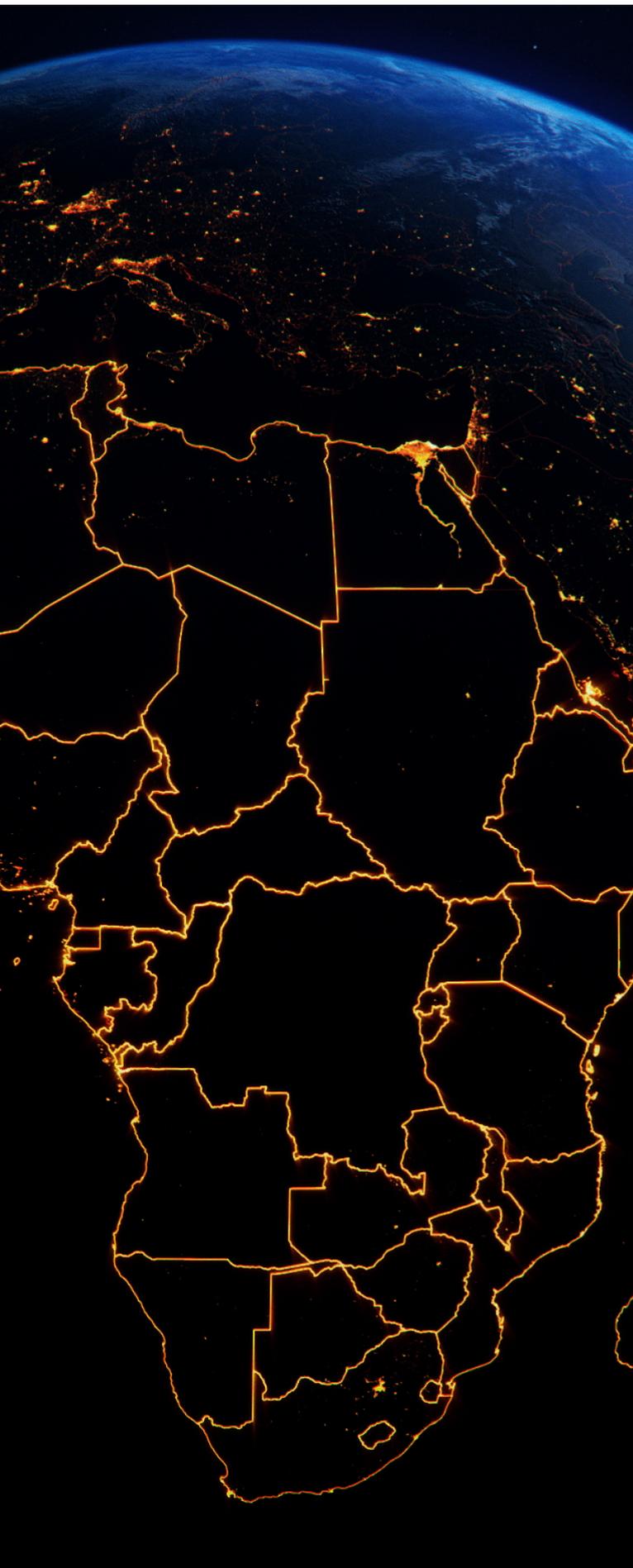


INNOVATION

AT THE SOUTH AFRICAN
MEDICAL RESEARCH COUNCIL

TECHNOLOGY BRIEFS





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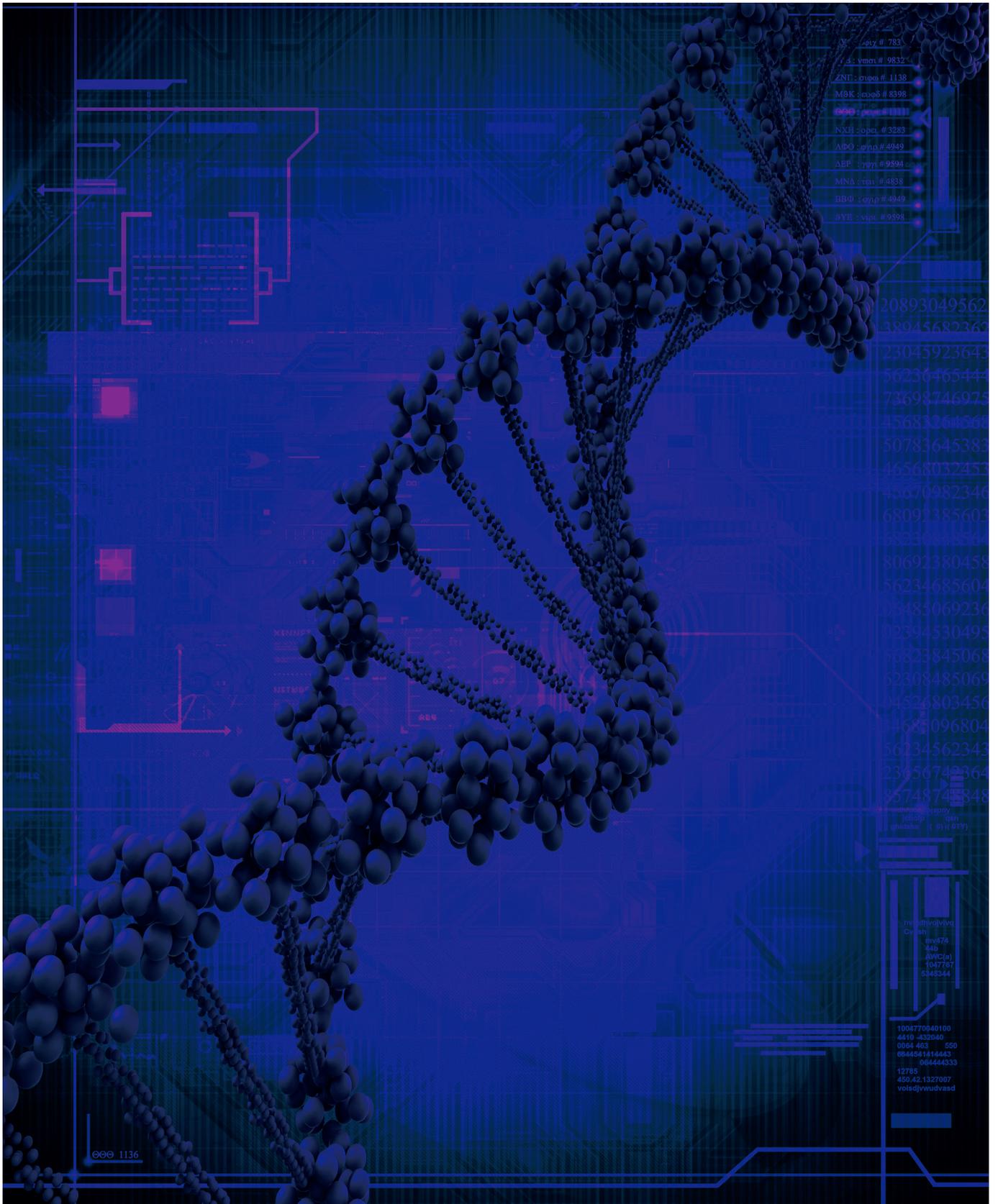
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DIAGNOSTICS

PILOT SCALE PRODUCTION PROCESS FOR A BST POLYMERASE

TECHNOLOGY DESCRIPTION

Bst polymerase is a key component for accurate, affordable, field-deployable DNA-based diagnostics. Bst polymerase fits these criteria as the basis for loop-mediated isothermal amplification (LAMP), a nucleic acid amplification technique (NAAT) that is becoming increasingly popular globally as a more accessible alternative to PCR in a variety of applications. Compared to other nucleic acid amplification techniques, LAMP can be 10 to 100-fold more sensitive than PCR, showing a higher specificity with an amplification time usually less than 1 h at 60–65°C. Additional advantages include not requiring an initial template denaturation step at 95°C and being less prone to inhibitory substances often present in biological samples. Perhaps one of the most interesting benefits is that LAMP output may be visualized by the naked eye (e.g., turbidimetry), making it ideal for low resource settings and point-of-care applications.

LAMP has been used for the detection of pathogens such as Adenoviral keratoconjunctivitis and cancer diagnostics such as detecting metastasis of gastric cancer. More recently, LAMP has been applied to the molecular detection of SARS-CoV-2 due to the rapidity and specificity of its amplification mechanisms. Additionally, LAMP has played an important role in the quality control of food and dietary products, such as rapid detection of Salmonella, Staphylococcus aureus, and E. coli.

The enhanced Bst polymerase developed by DHS Healthcare is envisaged to be incorporated into diagnostic kits and used in point-of-care medical devices.

BENEFITS/VALUE PROPOSITION

- A locally developed and produced reagent to stimulate the growth of the diagnostics and reagents industry in Africa.
- Offers a solution for accurate, affordable, field-deployable DNA-based diagnostics.
- No instrumentation required for visualization, allowing use in low resource settings and point-of-care applications.

CURRENT STATUS

- Plasmid of interest successfully transformed into competent cells and established a master cell bank.
- Successfully produced Bst polymerase at laboratory scale
- The team are preparing for pilot scale production using an automated Chi.Bio platform.

OPPORTUNITIES

The team is seeking the following:

- Active engagement with potential funders and partners to open new sales and distribution networks and assist in obtaining regulatory certifications.
- Expert guidance and collaborations with clinicians and consultants.
- In addition, DHS Healthcare has a pipeline of enzymes, reagents and associated equipment in various stages of development, and welcomes engagement with potential funders and partners to explore these.

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A POINT-OF-CARE MULTIPLEX RAPID TEST FOR THE DETECTION OF ACUTE KIDNEY INJURY



Point-of-care diagnostics technologies for disease detection

Point-of-care diagnostic technologies to detect human, animal and zoonotic diseases, as well as food pathogens

The CSIR has developed technologies that include lateral-flow rapid tests, loop-mediated isothermal amplification and lab-on-chip devices that meet the need for diagnostics that are affordable, sensitive, specific, user-friendly, rapid, equipment-free and deliverable (ASSURED). The technologies support the growing medical devices and diagnostics industry through accelerated development of innovative patient-centric solutions that provide equitable health care for everyone.



TECHNOLOGY DESCRIPTION

In South Africa, as well as other developing countries, HIV patients are administered a drug regimen based on Tenofovir disoproxil fumarate (TDF). One major side effect of this drug is Acute Kidney Injury (AKI), which occurs in approximately 10% of patients. Current methods for the detection and characterization of AKI rely on increased serum creatinine (sCr) levels with a decrease in glomerular filtration rate (GFR); however, these are not only insensitive and nonspecific, but also manifest only after significant kidney damage has occurred. Consequently, patients with AKI have decreased adherence to antiretroviral therapy and often require hospitalization and subsequent dialysis until normal kidney function is regained, if at all.

The innovators from the Council for Scientific and Industrial Research (CSIR) have developed a point-of-care (POC) multiplex rapid test for early detection of AKI. The technology is based on an immunochromatographic assay, which detects early markers of AKI in non-invasive samples (urine/ blood).

BENEFITS/VALUE PROPOSITION

The technology will allow for early and accurate detection of kidney injury before it becomes significant or irreversible. This in turn will allow better patient management and adherence, as well as concomitant decreases in costs related to adverse drug reactions. Some of the key benefits of this technology include:

- Ease of use by non-technical personnel.
- Reduced time to obtaining results (~10 min).
- Non- invasive sample required (urine/ blood).
- The rapid test is relatively inexpensive due to use of paper material and no additional instrumentation and laboratory facilities are required.
- Suitable for use in remote, resource-limited areas.

CURRENT STATUS

- Successfully developed multiplex prototypes using 3 targets.
- The AKI rapid test is currently at clinical validation stage.

OPPORTUNITIES

The innovators are seeking funding to conduct field trials, as well as commercialization partners.

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MEDICAL DIAGNOSTECH



TECHNOLOGY DESCRIPTION

Diagnostics is an integral part of the healthcare sector. Medical Diagnostech (MD) Pty Ltd has identified a gap in the African diagnostic test kit development & manufacturing market and is leading the local development of new diagnostics for priority health areas. In response to the recent pandemic, MD has developed a COVID-19 antigen test, which offers a rapid visual immunoassay for the qualitative detection of COVID-19 antigens from nasopharyngeal and nasal swabs. The test was launched in March 2023, as the first South African COVID-19 Antigen Self-Test with companion mobile phone applications, HealthPulse and TestNow. These applications support self-testers with the administration and interpretation of rapid diagnostic tests (RDT). It helps ensure the accurate use of RDTs through easy-to-follow instructions, process control timers, and guided result interpretation. The solution seamlessly integrates with public health reporting systems and ensures that self-testing data is reported, providing a more comprehensive understanding of disease prevalence. The HealthPulse and TestNow applications also serve as an introduction for additional rapid tests covering other diseases of concern such as HIV and Malaria.

VALUE PROPOSITION

MD's SAHPRA-approved COVID-19 Antigen Self-Test offers a reliable home-testing solution for those wishing to identify possible infection with COVID-19 and comes with a companion smartphone application that reports all results to the South African National Health Database via the National Institute for Communicable Diseases (NICD).

BENEFITS

- MD's products are locally developed and manufactured in Brackenfell, Cape Town.
- MD's proprietary technology allows the development and manufacture of diagnostic tests at a low cost.
- The COVID-19 Antigen Self-Test meets the stringent SAHPRA specificity and sensitivity requirements and offers a companion

OPPORTUNITIES

Medical Diagnostech is currently expanding operations with improved technologies, which makes the organization ideal for collaborations and partnerships with companies seeking technology transfer and licensing agreements. With its exciting pipeline of products undergoing final validations, the company is also seeking financial investments to bring these products to market.

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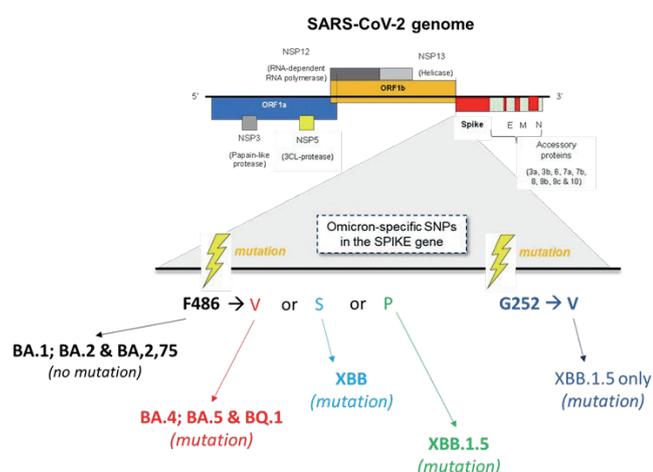
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DEVELOPMENT AND DEPLOYMENT OF COVID-19 PCR TESTS THAT CAN RAPIDLY DISTINGUISH VIRAL VARIANTS

Production of assays with rapid turn-around time to distinguish variant-defining single nucleotide polymorphisms (SNPs) to augment genomic surveillance.



TECHNOLOGY DESCRIPTION

The products described herein make use of highly specific minor groove-binding (MGB) fluorescent probes that only detect and amplify cognate sequences associated with any given variant of SARS-CoV-2. These probes have been formulated into a single PCR diagnostic test that is able to deliver a result within 2 hours. The high specificity of these MGB probes render them potentially useful for scaling Covid-19 genomic surveillance using rapid, low-cost approaches. The test can be applied to any real-time PCR machine with appropriate fluorescence detection, without the need for complex integrated devices or cumbersome analytics. The overall composition of the diagnostic test can easily be modified to detect new emerging variants of SARS-CoV-2.

VALUE PROPOSITION

In the context of genomic surveillance, the identification of SARS-CoV-2 variants typically relies on whole genome sequencing (WGS) of clinical isolates obtained from symptomatic individuals collected in the clinical setting. There are at least two problems with this approach in resource-limited settings: 1) the cost is substantial with respect to resources, infrastructure and skills required for large scale adoption (i.e. every clinical isolate must be sequenced); and 2) by the time the strain is identified, it is likely that the strain is already widely circulating in the community which limits real-time epidemiological tracking.

BENEFITS

Targeted PCR assays can be used to rapidly identify variant-defining mutations, which will assist with genomic surveillance. This approach utilizes multiple fluorophores which are typically detected on most qPCR machines. These can be used in single- or multi-plex formats. Rollout and adoption of these assays can therefore be on a wide-scale, at reduced cost. As a result, the cost of genomic surveillance will be dramatically reduced relative to WGS approaches. The tests can also be used at near-point-of-care in secondary hospitals with laboratory facilities.

OPPORTUNITIES

These products are robust and can be stored for extensive periods at -80°C for use in diagnostic and/or research laboratories. New assays can be rapidly developed once the relevant mutations are identified, with a relatively quick turnaround time. We are seeking partners to further develop and test these Omicron-specific assays and new products related to SARS-CoV-2 and other diseases. Similar products for HPV, tuberculosis and other infectious diseases are currently being developed.

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ANTIMONIA

Differential diagnosis of viral versus bacterial pneumonia using a CD-shaped point-of-care (POC) platform

BACKGROUND

Pneumonia is the single largest infectious cause of death in children worldwide, resulting in approximately 16% of all deaths in children under five years. This deadly disease is most prevalent in low- and middle-income countries (LMICs) (South Asia and sub-Saharan Africa). Pneumonia can be caused by pathogens of different nature, mainly viruses and bacteria, and therein lies the challenge in diagnosis. The treatment of bacterial and viral pneumonia involves the use of antibiotics and antiviral medication, respectively. However, with bacterial pneumonia, the challenge is the time it takes to identify the type of bacteria causing the pneumonia in order to provide the correct antibiotic for the treatment. There is therefore a need to find methods to guide the patient treatment process and to ensure appropriate medication.

TECHNOLOGY DESCRIPTION

Antimonia technology uses the combination of high sensitivity and specificity offered by nucleic acid amplification techniques with inexpensive and robust applicability of Lateral Flow Assays (LFAs) and a Lab disk platform, by supplementing a fully automated microfluidic disk format with easy-to-use immunochromatographic LFA tests. The nucleic acid amplification is monitored in real-time on the disk via fluorescence intensity. The LFAs then provide the identity of protein markers as well as detection of HIV-positive patients (all of which exacerbate the burden of disease and management of treatment) via either a visual inspection or readout by a mobile device/app. The combination of LabDisk and LFAs offers the advantage of diagnostic reliability and enhances the detection of coinfections, including HIV. The technology provides a de-centralised patient management system by shifting from hospital to chair/bed-side diagnosis with minimum need for user intervention. It also has a personalised monitoring and a decision-making tool closely linked to the patient treatment management. The technology can also be customized to detect pathogens (bacteria, viruses) depending on application requirements, or particular customer/end-user needs. This leads to substantial cost-savings at several levels, including reduced prescription of antibiotics for patients not indicated for treatment, providing more efficient treatments, and therefore better outcomes, for patients suffering from pneumonia, and most importantly, preventing infant deaths due to pneumonia.

VALUE PROPOSITION

Simply to use, reliable and robust point of care diagnostic system/solution for differential diagnosis of bacterial versus viral pneumonia in less than 40 minutes.

CURRENT STATUS

The technology is currently at technology readiness level 6. A prototype has been built and validated in relevant environments (countries).

- The assay development stage for pneumonia detection and differentiation has been completed, the team is currently finalising the in-situ sample preparation and final detection of product.
- Technical feasibility of the LabDisk platform has been completed (the system is divided into two segments, one for automating the in-situ sample preparation, and one for automating the in-situ DNA/RNA amplification and detection).
- The diagnostic panel has been developed and 26 target pathogens screened, including 4 bacteria and 22 viruses, all responsible for respiratory infections.
- Biochemical components have been successfully integrated in the disk.
- A dedicated amplification module has been designed and microfluidically tested. It is expected that no further microfluidic engineering optimization is needed for this module.
- Merging of the DNA/RNA extraction and amplification module have been completed; microfluidic and biochemical tests of the "full sample-to-answer" disk in lab are in final validations at Hahn-Schickard in Germany.

Further studies:

The lateral flow assays have been demonstrated to work using a model organism and colloidal gold, however, Life Assay requires the incorporation of Nano-platinum particles in place of the colloidal gold. This study is underway.



ANTIMONIA

INTELLECTUAL PROPERTY STATUS & PUBLICATIONS

Know-how (system integration and components assembly)

OPPORTUNITIES

The SAMRC and Life Assay are seeking potential customers, including NGOs active in Sub-Saharan Africa, to assist with market entry in low- and middle-income countries. Life Assay has already secured two manufacturers for the technology.

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CONTINUOUS QUALITY MONITORING OF SARS-COV-2 MOLECULAR TESTS FOR IMPROVED LABORATORY PERFORMANCE

TECHNOLOGY DESCRIPTION

Polymerase chain reaction (PCR) testing is a sensitive and accurate technology used to detect the presence of viral RNA in COVID-19 infections and is the diagnostic used to test for COVID-19. Any trace amounts of viral RNA are amplified to make RNA copies for COVID-19 detection and help control the spread of COVID-19. Ct is a semi-quantitative value to categorize the concentration of viral genetic material after PCR testing as low, medium or high, related to the quantity of viral genetic material. The implementation of a continuous quality improvement program aims to create warning systems on validity of tests, testing constraints and clinical parameters; standardize molecular SARS-CoV-2 technology Ct outputs across testing platforms to inform technology placement and continuous quality laboratory monitoring; support field teams and laboratories with remote monitoring; and establish required support processes to troubleshoot and manage performance challenges. Rapid PCR test results could improve estimates of the prevalence in low-resource settings where genomic sampling is absent, infrequent, or characterized by long turnaround times.

Tracking SARS-CoV-2 lineages and variants provides valuable information about their spread in close to real time. By acting with speed, transparency, and consistency, we can establish norms to support better global responses to newly emerging variants. The value of the population SARS-CoV-2 Ct is evident as an early warning predictor of an increase in case positivity and the introduction and circulation of new variants of concern. The team aims to refine the role and importance of Ct values in big data analytics for disease monitoring, surveillance, and laboratory operations, while assisting in improving algorithms for use cases of other diagnostic tests such as rapid antigen tests. The uniqueness of population Ct monitoring in South Africa is attributed to the single laboratory information system of the National Health Laboratory Service (NHLS) with central data that can be analyzed in near real-time. Research into the SARS-CoV-2 Ct as a potential marker for predictive analysis may provide additional insight into COVID-19 disease progression at a population level.

CURRENT STATUS

- Continuing to streamline CQM processes to provide near real-time laboratory diagnostic updates that can inform the emergence of variants, with continued engagement of key opinion leaders for ongoing input on data outcomes and insights which can be applied to other diseases such as TB for program monitoring when COVID-19 testing is decreased.
- Developing alert systems through CQM protocols to flag potential laboratory diagnostic issues that can assist in variant detection and better inform national program diagnostics, by implementing analytical thresholds and alerting changes in diagnostic performance
- Performing sequencing on flagged specimens as a validation tool
- Continued advancement of data visualization and dashboard tools to generate and share near real-time laboratory diagnostics and applications to other priority diseases
- Development of near fully automated processes have enabled the near real-time update of data, and report generation, aiding CQM of Ct values and epidemic dynamics, but which is dependent on testing uptake
- The SARS CoV-2 molecular Ct values provided added value in epidemiological monitoring of COVID-19
- Statistical analyses (regression and time-series normalized cross correlation) were implemented to measure the predictive capabilities of daily median Ct data in relation to COVID-19 epidemic parameters
- The team translated analytical skills to TB data to reproduce and inform analyses on Ct data in the TB program
- Ct data analytics were streamlined together with SARS-CoV-2 sequencing bioinformatics for molecular laboratory and clinical interpretation
- Further studies: Continuous quality monitoring of SARS-CoV-2 molecular tests for improved laboratory performance to be used for COVID-19, TB and HIV next-generation sequencing (NGS) and analyses on Ct data for TB

CONTINUOUS QUALITY MONITORING OF SARS-COV-2 MOLECULAR TESTS FOR IMPROVED LABORATORY PERFORMANCE

PUBLICATIONS

- Scott, L., Hsiao, N., Moyo, S. et al. Track Omicron's spread with molecular data. *Science* 374, 1454-1455 (2021). <https://DOI:10.1126/science.abn4543>
- Viana, R., Moyo, S., Amoako, D.G. et al. Rapid epidemic expansion of the SARS-CoV-2 Omicron variant in southern Africa. *Nature* 603, 679-686 (2022). <https://doi.org/10.1038/s41586-022-04411-y>
- Tegally, H., Moir, M., Everatt, J. et al. Emergence of SARS-CoV-2 Omicron lineages BA.4 and BA.5 in South Africa. *Nat Med* 28, 1785-1790 (2022). <https://doi.org/10.1038/s41591-022-01911-2>

OPPORTUNITIES

The SAMRC and Wits Health Consortium are seeking international partners and funding to assist with applying and advancing the diagnostic in LMICs.

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This research is performed in partnership with the National Priority Program of the National Health Laboratory Service in South Africa and is part of the new Wits Diagnostic Innovation Hub.

GENITAL INFLAMMATION TEST FOR HIV PREVENTION

TECHNOLOGY DESCRIPTION

Mis-diagnosed and untreated sexually transmitted infections (STIs) and bacterial vaginosis (BV) are associated with adverse reproductive outcomes, and local inflammation caused by these is associated with increased risk of HIV transmission and may reduce the efficacy of topical antiretroviral prophylaxis. A large number of women with these are frequently asymptomatic, or do not recognize their symptoms, and are therefore not treated. For those who do present with symptoms, laboratory-based tests are used to diagnose STIs and BV, but these are expensive, require experienced laboratory staff and equipment, and do not offer immediate results.

The Genital Inflammation Test (GIFT) is an inflammatory biomarker Point-of-Care (POC) screening test for the identification of genital inflammation in both symptomatic and asymptomatic individuals. The test detects key biomarkers of inflammation in the female genital tract caused by a wide range of STIs, BV and pathogenic bacteria, making this an ideal single, inexpensive, rapid POC screening tool to identify the large pool of women who have STIs, BV or inflammatory bacterial infections, and are at increased risk of HIV infection and reproductive complications. It is envisaged that the device will be used as a routine part of HIV prevention and reproductive healthcare programmes.

VALUE PROPOSITION

A low-cost, point-of-care test to identify genital inflammation associated with sexually transmitted infections in symptomatic and asymptomatic women.

BENEFITS

The genital inflammation test (GIFT) is an inexpensive, user-friendly, rapid, equipment-free point-of-care screening device which would allow women to be tested for genital inflammation at any healthcare facility and treated appropriately, in order to increase case finding, reduce the overall STI and BV burden, reduce the risk of HIV acquisition and improve reproductive health.

OPPORTUNITIES

The technology developers are seeking partnerships to reduce the cost of the antibodies used on the device. The technology partner is also seeking to work with Governments, commercial entities and other end users to discuss the deployment of the device in their healthcare settings.

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NOVEL TB BIOMARKERS

TECHNOLOGY DESCRIPTION

Tuberculosis (TB) is the leading cause of death in Sub-Saharan Africa and South Africa and current diagnostic tools are not able to diagnose all types of TB in all patient populations. New TB biomarkers are needed to improve diagnostic tools. A subset of novel urinary TB biomarkers have been identified that correlate with disease status, distinguishing active TB from latent TB infection and from non-TB infection. Additionally, a sub-set of biomarkers potentially identify sub-clinical TB, thus making them ideally suited to form the basis of a stand-alone diagnostic for TB and replacement novel mass population screening tool for active case finding. The project's goal is to generate antibodies and/or aptamers against these validated biomarkers and apply them to appropriate TB diagnostic POC platforms. In contrast to immunological markers in peripheral fluids, the POC test based on these biomarkers will rely on the direct detection of mycobacteria antigens in urine and would give a simple yes/no answer, without the need to define quantitative cut-points. The ultimate goal, therefore, is to develop a diagnostic test that works with >90% sensitivity and specificity in urine, enabling TB diagnosis at the point of care in rural settings for all patients, including those who cannot give a sputum sample, such as HIV-positive individuals and Children.

VALUE PROPOSITION

Novel urinary TB biomarkers for point of care diagnosis of Tuberculosis disease in low resource settings

BENEFITS

Simple, low-cost, point-of-care TB diagnostic test for diagnosis of the different disease stages of TB with high sensitivity and specificity. This test will utilize urine samples, allowing for the diagnosis of all patients, including those who cannot produce sputum.

OPPORTUNITIES

The technology developers are seeking funding for further biomarker validation and adaption of these biomarkers into existing or novel POC TB diagnostic platforms, including the TB PROTEC and TB SERS Biosensor.

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POINT-OF-CARE SCREENING (PARADNA) TEST

A pharmacogenomics platform comprising point-of-care screening tests and whole genome sequencing for optimizing cancer treatment

TECHNOLOGY DESCRIPTION

The ParaDNA POC technology has been developed by the Laboratory of Government Chemists Limited (LGC, Teddington, UK) to allow direct DNA analysis of a range of sample types to deliver a genomic profile. It uses real-time polymerase chain reaction (PCR) amplification followed by HyBeacon probe detection of allele lengths in a closed tube system. The utilisation of HyBeacon probes provides a homogeneous method for fluorescence-based sequence detection, allele discrimination and DNA quantification. Hybridization of the HyBeacon probes to complementary DNA target sequences results in a measurable elevation of probe fluorescence emission. The HyBeacon probes included in the PCR reactions can detect the presence and monitor the accumulation of specific DNA sequences which, in turn, are assessed for clinical relevance using the uniquely SA pathology-supported genetic testing (PSGT) and reporting platform. This involves a three-tier approach from sample collection to patient report, starting with 1) an online questionnaire-based assessment to inform appropriate use of 2) POC DNA testing of key NCD pathways that are evaluated during or after a genetic counselling session to 3) inform the need for extended testing using next generation sequencing technologies such as WGS in uninformative cases. Ultimately, different aspects of cancer will be addressed according to inherited, lifestyle-triggered or therapy-induced genetic risk in each patient. Therefore, the POC test kit includes both distinct genetic risk factors (BRCA assay) and shared disease pathways (NCD assay). The BRCA POC assay is based on a founder effect previously described in SA, while the NCD assay is based on known pleiomorphic effects of APOE-cholesterol, MTHFR-homocysteine, FII/FV-blood clotting, HFE/TMPRSS6-iron metabolism and CYP2D6-drug metabolism pathways, all combined into a novel PSGT test kit incorporating WGS in eligible cases.

CURRENT STATUS

The technology is currently being used in three implementation studies at technology readiness level 6. A prototype has been built for validation in different environments, with recent expansion under a joint TIA-funded SA-Kenya grant application (pending).

- A detailed protocol was developed and approved for exploring a number of data analysis approaches: This involves the use of bioinformatics tools such as Varsome (variant data discovery tool), Annovar (annotate genetic variants detected from diverse genomes), Clinvar (aggregates information about genomic variation and its relationship to human health) in an ongoing master's degree study to identify the knowledge gaps and most appropriate next steps. This data science project is addressing many technical challenges of implementing WGS with the objective to provide recommendations for improvement of the diagnostic POC-to-WGS workflow and to maximise the computational performance in variant classification.
- Identified a new founder BRCA1/2 variant that was published: Oosthuizen J, Kotze MJ, Van Der Merwe N, Myburgh EJ, Bester P, van der Merwe NC. *Globally Rare BRCA2 variants with founder haplotypes in the South African population: Implications for point-of-care testing based on a single-institution BRCA1/2 next-generation sequencing study.* *Front Oncol* 2021; 10:619469. doi: 10.3389/fonc.2020.619469.
- The new BRCA2 pathogenic founder variant has been added in SA to the initial 8-variant POC assay originally developed by LGC in the UK, which was analytically validated in the publication by Mampunye et al. 2021: *Pioneering BRCA1/2 point-of-care testing for integration of germline and tumor genetics in breast cancer risk management: A vision for the future of translational pharmacogenomics.* *Front Oncol* 2021; <https://doi.org/10.3389/fonc.2021.619817>

POINT-OF-CARE SCREENING (PARADNA) TEST

- A protocol was developed and approved for a pilot study evaluating the effect of pharmacogenetics on warfarin dosing and shortening the time to a therapeutic International Normalised Ratio (INR) in an ongoing MMed study. The performance of a similar ParaDNA POC assay recently implemented in the UK (pilot study) is used to compare the results obtained in SA patients with laboratory-based genotyping using real time PCR to confirm the accuracy of the ParaDNA testing device and kits.
- The NCD pathways panel has been validated as an internal quality control measure from sample-to-reports.

INTELLECTUAL PROPERTY STATUS & PUBLICATIONS

Know-how comprising reporting algorithms, and POC qPCR test kit manufacture. Licensed patent from LGC.

OPPORTUNITIES

We are seeking collaboration with innovative molecular diagnostic companies or geneticist teams in universities so as to bring affordable, clinically relevant, genetic testing (e.g. BRCA) to low- and middle-income countries, particularly in Southern Africa.

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THE DIAGNOSIS OF COVID-19 USING APTAMERS

TECHNOLOGY DESCRIPTION

Aptamers are oligonucleotide or peptide molecules that bind to a specific target molecule and offer significant opportunity for use in diagnostics. Aptamers are usually created through selection from a large random sequence pool, but natural Aptamers are also known to exist. Aptamers binds to their target receptors, such as a virus, in a highly specific manner and with high affinity. These binding properties are being exploited for use in diagnostics, including for COVID-19.

VALUE PROPOSITION

Aptamers operate in a far lower concentration limit than antibodies. Thus, the technology can be applied as soon as an infection is suspected without the disease having to show severe clinical symptoms. This translates into a very early detection system and thus an immediate treatment regimen, leading to a better prognostic outcome. Secondly, the cost of Aptamers is at least 10-fold lower than that of antibodies, translating into a much more affordable diagnostic for the end-user. Thirdly, Aptamers show a much higher affinity for their targets, minimizing the risk of a false positive or negative result. Finally, the potential application of this technology is very broad, from diagnosis of any disease where the causative agent is of a viral, bacterial, fungal or parasitic nature as well as uses in therapeutics.

BENEFITS

The use of Aptamers in diagnostics offers several advantages that overcome the shortcomings associated with antibodies, which are normally used in Lateral Flow Devices (LFD's). These include their small size, rapid and reproducible synthesis, simple and controllable modification, high stability, and non/low toxicity. In addition to this, traditional antibody-based

kits carry a high cost due to the cost of antibody production, whereas Aptamers can be produced at larger volumes and at 1/10th of the cost. A major disadvantage of widely used antibodies in LFDs is that they tend to target the same antigenic region/epitope that elicits an immune response in an infected individual thereby competing with the infected individual's own antibodies that are produced after sero-conversion in a bid to neutralize the virus. This phenomenon has been linked with false negative test results. Aptamers can be specifically designed not to interact with antigenic regions and can thus target a different part of the virus for its diagnosis. A very recent development was the modification of Aptamers with other bio-molecules, such as Chitosan. Chitosan is a bio-stimulant for the production of high protein content within commercially viable crops as well as offering protection to plants against pathogens. The use of this combined molecule offers a very targeted approach in the agricultural sector in terms of food security and scarcity. To this end a category 3 fertilizer has been produced in partnership with API Bio Pty (Ltd).

OPPORTUNITIES

The technology platform requires further development to maximize the product opportunities. The developers are thus seeking local and international collaborations as well as additional funding to move towards full-scale commercialization.

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PRCR URINE DIPSTICK TEST

TECHNOLOGY DESCRIPTION

Life Assay Diagnostics has developed a simple to use Protein-to-Creatine (PrCr) radiometric urine dipstick test. The PrCr urine dipstick test consists of two detection pads that have been specifically formulated to detect protein and creatinine in urine with specific concentrations. The chemical formulation of the pads reacts in such a way resulting in a colour change, which then corresponds to a particular colour block provided on the product label. A woman's proteinuria result is then determined by using an easy-to-use colorimetric chart which corresponds to the specific protein-creatinine ratios. The colorimetric chart has already undergone initial refinement based on feedback received from target users in Ghana during a usability evaluation study. The PrCr test is intended for use by health care providers across the health care system in developing countries, including at the community level where the majority of women receive routine antenatal care.

VALUE PROPOSITION

A protein-creatinine rapid test for determining proteinuria status as an indicator for the onset of preeclampsia/eclampsia.

BENEFITS

The PrCr radiometric urine dipstick test is a low-cost, highly sensitive and specific screening test that is intended to improve antenatal care decisions related to preeclampsia in low- and middle-income countries (LMICs). The test allows an immediate evaluation of proteinuria status before the patient leaves the clinic, allowing rapid response for the treatment of preeclampsia, where indicated. The characteristics of the PrCr dipstick test are aligned with the WHO-standards and those of the current protein-only dipstick test, which makes it easier for market adoption. The test will provide access to more accurate proteinuria screening across antenatal care settings, which will help identify more women at risk and provide proper interventions to ensure that those that are vulnerable receive proper health care.

OPPORTUNITIES

The PrCr test has been successfully commercialized in 3 African countries, namely Ghana, South Africa and Kenya. It is also being procured for use in Pakistan, Philippines, Indonesia, and Egypt. The project is seeking additional funding and partnerships to scale the PrCr test into additional countries in Sub-Saharan Africa and other LMICs.

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HEALTH INTERVENTIONS

THE DIETARY INTAKE ASSESSMENT TOOL FOR SOUTH AFRICA (DIASA)



TECHNOLOGY DESCRIPTION

The foundation of sound nutrition research and practice starts with sound dietary intake assessment. However, the collection of this important data comes with many challenges. The global need for more effective methods has led to the development of many digital automated methodologies and tools across the globe. The absence of such an automated digital tool for South Africa highlighted the need to develop an application which could be used broadly across all practices in the nutrition research fraternity. The newly developed DIASA app is a web-based, android driven mobile application which employs multi-pass 24-hour dietary intake assessment methodology, linking the South African food identity and food quantity databases for automated quantification and coding with the aim to assist in dietary intake assessment research.

VALUE PROPOSITION

A multi-pass 24-hour recall dietary intake assessment mobile application utilizing the South African validated food quantities database and food identification system of the national South African food composition database (SAFoods).

BENEFITS

The DIASA is a mobile application developed to assist with research by enabling guided multi-pass intake methodology and submission of collected intake data to a research manager for real time quality assurance, data approval or rejection with in-app notifications. The application facilitates automated communication between fieldworkers collecting data and research managers/PIs responsible for dietary intake assessments. DIASA enables food code linking, portion size auto-calculation, and coding for multi- export modalities. It also allows the option of collecting additional individualized information and data to facilitate flexibility.

OPPORTUNITIES

The DIASA application is available for subscription through the SAMRC for those involved in clinical and other research in South Africa that requires dietary intake assessment.

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PREDICTIVE HEPATOTOXIC SOLUTIONS: *IN VITRO* INNOVATION

TECHNOLOGY DESCRIPTION

An increase in public health awareness of liver injury has resulted in an increase in the need for *in vitro* screening models to minimize potential harmful toxicity. Drug/herb-induced liver injury results from either direct toxicity from the administered agent or the drug-metabolites, as well as from immune-mediated mechanisms. One major contributing factor to drug-induced liver injury specifically is the lack of *in vitro* screening as the current screens are poorly predictive of toxicity in humans. In drug development, interest has been drawn to the use of 3D systems, which have opened a range of potential new platforms for evaluating *in vitro* toxicity. The Biomedical Research and Innovation Platform (BRIP) at the South African Medical Research Council (SAMRC) has been involved in the development and use of a 3D culture model that produces liver tissue-like human spheroids that closely mimic liver metabolism. This model provides a screening platform that is more physiologically relevant and facilitates the development of safer guidelines for the use of herbal remedies and traditional medicines, as well as potential new drugs, with improved management of hepatotoxins without or at least limiting the use of sentient animals. The novelty of this 3D model allows for the *in vitro* recapitulation of *ex vivo* hepatic characteristics, such as cell-to-cell communication and structural integrity, which are imperative for more accurate predictive toxicity screening.

VALUE PROPOSITION

An innovative and cost-effective solution for pre-clinical hepatotoxicity screening that reduces the use for sentient animals, while providing essential and physiologically relevant pre-clinical toxicity data.

BENEFITS

The 3D liver spheroid model allows for repeated dosing over extended periods of more than 30 days. The hepatic biomass obtained from 3D culture allows for an integrated approach of physiological characterization following exposure to a chemical or compound, as well as offering deeper insight on a molecular level through gene and protein expression analysis.

OPPORTUNITIES

The SAMRC is seeking funded collaborations to utilize this advanced technology for the evaluation of plant-based and allopathic drugs.

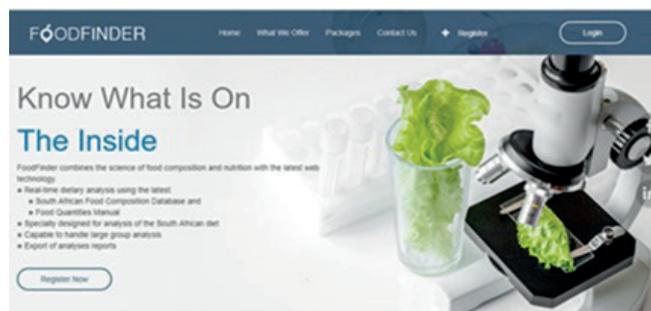
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SOUTH AFRICAN FOOD DATA SYSTEM (SAFOODS)



TECHNOLOGY DESCRIPTION

Understanding and quantifying the nutritional content of food consumed and using this as a planning and management tool for improved health outcomes has significant benefits at all user levels. The SAMRC has developed the South African Food Composition Database (SAFOODS), Food Composition Tables (FCT) as well as Food Quantities Manual and related tools and products based on SAFOODS, including FoodFinder, a dietary intake assessment software program. The database and related tools are maintained and updated by the SAMRC, with the most recent update published in 2023. The current database serves as the definitive South African food composition database guided as such, by the National Department of Health. The data in SAFOODS has been made available as a resource to dietitians, students, universities, researchers and members of the food industry through the published Food Composition Tables and FoodFinder.

VALUE PROPOSITION

The definitive South African food composition database, as guided by the National Department of Health.

BENEFITS

SAFOODS, together with FoodFinder and the Food Composition Tables (FCT), are essential for the provision of accurate dietary information on, as well as for labelling of, food products available and consumed in South Africa. The database is continually updated as new products and guidelines are released. SAFOODS offers the potential to develop country specific dietary and nutrition management tools, services and products for individuals, companies and for research purposes.

OPPORTUNITIES

The SAMRC is seeking partnership opportunities with companies, non-profits and/or NGOs to utilize the food composition data in SAFOODS for the development of nutrition and dietary related products and services for a variety of target markets aimed at improving health outcomes.

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A "ONE-STOP SHOP" FOR THE BROAD-SPECTRUM BIOACTIVITY SCREENING OF EXTRACTS AND PHYTOCHEMICALS IN METABOLIC DISEASE MODELS

TECHNOLOGY DESCRIPTION

It is evident that many successful drugs that have been on the market for several decades, including atropine, morphine and metformin, have come into use through the study of indigenous remedies. The use of herbal medicines continues to increase precipitously across the world, with many people resorting to these products for treatment of various health conditions. Approximately 80 % of the South African population use traditional medicines, either alone or in combination with conventional pharmaceutical drugs. The country is involved in substantial ethnopharmacological research aimed at documenting indigenous knowledge systems and elucidating the medicinal properties of popular South African traditional medicines (SATM), including detailed chemical and biological evaluation.

The Biomedical Research and Innovation Platform (BRIP) at the South African Medical Research Council (SAMRC) has developed a bioactivity screening platform that offers a standardized service for the broad-spectrum biological screening of natural-product extracts, with focused attention on the identification of medicinal properties against metabolic diseases including diabetes, obesity and cancer. The platform also provides opportunities for capacity development of young scientists to industry-ready professionals. The streamlined filtering process of extracts ensures a strict "go, no go" protocol, thus saving time and money. The data generated from this research can be used to generate a crucial pharmacopeia that may be used to further enrich African indigenous knowledge systems.

VALUE PROPOSITION

An all-inclusive one-stop-shop drug-discovery pipeline for plant-based medicines, focused on metabolic diseases.

BENEFITS

The optimized protocols utilized in the platform's screening process have been established within the unit by specialist scientists and have been successfully implemented in various natural product research projects. The platform offers broad spectrum screening for bio-activity as well as specialization in metabolic diseases. The "go, no go" protocol may be tailored for each customer's requirements.

OPPORTUNITIES

The SAMRC is seeking local and international collaborations with developers of plant-based and allopathic medicines to test their products, as well as collaborative partners and investors to expand on the platform offering to include targeted and rare disease therapeutics.

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MEDICAL DEVICES

LIGHTWEIGHT, COST-EFFECTIVE, SINGLE USE POLYMER SURGICAL BULLDOG CLAMPS



BACKGROUND/TECHNOLOGY DESCRIPTION

Coba Manufacturing has developed a disposable, sterile bulldog clamp with a soft textured foam jaw liner that provides constant and consistent atraumatic clamping pressure. A surgical bulldog clamp is a medical device used during surgical procedures to control or temporarily stop blood flow in blood vessels. It is a clamp with a scissor-like structure that is used to compress a blood vessel to prevent or reduce blood flow to that area. The bulldog clamp is designed to be placed on an artery or vein to restrict the flow of blood to a specific area of the body during surgery. The clamp can be used in a wide range of surgical procedures, including cardiovascular surgery, plastic surgery, and orthopedic surgery. The surgical bulldog clamp comes in different sizes and shapes, depending on the specific surgical procedure and the size of the blood vessel that needs to be clamped. With traditional, reusable metal bull clamps, the pressure degrades over time, resulting in inconsistent and unreliable clamping force. Additionally, the hard metal surface of traditional clamps damages the outer wall of the vessel which leads to complications. COBA Manufacturing's affordable single-use polymer bulldog clamps offer consistent and safe clamping pressure. The soft textured foam jaws result in safe and secure atraumatic clamping of the vessels. Additionally, the use of injection moulding technology has made the manufacturing process more cost-effective to ensure an affordable disposable device. They are lightweight, cost-effective, and offer consistent

atraumatic clamping pressure with each use. Having constant clamping pressure ensures that the bulldog clamp maintains a secure and stable occlusion of the blood vessel during a surgical procedure, reducing the risk of complications. The soft textured foam jaws of COBA Manufacturing's bulldog clamps also provide atraumatic occlusion of the blood vessel, resulting in less tissue damage and faster healing time for the patient.

CURRENT STATUS

The technology has been fully developed.

- All clamp variants have been tested and validated.
- The team has partnered with an international distributor of surgical instruments.
- The developed bulldog clamps have been used in surgeries with great success.
- The products are FDA registered.

INTELLECTUAL PROPERTY AND PUBLICATIONS

- Know-how – cost effective injection molding manufacturing process developed in-house.
- Proprietary clamp designs informed by surgeons.

OPPORTUNITIES

To further the technology development and commercialization of these single-use plastic bulldog clamps, COBA Manufacturing is seeking international partners to increase the distribution of the device worldwide. Additionally, funding is needed to obtain the CE mark for the device, as it is currently only registered with the FDA. The company is also looking for investors, funders, and regulatory assistance to help bring this innovative technology to more surgical procedures and patients worldwide.

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PEAKO MEDICAL - UNKINK



TECHNOLOGY DESCRIPTION

The kinking of medical tubing is an inherent problem faced daily by staff in hospitals. At present, the tube coming from a catheter makes a sharp 180° turn up towards a connected IV bag which often creates a kink in the tubing. This kink in the tubing poses a significant risk to patients as it presents the danger of fluid blockage of critical drugs. This can lead to blood clotting and unpredictable chemical reactions. The current solution to this problem is the use of makeshift medical tape which is unreliable and time consuming to set up.

Peako medical has developed a device that ensures that the critical portion of the IV tubing does not kink by firmly gripping the tubing and re-directing the tubing at an angle of 180° whilst doubling as a securement device for easy attachment to the patient.

BENEFITS

- Significant reduction of inconsistent medical fluid flow.
- Limit adverse patient consequences due to unreliable fluid flow.
- Compatibility with a variety of tubing sizes.
- 2 in 1 securement device for easy application to a patient.
- Easily added to an existing IV-line setup.
- Ensures efficiency and reliability of IV-lines in place over multiple days.

CURRENT STATUS

- The concept has been successfully demonstrated.
- Injection moulded samples to be produced to validate the device in clinical settings.

INTELLECTUAL PROPERTY

- Patent application filled.

OPPORTUNITIES

The team is seeking funders and regulatory assistance to help bring the technology to the global market.

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MEDI-SAFE: SAFE SHAVE BIOPSY DEVICE

A “shave biopsy device” with added safety features to prevent a sharp injury and designed for ease of use by surgeons

TECHNOLOGY DESCRIPTION

Medi-Safe Surgicals, in collaboration with Myco Medical in the USA, has designed a shave biopsy device that has safety features to reduce the risk of a “sharps injury”. The device is used to shave part of the skin or lesion to gain a biopsy sample for laboratory testing. The razor blade is held behind a protective guard in which the razor blade is only extended exposing the sharp end once the surgeon activates it prior to the surgical procedure.

Medi-Safe are experts in the field as they are currently selling three safety scalpel devices that also help prevent surgical scalpel injuries and reduce the risk to health professionals of contracting blood-borne diseases.

BENEFITS

- The safe shave biopsy device has enhanced ambidextrous grips that make the device easier to use.
- The device holds and fixes the bowed profile of the razor blade in place during use and keeps the surgeon’s hand away from the razor blade. This is the first shave biopsy device designed with such safety features.

CURRENT STATUS

- The technology is fully developed.
- Ready for distribution in South Africa and the USA

INTELLECTUAL PROPERTY

The device has granted patents in USA, UK, RSA and Japan.

OPPORTUNITIES

Medi-Safe Surgicals and Myco Medical are actively engaging with potential distributors in the USA. The company is also ready to licence the device to manufactures under an OEM arrangement.

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SECURE AIRWAY CLAMP FOR USE DURING ANESTHESIA

TECHNOLOGY DESCRIPTION

Jirehsa Medical (Pty) Ltd has developed a low-cost, disposable medical device for retaining either endotracheal tubes or laryngeal mask airways during anesthesia. The device is self-inserted prior to anesthesia by the patient and enables simple endotracheal intubation and fixation. It includes a tube fixation function, to maintain the tube in place and prevent movement, even if fluids are present and without the need for adhesive tape. The integrated bite block prevents the life-threatening occlusion of the tube by patients during recovery, as well as chipping or damage to the patient's teeth. In addition, the device enables the anesthetist to rapidly reintubate the patient in the event of airway blockage following tube removal. None of these safety features are possible with the present fixation methods.

VALUE PROPOSITION

Low-cost, disposable device, containing an integrated bite block, for easy insertion and fixation of endotracheal tubes and prevention of tooth damage and occlusion of the tube during anesthesia and in trauma situations.

BENEFITS

This unique, low-cost, disposable device:

- Allows for easy and safe insertion of the endotracheal tube and fast re-intubation if necessary;
- Fixes the endotracheal tube in position through a secure clamp, overcoming the need for fixation using adhesive tape onto the patient's face;
- Prevents movement of the endotracheal tube once in position; and
- Through its integrated bite block, prevents tooth damage and possible occlusion of the tube caused by the patient's biting reflex.

Intellectual Property

The device design is protected in South Africa, the USA and Europe.

OPPORTUNITIES

The technology developers are seeking partners for the commercialization and international marketing of the product as an intubation device to be used in the anesthesiology and emergency medical services sectors.

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COBA BIOMEDICAL: NERO BUR

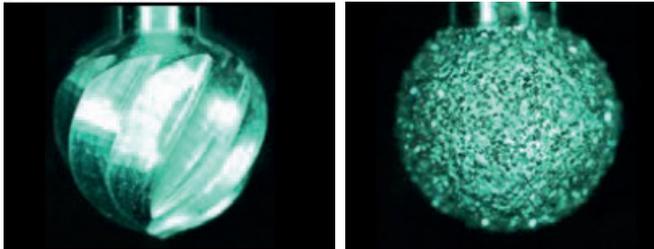


Figure 1. Cobra Biomedical produced fluted and diamond coated bur

BACKGROUND

Spherical cutting burs are utilized in a wide range of medical operations, including dental procedures, large and small bone surgeries, maxillofacial surgery, spinal and orthopaedic surgery, and cranial surgery. The cutting burs are sold as sterile consumable medical products. These devices are manufactured on 5 axis CNC (Computerized Numerical Control) grinding machines with specific grinding wheels. These machines are conventionally used to produce cutting tools such as endmills for the metal processing industry. Cobra Biomedical has developed the full manufacturing process to produce, clean, package and sterilize these surgical burs.

TECHNOLOGY DESCRIPTION

The medical grade cutting burs consists of a shaft and fluted cutting head. The bur, which is designed to fit into an appropriate powered hand piece, is produced of high-grade steel. The spherical cutting head is heat treated to ensure an effective cutting device for excavating/shaping and/or removing bone tissue and biomaterials during maxillofacial, spinal, or orthopaedic surgery. Burs fluted or diamond coated, can be produced in a number of head styles and sizes to suite the surgical application.



Figure 2. Cobra Biomedical produced 6mm fluted ball burcoated bur

VALUE PROPOSITION

Cobra Biomedical offers manufacturing of high quality, affordable rotary burs in South Africa for the local, regional and international market.

CURRENT STATUS

All processes for manufacture of the device have been established, including all protocols and reports for performance testing and useability. The medical cutting burs are registered on COBA Biomedical's South African Health Products Regulatory Authority license. The project is in the final stages of registration with the FDA.

OPPORTUNITIES

Cobra Biomedical is seeking export opportunities for these medical consumable cutting products.

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SILICONE PROSTHETIC LINERS FOR WIDESPREAD ACCESS

TECHNOLOGY DESCRIPTION

Silicone prosthetic liners are currently only available to patients who have access to private healthcare. Although private hospitals are equipped with prosthetic liners, these are all imported. Amputees who access public health facilities are issued with cotton socks to wear between the residual limb and the prosthesis. Consequently, long-term use causes abrasions and bruising, leading to infection. This discourages amputees from fully using their prosthetics due to the pain caused by friction of the socks on the residual limb. A prosthetic liner is a medical device worn by amputees before inserting the residual limb into the prosthesis. The prosthetic liner is made of medical grade silicone that absorbs all the shock involved in walking and distributes weight equally during the walking cycle.

VALUE PROPOSITION

Prosthetic Engineering Technologies has developed the capability to localize the manufacture of prosthetic liners in South Africa, thus giving patients who access public health facilities state-of-the-art products that will significantly improve their quality of life. Prosthetic Engineering Technologies will make low-cost, high-quality prosthetic liners available to amputees who could not previously afford them. This will allow amputees a much higher level of comfort and improve mobility.

CURRENT STATUS

The capability to manufacture the silicone prosthetic liners has been established, including the required molds. Prosthetic Engineering Technologies will apply for ISO 13485 certification and a SAHPRA license to manufacture these silicone liners in-house. Sample silicone liners will be handed to amputees at public health facilities for user testing and improvement, where required.

OPPORTUNITIES

Prosthetic Engineering Technologies is seeking international partners to assist with market entry strategies into LMICs and partners for assistance with the regulatory approvals of the device (ISO 13485 and SAHPRA registration) in South Africa and elsewhere.

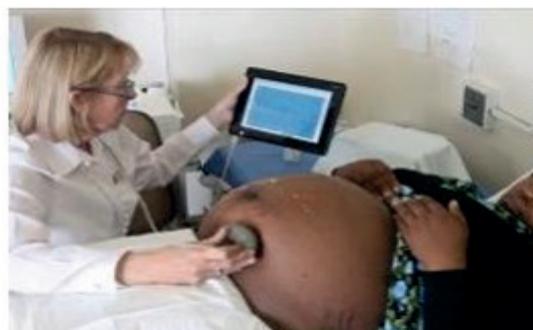
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UMBiflow™



BACKGROUND

Globally, the rate of stillbirths remains unacceptably high, at 2.8 million stillbirths worldwide. The causal pathways for stillbirths often involve impaired placental function, either with foetal growth retardation or preterm labour, or both. In South Africa, two thirds of all stillbirths occur in the antenatal period and a large number of these occur in healthy women who had antenatal care as a low-risk pregnancy. At the same time, pregnant women with constitutionally small but healthy foetuses are being referred unnecessarily to higher level care for further investigation, which is more costly to both the patient and the public health sector. It is therefore important to be able to detect undiagnosed placental insufficiency at the primary health care level in otherwise healthy pregnancies, allowing intervention to ensure a good birth outcome, and to distinguish between a constitutionally small but healthy foetus and a pathologically small and therefore compromised foetus to ensure more effective and efficient decision making on specialist referrals. The Umbiflow device addresses these issues by offering a low-cost solution for broad screening of pregnant women at any level of healthcare. The device has been used in clinical studies on >19,000 pregnant women in South Africa and internationally (Ghana, India, Kenya, and Rwanda). The studies have demonstrated that Umbiflow can detect abnormal resistive index (RI) measurements, which are directly associated with lower birth weights across all weight centiles, and that intervention in such cases can lead to a reduction in the stillbirth rate of up to 43%. This work has directly contributed to saving the lives of babies and has initiated the “Umbi-baby” program, which monitors babies identified as being at risk at an early stage and provides subsequent interventions.

TECHNOLOGY DESCRIPTION

The UMBiflow™ technology uses Doppler waveform analysis for reliable and cost-effective antenatal screening. The technology evaluates blood flow in the umbilical artery of the foetus in the third trimester of pregnancy. From such a measurement, decisions can be made about the ability of the placenta to provide sufficient nutrients and oxygen in order to sustain the required foetal growth rate during this trimester. The ultrasonic Doppler probe connects via a USB port or wireless to a standard PC or laptop onto which is loaded the UMBiflow™ software. The system allows for a database facility, serial monitoring, and plotting of results. Captured data is automatically compared to the onboard clinical database information and a clinical assessment is provided to the clinician or midwife.

VALUE PROPOSITION

UMBiflow™ is a simple-to-use, cost-effective, mobile-connected, portable device for antenatal screening of placental function by primary health care workers.

CURRENT STATUS

The technology has been licensed to a partner for manufacturing, sales, and marketing in both South Africa and internationally. The initial rollout of the technology is planned for the Southern African Development Region, with Botswana being the first international distribution site identified.

UMBiflow™

INTELLECTUAL PROPERTY STATUS & PUBLICATIONS

The device and proprietary algorithms are protected as trade secrets and the software is protected by means of copyright.

See the following publications for details on the studies conducted:

- Hlongwane, T.M.A.G., Cronje, T., Nkosi, B.S.S., Pattinson, R.C. (2021). The prevalence of abnormal Doppler's of the umbilical artery in a low-risk pregnant population in South Africa, *EClinicalMedicine*, available at: <https://doi.org/10.1016/j.eclinm.2021.100792>.
- Mufenda, J., Gebhardt, S., van Rooyen, R., Theron, G. (2015) Introducing a Mobile-Connected Umbilical Doppler Device (UmbiFlow™) into a Primary Care Maternity Setting: Does This Reduce Unnecessary Referrals to Specialised Care? Results of a Pilot Study in Kraaifontein, South Africa. *PLoS ONE* 10(11): e0142743. doi:10.1371/journal.pone.0142743

- Nkosi, S. Makin, J. Hlongwane, T. Pattinson, R. C. (2019). Screening and managing a low-risk pregnant population using continuous-wave Doppler ultrasound in a low-income population: A cohort analytical study. *South African Medical Journal* 2019;109(5):347-352. DOI:10.7196/SAMJ.2019.v109i5.13611

OPPORTUNITIES

The SAMRC and CSIR are seeking international partners to assist with market entry strategies into LMICs and partners for assistance in the regulatory approvals of the device in various countries.

Funding is also sought for a large multi-site randomized control trial on the device.

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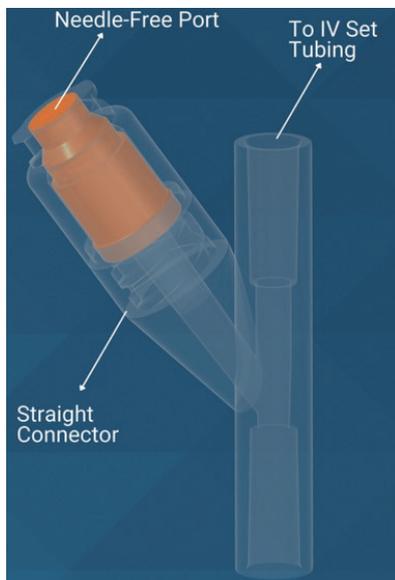
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VIVASITE NEEDLELESS IV INJECTION SITE



Figure 1: adaptation process of the VIVASite Needleless IV Injection Site



BACKGROUND

Needle stick injuries are a major concern to healthcare workers in South Africa. These injuries expose healthcare workers to the risks of contracting HIV and other diseases. Needle stick injuries account for 58 new HIV, and 53 Hepatitis B cases per year. Currently, no manufacturer of a needle-free medical device exists on the African continent, where HIV is most prevalent. Needle-free valves are standard in the rest of the world and currently used in several hospitals in South Africa. The WHO estimates that ~170 million injections are administered in South Africa, per year.

Unfortunately, all needle-free medical devices are imported, and the cost poses a barrier to entry in most public hospitals. The estimate is that a mere 40% of public hospitals are using needle free valves to protect their healthcare workers and patients. The complexities of importation are that these valves are costly (approx. 1US\$ each) and they incur customs duties of up to 20% as they are imported as plastic components.

TECHNOLOGY DESCRIPTION

All South African manufacturers currently import needle-free valves to build into their infusion administration sets. VIVA Medical supplies locally in South Africa and exports into Asia and the rest of Africa. VIVA Medical has developed prototype VIVASite needleless IV injection sites and will go to market with these in January 2024. The most appropriate designs have been integrated into the design that will comply with international standards. This design is less expensive to manufacture, easier to use and could be customize for use in adult and paediatric patients. The project aims to localize the manufacturing of needleless IV injection sites, thereby eliminating import costs and reducing the trade imbalance. By collaborating with world-class specialist anesthesiologists and other relevant stakeholders, sufficient due diligence and market research has been completed.

VALUE PROPOSITION

Locally manufactured, low-cost, highly effective, and safe needleless IV Injection Site.

CURRENT STATUS

The first prototypes for non-clinical evaluation have been produced and will be tested, followed by product registration.

OPPORTUNITIES

The SAMRC and VIVA Medical are seeking international partners to assist with market entry strategies into LMICs and partners for assistance in the regulatory approvals of the device in South Africa and other countries.

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ELLAVI UTERINE BALLOON TAMPONADE

TECHNOLOGY DESCRIPTION

A Uterine Balloon Tamponade (UBT) is a minimally invasive intervention that can effectively stop bleeding as part of a post-partum hemorrhage (PPH) management and care bundle, in combination with other treatments such as uterotonics. When inserted into the uterus and filled with water, it exerts pressure on the uterus causing the bleeding to stop in approximately 5 to 15 minutes. The technology works rapidly and effectively, reducing the need for risky and costly surgical interventions and blood transfusions. However, the use of UBT in many settings has been restricted due to the high costs of such devices. Sinapi Biomedical, in partnership with PATH, has developed the Ellavi UBT, an affordable, free flow, pressure-controlled device. Use of this device has been demonstrated to reduce maternal mortality, especially in low resource settings. Research findings from studies on the Ellavi UBT conducted in South Africa at all levels of healthcare indicated a success rate of >85% in stopping the bleeding. Required surgical interventions in a small number of cases were related to tears. All mothers had a good outcome. Studies in Kenya and Ghana on the Ellavi UBT confirmed these South African findings.

VALUE PROPOSITION

A low-cost, pre-assembled, free flow, pressure controlled UBT designed for management of PPH at all levels of healthcare, including in LMICs.

BENEFITS

The Ellavi UBT is the first pre-assembled, free flow, pressure controlled UBT that is easy to use and cost-effective. The Ellavi UBT can be used at the lowest level of healthcare to stop the bleeding while transferring the mother to the next level of healthcare. The inclusion of the Ellavi UBT, in combination with other treatment options, can safely strengthen PPH management bundles in low resource settings. It is a fully assembled system with a gravity-fed filling mechanism that makes it easier and faster to use and designed to conform to the shape of the uterus, applying optimal pressure to stop bleeding. The free flow system allows the natural contraction of the uterus without an increased risk of necrosis.

OPPORTUNITIES

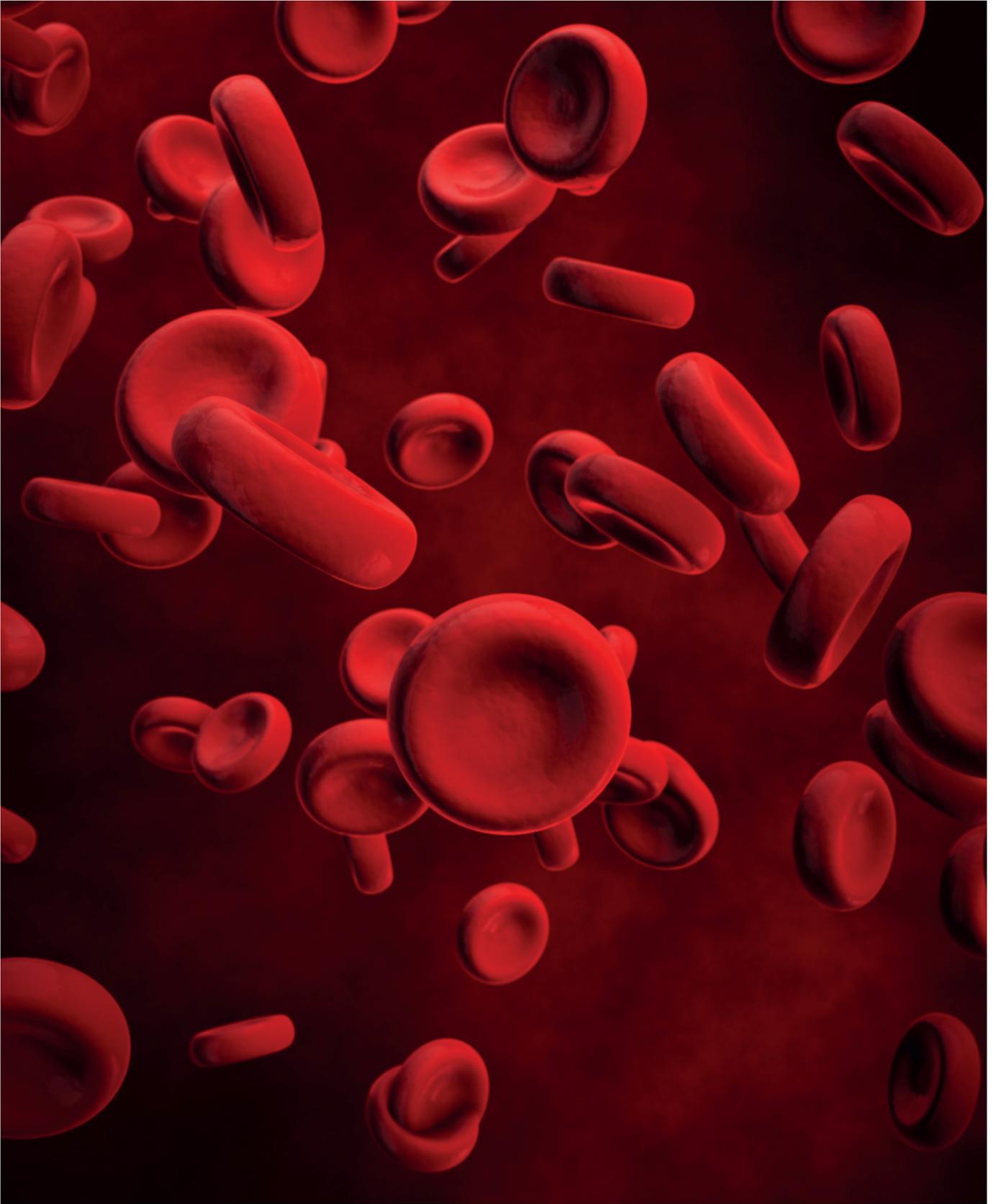
The innovators are seeking international partners to assist with market entry strategies into LMICs, as well as partners for assistance with regulatory approvals of the device in Africa.

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THERAPEUTICS

GREEN ROOIBOS EXTRACT



TECHNOLOGY DESCRIPTION

Rooibos and its biologically active phenolic compound, aspalathin, have been shown to possess a number of beneficial effects relevant to the management of Type 2 Diabetes and Cardiovascular disease. The aspalathin content of the rooibos plant, however, varies depending on a number of factors, and its level in the plant material drops even further during the oxidation process used to produce fermented rooibos, the product commonly prepared as a herbal tea. The South African Medical Research Council (SAMRC) and the Agricultural Research Council (ARC) have developed a method for the production of aspalathin-rich unfermented green rooibos extract (GRT Extract), containing a minimum of 12% aspalathin, and having a number of beneficial effects in the management of conditions linked to glucose and lipid metabolism. These include a glucose lowering effect, ameliorated insulin resistance in vitro, protection of pancreatic beta cells against oxidative stress, protection of heart cells and lowering of cardiovascular risk factors.

VALUE PROPOSITION

Aspalathin-rich green rooibos extract (GRT Extract) has potential for incorporation in novel therapeutic preparations for the treatment and management of metabolic disease in humans and animals.

BENEFITS

Aspalathin-rich green rooibos extract (GRT Extract) can be utilized in novel therapeutic preparations for the treatment and management of metabolic dysfunction, including the modulation of glucose and cholesterol, thereby lowering cardiovascular risk. The products have application in the complementary medicine, nutritional supplement and veterinary markets.

OPPORTUNITIES

The SAMRC is seeking international partners for the formulation and sale of GRT Extract into novel products for a variety of markets.

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PLANT BASED MORPHOGENETIC FACTORS (PBMF) IN TISSUE ENGINEERING OF BONE AND CARTILAGE

TECHNOLOGY DESCRIPTION

Repair of bone and cartilage continues to be a challenging clinical problem. Autologous and allografts are the gold standard for the treatment of bone and cartilage but have several limitations. They involve an invasive, open surgical procedure that requires tissue to be harvested from an alternative site within the patient. Global Health Biotech is a company that manufactures plant based morphogenetic factor implants from medicinal plants, which are natural products and do not have the same disadvantages as autografts and allografts. Plant-based morphogenetic factor products offer novel and alternative treatment opportunities for tissue engineering of bone and cartilage. Plant based morphogenetic factor (PBMF) implants offer orthopedic patients and patients suffering from osteoarthritis and bone loss an alternative standard for allogeneic and/or autogenic osteochondral transplants and bone grafting procedures currently in use today. The products are set to revolutionize approaches adopted by surgeons when treating defects of bone and cartilage regeneration. According to the World Health Organization (WHO), in the United States the bone graft market is estimated at US\$ 850 million, and the world market is estimated at \$US 9.1 billion. The cost competitiveness of the plant-based morphogenetic factors implant is hoped to place this product as a leading seller in the cartilage and bone regeneration market compared to allogeneic and/or autogenic osteochondral transplants and bone grafting procedures typically performed by orthopedic surgeons and periodontist.

BENEFITS

Plant based morphogenetic factor implants offer the opportunity to fulfil the mounting needs of patients suffering from osteoarthritis, degenerative diseases, genetic disorders, non-unions of fractures, and traumatic or post-surgical tissue defects of the skeleton. A study is underway to develop an efficient, safe and affordable implant technique and will demonstrate an innovative strategy to repair and regenerate bone and cartilage that has been affected by trauma (such as that caused by gunshot wounds and motor accidents that are common in South Africa). It is anticipated that these alternative morphogenetic factors will improve the quality of life and bring pain relief to patients suffering from large bone defects, non-unions, articular cartilage defects, and osteoarthritis.

OPPORTUNITIES

Global Health Biotech is seeking commercialization partners for the technology.

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NEGATIVE PRESSURE WOUND THERAPY (NPWT) – WITH INNOVATIVE APPLICATION: WALL SUCTION

TECHNOLOGY DESCRIPTION

Negative pressure wound therapy (NPWT), also called vacuum-assisted wound closure, is a medical treatment method used for the management of acute and chronic wounds. With the aid of layers of foam, special dressing sealed over the wound and gentle application of suction (negative pressure), fluids and infectious bacteria from the wound are drawn out to improve wound healing. This method is usually recommended for, among others, the treatment of surgical wounds, traumatic wounds, burn wounds, pressure, and diabetic ulcers. NPWT improves wound healing by reducing the risk of potential infections, decreases local tissue swelling, optimizes blood flow in the wound bed and promotes the growth of new tissue.

Currently, in South Africa and resource-limited countries, NPWT is not applied to patients in need due to the high costs associated with the treatment modality. SINAPI Biomedical has developed an affordable and flexible NPWT system with improved suction, that can either be mobile or static (mounted to the wall).

The Sinapi NPWT system has undergone clinical testing and was successful in treating wounds through the application of negative suction. Indications for applying the NPWT include laparotomy wound sepsis, thoracotomy wound sepsis, open abdomen post-damage control surgery and soft tissue wound post-major debridement.

BENEFITS

The Sinapi NPWT system provides flexibility in that it can be mobile and static. The system is more affordable and also results in cost saving for the hospitals/treatment facility. In clinical settings the team was able to prove the following:

- The Sinapi NPWT system achieved wound closure similar to that of competitor products currently available.
- The Sinapi NPWT system achieved wound closure by either applying wall suction or suction from the mobile pump. The application of wall suction is unique to the Sinapi NPWT system.
- By using the Sinapi NPWT system, the hospital saw a net saving of over 70% for wound treatment (cost excludes hospital stay, operating theatre visits and labour costs).

CURRENT STATUS

- The technology is fully developed.
- Version 1 is currently being marketed and sold in South Africa.
- Industrialization of the improved version is underway - injection molds for components of the new designs are currently being validated.

INTELLECTUAL PROPERTY

The IP lies in the design and improved functionality of the NPWT system.

OPPORTUNITIES

SINAPI is currently seeking investors and commercial partners for the technology.

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WITS - DNA LIBRARIES OF CORONAVIRUS SARS-COV-2 VARIANTS

Production with rapid turn-around time to generate libraries of complete coverage of the SARS-CoV-2

TECHNOLOGY DESCRIPTION

In a background of molecular diagnostic methodology to detect bacterial and viral diseases, verification material is an essential component required for successful implementation in a health system. A nucleic acid of known sequence is required to confirm that all steps of the process function correctly, at the level of staff training, sample collection, workflow and diagnostic procedure. In the early stages of the Covid-19 pandemic, these nucleic acid sequences were made publicly available, benefitting worldwide efforts to control the disease. However, over time it became evident that mutations in these initial targets led to incorrect diagnostic outcomes. Subsequently, commercial assays were brought to market that targeted sequences elsewhere on the 30 kb SARS-CoV-2 genome. The novel product described here aims to produce verification material for SARS-CoV-2 variants as they arise, and to cover the entire genome where target sequences of diagnostic assays are not known. It has been successfully used to generate libraries for the wild type, beta, delta and omega variants. The methodology will be applicable to other disease-causing organisms and variants as they arise.

BENEFITS

The absence of the pathogen itself in the control materials has benefits in avoiding exposure of laboratory and hospital staff. The approach taken allows for production in several formats. Nucleic acid sequence can be supplied as naked DNA, as packaged DNA, or as packaged RNA. These all produce the diagnostic output as expected from the presence of the pathogen. By producing material as libraries rather than complete genomes, accidental reconstitution of pathogenic nature is avoided.

Additionally,

- The product series is stable at room temperature and can easily be deployed in resource limited settings.
- The approach can be modified for any other bacterial or viral disease and, thus, is an excellent tool to enhance pandemic readiness.
- New derivatives can be developed with a quick turn-around time, with rapid move to market.

CURRENT STATUS

- Construction and verification of full coverage SARS-CoV-2 library for use as a universal control is complete.
- Methodology for production of Virus-Like Particles (VLPs) for SARS-CoV-2 successfully tested for HIV and HCV, before moving to SARS-CoV-2 for expression as VLPs.
- The production methodology is ready for commercial scaling.

INTELLECTUAL PROPERTY

- Patent registration in progress.

OPPORTUNITIES

The team is seeking commercial partners to implement the controls and related new products internationally.

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A SMART-SCREENING DRUG DISCOVERY PLATFORM FOR MALARIA ELIMINATION

TECHNOLOGY DESCRIPTION

The South African Malaria Transmission-Blocking Consortium (SAMTC) has developed the Drug Discovery For Malaria Elimination platform (DMEP) to identify and develop compounds that will kill the sexual stages of *P. falciparum*, which are transmitted to the *Anopheles* vector. The DMEP includes *in vitro* assays targeting different biological endpoints to detect activity of compounds against gametocytes and gametes. A standard membrane feeding assay has also been established to evaluate the *in vivo* effect of compounds against the development of oocysts and sporozoites in African mosquito vectors. Clinical isolates from patients with currently circulating *P. falciparum* parasite strains provide a resource for evaluating potential resistance against lead compounds.

VALUE PROPOSITION

An *in vitro* platform for use in identifying transmission-blocking antimalarial compounds for use in malaria elimination strategies.

BENEFITS

The SAMTC has designed a unique, 3-tiered smart screening platform to be used as a road map for screening transmission-blocking antimalarial compounds. The combined expertise within the SAMTC has clearly placed it as a main international role player in the field and a reference for interrogating large compound libraries. The SAMTC has built capacity and trained a core group of young scientists in cutting-edge technologies in the malaria field. In addition, this geographically centralized consortium in a malaria-endemic African country, with access to malaria patients and African *Anopheles* vector species, places the group in the unique position of being able to interrogate all stages of the parasite life cycle. It is anticipated that the SAMTC will contribute significantly to the global malaria elimination agenda by spearheading the identification, prioritization, and development of a new generation of validated compounds with a target candidate profile that will block transmission of the parasite to the vector and prevent the spread of the disease.

OPPORTUNITIES

The SAMTC is looking for partnerships for the screening and identification of transmission-blocking antimalarial compounds.

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