bio-stream DIAGNOSTICS INC

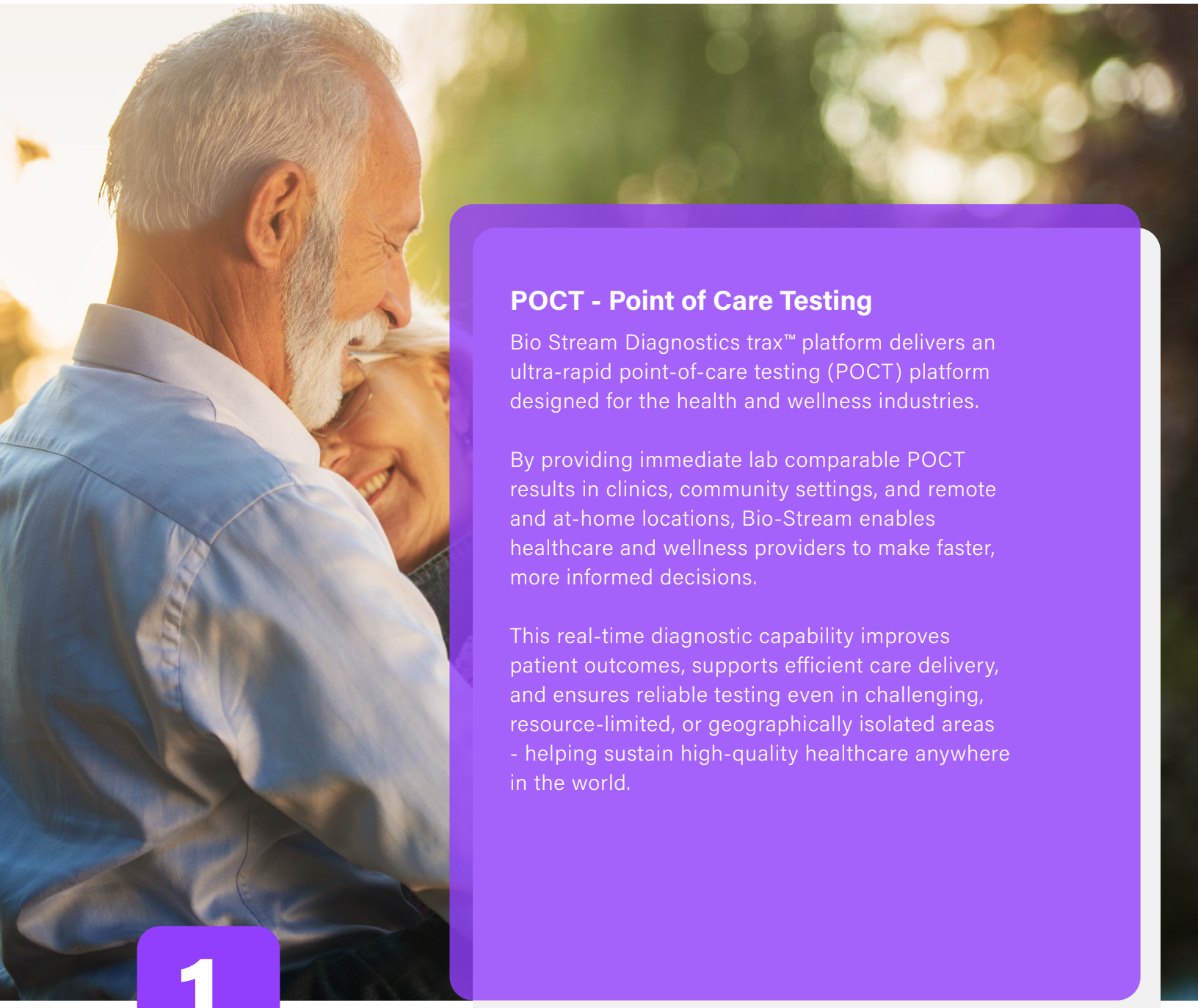
trax™

A Sensor Development and Commercialization Platform

About Us

Bio-Stream Diagnostics Inc. is a privately owned medical device manufacturing and software development company headquartered in Edmonton, Alberta, Canada.

We are a diagnostic technology company focused on accelerating the translation of biomarker science into accessible, real-world testing solutions.



POCT - Point of Care Testing

Bio Stream Diagnostics trax™ platform delivers an ultra-rapid point-of-care testing (POCT) platform designed for the health and wellness industries.

By providing immediate lab comparable POCT results in clinics, community settings, and remote and at-home locations, Bio-Stream enables healthcare and wellness providers to make faster, more informed decisions.

This real-time diagnostic capability improves patient outcomes, supports efficient care delivery, and ensures reliable testing even in challenging, resource-limited, or geographically isolated areas - helping sustain high-quality healthcare anywhere in the world.

Bio-Stream's trax™ Platform

The core pieces of the trax™ platform are disposable sensors, a reusable reader, and the related software. The platform is based on electrochemical biosensing with aptamers, antibodies or enzymes as bait molecules to capture targets in blood, serum, plasma, urine, sweat, saliva or swab medium. The technology works by detecting the electrical signal produced when a bait (such as an antibody or aptamer) that has been functionalized onto the gate of the sensor is exposed to its corresponding biomarker target such as a protein, metabolites, DNA or small chemical. The bait/target combination will generate electrical changes in nA to μA range that will be detected by the small, inexpensive and universal trax reader to produce a positive/negative or quantitative result. The trax platform can also detect ionic changes in a non-bait dependent manner.

Figure 1

The universal, reusable trax reader is uniquely developed to accept Bio-Stream trax sensor strips as well as those made by many other companies.

Researchers can use the trax reader in combination with software, traxInsight™, to capture, view and analyze a sensor's response. The trax reader can be easily customized to perform numerous measurement types and diagnostic tests for a range of common health and non-health applications. Other measurement types include but are not limited to: linear sweep voltammetry (LSV), cyclic voltammetry (CV), square wave voltammetry (SWV), differential pulse voltammetry (DPV), normal pulse voltammetry, zero resistance amperometry, multi-step amperometry, pulsed amperometric detection, electrochemical impedance spectroscopy (EIS) and multiple pulse amperometric detection and open circuit potentiometry.

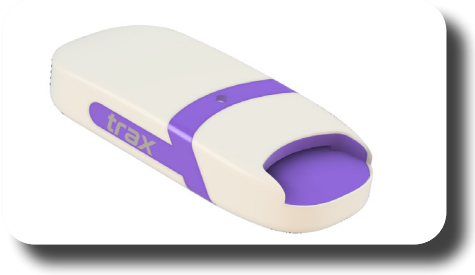


Figure 2

Developing a test on the trax platform

In order to speed up development of new biosensors, Bio-Stream has a workflow process to validate the performance of an electrochemical based biosensors. This workflow includes preliminary analysis to select the most optimal target capture protocol, electrochemical measurement protocol and sensitivity/specificity needed to detect within the clinical range. Validation data is provided below for proof-of-concept tests for detection of an antibiotic (vancomycin), and glucose using an enzymatic reaction.

The trax platform - for developers

The primary elements of the trax platform used to develop a test includes trax sensors, the trax reader and traxInsight™ development software.

Figure 3

Trax sensors may contain either one or multiple gates. These gates are functionalized by the test developer, attaching a bait which will bind to the target of interest when the test is used.

Figure 4

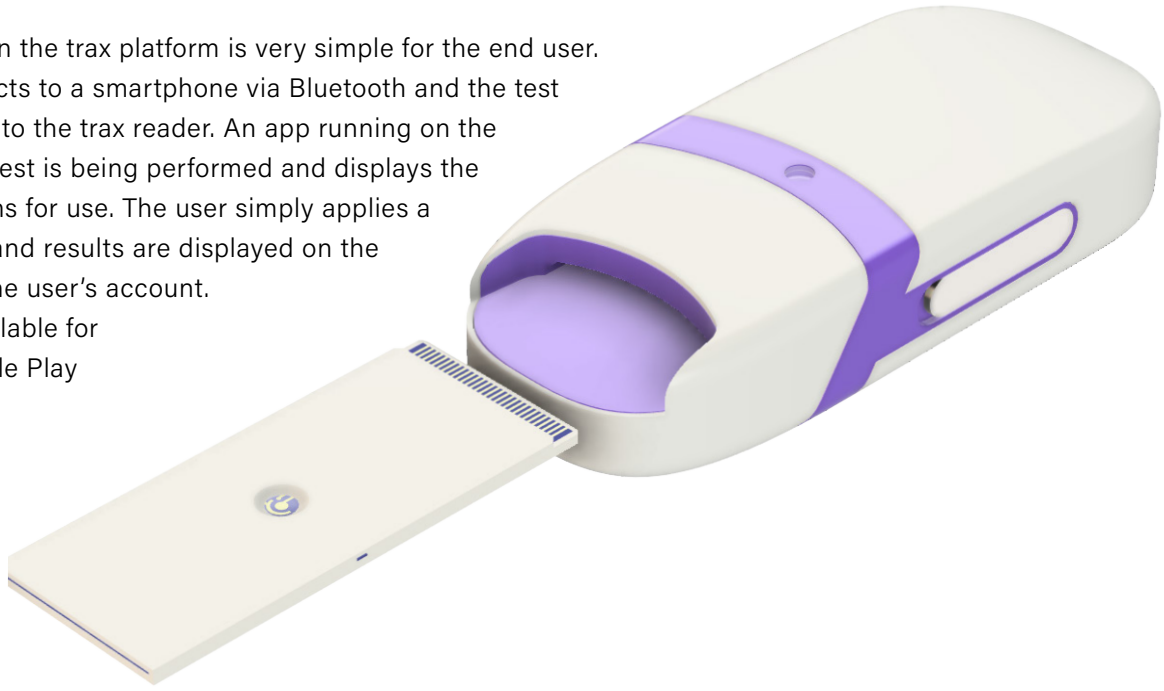
The trax reader will capture the electrochemical signal change on the trax sensor and produce a quantitative description of the amount of target. During the development of a test the trax reader is typically connected to a laptop running traxInsight.

Figure 5

traxInsight is the development software used to capture, view and analyze the data provided by traxReader™ to establish and optimize settings for a new test and provide a yes/no or quantitative answer for presence of the target.

The trax platform - for the end user

A point-of-care test on the trax platform is very simple for the end user. The trax reader connects to a smartphone via Bluetooth and the test cartridge is inserted into the trax reader. An app running on the phone detects which test is being performed and displays the appropriate instructions for use. The user simply applies a sample to the sensor and results are displayed on the phone and stored in the user's account.
The mytrax app is available for download in the Google Play or Microsoft store.



How it works

Schematic of bait/target detection of the trax platform

Bait (such as an antibody or aptamer) capture of a biomarker will result in a binding event to promote an electrochemical change detected by the trax reader. Several measurement tactics can be utilized to quantify this binding event including LSV, SWV, CV or chronoamperometry (CAP), to result in the production of curves to give a positive/ negative or quantitative difference between target and no target states.

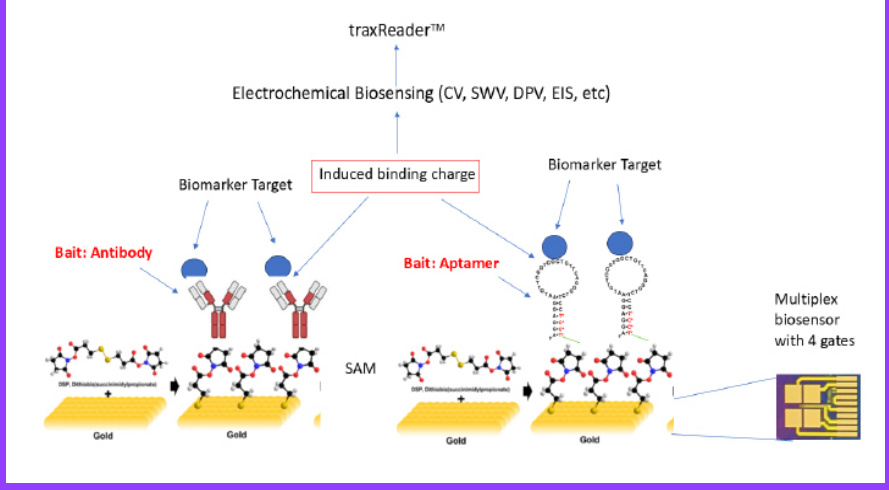


Figure 6

Workflow Process for Electrochemical Biosensor Development

The selection of appropriate bait molecule to capture target in blood, urine, saliva, sweat, swab or water will be based on knowledge of the binding kinetics of bait/ target, pI of bait and target or conformational change of bait upon target binding. Assay developers utilize a variety of techniques such as traditional dot blot immunoassays or other established binding assays in order to determine the best bait type to be utilized on the trax platform.

Monoclonal antibodies are highly recommended for antibody based bait (Figure 7A). For aptamers, the workflow utilizes computational biology, circular dichroism analysis (Figure 7B and C) or other techniques to select the optimal bait aptamer to bind to target AND undergo significant conformational change upon binding target. For enzymes, highly specific ones are selected that have activity in the appropriate target medium and generate products not found in target medium.

We collaborate with numerous TRL3 and TRL6 assay developers to identify the most appropriate bait to capture a target. Once bait molecules are pre-screened for selectivity and specificity, they are functionalized (covalently bound) to the gate surface by assay developers using bait specific-coupling chemistries for antibodies/enzymes or thiol linkage for aptamers with the appropriate non-specific self assembled monolayer. After functionalization, detection of bait/target is carried out via the appropriate electrochemical detection modality. Results are analyzed via traxInsight. Analysis in traxInsight will produce a “POSITIVE” or “NEGATIVE” result or can be quantitated, and these results will be stored on Bio-Stream’s secure cloud servers.

Pre-screening validation

Examples of pre-screening workflow for antibody and aptamer selection (Figure 7 A to C).
(A) Dot blot test of sensitivity comparison between two antibodies with a limit of detection (LOD) of < 0.2 pg/µL whereas the ThermoFisher antibody has an LOD of > 0.2 ng/µL; clinically, CRP detection is at > 10 mg/dL or 0.1 ng/µL for infections. Generally, when an antibody is applied to the trax platform, the LOD is 1,000x more sensitive than observed by dot blotting (Figure 7A) if an appropriate transistor is utilized.

(B) Circular dichroism analysis of two target/bait combinations. (Figure 7B and C) shows the binding of GFAP, a marker of traumatic brain injury and stroke, to a GFAP aptamer to induce a conformational change in aptamer shape. (Panel B)

Panel C shows C-reactive protein (CRP), a marker of inflammation, binding to a CRP aptamer to also induce a conformational change in its aptamer shape. The frequency monitors vibration of the chemical structures within the aptamer and > 40% change can be observed in chemical vibrations between 200 and 320 nm for both aptamers. The aim is to have a substantial change upon target binding so when a redox tracer is attached to the 3' end of the aptamer, the conformational change will displace the redox tracer and induce an electron positional change. These events will trigger an electrical charge change to be picked up by the trax reader on the trax platform (an example is shown in Figure 8).

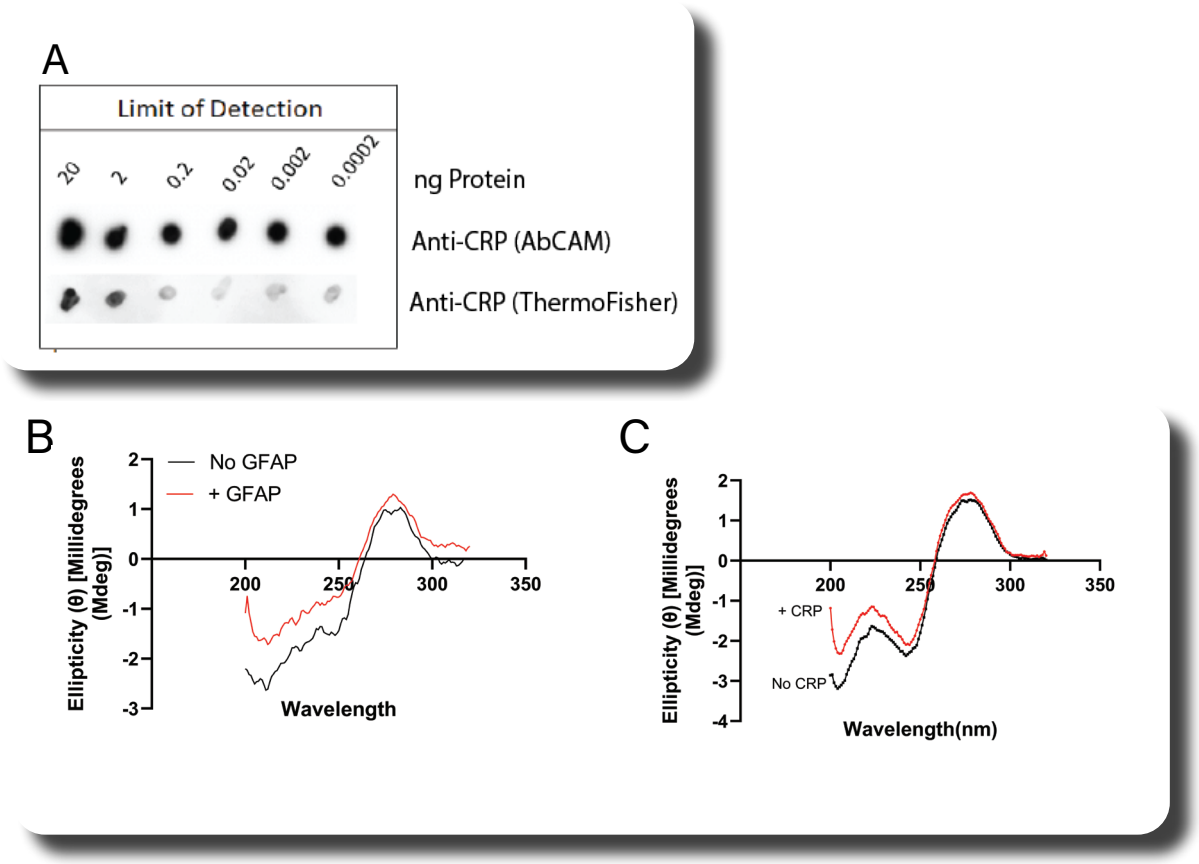
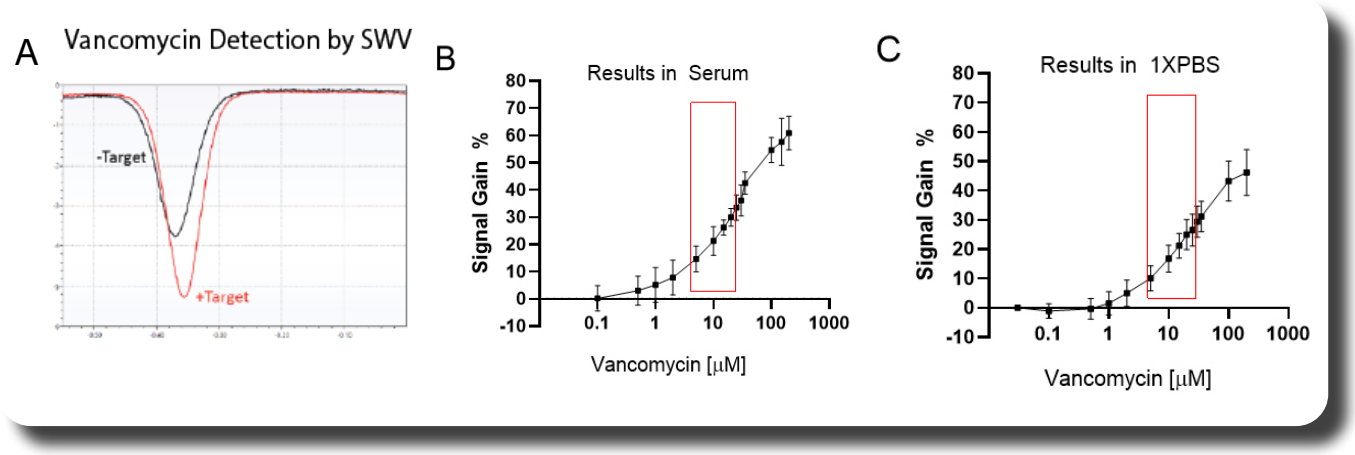


Figure 7 Panel A, B, C

Electrochemical aptamer based biosensor (E-AB) to detect vancomycin (Proof of concept 1)

Electrochemical detection of vancomycin binding (+target) to its aptamer using the trax platform (Figure 8, panel A). In addition, at various concentrations of vancomycin in 1XPBS and in serum (Figure 8, panels B and C), we can observe stronger current responses (reflected in the signal gain %), confirming the sensor's sensitivity to vancomycin at clinically relevant concentrations (the red rectangle marks the therapeutic concentration range for vancomycin). Interestingly, we can observe an enhancement of this binding in the presence of serum (from over 40% to over 70% signal gain at maximum vancomycin concentration). Furthermore, the detection of vancomycin binding to its aptamer is specific to the vancomycin E-AB (Figure 8, panel D).



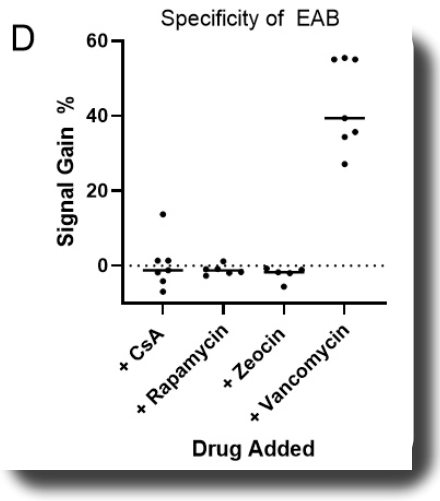


Figure 8 Panel A, B, C, D

These data suggest that the vancomycin aptamer is responsive to increasing amounts of target.

The signal gain % in response to non-vancomycin drugs is plotted in Figure 8D (208 nM for CsA, 16.4 nM for Rapa, 58.3 μM for Zeocin are the highest clinical concentrations of these drugs). This response is compared to a vancomycin concentration of 25 μM (an amount in the middle of the clinical range for vancomycin detection).

Panel D confirms specificity of the vancomycin aptamer to only detect vancomycin.

Concentration of Vancomycin	Average Signal Gain %	Sensitivity (%)	Specificity (%)	P-value (target vs buffer)	N-value
25 µM (1X PBS)	25.6 ± 5.2	94	100	< 0.0001	18
25 µM (Serum mimic buffer)	39 ± 4.4	100	100	< 0.0001	5
25 µM (in 100% serum)	33.5 ± 4.7	100	100	< 0.0001	5

Assay outcomes for vancomycin detection using SWV.

Electrochemical based method for glucose detection (Proof of concept 2)

Electrochemical detection of glucose concentrations via chronoamperometry method using the trax platform demonstrates robust analytical performance across a wide dynamic range (0–2500 mg/L). By integrating commercial glucose strips with the trax reader, we achieved a highly linear calibration (R2 = 0.9943) in DI water, confirming the system's sensitivity and readiness for TRL-6 research applications (Figure 9A). We confirmed specificity of detection (Figure 9B) with negligible current interference (<1.5%), consistent, high response to glucose even when mixed with high concentrations of sucrose, proving the strips' high specificity in the presence of common sugars. Linearity of detection of glucose was achieved that illustrates the platform's high precision, reproducibility (<4% error), and suitability for research purposes.

Figure 19A on the left is calibration curves for glucose in deionized water at concentrations of 0, 500, 750, 1000, 1250, 1500, 1750, 2000, 2250, and 2500 mg/L. Data are expressed as mean ± SD (n = 15; 3 batches, 5 replicates each batch), with error bars representing the standard deviation. The linear regression fit is shown in the Figure 9A overlayed with the data points from the calibration. Figure 9B on the right is the response current (I, µA) of glucose strips in the various solutions for glucose or sucrose. Data are expressed as mean ± SD (n = 15; 3 batches), with error bars representing the standard deviation. Accuracy of the sensor was examined within the mentioned concentration range and showed <7% error relative to the actual concentration.

Figure 9A

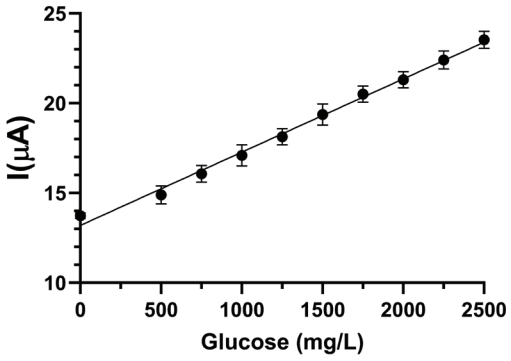
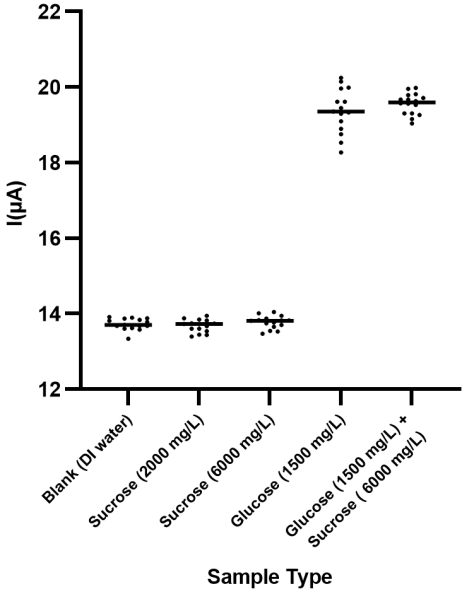


Figure 9B



Summary of the glucose sensor's performance on the trax platform

Criteria	Result	n / Concentration point
Sensitivity & LOD	Sensitivity= (0.0041 μA·L/mg) LOD =112.96 mg/L.	n = 15 (3 batches)
Dynamic Range	0 – 2500 mg/L, R^2 = 0.9943	n = 15 (3 batches)
Reproducibility	Coefficient of Variation (CV) error < 4%	n = 15 (3 batches)
Selectivity	Interference < 1.5%	n = 15 (2 batches)
Accuracy	Error < 7%	n = 15 (3 batches)
Response Time	60 sec	n= 216 (3 batches)

Analysis of ELISA vs electrochemical biosensing (EB) result

Process speeds of ELISA vs EB methodologies are shown below. Comparisons are made based on time to process 96 samples using ELISA, less than 5 minutes to process each sample on trax sensors and 15 minutes to process samples using lateral flow platforms.

Test Name	Protocol Method	Sample Type	Number of Tests	Data Link to Patient	TIme for Results
ELISA	Antibody based	Limited to serum or plasma	48 samples in duplicate in 6 hrs (8 samples/hr)	No	4-6 hours
Bio-Stream trax platform	Versatile to include antibody capture	Versatile to include whole blood	75-80 samples in duplicate in 5 hrs (30 samples/hr)	Bluetooth enabled reader, YES	<5 minutes
Lateral Flow	Antibody based	Versatile to include whole blood	48 samples in duplicate in 16 hr (3 samples/hr)	No	15-20 minutes
Flow Cytometry	Antibody based	Various including blood	>90 samples within 15-20 minutes	No	15-20 minutes
Mass Spectrometry	Elemental analysis of sample	Various including blood	Several hours for 100 samples	No	1-3 hours

Bio-Stream Diagnostics Inc. is a diagnostic technology company focused on accelerating the translation of biomarker science into accessible, real-world testing solutions. The trax platform is a collection of hardware, software, and business strategy through which Bio-Stream translates biosensor technology into practical point-of-use diagnostic testing using a single, reusable, universal reader.

The company operates on the belief that the value of biomarker discovery is only realized when testing becomes timely, accessible, and actionable. Bio-Stream prioritizes advanced biomarker detection science, collaborative development with researchers (companies and universities around the world), and equitable access to diagnostic knowledge for everyday people.

We work to ensure that promising biosensors quickly reach clinicians, patients, and industries where early detection and monitoring can greatly improve health and wellness outcomes.

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