Key Opportunities and Trends in Biosensors

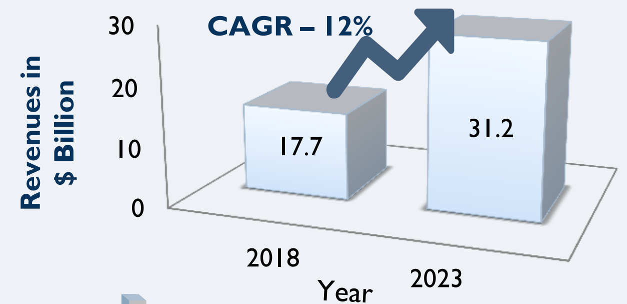
TechVision Group, Frost & Sullivan

Key Trends in Biosensors

A biosensor incorporates a biological sensing element and picks up electrical signals generated by the interaction of a biological element and an analyte. A biosensor incorporates a biological sensing element and picks up electrical signals generated by the interaction of a biological element and an analyte.

- Advances in manufacturing processes, and device integration are propelling developments in biosensors
- **High Sensitivity and Selectivity:** The ability to detect analytes at the molecular level boosts the adoption rate with continuous improvement in characteristics such as long-term stability, selectivity, and response time.

Biosensor Market: Revenue Forecast, Global, 2018 and 2023



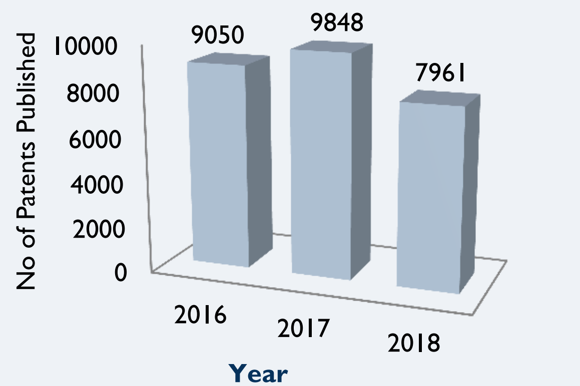
~US $31.2 Billion Opportunity

- According to *Frost & Sullivan* analysis, the global biosensor market is expected to grow at a 12%compound annual growth rate (CAGR) during 2018 -2023, from revenues of $17.7 billion in 2018, to reach $31.2 billion by the end of 2023.
- Key application segments include healthcare (e.g., point-of-care, home diagnostics), food, water quality, indoor/outdoor air monitoring, agriculture, security. Key opportunities await wearable biosensors to provide non-invasive monitoring of heart rate, breathing rate, glucose, disease diagnosis/detection.
- Opportunities will also more fully emerge for biometric sensors to monitor a driver's vital signs such as respiration, heart rate, temperature, skin conductance, to combat driver distraction or fatigue.
- Growth opportunities driven by miniaturization of sensors leading to ease of integration; increase in aging population; high demand for enhanced safety; and growth in real-time, and remote monitoring that reduces healthcare expenses.

Source: Frost & Sullivan

Biosensor R&D

Biosensor Patent Publication Trends, Global, 2016-2018



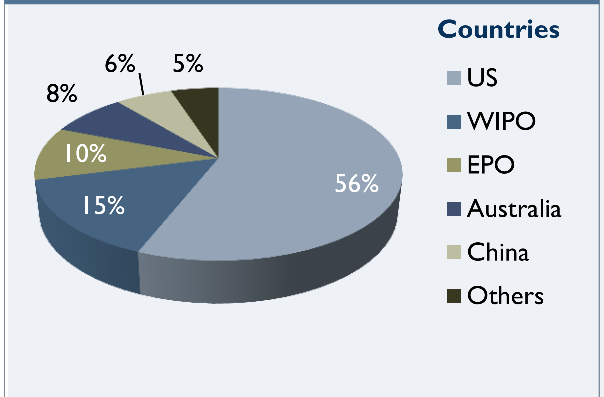
- Development of implantable biosensor for long-term usability is one of the key research and development (R&D) focus areas.
- Consumer electronics companies are increasingly involved in R&D activities, indicating the potential of integrating biosensors into products such as smartphones and wearables.
- According to the patent publication trends from 2016 to 2018, **US leads the world with 56%** of the total patents published in the region, followed by WIPO (15%), EPO (10%) and Australia (8%). This shows a strong focus on developing biosensor-based systems for varied applications in the United States and Asia-Pacific (APAC) region.

Top Patent Applications

Total number of patents published between 2016-2018 is 26859

- Genentech Inc.
- Samsung Electronics Co Ltd.
- Regeneron Pharma
- Hoffmann La Roche
- Novartis Ag
- University of California

Top Patent Jurisdictions, Global, 2016–2018



Funding Trends – Healthcare is a Key Focus Area

- Government agencies such as US National Institutes of Health (NIH) are bolstering biosensor research activities.
- For example, NIH funded research that used an antibody biosensor to discover that opioids used to treat pain, such as morphine or oxycodone, also bind to receptors inside neurons that are not a target for naturally occurring opioids. The medically used therapeutic opioids do not only act on the same surface receptors as the endogenous opioids produced naturally in the brain. The biosensor generates a fluorescent signal when a G protein coupled receptor (which opioids bind to) is activated. This knowledge could lead to designing pain relievers that do not produce addiction.

Source: Frost & Sullivan/Lens.org Patents search range: 2016-2018

Key Areas of Innovation: Point of Care Diagnostics

- A major growth area for biosensors is point-of-care (POC) testing and diagnostics to enable real-time, remote health monitoring. Biosensors provide more convenient, efficient, and sensitive detection of diseases or infections, such as diabetes, cardiovascular diseases, cancer, infectious disease. Microfabricated POC devices will be able to detect a range of pathogens. To be used as a complete diagnostic tool rather than just for initial screening of bioagents or pathogens, POC devices need to achieve sensitivity comparable to that of lab instruments. Paper-based biosensors, which further decrease the cost and increase the disposability of biosensors for POC will find expanding opportunities in underdeveloped or developing regions.

- Opportunities for biosensors will also be driven by the further proliferation of mobile phones for easier communication of health data.

- Historically, biomedical analysis has required collecting samples of, for example, blood, urine or genetic material and analyzing the sample at a laboratory away from the point-of-care. Biosensors possess the capabilities, such as high sensitivity, rapid detection, portability, and ability to provide non-invasive detection, to enable real-time diagnosis at the patient's location by non-professionally trained individuals.

- Drivers for biosensors for point-of-care diagnostics include the aging of the population, increasing need to decrease healthcare expenditures, the rise of cardiovascular diseases and cancer globally, and unhealthy lifestyles (e.g., lack of physical activity, obesity). Another driver is the rising demand for improved healthcare in emerging countries such as China and India

Key Areas of Innovation: Wearable Biosensors

- Wearable biosensors find increasing opportunities for continuous monitoring of vital signs of patients, premature infants, children, athletes or fitness buffs, and individuals in remote areas far from medical and health services.

- Wearable biosensors can alleviate the burden on the healthcare system by facilitating self-monitoring to control one's health and prevent disease. Wearable, connected biosensors enable remote monitoring to allow patients to avoid hospitalization or leave earlier. By enabling telemedicine (monitoring and transmitting physiological data from outside the hospital), wearable biosensors can ease the burden on healthcare personnel and free up hospital space for more responsive care. Smart textiles with sensors in the fabric can provide a simple, more convenient system to monitor vital signs . Biosensor patches or tattoos, leverage conformal, printed electronics, can better enable physicians to collect data on a patient for long periods of time. Such sensors dovetail with the quantified self trend to track one's biological data to optimize one's health. Moreover, disposable patches can allow analyzing key biomarkers such as sodium, potassium, glucose, in sweat or other substances (e.g., saliva).

- There is also potential for wearable biochemical sensors that monitor alcohol consumption through detection of ethyl glucuronide (EtG) in human sweat.

Noninvasive Glucose Monitoring

- Noninvasive monitoring of glucose has been a holy grail in diabetes monitoring. Measuring blood glucose is challenging, as sugar is colorless and present in minute concentrations. Measurement of glucose is subject to noise, due to interferences from water, cells, circulating metabolites. Devices that measure glucose directly in blood or other fluids try to work around the interference using, for example, glucose oxidase to trigger a measurable reaction.

- A noninvasive technique that could replace finger pricks would significantly transform monitoring and care of diabetics. It has been elusive to produce a needle-free technique with sufficient precision for diabetes monitoring and care.

- Varied techniques have been, and continue to be investigated, such as infrared spectroscopy to measure glucose level through the skin, electrical current to draw sugar from interstitial fluid, monitoring glucose in sweat, smart contact lenses to measure glucose, electrochemical biosensors that use graphene and magnetic nanoparticles, etc.

- Cygnus had a promising technology, the GlucoWatch Biographer, which uses electric current to draw glucose from interstitial fluid under the skin's surface into a sensor where the sugar was oxidized by an enzyme to produce hydrogen peroxide detected by a biosensor. The device was approved by the US FDA in 2002 and intended to complement rather than replace the finger prick method. Although the technology generated great fanfare, it had problems such as generating rashes in the skin from the irritating electric currents, a long (3 hour) warm up time, and too many false alarms for low glucose levels.

Key Areas of Innovation: Vital Sign Monitoring in Vehicles

- Biometric sensors or biosensors are poised for use in vehicles to monitor driver vital signs, stress and emotion levels. Such sensors can be placed in seats, seatbelts or on the steering wheel. Biosensors for driver health monitoring have increasing opportunities as self-driving vehicles gain adoption. For example, non-contact ECG monitors in the driver's seat record signal through the driver's clothes. Capacitive plates register the electric charges between the plates and the driver's body, which vary with each heartbeat. There are also opportunities for glucose monitors in the vehicle (e.g., using the in-car communications system to track a driver's blood glucose), and for non-contact heart rate and respiration monitors.

- In addition, biosensors are finding opportunities in vehicles for applications such as alcohol detection.

Industry Transactions and Investments

Key Innovators

Causeway, Northern Ireland

Causeway Sensors (Northern Ireland), a spin-off of Queens University Belfast which has developed a novel technique to distinguish a viral from a bacterial infection in areal-time point-of-care setting, received 1.2 million pounds (about US$1.56 billion at the current exchange rate) in funding from Bank of Ireland's Kernel Capital Growth Fund, Innovate UK, Invest NI, QUBIS and private investors. The technology can reduce the ineffective use of antibiotics for viral infections.

Carterra, US

Carterra, Inc, formerly Wasatch Microfluidics, garnered $10 million in financing from Telegraph Hill Partners. The funds will be used to achieve commercialization of Carterra's LSA™ automated, high-throughput monoclonal antibody characterization platform. The instrument enables more efficient label-free binding experiments to obtain high-resolution data early in the drug discovery process with minimum sample consumption.

Profusa, US

In 2016, Profusa won a $7.5 million grant from US Defense Advanced Projects Research Agency (DARPA) and the US Army Research Office to develop Profusa's implantable tissue-integrated biosensor for continuous, simultaneous monitoring of multiple body sensors to provide real-time monitoring of the combat soldier's health status. The company has envisioned providing a biosensor that provides continuous data for key biomarkers such as oxygen, glucose, lactate, etc.

Profusa also received the CE Mark for use of the company's Lumee™ oxygen platform for detecting tissue oxygen in the EU and countries accepting the CE Mark .A smart biosensor gel, placed below the skin, is linked to a fluorescent molecule that signals the presence of oxygen. Using an optical reader of the fluorescent signals, the biosensor emits fluorescent light proportional to the concentration of molecules in the target region. In summer 2018, Profusa captured over $45 million in Series C funding, which will be used to drive Lumee's commercialization.

Source: Frost & Sullivan

Industry Transactions and Investments (continued)

Key Innovators

Biolinq, US

Near the end of 2017, Bioliinq, leveraging research at the University of California, San Diego, garnered $10 million in Series A funding led by M Ventures in cooperation with Hikma Ventures. Biolinq's wireless biosensor patch is able to continuously monitor multiple parameters. Their initial product will be an intradermal, needle-free continuous glucose monitor.

VitalConnect, US

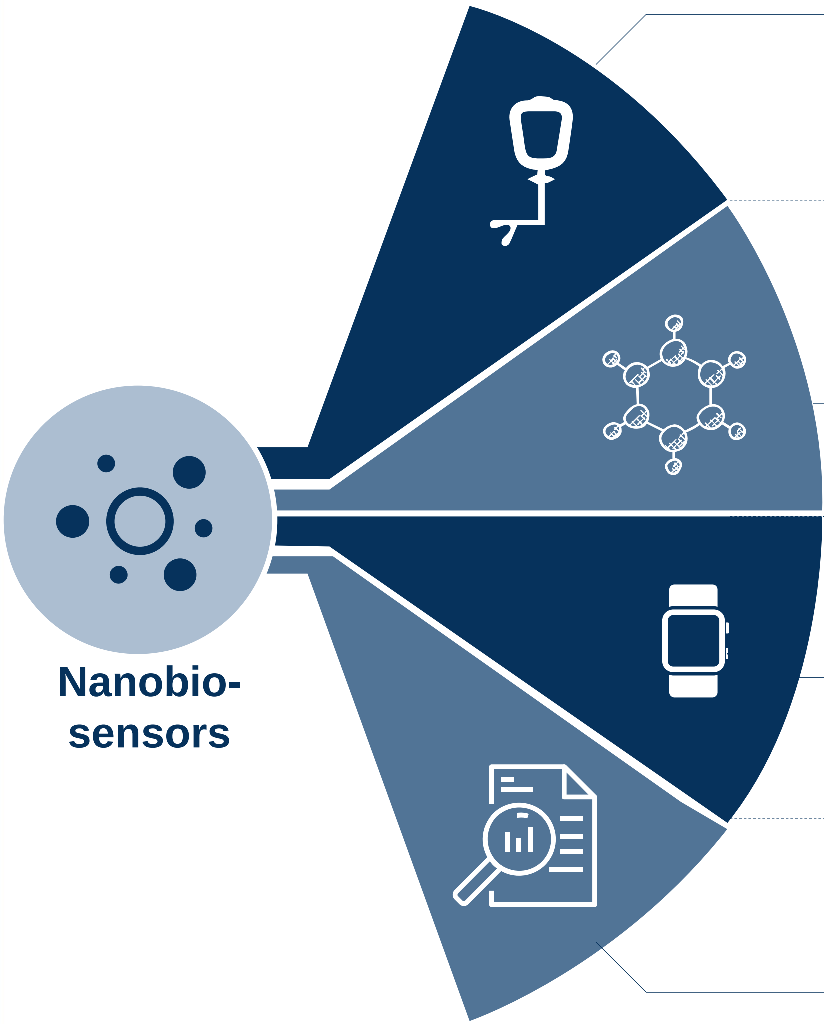
As of late November 2017, VitalConnect, an innovator in medical-grade wearable biosensors, founded in 2011, had raised a total of $86.7 million in 4 founding rounds. Investors include Oxford Finance Corp., Baxter Ventures, MVM Life Science Partners, Perceptive Advisors. The VitalPatch can provide continuous patient monitoring and consolidates 8 vital or physiological signs (heart rate, heart rate, heart rate variability, respiratory rate, skin temperature, ECGs, body posture, fall detection, activity) into one wireless biosensor. The sensors in VitalPatch include ECG electrodes for heart rate, a 3-axis accelerometer to detect motion, and a thermistor for skin temperature. The solution enables healthcare away from the traditional clinical setting.

Microbiosensor ltd., UK

In late 2017, Microbiosensor ,received 1.4 million pounds (about US$1.82 million at the current exchange rate) completed via the Northern Powerhouse Investment Fund. NPIF is supported by the EU through the European Regional Development Fund (ERDF). The funds will enable Microbiosensor to take its disposable point-of-care medical devices for diagnosis of microbial infections through development and clinical trial and bring them to the marketplace. Microbiosensor is developing disposable point-of-care monitors for detecting microbial infection, including detection of urinary tract infection, microbial infection at the wound cite, and management of kidney infection for peritoneal dialysis therapy.

Source: Frost & Sullivan

Key Biosensor Technologies Driving Growth Opportunities



Nanobisensors, composed of materials with one of their dimensions between 1 and 100 nanometers, can enable faster, more intelligent and precise, less costly and more user-friendly biological detection. Key types of nanomaterials used to improve biosensors include carbon nanotubes (CNTs), nanoparticles, quantum dots, nanowires, nanorods.

Nanobiosensors have promise in a range of applications such as biomedical and diagnostics, environmental monitoring,(e.g., detection of nitrates, inorganic phosphates, biological oxygen demand, remediation), industrial (e.g., separation of impurities in metallurgical applications), food production, crop protection, pathogen and toxic detection, water/waste water treatment. Nanobiosensors improve the specificity, sensitivity, and detection limit of chemical analysis of food and beverages.

Minimizing the biosensor's dimensions to the nanoscale addresses the functional requirements of point-of-care and wearable applications; and improves the biosensor's signal-to-noise ratio. However, minimization can lengthen the biosensor's response time (it takes longer to collect target analytes on the sensor's surface).

Researchers at Kyushu Institute of Technology and University of Malaya fabricated a bioinspired nanobiosensor, comprised of CNTs, that uses electronic-based taste receptors for diagnosing glucose (glucose oxidase). The electrochemical (amperometric) biosensor with taste bud-inspired circuits provided an increase in the frequency of the output pulse based on glucose concentration.

Source: Frost & Sullivan

Key Biosensor Technologies Driving Growth Opportunities (continued)

Magnetic Biosensors

Opportunities also exist for giant magnetoresistance (GMR) biosensors that provide faster, streamlined detection of diseases or drugs. Laboratory testing health diagnostics techniques tend to be complicated, to require sophisticated and expensive equipment, trained operators and have a slow turnaround time. Such techniques are not suitable for point-of-care use or applications in remote areas or non-clinical areas such as homes, offices, or schools.

MagArray (Milpitas, CA), formed in 2005, licensed GMR nanobiosensor technology developed at Stanford University that is easy to operate and can perform a one-stop immunoassay. At present, MagArray is targeting providing lab services to physicians, focusing on lung detection. The company's REVEAL lung characterization blood test non-invasively measures unique biomarkers associated with lung caner. The test indicates the risk of nodule malignancy in patients with pulmonary nodules in the range of 6 mm-3 cm). REVEAL helps pulmonologists identify lung nodules with a high probability of being benign or malignant. Currently, lung nodules are detected using a CT scan, which may not enable the physician to distinguish benign from malignant nodules. Patients tend to be diagnosed at an advanced stage of lung cancer when the prognosis is poor. According to the American Cancer Society, lung cancer is the second most common type of cancer in both men and women (excluding skin cancer); and lung cancer is the leading cause of death among men and women.

Source: Frost & Sullivan

Key Biosensor Technologies Driving Growth Opportunities (continued)

Fiber Optic Biosensors

Researchers at Shenzhen University have fabricated a highly sensitive and label-free disposable fiber optic surface plasmon resonance (SPR) biosensor for specific detection of C-reactive protein. Dopamine is used a cross-linking agent to immobilize the anti-CRP monoclonal antibody, which is an efficient and simple method for specific modification of the fiber optic SPR sensor.

The researchers noted that CRP is considered one of the most important inflammation markers in the human body. In addition, it is found that CRP is helpful for the monitoring exacerbations in chronic inflammatory conditions, including rheumatoid arthritis, inflammatory bowel disease, and a number of vasculitic syndromes.

Methods developed for CRP detection, such as enzyme linked immunosorbent assay (ELISA), immunofluorescence assay and latex agglutination, have the limitations of being time-consuming, semi-quantitative, and lack of miniaturization, and the requirement of on-site analysis.

Source: Frost & Sullivan

Key Biosensor Technologies Driving Growth Opportunities (continued)

Graphene Biosensors

Graphene, which consists of 2D hexogonally arranged carbon atoms, enables very sensitive biosensors, due to its physical and chemical properties. Graphene is extremely strong and light, offers good electrical conductivity, excellent thermal conductivity, good optical transparency. It is also conducive for fast, multiparameter sensors.

However, there are challenges in integrating delicate graphene into standard high-volume production processes. The steps in producing a graphene biosensor include electrode pattering, graphene growth, patterning and deposition, and wafer passivation with a dielectric. The process should be free of contamination.

Nanomedical Diagnostics (San Diego, CA) offers a field-effect NEMS (nanoelectromechanical systems) graphene biosensor (AGILR R100) that provides real-time, label-free, kinetic binding and affinity data, enabling more cost-effective, streamlined drug development and discovery. Rogue Valley Microdevices (RVM, Medford, OR), a MEMS foundry, designed the process to manufacture the graphene biosensors. To enable production of the graphene biosensors, RVM optimized the resist to minimize graphene contamination, optimized oxide adhesion to the graphene, and guarded against over- or under-etching.

Source: Frost & Sullivan

Key Biosensor Technologies Driving Growth Opportunities (continued)

Organ -on-Chip Biosensors

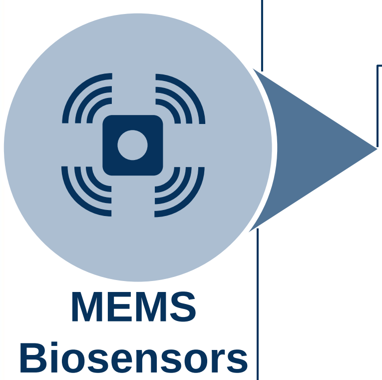
An organ-on-a-chip (OOC) is a 3D microfluidic device or structure that mimics the function of human organs. OOCs enable modeling of human physiology and disease and are emerging as a viable platform for drug development and screening, personalized precision medicine and disease modeling. In OOC systems, biosensors can provide real-time monitoring of biological and physical parameters. The ability to collect data continuously from OOC systems without affecting the system's operation is very valuable, as bioassays and other techniques for collecting data on OOCs destroy the tissue. Moreover, it is challenging to manufacture OOCs, which are complex and can contain elements such as the microfluidic chip, live cells/tissues, and sensors for data readout. Furthermore, integrated multisensor systems facilitate automated, in-situ monitoring of biophysical and biochemical parameters.

Researchers at Harvard University, Wake Forest School of Medicine and other institutions developed an integrated modular physical, biochemical and optic sensing platform that uses a microfludics-controlled breadboard for routing fluids to interface physical sensors for monitoring micro environmental parameters, electrochemical immunobiosensors for measuring soluble biomarkers and miniature microscopes to observe organ morphology. The sensing allowed long term monitoring of drug induced organ toxicity.

The system allows long-term monitoring of drug-induced toxicity in a dual organ human liver-and-heart-on-a-chip platform and in a dual organ human liver-cancer-and-heart-on-a-chip platform. The multisensor-and-organ-on-chips platform was relatively large and efforts were made to compact and simplify the system.

Source: Frost & Sullivan

Key Biosensor Technologies Driving Growth Opportunities (continued)



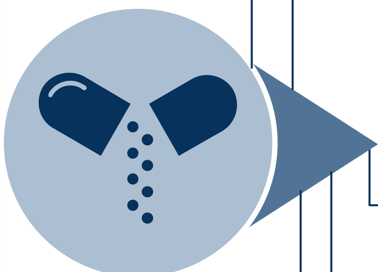
Microelectromechanical systems (MEMS) technology allows miniaturization of biosensors, which enables previously inaccessible signals to be obtained from inside the patient. MEMS biosensors (BioMEMS) enable a very small footprint, which minimizes power consumption and difficulties of implantation along with the transport time for chemical analytes. MEMS fabrication reduces the biosensor's response time and enables mass production and ease of scale-up without sacrificing the high reproducibility and reliability of MEMS fabrication. MEMS processes also can allow seamless integration with control circuitry and telemetry produced using similar materials and fabrication steps. MEMS biosensors that are integrated with drug delivery devices (which can be MEMS-based) would realize closed loop drug delivery.

MEMS biosensors also are attractive for food and agriculture applications due to their small size, which enhances sensitivity. MEMS technology is conductive to incorporating organic materials. MEMS biosensors that use flexible materials (such as flexible microcantilevers and flexible organic substrates, can detect very small elements such as chemical molecules, bacteria, or mycotoxin in low concentrations

Tarabios (Turkey),a spin-off from Koc University, is developing point-of-need blood diagnostic systems based on a proprietary MEMS platform technology that can be customized to screen print tiny quantities of blood and other samples in different settings (e.g., hospitals, physician's office, the patient's home). An initial target application is affordable ultra portable and simple to use devices for blood coagulation patient self testing. The company is developing two main types of sensors, based on the same platform technology: sensors for immunoassays/clinical diagnostics and direct mechanical sensors to measure viscosity The biosensors use micro-cantilevers placed on a low cost, single use disposable cartridge. The cantilever shows very high sensitivity to mass loading (biomarkers attached on the free end) and to the viscosity of the medium they are contained in. In contrast to systems currently on the market and based on electrical testing methods to measure the viscosity of the blood indirectly, the Tarabios system can very reliably directly measure the viscosity of blood.

Source: Frost & Sullivan

Key Biosensor Technologies Driving Growth Opportunities (continued)



Ingestible Biosensors

- Ingestible biosensors able to reside in the body for a long period of time have keen promise for transforming drug delivery and clinical treatment and diagnosis.. The devices can also enable improved patient adherence to ingestion of medication by transmitting signals that provide unobtrusive evidence of medication injection
- Researchers at Massachusetts institute of Technology (MIT) designed an ingestible biosensor with genetically engineered bacteria that can diagnose bleeding in the stomach or other gastrointestinal issues. The biosensors responded to heme, a blood component They also designed sensors able to respond to a molecule that is a biomarker for inflammation. The researchers engineered a probiotic strain of E.coli to express a genetic circuit that causes the bacteria to emit light in the presence of heme. Phototransistors measure the amount of light produced by the bacterial cells and can send wireless signals to a smart phone. The researchers tested the ingestible sensor in pigs, where it could determine the presence of blood in the stomach. Currently, patients suspected of bleeding from a gastric ulcer undergo endoscopy to diagnose the issue
- The goal off the MIT researchers is to enable the patient to ingest a capsule and soon know if a bleeding event occurred. The bacteria could be engineered to sense different molecules related to different diseases; and the sensors could be designed to carry multiple strains of bacteria to diagnose a range of conditions
- Enhancements in powering ingestible biosensors will drive greater opportunities for them. Powering ingestible sensors is challenging, since batteries can be incompatible with the mucosal lining of the GI tract and have a limited lifetime in the body. Near field wireless transmission, involving two antennas, can have a limited range
- Researchers at Draper, MIT and Brigham and Women’s Hospital, in work conducted on a pig, demonstrated midfield transmission remote-charging could be suitable for in-vivo applications. Power from an antenna outside the body is transmitted to another antenna inside the digestive tract, generating sufficient power to operate sensors to monitor heart rate, temperature and levels of particular nutrients or gases in the stomach. The technique can also provide power to sensors that provide drug delivery vehicles and can remain in the digestive tract for weeks or months

Source: Frost & Sullivan

Key Biosensor Technologies Driving Growth Opportunities (continued)

Multi-parameter Biosensors

Multiparameter biosensors, capable of measuring simultaneously different parameters, can improve disease monitoring and analysis, enabling verifications of the stage of a certain disease, screening risks for pre-disposition and therapeutic control. Multiparameter monitoring can benefit patients with severe metabolism defects and better control the metabolism of diabetics by monitoring an additional parameter such as lactate .Implantable multiparameter biosensors can help drive personalized medicine and therapy. Multiparameter biosensor arrays for simultaneous monitoring of cell growth and acidification can facilitate miniaturized, automated cell-based assays .Furthermore, multiparameter biosensors can facilitate continuous measurement of water pollutants such as fecal bacteria, heavy metals, environmental toxins.

Researchers at University of York (UK) designed an electrochemical silicon photonics biosensor capable of very sensitive and multiparameter profiling of biomarkers. Electrochemical control allows site-selective immobilization of different biomolecules on individualized micro-rings with the sensor array The doping profile of the silicon photonic micro-ring resonator is controlled to optimize the doping density to be sufficiently conductive to support electrochemical processes while thin enough to minimize losses of the optical mode confined within the resonant structure.

The silicon photonics biosensor, which is capable of detecting multiple proteins and enzymes, has potential to accelerate diagnosis of diseases such as cancer. Current methods often only detect one protein per sample, requiring multiple tests to diagnose cancer and infectious disease. The silicon photonics biosensor uses light and electricity to characterize the biomolecules.

Source: Frost & Sullivan

Key Biosensor Technologies Driving Growth Opportunities (continued)

Electro-chemical Biosensors

Electrochemical biosensors offer benefits such as real-time monitoring, miniaturization, and the enhancement of selectivity and sensitivity. Such sensors also deliver electronic signals, and may not require complex signaling elements; and are conducive to development of portable systems for applications such as clinical testing and on-site environmental monitoring

Researchers at Kwangwoon University, Korea University, Chung-Ang University, and Sangmyung University developed a single-walled carbon nanotubes (SWCNTs)-based electrochemical biosensor for detecting bacillus subtilis, a micro-oragnism found in Asian dust events, which cause asthma, pneumonia and other respiratory diseases.

The SWCNTs served as a transducer with regard to the antigen/antibody reaction. In the biosensor's specificity test, the amount of target B. subtilis was the highest, compared to other tested microorgamisms (staphylococcus aureus, flavobacterium psychrolimnae, aquabacterium commune).

Source: Frost & Sullivan

Key Biosensor Technologies Driving Growth Opportunities (continued)

Lateral Flow Immunoassay Pint-of-Care Test

US-based Optimum Imaging Diagnostics (OIDx) is developing rapid, highly sensitive and accurate diagnostic tests for point-of-care and retail pharmacies. The technology eliminates the cost and delay of using a central laboratory.

OIDx's patent-pending platform uses lateral flow assay technology in a convenient cartridge with an on-board calibrator that delivers accurate, quantitative results in under 10 minutes (from patient blood draw to the cartridge reader results). Lateral flow technology is typically used in diagnostic tests in a quantitative fashion to detect the presence or absence of an analyte but not the degree of the analyte. Lateral flow immunoassay technology uses capillary beds that draw the sample to the test line containing the antibody.

OIDx's roadmap includes tests for histoplasma capsulatum, infectious diseases (legionella pneumophila, streptococcus pneumonia, influenza A and B, respiratory syncytial virus, streptococcus A), lyme disease, and others.

OIDx's platform can support many types of immunoassay such as RNA (ribonucleic acid, the genetic material of HIV), DNA, enzyme chemistry, any viable point-of-care assay, on any sample required.

The company's technology includes trade secrets around sample prep techniques that can increase sensitivity up to 40%, coupled with statistical methods and algorithms for sample reading, antibody optimizations, capillary action optimizations in cassette construction, and blood cell separation and handling techniques.

Validation of the company's technology is underway at ley institutions such as CDC, Mayo Clinic, Johns Hopkins

Source: Frost & Sullivan

Key Biosensor Technologies Driving Growth Opportunities (continued)

Lateral Flow Immun-oassay Pint-of-Care Test-2

- The platform patent pertains to a device capable of quantitatively analyzing a sample by creating a calibration curve based on signals measured from a calibration strip with known analyte concentrations.
- OIDx's point-of-care rapid diagnostic test platform and lateral flow technology uses a dial-strip cassette with on-board calibration. The left strip plots a calibration curve while the right strip test the patient's sample, The sample is simplified the sample value is interpreted against a calibration curve on the OIDx reader.
- The POC test with the on-board calibrator can provide accurate, quantitative tests in as short a time as 2 minutes, with performance equivalent or similar to central labs.
- OIDx's platform for a histoplasma urinary antigen EIA test can provide results in les than 2 hours s compared to days for a reference lab.. OIDx notes that there is no quantitative POC test for histoplasma capsulatum avaialble.
- Enzyme-Linked ImmunoSorbent Assay (ELISA) is a common high-throughput immunoassay technique that specifically binds to the target to be detected often antibodies. Whereas other ELISAs include extra steps and washes, and require more time for results, OIDX's histoplasmosis ELISA can require only an hour wait after sample addition and only requires three main steps: add the sample and conjugate (simultaneous assay), add a color developer, and measure. OiDX's initial product is a central lab-based histoplasma urinary antigen EIA test.
- OiDX has achieved central-lab quality quantitative results for TSH (hyper and hypo thyroid stimulating hormone) hormone and expects CE and 510K approval in 2019, and is on track for initial revenue around in Q2 2020. There is a lack of rapid POC tests for TSH on the market.
- The POC tests are targeted at physicians, while the TSH tests will be targeted at hospitals that conduct TSH tests.
- OIDx seeks partnerships for global distribution, new test OEM initiatives, strategic investment, and commercial partnerships within the diagnostic ecosystem. Logical sources of funding include the POC industry.

Source: Frost & Sullivan

Needs for Biosensor Research and Development

In applications such as point-of-care and wearables, there are opportunities to ensure that minimizing the biosensor's dimensions to the nanoscale does not unduly lengthen the biosensor's response time.

In POC testing, a need exists for POC assays for rapid determination of biomarkers to detect a stroke

There are also opportunities for paper-based POC tests with improved stabiltiy for sickle cell anemia.

Key opportunities exist to provide non-invasive yet highly accurate monitoring of blood glucose, with improved sensitivity, immunity to interferences such as water or metabolites, and greater immunity to false alarms.

In wearables, there is a need for biosensors to more conveniently, non-invasively, selectively measure multi-parameters, such as lactose, glucose, sodium, potassium, in sweat in a wearable configuration (such as a headband). For wearable sweat-based biosensors to emerge and proliferate, such biosensors should have improved detection stability and reliability, more controllable extraction of sweat biomarkers, and a high correlation between the level of the sweat biomarker and a target physiological or clinical condition.

There also needs for the next generation of wearable biosensors that, rather than monitoring wellness and fitness, can provide long-term, continuous monitoring of chronic diseases, such as COPD, diabetes, or peripheral artery disease.

Needs exist for biosensors with improved sensitivity and selectivity that can provide faster, less expensive food testing (for example, E. coli).

Source: Frost & Sullivan

Needs for Biosensor Research and Development (continued)

In environmental monitoring, there are requirements for more sensitive, selective, less expensive and rapid portable biosensing devices to monitor pollutants in the field such as pesticides. Nanomaterials and nanocomposites have promise to enable improved sensitivity and detection limit.

In passive in-vehicle driver breath alcohol detection, based on infrared spectroscopy detection of CO_2 and alcohol, improvements in sensor resolution and system ruggedness are required.

Touch-based in-vehicle sensors that would use infrared spectroscopy (IR light) to measure blood alcohol content in the capillaries under the skin need improvements in size, durability, and cost.

As noted by researchers at RWTH Aachen University and MIT, unobtrusive, non-contact technologies (such as radar or capacitive-based ECG techniques) for monitoring vial signs (e.g., heart rate, respiration, etc.), experience challenges from motion due to vehicle or driver movement. There is a need for improved immunity from interference due to such motion artifacts This can be mitigated using sensor fusion, which combines data from different sensors to provide enhanced information compared to that from an individual sensor.

Source: Frost & Sullivan

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