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Sixth International

Molecular Diagnostics EUROPE

22-24 MAY 2018 | LISBON, PORTUGAL

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CONFERENCE PROGRAMS

22-23 MAY 2018

- Advances in Prenatal Molecular Diagnostics
- Advanced Diagnostics for Infectious Disease
- Clinical Application of Cell-Free DNA

23-24 MAY 2018

- Enabling Technologies for Cell-Free DNA
- Point-of-Care Diagnostics
- Circulating Tumour Cells

PLENARY PANEL: CHANGING LANDSCAPE FOR IVDs IN THE EU

David E. Barton, PhD

Chief Molecular Geneticist, Our Lady's Hospital for Sick Children

Jörg Engelbergs, PhD

Paul-Ehrlich-Institut (PEI), Federal Institute for Vaccines and Biomedicines

Sue Spencer

Global Service Director, Regulatory, UL

Andreas Stange, PhD

Vice President MHS Global IVD, TÜV SÜD

Doris-Ann Williams, MBE

Chief Executive, British In Vitro Diagnostics Association

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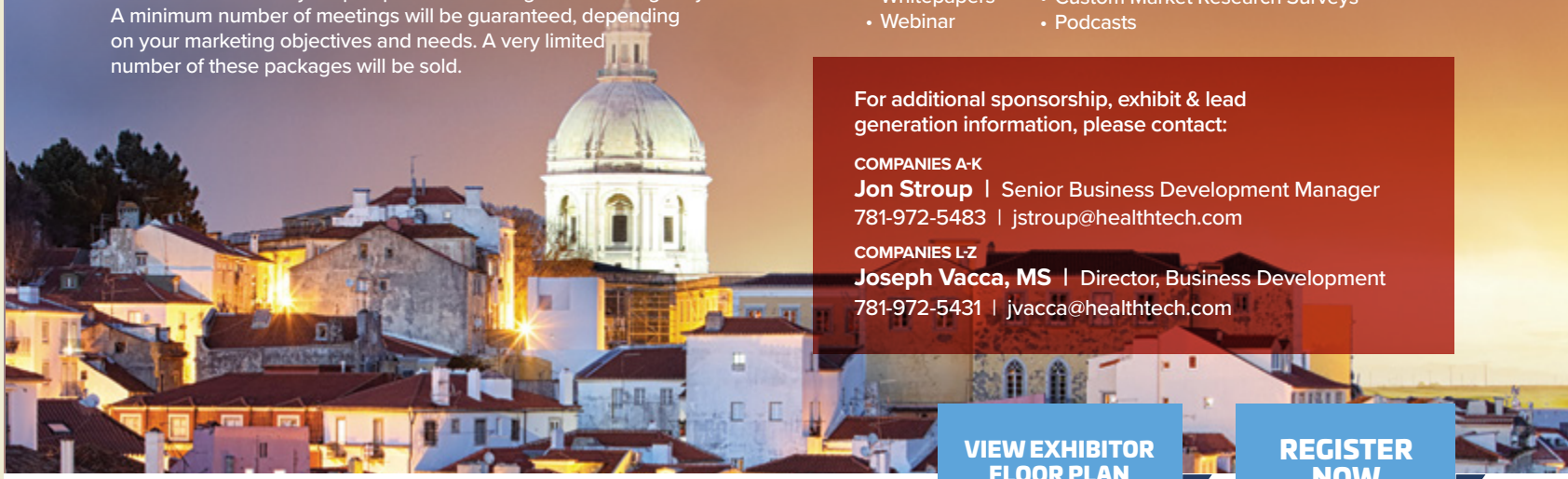

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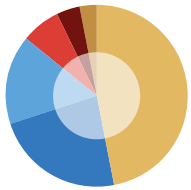

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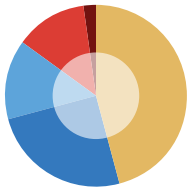

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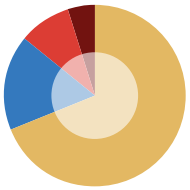

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About the Event

Cambridge Healthtech Institute's Sixth International **Molecular Diagnostics Europe** event will return to Lisbon on 22-24 May 2018. This meeting provides a nexus for diagnostic developers in academia and industry as well as end-users in the pharmaceutical and healthcare sector to gain a comprehensive picture of molecular diagnostics in prenatal, oncology, infectious disease, point-of-care, and liquid biopsy. This exciting area has attracted attendance of over 400 delegates to learn what novel technologies, platforms and applications are emerging that will impact future healthcare delivery and pharmaceutical research. Join us this spring at this expanding event at the epicenter of diagnostics.

CONFERENCE-AT-A GLANCE

	Monday, 21 May	Tuesday, 22 May	Wednesday, 23 May	Thursday, 24 May
AM		Advances in Prenatal Molecular Diagnostics		
PM	Short Course*		Enabling Technologies for Cell-Free DNA	
AM		Advanced Diagnostics for Infectious Disease		
PM	Short Course*		Point-of-Care Diagnostics	
AM		Clinical Application of Cell-Free DNA		
PM	Short Course*		Circulating Tumour Cells	

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Cambridge HEALTHTECH Institute

Pre-Conference Short Courses*

MONDAY, 21 MAY 2018 | 14:00-17:00

SC1: Technologies, Applications and Commercialization of Point-of-Care Diagnostics

Holger Becker, PhD, Founder & CSO, microfluidic ChipShop GmbH, Germany

This short course will provide an overview on the technological aspects of POC system developments. It will introduce current technologies such as microfluidics, sensors, paper- and smartphone-based approaches and discuss their trends and limitations. The course will discuss a variety of POC systems in different stages of their development, from early stage to established diagnostic systems in the clinical routine. Market aspects of POC systems as well as practical examples of commercialization for molecular diagnostic, immunological and clinical tests will be presented.

SC3: Liquid Biopsy for P4 Medicine: Predictive, Preventive, Personalized and Participatory

Lorena Diéguez, PhD, Staff Researcher, Diagnostic Tools and Methods Research Group, Life Sciences, International Iberian Nanotechnology Laboratory, Portugal

Clotilde Costa Nogueira, PhD, Head, Liquid Biopsy Line, Roche-Chus Joint Unit, University Hospital of Santiago de Compostela, Spain

P4 Medicine is Predictive, Preventive, Personalized and Participatory. The P4 medicine concept is fully realised in the context of Liquid Biopsy, since the patient's blood is used as a biomarker for the prognosis and diagnosis of the disease status. Therefore, Liquid Biopsy provides the ideal scheme to personalize the treatment in precision medicine. P4 medicine will permit to identify predictive and preventive biomarkers and genomic mapping, adapting treatments to each patient, and having the patients engaged for a successful outcome.

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Advances in Prenatal Molecular Diagnostics

TRENDS, ADVANCES AND PROSPECTS

RECOMMENDED SHORT COURSE*

Preimplantation Genetic Diagnostics and Screening

**Separate Registration required. See page 3 for details.*

TUESDAY, 22 MAY

CELL-FREE DNA SCREENING

08:00 Registration and Morning Coffee

09:00 Chairperson's Remarks

Patrizia Paterlini-Brechot, PhD, MD, Cellular & Molecular Biology, University Paris Descartes, France

09:05 KEYNOTE PRESENTATION: **Extending the Scope of Prenatal Diagnosis for Monogenic Disorders: Non-Invasive Prenatal Diagnosis**

Lyn Chitty, PhD, MBBS, MRCOG, Professor, Genetics and Genomic Medicine, UCL Great Ormond Street Institute of Child Health and North-East Thames Regional Genetics Service, Great Ormond Street Hospital for Children NHS Foundation Trust, United Kingdom

Traditional prenatal diagnosis has involved invasive tests. The analysis of cell free DNA in maternal plasma has led to widespread introduction of less invasive testing for aneuploidy, but less so for monogenic disorders. In this presentation I will explain how, in our accredited public service genetics laboratory, we have developed a comprehensive diagnostic service for the non-invasive prenatal diagnosis of monogenic disorders. Such that we now deliver >30% of genetic diagnosis using NIPD and for more than 50 different genetic conditions.

09:35 Non-Invasive Prenatal Diagnosis of Maternally-Inherited Monogenic Disorders by Droplet Digital PCR Combined with Uniformly Most Powerful Likelihood Ratio Test

Juliette Nectoux, PharmD, PhD, Molecular Genetics, HUPC Hôpital Cochin, France

In order to non-invasively identify the fetal status in most cases of maternally-inherited monogenic disorders, we propose a strategy based on iterative collection of plasma samples during pregnancy, followed by droplet digital PCR experiments which allow to accurately quantify the probability for an allele to be mutant. Finally, hypotheses "fetus affected" versus "fetus unaffected" are tested from cumulated experiments using a dedicated statistical model. We study NIPD performance empirically and provide examples from real data to explain how it should be interpreted. This proof-of-concept study of non-invasive droplet-digital PCR technology for the analysis of both paternally and maternally inherited fetal alleles demonstrates that NIPD for single-gene disorders is now becoming achievable.

10:05 Patient-Like Reference Materials to Enable and Accelerate NIPT Assay Validation and Routine Monitoring

Sponsored by seracare

Ram Santhanam, Senior Director, Product Marketing, SeraCare Life Sciences

As non-invasive prenatal testing (NIPT) expands globally and comes under increased regulatory scrutiny, there is a critical need for patient-like reference materials to accelerate assay development, validation, external quality assurance (EQA) and routine monitoring. We will discuss case studies from a cross section of laboratories successfully utilizing these reference materials.

10:20 Sponsored Presentation *(Opportunity Available)*

10:35 Grand Opening Coffee Break in the Exhibit Hall with Poster Viewing

11:15 Trends in Non-Invasive Prenatal Diagnosis of Cystic Fibrosis

Claire Guissart, PhD, Laboratory of Genetic Medicine, University of Montpellier, France

Analysis of circulating cell-free fetal DNA (cff-DNA) in maternal plasma is very promising for early diagnosis of monogenic diseases. Several methodological approaches have been developed for NIPD of cystic fibrosis, which is the most common life shortening, childhood onset autosomal recessive disorder in populations of European descent. As we started the translation of our latest noninvasive prenatal diagnosis approach from research into clinical practice, we provide detailed feedback on current cystic fibrosis NIPD clinical practice and prospects.

11:45 Early User Experiences with NIPT: Findings from a Qualitative Study of Private Patients in the UK

Heather Strange, PhD, Research Associate, Centre for Trials Research, Cardiff University, United Kingdom

The UK Department of Health announced plans to integrate NIPT testing into routine prenatal testing in November 2016, and national roll-out is expected to occur in 2018. NIPT testing has been available for pregnant women to access via private prenatal testing services since 2012. Such private testing services are likely therefore to remain in place, and may also expand in size and scope. This work reports on the findings of a small qualitative dataset, generated out of two studies examining NIPT in the UK. This small body of evidence on the private NIPT patient experience is of clear value as it sheds light on early user experiences at a crucial time.

12:15 The Diagnostic Effect of the Introduction of Two NIPT Approaches in a Laboratory Where a Routine SNP Array Is Offered in All Pregnancies

Malgorzata Srebniak, PhD, Laboratory Specialist in Clinical Genetics, Clinical Genetics, Erasmus Medical Center, The Netherlands

After initially applying the genomic SNP chromosomal microarray only in fetuses with ultrasound abnormalities, since July 2012, we routinely performed the SNP array also in cases without fetal ultrasound anomalies where

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invasive prenatal diagnosis was indicated. In 2013, NIPT became commonly available in Europe which led to a decrease in the number of prenatal invasive procedures. From 2014, NIPT was offered as a second-tier screening test in The Netherlands, when the first trimester combined test showed increased risk for either trisomy 21, 13 or 18. Since April 2017, NIPT is offered as a first-tier screening test. Based on our own regional data, we will show the effect of the genomic SNP array testing and these two NIPT approaches on the diagnostic yield within the last 9 years.

12:45 Sponsored Presentation *(Opportunity Available)*

13:15 Luncheon Presentation *(Sponsorship Opportunity Available)* **or Enjoy Lunch on Your Own**

13:45 Session Break

EXAMINING THE IMPORTANCE OF PRE-TEST COUNSELING

14:15 Chairperson's Remarks
Ida Vogel, MD, Head, Clinical Genetics, Aarhus University Hospital, Denmark

14:20 The Importance of Pre-Test Counseling in Aneuploidy Screening by cffDNA: Patients' Experiences
Vedran Stefanovic, PhD, Professor, Maternal and Fetal Medicine, Department of Obstetrics and Gynecology, Helsinki University Hospital, Finland
The unique 95% uptake of first trimester combined and free-of-charge screening in Finland provides cffDNA second-tier screening for all screen-positive women and those with a priority high risk for aneuploidy. Here we present the global overview of pre-test counseling importance in the context of prenatal aneuploidy screening by cffDNA with special emphasis on patients' experiences and choices in the tertiary teaching university hospital which provides cffDNA screening free of charge for all high-risk pregnancies and personal non-directive counseling. We present our three-year implementation results and the detailed analysis

SOLATION AND ANALYSIS OF FETAL CELLS FROM MATERNAL BLOOD

14:50 How Fetal Cells in Maternal Blood Change the NIPT Paradigm
Ripudaman Singh, PhD, COO, ARCEDI Biotech Aps, Denmark
By using a proprietary technology, we have shown that we can isolate fetal cells from every pregnant sample and use the DNA from isolated fetal cells to detect chromosomal and sub-chromosomal changes in the fetal genome. The results from the cbNIPD were verified by the results from chorionic villi sampling. Having performed a preliminary study for implementing our method in a clinical setup, we are in the process of launching a cell-based clinical test in Denmark. In this test, results from the cell-based prenatal analyses on high risk pregnancies will be compared with cell-free non-invasive prenatal testing (cfNIPT).

15:15 Technical Advances for Isolation and Genetic Analysis of Circulating Trophoblastic Cells
Patrizia Paterlini-Brechot, PhD, MD, Cellular & Molecular Biology, University Paris Descartes, France
Circulating fetal cells offer an interesting opportunity to analyze fetal DNA not mixed with maternal DNA aiming to develop a non-invasive approach for prenatal genetic diagnosis (NI-PND). Critical issues for this goal are the number of fetal cells which can be recovered from a blood sample, the purity of cell recovery, the quality of the recovered fetal cells DNA and the assay workflow allowing to develop a high-throughput analysis generating reliable results at a very affordable price. We will show results using the ISET patented method to isolate trophoblastic cells without the use of antibodies and analyze their DNA for non-invasive prenatal diagnosis. We will discuss the different critical issues and the possible solutions in order to bring to the market a new test for NIPND.

BIOMARKERS FOR PREECLAMPSIA AND PRE-TERM BIRTH

15:40 Preeclampsia: Where Is the Progress of the Last Decade?
Berthold Huppertz, PhD, Professor of Cell Biology, Gottfried Schatz Research Center for Cell Signaling, Metabolism and Aging, Medical University of Graz, Austria
Preeclampsia has been and still is the syndrome of hypotheses. Much has been discussed and hypothesized, but little has been achieved. The etiology of the syndrome is still in the dark. Also, the identification and use of early predictive biomarkers has not been successful but rather has been hindered by non-scientific movements. Here, a wind of change is needed to succeed in developing treatments to help women suffering from preeclampsia.

16:00 Using Liquid Biopsies and Bioinformatics for Non-Interventional Molecular Recognition of Patients at Risk to Develop Preeclampsia
Hamutal Meiri, PhD, MBA, Coordinator, International Research, ASPRE Consortium, Israel
The study focuses on the discovery, confirmation and validation of novel biomarkers in a non-interventional manner applying NGS, multiplex PCR and miRNA technologies to determine the biomarkers according to free circulating DNA, RNA, miRNA of maternal plasma, serum and white blood cells along with the use of extracellular vesicles. Bioinformatics enables to link the biomarkers to the underlying pathways thus illuminating the signaling pathways and direct therapeutic treatment.

16:20 Refreshment Break in the Exhibit Hall with Poster Viewing

17:00 Breakout Discussions

18:00 Welcome Reception in the Exhibit Hall with Poster Viewing

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19:00 Close of Day

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WEDNESDAY, 23 MAY

WHOLE EXOME AND WHOLE GENOME SEQUENCING IN PRENATAL DIAGNOSTICS

08:00 Registration and Morning Coffee

09:00 Chairperson's Remarks

Malgorzata Srebniak, PhD, Laboratory Specialist in Clinical Genetics, Clinical Genetics, Erasmus Medical Center, The Netherlands

09:05 Using Exomes in Prenatal Diagnostics

Ida Vogel, MD, Head of Clinical Genetics, Aarhus University Hospital, Denmark

Over the last two years, we have gradually implemented WES in pregnancy – first on terminated pregnancies and now also in ongoing. 44 % fetal exomes (trio) provided a diagnosis for the fetus in cases not solved by CMA. Thus, WES analysis can reveal an unexpected diagnosis and thereby completely alter the premises for decision-making regarding current and future pregnancies – now based on a specific diagnosis and knowledge of recurrence risk. Moreover, utilizing WES in the third trimester can provide a diagnosis and may substantially improve the treatment plan for the neonate in a non-acute setting.

09:35 Array-CGH as a First-Tier Test in All Invasive Prenatal Samples: A Year of Experience

Julian Nevado, PhD, Responsible for Genomics and Quality Manager, INGEMM, Spain

In a moment with prevalence of NIPD testing in the prenatal diagnosis, what should we do with the invasive prenatal samples? Based on our experience and current data, we will try to recommend our best option for a complete genetic prenatal diagnosis.

10:05 Ethics of NIPT Whole Genome Tests

Francois Jacquemard, PhD, Gynecology & Obstetrics, American Hospital of Paris, France

This talk will examine a number of ethical issues related to whole genome NIPT tests, including when to use this type of testing, how to analyze and present the information to patients, and the role of genetic counseling. This talk will also examine different perspectives across Europe.

10:35 Sponsored Presentation *(Opportunity Available)*

11:05 Coffee Break in the Exhibit Hall with Poster Viewing

PLENARY SESSION

11:35 Plenary Introduction

John Carrano, CEO, Paratus Diagnostics, LLC, United States

11:45 The New EU IVD Regulation – What Will It Mean for Your Lab?

David E. Barton, PhD, Chief Molecular Geneticist, National Centre for Medical Genetics, Our Lady's Hospital for Sick Children, Ireland

In May 2017, Europe passed a new Regulation on *in vitro* Diagnostic Devices (IVDs). The regulation sets up a framework for controlling the market for diagnostic tests within the EU, setting out standards for the design and manufacture of in-vitro diagnostic devices (IVDs) and providing mechanisms for the oversight of these standards. This presentation will outline the content of the new regulations, with a particular focus on molecular diagnostics, and highlight the new requirements for clinical laboratories.

12:15 PANEL DISCUSSION: Changing Landscape for IVDs in the EU

Moderator: Charlotte Ryckman, Covington & Burling LLP, Belgium

Panelists: David E. Barton, PhD, Chief Molecular Geneticist, National Centre for Medical Genetics, Our Lady's Hospital for Sick Children, Ireland

Jörg Engelbergs, PhD, Section Mono- and Polyclonal Antibodies, Scientific Expert Biomedicines, Quality, Non-Clinic & Personalized Medicine (Biomarker/CDx), Paul-Ehrlich-Institut, Federal Institute for Vaccines and Biomedicines, Germany

Maria Judite Neves, Health Products Director, Health Products Directorate, INFARMED – National Authority of Medicines and Health Products, Portugal

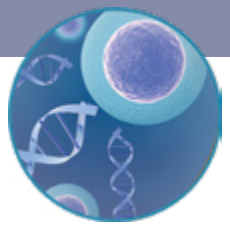
Sue Spencer, Global Service Director, Regulatory, UL, United Kingdom

Andreas F. Stange, PhD, Vice President MHS Global IVD, TÜV SÜD, Germany

Doris-Ann Williams, MBE, Chief Executive, British In Vitro Diagnostics Association (BIVDA), United Kingdom

- Practical impact of the new IVD Regulation
- Regulatory aspects of companion diagnostics
- Challenges for validation
- Role of IVDs in the market

13:30 Close of Advances in Prenatal Molecular Diagnostics



Enabling Technologies for Cell-Free DNA

IMPROVING ASSAYS FOR CLINICAL USE

RECOMMENDED SHORT COURSE*

Liquid Biopsy for P4 Medicine: Predictive, Preventive, Personalized and Participatory

**Separate Registration required. See page 3 for details.*

WEDNESDAY, 23 MAY

NOVEL TECHNOLOGIES AND APPROACHES FOR CELL-FREE DNA ANALYSIS

14:30 Chairperson's Remarks

Christa Noehammer, PhD, Senior Scientist, Molecular Diagnostics, Austrian Institute of Technology GmbH, Austria

14:35 KEYNOTE PRESENTATION: **Multi-Step Real-Time PCR Coupled with HRM Enables Rapid Mutation and MSI Assessment Prior to Targeted Re-Sequencing**

G. Mike Makrigiorgos, PhD, Professor, Radiation Oncology, Dana Farber and Harvard Medical School, United States

Targeted re-sequencing often entails discrete amplification and ligation steps during sample preparation that increase both cost and time to results. We provide novel forms of real time PCR that reduce the effort for sample preparation while also providing rapid assessment of mutation status prior to targeted re-sequencing. The new method incorporates implementation of mutation enrichment via COLD-PCR or NaME-PrO together with high resolution melting. Application in detecting mutations and microsatellite instability (MSI) using circulating DNA from clinical cancer samples will be presented.

15:05 Identification of Rare Mutations and DNA Methylation Patterns in Cell-Free DNA Using Multiplexed Enhanced-ice-COLD-PCR

Jorg Tost, PhD, Director, Laboratory for Epigenetics & Environment, Centre National de Genotypage, CEA – Institut de Génomique, France

We have developed a modified version of the ice-COLD-PCR assay called Enhanced-ice-COLD-PCR for KRAS, BRAF and NRAS mutation detection and identification, which allows the enrichment of the most frequent mutations and requires only a small amount of starting material (frozen, FFPE or plasma) permitting the sensitive detection and multiplexed sequence identification of mutations within three hours. We have recently extended the applications to the analysis of methylated molecules in primary tumors and ccfDNA. Enhanced-ice-COLD-PCR has been applied to different collections of cancer samples.

15:35 Use of Digital PCR and Optimized NGS for Cell-Free Tumour DNA Analysis

Valerie Taly, PhD, Group Leader, CNRS Researcher, UMR S1147, University of Paris Descartes, CNRS, France

We will present several strategies based on digital PCR and/or optimized NGS that permit highly sensitive and precise detection of circulating tumor DNA for the follow up of cancer patients. Interests and potential complementarity of these technologies will be presented through different examples.

16:05 Refreshment Break in the Exhibit Hall with Poster Viewing

17:05 Building a Liquid Biopsy Platform for Cancers with a Low Burden in Plasma

Milana Frenkel-Morgenstern, PhD, Senior Lecturer, Faculty of Medicine in Galilee, Bar-Ilan University, Israel

Non-invasive diagnostics of highly mutated cancers will advance the cancer monitoring and prognosis. We aim to build a novel liquid biopsy platform for the cases with a low burden in plasma using a sensitive whole genome, whole methylome and epigenetics analyses. Our methodology enables the discovery of unique biomarkers at a single molecule level for personalized therapy approaches.

PRE-ANALYTICAL CHALLENGES: DETECTION, EXTRACTION, ISOLATION, CHARACTERISATION

17:35 Pre-Analytical Standardization for Isolation of Extracellular Vesicles

An Hendrix, PhD, Professor, Laboratory of Experimental Cancer Research, Ghent University, Belgium

An Hendrix will discuss the impact of pre-analytical factors and isolation methods on the identification of extracellular vesicle-associated biomarkers in liquid biopsies. She will present the development and implementation of reference materials for extracellular vesicles and how this can help to compare and normalize results.

18:05 Breakout Discussions

19:05 Close of Day

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THURSDAY, 24 MAY

PRE-ANALYTICAL CHALLENGES: DETECTION, EXTRACTION, ISOLATION, CHARACTERISATION (CONT.)

08:30 Registration and Morning Coffee

09:00 Chairperson's Remarks

Rikke Fredslund Andersen, PhD, Molecular Biologist, Department of Clinical Biochemistry, Vejle Hospital, Denmark

09:05 Pan-Cancer Characterization and Exploitation of Plasma DNA Fragmentation with Genome-Wide Sequencing

Florent Mouliere, PhD, Postdoctoral Research Associate, Cancer Research UK Cambridge Institute, University of Cambridge, United Kingdom

The sensitivity for detecting the presence of genomic changes in circulating tumour DNA (ctDNA) is limited by its low concentration in plasma. Here I will present new approaches tailoring sequencing to the biological properties of ctDNA. Notably, we studied the feasibility for enrichment of ctDNA by physical and *in silico* size selection in plasma samples collected in 51 patients from multiple cancer types. Size selection of DNA fragments between 90-150 bp yielded enrichment up to 118-fold, unlocking untargeted genome-wide sequencing for liquid biopsy.

09:35 Isolation and Quantification of Cell-Free DNA in Cerebrospinal Fluid

Alison Devonshire, PhD, Science Leader, Molecular and Cell Biology, LGC Ltd., United Kingdom

Cerebrospinal fluid (CSF) is a medium containing biomarkers of traumatic injuries, neurodegenerative disorders and brain malignancies. Cell-free DNA (cfDNA) is another potential CSF biomarker for such pathologies, yet standardized isolation and quantification methods remain to be defined. We evaluate methods for cfDNA extraction from CSF and quantify nuclear and mitochondrial genomic targets in cases of Alzheimer's disease, primary or secondary brain cancer and controls.

10:05 Enabling Confidence in Liquid Biopsy Testing using Patient-Like Reference Materials

Sponsored by seracare

Sandi Deans, PhD, Director, Genomics Quality Assessment (GenQA), Department of Laboratory Medicine, Royal Infirmary of Edinburgh

The testing of ctDNA (liquid biopsy) is rapidly being implemented into clinical practice as a surrogate for solid tumor biopsies. This presentation will discuss the use of patient-like reference materials to drive accurate patient testing and subsequent drug treatment decisions based on the presence of pathogenic EGFR gene variants.

10:05 Multiplex Assays for Cancer Management Using πCode MicroDisc Technology

Sponsored by PlexBio

Stuart Palmer, PhD, COO, Administration, PlexBio Co., Ltd., Taiwan

PlexBio has developed a platform for high complexity mutation analysis. The IntelliPlexTM Lung Cancer Panel assesses the status of 57 somatic mutations and gene re-arrangements in liquid biopsy samples. The test offers a rapid, comprehensive and cost-effective way to interrogate patient samples with achievement of sensitivities of 0.01%-0.1%.

10:35 Coffee Break in the Exhibit Hall. Last Chance for Poster Viewing

11:20 Preanalytical Blood Sample Workup for Cell-Free DNA Analysis Using Droplet Digital PCR for Molecular Diagnostics

Manon M. H. Huibers, PhD, Clinical Scientist in Molecular Pathology, Pathology, University Medical Center Utrecht, The Netherlands

Pitfalls in pre-analytical steps for liquid biopsy material handling will be presented including different methods and protocols for sample collection, storage, centrifugation, isolation, and quantification of cfDNA. Examples will be given using liquid biopsy sample input from blood, cerebrospinal fluid, urine, and eye fluid. All these liquid biopsy samples could be used in different diagnostic fields, which will be addressed in this presentation.

11:50 Results of an External Quality Assessment Scheme (EQA) for Isolation and Analysis of Circulating Tumour DNA (ctDNA)

Verena Haselmann, MD, Physician, Institute for Clinical Chemistry, University Medicine Mannheim, Germany

In these pilot EQA schemes for analysis of ctDNA, 42 European laboratories participated and reported the methods used for isolation and quantification of cfDNA as well as for genotyping of ctDNA. The results obtained illustrate the current variability in multiple phases of cfDNA processing and analysis of ctDNA, resulting in an overall error rate of 6.09%. Therefore, there is an urgent need for harmonization of procedures in this new diagnostic field.

12:20 Sponsored Presentation *(Opportunity Available)*

12:50 Luncheon Presentation *(Sponsorship Opportunity Available)* **or Enjoy Lunch on Your Own**

13:20 Session Break

NOVEL APPROACHES FOR BIOFLUIDS, RNA, AND METHYLATED DNA

13:50 Chairperson's Remarks

Verena Haselmann, MD, Physician, Institute for Clinical Chemistry, University Medicine Mannheim, Germany

14:00 RNA vs. DNA: Pre-Analytical Steps

Jo Vandesompele, PhD, Professor, Functional Cancer Genomics and Applied Bioinformatics, Ghent University, The Netherlands

We are examining the effects of blood collection tubes, extraction kits, and time and how they influence the transcriptome of RNA. The goal of this study is to create standardisation and reproducibility.

14:30 Circulating Biomarkers and Exosomes in Salivary Diagnostics

Christa Noehammer, PhD, Senior Scientist, Molecular Diagnostics, Austrian Institute of Technology GmbH, Austria

Our current focus is to investigate saliva for its suitability for any type of circulating biomarker diagnostics. Along these lines we will present proof of concept data for salivary DNA-methylation - and autoantibody-based biomarkers in a breast cancer patient cohort.

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ENABLING TECHNOLOGIES FOR CELL-FREE DNA, Continued

15:00 Methodological Aspects of Analyses of Mutated vs. Methylated Circulating Cell-Free DNA

Rikke Fredslund Andersen, PhD, Molecular Biologist, Department of Clinical Biochemistry, Vejle Hospital, Denmark

Tumor-specific methylations in circulating cell-free DNA have potential to become clinically applicable markers to monitor cancer patients. A few markers can potentially substitute mutational analyses where large numbers of markers are needed to cover all patients. Methodological aspects of these analyses will be discussed as well as comparisons with mutation analyses in plasma.

15:30 Sponsored Presentation *(Opportunity Available)*

16:00 Refreshment Break in the Foyer

16:20 Identification of Tissue-Specific Cell Death Using Methylation Patterns of Circulating DNA

Ruth Shemer, PhD, Senior Lecturer, Department of Developmental Biology and Cancer Research, Hebrew University, Israel

Cell-free circulating DNA (cfDNA) is emerging as a powerful biomarker, however its utility is limited to cases where the tissue of interest differs genetically from the host. Here we present an approach to identify the tissue origins of cfDNA, based on tissue/cell-specific methylation pattern. We used this approach to determine the source-tissue distribution in a serum sample of patients with various diseases including cancer.

16:50 Peripheral Monitoring of Neurodegeneration Using cfDNA Methylation

Zac Chatterton, PhD, Lecturer, Brain and Mind Centre, The University of Sydney, Australia

Neurodegeneration occurs in a variety of human diseases however molecular profiling of the brain is restrictive. Cell-free DNA (cfDNA) derived from neurological tissue holds great potential for neurodegenerative detection and monitoring. Within our lab we exploit the unique DNA methylation profiles of brain cells to create molecular diagnostic assays capable of detecting peripheral neurological cell free DNA.

17:20 Close of Conference

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CONFERENCE VENUE AND HOTEL:

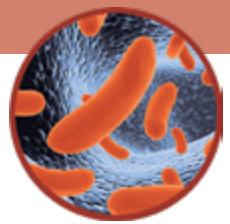
Sheraton Lisboa Hotel & Spa

Rua Latino Coelho, 1
1069-025 Lisbon, Portugal
Phone: (351)(21) 3120000

Discounted Room Rate: €190 single/€210 double, includes breakfast

Discount Cut-off Date: 11 April 2018

Reservations: Go to the travel page of www.moleculardxeurope.com



Advanced Diagnostics for Infectious Disease

NEW FRONTIERS IN INFECTIOUS DISEASE TECHNOLOGY

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RECOMMENDED SHORT COURSE*

Technologies, Applications and Commercialization of Point-of-Care Diagnostics

Separate Registration required. See page 3 for details.

TUESDAY, 22 MAY

NOVEL TECHNOLOGIES

08:00 Registration and Morning Coffee

09:00 Chairperson's Remarks

François Jean, PhD, Associate Professor, Department of Microbiology and Immunology, University of British Columbia, Team Leader, NCE IC-IMPACTS Grant in Next Generation Molecular Diagnostics for Emerging Viral Diseases, and CIHR Grant in Anti-Flavivirus Drug Discovery, Canada

09:05 KEYNOTE PRESENTATION: An Overview on the Emergence of Arbovirus Epidemics in the World and Their Consequences

Pedro Fernando da Costa Vasconcelos, MD, PhD, Medical Virologist, Director, Evandro Chagas Institute, Ministry of Health, Brazil

Studies have showed that Zika Virus (ZIKV) is associated with severe disease for people with immunologic disorders. For neonates and immunodeficient patients, an important involvement of innate and adaptive immune responses is critical in the host response and pathogenesis. The development of a live attenuated ZIKV vaccine was aimed to prevent the microcephaly and other congenital defects associated with infection during pregnancy. In this presentation, the participation of immune cells and cytokine/chemokine expression and changes in target organs and the approach used for the development of a live-attenuated ZIKV vaccine will be addressed and discussed considering the pivotal role of immune system in the pathogenesis of ZIKV infection, disease presentation and outcome.

10:05 Pushing the Frontiers of Clinical Proteomics: Absolute Quantification of Circulating Infectious Virus Particles by MRM-MS

François Jean, PhD, Associate Professor, Department of Microbiology and Immunology, University of British Columbia, Team Leader, NCE IC-IMPACTS Grant in Next Generation Molecular Diagnostics for Emerging Viral Diseases, and CIHR Grant in Anti-Flavivirus Drug Discovery, Canada

The four serotypes of dengue virus (DENV-1/2/3/4) impose a significant global health burden, an important risk factor for developing life-threatening severe dengue is a prior infection with a heterologous DENV serotype. Therefore, accurate serotype-specific diagnoses of all 4 DENVs and their maturation states are important. Here we report novel multiplexed multiple reaction monitoring-mass spectrometry (MRM-MS) assays, i.e., N-terminal acetyl (NTAc) labeling MRM assays, for determining the absolute numbers of DENV pre-membrane (prM) and cleaved M-anchored surface glycoproteins on circulating virions. Our multiplexed NTAc-MRM assays are the first DENV-targeted MRM-MS assays for detecting and quantitating the degree of maturity ("infectiveness") of all four circulating DENV particles in biological samples.

10:35 Coffee Break in the Exhibit Hall with Poster Viewing

11:15 Highly Pathogenic Polyomavirus Strains and Viral MicroRNA Expression

Eeva Auvinen, PhD, Senior Laboratory Supervisor, Department of Virology and Immunology, Helsinki University Hospital Laboratory, Finland

Rearrangements in the JC polyomavirus genome are required for development of PML, a fatal brain disease. We have shown by massive parallel sequencing of complete viral genomes that several rearranged JC strains may be found in the brain of PML patients. However, in BK nephropathy and in the rare JC nephropathy, viral strains harbor few rearrangements in the regulatory region. Viral microRNAs are frequently expressed and have biomarker potential. Viral strain variations may be associated with altered viral microRNA expression.

11:45 Matrix-Assisted Laser Desorption/Ionization Time-of-Flight (MALDI-TOF) Mass Spectrometry Applied to Virus Identification

Adriana Calderaro, MD, PhD, Associate Professor, Clinical Microbiology, Unit of Microbiology and Virology, Clinical and Experimental Medicine, University Hospital of Parma, Italy

The innovative application of MALDI-TOF mass spectrometry to virology, recently performed in our laboratory for the identification and/or serotyping of different viruses infecting humans including polioviruses, respiratory viruses, adenoviruses was described. Moreover, a preliminary application to HBV/HCV positive serum samples will be described.

12:15 Late Breaking Presentation

12:45 Recent Advances in qPCR Reagent Lyophilization

Sponsored by ThermoFisher SCIENTIFIC

Junko Stevens, Senior Director, Research & Development, Genetic Sciences Division, Thermo Fisher Scientific

13:15 Luncheon Presentation *(Sponsorship Opportunity Available)* **or Enjoy Lunch on Your Own**

13:45 Session Break

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PATHOGEN IDENTIFICATION AND OUTBREAK SURVEILLANCE

14:15 Chairperson's Remarks
Matthew Cotten, PhD, Senior Staff Scientist, Viroscience, Erasmus Medical Center, the Netherlands

14:20 Challenges of Using Next-Generation Sequencing for Diagnostic Applications
Matthew Cotten, PhD, Senior Staff Scientist, Viroscience, Erasmus Medical Center, the Netherlands
Advances in next-generation sequencing (NGS) allow investigators to quickly generate detailed sequence data from a variety of clinical samples. These methods can provide viral genomic sequences from clinical samples for a variety of uses. Classification algorithms are needed that can rapidly detect and classify low frequency virus sequences amidst a high sequence background. New technologies are sensitive to contamination and new algorithms to detect and set thresholds for contamination are being developed. I will discuss some the challenges faced as we apply NGS to viral diagnostics and describe how we are meeting these challenges with examples from our work on Ebola virus, MERS coronavirus, norovirus and respiratory syncytial virus.

14:50 Selected Poster Presentation: Cross Platform Comparison of PCR Assay for Detection of H. pylori and Mutations
Erin Beckman, Research Assiciate, Meridian Bioscience, United States
Clarithomycin is a first-line drug of choice for treatment in Helicobacter pylori infection; as such there is increasing importance for detecting resistance strains. In addition, testing for these resistant strains with a biopsy specimen requires an endoscopic procedure that carries its own risks. This talk will review a study that aimed to verify that the H. pylori genotyping assay from stool can be app lied to several real-time PCR platforms. Results show that the limit of detection and stool specimen performance is comparable across platforms when the appropriate parameters are applied. All platforms are capable of distinguishing genotype by the melt curve function.

15:20 New Opportunities in the Control of Infectious Diseases in an Era of European Clinical Microbiology Laboratories Consolidation
Olivier Vandenberg, MD, PhD, Professor, Microbiology, Laboratory Medicine, Laboratoire Hospitalier Universitaire de Bruxelles, Belgium
European clinical microbiology laboratories (CMLs) are currently undergoing a process of consolidation involving a shift towards laboratory amalgamation. The centralization of diagnostic services over a large geographical region gave rise to the concept of regional-scale "microbiology laboratories network." In this lecture, we describe the range of opportunities that the changing landscape of CMLs in Europe can contribute towards improving the quality of patient care but also the early detection and enhanced surveillance of public health threats caused by infectious diseases.

15:50 PANEL DISCUSSION: Future Directions and Technologies for Virus Identification
Moderator: François Jean, PhD, Associate Professor, Department of Microbiology and Immunology, University of British Columbia, Team Leader, NCE IC-IMPACTS Grant in Next Generation Molecular Diagnostics for Emerging Viral Diseases, and CIHR Grant in Anti-Flavivirus Drug Discovery
Panelists: Adriana Calderaro, MD, PhD, Associate Professor, Clinical Microbiology, Unit of Microbiology and Virology, Clinical and Experimental Medicine, University Hospital of Parma, Italy
Eeva Auvinen, PhD, Senior Laboratory Supervisor, Department of Virology and Immunology, Helsinki University Hospital Laboratory, Finland
- Host-derived biomarkers to diagnose and monitor infectious disease
- Emerging techniques and technologies
- Advancements in mass spectrometry-based detection
- Rapid detection strategies

16:20 Refreshment Break in the Exhibit Hall with Poster Viewing

17:00 Breakout Discussions

18:00 Welcome Reception in the Exhibit Hall with Poster Viewing

Sponsored by BIO-RAD

19:00 Close of Day

WEDNESDAY, 23 MAY

ANTIMICROBIAL RESISTANCE AND HOST RESPONSE

08:00 Registration and Morning Coffee

09:00 Chairperson's Remarks
Till T. Bachmann, PhD, Reader, Personalised Medicine in Infectious Disease; Deputy Head, Division of Infection and Pathway Medicine, dinburgh Medical School, College of Medicine and Veterinary Medicine, University of Edinburgh, United Kingdom

09:05 Towards the Right Target Product Profiles for Rapid Diagnostics to Reduce Antimicrobial Resistance
Till T. Bachmann, PhD, Reader, Personalised Medicine in Infectious Disease; Deputy Head, Division of Infection and Pathway Medicine, Edinburgh Medical School, College of Medicine and Veterinary Medicine, University of Edinburgh, United Kingdom
A wide range of technological approaches to address antimicrobial resistance has been researched and subsequently, commercial tests have been developed. Unfortunately, a wide adoption of rapid tests to guide antimicrobial therapy is still lacking and the issue of AMR is escalating. The Joint Programming Initiative on Antimicrobial Resistance (JPIAMR) specifically reviewed the barriers for development and adoption of rapid diagnostics. The absence of suitable and accessible Target Product Profile was identified as a major barrier and proposed solutions on how to overcome this which will be discussed in the presentation.

09:35 HostDx Sepsis: Diagnosing Presence, Type, and Severity of Acute Infections through Host Response
Oliver Liesenfeld, MD, CMO, Inflammatix, United States
Diagnostics for acute infections and sepsis typically focus on 'finding the bug', but most patients with infections never have pathogens in their bloodstream.

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HostDx Sepsis uses robust patterns of mRNA biomarkers from whole blood to determine the presence, type, and severity of any acute infection in an inpatient setting. We will present interim results from new prospective trials, including comparisons with known biomarkers such as procalcitonin. HostDx Sepsis is being translated into a < 60-minute turnaround point-of-need test.

10:05 Beyond Antibiotic Resistance: Consequences of Overtreating Infectious Disease

Norman Moore, PhD, Director, Scientific Affairs, Abbott, United States

Antibiotics not only kill pathogens, but disrupt a person's microbiome. Changes in the microbiome have now been linked to obesity, mood disorders, autoimmune diseases, and a host of other issues. This lecture will go through the latest data on diseases associated with imbalances in the human microbiome.

10:35 Recent Advances in Manufacturing Technologies of Microarrays for Diagnostic of Infectious Diseases

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Wilfried Weigel, PhD, Vice President, Research & Development, Scienion, Germany

Planar microarrays are cost effective tools for the multiplexed detection of pathogens in infectious diseases. Key steps in development and high throughput production of these microarrays, are the printing and immobilization of probes on the different supports materials, such as microtiter plates, lateral flow strips, slides or biosensors.

10:50 Sponsored Presentation *(Opportunity Available)*

11:05 Coffee Break in the Exhibit Hall with Poster Viewing

PLENARY SESSION

11:35 Plenary Introduction

John Carrano, CEO, Paratus Diagnostics, LLC, United States

11:45 The New EU IVD Regulation – What Will It Mean for Your Lab?

David E. Barton, PhD, Chief Molecular Geneticist, National Centre for Medical Genetics, Our Lady's Hospital for Sick Children, Ireland

In May 2017, Europe passed a new Regulation on *in vitro* Diagnostic Devices (IVDs). The regulation sets up a framework for controlling the market for diagnostic tests within the EU, setting out standards for the design and manufacture of in-vitro diagnostic devices (IVDs) and providing mechanisms for the oversight of these standards. This presentation will outline the content of the new regulations, with a particular focus on molecular diagnostics, and highlight the new requirements for clinical laboratories.

12:15 PANEL DISCUSSION: Changing Landscape for IVDs in the EU

Moderator: Charlotte Ryckman, Covington & Burling LLP, Belgium

Panelists: David E. Barton, PhD, Chief Molecular Geneticist, National Centre for Medical Genetics, Our Lady's Hospital for Sick Children, Ireland

Jörg Engelbergs, PhD, Section Mono- and Polyclonal Antibodies, Scientific Expert Biomedicines, Quality, Non-Clinic & Personalized Medicine (Biomarker/CDx), Paul-Ehrlich-Institut, Federal Institute for Vaccines and Biomedicines, Germany

Maria Judite Neves, Health Products Director, Health Products Directorate, INFARMED – National Authority of Medicines and Health Products, Portugal

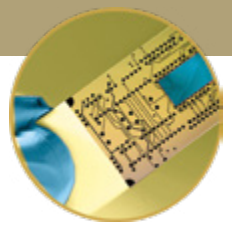
Sue Spencer, Global Service Director, Regulatory, UL, United Kingdom

Andreas F. Stange, PhD, Vice President MHS Global IVD, TÜV SÜD, Germany

Doris-Ann Williams, MBE, Chief Executive, British In Vitro Diagnostics Association (BIVDA), United Kingdom

- Practical impact of the new IVD Regulation
- Regulatory aspects of companion diagnostics
- Challenges for validation
- Role of IVDs in the market

13:30 Close of Advanced Diagnostics for Infectious Disease



Point-of-Care Diagnostics

MEETING THE DEMAND FOR RAPID RESULTS AND IMPROVED OUTCOMES

RECOMMENDED SHORT COURSE*

Technologies, Applications and Commercialization of Point-of-Care Diagnostics

**Separate Registration required. See page 3 for details.*

WEDNESDAY, 23 MAY

DIGITAL HEALTH AND HOSPITAL 4.0: THE ROLE OF POCT IN A DIGITALIZED CONTINUUM OF CARE

14:30 Chairperson's Remarks

Wilfried von Eiff, PhD, Professor, International Health Care and Hospital Management; Academic Director, Center for Health Care Management and Regulation, HHL, Leipzig Graduate School of Management; Director, Center for Hospital Management, University of Muenster, Germany

14:35 Digitalization of Healthcare: The New Role of POCT

Wilfried von Eiff, PhD, Professor, International Health Care and Hospital Management; Academic Director, Center for Health Care Management and Regulation, HHL, Leipzig Graduate School of Management; Director, Center for Hospital Management, University of Muenster, Germany

The "Digitalization of Healthcare" will contribute to unburden medical services from routine tasks (Smart Contract Function), to enhance precision in diagnosis and therapy (Precision Medicine, TheragNostic, Big Data) and to force the use of POCT technology in all areas of medical provision (primary care, emergency care, acute care, rehabilitation). Additionally, a new sector of care is predicted to emerge (first-line medicine), which is characterized by intensive use of POCT technology even deployed by patients at home.

15:05 Process Optimization in the Emergency Department by the Use of Point-of-Care-Testing (POCT) in Life-Threatening Conditions

Sandra C. Buttigieg, MD, PhD, FFPH, MSc, MBA, MMCFD, Associate Professor, Head, Health Services Management, Faculty of Health Sciences, University of Malta, Malta; Consultant, Public Health Medicine, Clinical Performance Unit, Mater Dei Hospital, Malta; Honorary Senior Research Fellow, School of Social Policy, College of Social Sciences, University of Birmingham, United Kingdom

Point-of-care testing (POCT) at the Emergency Department (ED) attains better objectives in patient care while aiming to achieve early diagnosis for faster medical decision-making. This study assesses the benefits of POCT in the ED by providing examples. We utilize multiple case study approach using Six Sigma. This study provides clear examples of the effectiveness of POCT in life-threatening conditions, as compared to the use of traditional central lab or the medical imaging department.

15:35 Smart Homes Technologies for Health Care and Well-Being

Joost van Hoof, PhD, MSc, Eur Ing, Professor, Urban Ageing, The Hague University of Applied Sciences, The Netherlands

Smart homes can help people monitor their health status, can support occupants in controlling the environment, connect residents with remote relatives and care professionals, and detect emergencies and notify others by generating alarms. Smart home technologies hold a great promise for the future of healthcare and well-being. Technology can support us within our homes, but not unconditionally. In this presentation, the complex field of smart home technology is presented.

16:05 Refreshment Break in the Exhibit Hall with Poster Viewing

17:05 POCT: Impact beyond the Point-of-Care

Gyorgy Abel, MD, PhD, Director, Molecular Diagnostics, & Clinical Chemistry/ Immunology, Division of Pathology and Laboratory Medicine, Lahey Hospital & Medical Center, United States

With integration and decentralization of healthcare delivery systems and shift of care from the hospital to the community, POCT is gaining ground. Advanced implementation includes secure data transfer into electronic medical records (EMR), notification/alerts to providers via personal digital devices with capability of bidirectional flow of results, knowledge resources, and clinical decision-support tools. EMR integrated with the laboratory information system enables instant access to POCT results across the system, collaboration of care teams, and assessment of impact on quality metrics.

17:35 Disruptive Technologies in Health Care: The Significance of Digital Innovations for POCT

Stefanie Steinhauser, PhD, Research Associate, Chair for Innovation and Technology Management, University of Regensburg, Germany

Disruptive innovations can substantially change industries and make their products and services cheaper and more accessible. Digital innovations present potentially disruptive innovations that represent a drastic departure from the predominant method of health care delivery. Ubiquitous connectivity and data availability as well as networks can foster POCT by providing additional data for rapid clinical decision making. Contrariwise, POCT can provide valuable inputs for digital applications such as telemedicine.

18:05 Health 4.0 – Together on a DigITal Journey

Sarah Peuling, Senior Solution Advisor, Center of Competence Clinicals & Innovations, Cerner Health Services Deutschland GmbH, Germany

Across the globe, health systems need to fundamentally transform how care is delivered to address long-term challenges through rising demand against fixed supply. Sustainable change requires large-scale transformation. Hospitals are facing a journey through technology adoption and maturity to drive performance, quality and safety improvements with opportunities and challenges for POCT.

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18:35 Breakout Discussions

19:05 Close of Day

THURSDAY, 24 MAY

FULLY INTEGRATED DIAGNOSTIC DEVICES

08:00 Registration and Morning Coffee

08:30 Chairperson's Remarks
Holger Becker, PhD, Founder & CSO, microfluidic ChipShop GmbH, Germany

08:35 Molecular Diagnostics at the Point-of-Care by Centrifugal Microfluidics
Roland Zengerle, PhD, Executive Board Member, Laboratory for MEMS Applications, IMTEK - Department of Microsystems Engineering, University of Freiburg, Germany
Centrifugal microfluidics enables efficient miniaturization, integration, parallelization and automation of biochemical assays in disposable microfluidic cartridges. This talk will demonstrate fully integrated sample-to-answer genotyping assays from whole blood which enable rapid and multiplexed molecular diagnostics of infectious diseases at the point-of-care. Advanced functions will be presented such as splitting a sample into thousands of micro droplets which provide the ground for fast digital assays without the need for calibration.

09:05 POCT and Optics: A Successful Marriage
Francesco Baldini, PhD, Senior Scientist, Institute of Applied Physics "Nello Carrara", National Research Council, Italy
In recent years, requests by doctors have grown tremendously for devices capable of measuring chemical and biochemical parameters of clinical interest in a reasonably short time that are also sufficiently compact, as to be located near the patient's bed. In this area, optical biosensors play a fundamental role, allowing the implementation of compact platforms. Moreover, the use of optical fibers can also lead to invasive continuous measurements within the human body.

9:35 *In vitro* Molecular Point-of-Care Diagnostics for Bacteria Identification
Filipe Arroyo Cardoso, CTO, Magnomics, Portugal
Bacteria identification is becoming a key information to reduce the number of multi-resistant bacteria events. Cell culture has been the gold standard used for this identification. More recently, faster alternatives based on molecular technologies have been developed. The emergence of miniaturization technologies in the market, such as microfluidics and microelectronics, has further enabled molecular point-of-care platforms. This has opened new opportunities in a market that is struggling against bacteria resistance.

10:05 Commercializing Point-Of-Care Diagnostic Solutions
Sponsored by Paratus Diagnostics
John Carrano, CEO, Paratus Diagnostics, LLC, United States
In his seminal book, The Innovator's Prescription, business thought leader Clayton Christensen posits that point-of-care diagnostics for infectious diseases will prove one of the key innovations in healthcare delivery in the coming years. We will use as an example the patent protected PreparedNow® System developed by Paratus Diagnostics of how one can in fact implement an approach for the realization of high-accuracy multiplexed testing for a variety of infectious disease applications.

10:35 Coffee Break in the Exhibit Hall. Last Chance for Poster Viewing

11:20 Cell Function Diagnostics at the Bedside
Mathias Reisbeck, PhD, Postdoc, Chair, Biomedical Electronics, Electrical and Computer Engineering, Technical University Munich, Germany
Point-of-care diagnostics of single cell function requires workflow integration with minimal pre-analytical effort. Magnetic biosensors offer great potential for non-optical read-out with negligible background in optically opaque biological matrices such as whole blood. Here, we present magnetic in-flow detection to probe single cell volume, immunomagnetic binding capacity, and cell morphology. We further integrated this quantitative approach into a credit-card sized cartridge for bedside testing.

11:50 Lab-Disc for Point-of-Care Diagnostics at Resource Limited Settings
Aman Russom, PhD, Associate Professor, Division of Proteomics and Nanobiotechnology, Science for Life Laboratory, Royal Institute of Technology, Sweden
LOC devices are poised to eventually transform the diagnostic methods from laboratory-based to point-of-care (POC) diagnostics systems. Among LOC devices, centrifugal microfluidics platforms carry most capabilities. To this end, we recently modified a DVD player to perform blood tests, including a check for HIV. The breakthrough creates the possibility of an inexpensive and simple-to-use tool that could have far-reaching benefits in health care in low- and middle-income countries.

12:20 MDx and Mass Transport: The Role of Mixing in Molecular Assays
Sponsored by RedbudLabs
Jay K. Fisher, PhD, Vice President, Engineering, Redbud Labs, Inc., United States

12:35 A Robot in A Coffee Pod – An Overview of TTP's 'Puck', a Point-of Care Diagnostics Platform
Sponsored by ttp
Piers Harding, C.Eng FIMechE, Mechanical Engineer/Consultant, TTP plc
The past 5 years has seen a wave of new PoC diagnostic platforms entering the market, with intense competition to establish a leading position. Clearly, only a few of the contenders will be successful. At TTP, Europe's leading independent technology development company, our engineers and molecular biologists have teamed up to create a truly flexible and exceptionally low-cost platform technology: "Puck". Workflow automation in miniature - find out how Puck stands poised to revolutionise the PoC diagnostics field.

12:50 Luncheon Presentation *(Sponsorship Opportunity Available)* **or Enjoy Lunch on Your Own**

13:20 Session Break

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POCT FOR ANTI-MICROBIAL STEWARDSHIP

13:50 Chairperson's Remarks

Daniel Berman, Lead, Longitude Prize, Challenge Prize Centre, Nesta, United Kingdom

14:00 KEYNOTE PRESENTATION: Upcoming New Diagnostic Regulations and How They Will Impact Developers of AMR POC Tests

Doris-Ann Williams, MBE, Chief Executive, British In Vitro Diagnostics Association (BIVDA), United Kingdom

14:20 Innovations in Connectivity in AMR Diagnostics

Rachel McKendry, PhD, Professor, Biomedical Nanotechnology, London Centre for Nanotechnology, United Kingdom

14:40 Developing Assays for Home Monitoring and Management of Patients with COPD

Julie Hart, Head, Diagnostics & Precision Medicine, Strategic & Industry Partnerships, Oxford Academic Health Science Network

COPD is the second most common cause of emergency admissions in the UK, responsible for one in eight (130,000) acute adult medical admissions.The acute and sustained worsening of the symptoms is termed an acute exacerbation of COPD. Mologic has developed two products for patient stratification both based on the use of biomarkers in a multiplex lateral flow format. The first test HeadStart will clearly identify or confirm the first signs of exacerbation with sufficient reliability and clarity for the patient to know when to seek medical attention. The second product is Rightstart, for use by primary care to identify whether to use antibiotics or corticosteroids. Use of RightStart to identify the cause of the exacerbation helps ensure the correct treatment is given and also has the potential to reduce unnecessary antibiotic treatment which supports the UK governments strategies for Antimicrobial Stewardship.

15:00 PANEL DISCUSSION

Sponsored by CHROMA

15:30 Optical Filters for Medical Devices

Georg Draude, General Manager, Chroma Europe, Chroma Technology, Germany

High precision optical filters find usage in classical medical instruments as well as in miniaturized devices. This talk should give an overview on optical applications and instruments used for medical diagnosis and research and the role of state-of-the-art optical filters.

16:00 Refreshment Break in the Foyer

IS THERE A ROLE FOR RAPID TESTING IN CANCER DIAGNOSTICS AND MONITORING?

Chairperson's Remarks

Gyorgy Abel, MD, PhD, Director, Molecular Diagnostics, & Clinical Chemistry/ Immunology, Division of Pathology and Laboratory Medicine, Lahey Hospital & Medical Center, United States

16:20 Graphene Biosensor for Early Diagnostics of Ovarian Cancer

Sofia Teixeira, PhD, Research Fellow, Engineering, Swansea University, United Kingdom

The poor prognosis in ovarian cancer (OC) is primarily due to the fact that the majority of women present with extra-ovarian disease, reflecting the absence of major symptoms in the early stages. Importantly, when OC patients are detected at early stages of disease, the prognosis is far more favourable with a 5-year survival rate increasing to over 90%. Here we describe the development and evaluation of a graphene immune-sensor platform, that can be used to detect a range of clinical biomarkers including simultaneous detection of multiple biomarkers which is important in the diagnosis of complex diseases such as OC.

16:50 Epigenetic Immune Cell Profiling - A Novel Approach to Point-of-Care Immune Monitoring

Christoph Sachsenmaier, PhD, Vice President, Strategic Business Development, Epimune GmbH, Germany

Epigenetic immune cell profiling provides a novel approach to molecular immune cell profiling. Using DNA-based, epigenetic markers, immune monitoring can be obtained from minute amounts of fresh or archived clinical samples. Epimune is applying this technology to develop MDx applications in multiple clinical fields like primary immunodeficiency, infectious diseases and cancer.

17:20 Close of Conference

Clinical Application of Cell-Free DNA

A STEP CLOSER TO IMPLEMENTATION AND ROUTINE TESTING

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RECOMMENDED SHORT COURSE*

Liquid Biopsy for P4 Medicine: Predictive, Preventive, Personalized and Participatory

**Separate Registration required. See page 3 for details.*

TUESDAY, 22 MAY

MOLECULAR STRATIFICATION AND PROFILING

08:00 Registration and Morning Coffee

09:00 Chairperson's Remarks

Jacqui Shaw, PhD, Professor, Translational Medicine, University of Leicester, United Kingdom

09:05 KEYNOTE PRESENTATION: Liquid Biopsies: Detection and Monitoring of Breast and Lung Cancer

Jacqui Shaw, PhD, Professor, Translational Medicine, University of Leicester, United Kingdom

We have systematically reviewed ctDNA blood biomarkers for the early detection of cancer. Pre-analytical, analytical, and post-analytical considerations were identified which need to be addressed before such biomarkers enter clinical practice. The value of small studies with no comparison between methods, or even the inclusion of controls is highly questionable, and larger validation studies will be required before such methods can be considered for early cancer detection.

09:35 Impact of Circulating Tumor DNA Analysis on Prognosis and Therapy Monitoring in Metastatic Cancer Patients

Ellen Heitzer, PhD, Associate Professor, Institute of Human Genetics, Medical University Graz, Austria

Tumor-specific sequence alterations in plasma were used to quantify tumor burden or for genome-wide analyses of tumor genomes, and it has been shown that ctDNA can be used to monitor tumor dynamics. Here, the use of untargeted ctDNA analysis, i.e plasma-Seq and mFAST-SeqS, for patient stratification and monitoring treatment response will be discussed.

10:05 Implementation of Digital PCR in a Molecular Diagnostic Laboratory: Evaluation of Minimal Residual Disease

Sponsored by STILLA

Benjamin Tournier, PhD, Laboratoire d'anatomie pathologique, CHU Dijon, France

In the Molecular Pathology department of the Dijon University Hospital, liquid biopsy analyses were set up since March 2016. Here we present the implementation of the 3-color Crystal Digital PCR system in our laboratory for the management of melanoma and lung cancer patients under targeted therapy.

10:35 Coffee Break in the Exhibit Hall with Poster Viewing

11:15 Tracking Circulating Tumor DNA for Cancer Patient Follow-Up

Valerie Taly, PhD, CNRS Research Director (Dr2), Group Leader, Co-Director Ediag Platform, UFR Des Sciences Fondamentales Et Biomedicales, France

Droplet based digital PCR and newly developed optimized NGS technologies allow us to highlight rare genetic events with an unprecedented sensitivity and precision. The application of these strategies to solve important challenges in personalized medicine will be exemplified. Results of retrospective and prospective studies will be presented. In particular, we will highlight the pertinence of the quantitative analysis of circulating tumor DNA to: (i) perform advanced or locally advanced cancer patients follow up including specific application to treatment efficiency monitoring and (ii) detect early recurrence of cancer for localized cancer patients.

11:45 Circulating Cell-Free DNA for Metastatic Cervical Cancer Detection, Genotyping and Monitoring

Liang Cao, PhD, Head, Molecular Targets Core Lab, National Cancer Institute (NCI), MD, United States

We developed novel cell-free DNA (ccfDNA) assays and showed that ccfDNA analysis is effective for genotyping of tumor HPV in patient selection for a targeted T-cell therapy. In addition, our data further demonstrate a potential for ccfDNA for assessing the response and monitoring remission in recurrent metastatic cervical cancer patients with complete responses to the HPV-specific T cell therapy.

12:15 Epigenetic Biomarkers for Early Detection and Monitoring of Cancer

Guro Elisabeth Lind, PhD, Professor and Group Leader, Molecular Oncology, Institute for Cancer Research, Oslo University Hospital, Norway

Highly sensitive analyses of body fluids have emerged as a promising approach for identifying disease-specific molecular alterations. We will demonstrate how analyses of DNA methylation biomarkers in biomaterials such as urine and bile can be used for early detection of cancer and for monitoring of disease.

12:45 Nucleosomics® - Development and Clinical Applications of Cell Free Circulating Nucleosome Profiling Immunoassays

Sponsored by Volition

Mark Eccleston, Business Development Director, Volition, Belgium

Volition has developed a range of low cost, simple to use Immunoassays to quantify epigenetic features on nucleosomes. These Nu.Q™ assays can be used to profile circulating cell free nucleosomes in blood samples in a range of cancers to generate profiles with diagnostic and screening applications. Volition is finalising diagnostic and screening panels for colorectal cancer in large clinical studies. The Nu.Q™assay range is being developed for research use applications to explore additional application.

13:15 Luncheon Presentation (Sponsorship Opportunity Available) or Enjoy Lunch on Your Own

13:45 Session Break

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MOLECULAR STRATIFICATION AND PROFILING (CONT.)

14:15 Clinical Relevance of Circulating, Cell-Free and Exosomal microRNAs in Plasma and Serum of Breast and Ovarian Cancer Patients

Heidi Schwarzenbach, PhD, Associate Professor, Group Leader, Tumor Biology, University Medical Center Hamburg-Eppendorf, Germany

Our studies show a network of deregulated cell-free and exosomal microRNAs involved in regulation of cancer-associated signaling pathways and associated with a particular biology of gynecological tumors. Moreover, the excessive secretion of exosomes in breast and ovarian cancer patients is reflected by a predominant microRNA presence in exosomes.

CLINICAL STUDIES AND IMPLEMENTATION OF cfDNA IN THE CLINIC

14:45 Chairperson's Remarks

Daniel Wetterskog, PhD, Senior Scientific Officer, Treatment Resistance, Molecular Pathology, ICR, Royal Marsden NHS Foundation Trust, United Kingdom

14:50 Predicting Response to Radical (Chemo)Radiotherapy with Circulating HPV DNA Locally-Advanced Head and Neck Squamous Carcinoma

Shreerang Bhide, PhD, MBBS, MRCP, FRCR, Consultant Clinical Oncologist and Honorary Senior Lecturer, The Royal Marsden Hospital, The Institute of Cancer Research, United Kingdom

Following chemo-radiotherapy (CCRT) for human papilloma virus positive (HPV+) locally advanced head and neck cancer, patients frequently undergo unnecessary neck dissection (ND) and/or repeated biopsies for abnormal PET-CT, which causes significant morbidity. We assessed the role of circulating HPV DNA in identifying "true" residual disease. We demonstrate that HPV16-detect is a highly sensitive and specific test for identification of HPV DNA in plasma at diagnosis. HPV DNA post-treatment correlates with clinical response.

15:20 Clinical Implication and Real-World-Experience of PCR-Beaming in RAS Assessment in Metastatic Colorectal Cancer Patients

Jesus Garcıa-Foncillas, MD, PhD, Director, Cancer Institute, University Hospital "Fundacion Jimenez Diaz", Autonomous University, Madrid, Spain

The importance of RAS mutation for advanced colorectal cancer treatment is well established. However, due to delays in turnaround time, low-quality tissue samples, and/or lack of standardization of testing methods, a significant proportion of patients are being treated without this information. The overall concordance between liquid biopsy and standard of care tissue testing is very high. This presentation reviews the clinical utility and potential applications of this minimally invasive method.

15:50 Clinical Application of Liquid Biopsies in the Management of Patients with Prostate Cancer

Daniel Wetterskog, PhD, Senior Scientific Officer, Treatment Resistance, Molecular Pathology, ICR, Royal Marsden NHS Foundation Trust, United Kingdom

Our group has been using liquid biopsies to interrogate resistance in castration-resistant prostate cancer (CRPC) and develop biomarkers for selecting treatment. Previously, we demonstrated the potential utility of analyzing circulating tumour DNA to identify prostate cancer patients likely to benefit from the targeted therapies abiraterone and enzalutamide. Our current projects are investigating RNA expression profiles and methylation status of ctDNA found in liquid biopsies as predictive and prognostic biomarkers. In addition, using a rapid autopsy program, we have gained understanding how ctDNA reflects the genomic and epigenomic landscape of different metastatic lesions.

16:20 Refreshment Break in the Exhibit Hall with Poster Viewing

17:00 Breakout Discussions

18:00 Welcome Reception in the Exhibit Hall with Poster Viewing

19:00 Close of Day

WEDNESDAY, 23 MAY

CLINICAL STUDIES AND IMPLEMENTATION OF cfDNA IN THE CLINIC (CONT.)

08:00 Registration and Morning Coffee

09:00 Chairperson's Remarks

Daniel Wetterskog, PhD, Senior Scientific Officer, Treatment Resistance, Molecular Pathology, ICR, Royal Marsden NHS Foundation Trust, United Kingdom

09:05 Liqbiopsens: A Novel, Reliable and Affordable Platform for Colorectal Cancer Patients Screening.

M. Jose Serrano Fernández, PhD, Director, Liquid Biopsies Division, Liquid Biopsies & Metastasis Group Senior Research UGC Oncologia, Hospital Virgen de las Nieves, Spain

The overall aim of LIQBIOPSENS project is the further development and validation in real settings of a novel diagnostic platform for the early and fast detection of ctDNA and their KRAS and BRAF mutations associated to colorectal cancer through blood samples. The main features of LIQBIOPSENS are: reliability (detection rates vary from 95–100 %), low-cost (40-50 € per sample analysis), sensitivity (in the zM range), multiplexing capabilities (analysis of 27 KRAS and BRAF mutations simultaneously), short analysis time (30-60 min.), user-friendly interface and flexibility.

cfDNA AND ITS APPLICATIONS BEYOND ONCOLOGY

09:35 The Role of Cell-Free Nucleic Acids in Prognosis Prediction and Neurorestoration after Severe Traumatic Brain Injury

Andrea Regner, MD, PhD, Professor, Cellular and Molecular Biology Applied to Health, Course of Medicine, Lutheran University of Brazil, Canoas, Brazil

Traumatic brain injury (TBI) is the leading cause of mortality in young individuals worldwide. In this context, the investigation of cell-free nucleic acids following acute neural injuries may indicate patients at higher risk for deterioration and guide novel therapeutic strategies. We will present (i) results of a prospective cohort including 400 severe TBI patients, and (ii) discuss the role of cell-free nucleic acids in prognosis prediction and neurorestoration after neurotrauma.

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10:05 Identification of Tissue-Specific Cell Death Using Methylation Patterns of Circulating DNA

Yuval Dor, PhD, Professor, Developmental Biology and Cancer Research, The Hebrew University-Hadassah Medical School, Jerusalem, Israel

We have developed a method of detecting tissue-specific cell death, based on cfDNA methylation patterns. We identified tissue-specific DNA methylation signatures, and used bisulfite sequencing to detect these in cfDNA. I will present analysis of the tissue sources of cfDNA in healthy individuals and in diabetes, myocardial infarction, sepsis and cancer. The approach allows monitoring a broad spectrum of human pathologies, as well as better understanding of normal tissue dynamics.

10:35 Cerebrospinal Fluid ctDNA: A Potential Tool for the Molecular Diagnostics of Gilomas using Droplet Digital PCR

Sponsored by BIO-RAD

Regina Mayor Ferreras, PhD, Vall d'Hebron Institute of Oncology

Diffuse gliomas are the most common primary tumors of the brain and include different subtypes with diverse prognosis. The genomic characterization of diffuse gliomas facilitates their molecular diagnosis. Taking advantage of the presence of circulating tumor DNA in the cerebrospinal fluid of glioma patients, we have developed a molecular platform, to simultaneously and rapidly genotype seven genes by targeted exome sequencing and droplet digital PCR, facilitating patient sub-classification to support their surgical and clinical management.

11:05 Coffee Break in the Exhibit Hall with Poster Viewing

PLENARY SESSION

11:35 Plenary Introduction

John Carrano, CEO, Paratus Diagnostics, LLC, United States

11:45 The New EU IVD Regulation – What Will It Mean for Your Lab?

David E. Barton, PhD, Chief Molecular Geneticist, National Centre for Medical Genetics, Our Lady's Hospital for Sick Children, Ireland

In May 2017, Europe passed a new Regulation on *in vitro* Diagnostic Devices (IVDs). The regulation sets up a framework for controlling the market for diagnostic tests within the EU, setting out standards for the design and manufacture of in-vitro diagnostic devices (IVDs) and providing mechanisms for the oversight of these standards. This presentation will outline the content of the new regulations, with a particular focus on molecular diagnostics, and highlight the new requirements for clinical laboratories.

12:15 PANEL DISCUSSION: Changing Landscape for IVDs in the EU

Moderator: Charlotte Ryckman, Covington & Burling LLP, Belgium

Panelists: David E. Barton, PhD, Chief Molecular Geneticist, National Centre for Medical Genetics, Our Lady's Hospital for Sick Children, Ireland

Jörg Engelbergs, PhD, Section Mono- and Polyclonal Antibodies, Scientific Expert Biomedicines, Quality, Non-Clinic & Personalized Medicine (Biomarker/CDx), Paul-Ehrlich-Institut, Federal Institute for Vaccines and Biomedicines, Germany

Maria Judite Neves, Health Products Director, Health Products Directorate, INFARMED – National Authority of Medicines and Health Products, Portugal

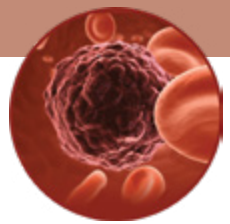
Sue Spencer, Global Service Director, Regulatory, UL, United Kingdom

Andreas F. Stange, PhD, Vice President MHS Global IVD, TÜV SÜD, Germany

Doris-Ann Williams, MBE, Chief Executive, British In Vitro Diagnostics Association (BIVDA), United Kingdom

- Practical impact of the new IVD Regulation
- Regulatory aspects of companion diagnostics
- Challenges for validation
- Role of IVDs in the market

13:30 Close of Clinical Application of Cell-Free DNA



Circulating Tumour Cells

UNDERSTAND THEIR BIOLOGY AND CLINICAL SIGNIFICANCE

RECOMMENDED SHORT COURSE*

Liquid Biopsy for P4 Medicine: Predictive, Preventive, Personalized and Participatory

**Separate Registration required. See page 3 for details.*

WEDNESDAY, 23 MAY

MOLECULAR CHARACTERISATION OF CTCs

14:30 Chairperson's Remarks

Jens K. Habermann, MD, PhD, Director, Interdisciplinary Center for Biobanking-Lübeck; Head, Section of Translational Surgical Oncology and Biobanking; Scientific Director, Surgical Center for Translational Oncology-Lübeck, Germany

14:35 Epigenetic Alterations in CTCs and Corresponding ctDNA

Evi Lianidou, PhD, Professor, Analytical Chemistry, Clinical Chemistry, Chemistry, University of Athens, Athens

Our group was the first to demonstrate epigenetic alterations in CTCs and corresponding ctDNA (Chimonidou et al., Clin Chem 2011, Clin Chem 2013). Epigenetic silencing of estrogen receptor gene (ESR1) could be of clinical relevance especially for its potential impact on endocrine treatment efficacy. In this study, we evaluated for the first time ESR1 methylation in CTCs, paired ctDNA and primary tumors of breast cancer patients.

15:05 Data-Driven Discovery of Extravasation Pathway and Integrated Regulatory Network for Epithelial-Mesenchymal Transition in Circulating Tumor Cells

Prashant Kumar, PhD, Faculty Scientist, Molecular Oncology, Institute of Bioinformatics, Bangalore, India

The talk will uncover promising CTC-driven signaling nodes in the extravasation pathway and identified the key contributors that may determine favorable clinical outcomes. These CTC-associated signaling profiles will provide a valuable resource to identify downstream events crucial to the functioning of CTCs in the metastatic cascade. These findings bring us further toward understanding the mechanisms of various biological processing pathways within the circulating cell.

15:35 Epithelial-to-Mesenchymal Transitions and Coagulation: Impact on the Metastatic Competence of Circulating Tumor Cells

Christine Gilles, PhD, Senior Research Associate FRS-FNRS, GIGA-Cancer, University of Liège, Belgium

Increasing data support the contribution of Epithelial-to-Mesenchymal Transitions (EMTs) in providing Circulating Tumor Cells (CTCs) with enhanced metastatic competence. Our most recent work shows that EMT endow tumor cells with coagulant properties, thereby facilitating early metastasis. Characterizing and targeting EMT-shifted subpopulations of coagulant CTCs constitute our future lines of research.

16:05 Refreshment Break in the Exhibit Hall with Poster Viewing

17:05 Tumor Heterogeneity Inferred from Single CTC Sequencing and CTC-Derived Explants (CDX)

Françoise Farace, PhD, Head, Rare Circulating Cells Translational Laboratory, Gustave Roussy, Université Paris-Saclay, France

Our results show that sequencing of individual CTCs can reveal undiagnosed mutations in matched-metastasis and provide a unique representation of metastasis mutational content that is otherwise inaccessible. We established and characterized four NSCLC and one prostate cancer CTC-derived explants (CDX). Genetic profiling of CDXs, CTCs and matched-tumor biopsies enabled the construction of phylogenic mutational trees and the identification clonal mutations and dominant clones with tumorigenic potential.

17:35 CTCs Characterization from a Triple Negative Breast Cancer Patient CDX

Clotilde Costa, PhD, Head, Liquid Biopsy Line, Roche-Chus Joint Unit, Clinical Hospital of Santiago de Compostela, Spain

The development of CTC-derived xenografts (CDX) is a powerful strategy for preclinical drug screening, biomarker identification, biologic studies, and personalized medicine strategies and is expected to provide crucial information on mechanisms involved in metastatic progression. We report the establishment and characterization of a triple negative breast cancer CDX using RNA-sequencing technology. We conclude that CDX technology is feasible in triple negative breast cancer, and this approach opens a promising way to reach a precision oncology in patients.

18:05 Breakout Discussions

19:05 Close of Day

THURSDAY, 24 MAY

EMERGING TECHNOLOGIES FOR CTC ISOLATION AND ANALYSIS

08:30 Registration and Morning Coffee

09:00 Chairperson's Remarks

Nikolas Hendrik Stoecklein, MD, Professor, Experimental Surgical Oncology, Department of General, Visceral and Pediatric Surgery, University Hospital and Medical Faculty of the Heinrich-Heine University Düsseldorf, Düsseldorf, Germany

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09:05 Label-Free Isolation of Tumor Cells from Body Fluids and Multiplex Analysis on a Chip

Lorena Diéguez, PhD, Staff Researcher, Life Sciences, International Iberian Nanotechnology Laboratory, Portugal

Tumor cells from body fluids were isolated using a high-efficiency label-free microfluidic system, and their phenotype characterized by Surface Enhance Raman Scattering. Gold nanostars were synthesized and labelled with different Raman reporters and conjugated with different biomarkers against proteins in the cell wall. Each Raman reporter matched a cell receptor, and so the heterogeneity of each cell could be assessed on chip without the need of cell recovery and manipulation.

09:35 Detection of Viable Circulating Tumor Cells at the Single Cell Level Using Digital Microfluidics

Jean Baudry, PhD, Laboratoire Colloïdes et Matériaux Divisés (LCMD), ESPCI Paris, PSL Research University, CNRS UMR8231 Chimie Biologie Innovation, Paris, France

To enumerate CTCs and characterize their heterogeneity in peripheral blood, we have developed a massively-parallel-kinetic analysis of single CTCs. The method uses living cells, so real phenotypic properties of the CTCs are assayed, like secretion of protein of interest, as well as more classical surface markers quantification.

10:05 Multiplex Assays for Cancer Management Using πCode MicroDisc Technology <*sponsored by* PlexBio>

Stuart Palmer, PhD, COO, Administration, PlexBio Co., Ltd., Taiwan

PlexBio has developed a platform for high complexity mutation analysis. The IntelliPlexTM Lung Cancer Panel assesses the status of 57 somatic mutations and gene re-arrangements in liquid biopsy samples. The test offers a rapid, comprehensive and cost-effective way to interrogate patient samples with achievement of sensitivities of 0.01%-0.1%.

10:35 Coffee Break in the Exhibit Hall. Last Chance for Poster Viewing

11:20 The Molecular Second Look: A "Novel" Method for Identifying and Genetically Characterizing Residual Disease in Ovarian Cancer Patients following Surgery and Completion of Chemotherapy

John Martignetti, PhD, Professor, Genetics and Genomic Sciences, Icahn School of Medicine at Mount Sinai, United States

With the ultimate complementary goals of earlier detection of residual disease, defining tumor heterogeneity, optimizing ovarian cancer treatment and improving survival, we propose a novel method of cancer surveillance. We have used ultra-deep, targeted gene sequencing of peritoneal washes following a patient's surgery and completion of chemotherapy to provide a more sensitive means of detection of persistent disease as well as provide specific information about a tumor's genetic features.

11:50 Circulating Tumor Cell (CTC) Analysis in Preclinical Models of Cancer Metastasis

Alison Allan, PhD, Senior Oncology Scientist, Associate Professor, Oncology and Anatomy & Cell Biology, Western University

The use of *in vivo* preclinical models that allow assessment of metastasis is critical for development of effective new cancer therapies. This presentation will discuss the use of circulating tumor cell (CTC) analysis as an effective means of tracking and characterizing metastatic disease progression in preclinical mouse models of breast and prostate cancer. In particular, the use of clinically-relevant CTC technologies such as the CellSearch and Parsortix platforms for pre-clinical CTC studies can serve to enhance the understanding and translation of cancer biology and new cancer therapies from animal to patient.

12:20 PANEL DISCUSSION

Moderator: Nikolas Hendrik Stoecklein, MD, Professor, Experimental Surgical Oncology, Department of General, Visceral and Pediatric Surgery, University Hospital and Medical Faculty of the Heinrich-Heine University Düsseldorf, Düsseldorf, Germany

- What are the barriers for propagation and culture of CTC?
- What advances are needed to make the ease of CTC capture, analysis and interpretation easier, more reliable and more user-friendly?
- How can we address the challenge of clinical correlation with the detection of various tumor-associated circulating cells and other circulating targets?
- What strategies can we use to come to consensus on quality control and standardization for CTC characterization and analysis?

12:50 Luncheon Presentation: Parsortix™ System Makes Unbiased Isolation and Identification of CTCs Possible

Sponsored by ANGLE

Anne-Sophie Pailhes-Jimenez, PhD, Project Manager, ANGLE plc, United Kingdom

The enumeration of circulating tumour cells (CTCs) in peripheral blood has shown prognostic relevance in several cancer types. The ParsortixTM system allows an epitope-independent enrichment of CTCs based on cell size and compressibility using a disposable cassette. We developed an in-cassette immunofluorescent staining to specifically identify CTCs from patient samples. This is a sensitive, flexible and semi-automated method for the capture, enumeration and characterisation of CTCs that has the potential to provide clinical value.

13:20 Session Break

CLINICAL RELEVANCE OF CTC DETECTION

13:50 Chairperson's Remarks

Françoise Farace, PhD, Professor, University of Paris-Sud, Université Paris-Saclay, France

14:00 KEYNOTE PRESENTATION: Phenogenomic Subtyping of CTCs to Identify Biomarkers that Improve Prostate Cancer Patient Outcomes

Howard I. Scher, MD, D. Wayne Calloway Chair, Urologic Oncology; Co-Chair, Center for Mechanism Based Therapy; Head, Biomarker Development Initiative; Office of the Physician in Chief; Member and Attending Physician, Genitourinary Oncology Service, Medicine, Sidney Kimmel Center for Prostate and Urologic Cancers, Memorial Sloan Kettering Cancer Center, United States

With the aim of rapidly identifying circulating tumor (CTC) populations that are sensitive to specific classes of drug to guide treatment selection, and building on the technology enabling clinical utility established in the area of the cytologic

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evaluation of Pap smears, we evaluated protein and morphologic features on individual CTC using the validated EPIC Sciences technology to define 15 unique cell populations. Sensitivity to specific drug classes was determined by the reduction in frequency of a particular cell type which was then sequenced to associate genotype to phenotype. The associations between cell type and response will be presented.

14:30 CTC Count in Breast Cancer: Clinical Validity Results & Utility Trials

Jean-Yves Pierga, MD, PhD, Institut Curie, Medical Oncology and Circulating Tumor Biomarkers Laboratory, SiRIC, Université Paris Descartes, Paris, France

Circulating tumour cell count has demonstrated a very significant clinical validity as a prognostic marker in both metastatic and early breast cancer patients. We will summarize the results obtained and present the ongoing attempt to demonstrate its clinical utility.

15:00 Workflows to Advance CTC-Based Liquid Biopsies

Nikolas Hendrik Stoecklein, MD, Professor, Experimental Surgical Oncology, Department of General, Visceral and Pediatric Surgery, University Hospital and Medical Faculty of the Heinrich-Heine University Düsseldorf, Düsseldorf, Germany

We developed workflows to profile individual CTCs for genetic and epigenetic alterations, e.g. to monitor genomic profiles of CTCs during therapy, which might help to identify genetic resistance mechanisms. However, a major challenge to use CTC-based liquid biopsies remains their extreme low concentration of CTCs and the minimal amount of investigated blood in standard CTC-tests. To tackle this problem, we introduced Diagnostic Leukapheresis (DLA), which resulted in an increase in CTC detection frequency and an escalation of the median CTC numbers. We hope that DLA, or similar approaches derived thereof, will advance the clinical utility of CTC-based liquid biopsies.

15:30 How Clinical Biobanks Can Support Precision Medicine: From Standardized Preprocessing to Treatment Guidance

Jens K. Habermann, MD, PhD, Director, Interdisciplinary Center for Biobanking-Lübeck; Head, Section of Translational Surgical Oncology and Biobanking; Scientific Director, Surgical Center for Translational Oncology-Lübeck, Germany

CTCs harbor an enormous potential for precision medicine. However, clinical implementation requires standardization. This is in contrast to e.g., CTC assessment in colorectal cancer, which is still hampered by major inter-study heterogeneity. This talk will address (i) current challenges and solutions for standardized CTC assessment and (ii) how clinical biobanks can support CTC research for precision medicine, the latter one being exemplarily demonstrated by CTC detection emphasizing distinct surgical procedures.

16:00 Refreshment Break in the Foyer

16:20 Biological Role and Clinical Significance of Experimentally-Derived CTC-Specific Genes in Breast Cancer

Emanuela Fina, PhD, Biomarkers Unit, Experimental Oncology and Molecular Medicine, Fondazione IRCCS Istituto Nazionale dei Tumori, Italy

Circulating tumor cells (CTCs) represent a unique source of information that might help to clarify numerous aspects of metastasis biology and identify new clinically useful biomarkers. CTC specific genes, including TFF3 and FADS3, derived from the MDA MB 231 xenograft model, were investigated i) to explore their role in metastasis by functional assays and ii) to assess their prognostic role when detected in CTC samples obtained from clinically non-metastatic and metastatic breast cancer patients.

16:50 Hypermetabolic Circulating Tumor Cells Predict Progression-Free Survival in Metastatic Breast Cancer Patients

Fabio Del Ben, MD, PhD, Research Collaborator, Cancer Research and Advanced Diagnostics, Immunopathology and Cancer Biomarkers Unit, CRO Aviano IRCCS National Cancer Institute; Clinical Pathology Resident, Medical Area, University of Udine, Italy.

We present here the preliminary results of a pilot clinical trial on metastatic breast cancer aimed at assessing the correlation of hypermetabolic CTC to disease progression in metastatic breast cancer. We enumerated CD45(-), ECAR(high) cells in the peripheral blood of metastatic breast cancer patients (N=25), which had measurable disease and beginning a new therapy line. Blood was analyzed before therapy, and after 3-4 weeks. A parallel sample was analyzed with the CellSearch® system. Blood samples of healthy donors (N=19) were analyzed as well. Patients showing more than 5 cells at baseline (N=10) had significantly shorter Progression Free Survival (PFS, p<0.002 in Log-rank test, hazard ratio of 5.8), with a median PFS of 123 vs 260 days of patients with less than 5 cells. When considering patients with more than 5 cells either at the baseline or at follow-up (N=12) the difference of 129 vs 260 days was even more statistically significant (p<0.0006, hazard ratio of 6.3). Comparing our counts with CellSearch® test results, Pearson coefficient was 0.98, indicating good correlation. NGS of target ESR1 and PI3KCA genes showed the presence of hotspot mutations in 90% of samples (ESR1 in 9/9 and PI3KCA in 2/9). This confirms at the same time the feasibility of the downstream analysis pipeline, and the neoplastic nature of cells. Multiple (two to four) different ESR1 missense mutation was reported in the same sample indicating heterogeneity of harvested CTC. Results suggest that hypermetabolic CTC as defined by the present study are a promising biomarker of progression of disease and candidate substrate for studying intratumoral heterogeneity and drug resistance profiles. A larger clinical study is planned to further validate these results.

17:20 Close of Conference

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P3: Clinical Application for Cell-Free DNA	P6: Circulating Tumour Cells

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21 May
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~~SC2: Preimplantation Genetic Diagnostics and Screening~~
SC3: Liquid Biopsy for P4 Medicine: Predictive, Preventive, Personalized and Participatory

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Poster Submission - Discount (€50 Off): Poster abstracts are due by 13 April 2018. Once your registration has been fully processed, we will send an email containing a unique link allowing you to submit your poster abstract. If you do not receive your link within 5 business days, please contact jring@healthtech.com. *CHI reserves the right to publish your poster title and abstract in various marketing materials and products.

REGISTER 3 - 4th IS FREE: Individuals must register for the same con¬ference or conference combination and submit completed registration form together for discount to apply.

Alumni Discount: CHI appreciates your past participation at Molecular Diagnostics Europe. As a result of the great loyalty you have shown us, we are pleased to extend to you the exclusive opportunity to save an additional 20% off the registration rate

Group Discounts: Discounts are available for multiple attendees from the same organization. For more information on group rates contact Cheryl Rosenberg at +1-781-972-5489, crosenberg@healthtech.com.

If you are unable to attend but would like to purchase the 2018 Molecular Diagnostics Europe CD for €600 (plus shipping), please visit MolecularDxEurope.com. Massachusetts delivery will include sales tax.

ADDITIONAL REGISTRATION DETAILS

Each registration includes all conference sessions, posters and exhibits, food functions, and access to the conference proceedings link.

Handicapped Equal Access: In accordance with the ADA, Cambridge Healthtech Institute is pleased to arrange special accommodations for attendees with special needs. All requests for such assistance must be submitted in writing to CHI at least 30 days prior to the start of the meeting.

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Video and or audio recording of any kind is prohibited onsite at all CHI events.