

#### 4<sup>th</sup> Swiss Symposium in Point-of-Care Diagnostics held at the Davos Conference Center on 21 October, 2021

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**Abstract:** After last year's successful online symposium, the 4<sup>th</sup> edition of the Swiss Symposium in POC Diagnostics gathered more than 150 participants from medicine, industry and science as well as from different European countries to meet at the Davos Conference Center for an exciting program with 13 expert speakers, a poster session and a product & technology exhibition. The mandatory COVID-certificate to access the event has allowed people to meet (again at last!), network and share their views and success stories in the field of POC Diagnostics that continues to be propelled by digitalization, new technological possibilities, user needs and the COVID-19 pandemic.

**Keywords:** Blood protein biomarkers · Bovine meat and milk factors (BMMF) · Cancer · Diabetes technology · Ergonomics · High-sensitivity Troponin I · Nanomechanical measurements · Novel class of cardiac agents · Sexually transmitted diseases (STD) · Skin barrier integrity · Traumatic brain injury (TBI)

The following topics were covered by the speakers from medicine, science and industry:

#### 1. Point-of-care Analyses of Skin Barrier Integrity by Electric Impedance and its Implications for Skin Diseases

Allergic and autoimmune diseases of the skin, mucosa, and deep tissues have seen a huge rise during the last 60 years affecting more than one billion people worldwide. **Prof. Cezmi Akdis**, Director of the Swiss Institute of Allergy and Asthma Research (SIAF) in Davos, reminded during his symposium kick-off speech that “intact skin and mucosal barriers are crucial for the maintenance of tissue homeostasis, and they protect host tissues from infection, environmental toxins, pollutants and allergens”. In fact, bacteria, fungi, viruses, laundry and dishwasher detergents, household cleaners, cigarette smoke, particulate matter, diesel exhaust, ozone, microplastic, *etc.* can all damage the epithelial barrier. At the SIAF a method was established to directly assess the *in vivo* status of the epithelial barrier by electrical impedance spectroscopy (EIS), for early diagnosis, prediction of disease and lesion development and evaluation of skin barrier response to treatment (Fig. 1). When the Nevisense device interrogates the skin – quasi at point-of-care – small electrical signals at different frequencies can reveal irregularities below the skin surface caused by barrier defect and tumors. EIS and transepidermal water loss (TEWL) were measured in both lesional and non-lesional skin of atopic dermatitis (AD) patients and healthy controls. EIS showed a very good diagnostic ability to discriminate between AD patients and healthy

controls. The EIS scores also correlated well with clinical healing during therapy at the hospital and correlated inversely with protein biomarkers significantly upregulated in serum of patients and associated to inflammatory pathways that may influence the epithelial barrier. “In the clinical context, EIS could help in the assessment of progression and severity of AD, for the evaluation of the therapy efficacy and for the identification of patients at risk or relapse”, concluded Prof. Akdis his sound and captivating presentation.

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Fig. 1. Close-up view of the first version of the EIS sensor for the direct assessment of the skin epithelial barrier *in vivo* status. Photo by Cezmi Akdis (SIAF).

#### 2. Driving the Translation from Ideas towards Products in Diabetes Technology

The global prevalence of diabetes continues to increase beyond the 463 million of adults estimated for the year 2019. “The International Diabetes Federation (IDF) estimates that there will be 578 million adults with diabetes by 2030”, emphasized **Derek Brandt**, CEO of the Global Center for Technology Innovation in Diabetes in Bern (DCB). “The DCB is a private, independent Swiss foundation that aims at reducing the burden of diabetes on those affected by it and supports the development of solutions to make treatments fully automated”, explained Mr. Brandt. The DCB bridges gaps between translation research, technology (product) development, open innovation, entrepreneurship, clinical trials and funding. Glucose meters and multiple daily insulin injections with pens and syringes still constitute the majority of tools used in diabetes healthcare. Insulin pumps with a subcutaneous cannula and a (patch) pump allow a programmable basal insulin rate combinable with a manual delivery at meals. This helps with reducing glycemic variability and hypoglycemia. Automated insulin delivery systems (AID), so-called ‘closed-loop’ systems, combine glucose sensing with insulin delivery which are very effective at maintaining glucose target ranges as clinical studies have shown. Remarkable is the Open Artificial Pancreas System (OpenAPS) developed quasi ‘do-it-yourself’ by Dana Lewis, a Seattle-based young woman with type-1 diabetes, who was tired waiting for others to come up with a solution. As of May 2021, more than 2300 individuals worldwide use such OpenAPS closed-loop solutions which were shown to increase the average time within target glucose range and a reduction in hemoglobin A1C (HbA1c) values. The Headwind Drive Simulator is one example of translational research conducted at the DCB in collaboration with the Insel Hospital Berne, department of Diabetes, Endocrinology and Metabolism (UDEM). The ‘Headwind’ is a hypoglycaemia

warning system for the prevention of road traffic accidents that uses continuous analysis of vehicle data and artificial intelligence. Mr. Brandt concluded his stimulating talk by quoting Steve Jobs: “Innovation is the only way to win!”.

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### 3. Biomarkers of Traumatic Brain Injury – The Biggest Challenge of Brain Biomarker Diagnostics?

Traumatic brain injury (TBI) is a major public health concern, with an estimated 50 million new victims annually worldwide and costs possibly exceeding 500 billion Euro per year in Europe alone. Falls (elderly!), sports and vehicle accidents, aggression and war are among the major causes for TBI. Keynote speaker **Prof. Olli Tenovuo**, Head of the Turku Brain Injury Centre at the University of Turku in Finland (Fig. 2), stated: “The varying types and magnitudes of head impacts, inter-individual variability, differing biomarker kinetics and injury dynamics and unique anatomical conditions (*cf.* blood–brain barrier, glymphatic system, *etc.*) as well as brain complexity makes it very challenging to develop biomarker based diagnostic tests”. Thus, effective tools are missing to rule out the presence of TBI, assess true severity, identify ongoing pathophysiological processes, monitor reliably treatment efficacy, and to make accurate outcome predictions. Despite the undeniable importance of the brain and its injuries, many – especially mild, yet significant – TBIs remain undiagnosed. Biomarkers such as microRNAs, metabolites and proteins have been studied over the years, many of the latter showing rapid (*e.g.* the calcium binding protein S100 $\beta$  and glial fibrillary acidic protein, GFAP, within hours) serum increases and decreases during the acute phase while others (*e.g.* neurofilaments, NF) including inflammatory markers rise and decline within weeks and months later during the subacute phase. “A POC diagnostic device capable of measuring reliably a panel of biomarkers and connected to a central database, would be a very useful tool for physicians and especially neuro-traumatologists”, Prof. Tenovuo concluded. “Measuring biomarker serum concentrations at multiple time-points, as early as at the accident site, upon arrival at the hospital and hours and days later would likely provide clinically very useful data”, he explained. “A single measurement after the injury may lead to false conclusions. Blood-based biomarkers have a realistic potential to revolutionize almost everything in clinical TBI medicine, but the greatest challenges are to find the best panels for different clinical questions and to validate them for clinical practice. And here a smart POC diagnostic solution would be an important enabling tool in the toolbox”, summed up Prof. Tenovuo his exciting keynote lecture.

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Fig. 2. Left: Prof. Harald zur Hausen inspiring the audience during his keynote lecture in Davos on the epidemiology and links of BMMF and their role in human cancers. Right: Keynote speaker Prof. Olli Tenovuo from the University of Turku in Finland presenting the challenges and opportunities in traumatic brain injury (TBI) diagnostics. Photos by Sara Foser (Foto Fetzter).

### 4. A Vital Leap Forward in Cardiac Testing: Expediting the Diagnosis and Risk Stratification of Chest Pain Patients with High-Sensitivity Troponin I at the Point-of-Care

Cardiovascular disease is still the no. 1 cause of death globally: 17.7 million people die every year from CVDs, an estimated 31% of all deaths worldwide. But only 10% of patients who go to the emergency department (ER) with chest pain are actually experiencing a heart attack. So, crowded ERs with 90% of the patients unnecessarily occupying beds and clinician time put pressure on quick and reliable diagnosis. There is also a strong correlation between increased length of stay and poorer patient outcome. “We can address this and reduce costs (associated with a longer length of stay) with improved efficacy by using rapid diagnostic strategies and more specifically high-sensitivity cardiac Troponin I (hs-cTnI) assays”, explained **Dr. Friederike Rhein** and **Dr. Max Kuhne** from Siemens Healthcare. High sensitivity means that these tests must be able to detect cTn in at least 50% of healthy individuals and must have <10% CV at 99<sup>th</sup> percentile of normal. As opposed to contemporary tests that measure ng/mL concentrations, hs-cTnI assays can reliably detect pg/mL cTnI concentrations. “Doing this with the Atellica VTLi hand-held/portable immunoassay system (Fig. 3) from a finger prick in less than 8 minutes is a game changer” continued Dr. Rhein and Dr. Kuhne. “It helps separating those in immediate need of care from those who are not, by timely putting accurate results in the hands of the ER staff.” Indeed, by side-by-side comparing and visualizing the workflows and processes – current versus new – the Siemens speakers made a strong case for POC diagnostics: Improved speed/throughput, fewer steps, elimination of sample transport, mitigation/reduction of medical errors and last but not least reducing patient anxiety. What was particularly appreciated was the concluding expert discussion that included the involvement of the first customer, **Manuel G. Burkert** from the Schön Clinic in Hamburg. During the interesting discussion with the audience different opinions were expressed, and it became clear that not only product innovation, but also clinical adoption are processes that take time and need additional evidence. As Mr. Burkert stated at the end of this inspiring Special Innovation Talk, actual progress in medicine requires physicians to stay open-minded and interested in new diagnostic solutions.

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Fig. 3. Atellica VTLi hand-held POC diagnostic system with sample preparation cartridge for high-sensitivity cardiac Troponin I (hs-cTnI) measurements in patients suspected of having experienced a heart attack. Photo by Friederike Rhein (Siemens Healthcare).

### 5. Nanomechanical Measurements of Tissues *in situ* for Diagnosis and Treatment Optimization of Solid Tumors

Mechanical properties of cancer cells and their microenvironment play a critical role in cancer invasion, progression and immune cell infiltration. Mechanical alterations on the (sub-)cellular (nanoscale) level in cancer are potentially suitable markers of cancer aggressiveness and therefore might help to optimize cancer diagnosis and orientate therapy choice. **Dr. Marija Plodinec**, CEO of ARTIDIS AG highlighted in her presentation: “We founded ARTIDIS based on the many years of work at the University of Basel using Atomic Force Microscopy to study nanomechanical

cal properties of soft biological tissues. We developed a novel platform, which harnesses the power of nanotechnology and advanced analytics. The platform consists of the ARTIDIS device for nanomechanical measurements combined with the digital data platform ARTIDISNET which enables reproducible measurement in the clinic". ARTIDIS measurements can increase the overall number of patients eligible for targeted treatments, identify the non-responders to become responders and measure which patients after radiation and chemotherapy will respond to immuno-, targeted, and cell therapy. "Soft cells navigate more easily through the basement membrane (BM) and fibrillar matrix" explained Dr. Plodinec, "and carcinoma associated fibroblasts (CAFs) remodel BM and collagen I matrix to promote invasion of soft cells". ARTIDIS accompanies every step of the cancer journey, from diagnosis through all treatment lines. It provides a nanomechanical score (NS) that is based on more than 5 million nano-palpations per tissue type, 10'000 measurements per specimen and is exceeding 128 analysed nanomechanical parameters that can be compared to more than 180 clinical parameters per patient. ARTIDIS' clinical focus is on breast, lung and pancreatic cancer. In a first clinical validation study the ARTIDIS nanomechanical profiling was compared to pathohistological gold standard analyses and diagnosis. The biomarker validation primary endpoint (*i.e.* distinguishing benign vs. malignant specimens) with 100% sensitivity and 90% specificity were met. "There are countless applications of the ARTIDIS nanotechnology platform beyond oncology where characterization of living tissue under physiological conditions provides new insights for actionable health information", concluded Dr. Plodinec her convincing and impressive talk.

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## 6. Testmate – A Rapid Self-test for Sexually Transmitted Diseases that Provides Results in Minutes, Supported by Digital Health

Self-care interventions are among the most promising new approaches to improve health and well-being, with the WHO creating guidelines to support innovation in this domain. However, testing for sexually transmitted diseases (STDs) today still takes a minimum of 3 days and requires the user to post or drop-off samples at a laboratory for processing. Testmate Health is developing a urine based multiplexed self-test for the four common STD (chlamydia, gonorrhoea, trichomonas and mycoplasma genitalium) that provides results directly at home in minutes (Fig 4.). "The user is guided through the test with a paired smartphone app and captures the result at the end of the test, allowing the user to be connected to a healthcare professional in the case of a positive results", explained **Dr. Siew-Veena Sahi**, CEO of Testmate Health. "The technological challenges in self testing are 1) the pathogen concentration step, 2) maintaining a constant temperature across the reaction chamber, 3) sample aliquoting in multiple reaction chambers and 4) a robust colorimetric read-out, resulting in an easy-to-use and scalable disposable", complemented **Dr. Vincent Revol**, the CSEM project and product development partner. Testmate Health aims to finalize prototype development and aims to start pre-clinical studies in 2022. After clinical studies and industrialization ramp-up, market approval in Europe and the United States are planned for 2025. "Clearblue changed the way we test for pregnancy. We want to do the same for STDs", concluded Dr. Sahi an exciting talk on a promising future application.

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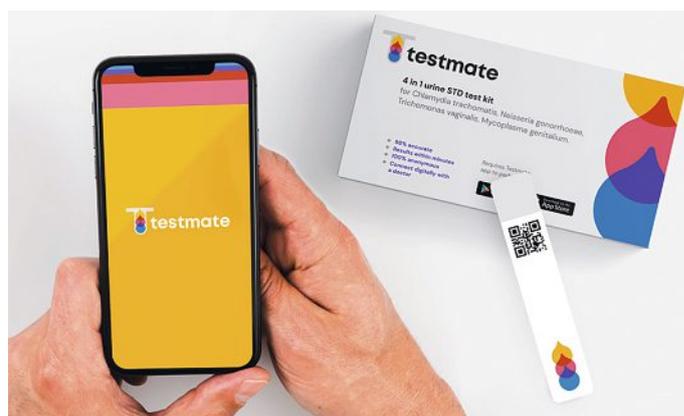


Fig. 4. A urine-based multiplexed self-test in development by Testmate Health for the detection of four common sexually transmitted diseases (STD) that provides results directly at home in minutes. Photo by Siew-Veena Sahi (Testmate Health).

## 7. Detection of Blood Protein Biomarkers Relevant to Mild Traumatic Brain Injury (mTBI): Towards a Point-of-Care Application

Based on the severity of the condition TBIs are typically classified as mild (GCS 13–15), moderate (GCS 9–12) and severe (GCS 3–8), using the Glasgow Coma Scale (GCS), which is an assessment of conscious level of the patient motor, eye, and verbal responses. "Mild TBI (mTBI or concussion) accounts for 70–85% of TBI and it is particularly challenging to diagnose due to the frequent lack of well-pronounced post-injury symptoms. However, if left untreated mTBI (especially when repetitive) can lead to serious long-term implications, including cognitive and neuropathological disorders" emphasized **Dr. Milica Jovic**, senior research scientist in the Diagnostic Systems research group at the HES-SO Valais-Wallis in Sion, in her introductory words. Presently, the diagnosis of mild TBI is based on patients' history, clinical findings, and neuroimaging tools, which are costly, require well-trained personnel and are difficult to adapt for on-site measurements. As highlighted during the morning 'medical needs' session by Prof. Tenovuo, alternatively, mTBI diagnostics can be achieved by detection of mTBI biomarkers from patients' blood. A minimally invasive multiplexed detection device that would provide rapid and reliable detection of mTBI biomarkers at the point-of-care would meet a significant medical need, to enable an accurate, inexpensive diagnosis, and fast decision-making in the treatment of mTBI. Dr. Jovic presented in her talk a novel sensor concept that could be a key to a future portable POC diagnostic device for mild TBI (Fig. 5). New devices and biomarkers have in recent years come to the market, including Abbott's FDA-approved i-STAT TBI plasma POC system that measures the concentration of the biomarkers Ubiquitin C-terminal hydrolase L1 (UCH-L1) and GFAP, but a diagnostic solution that truly meets all requirements has yet to come. The BRIDGE DISCOVERY funded ongoing project aims to address this three-fold: the combination of an improved biomarker panel established in Prof. Sanchez's group at the University of Geneva, a sensitive multiplex assay developed in the group of Prof. Pfeifer at the HES-SO Valais-Wallis and a smart electrode fabrication and integrated cartridge solution conceived in the laboratory of Prof. Passeraub at the HES-SO Geneva, can possibly become a game changer in TBI diagnostics. "Our preliminary results with a 3-plex assay on a demonstrator system are very encouraging, but there are still important improvements necessary and loose ends to be tied before we can systematically evaluate the system with TBI patient samples", resumed Dr. Jovic her excellent talk.

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### 8. The Contribution of Ergonomics to the Evaluation and Design of POCT Systems (Usability, Safety and Acceptability)

The development of mobile technologies, especially diagnostic, to improve medicine at the point of care is quickly expanding; both among health professionals and among non-expert users. These technologies have many advantages: the diagnostic tests can be performed in any location, they provide an immediate result, they do not require complex laboratory equipment, they can be used by a wide range of users, *etc.* Most of the time, POC(T) systems are developed by scientists and engineers active in specialized research groups and in vitro diagnostic (IVD) companies. “While the analytical and clinical performances of these various tests are key, the technical and medical characteristics of these systems are not sufficient to guarantee their safe use and acceptance, if ergonomic characteristics and user needs are not or inadequately taken into account during design and development”, **Prof. Javier Barcenilla** from the University of Lorraine in France explained. In his presentation he focused on how ergonomics can bring solutions to the design and evaluation of these technologies to improve their degree of appropriation, *i.e.* how an individual personally invests in the object or system and to what extent it makes him/her want to act upon it. By presenting several case examples Prof. Barcenilla underlined the context of use of such POC diagnostic devices, the degree of integration into a workflow and user activities and how it contributes to transforming these activities. Insofar this relevant talk joined nicely the user-centered product aspects described in the presentation by Dr. Rhein and Dr. Kuhn from Siemens earlier in the afternoon.

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### 9. Epidemiology and Links of Bovine Meat and Milk Factors (BMMFs) and their Role in Human Cancers

Early studies on global incidences of colon and breast cancer suggested a remarkably similar frequency of these cancers for most regions globally. “The initial suggestion by Sugimura and his colleagues in Japan, that chemical carcinogens arising during broiling, barbecuing and roasting of ‘red meat’ were responsible for the increased risk in particular for colon cancers (CRC) did not answer the question, whether this consequence resulted generally from red meat consumption or whether specific types of red meat are particularly risky”, Nobel Laureate **Prof. Harald zur Hausen** from the German Cancer Research Center (DKFZ) (see Fig. 2 and 6) emphasized at the beginning of his keynote lecture. “Therefore, we analyzed published epidemiological data on prevalent types of red meat consumed in CRC high and low risk countries”, he continued. Results of these initial analyses pointed to a special risk linked to consumption of beef from Eurasian dairy cattle. The population in a country with the lowest rate of CRC (India) had globally the lowest rate of beef consumption. Even a country with a high rate of red meat consumption (Mongolia) had remarkably low incidences of CRCs and breast cancers. Although beef consumption is

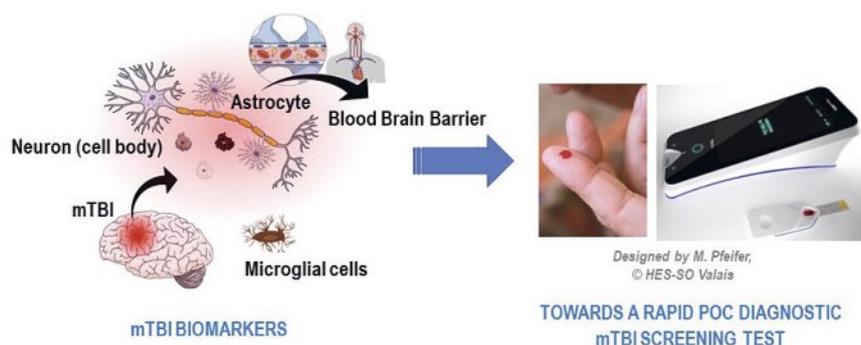
relatively common in Mongolia (fried, grilled or air-dried), it originates from different species of cattle (Yaks or Zebu crossbreeds). “This resulted in our hypothesis since not all cattle breeds carry the respective risk factors, a species-specific infection may play a role”, Prof. zur Hausen explained. With the aid of veterinarians from the University of Leipzig, his research group received sera from 120 cows. These sera (and of commercially available dairy products) were analyzed for the presence of single-stranded circular DNA, based on preceding work with human TT viruses. A new class of infectious agents, ‘Meat and Milk Factors’ BMMFs, were identified and characterized (detailed in the presentation by E.-M. de Villiers). Monoclonal antibodies generated against a specific protein (Rep) of a BMMF1, H1MSB.1 led to the identification of BMMFs in a large number of CRCs, but also in breast and prostate cancer biopsies. “As an initial surprise, we did not discover BMMF components within the cancer cells, but in adjacent CD68-positive macrophages and interstitial cells”, highlighted Prof. zur Hausen the facts. This supported the hypothesis that inflammatory reactions, initiated by BMMF/macrophage interactions *via* production of oxygen radicals, exert mutagenic activity in replicating progenitor cells of these cancers (without persistence of BMMF in malignant or premalignant cells). Thus, this suggests that BMMF mainly act as infectious indirect carcinogens. 8-Hydroxy guanosine was detectable around BMMF-positive foci, as indicator for reactive oxygen mutagenic activity. “At this stage, our studies resulted in the identification of a novel class of zoonotic infections characterized by their ability to induce chronic inflammatory reactions, which eventually (commonly after several decades) may result in malignant growth. Since we previously reported links of such infections to additional cancers, chronic neuropathies and type 2 diabetes mellitus, this requires novel approaches in prevention and therapy of very common severe diseases of hitherto unknown etiology”, concluded Prof. zur Hausen his awe-inspiring keynote presentation in front of young and old symposium participants, impressed and inspired by the exploratory thoroughness of his research and his tireless drive to uncover the unknown.

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Fig. 6. Keynote speakers Nobel Laureate Prof. Harald zur Hausen and Prof. Ethel-Michele de Villiers from the DKFZ with the symposium chairs. Photo by Sara Foser (Foto Fetzter).

Fig. 5. Cell-type specific biomarkers released during a (mild) traumatic brain injury (m)TBI could be rapidly measured with a future portable POC diagnostic device both by first responders on-site of an accident and by healthcare professionals during subsequent medical check-ups, respectively. Graphic by Milica Jovic, device designed by Marc Pfeifer and MADI (HES-SO Valais-Wallis).



## 10. A Novel Class of Infectious Agents Linked to Colon, Breast and Prostate Cancers. Characterization of the Respective Agents

Bovine meat and milk factors (BMMF) were initially identified by density gradient centrifugation of bovine sera from 120 German dairy cows. “DNA was isolated from individual fractions and single fragments cloned and sequenced”, Prof. *Ethel-Michele de Villiers* from the DKFZ (Fig. 6) explained during her keynote speech. Inverse PCR was applied to isolate small circular DNA molecules. Subsequent *in silico* analyses of these molecules resulted in the identification of a novel class of infectious agents sharing characteristics of both known viruses, as well as bacterial plasmids. The isolates were phylogenetically grouped into BMMF 1 and BMMF2. A larger set of PCR primers were then applied on rolling circle amplified DNA in order to identify additional members of these groups. More than 120 individual isolates of BMMF1 and BMMF2 were obtained by screening a number of dairy products. “We also analyzed biopsies from Multiple sclerosis brain and -serum and here indeed we obtained 2 BMMF1 isolates from the MS brain”, Prof. de Villiers continued. Satellite-type small plasmids with partial homology to larger genomes were also isolated in both groups. Identification of a larger putative replication gene in all isolates allowed for the generation of antibodies against this protein. These antibodies were used to identify the presence of the Rep protein in biopsies from a series of human tissues. “By using laser dissection microscopy (LMD), we could recover several copies of the DNA genome of one BMMF1 isolate, H1MSB.1, from the lamina propria of peritumoral colon tissue”, Prof. de Villiers further explained. Sequence analyses of these isolates identified modifications from the original H1MSB.1 isolate which also resulted in modifications of the putative open reading frames (ORFs). *In vitro* studies are now needed to clarify the biological consequences of these modifications. “Similar studies are ongoing for pancreas, prostate and breast cancer”, Prof. de Villiers concluded an impressive and sound keynote lecture.

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One of the invited speakers, Dr. med. dent. Miodrag Savic from the University Hospital Basel was unfortunately not able to come to Davos, but we hope that he may give his talk at the upcoming 5<sup>th</sup> edition of the SWISS SYMPOSIUM in Point-of-Care Diagnostics that will take place on 20<sup>th</sup> of October 2022 at the new FHNW Campus in Muttenz. The title of his presentation

‘From management of pandemics to medical innovation, a recurring problem’, we speculate, will still be topical next year!

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Fig. 7. Group photo with speakers and chairs (top, left to right): Dr. F. Rhein, Siemens; Mr. D. Brandt, DCB; Prof. C. Akdis, SIAF; Dr. V. Revol, CSEM; Prof. M. Pfeifer, HES-SO Valais-Wallis, Co-Chair; Mr. M. Caduff, Head of the Department for Economic and Social Affairs, Kanton of Graubünden; Dr. M. Kuhn, Siemens; Mr. M. Burkert, Schön Clinic Hamburg; (bottom, left to right): Dr. J. Weber, BÜHLMANN Laboratories, Session Chair; Dr. S.-V. Sahi, Testmate Health; Prof. O. Tenovuo, University of Turku; Dr. S. Paoletti, CSEM, Chair; Nobel Laureate Prof. H. zur Hausen, DKFZ; Prof. E.-M. de Villiers, DKFZ; Prof. B. Schnyder, HES-SO Valais-Wallis; and Dr. M. Jovic, HES-SO Valais-Wallis). Not on photo: Dr. M. Plodinec, ARTIDIS; Prof. J. Barceñilla, University of Lorraine and Prof. D. Meinel, FHNW, Session Chair. Photo by Samantha Paoletti.



Fig. 8.: David Schmid (left), representative of the scientific poster jury handing over the best poster award to winner Benjamin Ricken. Networking during the technology and product exhibition. Photos by Samantha Paoletti and Sara Foser (Foto Fetzer).

