At-home *i*Diagnostics for Optimizing Your Rejuvenation Interventions

No more flying blind with no plan to land. Get actionable, multiomic precision diagnostics to fine-tune your personalized rejuvenation efforts at home

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Investment Memorandum & Technical Proposal Outline

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Principal Investigator	Alexander N. Asanov, PhD | iDiagnostics TIRF multiomic arrays | TIRF Analytix instruments
Assay Development Partner	Aptagen, LLC, - anticipated subcontractor, subject to final teaming agreement.
Assay Development Investigators	G. Thomas Caltagirone, PhD, President & CEO | Albert M. Liao, B.Sci., Lab Director, Aptagen.
Current Maturity	● Beta-prototype of *i*Diagnostics tested by 3 independent groups. Data published in peer-reviewed journals [1-6]. ● TIRF Analytix – commercialized instruments for laboratory settings. 83 groups worldwide acquired TIRF Analytix products and published articles in peer-reviewed journals.
Period / ROM	24 months | Months 1-12 - $3.2M | Months 13-24 -$4.4 M | Total ROM $7.6 M.
Document Status	Investment Memorandum & Technical Proposal Outline Prepared November 21, 2026 | TIRF Labs Proprietary

TIRF Labs is seeking investments and donations to advance the **iDiagnostics** beta-prototype into a robust system for at-home, highly multiplexed multiomic tests. iDiagnostics uses disposable cartridges to detect up to several hundred aging clocks and rate-of-aging biomarkers - including protein, metabolite**,** RNA, and DNA markers - essential for the personalized optimization of rejuvenation interventions. Operating within a **$5 billion market** growing at a **~15% CAGR**, the iDiagnostics device stems from a commercially successful line of products TIRF Analytix previously developed by TIRF Labs for use in laboratory settings. To the best of our knowledge, there is no other technology for at-home use with sensitivity down to single molecules, limits of detection covering the entire range of clinically significant concentrations, highly multiplexed multiomic detection requiring little to no sample preparation, rapid results delivered in 5–10 minutes, and with negligibly small false-positive and false-negative errors. Whole blood, saliva, nasal and buccal swabs can be tested in parallel using a single iDiagnostics cartridge. Furthermore, the iDiagnostics platform is reconfigurable for numerous other applications.

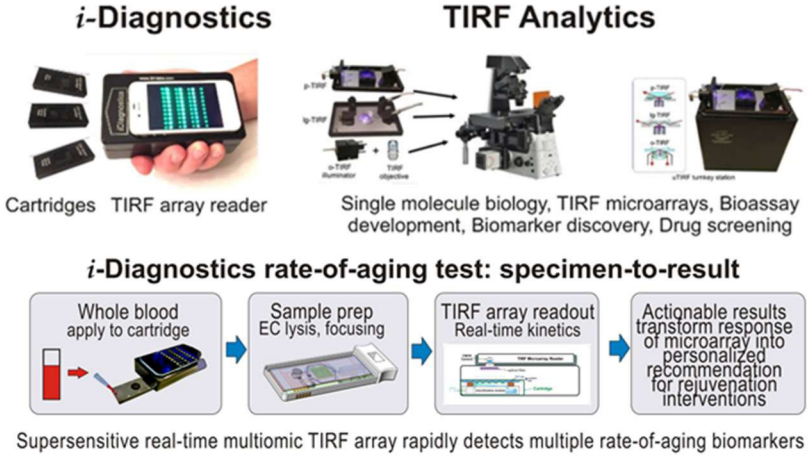
At-home iDiagnostics for Optimizing Your Rejuvenation Interventions

*i*Diagnostics provides the at-home precision data you need to optimize personalized rejuvenation efforts

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Objective: Advance iDiagnostics beta-prototype into a robust multiomic platform for at-home tests of panels of aging clocks and the rate-of-aging biomarkers. When manufactured in volume, disposable cartridges will cost ~$2 - $8, and the iDiagnostics reader equipped with 3 CMOS cameras, 8-hour battery, 5G, and Wi-Fi connectivity will cost ~$100.

Description of Efforts: (i) Leverage fully commercialized TIRF Analytix instruments for the advancement of iDiagnostics platform for detecting of aging markers. (ii) Utilize innovative silk-fibroin scaffolds to amplify molecular and aptamer beacons and perform sample preparation. (iii) Implement innovative TIRF-electro-chemical control for bioassay enhancement and sample preparation. (iv) Develop high density TIRF arrays featuring 196+ molecular and aptamer beacon assays tailored for comprehensive rate-of-aging biomarkers.



Benefits of Proposed Technology: iDiagnostics leverages a real-time TIRF microarray technique combined with innovative silk-fibroin scaffolds and electrochemical control (TIRF-EC). It achieves limits-of-detection that cover the entire clinical range for nucleic acid, protein and metabolite biomarkers. Highly multiplexed detection of nucleic acids and proteins enables superior diagnostic accuracy and precision.

Challenges and Mitigation: (i) Engineering a TIRF microarray reader at a target cost of ~$100. (ii) Manufacturing disposable TIRF cartridges at a high-volume cost of ~$2 to $8.

Technology Maturity: iDiagnostics stems from the commercialized TIRF Analytix products that were acquired by 83 research groups worldwide. Patents are pending for silk-fibroin scaffolds and TIRF-EC functions. Data on multiomic TIRF detection published in peer-reviewed literature [1–6].

Major Milestones and Rough Order of Magnitude

- **Months 0-12 | $3.2M |** Design molecular and aptamer beacons for detection of 196+ biomarkers of aging clocks and rate-of-aging; optimize silk-fibroin scaffold, TIRF reader, and cartridge. Prepare FDA Q-Submission and premarket FDA 510(k) submission.
- **Months 13-24 | $4.4M |** Analyze standard samples of blood, saliva, nasal and buccal swabs for aging and rate-of-aging. Measure response time, precision, accuracy, and stability. Prepare FDA 510(k) submission. Demonstrate rapid response, sensitivity, field stability, FDA-approved cartridge and readers production. Create ISO 13485 certified R&D and manufacturing facilities at North Carolina Research Triangle Park. Start marketing and sales of iDiagnostics.
- **Total ROM: $7.6 M.**

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1. Executive Summary

TIRF Labs is seeking investments and donations to advance the beta-prototype of iDiagnostics into a robust system for **at-home**, highly multiplexed multiomic tests suitable for optimizing rejuvenation interventions on a weekly or bi-weekly basis. The device uses disposable cartridges to detect up to several hundred aging clocks and rate-of-aging biomarkers – including proteins, metabolites, RNA, and DNA markers. Operating within a **$5 billion market growing at a ~15% CAGR**, the iDiagnostics device stems from a commercially successful line of products TIRF Analytix previously developed and successfully marketed by TIRF Labs for use in laboratory settings. To the best of our knowledge, there is no other technology for at-home use with sensitivity down to single molecules, limits of detection covering the entire range of clinically significant concentrations, highly multiplexed multiomic detection requiring little to no sample preparation, rapid results delivered in 5–10 minutes, and with negligibly small false-positive and false-negative errors. Whole blood, saliva, sweat, urine, nasal and buccal swabs can be tested using a single cartridge. Furthermore, the iDiagnostics platform is reconfigurable for numerous other applications.

Paradigm Shift towards monthly at-home diagnostics. Personalized optimization of rejuvenation interventions requires transitioning from annual bloodwork tests to weekly/monthly measurements of the aging clocks and rate-of-aging panel to adjust personalized rejuvenation interventions. Epigenetic aging clocks often yield inconsistent, hard-to-interpret results. In contrast, proteomic clocks, by tracking the immediate effectors of biological change, may excel in providing rate-of-aging biomarkers or mechanistic insight. iDiagnostics project plans to compare six proteomic clocks: ProtAge, OrganAgemortality, OrganAgechrono, PAC, ipfP3GPT and PAOPAC versus epigenetic clocks Horvath Clock, Hannum Clock, PhenoAge, GrimAge / GrimAge2, and epigenetic aging speedometer DunedinPACE. Current rejuvenation protocols (senolytics, partial reprogramming, NAD+ boosters, metabolic adjusters) are expensive and unoptimized because users lack a continuous, responsive feedback loop to measure efficacy.

Value Proposition: iDiagnostics will fill the gap of at-home weekly/monthly diagnostics by providing rapid, highly multiplexed, quantitative proteomic, genomic, epigenetic, metabolic, and inflammatory biomarker readouts from a single finger-prick blood sample, saliva, sweat, nasal or buccal swab, delivering actionable precision insights within minutes, at-home. An on-device, real-time TIRF microarrays, at-home multiomic platform represents an entirely **blue-ocean** category, bridging the massive gap between slow, mail-in laboratory sequencing and the immediate, actionable at-home feedback required to optimize rejuvenation interventions.

Funding Objective: TIRF Labs is seeking ~$3.2M - $7.6M investments for the development of iDiagnostics rate-of-aging clocks, final verification, manufacturing scale-up, and FDA regulatory submissions for iDiagnostics at-home decentralized longevity/rejuvenation monitoring.

2. Advantages of iDiagnostics

iDiagnostics combines a unique set of advantages not found in alternative technologies.

A. Ultimate sensitivity – TIRF is capable of detecting single molecules, which enables iDiagnostics with limits-of-detection (LOD) covering the entire range of clinically significant concentrations of DNA, RNA, proteins, and metabolites.

B. No or minimal sample preparation is required for TIRF arrays with silk-fibroin scaffolds.

C. Highly multiplexed real-time TIRF array (up to 8,000 assays per TIRF slide) enables the broad spectrum of applications. In most practical cases only 10-30 assays per slide are sufficient.

D. Multiomic detection of RNA, DNA, proteins, and metabolites allows for simultaneous capture of protein biomarkers, inflammatory cytokines, glycans, DNA, RNA, lipids, and metabolic indicators, rather than relying solely on a single analyte class.

E. Real-time TIRF microarrays provide quantitative results – measure concentrations of markers.

F. Rapid response - from 1 to 15 minutes.

G. The combination of high sensitivity, multiplicity, and multiomic detection provide negligibly small rates of false-negative and false-positive errors.

H. Low cost of iDiagnostics reader ~$100, cost of cartridge - $1-10, if manufactured at commercial scale.

I. Suitable for at-home and point-of-care applications. Requires minimal training.

J. Enables true closed-loop optimization of rejuvenation interventions: "measure/ intervene/ retest" on a weekly or bi-weekly basis, which is too difficult with traditional send-away kits.

K. iDiagnostics platform is reconfigurable for detection of different infectious pathogens, as well as DNA, RNA, protein, glycan, and metabolite biomarkers of cardio-, cancer, neurological and other diseases.

3. Core Innovations: Silk Fibroin Scaffolds & Electric Field Control (Patents Pending)

iDiagnostics incorporates 3 recent sets of innovations that have been published in peer-reviewed journals [1-6]. Proprietary part of technology is protected by 2 pending patent applications.

(i) Enhancement of TIRF signal by silk-fibroin gel whose refractive index is ~1.51 [2, 3].

(ii) Use of silk-fibroin as a biologically friendly scaffold for bioassays.

(iii) Application of electric field for sample preparation, TIRF signal amplification and running on-the-cartridge microfluidics and sample preparation.

iDiagnostics leverages unique properties of biocompatible, optically transparent silk-fibroin hydrogels and silk fibroin films to stabilize capture antibodies, molecular beacons, and aptamers at ambient temperatures without refrigerating. Tunable pore sizes (1 to 1,000 nm) and refractive index matching (n = 1.46 -1.52) optimized for evanescent wave penetration and efficient macromolecule diffusion.

Electric Field Control, Sample Preparation and Microfluidic Pumping is achieved via on-chip electric field lysis, electrokinetic and electrolysis-driven micro-pumping. Proprietary technology includes the use of transparent electroconductive electrodes (ITO and SnO2) to drive microliter fluid samples through 2–5 micrometers channels without external mechanical pumps. Active molecular focusing electric field-enhanced binding kinetics drastically shorten incubation times.

Intellectual Property: Pending provisional patent applications filed via the USPTO protect proprietary part of iDiagnostics technology. Scientific papers published in peer-reviewed journals [1-6] establish priority of TIRF Labs' discovery and development of the TIRF sensor architecture with integration of silk fibroin into TIRF microarrays, electric field for fluidics control and TIRF microarray readers.



Fig. 1. Beta-prototype of *i*Diagnostics: TIRF microarray reader and disposable cartridges – left panel. Cartridge inserted, TIRF microarray imaged – right panel.

4. Principles of iDiagnostics and TIRF Analytix

Figure 1 shows the beta-prototype of the iDiagnostics, which consists of iDiagnostics reader and disposable cartridges. Basic principles of iDiagnostics, as mentioned above, have been described

in peer-reviewed scientific journals [1-6]. Proprietary part of the technology is protected by two pending USPTO patent applications.

The iDiagnostics system stems from the TIRF Analytix line of products (Figure 2), which represents commercially successful TIRF systems acquired by 83 research groups worldwide. TIRF

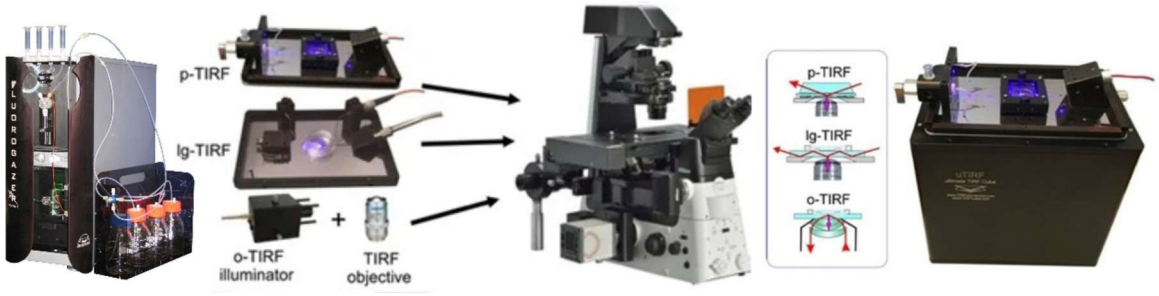


Fig. 2. TIRF Analytix line of products. Applications include: single molecule biology, super-resolution microscopies, biomarker discovery, bioassay development, multi-omic real-time TIRF microarrays for medical diagnosing, drug screening, leads optimization, and vaccine development.

Analytix products are designed for use in laboratory settings. TIRF Analytix' applications include: single molecule biology, super-resolution microscopies, biomarker discovery, bioassay development, multi-omic real-time TIRF microarrays for medical diagnosing, drug screening, leads optimization, and vaccine development.

Both iDiagnostics and TIRF Analytix are based on the phenomena of total internal reflection and the evanescent wave (Figure 3) that take place at the interface between optically dense medium (e.g. glass n=1.51) and less dense medium (e.g. water n=1.33). If the angle of incidence is larger than critical (~63 degrees for glass/water), the excitation light is reflected back into the glass lightguide and exponentially decaying evanescent wave penetrates into the solution phase. Molecules that are at the surface or in close proximity to the interface ~ 100 nm are excited and fluoresce, while molecules that are in the bulk of solution are not excited and do not fluoresce. This feature allows for testing complex specimen, such as whole blood, with no or minimal sample preparation stages.

$$\Theta_c = \sin^{-1}(n_2/n_1) \quad (1)$$

$$d_p = \frac{\lambda_i}{2\pi n_1\sqrt{\sin^2\Theta_i-(n_2/n_1)^2}} \quad (2)$$

$$E_z = E_o\exp(-z/d_p) \quad (3)$$

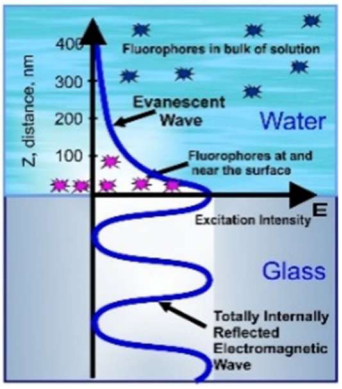


Fig. 3. Phenomena of the evanescent wave and total internal reflection fluorescence.

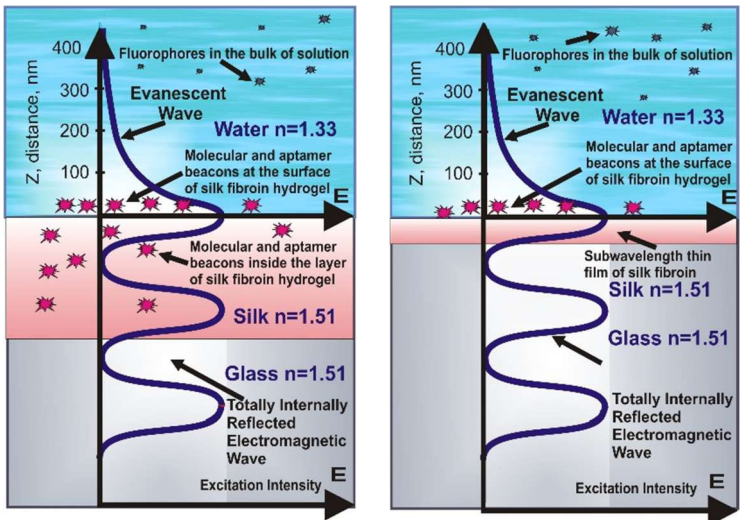


Fig. 4. Refractive index of silk fibroin n=1.51 is close to that of glass. Either a sub-wavelength film of silk fibroin (right panel) or a thick layer of silk fibroin hydrogel (left panel) extends the TIRF lightguide into the "z" dimension. Silk fibroin surface and bulk of the hydrogel provide biologically friendly environment for bioassays of molecular and aptamer beacons.

Figure 4 illustrates the effect of thin film (right panel) and relatively thick layer of silk fibroin hydrogel (left panel) deposited onto glass lightguide with refractive index close to 1.51. Subwavelength thin film of silk fibroin provides a biologically friendly environment for surface immobilization of bioassays. It does not essentially increase the volume for bioassay immobilization, unlike the thicker layer of silk hydrogel, which extends into the third dimension the volume of TIRF lightguide available for immobilization. Total internal reflection and the evanescent wave phenomena take place at the silk/water interface. However, the microporous structure of the silk hydrogel increases the number of immobilized assay molecules by a thousand-fold. Functionalization of TIRF surface with silk fibroin allows for eliminating background scatter and autofluorescence from complex biological matrices (whole blood, plasma, lysate) without laborious washing or centrifugation steps.

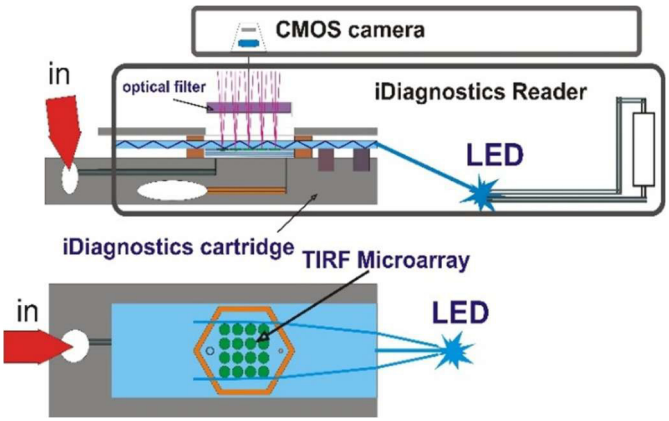


Fig. 5. Schematics of iDiagnostics reader and cartridge.

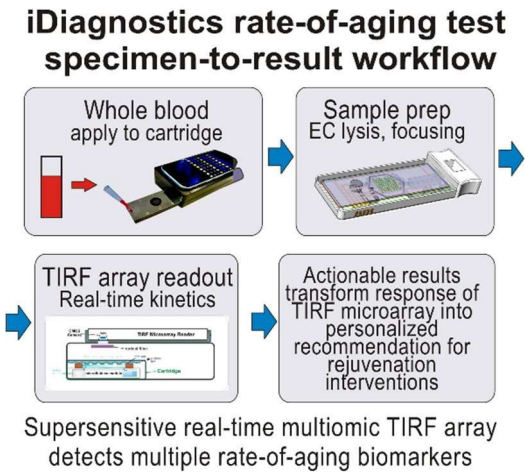


Fig. 6. Specimen-to-result workflow for iDiagnostics rate-of-aging test. Sample preparation module is embedded into iDiagnostics cartridge.

Figure 5 shows that the iDiagnostics sensor consists of: (i) TIRF microarray reader and (ii) disposable cartridge. The latter contains a TIRF-EC sensor chip, typically of the size of standard microscopy slide 1" x 3" x 1 mm. TIRF microarrays comprising DNA and RNA detection molecular beacon and aptamer beacon assays for detecting protein and metabolite biomarkers can be printed over the entire 1" x 3" surface. Both types of beacon bioassays are encapsulated into silk-fibroin scaffolds, which enhances fluorescence response in comparison with that of beacon immobilization at bare TIRF-EC surface. The TIRF array also contains controls, and quantitation members printed at the same array. General views of the beta prototype of iDiagnostics reader and cartridges are shown in Fig. 1; the schematics of the reader and cartridge are shown in Figs. 5 and 6.

iDiagnostics Reader. For the initial stages of the project, TIRF Labs will use the reader equipped with Pixel 10a phone and respective app running under Android operating system. By the 24th month of the project, TIRF Labs will develop from blank pages a dedicated iDiagnostics reader equipped with 3 low-light CMOS cameras as shown in Figure 7. The reader will be equipped with LCD, controller, embedded software, excitation LED, 8-hour battery, cellular and Wi-Fi wireless communication. If manufactured at commercial scale, the reader will cost ~$100 (including 3 CMOS cameras that cost $3-$5) and cartridges from $1 to $10, depending on the application. Three CMOS cameras will serve for fluorescence imaging of up to six separate flow chambers that enclose up to six TIRF arrays, as shown in Fig. 7. Six flow chambers can be populated with up to 8,000 bioassays.

Figure 8 illustrates the microporous structure of the multiwavelength-thick layers of silk fibroin gel with 20-30% water content. Such hydrogel contains micropores with sizes from 1 nm to 1,000 nm that are appropriate for immobilization of molecular beacon and aptamer beacon bioassays. Silk hydrogel provides a biologically friendly environment for their immobilization via covalent binding to silk fibroin reactive groups. Controlled dehydration down to certain content of water in silk fibroin hydrogel populated with bioassays results in formation of the microporous structure, which is

biologically friendly scaffold for bioassays and high optically transparent media with refractive index ~ 1.51. The micropores of 1 nm - 1,000 nm in size are suitable for diffusion of target molecules, but prevent transport of irrelevant large components of samples such as whole blood.

Amine, carboxyl, sulfhydryl, imidazole and hydroxyl groups of silk fibroin macromolecules are available for covalent immobilization of molecular beacon and aptamer beacon bioassays in the pores or on the silk fibers. Controlled dehydration of silk fibroin hydrogel results in formation of microporous with desirable sizes for biodetection and optical medium with refractive index close to 1.51. Micropores with sizes from 10 nm to 1,000 nm are suitable for diffusion of target molecules, but prevent the transfer of irrelevant large components of the sample, such as whole blood.

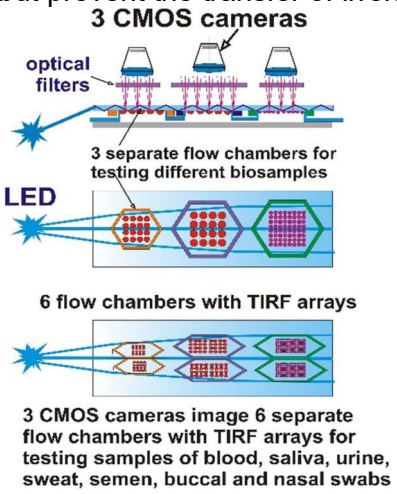


Fig. 7. iDiagnostics with 3 CMOS cameras and cartridges with up to 6 independent flow chambers.

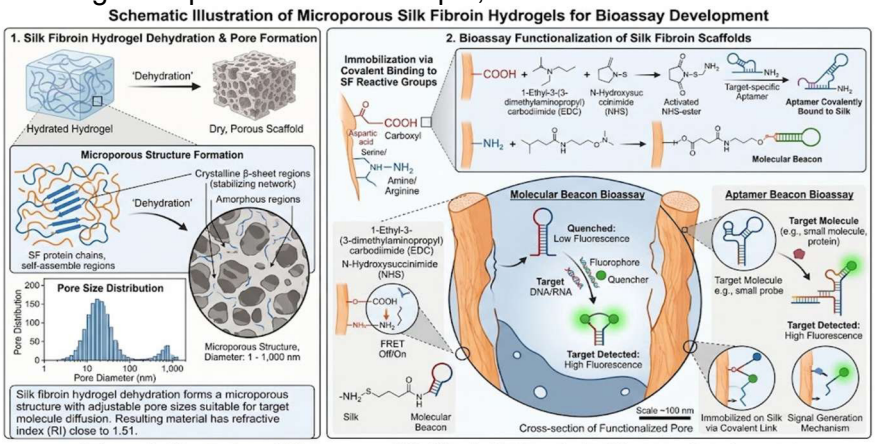


Fig. 8. Microporous structure of silk fibroin gel with pores from 1 nm to 1,000 nm. Molecular- and aptamer-beacons are immobilized in the pores via covalent binding. Silk fibroin gel produces optical medium with refractive index 1.51, and micropores suitable for diffusion of target molecules, but preventing transport of large irrelevant components.

Immobilization of a bioassay at the surface of an optical sensor is a challenging task. Silk fibroin offers a variety of architectures for immobilization. Numerous modification techniques have been developed with the aim of tailoring the surface with desired biocompatibility, including chemical grafting of functional groups and non-covalent physical sorption of specific molecules. While these methods are effective for specific needs, they also present limitations with respect to complexity of processing, loss of bioactivity of biomolecules to be delivered, and limited control of biodegradation. Silk fibroin scaffold offers a broad spectrum of advantages and just a few limitations.

5. Biological Age Clocks and Rate-of-Aging Clocks

Epigenetic clocks including Horvath, Hannum, PhenoAge, GrimAge, DunedinPACE rely primarily on DNA methylation patterns. While powerful for population-level mortality risk and long-term trends, methylation changes slowly (weeks to months) and exhibits high intra-assay variability and poor short-term responsiveness.

On the other hand, circulating plasma proteins reflect immediate physiological state, tissue damage, and active inflammatory cascades. However, traditional microarray assays or mass-spectrometry proteomics are expensive, centralized, and slow. Discrepancies arise when static epigenetic clocks contradict dynamic metabolic/inflammatory shifts. An intervention (e.g., a brief round of intense training or a new peptide regimen) may alter a user's functional proteome and inflammatory profile immediately, while their epigenetic methylation signature remains static for

months. Therefore, highly multiplexed multiomic panels related to aging and rate-of-aging processes are necessary for personalized fine-turning of the rejuvenation interventions.

The choice of aging clocks and rate-of-aging biomarker panels for iDiagnostics will be aligned with the data of The Biomarkers of Aging Consortium [8] as well as with the analysis of most recent literature. DNA methylation and other epigenetic models of aging clocks often yield inconsistent, hard-to-interpret results [7]. In contrast, proteomic clocks may excel in providing aging biomarkers or mechanistic insights by tracking the immediate effectors of biological changes. For example, IgG glycan tests measure rapid dynamics of inflammation and immune system response, while DNA methylation changes slowly over months. Glycans respond rapidly to therapeutic or dietary interventions. It is considered to be an advanced platform for measuring short-term inflammatory status and confirming if an anti-aging protocol is actively working.

TIRF Labs will compare six proteomic clocks: ProtAge, OrganAgemortality, OrganAgechrono, PAC, ipfP3GPT and PAOPAC. A recent study measured the variance between the clocks and found that all six clocks consistently predicted lower biological age in treated arms [7]. However, proteomic clocks alone cannot deconvolute aging and disease-specific effects. The iDiagnostics project will address these issues through pathway analyses that identify potential anti-aging shifts in senescence and metabolic processes. We will consider using iDiagnostics reader with 3 CMOS cameras imaging TIRF microarrays enclosed into 6 separate flow chambers for testing samples of blood, saliva, urine, sweat, semen, buccal and nasal swabs as shown in Fig. 7.

Rate-of-aging panel should measure how quickly a person's body is deteriorating over time compared to their chronological age. Biomarkers of aging categorizes these metrics into 3 main domains:

(i) Epigenetic & molecular clocks – these markers track changes at the DNA and cellular levels, serving as the most precise modern measures of aging rates. DNA methylation (epigenetic clocks) tests include the Horvath, Hannum, PhenoAge, and DunedinPACE clocks track chemical marks on DNA to gauge the biological pace of aging.

(ii) Proteomic signatures panel 1 includes molecular clocks that analyze patterns in hundreds of circulating blood proteins, capturing individual organ system aging. Telomere length measures the protective caps at the ends of chromosomes that shorten as cells divide. This panel includes Inflammatory & Immune Markers ("Inflammaging"), chronic, low-grade systemic inflammation as one of the main drivers of the rate of aging, including high-sensitivity C-reactive protein (hs-CRP) - a core biomarker of chronic systemic inflammation; interleukin-6 (IL-6): a key inflammatory cytokine that typically rises with age and functional decline; and immune cell ratios: shifting balances in white blood cell counts, red cell distribution width (RDW), and lymphocyte percentages reveal immune system competence.

(iii) Proteomic signatures panel 2 comprises physiological and metabolic markers that track nutrient sensing, metabolic health, and organ functions. Panel 2 includes insulin-like growth factor 1 (IGF-1): a hormone reflective of nutrient sensing and growth pathways that directly correlates with lifespan control; growth differentiation factor 15 (GDF-15): a prominent stress-response protein linked to mitochondrial dysfunction and aging outcomes; and standard metabolic panel: fasting glucose, HbA1c, albumin (liver and nutritional reserve), and creatinine (kidney function). These biomarkers collectively calculate algorithmic biological age.

Multiomic diagnostics is essential for rejuvenation efforts because it provides a comprehensive view of biological aging that a single marker cannot capture. While a standard blood panel or single genetic test only shows a snippet of your health, multiomic test integrates data across genomics, epigenomics, transcriptomics, proteomics, metabolomics, and microbiomics to map out a precise, "systems-biology" view of your true biological age. Proteomic clocks, by tracking the immediate effectors of biological change, may excel in providing aging biomarkers or mechanistic insight. Highly multiplexed multiomic detection capability of iDiagnostics capturing hundreds of molecular markers simultaneously on a compact, low-cost diagnostics, fills the gap of at-home analysis and opens a new era of personalized optimization of rejuvenation interventions.

6. Molecular beacon, aptamer beacon, and CRISPR-CAS-based assays

Molecular and aptamer beacons will be used for populating iDiagnostics microarrays for detection of biological age clocks panel and rate-of-aging clocks panel of markers. These detections will be performed with molecular beacon assays targeting DNA and RNA molecular markers and aptamer beacons targeting antigens – protein and metabolites biomarkers. Optionally, we will compare the performance of CRISPR-CAS-based bioassays for detecting DNA/RNA markers with that for molecular beacons.

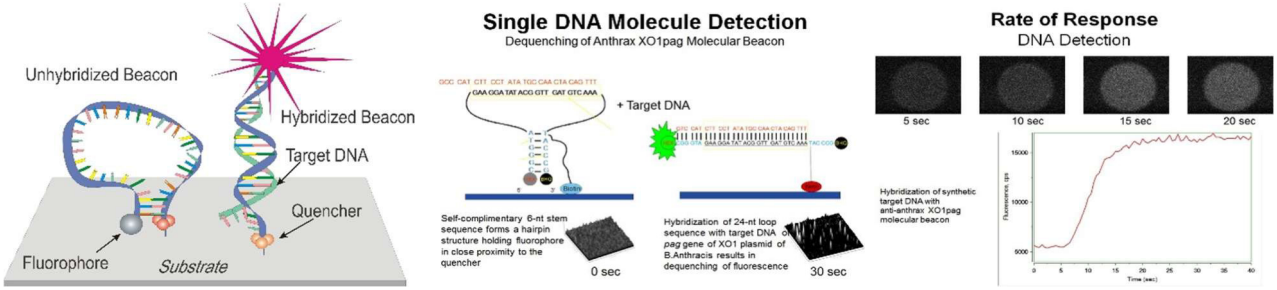


Fig. 9. Dequenching of fluorescence upon beacon hybridization with target nucleic acid (left panel); single DNA molecule detection (middle panel); and the kinetics of response (right panel).

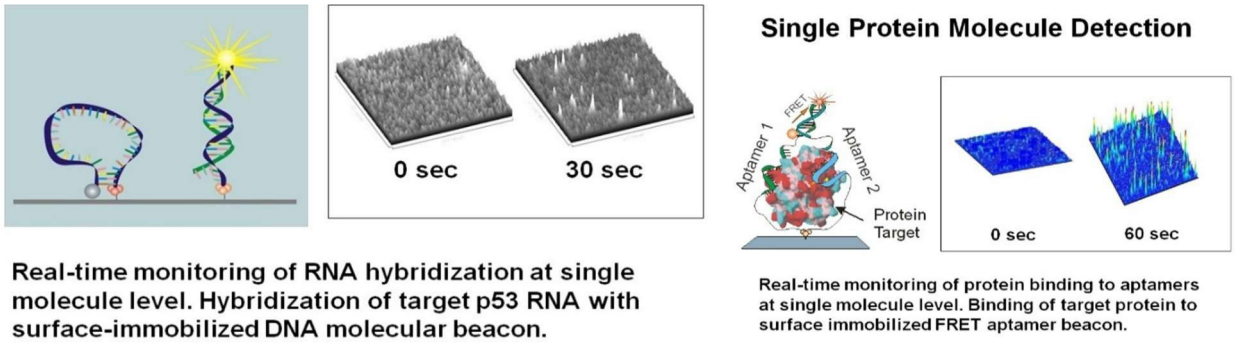


Fig. 10. TIRF arrays for monitoring single RNA and single protein molecule detection. Two panels at the left show RNA detection. Panels at the right show target protein molecule detection by FRET aptamer beacons.

TIRF Labs has entered into preliminary agreement and will subcontract with Aptagen, LLC, to develop high-affinity molecular and aptamer beacons with rapid rate of response. Three other U.S. companies expressed their interest in subcontracting for assay development for the suggested iDiagnostics project. CRISPR-CAS-based bioassays are currently developed by several groups. If intellectual property arrangements prevent the straightforward use of CRISPR-CAS-based bioassays, TIRF Labs will offer a collaboration on the basis of an open innovation business model.

In our previous studies (selected publications: [1 - 6]) TIRF Labs has acquired in-depth experience of using the effect of electric field on molecular and aptamer beacons, as well as the enhancement of bioassay response in silk-fibroin scaffolds. Fig. 9 (left panel) illustrates the principles of dequenching molecular beacon fluorescence upon binding to target DNA. The panel in the center shows detection of single DNA molecules. The panel at the right demonstrates a rapid rate of response detected by a molecular beacon immobilized at the TIRF-EC surface.

Aptamers are stable DNA or RNA ligands, analogs of antibodies, that bind with high affinity and specificity to metabolites, peptides, proteins, and whole cells. For example, RNA aptamers have been designed that show greater than ~10,000-fold affinity for theophylline over caffeine, which differ only by a few atoms. Recently, a DNA aptamer has been developed with 250,000-folded specificity

against the same small molecules. Figure 10 shows the principles of aptamer beacons and their application for single molecule detection.

TIRF Labs has successful experience of using molecular and aptamer beacons for detection of RNA, DNA and protein biomarkers [1 - 6]. Silk-fibroin provides a biologically friendly environment to bioassays, enables enhanced effects of electric field, and increases the volume of fluorescence excitation without compromising the evanescent wave effect, which results in brighter fluorescence in response to the same concentration of target biomarker in the solution phase.

CRISPR-Cas-based assays. CRISPR-based assays offer rapid, sensitive, and specific detection of DNA and RNA targets. Principles of CRISPR-based assay are shown in Figure 11. Detection of protein targets with CRISPR assays requires indirect interactions of CRISPR-Cas with aptamer intermediates that bind the target protein. The applications of CRISPR assays include infectious disease surveillance, cancer biomarker detection, and genetic disorder screening, emphasizing key advantages such as speed, high sensitivity, specificity, portability, and cost-effectiveness, particularly for point-of-care (POC) testing in resource-limited settings.

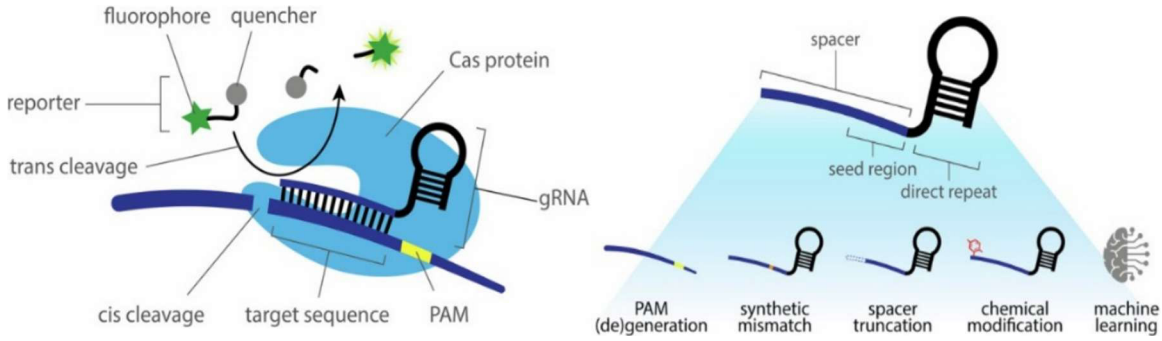


Fig. 11. Principles of CRISPR-based fluorescence assays for detecting DNA and RNA markers.

TIRF Labs plans to explore the challenges of CRISPR-assays, including sensitivity limitations without pre-amplification, specificity issues, and complex sample preparation. CRISPR assays address certain unmet needs of diagnostics and offer an alternative by providing rapid, highly sensitive, and specific detection capabilities useful for critical areas, including swift pathogen identification during outbreaks, early detection of complex diseases like cancer, and the advancement of personalized medicine through precise genetic screening. During Year 1 we plan to carefully explore the opportunity of using CRISPR-Cas-based assay in iDiagnostics for rejuvenation interventions optimization.

During the initial stage of the project, we plan to focus on the development and optimization of molecular and aptamer beacons, specifically, beacons immobilized into silk-fibroin scaffolds deposited onto TIRF-EC surface. Electric field geometry, amplitude, frequency and DC shift are subjects for optimization. In parallel, respective app for data acquisition by CMOS cameras, 'on-the-fly' data analysis and rapid results reporting will be developed. We also plan to explore the promising future trajectories like the integration of artificial intelligence (AI). The final reporting algorithm will be locked from analytical and clinical data and confirmed with FDA.

7. Market Analysis: Size, Growth, and Dynamics

The market of diagnostics dedicated to the optimization of rejuvenation interventions is experiencing rapid expansion as geroscience transitions from academic research into clinical personalized precision medicine. Current market size is valued at approximately **$3 billion** with broader longevity-focused offerings and biomarker tracking platforms scaling significantly higher depending on whether direct-to-consumer (DTC) wellness testing or clinical-grade multi-omics profiling is included. The market is projected to expand to **$5 billion** over the next decade, posting a steady compound annual growth rate (**CAGR**) ranging from **7% to 15%,** driven heavily by consumer and clinical interest in personalized rejuvenation interventions. Currently, the fastest

growing test modalities of age clocks are DNA methylation panel and genomic markers. Although they hold the largest initial revenue shares, **rate-of-aging clocks based on proteomics and multiomic biomarker technologies** are registering the fastest adoption rates (projected CAGRs exceeding 15%. This reflects a shift from static genetic risk toward dynamic, quantifiable physiological tracking.

Channels & End-Users. Direct-to-Consumer and Wellness platforms historically capture a major share of initial testing volume (~40%), driven by consumer self-pay behavior and health span optimization trends. However, currently there are no at-home tests for rate-of-aging panel and optimization of rejuvenation interventions. iDiagnostics will be the first at-home test system; it will fill the gap. At the present time, specialized clinical centers represent the fastest-growing end-user segment (projected CAGRs above 12%), as practices increasingly build integrated diagnostic-to-treatment pathways.

Regional Distribution. North America commands the largest regional share (44%) due to high per-capita wellness spending, advanced laboratory infrastructure, and the concentration of biotechnology innovators. Meanwhile, the Asian and Pacific regions represent the fastest-growing market, propelled by rapidly aging demographics in countries like Japan and South Korea alongside expanding middle-class disposable incomes.

Core Market Dynamics features the shift from chronological to biological age. Healthcare systems and individuals are moving away from reactive, age-based disease management toward proactive, personalized, preventive, precision medicine. iDiagnostics will provide the quantitative baseline required to evaluate whether anti-aging interventions (e.g., senolytics, lifestyle protocols, or early-stage cellular reprogramming trials) are successfully slowing or reversing physiological decline.

Integration of Multi-Omics and AI Analytics: The convergence of high-throughput technologies—such as iDiagnostics, next-generation sequencing (NGS), mass spectrometry-based proteomics, and metabolomics—with AI-powered predictive algorithms will dramatically improve the resolution of biological age tracking. These tools will allow researchers and clinicians to monitor molecular shifts with high precision.

Bridging Therapeutics and Diagnostics: As emerging rejuvenation therapies advance through preclinical and human clinical pipelines, the demand for companion at-home diagnostics capable of establishing objective surrogate endpoints for health span and biological rejuvenation is intensifying. Regulatory pathways and clinical validation remain critical focal points for scaling these diagnostic tools from wellness markets into formal medical practice.

Total Addressable Market (TAM): The global rejuvenation, anti-aging, longevity, and preventive health market, experiences exponential growth and is projected to scale past hundreds of billion dollars as soon as geroscience shifts from academic theory to consumer-driven healthcare. At the present time, the first eye rejuvenation protocol ER-100 developed by Dr. David Sinclair and co-workers undergo clinical trials [9].

Serviceable Obtainable Market (SOM) includes early adopters, biohackers, rejuvenation and longevity scientific and clinic networks, and decentralized biodefense diagnostic monitoring users in North America, Asia-Pacific region and Europe. There are numerous longevity/rejuvenation conferences that provide efficient avenues for iDiagnostics advertising. These conferences include the Longevity Summit at Dublin, Ireland. Rising consumer awareness of health-span vs. life-span, explosion of rejuvenation technologies and interventions, rise of longevity clinics, and the shift from reactive symptom treatment to proactive, quantified self-optimization stimulate further growth of the area. The premium longevity optimization, biohacking, and concierge medicine market comprising high-net-worth individuals and proactive health seekers investing heavily in biological age testing, supplements, and clinical interventions.

8. Competitive Landscape

Unique set of competitive advantages of iDiagnostics. At the present time, as mentioned above, there are no at-home, highly multiplexed, multiomic diagnostic systems similar to iDiagnostics

that would be suitable for optimizing rejuvenation interventions. TruDiagnostic products, the closest alternative technology, relies on a decentralized sample collection phase done at-home via finger-prick blood, saliva, or urine kits. However, the analytical phase of these products requires sophisticated laboratory equipment operated by certified technicians in centralized labs.

Traditional high-complexity multiomic systems, such as traditional multiplexed protein arrays, mass-spectroscopy metabolomics, and whole-genome methylation profiling - require strict quality control, precise temperature regulation, and compliance with FDA CLIA standards that cannot currently be miniaturized into a reliable, low-cost disposable cartridge. iDiagnostics will fill the gap.

In the meantime, the market for biological age testing and rejuvenation optimization has transformed into a multi-tiered industry. Modern platforms have largely evolved from simple biological age estimates, focusing on aging clocks, instead on pace-of-aging tests, organ-specific biological noise, and functional multi-omics. Companies that lead specific verticals within the rejuvenation optimization testing include **TruDiagnostic, Generation Lab, Tally Health, Elysium Health, GlycanAge**, **Function Health, InsideTracker, and Viome.**

These companies and their technologies cover two major avenues: **1. Epigenetic & DNA Methylation tests** and **2. Comprehensive Blood & Multi-Omic Diagnostic Platforms.** At the avenue 1 **TruDiagnostic [TruAge]** focuses on DNA methylation and epigenetic clocks (analyzing over 900,000 to 1 million CpG loci). They run the **DunedinPACE** algorithm (developed by Duke U and Columbia U), which measures the current speed of biological aging, rather than just a static age number. They also offer system-level epigenetic reports analyzing brain, heart, immune, and liver biological markers via blood-spot collection. **Generation Lab [SystemAge]** focuses on measuring "biological noise" and loss of epigenetic control across distinct organ systems. Emerging as a clinical favorite (backed by UC Berkeley research), instead of relying solely on traditional clocks, SystemAge quantifies molecular noise and tissue-specific drift, helping users tailor interventions to specific organ systems. **Tally Health [TallyAge]** leverages consumer-friendly, cheek-swab-based epigenetic tracking. Co-founded by Dr. David Sinclair, Tally Health emphasizes consumer accessibility (avoiding blood pricks) and integrates its test results with continuous lifestyle coaching and proprietary longevity supplements. Tally Health and TruDiagnostic operate under the consolidated Infinite Epigenetics group. **Elysium Health** performs saliva-based DNA methylation testing coupled with systemic health tracking. It utilizes proprietary epigenetic algorithms developed with Yale researchers to track rate-of-aging and systemic health indices.

Functional & Immuno-Aging technologies**,** including **GlycanAge,** employ Glycomics (IgG glycan analysis) to measure chronic inflammation and immune system age. While DNA methylation changes slowly over months, glycans respond rapidly to therapeutic, lifestyle, or dietary interventions. It is widely considered the best platform for measuring short-term inflammatory status and confirming if an anti-aging protocol is actively working.

Comprehensive Blood & Multi-Omic Diagnostic Platforms include **Function Health, Inc.,** with core focus on broad-spectrum clinical biomarker tracking (~100+ lab tests twice a year), which provides an accessible recurring membership for comprehensive organ, metabolic, hormone, and cardiovascular biomarker panels, giving biohackers the baseline chemistry needed to monitor protocol safety and systemic efficacy. **Inside Tracker [InnerAge 2.0]** focuses on blood biomarker algorithms paired with DNA and wearable data. "InnerAge" is using key blood markers (e.g., ApoB, hsCRP, HbA1c, hormone levels) and algorithmic decision engines to provide immediate nutritional and athletic intervention recommendations. **Viome [Health Intelligence]** detects Metatranscriptomics (microbiome mRNA expression) and cellular gene expression via finger-prick blood and stool samples. **Viome** focuses on active gene expression rather than static DNA, evaluating mitochondrial health, gut immune pathway activation, and cellular stress. There are several companies that perform specialized single-pathway tests, including **Renue by Science, Chromadex,** and **ProHealth Longevity**. They employ target-specific assays, most notably intracellular NAD+ blood testing, which allows consumers taking NAD+ precursors (NR, NMN) or undergoing IV protocols to verify whether cellular NAD+ levels are actually increasing in whole blood.

Thus, the market for at-home diagnostics focused on rejuvenation interventions optimization relies primarily on a hybrid model: users collect biological samples at home using mailed kits and mail the kits back. The actual analyses of the samples are performed in certified central reference laboratories using high-throughput instrumentation (such as traditional microarrays, mass spectrometry and next-generation sequencing). iDiagnostics will fill the gap of true at-home, point-of-care, zero-send-out testing. **The iDiagnostics Opportunity** features a true on-device, at-home multiomic detection platform, which represents an entirely blue-ocean category, filling the massive gap between slow mailed-in sequencing labs and immediate needs of consumer feedback.

9. Offeror's capabilities and experience. Prior grants and results. The U.S. Government has awarded TIRF Labs' team multiple grants, including a Broad Agency Announcement (BAA) award from HSARPA/DHS and SBIR grants from the NIH (operating previously under the names BioElectroSpec and TIRF Technologies). Across ~$4.3M in grant funding, our team exceeded all BAA and SBIR program milestones, resulting in the commercialized TIRF Analytix product line and downsized the real-time TIRF microarrays to a handheld iDiagnostics. The U.S. Department of Defense ranked our TIRF systems in the top tier of diagnostics for chemical and biological defense [12]. During our HSARPA BAA program, TIRF Labs' team gained extensive experience detecting biomarkers of Bacillus anthracis and other high-consequence biological threats.

10. Broad Spectrum of Applications

While this submission focuses on at-home multiomic diagnostics for the personalized optimization of rejuvenation interventions, the iDiagnostics platform will benefit numerous adjacent areas of public health. Highly multiplexed multiomic TIRF microarrays can be rapidly reconfigured to detect biothreats and biomarkers of infectious, chronic, and oncological diseases, directly supporting the goals outlined in the National Blueprint for Biodefense published by the U.S. Bipartisan Commission on Biodefense [10, 11]. These areas will be pursued separately, because they need separate FDA regulations.

Alignment with the National Blueprint for Biodefense: The U.S. Bipartisan Commission on Biodefense established the Apollo Program for Biodefense and the National Blueprint for Biodefense to prevent future pandemics and mitigate the impact of biological threats [10, 11]. The Blueprint outlines 36 recommendations and 185 action items [11]. While foundational laboratory technologies exist, a critical diagnostic gap remains in point-of-care (POC) and remote, low-resource settings. iDiagnostics will close this gap and equip U.S. national biodefense with rapid, affordable POC and at-home diagnostic tools.

11. Regulatory Roadmap

By the end of Year 1, TIRF Labs plans to achieve laboratory testing readiness for iDiagnostics with up to 200 aging clocks and rate-of-aging bioassays based on molecular and aptamer beacons. Year 1 efforts include optimizing the silk-fibroin scaffold, refining the TIRF reader paired with an Android smartphone, and developing the iDiagnostics mobile application for sensor control, data acquisition, analysis, and reporting. A substantial portion of Year 1 will focus on developing the disposable iDiagnostics cartridge with embedded sample preparation modules. Figure 6 illustrates the specimen-to-result workflow for iDiagnostics rejuvenation applications, and 3D CAD schematics depicts the single-flow-cell cartridge architecture. Because TIRF requires minimal sample preparation, all sample-handling modules are fully integrated within a sealed cartridge featuring at least two layers of containment against biohazardous leakage. By Month 6, we plan to submit an FDA Q-Submission and by Month 11 prepare our FDA 510(k) premarket notification.

510(k) Premarket Pathway: For FDA clearance, TIRF Labs will pursue the 510(k) pathway based on Substantial Equivalence to existing marketed predicate devices, including diagnostic offerings from TruDiagnostic, Generation Lab, Tally Health, Elysium Health, GlycanAge, Function Health, InsideTracker, and Viome, as iDiagnostics shares the same overarching intended use.

Verification experiments will establish limits of detection (LOD), precision, interference profiles, and response times, followed by clinical agreement studies comparing iDiagnostics against predicate devices and reference standards. Typically, the 510(k) pathway follows a 90-day FDA review clock. Navigating the regulatory landscape for a point-of-need (PON), point-of-care (POC), or at-home diagnostic device—particularly one spanning consumer wellness, clinical care, and biodefense—requires aligning the device's intended use and Indications for Use (IFU) with the distinct regulatory framework of each market segment.

Strategic Considerations for Point-of-Need / At-home Devices:

- CLIA Waiver (Dual Submission): To enable operation in non-laboratory settings (clinics, pharmacies, or at home), iDiagnostics will obtain a CLIA Waiver (or Over-the-Counter [OTC] clearance for home use). TIRF Labs plans to utilize the FDA's Dual 510(k) and CLIA Waiver by Application pathway, enabling simultaneous FDA review of analytical and clinical performance alongside lay-user usability and flex studies (simulating potential user errors).
- Pre-Submission (Q-Sub) Meetings: In mid-Year 1, TIRF Labs will engage the FDA's Office of Health Technology 7 (OHT7: Office of In Vitro Diagnostics) via a Q-Submission to confirm predicate device suitability and verify that a De Novo classification request is unnecessary. Through this process, TIRF Labs will finalize clinical study endpoints and usability sample sizes, engaging 300+ lay users for OTC/home-use validation.

Bridging Consumer Cash-Pay Wellness and Clinical/Biodefense Markets: Operating across consumer longevity/wellness, reimbursed clinical diagnostics, and federal biodefense requires a modular, phased regulatory strategy so commercial revenue is not bottlenecked by the longest clinical trial:

- Phase A — General Wellness & Consumer Cash-Pay Entry: Under the FDA's General Wellness: Policy for Low-Risk Devices guidance, products intended solely to maintain or encourage a general state of health—without claiming to diagnose, treat, cure, or prevent a specific disease—are exempt from premarket clearance (comparable to the commercial model used by Viome). TIRF Labs will initially market the iDiagnostics platform for wellness tracking, nutritional optimization, and biological age/lifestyle monitoring. All rejuvenation marketing copy, app interfaces, and biomarker reports will strictly avoid disease claims, utilizing compliant phrasing such as "supports cellular resilience" rather than "detects chronic inflammatory pathology." Commercially, this generates immediate cash-pay revenue and HSA/FSA eligibility (via Letters of Medical Necessity or eligible wellness categories) while building a robust real-world dataset of hardware reliability, reagent stability, and user interface performance.
- Phase B — Clinical Diagnostics & Reimbursed Care via 510(k): To unlock insurance reimbursement (Medicare, Medicaid, and commercial payers via CPT codes) and broad physician adoption, the exact same hardware platform will be submitted for FDA 510(k) clearance with specific disease-state IFUs (e.g., quantifying validated inflammatory cytokines or specific pathogen nucleic acids and proteins). We will initiate regulatory scoping for these clinical panels during Year 1.
- Hardware/Software Partitioning (Design Lock): We will freeze the core hardware design of the iDiagnostics reader and microfluidic cartridge ("design lock") during the wellness phase so that analytical verification data (shelf-life, electrical safety, and electromagnetic compatibility) can be directly leveraged into the 510(k) dossier.
- Software as a Medical Device (SaMD) Firewall: Within our cloud and mobile app architecture, we will strictly partition consumer wellness algorithms from regulated clinical diagnostic algorithms, allowing the FDA to clear the specific assay cartridge, reader, and clinical diagnostic software module as a closed system.

To meet FDA quality expectations from the beginning, TIRF Labs will implement ISO 13485 quality management standards from Day One—even during our initial non-regulated wellness launch. Following design lock of the core reader and microfluidic cartridge, we will execute targeted clinical agreement and lay-user usability studies on high-reimbursement clinical assays to secure 510(k) clearance. For future market expansion, we will leverage the cleared iDiagnostics platform to introduce biodefense assay cartridges via Emergency Use Authorization (EUA) or targeted 510(k)

supplements utilizing contrived and animal validation protocols. Ultimately, TIRF Labs will demonstrate rapid response, high sensitivity, multiplexing, multiomic detection, and field stability across FDA-cleared cartridges and readers, establishing ISO 13485-certified R&D and manufacturing operations in North Carolina's Research Triangle Park (RTP).

12. Manufacturing

Reader Architecture & Cost Engineering: During Year 1, the iDiagnostics reader and rejuvenation rate-of-aging cartridge will advance to full readiness for laboratory trials, utilizing a Google Pixel 10a smartphone running a dedicated Android application for optical readout and sensor control. In Year 2, TIRF Labs will execute an engineering starting from a blank page (de novo) to develop a standalone, dedicated iDiagnostics reader equipped with 3 CMOS cameras.

When manufactured at commercial scale, this dedicated iDiagnostics reader is projected to cost $100 or less, while disposable cartridges will cost $1 to $10 depending on the panel of assays complexity. As illustrated in Figure 7, the standalone reader will integrate three low-light, mid-resolution (up to 2 MP) CMOS cameras with global/rolling shutters (costing $3–$5 per camera in volume), excitation LEDs, an LCD interface, an onboard controller, embedded software for sensor control and on-the-fly data reporting, an 8-hour battery, and cellular/Wi-Fi wireless connectivity.

The three CMOS cameras image fluorescence response across up to six independent flow chambers enclosing up to six TIRF microarrays printed on a TIRF-EC sensor chip 1"x3"x1mm.

- Camera 1 (Primary Multiomic Panel): Images the core TIRF microarray within a primary flow cell (e.g., a 400-spot rejuvenation rate-of-aging and aging clocks panel comprising RNA-detecting molecular beacons, protein/metabolite-detecting aptamer beacons encapsulated in silk fibroin scaffolds, plus internal calibration and quantitation controls; see Figures 1, 5, and 6).
- Camera 2 (Rapid "Heads-Up" Assays): Dedicated to a separate flow cell patterned with high-affinity, fast-kinetics assays engineered for applications requiring ultra-rapid (~1-minute) preliminary results.
- Camera 3 (Specialized / Expandable Assays): Reserved for specialized diagnostic panels. When required by a specific test architecture, the array footprint beneath each camera can be subdivided into two isolated flow cells, yielding up to six independent chambers (Figure 7, bottom panel).

Year 2 Validation & U.S. Manufacturing Scale-Up: Throughout Year 2, TIRF Labs will demonstrate rapid response times (1–10 minutes), low limits of detection and robust field stability, while completing validation at certified testing facilities. Concurrently, we will establish ISO 13485 certified R&D and FDA-registered manufacturing facilities in North Carolina's Research Triangle Park (RTP) area.

Leveraging RTP's established biotechnology infrastructure, regional supply chain partners, and technical workforce, these U.S. manufacturing facilities will be engineered to scale to over 1,000,000 iDiagnostics readers and 100,000,000 disposable cartridges annually. Supported by subsequent institutional and private capital, this manufacturing scale will position iDiagnostics to serve both decentralized personalized Medicine 4.0, rejuvenation markets and national biodefense needs outlined by the U.S. Bipartisan Commission on Biodefense [10, 11].

11. Literature cited:

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ADDENDUM

BIOGRAPHICAL SKETCHES of the KEY PERSONNEL

1. Alexander N. Asanov, PhD, Principal Investigator, CEO&Scientific Director, TIRF Labs.
Education: Moscow Institute for Physics and Technology, M.S. in Biophysics, 1975.
Institute of Chemical Physics, Russian Acad. Sci., Moscow, 1977, PhD in chemical physics, PhD advisor – Nobel Prize winner academician N.N. Semenov.

A. Personal Statement: My research interests focus on CBRNE security, TIRF spectroscopy, molecular diagnostics, single molecule biology, biomolecular interactions, ion channel studies, longevity and rejuvenation, and applications of TIRF-EC for biomolecular engineering. In the former USSR four Nobel Prize winners: N.N. Semenov – my PhD advisor, P.L. Kapitza, A.D. Sakharov, V.L. Ginzburg, academicians K. Zamaraev, A. Shilov, Drs. I. Sarkisov, E. Trukhan, and in the USA - Drs. W. Wilson, P. Oldham, L. DeLucas, L. Vaca, Z. Gryczynski, and dozens of other brilliant scientists trained me in several fields, which placed me into uniquely advantageous position in the area of molecular diagnostics and enabled me with the exceptionally broad spectrum of skills and knowledge. I am not taking this favor for granted - I am returning back to society. My gurus had similar feelings in their blood and granted to me their epigenetics together with their knowledge and skills. In 1999-2014, I served as Principal Investigator on BAA and SBIR grants, awarded by NIH and HSARPA, received $4.3 million. I assembled a team of scientists and engineers, who developed 2 clusters of innovative instruments: TIRF Analytix for laboratory settings and iDiagnostics for home-use and POC. We have pioneered several groundbreaking discoveries and accumulated unique experience in using TIRF for lifesciences applications. I have broad background in spectroscopy, electrochemistry, surface chemistry, molecular biology, cell biology, nanoengineering, mechanical and optical engineering, which are key areas for the proposed iDiagnostics project. Each of our prior projects resulted in the development of advanced TIRF devices and instruments, which exceeded expectations from typical research grants. Our customers from academic and pharmaceutical groups generated unique research data using our TIRF Analytix products, and published articles in leading scientific journals. I have a record of successful R&D projects in the area of molecular diagnostics and believe that my prior experiences have prepared me well to lead the proposed project.

B. Selected Publications in Peer-reviewed Journals:

2. Asanov A., Larina L. Electrochemical control of protein interactions with solid surfaces. Ed. A. Milton J. Charge and Field Effect in Biosystems-3, (1992), 13-27. Birkhaeuser, Boston, MA.
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11. Sampieri A, Asanov A, Vaca L. Hydrogel Silk-Based Microarrays and Molecular Beacons for POC Diagnostics. Front Bioeng Biotechnol. 2022;10:881679

2. Luis A. Vaca, PhD, Senior Lead Scientist on the proposed project. Dr. Vaca is a world-renowned scientist in the area of cell biology with exceptionally broad spectrum of interests from cell physiology to software development. Dr. Vaca received BS degree in surgery from UNAM in 1985, MS degree in biomedical research in 1989 from UNAM, and MS degree in computer science in 1994 from Institute for Computer Sciences, Houston, TX. In 1994 he received PhD degree in Biomedical Sciences from UNAM, Mexico. Dr. Vaca authored 140+ articles, received 26 awards, including Alexander von Humboldt Award in 1999. He gave 100+ invited lectures. Dr. Vaca is a long-term partner and collaborator of TIRF Labs (see “Literature cited” section on page 12). There is preliminary agreement with Dr. Vaca that he will relocate to RTP North Carolina, as soon as the project is funded. Selected published articles: www.ifc.unam.mx/investigadores/luis-vaca

3. Zygmunt Gryczynski, PhD, Texas Christian University**,** Senior Lead Scientist on the proposed project. Dr. Gryczynski is a world-renowned scientist in the filed of fluorescence spectroscopy. TIRF Labs enjoys long-term collaboration and partnership with Dr. Gryczynski and his research group. In 1982 Dr. Gryczynski graduated from University of Gdansk in with MS degree in chemical physics. In 1987 he received PhD degree in chemical physics from the University of Gdansk. Dr. Gryczynski published 210+ articles in peer-reviewed journals and gave numerous invited lectures at scientific meetings. Selected publications are posted at the URL: https://cse.tcu.edu/faculty-staff/view/zygmunt-gryczynski#selected-publications.

4. Thomas Caltagirone, PhD, Aptagen, CEO, assay development subcontractor on the project
Dr. Caltagirone graduated from the University of the Sciences in Philadelphia with a bachelor’s degree in Biochemistry, followed by a PhD degree in Neuroscience from Drexel University. Dr. Caltagirone has over 30 years of research and development experience in the field of lifesciences. He completed his PhD thesis on “Proton-Sensitive Ribozyme Switches with Molecular Memory” at Yale University. His training and technical skills are primarily in the area of Molecular Biology. Dr. Caltagirone authored several patents and publications, including: Liao A, Thoa T, Caltagirone GT. Aptamer-Based Target Detection Facilitated by a 3-Stage G-Quadruplex Isothermal Exponential Amplification Reaction. J Vis Exp. 2022 Oct 6;(188), and Thoa T, Liao A, Caltagirone GT. Determining Thermodynamic and Kinetic Association of a DNA Aptamer and Tetracycline Using Isothermal Titration Calorimetry. J Vis Exp. 2022 Aug 23;(186)

5. Albert M. Liao, BS, Aptagen's Lab Director, assay development subcontractor on the project. Albert Liao earned his bachelor's degree from Johns Hopkins University in the field of Biomedical Engineering. He participated in the internship program and graduated to assume the Lab Director position at Aptagen. During his tenure at Aptagen, Albert Liao contributed to many aspects of the R&D, including aptamer and oligonucleotide synthesis and modifications. Selected published articles: Liao A, Thoa T, Caltagirone GT. Aptamer-Based Target Detection Facilitated by a 3-Stage G-Quadruplex Isothermal Exponential Amplification Reaction. J Vis Exp. 2022 Oct 6;(188), and Thoa T, Liao A, Caltagirone GT. Determining Thermodynamic and Kinetic Association of a DNA Aptamer and Tetracycline Using Isothermal Titration Calorimetry.J Vis Exp. 2022 Aug 23;(186)

6. Ryan A. Sherry, MS, TIRF Labs, Senior embedded systems engineer on the proposed project. Mr. Sherry is a multitalented engineer and researcher with broad and in-depth experience in diagnostics for POC. In 2001 Mr. Sherry received his MS degree in electrical engineering and computer science from the Bucknell University, Pennsylvania. In 2006 he joined TIRF Labs and contributed significantly to the development of handheld i-Diagnostics, other hardware products, as well as in TIRF Labs' research activities. Selected article by Mr. Sherry: Asanov A, Sampieri A, Moreno C, Pacheco J, Salgado A, Sherry R, Vaca L. Combined single channel and single molecule detection identifies subunit composition of STIM1. Cell Calcium. 2015 Jan;57(1):1-13**.**