 1. Forensic Aspect on Drug Facilitated Assault

Timely diagnosis is severely hampered by the exceptionally rapid clearance of these drugs; native GHB clears from the urine in 3-4 hours, and ketamine is swiftly metabolized, meaning most victims present after standard detection thresholds have been passed [2,3]. Current diagnostic workflows rely on slow, centralized toxicology testing or generalized panels, which are fundamentally unsuited for the urgent, DFSA-specific screening required in acute care, often resulting in lost evidence [4]. In response to this gap, this project aims to develop a novel, point-of-care (PoC) urine diagnostic platform that delivers DFSA-relevant results in under 10 minutes, enabling decisive clinical and forensic action where speed is essential. This unmet need underscores the importance of rapid, DFSA-specific diagnostics designed for real-time clinical decision-making.

B. BACKGROUND & SIGNIFICANCE

DFSA remains profoundly underdiagnosed, a fact that starkly contrasts with surveys indicating approximately 1 in 13 U.S. college students report being drugged or suspecting drink spiking-yet toxicological confirmation is exceedingly rare [1, 5]. This striking disparity isn't rooted in low incidence, but rather in a problematic synergy between delayed victim presentation and fundamental biological detection limits. Confusion and amnesia often cause victims to seek care many hours post-event, a critical delay beyond which rapidly cleared substances are simply not measurable. This failure to confirm DFSA deprives clinicians of the necessary foundation for documentation, counseling, and evidence preservation, inflicting severe long-term costs on both patient recovery and the legal process.

From a biochemical perspective, standard toxicology cannot readily handle DFSA agents. Take GHB: it occurs endogenously at low baseline urine concentrations, which means simple concentration data is useless without contextual biomarkers, notably conjugated metabolites [6]. Similarly, ketamine and most benzodiazepines are metabolized so rapidly that the detectable signal shifts into low-concentration secondary compounds, frequently bypassing the sensitivity of routine point-of-care (PoC) tests [3, 7]. Therefore, current diagnostics inherently favor the analytical precision of the central lab over the acute, contextual relevance demanded by the emergency department. The only viable path forward is a diagnostic strategy that actively targets these DFSA-specific biosignals within the brief post-exposure window to safeguard time-sensitive forensic and clinical data.

C. BIOSIGNAL DEFINITION & BACKGROUND DATA

The proposed device uses a dual-modality biosignal strategy to enable rapid urine screening for drug-facilitated sexual assault (DFSA) by combining an optical lateral-flow lane with an electrochemical voltammetry lane in a single microfluidic cartridge. The optical biosignal is defined as the Test/Control (T/C) line-intensity ratio from a competitive lateral flow immunoassay (LFA), where increasing analyte concentration reduces test-line signal relative to the control line; quantitative LFA readout using ratio-based normalization is a common approach to improve robustness to lighting and strip-to-strip variability [8]. In this design, the calibrated detection rule is $T/C < 0.7$, converting continuous photodiode intensity into a Boolean call ("Detected"). In parallel, the electrochemical biosignal is defined as the square-wave voltammetry (SWV) peak current (μA -scale) at an analyte-specific potential; SWV-based ketamine identification on screen-printed electrodes has been demonstrated using characteristic oxidation peaks and current responses that scale with concentration [3]. Consistent with this concept, our reader is designed to resolve sub- μA to several- μA peak currents after amplification, using a 1 M Ω transimpedance amplifier (TIA) to convert electrode current into a measurable voltage.

These biosignals map to the DFSA clinical problem through both quantitative sensitivity targets and time-window logic suited to delayed presentation. For screening utility, we set aggressive analytical targets of 0.2–0.3 mg/L for GHB and 5–10 ng/mL for ketamine/norketamine and benzodiazepine equivalents, aiming to detect clinically relevant exposure even as parent drugs rapidly decline [2,3]. Critically, because GHB is endogenously present and concentration alone can be ambiguous, the cartridge incorporates a dual-marker approach by measuring both free GHB and a conjugated biomarker (e.g., GHB-pentose-linked species) whose reference distributions in healthy urine have been characterized and proposed for supporting forensic interpretation [9]. The algorithm uses the

parent-to-conjugate ratio to bin exposure into coarse windows [3, 11]. (e.g., <2 h, 2–6 h, >6 h) rather than estimating an exact timestamp. Finally, to reduce false positives from single-channel noise or matrix effects, the device requires concordant evidence across channels (optical + electrochemical) for a true positive, providing a clear quantitative basis for the final binary output. Although GHB and ketamine are emphasized here, this device and platform is also designed to include benzodiazepine metabolites and other sedative/anticholinergic agents by swapping antibodies and changing the voltammetric calibration.

D. HARDWARE

The overall system level hardware is captured in the block diagram (Fig. 2) A forensic nurse will collect a 1-2 mL urine sample from a patient into a typical collection cup, and then load ~500 μ L into a single-use microfluidic cartridge. The cartridge contains capillary channels that then split the sample into 2 sensing lanes. In the electrochemical lane, a part of the sample is routed into a disposable 3-electrode screen-printed cell (carbon working and counter; Ag/AgCl reference) [10], which is pre-loaded with a redox mediator and capture chemistry. In the antibody lane, the sample flows through three competitive lateral-flow strips that are specific for GHB/GHB-conjugate, ketamine/norketamine, and benzodiazepine metabolites. Each strip is illuminated by a 525 nm surface-mount LED, powered from 5 V through a 330 Ω series resistor. The reflected intensity is read by a silicon photodiode in a transimpedance configuration. Both lanes then converge into a handheld main board that holds the analog front end, low-power microcontroller, 2.4" LCD, and a small Li-ion battery plus 3.3 V LDO regulator to power the analog circuitry.

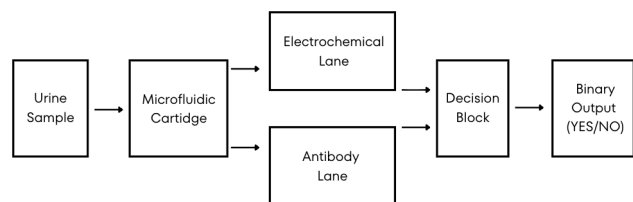


Fig. 2. Block Diagram

Fig. 3 shows a circuit schematic in more detail. The working-electrode current is transformed to voltage by a transimpedance amplifier. The non-inverting input of the op-amp connects to a ground node defined by the reference electrode. The inverting input ties to the working electrode and feedback network. A 1 M Ω feedback resistor R_f sets the transimpedance gain ($V_{out} \approx I_{WE} \times 1 \text{ M}\Omega$) [12], and a 10 nF capacitor C_f in parallel damps the response and limits the closed-loop bandwidth to ~16 Hz. An electrode double layer capacitance can be stabilized by square-wave voltammetry. The op-amp output, labeled as V_{out_TIA} , feeds into a first-order RC low-pass filter: a 10 k Ω series resistor (RLP), followed by a 0.27 μ F shunt capacitor CLP going to ground, providing a frequency of ~60 Hz to suppress noise before digitization. The filtered node is routed directly into one channel of the microcontroller's ADC, which samples the square-wave voltammogram, extracts peak amplitudes at characteristic potentials of metabolites, and sends results to the decision block

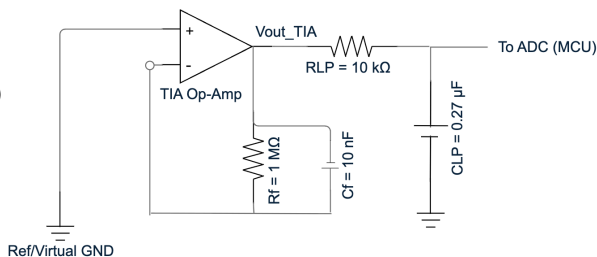


Fig. 3. Circuit Schematic

In real-world practice, the operator inserts a new cartridge, powers the reader, and selects the appropriate assay panel. The urine sample is loaded in, and the device begins a sequence of measurements. Onboard firmware drives the electrochemical lane with the programmed square-wave potential waveform using a DAC output and measures the resulting current via the TIA circuit. At the same time, TIA is reading T/C line ratios from the optical lane through use of ADC inputs and another TIA channel. The microcontroller then compares the measured optical and electrochemical signatures to pre-existing, stored calibration curves for each type of drug. It applies thresholds to create Boolean “detected/not detected” outputs, combining these with parent:metabolite ratios to provide a rough estimate of time-since-exposure windows. There, the final result is one reading per drug class with a simple yes/no call and a rough time window. This result is rendered on the LCD and can also be logged with a timestamp and cartridge ID for any further chain-of-custody documentation. Using the components and values from the schematic in Fig. 2, the analog front end for the electrochemical lane could be reproduced on a small two-layer PCB to create a functional prototype of the device.

E. POST-PROCESSING

After the urine sample flows through the microfluidic cartridge, both sensing lanes generate analog signals that must be filtered, scaled, and converted into a digital drug-present/drug-absent output. Each lane produces a different type of raw analog measurement, optical intensity for the antibody strip and current signals for the electrochemical SWV lane. These signals go through a dedicated signal-conditioning pipeline before being interpreted by the device.

Optical (Antibody) Lane: The photodiode measures line intensity from the competitive immunoassay. This voltage is amplified to increase resolution and then compared against a predefined T/C threshold [8]. As illustrated in the sample data on page 12, a T/C ratio below ~0.7 corresponds to a positive ketamine result, while values above 0.7 indicate no detection. The comparator converts this continuous intensity measurement into a binary output:

Below threshold → Positive
Above threshold → Negative

Electrochemical (SWV) Lane: The working electrode generates a small current during a square-wave potential sweep. The transimpedance amplifier (TIA) converts this current to voltage, and a low-pass RC filter removes 60 Hz noise and baseline drift (p. 10). The filtered signal is then passed into a comparator, which checks whether the SWV peak at the

drug-specific potential exceeds its calibrated threshold [3, 11]. The sample data on page 13 shows how increasing ketamine concentration yields a growing peak at ~0.4 V, which the comparator interprets as:

Peak above threshold → Positive

Peak below threshold → Negative

Threshold Logic and Digital Decision: Both lanes independently generate binary outputs, and the device's decision block fuses them (p. 11). Because false negatives in DFSA are dangerous, the system uses OR-logic, meaning:

If either lane detects a drug → Final Output = YES

If both lanes are negative → Final Output = NO

Optical lane T/C ratio = 0.55 → Below 0.7 → Positive

SWV peak current = 0.42 μ A → Above threshold → Positive

Final output: YES

This dual-modality, threshold-based post-processing pipeline reduces false positives, increases confidence, and allows the device to convert two complex analog signatures into a rapid, clinician-friendly binary result.

Because our T/C = 0.7 cut-off and 3σ SWV peak threshold are calibrated to low-ng/mL concentrations expected in the first ~6–8 hours after dosing, the test must be run within roughly the first night after a suspected DFSA event for the time-window labels to be reliable. Once a cartridge is inserted, the actual post-processing is fast (tens of milliseconds per sweep and a few seconds total), so the dominant time constraint is biological clearance of the drugs, not computation. It is important to note, most victims of drug-facilitated assault present to a medical center within 1–2 hours of drug ingestion, as these agents typically induce profound effects within 15–20 minutes, leaving individuals rapidly incapacitated and triggering urgent medical evaluation.

F. ANTICIPATED OUTCOMES

Fig 4. shows simulated optical immunoassay data for ketamine. The calibration curve displays a mean T/C ratio of ~1.0 at 0 ng/mL and ~0.65 at 10 ng/mL, with an assumed standard deviation of $\sigma \approx 0.03$ from replicate strips. This is typical for LFAs [8]. An example decision threshold is set to T/C = 0.70, represented by the dashed line. To have a true negative result of 0 ng/mL, the probability that noise sets the signal below threshold is $P(T/C < 0.7 | 0) = P(Z < (0.7 - 1.0)/0.03) = P(Z < -10) \approx 0$. This means that the specificity is >99%. For a true positive at the clinical cut-off of 10 ng/mL, the probability of a false negative is $P(T/C > 0.7 | 10) = P(Z > (0.7 - 0.65)/0.03) = P(Z > 1.67) \approx 0.05$, so sensitivity is ~95% at 10 ng/mL. Above 20–50 ng/mL the T/C ratio falls below threshold, so there is not expected to be any false negatives in that concentration range. Generic ED urine drug screens can frequently overlook low-dose ketamine, but this simulated result provides a much lower detection limit [1,7].

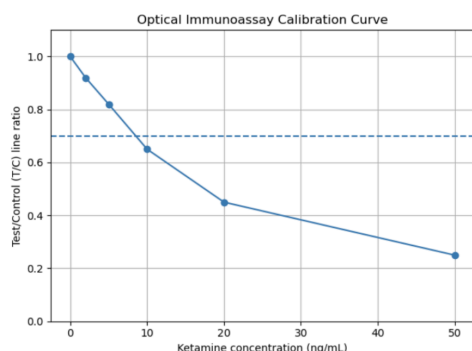


Fig. 4. Simulated optical immunoassay data for ketamine

The electrochemical lane in Fig. 5 shows simulated square-wave voltammograms for 0, 10, and 50 ng/mL ketamine, with peak currents at around 0, 0.4, and 1.1 μ A at 0.4 V [3,11]. After the TIA and RC filter, we assume noise of $\sigma \approx 0.05$ μ A, giving an SNR $\approx 0.4/0.05 = 8$ (18 dB) at 10 ng/mL and SNR $\approx 1.1/0.05 = 22$ (27 dB) at 50 ng/mL [10]. Using a detection rule of peak $> 3\sigma \approx 0.15$ μ A at the expected potential, the SWV lane alone should detect ketamine at roughly 5–8 ng/mL [3,11]. The multi-analyte time-since-exposure logic in Fig. 6 combines LFA outputs for GHB and GHB-conjugate with the SWV ketamine call [2,6]. Simulating three patterns (A: high GHB/low conjugate, B: medium GHB/medium conjugate, C: low GHB/high conjugate) and assigning them to <2 h, 2–6 h, and >6 h time window bins corresponds to contrast-to-noise ratios ≥ 3 if each category has $\sigma \approx 0.3$ of a step. Under that assumption, incorrect classification of time windows should be <10–15%. When the optical and electrochemical modes are combined in the decision block, we estimate panel-level sensitivity of ~90–95% and specificity of ~95–98% for the DFSA drug set. While this is similar to current lab panels in terms of accuracy, the edge lies in the point-of-care aspect where readings can be provided in 10 minutes instead of several days [4].

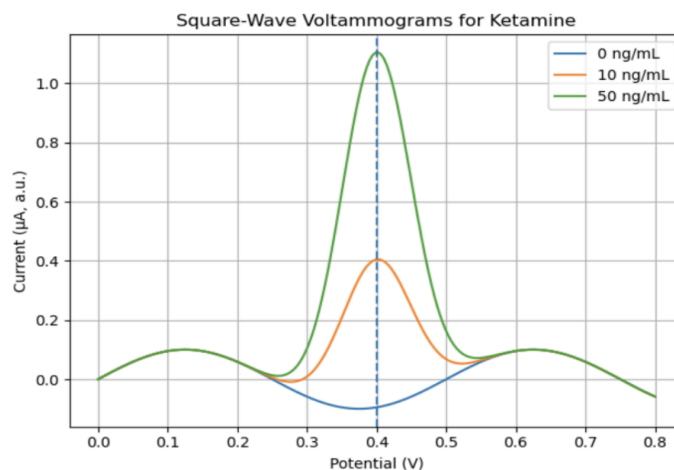


Fig. 5. Simulated square-wave voltammograms for 0, 10, and 50 ng/mL ketamine

Sample	GHB (LFA)	GHB-conjugate (LFA)	Ketamine (SWV)	Time window estimate	Output
A	High	Low	Negative	<2 h post-dose	GHB recent
B	Medium	Medium	Positive	2–6 h	GHB + K
C	Low	High	Negative	>6 h	Past GHB

Fig. 6. Multi-Analyte Panel & Time-Since-Exposure Logic

All sample data and anticipated outcomes presented have been simulated on Python, using models for competitive LFA curves

and SWV peaks. Noise levels and concentration ranges of detected drugs and metabolites were chosen to be consistent with reported values for GHB and ketamine in literature reviews, rather than being collected from actual patients.

G. COMPETING TECHNOLOGY

Existing methods that address drug-facilitated sexual assault are currently in the form of generic urine screening or lab LC/GC-MS panels. Both of these methods expose certain gaps that our device is equipped to fill. While the current standard ED immunoassay cups are rapid and low-cost, they are created for chronic substance use (THC, opiates, cocaine). They often exclude GHB or ketamine, or can only detect them at high cutoffs, so they have poor sensitivity to the short-half-life DFSA agents that are being targeted in our device. Results take the form of positive/negatives flags, but there is no time-since-exposure information window provided. This also means that they are subject to high cross-reactivity, since each result is based on a single antibody signal. Looking at the opposite extreme, although the LC/GC-MS in hospitals or reference labs can detect a larger panel with greater analytical sensitivity, it requires samples to be shipped out, handled by skilled clinicians, and up to days of time before results are provided. These panels are too slow for additional recommendations such as whether blood or hair samples should be collected, or to further assess whether a patient needs to go into prophylactic care. Neither of the current methods described include the rough time estimate-since-exposure windows or meet chain-of-custody needs for DFSA cases.

To address these shortcomings, our device is designed to be a bedside DFSA-based test that combines data processing and design in a unique but necessary way. In terms of hardware, our device merges competitive LFAs for parent drugs and metabolites with an electrochemical SWV lane on the same microfluidic cartridge. As a result, each drug class and respective output readings is supported by two independent physical signals rather than only one. The reader digitizes both the T/C ratios and SWV peak heights, compares them to stored calibration curves, and runs a simple decision-making algorithm to provide three outputs: (1) Boolean yes/no per drug class, (2) a rough time-since-exposure bin based on parent:metabolite patterns, and (3) a time-stamped record that can be used for chain-of-custody. In a practical sense, this allows ED and forensic teams to examine results with high sensitivity for GHB, ketamine, and benzodiazepine metabolites. Additionally, all of these results are provided in only <10-minute turnaround. The cost per test is similar to that of existing urine cups, which no existing technology can compete with.

H. MONEY

The current market for rapid drug-facilitated assault (DFSA) screening is fragmented, slow, and heavily dependent on centralized laboratory testing, which creates a strong opening for a point-of-care urine diagnostic.

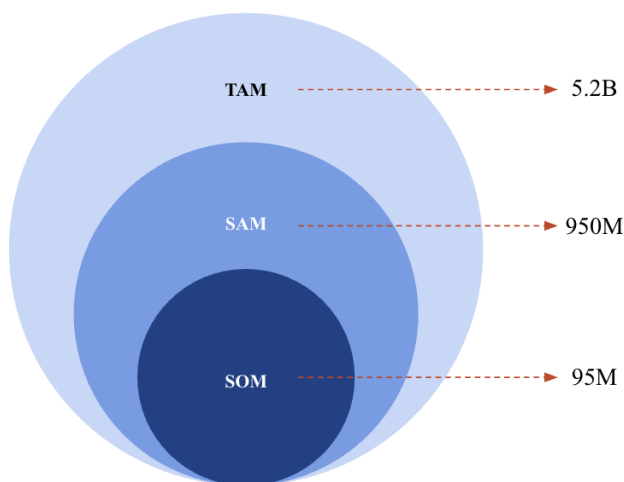


Fig. 7. TAM SAM SOM Market Analysis

Market Analysis: based on our TAM SAM SOM framework with a TAM of \$5.2B a SAM of \$950M and a target SOM of \$95M we estimate that in Year 1 we can capture 1 to 2 percent of the SAM which corresponds to \$9.5M to \$19M. This is achievable because the device requires no special training, fits into existing clinical and campus workflows and addresses an urgent diagnostic need that current tools do not meet. By Year 3 after forming partnerships with emergency departments, university clinics and urgent care networks we project capturing 6 to 8 percent of the SAM equal to \$57M to \$76M. Growth at this stage comes from trust built with early users additional clinical validation and improvements to device performance. By Year 5 with broader regulatory clearance national level adoption protocols and scaled production we anticipate capturing 12 to 15 percent of the SAM which represents \$114M to \$142M in annual revenue potential.

Part Name	Cost/Part	Quantity	Total Cost
Precision Op-Amp (TIA)	\$3.46	1	\$3.46
Feedback Resistor Rf (1 MΩ)	\$0.10	1	\$0.10
Feedback Capacitor Cf (10 nF)	\$0.12	1	\$0.12
Low-Pass Filter Resistor RLP (10 kΩ)	\$0.10	1	\$0.10
Low-Pass Filter Capacitor CLP (0.27 μF)	\$0.18	1	\$0.18
Reference Electrode Connector	\$0.35	1	\$0.35
Working Electrode Connector (2-pin)	\$0.40	1	\$0.40
Decoupling Capacitors (0.1 μF ×2)	\$0.12	2	\$0.24
ESD Protection Diode (optional)	\$0.25	1	\$0.25
PCB (2-Layer Prototype)	\$2.00	1	\$2.00
Misc. Passives (Resistors/Headers)	\$0.50	1	\$0.50

Fig. 8. Costs associated with device creation

Revenue Projections and Future Acquisition: As we scale along our SOM trajectory, annual revenue will increasingly be driven by high-margin cartridge and strip sales, creating predictable recurring income that strengthens long-term financial stability. Our fully loaded device manufacturing cost remains below \$20 (including the \$6.70 bill of materials, \$8–\$10 in assembly labor, and \$3–\$5 for packaging, testing,

and quality control). Yet the clinical value of rapid DFA detection and the reimbursement norms for toxicology testing, which often range from \$150–\$300 per encounter, support a substantially higher market price. Comparable point-of-care diagnostic readers used in ERs and university clinics routinely sell for \$200–\$500. Based on these benchmarks, we estimate a device price of \$175–\$225, a level that remains accessible for healthcare buyers while still yielding margins above 90%. This pricing reflects the device's ability to deliver medically actionable results within minutes, reduce clinician workload, and align with insurance reimbursement for medically necessary diagnostic testing. As recurring consumable revenue grows and clinical adoption expands, our platform becomes an attractive acquisition target for major diagnostics companies such as Abbott, BD, and Cepheid that are seeking to enter or strengthen their presence in rapid toxicology testing.

Insurance Coverage: This diagnostic test would qualify for insurance reimbursement because it falls under medically necessary diagnostic testing, similar to existing reimbursed point-of-care assays such as urine toxicology screens, rapid pregnancy tests, and fentanyl test strips. Importantly, insurance does not cover the hardware itself, clinics purchase the device, but they do receive reimbursement for each test performed.

Why We Are Appealing to Early Investors: Our device requires no specialized training, integrates seamlessly into existing urine-based workflows, and addresses a diagnostic gap that ERs, student health centers, and urgent-care systems have struggled with for years. The business model is especially compelling because revenue is dominated by strip sales, creating a recurring-revenue profile similar to pregnancy tests and fentanyl test strips, categories that historically provide strong margins and predictable growth. The platform is not limited to detecting GHB and ketamine; with minor modifications it can be expanded into a broad toxicology screening tool. The electrochemical lane can be retuned to identify any analyte with a measurable redox signature, including cocaine, MDMA, methamphetamine, select opioids, and emerging synthetic drugs, by simply adjusting the working-electrode coating or detection waveform while keeping the hardware unchanged. Lastly, early-stage investors don't just bet on an idea, they bet on the team behind it. Our group brings a combination of engineering and business acumen, reinforced by experience in consulting, venture strategy, and technical design. This blend of skills signals to investors that we have both the capability and the discipline to bring this device successfully to market.

F. ENDING NOTE

We hope that a device like this can one day save lives, provide peace of mind to parents as their children navigate college life, and meaningfully ease the burden on healthcare workers who are already overstretched.

G. ACKNOWLEDGMENTS

The authors would like to acknowledge Professor Vandsburger and GSI Samuel Rubin for their support, guidance, and encouragement throughout the semester!

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I. APPENDIX

[1] Relevant math from class

The quantitative analysis in this project applies standard mathematical tools introduced in BIOE 105 to support signal classification, noise analysis, and circuit design.

Optical immunoassay outputs are modeled as normally distributed variables and evaluated using Z-score-based thresholding, $z = \frac{x - \mu}{\sigma}$ to estimate sensitivity and specificity at a chosen T/C cutoff.

Electrochemical detection performance is characterized using

the signal-to-noise ratio, $SNR = \frac{\mu_{signal}}{\sigma_{noise}}$, which is used to estimate the achievable limit of detection.

Analog bandwidth limits are set using first-order RC filter theory, $f_c = \frac{1}{2\pi RC}$, and electrochemical working-electrode currents are converted to voltage using a transimpedance amplifier, $V_{out} = -I_{WE} R_f$.

[2] Code to take number outputs and create graph

Python Code for Fig. 4. Simulated optical immunoassay data for ketamine

```
import numpy as np
import matplotlib.pyplot as plt

concs = np.array([0, 2, 5, 10, 20, 50]) # ng/mL
tc_ratio = np.array([1.0, 0.92, 0.82, 0.65, 0.45, 0.25])

plt.figure()
plt.plot(concs, tc_ratio, marker='o')
plt.axhline(0.7, linestyle='--') # decision threshold
plt.xlabel("Ketamine concentration (ng/mL)")
plt.ylabel("Test/Control (T/C) line ratio")
plt.title("Optical Immunoassay Calibration Curve")
plt.ylim(0, 1.1)
plt.grid(True)
plt.tight_layout()
plt.show()
```

Python Code for Fig. 5. Simulated square-wave voltammograms for 0, 10, and 50 ng/mL ketamine

```
import numpy as np
import matplotlib.pyplot as plt

potential = np.linspace(0, 0.8, 200)

def swv_trace(peak_height):
    baseline = 0.1 * np.sin(2 * np.pi * potential * 2)
    peak = peak_height * np.exp(-0.5 * ((potential - 0.4) / 0.05) ** 2)
    return baseline + peak

currents_0 = swv_trace(0.0) # 0 ng/mL
currents_10 = swv_trace(0.5) # 10 ng/mL
currents_50 = swv_trace(1.2) # 50 ng/mL

plt.figure()
plt.plot(potential, currents_0, label="0 ng/mL")
plt.plot(potential, currents_10, label="10 ng/mL")
plt.plot(potential, currents_50, label="50 ng/mL")
plt.axvline(0.4, linestyle='--') # ketamine peak potential
plt.xlabel("Potential (V)")
plt.ylabel("Current (µA, a.u.)")
plt.title("Square-Wave Voltammograms for Ketamine")
plt.legend()
plt.grid(True)
plt.tight_layout()
plt.show()
```

[3] Marketing Sizing Calculation

The Total Addressable Market reflects ~2.3 billion globally at-risk individuals, based on demographics with higher nightlife participation, urban density, and travel exposure. Assuming an annual spend of \$2–\$3 on safety or drug-tampering detection tools, consistent with costs of consumer test strips and drink-test coasters, the global opportunity is \$5.2 B. The Serviceable Addressable Market focuses on early-adoption regions (U.S., U.K., EU, Australia) and includes ~88 million

high-risk or frequently screened individuals aged 18–35. Using an estimated per-person annual diagnostic value of \$10–\$12, the SAM is \$950 M. The Serviceable Obtainable Market assumes 10% penetration during early adoption, supported by the current lack of rapid DFSA testing and strong clinical need. This equals 8.8 million users, generating \$95 M in obtainable revenue given expected per-user revenue of \$100–\$110.