FLUXERGY

Powering Diagnostic Care™

POWERING PRECISE, AFFORDABLE, AND EASY-TO-USE HEALTH TESTING AT THE POINT OF CARE.

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How the Coronavirus SARS-CoV-2 Exposes the Flaws of Current Health Testing

The rapid spread of COVID-19, which has the potential to become a once-in-a-century pandemic, has demonstrated that current diagnostic testing methodology is too slow and too inaccessible to address today's dramatically changing healthcare challenges. New technologies are needed immediately that provide fast, accurate, and low-cost tests directly at the Point of Care.

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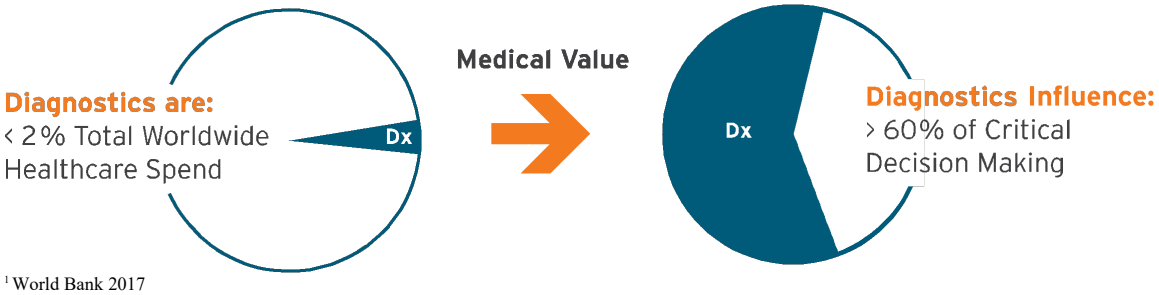
Abstract: COVID-19, which originated in Wuhan, China at the end of 2019 and within just a few months spread to more than 100 countries, demonstrates the pressing need for accessible and affordable health testing solutions at the Point-of-Care (PoC). Despite early public missteps in the emerging field of PoC diagnostics, important progress is now being made technologically toward bringing precise, yet affordable and accessible diagnostic health testing to the consumer-level, available not just through doctor's offices and urgent care clinics, but also through retail pharmacies, fitness and recreational settings, and ultimately in a patient's home. The clinical and cost-management needs for such solutions are readily apparent and urgent, especially in today's environment. But to realize the full potential to democratize health testing for consumers, important gaps in technology must still be overcome, including the ability to deliver multi-modal and multiplex testing panels utilizing molecular diagnostics (e.g., PCR), immunoassays, chemistry, and cytometry: functionalities that identify DNA, RNA, proteins, metabolites, and cells.

The rapid spread of the coronavirus, which has the potential to become a once-in-a-century pandemic, demonstrates that today's healthcare delivery system isn't prepared to respond to global health crises that may become more frequent than not. The SARS-CoV-2 pandemic may be just the tip of the iceberg, signaling the beginning of a rash of long-predicted novel viruses that could threaten the well-being of the human race.

In many ways, we are facing a perfect storm. The overall rate of global population growth, coupled with the extraordinary influx of aging Baby Boomer patients, is dramatically escalating the need for healthcare services for both acute and chronic diseases. The World Bank and World Health Organization (WHO) estimate that half the global population, nearly 3.6 billion people, already lack access to essential health services today.[1]



[1] World Bank 2017

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Additionally, rising rates of potentially life-threatening infectious conditions like respiratory infections such as COVID-19 (caused by SARS-CoV-2), or STIs with drug-resistant "superbugs," are challenging medical professionals to quickly diagnose and develop the right treatment methods. Also alarming is the rise of chronic diseases, like heart disease, stroke, cancer or diabetes, which already affects six in 10 Americans and presently account for more than 75 percent of total healthcare costs in the US.[2]

These challenges to health systems are creating a seemingly insurmountable "perfect storm" that has already driven global healthcare costs to an estimated $9 trillion annually,[3] while actually lowering life expectancy in the United States. In the U.S. an estimated $3.3 trillion is spent on healthcare services and technologies each year.[4] The need to prevent illness and shorten hospitalization is clearly increasing. In the case of a pandemic like COVID-19, it is becoming even more urgent to identify infections and determine who requires treatment and quarantine.

A swift diagnosis can be vital to controlling and treating many diseases in their earliest and least costly stage. Additionally, an estimated 60 percent of all critical healthcare decisions are influenced by diagnostic testing. Today, just two percent of healthcare spending is dedicated to in vitro diagnostics. In other words, our healthcare delivery system is not doing nearly enough to leverage the power of in vitro diagnostics to improve health and control rising costs.

WHY?

After all, few would doubt the extraordinary health and cost benefits that would arise if providers were able to utilize testing more routinely and comprehensively at the Point

THE MEDICAL FIELD IS JUST SCRATCHING THE SURFACE WHEN IT COMES TO LEVERAGING THE FULL BENEFITS OF HEALTH TESTING.

of Care (PoC) to catch illnesses earlier and promote overall long-term wellness. The field of medicine is increasingly transitioning to a more systematic approach to medicine that focuses on the "4Ps," i.e, Predictive, Preventive, Personalized and Participatory.[5]

In the Precision Medicine or 4P model, comprehensive health testing could play a vital role, delivering repeated longitudinal measurements (i.e. more frequent testing) with a broader range of biomarkers (e.g. blood and urine panels) to monitor the health status, manage acute and chronic care conditions, and better quantify wellness and even predict – ideally even prevent disease.[6]

[2] CDC, 2019
[3] Deloitte, 2018
[4] Center for Medicare and Medicaid Services website, 2015
[5] Science, 2004; 306(5696):640, Personalized Medicine, 2013; 10/6, 565
[6] Scientific Reports, 2018; 8:14865.

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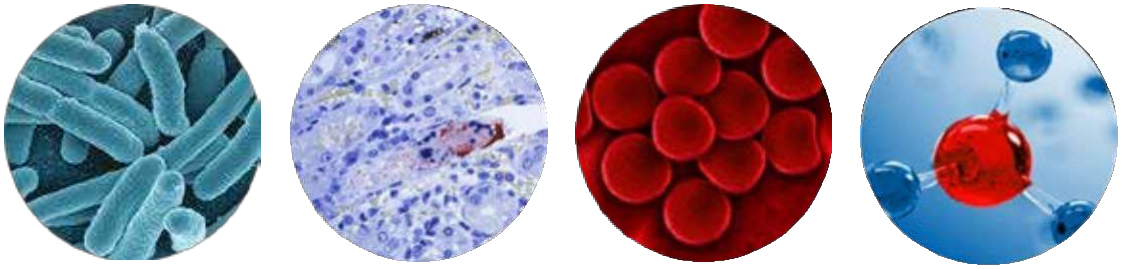
THE MULTIMODAL ADVANTAGE: FUTURE TESTING TECHNOLOGIES MUST BE ABLE TO DELIVER VARIOUS MODALITIES SIMULTANEOUSLY



PCR | Immunochemistry | Cytometry | Clinical Chemistry

Cutting-edge medicine today is providing researchers with ever-deeper insights into the inner mechanisms of many diseases, with human samples such as blood and urine opening new and dynamic diagnostic windows to assess not only an individual's current health but also compile a broader array of meaningful metrics for assessing and even predicting overall wellness in the long-term.

Clearly, these advancements have the potential to disrupt basic diagnostics testing and transform it into a far more comprehensive and outcomes-driven field, what we at Fluxergy call "Diagnostic Care." Under the Diagnostic Care model, providers and patients would have wide and convenient access to routine, real-time multimodal and multiplex testing, delivered where it is needed the most, at PoC, in the doctor's office, in clinics, at retail pharmacies, recreational facilities and even in-home.[7]

[7] Multimodality is also referred to as Multi-omics in the science of Precision Medicine. Multimodality in combination with multiplexicity is an indispensable prerequisite for a testing platform to be truly comprehensive in measuring health conditions: the platform must be capable of addressing various molecules utilizing molecular diagnostics, (e.g., PCR), immunoassays, chemistry, cytometry functionality that identify DNA, RNA, proteins, metabolites and cells. Furthermore, this platform needs to be accessible, affordable, reliable, cloud-connected and cybersecure to enable ubiquitous testing of health parameters and transformation of today's sporadic diagnostics testing to comprehensive Diagnostic Care that becomes a very powerful tool to prevent and intervene earlier in illnesses, optimize the management of chronic diseases, and promote long term wellness.

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MAKING THE CASE FOR CHANGE

One can easily imagine the benefits to all concerned – patients, providers and payors – if a doctor in a walk-in clinic suspects a patient has COVID-19 could quickly conduct a precise test that would deliver highly accurate results within 45 minutes, leveraging full PCR technology in combination with immunoassays on a multimodal basis for inflammation markers and cyto- metry. Imagine, still, if that system were no larger than a standard personal computer, didn't require trained technicians, and was available at one-tenth the cost patients (and payors) might pay for normal lab testing that currently takes two to five days to deliver results.

The doctor would be able to immediately rule in, or rule out, COVID-19, quickly putting the patient on the best pathway to recovery and avoid unnecessary treatments, or even quarantine, saving healthcare costs. While the number of tests employed in the Diagnostic Care model would increase as more providers and patients leveraged testing earlier and more routinely - significant savings ultimately would result by shifting costs for patient care from the more expensive intensive care settings that can occur as a result of delayed, missed diagnoses and misdiagnoses, to ear- lier, more efficient and less costly ambulatory care.

Hospitalizations could be reduced or even avoided, saving the health systems tens of thousands to even hundreds of thousands in hospitalization costs per patient, while rates of recovery would be expected to accelerate. These cost savings will likely be considerably larger than any incremental costs associated with more frequent health testing. Furthermore, the average expense of testing will likely decline as it becomes from routine, unlike in today's healthcare system where testing is less routine and more costly.

Importantly, the application of Diagnostic Care could be crucial in enabling earlier and better measurement of acute and chronic care conditions, which are the world's greatest health challenges.

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With an accessible and affordable, widely distributed in vitro PoC diagnostic testing, clinicians would be able to quickly confirm the presence of acute or chronic conditions and prescribe an appropriate course of treatment without having to wait several days for lab results. Longitudinal testing for monitoring health status also might help mitigate the risk
of further spread of diseases, worsening acute conditions improve the management of chronic diseases, and reduce hospitalization.

Wellness applications based on the concept of "Quantified Self" are another emerging area of high interest to consumers. "Quantified Self" is the process of accessing

PROVIDERS NEED ADVANCED TECHNOLOGY THAT ALLOWS THEM TO MAKE THE RIGHT CLINICAL DECISIONS AT THE POINT OF CARE.

and using personal data on an on-going basis to improve one's quality of life. At the core, these are repeated measurements of biomarkers found in blood and urine, such as hormones, lipids, vitamins, and other metabolite levels common to many lab tests. Longitudinal testing of these biomarkers promises improved and preventative care, a key goal of Precision Medicine.

Making blood and urinalysis widely available and convenient to consumers will further personalize diagnostic care. An expansion of these analyses could be used to actively manage one's health, unlike today's limited use of these technologies to detecting pathological conditions.

TODAY'S TECHNOLOGY LIMITATIONS

Clearly, the medical field is just scratching the surface in terms of the benefits that diagnostics can provide under the more comprehensive Diagnostic Care model.

FLUXERGY: POWERING THE FUTURE OF DIAGNOSTIC CARE

Democratized in vitro diagnostics requires the miniaturization and digitization of macro-scale chemistry- based testing of larger samples of human fluids (milliliters), down to the level of a table-top and ultimately hand- held instruments.

The FluxergyCard, a test card using microfluidics technology, shows considerable promise in being able to produce small, easy-to-use, fast, highly accurate sample-to-answer in vitro diagnostic tests that can be deployed at the Point-of-Care (PoC), in clinics and physicians' offices at first, and ultimately in retail pharmacies and even in the patient's home. These microfluidic devices are capable of using very small samples of human fluid (about 100 microliters), e.g. saliva, urine, blood, and sensing and measuring characteristics within the fluid down to the cellular and molecular levels.

Each test card is a fully self-contained and highly integrated electro-fluidic device that interfaces with the FluxergyAnalyzer.

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Standing in the way, however, has long been the technology of diagnostic testing itself. The sophisticated and high-cost nature of many vital tests has required that they are performed in large centralized labs, which have the resources to invest in expensive and precise testing equipment. Today, most of the in vitro diagnostic testing happens at large, centralized testing laboratories.

While the technology offered in the lab is precise, the problem can be turn-around time and limited accessibility in non-critical care settings. First, sample collection has to be scheduled at a primary provider location or a local collection center, which can disrupt productivity if a patient needs to take time off from work just for the sample collection. Then the patient sample needs to be shipped to a central lab for analysis. This process can be tedious and does not align with today's expectations of empowered patients and consumers. Then the analysis itself must be performed in centralized labs, which can be slow. Patients typically must wait from one to five days to get results back from tests sent to these labs. There's often an additional delay, not to mention added costs, if follow-up appointments with the provider are needed to communicate the results to the patient and prescribe treatment.

Ultimately, this time-consuming, multi-step process fails to provide doctors with what they need the most and patients or consumers want – real-time testing results that can guide providers in making the correct diagnosis and in determining the best course of treatment. Instead, doctors often have to make clinical decisions without all of the facts, increasing the chances of miscommunication, misdiagnosis and even prescription medication errors, as well as cause considerable delays in the actual delivery of care.

At best, such delays may be inconvenient and stressful to the patient, contributing to the unnecessary prescription of antibiotics or other drugs.

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At worst, the absence of timely diagnostic data can even catalyze life-threatening outcomes, delaying treatment or leading to an incorrect or incomplete course of care, often at considerable cost with potentially adverse consequences to the patient. Clinicians may also face liability repercussions: according to ECRI, diagnostic errors are considered the number one risk to patients in ambulatory care settings and represent the leading cause of malpractice liability claims against practitioners.[8]

The number of diagnostic technologies intended for the PoC is growing, pointing to the clear need. But most of these tests have boundaries that limit their effectiveness and widespread use in general. For instance, doctors can now use a 15-minute immunoassay test that can be performed in a physician's office, instead of the 'gold standard' PCR in the central lab, which can require several days. However, the CDC notes that rapid influenza testing has a sensitivity ranging from approximately 50% to 70% — meaning that in up to half of influenza cases, the flu swab results will still be negative. Consequently, some patients' conditions could worsen and even require higher-cost hospitalization because of an inaccurate or delayed diagnosis. In the case of COVID-19, false-negative test results would be detrimental to efforts to contain the pandemic.

Unfortunately, the handful of PoC products that perform more precise PCR tests at the PoC for suspected influenza, and which provide results within a few hours, can cost the payor or patient upward of $500, making them too expensive for widespread and routine use. Presently no commercial device exists at the PoC that can distinguish between viral and bacterial infections, an outcome that requires multimodality to make that distinction by simultaneously assessing DNA/RNA and protein markers.

Patterned microfluidic channels house the necessary reagents and reaction volumes needed to conduct an assay. The test card channels and printed electronics allow for easily adaptable designs to accommodate assay specific reaction volumes and requirements. FluxergyCards are manufactured using affordable plastics via processes borrowed from the printed circuit board manufacturing industry, which helps keep diagnostic testing accessible.

The FluxergyAnalyzer runs real-time PCR, immunochemistry, cytometry, and clinical chemistry tests by using a proprietary optical and electrical AI-enhanced system to detect various biomarkers. The modularity of FluxergyCards allows for a variety of assays and Multiplex panels, including PCR up to 12 targets; immunochemistry with 12+ markers; chemistry with 12+ markers; cytometry (e.g. cell counting); and mixed modality (e.g. syndromic testing) up to 30 different tests using only one card. Electrical, fluidic, chemical, and biological parameters also can be modified to quickly implement new assays and technologies on the platform.

[8] Safe Ambulatory Care Strategies for Patient Safety & Risk Reduction," ECRI 2019

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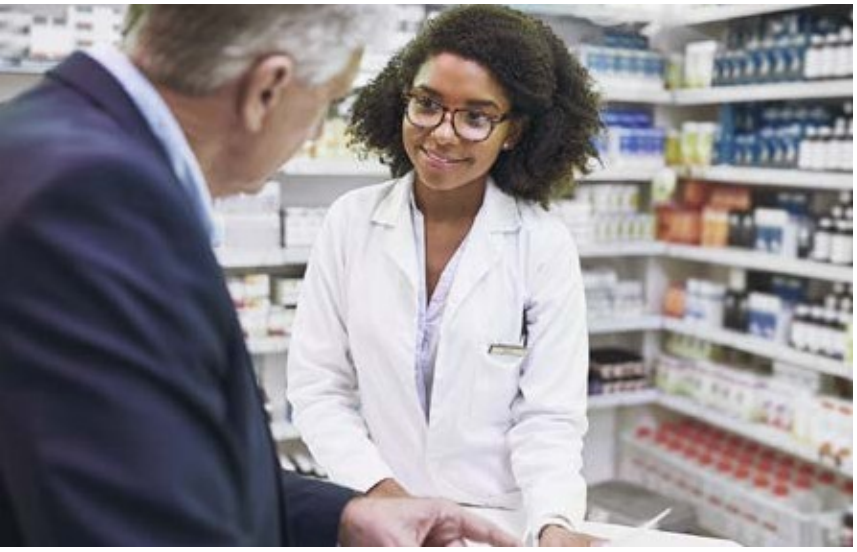
THE FLUXERGY HEALTH TESTING ECOSYSTEM: OPPORTUNITIES AND APPLICATIONS

The most promising of the new entries are systems that offer the potential, because of planned sophistication and low cost of use, to radically transform the way diagnostic testing is delivered to consumers. These innovative diagnostic testing solutions, being developed by a handful of companies including Fluxergy, are intended specifically for the PoC, providing the necessary combination of ease of use, small sample requirements, and significant cost- effectiveness. The Fluxergy system offers the added and essential ability to potentially deliver highly sophisticated multimodal and multiplex "sample-to-answer" testing solutions.



These new technologies would enable providers and ultimately even consumers at the PoC to cost-effectively conduct many of the tests that are currently only performed at centralized labs. In other words, this would give PoC providers the quality and precision of central lab testing, but make it closer to patients. This would finally unlock the true potential of diagnostics to play a far greater and more important role in the early detection and ongoing monitoring of health status, where and when it matters most: at the PoC.

At Fluxergy, this is our mission, and what we are working aggressively to achieve.

We are developing a new multimodal/multiplex in vitro "health testing ecosystem," leveraging Artificial Intelligence ("AI") that delivers on what's needed to power the transformation to the Diagnostic Care model: precision, ease-of-use, and cost-effectiveness. As the transformation

A PRECISE, AFFORDABLE, AND PORTABLE PLATFORM THAT CONSOLIDATES TESTING TO ONE DEVICE.

of PoC diagnostics for diabetes illustrates, we believe this system has the potential to create a Standard of Care (S.O.C.) for testing in which in vitro diagnostics plays a new and far more active and critical role in patient wellness.

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Under Fluxergy's vision for Diagnostic Care, fully functional, easy-to-use, and affordable "sample-to-answer" testing devices with multimodal/multiplex testing capabilities would be widely available on a distributed basis at various PoC locations, including doctors' offices, retail pharmacies, urgent care centers, and clinics.

Consumers would gain greater access to testing, providers would get the instantaneous data they need to make better and faster clinical decisions, and payors would get lower overall healthcare costs due to earlier intervention and better disease management.

With a successful transformation to a diagnostics marketplace powered by a highly distributed, accessible and affordable health testing ecosystem, the diagnostics market could very well expand substantially: A recent case reported in JAMA showed a nearly treble increase in testing rates for HIV if tests were made available in a highly accessible fashion.[9]

Imagine what the incremental market impact could be when new technologies-based product solutions such as the Fluxergy Health Testing Ecosystem enable providers, patients, and consumers at the PoC to routinely utilize highly advanced, easy-to-use, and low-cost testing platforms ubiquitously in sites ranging from traditional providers to retail clinics, or potentially even in settings such as fitness centers.

The market potential of expanding consumer access to a fully accessible and affordable (i.e. democratized) health testing ecosystem could represent very strong double-digit growth rates over the next few decades.[10]

When the FluxergyCard is inserted into the FluxergyAnalyzer, the analyzer controls and monitors the test card through a proprietary optical, fluidic, and electronic subsystems. The analyzer acts as a general sensor system for a modular test card allowing forfluorescent, colorimetric, image-based, and electrochemical measurements. Specific attention has been placed on the platform's architecture and workflow so that assays implemented on the platform are low complexity. The general testing

workflow has been designed for a user with minimal training, with most assays following a simple three step process: raw patient sample is collected; mixed with the reagent hydration buffer; and dispensed into the test card loading port using a transfer pipette.

[9] JAMA, 2019, https://doi.org/10.1001/jamainternmed.2019.5222
[10] Kalorama, 2017, Internal Analysis, Fluxergy

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Fluxergy is developing a health testing ecosystem with three core elements that have the potential to work together in delivering an entire in vitro diagnostic laboratory in a single, compact, and very affordable device:

FluxergyCard – essentially an entire "laboratory on a card," a highly integrated, modular cartridge used for handling samples with advanced microfluidics, and proprietary printed circuit board (PCB) technology with the potential to provide highly accurate and fast sample-to-answer testing.

FluxergyAnalyzer – a proprietary device featuring a homogenous multi-sensor system that eliminates the need for multiple heterogeneous laboratory analyzers and has the potential to accurately detect a range of markers from molecules to cells.

FluxergyWorks – a highly sophisticated, Cloud-based user interface capable of analyzing and disseminating test result data to users while maintaining cybersecurity and HIPAA compliance.

Unlike other existing PoC in vitro diagnostic technologies, which tend to focus on only one modality, such as either PCR or Immunochemistry assays, the FluxergyCard has been intentionally designed and is being developed to allow for the most comprehensive variety of assays and panels, including multiplex and multi-modal testing that could be designed and implemented together all on a single card. These may include:

PCR Multiplex panels with up to 12 targets

Immunochemistry and chemistry panels with up to 30 markers

Cytometry (e.g. cell counting)

Mixed modality panels (e.g. syndromic testing)

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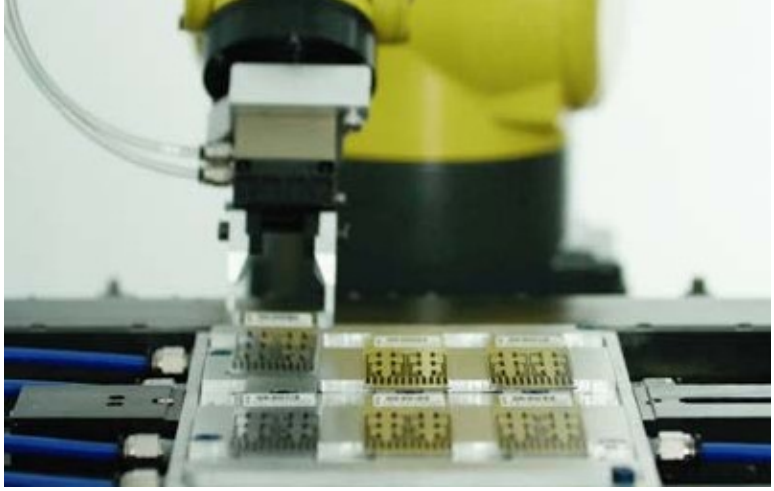

Fluxergy is presently developing infectious disease applications in both human and veterinary settings. We anticipate our first product launch will be for infections in animal health, slated for 2020. We are also developing in vitro diagnostic tests for time-critical diseases such as infections and foresee a future in comprehensive common blood panels for lipids and metabolism, as well as various wellness metrics

AN INNOVATIVE SOLUTION THAT CAN UNLOCK THE FULL POTENTIAL FOR HEALTH TESTING.

for applications in the Quantified Self. In addition, longer- term plans call for developing multiplex testing capabilities, with comprehensive testing panels capable of addressing various biomarkers simultaneously.

Fluxergy envisions that a fully-articulated democratized testing health system has the potential to reduce the likelihood and the ultimate severity of pandemics like COVID-19.

Furthermore, democratized testing with expanded test panels could help quantify key metrics for powering improved well- being, enhanced preventative care, and optimized monitoring of patients' progression with chronic conditions as part of Precision Medicine. For example, women's health panels could be developed that include simultaneous hormonal and disease-specific markers for pregnancy as well as tests for the presence of various STIs. Today, such multimodal testing is a complex undertaking that requires multiple samples and approaches to identify the presence of hormones, pathogen DNA and protein antibodies and currently not possible at the PoC.

Typically, test results are reported out between 10-45 minutes depending on the assay.
All data from Fluxergy technologies are stored on FluxergyWorks – the company's highly sophisticated, proprietary Cloud-based user interface used by health providers to review and interpret the test results, and to aggregate important data across multiple devices and sites. FluxergyWorks can be accessed from a user's laptop, tablet or smartphone,
and its modular system is expandable to accommodate up to 256 devices. It also has been designed to easily integrate into electronic laboratory and medical records (EHR) systems while maintaining cybersecurity and HIPPA compliance.

As its proprietary technology continues progressing into commercialization and widespread adoption, Fluxergy will play a pivotal role in transforming in vitro diagnostics from a complex, time-consuming and costly process into a more highly accessible, democratized diagnostic care and wellness management model.

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In the veterinary medical field, although Fluxergy is not yet marketing or distributing any diagnostic test kits, individual Fluxergy components have been used by laboratories to develop their own tests, and Fluxergy anticipates future development in the veterinary space. In particular, through its Beta Program, Fluxergy will be partnering with a number of veterinary sites that will utilize Fluxergy's individual testing components to create their own laboratory-developed tests. These field sites will give Fluxergy real-world usage information for its platform conducted by minimally-trained users in non-traditional (dirty, rural) care settings, with many of the sites operating devices stall-side.

Fluxergy's research and development work in both human and veterinary medicine is paving the way for the company to differentiate itself among other diagnostic companies by being uniquely prepared to address "One Health," which assesses the intersection of human health with both animal and environmental health. The importance of One Health has been dramatically illustrated with the virus SARS-CoV-2, a zoonotic pathogen that may have originated in bats.

Beyond traditional healthcare delivery settings, Fluxergy envisions partnering with go-to-market disruptors such as retail walk-in clinics and other synergistic healthcare innovators (e.g. Payors, Integrated Delivery Networks) and wellness and fitness providers (e.g. fitness centers, nutrition

PATIENTS SHOULDN'T HAVE TO WAIT FOR LIFE-CHANGING RESULTS.

companies) to catalyze rapid and deep market penetration in the initial years. The company envisions many empowered consumers wanting regular access to their diagnostic (health and wellness) data and will explore potential partnerships with healthcare innovators and potentially synergistic new market entrants that would be the most motivated to evolve today's status quo of central lab testing and incumbent players into the realm of Diagnostic Care.

Fluxergy intends to have a unique "go-to-market" approach that focuses on building an app store- like testing ecosystem, upon which 3rd parties can more easily develop assays, creating a system capable of featuring menus with comprehensive test panels.

Fluxergy is working to develop a simple to use yet highly sophisticated sample-to-answer diagnostic platform ecosystem that can be used for wide-ranging applications, including rapid multimodal identification and quantification of infectious diseases and blood chemistry tests with fully automated assays including PCR, immunochemistry, clinical chemistry, and cytometry. These applications have the potential to deliver rapid, comprehensive test results with reliability and accuracy that is comparable to central laboratories, with far greater time- and cost-efficiencies.

Ultimately, improving health and controlling costs depends on enhancing wellness, as well as the overall prevention, early detection and management of disease. Advancements in diagnostic testing technologies like those being developed by Fluxergy can and will play a major role in giving providers, patients and consumers the tools they need, at the PoC, to transform the concept of diagnostic and wellness testing to a far more powerful field of Diagnostic Care.

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