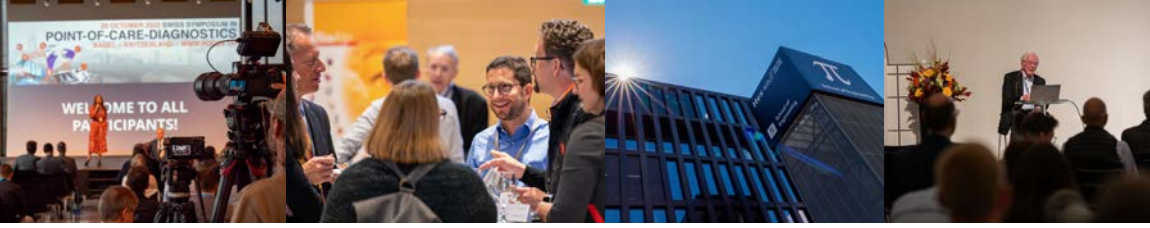

25/26 OCTOBER 2023 SWISS SYMPOSIUM IN POINT-OF-CARE DIAGNOSTICS

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WELCOME LETTER

Bienvenue à Sion!
Willkommen in Sitten!
Welcome to Sion!

Dear Symposium Participants

It is our great pleasure to welcome you to the **6th Swiss Symposium in Point-of-Care Diagnostics** taking place on the 25th and 26th of October 2023 here at the bustling and dynamic ENERGYPOLIS campus in Sion, home to the School of Engineering of the University of Applied Sciences and Arts Western Switzerland (HES-SO Valais-Wallis), the EPFL Valais, and the Ark Foundation.

Innovation can only take place with financial means and with regulatory approval. This is why the **Regulation & Investment** Day with experienced professionals, including the "Investing in POCDx" roundtable discussion, has become an integral part of this year's event.

Medical diagnostics and more specifically point-of-care testing (POCT) is a fundamental pillar of healthcare with all its facets. This will be reflected by the various contributions from this year's 12 expert speakers of the **Healthcare & Innovation** Day. And *decentralized testing* indeed assumes a whole new dimension in the context of future exploration spaceflight missions: We are thrilled to have **Prof. Benjamin Easter** from **NASA** and the **University of Colorado** (USA) give us an inspirational insight on this non-everyday topic in his keynote lecture.

Explore innovative companies' **exhibition stands** and engage with start-ups to discover new products and solutions. Connect with **poster** presenters to learn about their smart ideas and research results.

We extend our heartfelt thanks to our generous sponsors, whose invaluable support made this symposium possible and advance point-of-care diagnostics.

Join us for these educational and exciting days to deepen your POC Dx knowledge and network. We are delighted to have you here!

Sincerely yours

Silvia Anghel, Didier Maillefer, Samantha Paoletti, and Marc Pfeifer

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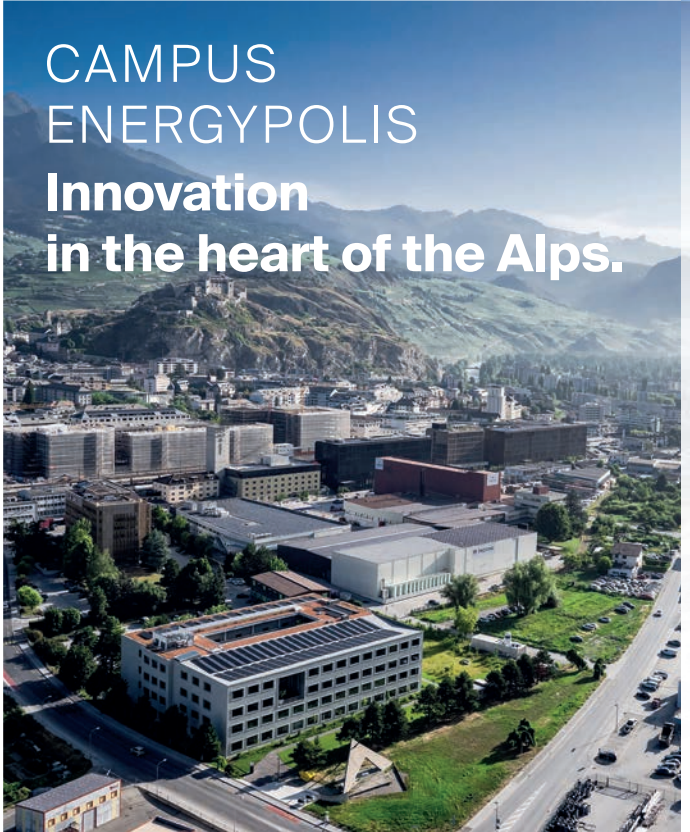

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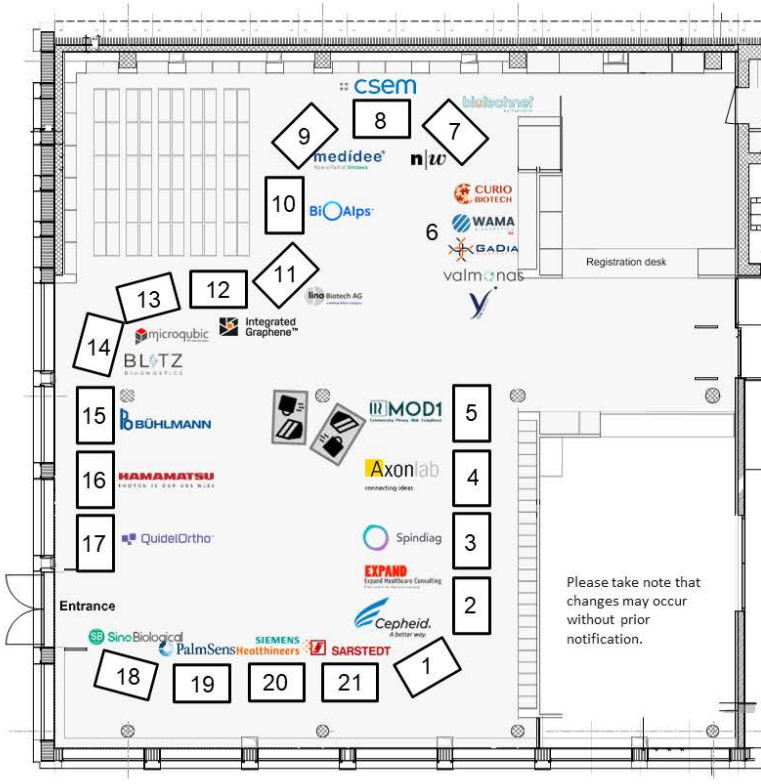
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SCIENTIFIC PROGRAM

Day 1 : 25th of October 2023 – 13:00 to 17:00

12:00	**Registration & Coffee**
13:00	**Welcome Message** **Prof. Didier Maillefer & Dr. Silvia Anghel** Symposium Chairs | HEIG-VD & Medidee, Veranex
	Regulation Session Session Chair: **Dr. Silvia Anghel** Symposium Chair | Medidee, Veranex
13:25	**Opportunities in filling data gaps for legacy product** **Dr. Julianne Bobela** Senior Consultant | Medidee, Veranex
13:40	**POCDx: What is special in the assessment of the design, usability and performance? Lessons learned from the first conformity assessment** **Dr. Laura Scrivano** Team Leader | TÜV SÜD Product Service
13:55	**Interoperability and compatibility: challenges when using POCDx** **Mr. Kim Rochat** Senior Vice President - Regulatory Clinical Quality | Medidee, Veranex
14:10	**Manufacturer's experience on the conformity assessment process under IVDR** **Dr. Iwan Märki** CTO and Co-Founder | Abionic
14:25	**Q&A on Regulatory** **All speakers**
14:40	**Break**
	Investment Session Session Chair: **Dr. Benjamin Ricken** Head of Point of Care and Self Testing Development | BÜHLMANN Laboratories
15:10	**Introduction to the investment topic and introduction of the panel** **Dr. Benjamin Ricken** Head of Point of Care and Self Testing Development | BÜHLMANN Laboratories
15:20	**Manufacturer's experience on the search of investment** **Dr. Vincent Zwaans** COO | Loop Medical
15:35	**Round Table: Investing in POCDx - Industry Trends and Investor Activity** **Dr. Andreea Wiese** Head of Partnering for Point of Care | Roche Diagnostics **Dr. Vincent Zwaans** COO | Loop Medical **Mr. Frédéric Gabriel** CEO | Carity
	Wrap-up discussion Session Chair: **Dr. Silvia Anghel & Dr. Benjamin Ricken**
16:05	**Discussion with experts and representatives**
16:35	**Closing remark** **Prof. Didier Maillefer** Symposium Chair | HEIG-VD
16:45	**Apéro & Networking**
19:00	**Dinner** (registration on www.pocdx.ch/registrations required)

Day 2: 26th of October 2023 – 10:00 to 18:00

9:00	**Registration & Coffee**
10:00	**Welcome Message** **Prof. Gaëtan Cherix** Director | School of Engineering, HES-SO Valais-Wallis **Prof. Marc E. Pfeifer & Dr. Samantha Paoletti** Symposium Chairs | HES-SO Valais-Wallis & CSEM
	Medical Needs Session Session Chair: **Prof. Daniel Paris** Medical Director and Head, Department of Medicine | Swiss Tropical and Public Health Institute
10:30	**Implementation of a point-of-care test in Swiss primary care: the example of procalcitonin** **Dr. Yolanda Müller** Senior lecturer | Center for Primary Care and Public Health (Unisanté), University of Lausanne
10:50	**POCT ISO 15189 accreditation in a hospital setting: Opportunities & Challenges** **Dr. Bettina Schmid** Institut für Labormedizin | Kantonsspital Aarau
11:10	**Break | Exhibition & Poster Session**
12:00	**Point of care diagnosis in mountain emergency medicine** **Dr. Pierre Métrailler** Head of the Rescue Service | Air Glaciers
12:20	**The impact of Oxford nanopore sequencing on clinical genetic testing** **Prof. Alexandre Kuhn** Professor | HES-SO Valais-Wallis
12:40	**Symposium Photo | Lunch Break | Exhibition & Poster Session**
	Product Innovation Session Session Chair: **Dr. Rainer D. Jäggi** Chapter Lead, Blood Gas & Electrolytes System Development & Integration | Roche Diagnostics
14:20	**Closing the gaps of a fragmented patient's rehabilitation journey after a heart attack** **Mr. Frédéric Gabriel & Mr. Marcel Wüthrich** CEO | Carity & Head of Business Development & Pharma/Diagnostics Business | Evoleen
14:40	Short: **A multiplex immunoassay as a simplifier of transfusion-transmissible infection diseases screening on blood bank activities** **Dr. Carlos Alberto Mestriner** COO | WAMA Diagnostics Switzerland
14:50	Short: **Can a rapid and easy test improve the management of Cervical cancer?** **Mr. Percevent J Ducrest** CEO | Gadia Diagnostics
15:00	**Break**
	Enabling Research & Technologies Session Session Chair: **Prof. Jean-Manuel Segura** Professor | HES-SO Valais-Wallis
15:20	**The role of POCT in diagnostic microbiology in Switzerland** **Dr. Alexis Dumoulin** Clinical microbiologist FAMH | Valais Hospital – Central Institute
15:40	**Electrochemical quantification of lateral flow rapid tests** **Dr. Thomas Maier** Research Engineer | Austrian Institute of Technology (AIT)
16:00	**Advancing Urinary Health Monitoring: fact-based nutrition for infants and lactating mothers** **Dr. Julia Kuligowski & Dr. Davide Migliorelli** Researcher | Health Research Institute Hospital La Fe (Spain) & Expert in Biosensing | CSEM
16:20	**Break**
16:45	KEYNOTE: **Prof. Benjamin Easter, MD, MBA** **Where is the Star Trek Sick Bay?: Maximizing Astronaut Health and Performance for Exploration Spaceflight Missions** NASA and University of Colorado School of Medicine
17:30	**Poster Award & Closing Words**
17:45	**Apéro riche & Networking**

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	Xpert Xpress CoV-2 *plus*	Rapid detection of SARS-CoV-2, the virus that causes COVID-19, with three gene targets in as soon as 20 minutes*	10	XP3SARS-COV2-10
	Xpert Xpress Strep A	Rapid detection of Group A *Streptococcus* DNA in as soon as 18 minutes*	10	XPRSTREPA-CE-10
	Xpert Xpress Flu/RSV	Rapid detection and differentiation of Flu A, Flu B, and RSV in as soon as 20 minutes^	10	XPRSFLU/RSV-CE-10
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	Xpert SA Nasal Complete	Pre-surgical testing of *S. aureus* and MRSA in about an hour	10 120	GXSACOMP-CE-10 GXSACOMP-120
	Xpert MRSA/SA BC	Detection of MRSA and *S. aureus* in positive blood cultures in about an hour	10	GXMRSA/SABC-CE-10
	Xpert MRSA/SA SSTI	Detection of MRSA and *S. aureus* skin and soft tissue infections in about an hour	10	GXMRSA/SA-SSTI-CE
	Xpert Carba-R	Detection and differentiation of KPC, NDM, VIM, IMP, and OXA-48 in 50 minutes	10 120	GXCARBARP-CE-10 GXCARBARP-CE-120
	Xpert Norovirus	Identification and differentiation of Norovirus GI and GII in less than 1 hour*	10	GXNOV-CE-10
	Xpert *C. difficile* BT	Detection of *Clostridioides difficile* infection with an independent call-out of binary toxin and differentiation of the 027 strain in around 45 minutes	10	GXCDIFFBT-CE-10
	Xpert *vanA/vanB*	Rapid VRE screening for active outbreak prevention and control in around 45 minutes	10	GXVANA/B-CE-10
TB & Emerging Infectious Diseases	Xpert MTB/RIF Ultra	Detection of *Mycobacterium tuberculosis* complex and Rifampin-resistance associated mutations in less than 80 minutes	10 50	GXMTB/RIF-ULTRA-10 GXMTB/RIF-ULTRA-50
	Xpert MTB/XDR	Detection of *Mycobacterium tuberculosis* complex and mutations associated with drug resistance towards Isoniazid, Fluoroquinolones, Second-Line Injectable Drugs and Ethionamide in less than 90 minutes, leveraging 10-color GeneXpert technology	10	GXMTB/XDR-10
	Xpert Ebola	Detection of Ebola Zaire virus in around 90 minutes	10 50	GXEBOLA-CE-10 GXEBOLA-CE-50
Blood Virology, Women's Health, & Sexual Health	Xpert CT/NG	Detection of *Chlamydia trachomatis* and *Neisseria gonorrhoeae* infections in about 90 minutes	10 120	GXCT/NGX-CE-10 GXCT/NGX-CE-120
	Xpert HPV	Detection of high risk Human Papillomavirus (HPV) — Identifies types HPV 16 and HPV 18/45; reports 11 other high risk types in pooled results in less than one hour	10	GXHPV-CE-10
	Xpert Xpress GBS	Intrapartum detection for Group B *Streptococcus* (GBS) during labor/delivery in approximately 30 minutes*	10	XPRSGBS-CE-10
	Xpert TV	Detection of *Trichomonas vaginalis* in male and female specimens in around one hour*	10	GXTV-CE-10
	*Resistance*Plus® MG FleXible#	Detection of *M. genitalium* and macrolide resistance in around two hours	10	S2A-2000410
	Xpert HBV Viral Load	Detection and quantitation of Hepatitis B virus (HBV) in less than one hour	10	GXHBV-VL-CE-10
	Xpert HCV Viral Load	Detection and quantitation of Hepatitis C virus (HCV) in 105 minutes	10	GXHCV-VL-CE-10
	Xpert HCV VL Fingerstick	Detection and quantitation of Hepatitis C virus (HCV) in about an hour	10	GXHCV-FS-CE-10
	Xpert HIV-1 Qual XC	Detection of Human Immunodeficiency Virus Type 1 (HIV-1) in around 90 minutes	10	GXHIV-QA-XC-CE-10
	Xpert HIV-1 Viral Load XC	Detection and quantification of Human Immunodeficiency Virus type 1 (HIV-1) in around 90 minutes	10	GXHIV-VL-XC-CE-10
Oncology & Human Genetics	Xpert BCR-ABL Ultra	Standardized measurement of BCR-ABL p210 transcript levels for individuals with Chronic Myeloid Leukemia (CML) in under 2 hours	10	GXBCRABL-10
	Xpert BCR-ABL Ultra p190	Quantitative monitoring of BCR-ABL p190 mRNA transcript levels for individuals with Chronic Myeloid Leukemia (CML) and Acute Lymphoblastic Leukemia (ALL) in approximately 2.5 hours	10	GXBCRABLP190-CE-10
	Xpert NMP1 Mutation	Quantitative monitoring of NPM1 mRNA transcript levels for individuals with Acute Myeloid Leukemia (AML) in approximately 3 hours	10	GXNPM1-CE-10
	Xpert Bladder Cancer Detection	Detection of the presence of bladder cancer in patients with hematuria in around 90 minutes	10	GXBLAD-CD-CE-10
	Xpert Bladder Cancer Monitor	Qualitative monitoring for recurrence in patients previously diagnosed with bladder cancer in around 90 minutes	10	GXBLAD-CM-CE-10
	Xpert Breast Cancer STRAT4	Semi-quantitative measurement of ESR1, PGR, ERBB2, and MKi67 from FFPE invasive breast cancer tissue in 70 minutes	10	GXBCSTRAT4-CE-10
	Xpert FII & FV	Identification of genetic risk factors for thrombosis in around 30 minutes	10	GXFIIFV-10

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ABSTRACTS ORAL PRESENTATIONS

Regulation & Investment

Regulation Session

Investment Session

Healthcare & Innovation

Medical Needs Session

Product Innovation Session

Enabling Research & Technologies Session

Keynote Speaker

REGULATION & INVESTMENT

RI.1 – Welcome message

Dr. Silvia Anghel – Symposium Chair

Silvia Anghel developed a strong scientific expertise in the fields of oncology, metabolism related disorders, and gastroenterology related to biomarker discovery and detection.

She acquired an industrial experience by working for more than 15 years at different positions in the healthcare industry in the field of In Vitro Diagnostics (IVD). She managed projects in various areas, including development, manufacturing, regulatory and quality. She gained throughout the years a valuable overview of the life-cycle of a product from its development to its production and commercialization.

Silvia is an Sr Director, Quality & Regulatory Affairs at Vernaex, where she is overseeing the In Vitro Diagnostic activities for the Swiss, German and Spain offices.

Prof. Didier Maillefer – Symposium Chair

Didier Maillefer earned an Engineering Diploma EPFL in Microtechnology in 1990. He is also a certified Project Management Professional (PMP).

He benefits from a 20 years experience in the Medtech industry, involved with the development of advanced Medical Devices based on MEMS technologies.

He is the inventor of 10 patent families granted in major countries.

Currently, Didier Maillefer is Professor at the University of Applied Science Western Switzerland (HEIG-VD), with teaching and research activity in medical technology.

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Regulation Session

RS.1 – Opportunities in filling data gaps for legacy product

Dr. Julianna Bobela

Dr. Julianne Bobela is a Life Scientist, qualified by more than ten years of professional experience in the field of translational research applied to Neuroscience and more than five years of experience Clinical, Regulatory and Quality Affairs related to Medical Devices and IVDs.

Her expertise includes conducting clinical evaluations for medical devices and performance evaluation for IVDs, preparing technical documentation and strategic planning for regulatory pathways. She is also an active member of the clinical team, supporting the setup, management and final analysis of clinical studies on medical devices, including IVDs.

Julianne is an Scientific Affairs Director at Vernaex.

Abstract :

- IVDs for near-patient testing: What type of clinical evidence is expected for IVDR transition?
- How can a manufacturer best identify gaps in available clinical data?
- Which IVDs are considered as Legacy Devices under IVDR?
- What IVDR requirements apply to legacy devices during the transition period?
- How can required PMS and PMPF activities best be used to fill gaps in available clinical data?Challenges encountered in navigating the IVDR conformity assessment process

RS.2 – POCDx: What is special in the assessment of the design, usability and performance? Lessons learned from the first conformity assessment

Dr. Laura Scrivano

Dr. Laura Scrivano studied classical molecular biology and did her PhD and PostDoc focusing on molecular virology.

In 2015, she joined the IVD Department of TÜV SÜD Product Service as a Product Specialist and Auditor, focusing on Technical Documentation Assessment under IVDD. Since the Notification of TÜV SÜD under IVDR, she gained further experience in the new IVDR regulation, especially including new products in the scope of Notified Bodies such as class A sterile IVDs, CDx and NPTs (POCs).

Since 2021, she has been leading a team of Product Specialists and Auditors, having successfully assessed and certified a high number of NPTs to date.

Abstract :

The key message of this presentation will include following :

- Definition of NPT according to IVDR;
- NPTs are NEW in the scope of Notified Body assessment: regulatory framework, product classification and conformity assessment route to apply;
- What to consider while defining relevant use environment as well as the intended user (Design / Usability / Performance studies);
- Labelling requirements for NPTs according to IVDR.

RS.3 – Interoperability and comptability: challenges when using POCDx

Dr. Kim Rochat

Kim Rochat is active in the field of medical devices since 15+. His areas of expertise are quality management, regulatory affairs, clinical evaluation on critical products such as active medical devices, active implants (AIMD), standalone software and borderline devices.

Kim's specialities include the regulatory compliance of software-based platform including learning machine, the design and follow-up of clinical investigations, the user interactions and usability as well as the compliance with requirements pertaining to information security and data privacy.

Kim is an Senior Vice President at veranex

RS.4 – Manufacturer's experience on the conformity assessment process under IVDR

Dr. Iwan Märki

Iwan Märki is the Co-Founder and Chief Technology Officer at Abionic SA, a Swiss company and spin-off from the Swiss Federal Institute of Technology Lausanne (EPFL). Iwan is an expert in optical technologies. After receiving a master's degree in microengineering from EPFL and a PhD on nano-optical devices from IMT, Neuchâtel, he has directed the research on single molecule spectroscopy and imaging at the Laboratory of Biomedical Optics, EPFL. In 2010, along with Nicolas Durand, he founded Abionic, dedicated to utilizing advanced nano-technology for point-of-care in-vitro diagnostic tools.

Under Iwan's leadership, Abionic has developed the abioSCOPE, the world's fastest diagnostic platform, offering rapid quantitative diagnosis for a range of applications, including sepsis, COVID-19, allergies, and iron deficiency. His journey with Abionic has seen the company progress from early development to full industrialization and successful commercialization.

Abstract :

- Challenges encountered in navigating the IVDR conformity assessment process
- Practical and valuable insights
- First experiences on design changes within IVDR

WAMA DIAGNOSTICS

WAMA Diagnostics (Switzerland) is dedicated to developing innovative in vitro diagnostic tests. We focus on the development of multiplex immunoassays and our current project is to combine the screening of transfusion-transmissible infections in a single test. This planar multiplex chemiluminescence-based assay includes the detection of specific antibodies against HIV-1&2, HCV, HBc, Syphilis, HTLV-I/II and Chagas and the detection of antigens HIV-1 p24 and HBsAg.

We look for investors to support final steps of product development and validation, partners that could evaluate this assay for diagnostic purposes, and IVD companies interested to out-license this technology.

Investment Session

IS.1 – Introduction of the investment topic and introduction of the panel

Dr. Benjamin Ricken – Session Chair

Benjamin Ricken is a biotechnologist by training. After his Bachelor in Aachen and Master in Münster he started his PhD in Basel. During his PhD he worked on the isolation and characterization of bacterial strains capable to mineralize antibiotics. Benjamin Ricken started to work for BÜHLMANN Laboratories AG as Scientist in 2017 and is Head of the POC & ST Development team since 2021. The team focuses on the development of immunoassays for the use in point of care and self-testing settings.

IS.2 – Manufacturer's experience on the search of investment

Prof. Vincent Zwaans

Passionate about developing start-ups and launching complex medical devices for more than 10 years, Vincent is Loop Medical's finance and operations guru. Vincent post-graduated in accounting and finance at the Conservatoire National des Arts et Métiers in Paris. Before joining Loop Medical, Vincent was co-founder and CEO of CybeReha SA (developing a robotic exoskeleton associated with closed-loop functional electrostimulation for stroke/spinal cord injured patients' rehabilitation) and previously worked for Edwards Lifesciences from 2003 to 2015 in various leadership and management positions in finance, project management, and business operations.

The latest included setting up and implementing a new product launch excellence framework applied to the successful launch of numerous advanced cardiovascular and critical care medical devices, notably transcatheter heart valves (THV). Prior to Edwards Lifesciences Vincent worked at Deloitte and AGFA in external audit and financial controlling.

Abstract :

Loop Medical's vision is to simplify access to clinical-grade blood testing for everyone, everywhere, and to unlock the tremendous potential of home testing.We are developing a painless, easy-to-use sampling device that collects a large volume of high-quality capillary blood and seamlessly integrates in high throughput analyzers.

We secured an initial non-dilutive grant of $400,000 to develop a proof of concept. Subsequently, we obtained a more substantial $3.2 million non-dilutive grant to reach design freeze and prepare for manufacturing transfer. We then successfully raised $6.3 million in a Series A round. This funding is earmarked for crucial milestones, including a first-in-man study, low-volume manufacturing setup, and rigorous FDA approval processes. Notably, the financial backing comes from three distinct investor types: non-dilutive grant providers, strategic investors, and venture capital firms. This diversified funding approach has enabled the startup to progress efficiently and lay a solid foundation for future growth and market entry.

IS.3 – Round Table: Investing in POCDx – Industry Trends and Investor Activity

Prof. Vincent Zwaans (IS.2)

Dr. Andreea Wiese

Andreea is a business director with cross-functional experience in sales, marketing and strategy. Currently, she is the Commercial Director for Roche Diagnostics France, looking after the sales organization.

Until this October, she has been leading the global Partnering team at Roche Diagnostics covering the Point of Care business. Her responsibilities were focused on bringing external innovation in. This covers a wide range of partnerships from distribution, R&D agreements to acquisitions.

Prior to Roche, Andreea started her career in an FMCG company where she had various roles in the marketing and sales organization. After this, she moved on to work for Microsoft as a Marketing Lead for the CEE region and then continued as a Strategy Lead for the same region.

Mr. Frédéric Gabriel

Frédéric Gabriel, CEO of Carity, has 15+ years' experience in Pharma and medical devices with the establishment of a cardiovascular drug portfolio and related product setup, approval and market launch with Genzyme / Sanofi. With Haselmeier, he managed various development programs for drug injection systems, led diverse organizations for business development and sales, then for product innovation. After having accompanied a successful sale of Haselmeier, Frédéric co-founded Carity with Evoleen. He holds few Board positions and lives with his family in Zürich.

HEALTHCARE & INNOVATION

Welcome message

Prof. Gaëtan Cherix

Professor Gaëtan Cherix is the Director of the School of Engineering at the University of Applied Science and Arts Valais (HES-SO Valais-Wallis) since 2016. He is responsible for the school's academic and administrative operations. He is also a member of the executive committee of HES-SO Valais-Wallis and the Engineering and Architecture Faculty Board of the HES-SO. He has played a key role in the creation of a cross-cutting and multidisciplinary R&D institute in the field of energy and environment, and has developed new models of industrial laboratories to strengthen academic and economic partnerships.

Prior to this position, he headed the Municipal Energy Research Center, a joint venture of EPFL and city of Martigny, which aims to support European and Swiss Municipalities, and national and regional utilities, to implement a sustainable energy transition. He is the author of numerous technical and scientific publications and conferences, has carried out international R&D projects, and has participated in the development of start-ups.

He obtained his Master of Science in Mechanical Engineering at the Swiss Institute of Technologies in Lausanne (EPFL), with a specialization in energy system. He has completed numerous continuing education programs in the fields of higher education management and leadership.

Dr. Samantha Paoletti

Dr. Paoletti Samantha is enabling collaborative innovation in the Life Sciences and the Healthcare domains. Working as Head of Research and Business Development for Life Science Technologies at CSEM, she is responsible for identifying market needs and for the strategic planning of internal activities towards specific industrial requests. CSEM plays a key role in the innovation value chain, leveraging public-private partnerships and narrowing the gap between fundamental research and industrialization.

Samantha has a strong interest and passion for personalized medicine and the development of novel technologies for a precise, robust, and accessible healthcare. She earned her Ph. D. Degree from the University of Fribourg and then worked as Post Doc at the Laboratory of Experimental Immunology in Basel. Samantha is a diversity and inclusion advocate promoting gender equity in business and healthcare.

Prof. Marc E. Pfeifer

Dr. Marc E. Pfeifer is a full professor and Head of the Diagnostic Systems research group at the Institute of Life Technologies. He is also Vice-Coordinator of the Health Technology Innovation Center (HTIC) of the HES-SO Valais-Wallis that promotes inter-institute research projects and activities. He is one of the founders of Biotechnet's thematic platform IVD and of the Swiss Symposium in POC Diagnostics. As a former global IVD industry manager he has extensive experience in molecular diagnostic product development, and a strong sense for customer as well as market needs. He has also broad know-how of regulatory requirements and submissions. Marc earned his Ph.D. in bioorganic chemistry from the University of Zurich.

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Medical Needs Session

Prof. Daniel Paris – Session Chair

Daniel Paris, MD, PhD, DTMH, is a clinical doctor, Associate Professor and Medical Director and Head of the Department of Medicine at Swiss TPH. His position incorporates the fusion of two predominantly service-oriented departments into a single medical department, with the addition of clinical translational research and diagnostic methodologies. Paris is a Swiss national, clinically trained at the University of Zurich. He spent many years working in clinical research in Southeast Asia for the University of Oxford, based in Bangkok as coordinator of clinical tropical medicine research with a focus on tropical rickettsial illnesses, diagnostics, clinical trials and causes-of-fever studies.

MN.1 – Implementation of a point-of-care test in Swiss primary care: the exemple of procalcitonin

Dr. Yolanda Müller

unisanté
Centre universitaire de médecine générale et santé publique · Lausanne

Yolanda Müller is a public health physician working at the department of family medicine of the Centre for Primary Care and Public Health (Unisanté) of the University of Lausanne. One of her research topics is the appropriate use of antibiotics in primary care.

Abstract :

In Switzerland, most antibiotics are prescribed in ambulatory care, with half of them prescribed for respiratory infections. A point-of-care procalcitonin test has been proven to reduce antibiotic use in primary care context, by helping physicians to differentiate between bacterial and viral infections. Despite the existing evidence, implementing such a test in Swiss primary care comes with a number of challenges. Implementation science can help to understand determinants of antibiotic use and inform strategies for successful implementation of innovations.

MN.2 – POCT ISO 15189 accreditation in hospital setting: Opportunities & Challenges

Dr. Bettina Schmid

KSA Kantonsspital Aarau

Bettina Schmid has completed her studies in pharmacy at the ETH Zurich in 2015. After a few years of working in a pharmacy and obtaining her PhD at the University Hospital in Zurich she shifted her professional focus towards laboratory medicine and is currently working at the Cantonal Hospital in Aarau, where she is a FAMH candidate in immunology and clinical chemistry. Next to immunology diagnostics she is involved in the point of care testing (POCT) at the hospital with the goal of further increasing its quality and documentation and a potential accreditation of POCT according to ISO 15189.

Abstract :

In December 2022 a revised version of the ISO 15189 has been released. One of its greatest changes is the implementation of point of care testing (POCT). This presentation will give an overview of the new regulations and options of accreditation of POCT according to the revised ISO 15189. Key points of a potential accreditation of POCT such as internal and external quality controls, trainings, and documentation will be elucidated. The presentation will further demonstrate the possibilities, challenges, and pitfalls of a potential accreditation of POCT according to the new ISO 15189 by giving an insight into practical approaches in a hospital setting.

MN.3 – Point of care diagnosis in mountain emergency medicine

Dr. Pierre Métrailler

Native from Nendaz in the Valais, my passion for medicine and the mountains led me to become an emergency doctor and mountain guide. I currently work in the emergency department of the CHVR in Sion and Martigny. This Trauma Center-level department deals with all types of medical and traumatic emergencies. I am also a doctor and head of the Rescue Service at Air-Glaciers, a company specializing in helicopter and mountain rescue.

In my work, I pay particular attention to patient safety and priorities in care. I regularly evaluate new diagnostic and treatment tools and organize their implementation in clinical practice. In my day-to-day work, I am confronted with sometimes tricky conditions of the high mountains, which severely test material and human limits. The quality of patient care, from the accident site to the emergency room, is essential to me. The people involved, their training, and the available equipment must meet the highest standards.

Abstract :

Every year, Air-Glaciers carries out over 3,000 helicopter rescue operations. We regularly evaluate new therapeutic and diagnostic tools to guarantee the best possible care for every patient. There are currently possibilities for conducting various analyses outside the hospital, which could be advantageous in certain situations and for certain patients. The particularities of a heliborne rescue operation in Valais as part of Air-Glaciers and the essential issues surrounding the diagnostic approach are presented. The successful implementation of out-of-hospital diagnostic tools requires collaborating with a wide range of players and identifying criteria and objectives. **There is great potential for optimizing the emergency chain in diagnosis and patient referral.**

MN.4 – The impact of Oxford nanopore sequencing on clinical genetic testing

Prof. Alexandre Kuhn

Alexandre Kuhn is a Professor at the Institute of Life Technologies of the Swiss University of Applied Sciences, HES-SO Valais-Wallis. His research group aims to develop new medical diagnostics based on nanopore sequencing. They focus on the molecular aspects of DNA preparation as well as on the development of novel bioinformatic analysis methods for clinically-relevant tests.

Previously, he made significant contributions to the molecular understanding of Huntington's disease, an inherited neurodegenerative disease, and to human population genetics. He worked at the National Institutes of Health (NIH) in the USA and at the Agency for Science Technology and Research in Singapore. He also led the development of genomics products for a Swiss biotechnology company.

Abstract :

In the past decade, next-generation DNA sequencing has become widely applied in clinical diagnostics. The most notable applications are pathogen detection and the identification of disease mutations, both in the case of acquired and inherited mutations. The medical potential of clinical sequencing, however, is far from being realized. In the case of suspected genetic disorders for instance, more than half of individuals remain unsolved after complete clinical evaluation.

In contrast to next-generation sequencing, third-generation sequencing comprises new technologies that allow for sequencing of long DNA fragments in real-time. Specifically, Oxford nanopore allows for portable and low-cost DNA sequencing. We will describe novel genetic tests that we and others are currently developing based on third generation sequencing. We will also discuss how these tests might provide fundamental improvements to clinical diagnostic and how they might significantly benefit patient health.

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Production Innovation Session

Dr. Rainer D. Jäggi – Session Chair

PI.1 – Closing the gapsof a fragmented patient's rehabilitation journey after a heart attack

Mr. Frédéric Gabriel & Mr. Marcel Wüthrich

Frédéric Gabriel, CEO of Carity, has 15+ years' experience in Pharma and medical devices with the establishment of a cardiovascular drug portfolio and related product setup, approval and market launch with Genzyme / Sanofi. With Haselmeier, he managed various development programs for drug injection systems, led diverse organizations for business development and sales, then for product innovation. After having accompanied a successful sale of Haselmeier, Frédéric co-founded Carity with Evoleen. He holds few Board positions and lives with his family in Zürich.

Marcel Wüthrich (EMBA), has been working in the Healthcare, Medtech and Diagnostics industry since 1995. He held various leadership positions within Disetronic Medical Systems and Roche Diagnostics, leading small and larger country and regional commercial organizations in Europe, Middle East, Latin America and Africa. In 2022 he changed to Evoleen AG Switzerland where he holds responsibility for the global business development. He is also an active board member and lives with his family in Basel.

Abstract :

Carity is providing digital services and support for patients during their rehabilitation after a cardiac event, in addition to the standard outpatient established program. Digital Health introduces new paradigms with regard to Point of Care and Diagnostics. In our specific cardiac rehabilitation case, we extend the Point of Care from sessions at the rehabilitation center to sessions at patient's home and introduce the opportunity of remote monitoring as additional input for diagnostic in real life and over longer time periods. However, the current healthcare system as well as regulatory requirements and boundaries for medical devices and acceptance level of monitoring devices, coming from the consumer goods field, make the realization of such opportunities still a challenge.

PI.2 – Short: A multiplex immunoassay as a simplifier of transfusion-transmissible infection deseases screening on blood bank activities

Dr. Carlos Alberto Mestriner

Carlos Alberto Mestriner is biologist with PhD in Genetic and Evolution and Post Doc in Molecular Biology. From 1997 to 2016, he worked on In Vitro Diagnostic field for Group Maricondi. He managed the R&D department of WAMA Diagnóstica from Brazil, when several projects of IVD assays development were conducted and resulted in several products released in the market. He was relocated to Switzerland in 2016 to manage R&D activities from WAMA Diagnostics (Switzerland), a new company established at Monthey at the same year. Since then, his focus has been on the development of multiplex assays.

Abstract :

WAMA Diagnostics (Switzerland) is developing an immunoassay that combines the screening of transfusion-transmissible infections in a single test. This planar multiplex chemiluminescence-based assay includes the detection of specific antibodies against HIV-1&2, HCV, HBc, Syphilis, HTLV-I/II and Chagas and the detection of antigens HIV-1 p24 and HBsAg.

The unlocked achievements and the hurdles that lie ahead in the final stages of the development of this product will be presented with its comprehensive performance analysis. The success of this project will lead to SAFEBLOOD MX-CLIA assay that will ultimately empower blood banks to streamline their routine analysis, as it will be able to run 192 samples in parallel with 7 results obtained for each blood donor after a single reaction run.

SAFEBLOOD is currently designed for high throughput demand of centralized laboratories. In the near future, a POC version will be developed for blood banks of limited resources and other applications.

PI.3 – Short: Can a rapid and easy test improve the management of Cervical cancer?

Mr. Percevent Ducrest

Percevent Ducrest is a dynamic Life Sciences engineer and entrepreneur specializing in microbiology and in vitro diagnostics (IVD). As the CEO & co-founder of GaDia SA since its founding in 2019, he has spearheaded innovation in the company, leading the development of IVD medical devices, including tests for COVID-19, fungal sepsis, and antimicrobial resistance. His commitment to quality is evident through ISO 13485:2016 certification and a rigorous Quality Management System (QMS). Percevent thrives on translating societal needs into innovative solutions and has presented GaDia SA at various international meetings. Beyond science, he is a tennis chair umpire, officiating in many tournaments, including Wimbledon and the Australian Open.

Abstract :

Cervical cancer is the fourth most common cancer among women globally, with an estimated 604'000 new cases and 342'000 deaths in 2020. About 90% of the new cases and deaths worldwide in 2020 occurred in low- and middle-income countries (LMIC). Poor access to HPV vaccination and screening is the main reason for this high prevalence in LMIC. PapilloDia is a revolutionary Point-of-Care rapid test based on lateral flow assay for screening specific oncoprotein markers in cervical swab samples. The test gives valuable results in only 15 minutes about the cancer stage. Preliminary results of the clinical study ongoing at the University Hospital of Geneva showed promising results. Such rapid and easy tests can support healthcare professionals in their fight against cervical cancer.

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Enabling Research & Technologies Session

Prof. Jean-Manuel Segura – Session Chair

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Jean-Manuel Segura is a professor of chemistry at the University of Applied Sciences Western Switzerland since 2008. He obtained his Ph.D. in 2000 from ETH Zürich in physical chemistry followed by post-doctoral and group leader positions at Leiden University, at EPFL and at the Ludwig Institute. His current research interests include the development of novel paper-based point-of-care in vitro diagnostic tests and the design and application of novel "smart" sensor molecules such as supramolecular biosensors or molecularly-imprinted polymers.

ER1 – The role of POCT in diagnostic microbiology in Switzerland

Dr. Alexis Dumoulin

Alexis Dumoulin studied biology at the Swiss Federal Institute of Technology in Zurich, where he obtained a degree in Natural Sciences in 2001, followed by a PhD in 2005. He then worked as a research associate at the Institute of Medical Microbiology at the University of Basel. In 2012, he obtained the title of FAMH specialist in laboratory medicine in the field of medical microbiology. He joined the Infectious Diseases Department at the Institut Central des Hôpitaux in Sion in 2013, where he is responsible for molecular biology and serology analyses.

Abstract :

Analyses in POCT format play a central role in microbiological diagnosis, mainly in the fields of infectious serology (antigen and antibody detection) and PCR. Their ease of use has enabled these analyses to be set up outside centralised laboratories, considerably speeding up the delivery of results. With the development of new technologies and changes in legislation, some microbiological tests (HIV and SARS-CoV-2 self-tests) are now available over the counter and can be used at home. However, because the Swiss legal framework restricts their use, POCT microbiology tests are still mainly used in the laboratory, rather than in the doctor's practice, in the presence of the patient.

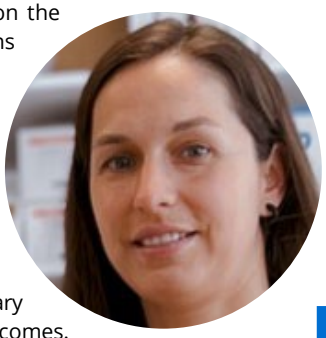
ER2 – Advancing Urinary Health Monitoring: fact-based nutrition for infants and lactating mothers

Dr. Julia Kulingowski & Dr. Davide Migliorelli

Davide Migliorelli earned a PhD in Chemistry from the University of Rome Tor Vergata. He advanced his career, at first as post-doc and then as R&D, at the Centre Suisse d'Electronique et de Microtechnique (CSEM) by focusing on the development of biosensors; his research was specifically oriented on the use of screen-printed electrodes for electrochemical detection of various analytes in saliva.

Recognized for his expertise, Davide Migliorelli assumed the position of Expert in biosensing at CSEM in the 2020. In this role, he is primarily responsible for the development of point-of-care sensor devices for body fluids analysis, as well as validating CSEM's extensive sensor portfolio.

Kulingowski Julia



Graduated in Biotechnology, PhD in Chemistry. Over the last years, during my post-doctoral fellowships at the Neonatal Research Group at the Health Research Institute La Fe (Valencia), I established a new research line focused on the detection of molecular biomarkers in biofluids of newborns with hypoxic-ischemic encephalopathy and severe hypoxia secondary to persistent pulmonary hypertension. More recently, my focus of interest shifted to the development of personalized nutrition approaches for the preterm infant. I have been evaluating the impact of maternal diet on the composition of human milk and how the different compounds present in milk affect growth, health, and development of the preterm infant. The obtained results might be relevant for the design of personalized dietary approaches for preterm infants, helping to optimize outcomes. Since 2020 I expanded my skills to the characterization of human milk extracellular vesicles, with special emphasis on their lipidic make-up, and how the properties of those vesicles could be exploited for disease prevention or treatment of preterm infants. Results of my work have been disseminated in publications in peer-reviewed, scientific journals (130 research papers and literature reviews with 3014 citations) and congresses and specific meetings (>160 communications).

Abstract :

Advancing Urinary Health Monitoring: fact-based nutrition for infants and lactating mothers

Human milk is the ideal source of nutrition for newborns. It is well-known that many factors influence the composition of human milk, and hence, we designed and performed a longitudinal study involving mother-infant dyads of term and preterm infants receiving own mother's milk (OMM) as well as preterm infants receiving donor human milk (DHM). Clinical and environmental information and questionnaires on nutrition as well as biological samples were collected from mothers and infants with the aim of studying which factors have a significant impact on the composition of human milk and how this, in turn, affects outcomes of preterm infants. The study also involved the development of portable sensor devices, including a pH sensor for urine. The screen-printed based pH sensor, together with a 6 channels electrochemical reader and a user-friendly graphical user interface (GUI), was developed and then validated in both laboratory and relevant operating environment conditions.

Modern healthcare requires the creation of point-of-care technologies for personalised medicine. These tools change how we manage health by enabling quick, on-the-spot diagnostic testing and therapy personalization. Point-of-care devices give healthcare personnel immediate access to vital information, enabling them to make decisions in real time that result in more accurate and efficient treatments. This method is particularly important for the treatment of cancer, monitoring infectious diseases, and controlling chronic disorders. It increases patient involvement and adherence to treatment approaches by empowering people to actively participate in their healthcare decisions. Additionally, by lowering the need for costly laboratory testing, hospital visits, and related expenses, these technologies streamline healthcare.

ER3 – Electrochemical quantification of lateral flow rapid tests

Dr. Thomas Meier

Thomas Maier is research engineer at the Center for Health & Bioresources at the AIT Austrian Institute of Technology GmbH. His research in the field of diagnostic biosensors focuses on miniaturized electrochemical biosensing platforms for the point-of-care.

After his studies of technical physics at the Technical University Graz (Austria) from 1986-1995, he earned his PhD at the TU Wien (Vienna, Austria) in 2000 for his thesis on the integration of surface-emitting laser diodes and resonance-enhanced photodetectors.

From 2001-2003 he worked as a research engineer on the process development for micromold fabrication at Fotec GmbH, Wiener Neustadt (Austria).

In 2004, he joined the AIT Austrian Institute of Technology GmbH in Vienna.

Abstract :

Thanks to their short time to result and high usability, rapid tests based on lateral flow devices (LFDs) have become an indispensable tool for point-of-care testing. During the COVID-19 pandemic, antigen tests were used at an unprecedented scale to perform tests in locations outside of conventional healthcare institutions. However, as the final reading is left to the end user, the “human factor” plays an important role in the interpretation of LFD test results. The electrochemical readout presented in this talk offers a more objective way to evaluate LFDs, and lends itself to an integration with microelectronic components, which not only read the electrical test result, but furthermore enable the transfer of the data to the test environment (e.g. mobile phone, health information system) via wireless near field communication.

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Keynote Speaker

Where is the Star Trek Sick Bay?: Macimizing Astronaut Health and Performance for Exploration Spaceflight Missions

Prof. Benjamin Easter, MD, MBA

Dr. Benjamin Easter is an Associate Professor of Emergency Medicine at the University of Colorado School of Medicine and Deputy Element Scientist for Exploration Medical Capability in the NASA Human Research Program. There, he provides clinical, technical, and scientific leadership to a team of clinicians and engineers that investigate and mitigate human health risks and design medical systems for exploration missions to the Moon and Mars. Ben is also the program director for the University of Colorado's dual degree program in medicine and aerospace engineering, which seeks to train future leaders in human spaceflight by instruction in both clinical and engineering curricula. He is the Assistant Medical Director for the Polar Medicine Service at the University of Colorado and has served as medic at Summit Station on the peak of the Greenland ice sheet, in rural Guatemela, and via sail to the outlying islands of Fiji.

Dr. Easter holds a Bachelor's degree from Princeton University, a medical doctorate from Harvard Medical School, and an MBA from the University of Colorado. He completed an emergency medicine residency at Denver Health Medical Center and a fellowship in Emergency Operations and Quality at the University of Colorado School of Medicine. Dr. Easter is a Fellow of the American College of Emergency Physicians and the Aerospace Medical Association. He is board certified in emergency medicine and works as an attending physician at University of Colorado Hospital.

Abstract :

Exploration missions to the Moon and Mars are fundamentally different from the International Space Station. The sheer distance to these destinations presents unprecedented communications latencies, limitations of resupply, and delayed or non-existent medical evacuation. Spacecraft will also face significant constraints on mass, volume, power, and consumables. These challenges will drive significant increases in the likelihood and consequence of medical conditions that impact astronaut health and performance. NASA has identified point-of-care medical diagnostic technology as a critical need for exploration missions to enable diagnosis, treatment, and monitoring of medical conditions. This presentation will review these challenges, future needs, and progress made to date on developing laboratory analysis capability for exploration missions.

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POSTER ABSTRACTS

Scientific Poster Chairs

Bruno Schnyder (HES-SO Valais)

Loïc Burr (CSEM)

Scientific Poster session jury

Jackie Weber (Bühlmann)

Alena Simalatsar (HES-SO Valais)

P1 – Critical values POCT harmonization

E.Bukovetzky PhD, Mrs M. Nasser
Ziv Medical Center, Sefad, Israel

Point-of-care testing (POCT) refers to laboratory tests performed outside of central laboratory near the patients site.

The POCT remarkable advantages like as faster turnaround time (TAT) and a tiny amount of sample permits to make clinical decisions immediatly. On the other hand POCT is a big challenge because its performed by personnel who are not trained as laboratory staff.

POCT test may be affect by interferences which may cause a delay of correct diagnosis and treatment. POCT coordinator responsibility is to promise an accurate results by comparison (harmonization) of POCT and laboratory results.

POCT Technologies we have are Nova strip (Glucose) and 3D Bilimeter for neonatal bilirubin measurement.

The aim of our study is to show a harmonization essential role in comparison of critical POCT results versus standard method (chemistry analyser AU 680).

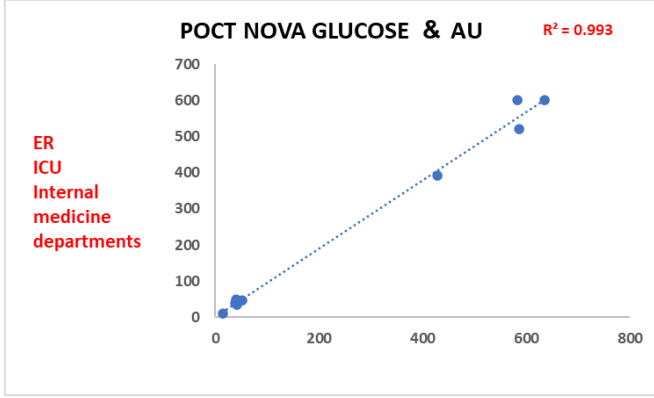
Our results show a significant correlation between the methods (R2 =0.99% in glucose and R2 =0.95% in bilirubin), uncertainty of both tests result was 1 and it highlight us a validity of results although effects of different technologies and operators.

We show a full compatibility to Proficiency Tests (PT) results: 100% in total bilirubin and 98% in glucose PT versus peer group. A per cent of accuracy in bilirubin independent QC (BioRad Liquichek Pediatric Control) in 3 D Bilimeter is 99 %.

This tight supervision and nurse staff teaching let us be sure about quality of results that reflect a real status of the patients.

Figure 1

A critical Glucose levels Correlation between POCT device and Automated chemistry analyzer.



P2 – POCT coordination role in result documented in patient file

E.Bukovetzky PhD, Mrs M. Nasser

Ziv Medical Center, Sefad, Israel

Point-of-care testing (POCT) has revolutionized the landscape of laboratory testing to be conducted at the patient's site.

The advantages of POCT as faster turnaround time (TAT) and reduced blood sample requirements are critical in providing results for urgent patient treatment. Despite its benefits, POCT presents several challenges that can compromise the quality of care and patient safety.

POCT is conducted by nursing personnel who may not have specialized laboratory training, which can result in inaccurate clinical decisions. To ensure accurate record-keeping and facilitate effective treatment decisions, it is crucial to document POCT results in the patient's file using patient ID data scanning.

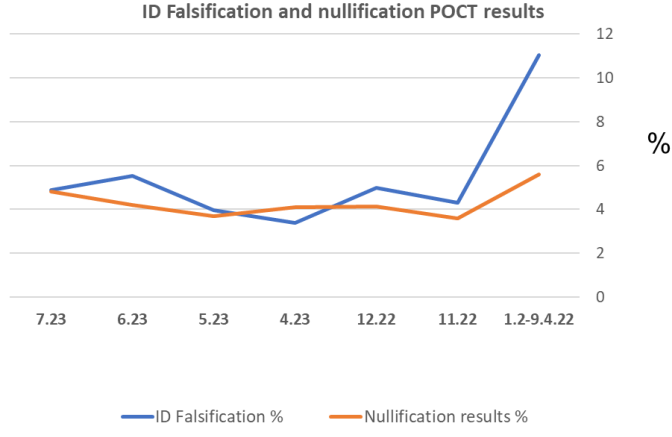
Supervision on the incoming results by POCT coordinator, becomes imperative not only for result quality but also to oversee critical measurement elements, including the identification and reduction of "ID falsifications" and the nullification of results.

The aim of this study is to demonstrate the impact of a POCT coordinator's intervention on enhancing the documentation process.

Data analysis was performed using the Nova Net System, and the documentation process witnessed a reduction in "falsifications" events, declining from 11 to 4 occurrences, and the percentage of invalidated samples reduced from 5.6 to 4.

This study underscores the vital role of close laboratory supervision and effective communication with nurse supervisors in ensuring the safety and efficacy of the POCT process.

Figure: The ID Falsification and nullification POCT results per cent decrease as result from POCT coordinator intervention.



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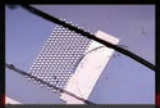
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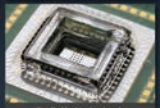
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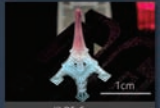

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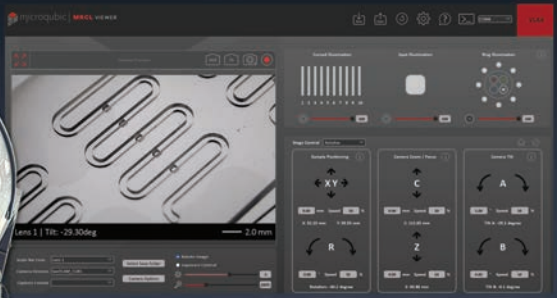

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P3 – 5C for Point-of-care and non-invasive Diagnostics and Self-Caring - Knowledge Structure in the First Interdepartmental Bachelor's Program "Biomedical Laboratory Diagnostics" in Switzerland

Sylvia Kaap-Fröhlich, Marc Fehlmann

Zurich University of Applied Sciences, Biomedical Laboratory Diagnostics Program, Wädenswil, Switzerland

Aim :What is the knowledge structure for POCT in this new study program that aligns the academic health profession with natural sciences in health care and research, and supports the academic program implementation?

Approach: Based on a field analysis by the professional Swiss association Labmed, and the laboratory diagnostic process (preanalytics, analytics, postanalytics) the proposed knowledge structure for POCT connects the different data for health care.

Discussion: The present knowledge structure is a first draft and needs to be discussed with experts from health and natural sciences.

Take Home Messages: For the implementation of a new bachelor degree program in Switzerland, the presented 5 C model was developed based on laboratory diagnostic and natural science, the CanMED model and basic testing approaches (Lab, POCT, self-Testing).

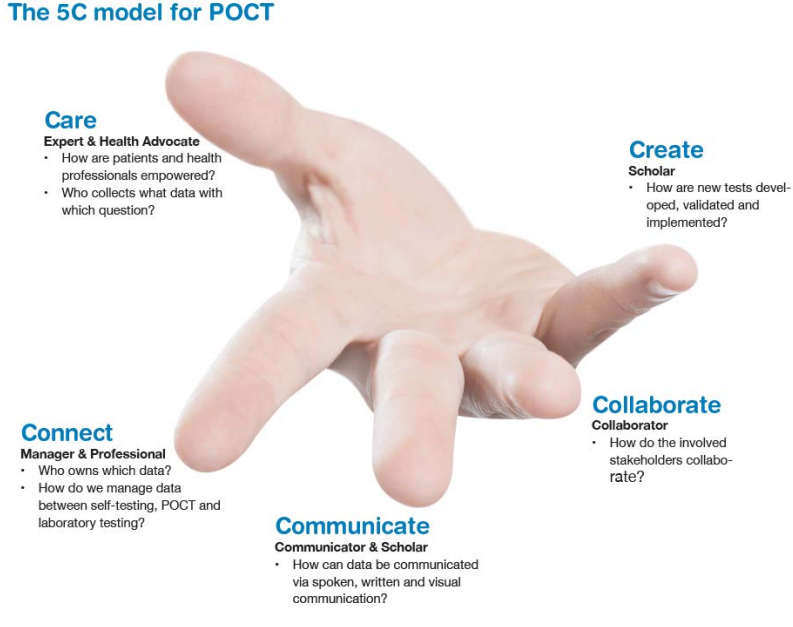


Fig 1: The five keywords of the developed knowledge structure

P4 – Microfabricated Self-Referencing Pulstrodes

Ayian Speck[1], Elena Zdrachek[1], Tara Forrest[1], Davide Migliorelli[2], Silvia Generelli[2], Loïc Burr[2], Eric Bakker[1]

[1] Department of Inorganic and Analytical Chemistry, University of Geneva, Sciences II, Quai Ernest-Ansermet 30, 1211, Switzerland

[2] Swiss Center for Electronics and Microtechnology, Rue Jaquet-Droz 1, 2002 Neuchâtel, Switzerland

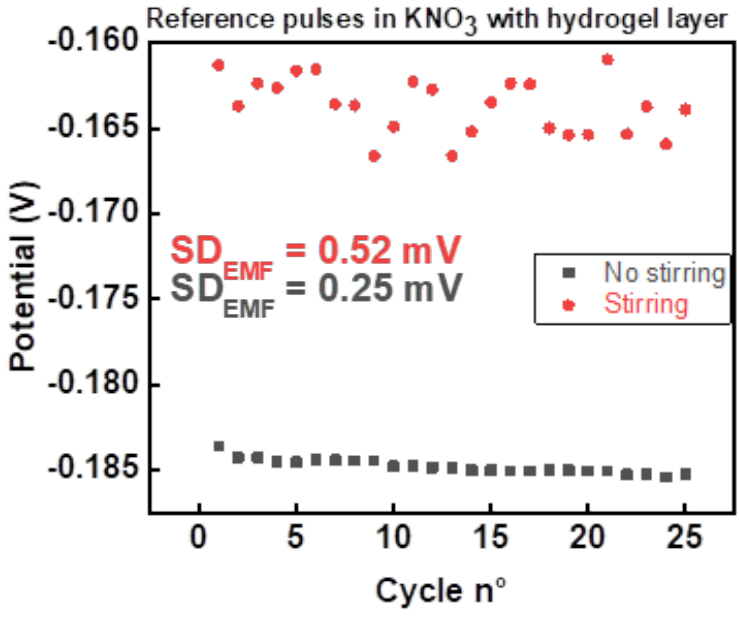
With an ever-increasing world population and life expectancy, public health often ranks as the second sector in terms of budgetary spending worldwide. Finding ways to reduce the costs, whether it is in the preventive care or therapeutic domain, is a crucial component of developing a sustainable health system. As a result, Point-of-Care Testings (POCTs) and wearable sensors have attracted a tremendous interest in the past decades. As opposed to traditional analysis, which are costly and time-consuming, POCTs and wearable sensors present, among others, the following advantages: they are cost-effective and allow rapid or continuous measurements, which lead to better reaction time and thus fewer costly complications [1]. Electrochemical sensors in that regard represent a good example of POCTs.

The reference electrode is an essential component of an electrochemical system, resulting in a high research activity in that domain [2]. The gold standard remains the Ag/AgCl double junction reference electrode. However, owing to its electrolyte-filled inner compartment its design is cumbersome and impractical for wearable sensors applications, which require miniaturization. From that point of view, all-solid state reference electrodes provide a promising alternative.

Gao *et al.* proposed a solid-state reference electrode which relies on an Ag/AgI element and acts as a pulstrode to self-generate a reference potential [3]. The pulstrode protocol consists of four distinct steps: 1) potentiometric measurement of the initial state of the system (OCP), 2) a cathodic current pulse, leading to the reduction of Ag^+ into Ag and the local release of a controlled amount of iodide, 3) measurement of the EMF (reference pulse) 4) application of the original OCP to regenerate the system into its initial state. The protocol has proven its reliability in terms of precision and stability over cycles on a macro-electrode.

In the present context of finding a reference electrode suitable for miniaturized systems, this work investigates the use of the pulstrode protocol on inkjet-printed electrodes provided by the Swiss Center for Electronics and Microtechnology.

Additionally, an attempt to improve the robustness of the described system against sample convection and sample density fluctuations was made by covering the electrode surface with an agarose gel layer.



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P5 – Development of a portable molecular amplification detection system using functionalized magnetic nanoparticles

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The start-up MagIA diagnostics has developed innovative multiplex no wash immunoassays exploiting micro-magnets to locally capture functionalised magnetic nanoparticles (MNP) and fluorescent detection. This technology is applied to diagnose sexually transmitted infections (STI) with a syndromic approach (HIV, HBV, HCV). However, co-infections with other STI like Chlamydia or Gonorrhoea are common and have to be diagnosed with nucleic acids amplification tests. This work presents a proof-of-concept based on DNA bacterial plasmid detection using MagIA technological bricks: MNP, microfluidic cartridge containing micro-magnets and MagIA fluorescence analyzer. We investigate the end-point detection of purified DNA amplified with 2 different techniques: PCR and LAMP. First, we set up the PCR and LAMP amplification using specific fluorescent and biotinylated primers. Second, amplified DNA is captured on streptavidin coated MNP. MNP are then injected in MagIA cartridge where micro-magnets are embedded. Finally, cartridge is inserted in the MagIA analyzer that performs a differential measurement of the specific fluorescence localized on the micro-magnets (amplified DNA) and unspecific fluorescence between the micro-magnets (free fluorescent primers). By employing MagIA technology, we achieved DNA end-point detection comparable to those obtained with the thermocycler. Combining molecular and immunoassays will enable MagIA to offer an innovative solution with a large STI syndromic panel.

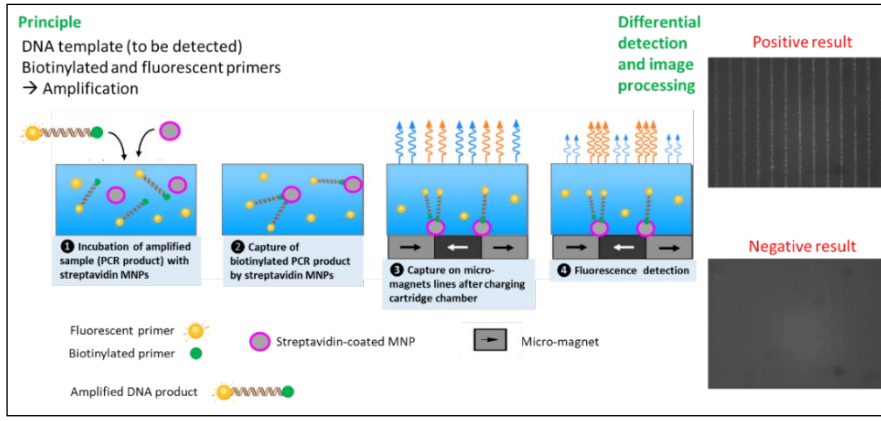

Figure: Magnetically localized and wash-free fluorescence technique for fluorescence-biotinylated nucleic acids amplification product using streptavidin MNP, micro-magnets and differential fluorescence analysis.

P6 – Integrated Enzyme-Immunosensor System with Magnetic Accumulation of Immunocomplexes and Electrochemical Delivery of Substrate

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Heterogeneous enzyme-immunoassays require labor intensive manipulation (washing steps) to remove unbound enzyme-labeled detection antibodies that would otherwise interfere with the output signal. Confining the substrate delivery to the binding site greatly simplifies those assays. Herein, we propose an integrated sensing system in a flow-cell for enzyme-linked immunoassays, where a dispersible magnetic probe containing a sandwich-type enzyme-immunocomplex is spatially resolved from the excess detection conjugate in the bulk solution by applying a magnetic field. Once the beads are on the surface of an ion selective membrane (ISM), an electrochemical excitation pulse delivers the enzyme substrate from the back side inner solution to the immunocomplexes side (see Figure 1 below). In the presence of the enzyme-linked immunocomplex on the surface of the ISM, the enzyme substrate ions instrumentally delivered are now partially consumed by the enzyme label. The potential response changes with time since the membrane is selective to the substrate activity and is proportional to the concentration of enzyme-immunocomplex, which allows the quantification of the target analyte. This integrated electrochemical immunosensor comprises the immunobinding, enzyme reaction, and electrochemical detection all occurring in the same system, controlled by electrochemistry and magnetic forces.

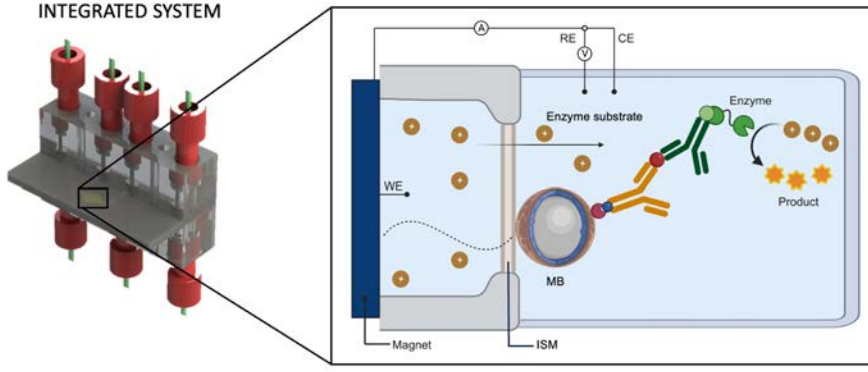

Figure 1. Schematic view of the integrated system and sensing principle. ISM represents the ion-selective membrane. A three-electrode cell contains the working electrode (WE), reference electrode (RE), and the counter electrode (CE).

P7 – Pain and sress decetion tool for autistic patients with non-verbal form of autism

Pauline Bornet[1], Benjamin Caillet[1], Josephine Convertini[23], Vincent Guinchat[23], Alena Simalatsar[1]

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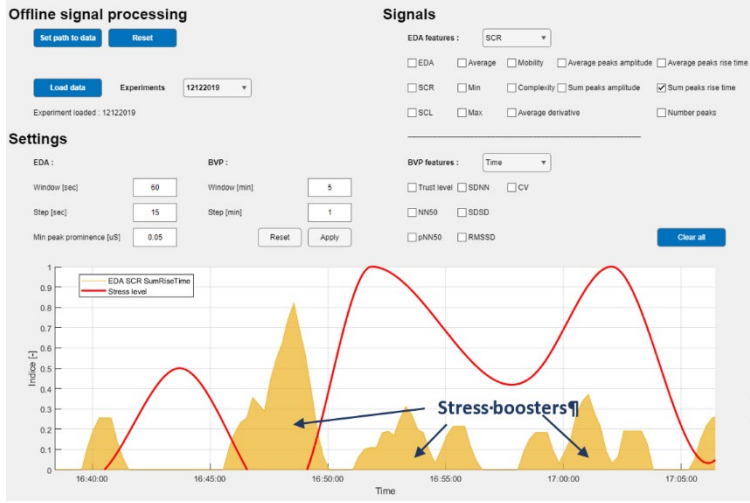
[2]CHUV, UPCHM Unité psychiatrique de crise dévolue au handicap mental/Epione

[3]STSA Service des troubles du spectre de l'autisme et apparentés

Patients with a non-verbal form of autism lack the ability to communicate with others and are likely to develop challenging behaviors. Some behaviors, e.g., self-injury, can be dangerous not only to the patient but also to their caregivers. Our project aims to develop a tool for detection and visualization of activation of sympathetic nervous system (SNS) known to correlate with acute pain and/or stress by analyzing physiological signals collected with the Empatica E4 wearable wristband, providing such measures as electrodermal activity (EDA), represented with variations in skin conductivity, blood volume pulse (BVP), temperature and 3D acceleration (ACC). Analysis of these metrics have a potential to allow to determine acute stress and/or pain as well as their levels in a non-invasive quantitative way and thus predict challenging behaviors, for non-verbal autistic patients.

This work presents the user-friendly graphical interface allowing to choose specific experimental data, e.g., EDA, BVP, temperature, and ACC, for processing, thereby pinpointing and visualizing the desired features. Presently, our software can already derive over fifty distinct features, setting the stage for in-depth data analysis. Our goal is to conceive a sophisticated system, harnessing the power of machine and deep learning, fine-tuned to detect pain/stress and therefore challenging behaviors of non-verbal autistic patients.



P8 – AI based depth of anesthesia index computation for veterinary practice

Benjamin Caillet[1], Steve Devenes[1], Gilbert Maitre[1], Darren Hight[3], Alessandro Mirra[2], Olivier Levionnois2, Alena Simalatsar[1]

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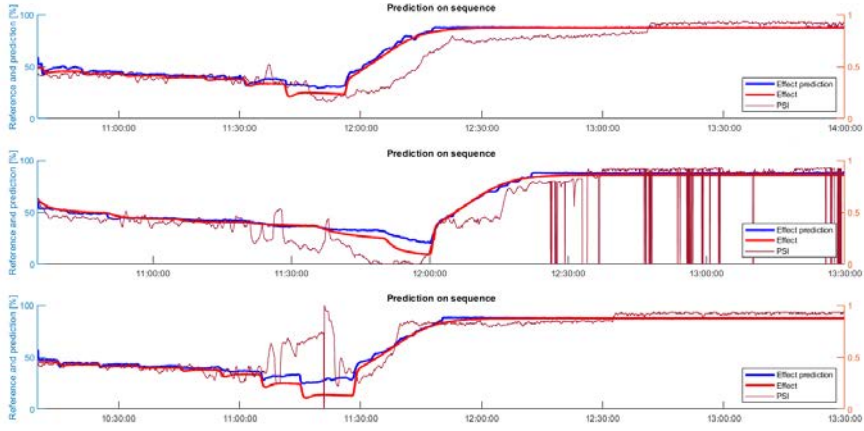
Real-time evaluation of patient depth of anesthesia (DoA) is a point-of-care practice based on physiological signals, e.g., Electroencephalogram (EEG). There exist several algorithms deriving EEG based DoA indices developed for humans, though their accuracy is still a subject of many debates. Some of these algorithms are used in veterinary practice, however, adapting them for animals is questionable due to physiological and morphological difference. Our initiative focuses on devising a system tailored for pigs, aiming to enhance veterinary anesthesia management.

Our research utilizes 258 EEG recordings from 28 distinct anesthesia events in pigs. 8 to 12 EEG signals were collected for each experiment by BIOPAC MP160 EEG acquisition device and SEDLINE device monitoring pigs anesthetized with propofol. In order to build our dataset, we extracted features relevant to the depth of anesthesia (DoA) carried by the EEG signal.

In constructing our predictive model, we've integrated Long Short-Term Memory (LSTM) networks, recognized for their proficiency with extended sequential data, alongside a Stacked Denoising Autoencoder (SDAE) to facilitate dimensionality reduction and enhanced feature extraction.

Preliminary evaluations showcase our model's remarkable stability and precision, particularly during the onset of sleep and arousal periods. A consistent decrease in DoA mirrors the uptick in propofol administration rates. Despite this, a notable variance appears in deep anesthesia stages, evidenced by a marked prediction error during deep sleep model validation.



BioAlps Networking Day

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Campus Biotech | 9 Nov | 9 am - 7 pm

P9 – Smartphone-based home test for fecal calprotectin revealed clinical performance comparable to high throughput central lab methods

Christian Reinhard, PhD, Benjamin Ricken, PhD, Marie-Eve Ueberschlag, Sabine Kräuchi, Daniela Trapani-Vondran, Romain Pénager, Pharm D, Laura Zurbrügg, Peter Kupchak, PhD, Thomas Schuster PhD
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Introduction

Endoscopy is the gold standard for detecting mucosal inflammation in order to differentiate between Irritable Bowel Syndrome (IBS) and Inflammatory Bowel Disease (IBD). Fecal calprotectin has been established as an excellent surrogate biomarker of intestinal inflammation. Different calprotectin assay formats are available, and it is essential that the biomarker is measured comparably across all assay methods. In this work, different assay methods were compared with clinical samples including a smartphone-based home test.

Methods

128 raw stool samples from patients diagnosed for IBD or IBS were used in this study. Each stool extract was measured on the BÜHLMANN fCAL ELISA, fCAL turbo (PETIA), Quantum Blue® fCAL extended lateral flow assay and smartphone based IB*Doc* fCAL home test. A Receiver Operating Characteristic (ROC) curve analysis was performed.

Results

ROC curves for each method were calculated in respect of differentiating between IBS and IBD with area under the curve (AUC) values ranging from 0.827 (IB*Doc* fCAL) to 0.835 (fCAL turbo). There was no significant difference between the methods. For all methods, a sensitivity up to 90.8 % and specificity up to 86.5% were obtained.

Conclusion

This study shows that all BÜHLMANN fecal calprotectin assays are very comparable. They show an excellent clinical performance irrespective of the assay method performed. This allows for the use of the methods interchangeably, depending on the needs of the patients and their care team.

P10 – Point-of-care testing of LDL cholesterol using molecularly imprinted polymers

de Gregorio Gian Luca[1], Prim Denis[1], Zavattoni Alberto[2], Mottini Italo[2], Pezzoli Daniele[2],
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Cholesterol is transported in the body within micellar assemblies called lipoproteins. Among these, Low Density Lipoproteins (LDL) are colloquially called "bad cholesterol" because they distribute cholesterol from the liver to the body and tend to accumulate on blood vessels' interior walls causing arteriosclerosis.

The determination of LDL cholesterol (LDL-C) levels in blood is therefore a key parameter to prevent cardiovascular diseases. Nowadays, LDL-C is quantified indirectly by assessing the quantity of total cholesterol and subtracting the amount of non-LDL lipoproteins. The analytical performance of this method is limited as the uncertainties of the individual measurements accumulate. The direct and specific determination of LDL-C using a dedicated assay would be a more accurate strategy. To develop such a specific assay, Molecularly Imprinted Polymers (MIPs) are an interesting class of polymer-based molecular recognition reagents engineered to bind to one single target compound. Selectivity is introduced during MIP synthesis thanks to a template molecule that guides the formation of specific imprints that are sterically and chemically complementary to the target analyte.

We will present the results of a project aiming at the development of a novel point-of-care test of LDL-C using MIP. We will describe the challenges and pitfalls encountered when using MIP with lipoproteins and the analytical performance that can be achieved.

P11 – Rapid rule-out of preeclampsia through protein ratio analysis at the point-of-care

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Preeclampsia is a life-threatening pregnancy condition affecting 2-8% of pregnancies worldwide where early detection is key to prevent short- and long-term health consequences for mother and babies. In this collaboration with FHNW and CSEM, MOMM Diagnostics develops high-sensitivity rapid diagnostic tests - opening previously laboratory-based markets for remote pregnancy monitoring, delivering information on the disease risk during pregnancy check-ups to help doctors to optimize treatment, reduce the stress and anxiety for expectant mothers, save lives and reduce costs.

Here we present the development of a lateral flow immunoassay with the sensitivity of ELISAs, all in a reader as simple as a blood glucose meter offering unprecedented sensitivity at the point-of-care.

P12 – Design research for point-of-care diagnosis: how to facilitate urine home monitoring.

Margherita Motta, Emily Groves, Andrea Schneider, Nicolas Henchoz, Delphine Ribes Lemay
EPFL+ECAL Lab, EPFL

Technological advances have enabled point of care testing for rapid diagnosis, long term patient monitoring, and home use. However, despite numerous studies focusing on technical advancements, there is a lack of research addressing the user experience and daily integration of such technologies. In collaboration with CSEM and ESTEE, the EPFL+ECAL Lab, the design research center of EPFL, presents the results of a design research study applied to the use case of home urine monitoring.

We employed a comprehensive methodology that integrated literature reviews, state-of-the-art analyses, and user studies to understand potential users' needs and preferences. This was complemented by iterative design phases, evaluated through in-context user tests using high-fidelity interactive prototypes. The outcome of this process is Aidee, a system that includes an app and an interactive device, designed to assist users in home urinalysis through qualitative data expression and ambient physicalization.

To validate the design, a between-subjects study involving 81 participants was conducted. The results showed user acceptance of qualitative data representation in the context of personal wellbeing, without diminishing data understanding or emotional engagement. Furthermore, the synergy between the app and the device not only gave users a serene environment for consulting results but also a sense of support that could counterbalance the fixation and stress often associated with monitoring practices.

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P13 – Development of a high-sensitivity assay for point-of-care detection of multiple acute myocardial infarction biomarkers

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Acute Myocardial Infarction (AMI) can lead to cardiac arrest or heart failure; it affects over 3 million individuals each year worldwide and is a leading cause of mortality[1]. AMI is the necrosis of tissue of the heart muscle due to a lack of oxygenation caused by the blockage of a coronary artery. Treatment of AMI is time-critical to restore blood flow and avoid permanent damage to the heart tissue.

AMI is currently diagnosed by the combination of symptoms observation, electrocardiogram and detection of biomarkers released by the necrosis of myocardial cells, most of the time cardiac troponins. Cardiac troponins can be measured in the blood three hours after the onset of chest pain, peak around 10-13 hours and persist for about seven days[2]. Electrocardiogram alone cannot detect all AMIs[1]. The kinetics of cardiac troponin are advantageous for late diagnosis of AMI, but limits early detection, which is crucial for rapid treatment. The development of high-sensitivity cardiac troponin tests allows for earlier detection of cardiac troponins and for a more precise definition of their healthy level. These tests open the possibility of detecting variations in the level of troponin earlier than with sensitive-contemporary assays[3].

High sensitivity detection of several AMI biomarkers with different and particularly more rapid kinetics using a point-of-care device would allow for even earlier diagnosis of AMI. The purpose of this study is to develop a multiplex microarray-type electrochemiluminescence immunoassay to allow simultaneous and sensitive quantification of two or more AMI biomarkers. This poster will present the rationale for the use of a multiplex assay and preliminary results of assay performance.

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P14 – Lyo-Beads Dispensing

Dieter Haberzettl
Harro Höfliger Verpackungsmaschinen GmbH

Dispensing of lyophilized Beads are getting more significant for POC products. The handling and separation of lyophilized beads from bulk must be carefully and sensitive.

It exists different possibilities to dispense lyophilized ingrediants in tubes, cartridges, plates or other devices.

P15 - PHOTO-SENS: Advancing PHOTOnic BioSENSors for Aquaculture Monitoring

Siegfried Graf, Thomas Valentin, Mark Fretz, Noa Schmid, Roman Arnet, Stephan Bitterli, Jakoba Heidler, Christian Seitz, Vincent Revol, Marko Dorrestijn

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Within the EU PHOTO-SENS consortium, CSEM are developing a cost-effective platform for detecting pathogens and identifying specific DNA biomarkers. Our use case is the detection of salmon pathogens as well as the identification of the sex of individual sturgeons (Figure 1a).

The system revolves around a desktop reader coupled with disposable microfluidic cartridges that house functionalized photonic chips (Figure 1b). These biochips are fabricated from silicon wafers through advanced cleanroom processes. To minimize costs, the team has designed and manufactured photonic chips with a smaller footprint, increasing the number of chips that can fit on a single wafer.

A major challenge lies in the packaging and integration of the photonic sensor within the microfluidic cartridge. The process required a leak-proof interface while allowing electronic access for actuation and read-out. Additionally, the cartridge will feature a rapid and efficient heating meander, an antifouling coating, a degassing chamber / bubble trap, and on-chip reagent storage using blisters. Designing the microfluidic with high-throughput manufacturing (injection molding) in mind further contributes to cost reduction.

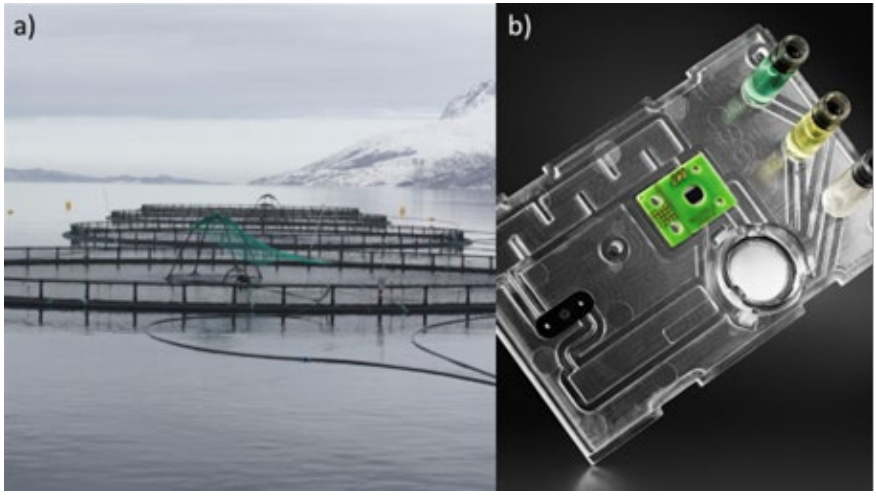

Figure 1: a) The use case of the PHOTO-SENS project is the detection of salmon pathogens as well as the identification of the sex of individual sturgeons. b) PHOTO-SENS builds upon the achievements of the previous EU project BIOCDx, in which CSEM developed a proof-of-concept prototype for pathogen detection. The picture shows the disposable BIOCDx cartridge.


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Wuethrich	Marcel	Evoleen AG - makes digital healthcare happen
Youell	James	Integrated Graphene
ZAMPICCOLI	EMANUEL	ZHAW
Zenklusen	Rosanna	Siemens Healthcare International
Zompa	Théo	