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Cell-Free DNA in Clinical Oncology
Enabling Technologies for Cell-Free DNA
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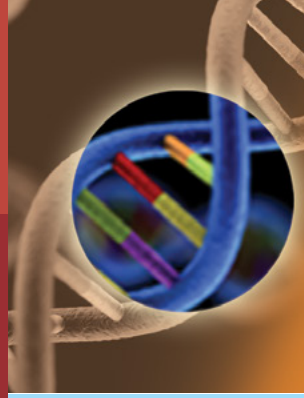


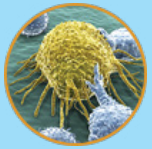
CAMBRIDGE HEALTHTECH INSTITUTE'S FIFTH INTERNATIONAL

Molecular Diagnostics EUROPE

10-13 APRIL 2017
SHERATON LISBOA HOTEL & SPA
LISBON, PORTUGAL

CONFERENCE PROGRAMS

10 - 12 APRIL
Advances in Prenatal Molecular Diagnostics

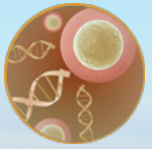


12 - 13 APRIL
Biomarkers for Immunotherapy

11 - 12 APRIL
Advanced Diagnostics for Infectious Disease

12 - 13 APRIL
Point-of-Care Diagnostics

11 - 12 APRIL
Cell-Free DNA in Clinical Oncology



12 - 13 APRIL
Enabling Technologies for Cell-Free DNA

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Ilana Quigley
Business Development Manager
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Conference Hotel:

Sheraton Lisboa Hotel & Spa
Rua Latino Coelho, 1
1069-025 Lisbon, Portugal
Phone: (351)(21) 3120000

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

Discounted Room Rate: €150 single/€170 double, includes breakfast
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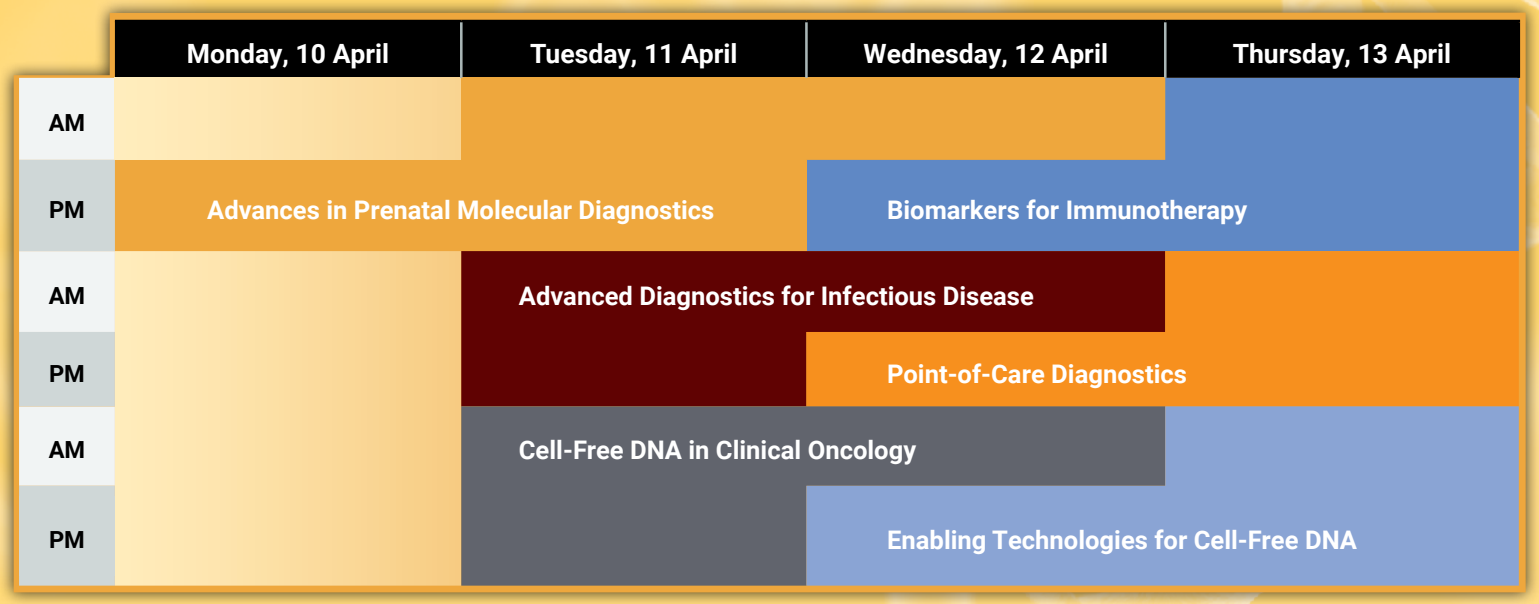

PRE-CONFERENCE SHORT COURSES* | MONDAY 10 APRIL 2017

09:00-12:00

SC1: Preimplantation Genetic Diagnostics and Screening

Anil Biricik, Ph.D., PGD Lab Manager, GENOMA Group, Italy

Joris Vermeesch, Ph.D., Professor, Molecular Cytogenetics and Genome Research, KU Leuven, Belgium

Tony Gordon, Ph.D., Laboratory Director (UK) and Managing Director (USA), Genesis Genetics, United Kingdom

Preimplantation Genetic Screening and Diagnosis offer the chance to avoid serious genetic disorders in our offspring by allowing us to select the most viable embryos for implantation. This short course will discuss the current state of PGS and PGD, latest advances in technologies such as next-generation sequencing, and the challenges we face with mosaic embryos.

14:00-17:00

SC2: Technologies, Applications and Commercialization of Point-of-Care Diagnostics

Holger Becker, Ph.D., 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.

** Separate Registration Required*

About the Event

Cambridge Healthtech Institute's **Fifth International Molecular Diagnostics Europe** event is returning to Lisbon this April and will feature six tracks: Prenatal Molecular Diagnostics, Biomarkers for Immunotherapy, Clinical Application of Circulating Cell-Free DNA in Oncology, Enabling Technologies for Circulating Cell-Free DNA, Point-of-Care Diagnostics and Advanced Diagnostics for Infectious Disease. This comprehensive look at molecular diagnostics spans the latest technologies and applications in fetal and maternal medicine, oncology, infectious disease, rapid diagnostics, liquid biopsy and immunotherapy. Join over 500 delegates expected this spring at this expanding event at the epicenter of diagnostics.

FINAL WEEKS TO REGISTER!

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Fourth Annual **10 - 12 APRIL**

Advances in Prenatal Molecular Diagnostics

Trends, Advances, and Prospects

Recommended Short Course*
SC1: Preimplantation Genetic Diagnostics and Screening
**Separate registration required. See page 2 for details*

MONDAY, 10 APRIL

08:00 Short Course Registration and Morning Coffee

12:00 Main Conference Registration

DEVELOPMENTS OF INVASIVELY-OBTAINED SAMPLES FOR PRENATAL TESTING

13:00 Chairperson's Opening Remarks

13:10 Chromosomal Microarray in Prenatal Diagnostics – Lessons from More Than 1500 Analyses
Ida Vogel, M.D., Head of Clinical Genetics, Aarhus University Hospital, Denmark
We found aneuploidy in 4.7% of samples with fetal malformations, pathogenic CNV in additional 5.4% and variants of unknown significance (VOUS), likely pathogenic, in 1.6%. We have successfully replaced conventional karyotyping with CMA with a higher detection rate, a shorter turn-around time in a clinically manageable way for both abnormal ultrasound and increased risk in a government financed system covering the central Denmark region of 1.2 million people.

13:40 Array-CGH (aCGH) as a First-Tier Test in All Invasive Prenatal Samples
Julian Nevado, Ph.D., Responsible for Genomics and Quality Manager, INGEMM, Spain
Given the increasing prevalence of NIPD testing for prenatal diagnosis, what is the best course of action with invasively-obtained prenatal samples? aCGH has been recommended by different experts and international guidelines as a first tier-test in many postnatal clinical settings, but should this also apply prenatally? Based on our experience we will try to answer whether aCGH should be applied for all invasive samples and if it should be used as a first test or in parallel to Karyotype. Current data in our lab, we will help to decipher the best option.

14:10 Sponsored Presentation *(Opportunity Available)*

14:25 Sponsored Presentation *(Opportunity Available)*

14:40 Refreshment Break

BIOMARKERS FOR PRE-ECLAMPSIA AND PRE-TERM BIRTH

15:15 Polymorphism in the Promoter Region of Placental Protein 13/ LGALS13 Gene as a Biomarker for Pre-Eclampsia
Hamutal Meiri, Ph.D., MBA, Coordinator of International Research, ASPRE Consortium, Israel
Gene polymorphisms are related to resilience/susceptibility to acquire various medical disorders including preeclampsia (PE). Our aim was to assess DNA polymorphisms in the LGALS13 sequence, encoding for placental protein 13 (PP13), in predicting PE, given PP13's unique placental expression and its potential role as a PE biomarker. It opens a new avenue for DNA-based prediction of a major pregnancy disorder related to placental dysfunction.

15:45 Risk Factors and Proteomic Biomarkers for Pre-Term Birth
A. Lopez Bernal, M.D., Ph.D., School of Clinical Sciences, Obstetrics and Gynecology, University of Bristol, United Kingdom
The mechanism responsible for the onset of human labour remains a mystery but labour and delivery provoke changes in maternal plasma proteins associated with immune and defence responses and with lipid transport. We have used Tandem Mass Tag (TMT) labelling for a comprehensive analysis of proteins in the maternal circulation, as well as with intrauterine tissues. Prostaglandins (PGs) have been implicated in parturition for many decades. We propose that reduced expression of certain biomarkers as a potential mechanism through which smoking may contribute to preterm labour. Proteomic biomarkers will provide valuable insight into the mechanism of human labour and inform further research to improve the prediction and management of preterm birth.

16:15 ROUNDTABLE BREAKOUT DISCUSSIONS
Topics include:
- Microarrays and Sequencing for Invasively-Obtained Samples
- Ethical and Genetic Counseling Issues for Prenatal Testing
- Developing Biomarkers for Preeclampsia and Pre-Term Birth Risk
- In-House vs. Service-Based Cell-Free DNA testing
- Prenatal Testing for Sub-Chromosomal Abnormalities
- Commercialization Potential for Fetal Cell-Based Non-Invasive Testing

17:15 Close of Day One

Fourth Annual **10 - 12 APRIL**

Advances in Prenatal Molecular Diagnostics

Trends, Advances, and Prospects

TUESDAY, 11 APRIL

08:00 Registration and Morning Coffee

cfDNA SCREENING FOR PRENATAL DIAGNOSTICS

09:00 Chairperson's Remarks

09:05 Mosaic Whole Chromosome Uniparental/Biparental Disomy: A Common Feature in Trisomic Placentas?

Diane Van Opstal, Ph.D., Laboratory Specialist in Clinical Genetics, Erasmus Medical Center, The Netherlands

The results of SNP array investigations of first trimester chorionic villi and term placentas, for confirmation of abnormal NIPT results, reflect the cytogenetic chaos that has been described in cleavage-stage embryos. Apart from confined placental mosaicism involving trisomies and different structural chromosome aberrations, we also found mosaic whole chromosome uniparental disomy (UPD)/biparental disomy (BPD) which is rarely described in the literature, but which seems to be common in trisomic placentas. Interesting cases will be presented.

09:35 Lessons from More Than 6000 NIPS from a Single Center, Including Use of NIPS in Complex Obstetrical Situations and Ultrasound Anomalies

Francois Jacquemard, Ph.D., Gynecology & Obstetrics, American Hospital of Paris, France

From January 2013, more than 6000 NIPS have been processed through the Prenatal Diagnosis Center of the American Hospital of Paris (France). Details related to indications for testing and clinical finds will be reported, including rates for PPV, sensitivity and false-positives. Lessons learned from these results, including that NIPS was also useful in some complex obstetrical situations when the risk of miscarriage or premature delivery was very high and contraindicated any invasive testing, allowing almost full exclusion of main aneuploidies.

10:05 Expediting NIPT Assay Development, Validation and Routine Monitoring

Sponsored by seracare

Ram Santhanam, MS, MBA, Director, Market Development - Reproductive Health, SeraCare Life Sciences, United States

As non-invasive prenatal testing (NIPT) becomes more mainstream, there is a critical need for patient-like reference materials to expedite new assay development, validation, external quality assurance (EQA) testing, and routine monitoring. We will discuss case studies and performance data from a cross section of laboratories successfully utilizing these reference materials.

10:20 cfDNA Testing for 22q11.2 Deletion Syndrome Using a Targeted Microarray Based Technology

Sponsored by Roche

Maximilian Schmid, M.D., Senior Director of Medical Affairs, Medical Affairs, Roche Sequencing Solutions, United States

Deletion of 22q11.2 is the second most common cause of developmental delay and major congenital heart disease after Down syndrome1. The Harmony® Prenatal Test, used for assessing the probability of Down syndrome (Trisomy 21) and other chromosomal conditions, has extended its menu to include 22q11.2 deletion testing. Top-line results of an analytical validation will be presented.

1. *Rauch et al. Am J Med Genet A. 2006 Oct 1;140(19):2063-74*

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

11:15 Frequency of Fetal Submicroscopic Chromosome Aberrations in Low-Risk Pregnancies – A Systematic Review of Literature

Malgorzata Srebniak, Ph.D., Laboratory Specialist in Clinical Genetics, Clinical Genetics, Erasmus Medical Center, The Netherlands

A systematic literature search was performed in order to establish the frequency of pathogenic submicroscopic copy number variants (CNVs) in fetuses without ultrasound anomalies and therefore no increased risk for unbalanced structural aberrations. The aim was to determine the clinical value of high resolution fetal testing in the general pregnant population. We will show combined data of the relevant studies indicating the background risk for pathogenic submicroscopic aberrations in ca. 10,000 fetuses without increased a priori risk.

11:45 Clinical Implications of Testing for Sub-Chromosomal Abnormalities with NIPT

Yaron Yuval, M.D., Director, Prenatal Genetic Diagnostic Unit, Tel Aviv Sourasky Medical Center, Israel

Detection rates for microdeletions may vary considerably depending on deletion size and positive predictive values (PPVs) - strongly influenced by prevalence - are expected to be low. Whole genome NIPS has recently been introduced, claiming the ability to detect copy number changes throughout the genome. The benefits and limitations of expanded NIPS will be discussed with the aim of assisting clinicians and policymakers in incorporating NIPS into clinical practice.

12:15 Sponsored Presentation *(Opportunity Available)*

12:45 Luncheon Presentation *(Sponsorship Opportunity Available)* **or Enjoy Lunch on Your Own**

cfDNA SCREENING FOR PRENATAL DIAGNOSTICS (CONT.)

13:45 Chairperson's Remarks

13:50 Non-Invasive Prenatal Testing of Monogenic Disorders by Droplet Digital PCR

Yves Rozenholc, Ph.D., Department of Statistics, University of Paris Descartes, France

Recently the use of NGS and digital-PCR using cell-free fetal DNA has been the basis for non-invasive prenatal tests for single-gene disorders. However, to date, it has mainly been offered for paternal and *de novo* mutation exclusion, the study of the maternal inheritance remaining challenging because of the high levels of maternal background. The development of a digital droplet PCR Uniformly Most Powerful Likelihood Ratio

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Test has been developed for a range of different single gene disorders. Results using this approach, and recommendations related to blood volume to collect, for each type of single-gene disorder, will be discussed.

14:20 Toward Refined Non-Invasive Prenatal Testing by Digital Droplet PCR and Free Fetal DNA Enrichment

Neil Avent, Ph.D., Molecular Diagnostic and Transfusion Medicine, School of Biomedical & Healthcare Sciences, Plymouth University, United Kingdom

Digital droplet PCR (ddPCR) is a significant enhancement over quantitative real-time PCR, and previous hardware associated with performing digital PCR. It has greater sensitivity and specificity than previously described methods, and has yet to impact fully on its application in non-invasive prenatal testing. We have performed ddPCR on maternal plasma samples to detect paternally inherited genes (RHD and SRY), and have proved its superiority over real-time methods. By pre-enrichment of maternal plasma samples this technique could readily be applied to the assessment of aneuploidy, providing a cheaper and more straightforward approach than current next-generation sequencing dependent methods to define aneuploidy.

14:50 Developing and Delivering a Non-Invasive Prenatal Diagnostic Service for Monogenic Disorders

Lucy Jenkins, FRCPath, Lab Director, Great Ormand Street Hospital, London, United Kingdom

The development of NIPD for single gene disorders, and particularly the impact of next-generation sequencing technologies that have been used to extend our service repertoire, will be presented. Previously limited to *de novo* mutations or paternal exclusion testing, we have extended this approach to the implement bespoke test development for families with rare disease. NGS has now facilitated relative haplotype dosage analysis (RHDO) for the diagnosis of recessive conditions, even where parents carry the same mutation. Uptake of testing in the UK will be discussed along with issues that arise during NIPD delivery.

15:20 Sponsored Presentation *(Opportunity Available)*

15:50 Refreshment Break in the Exhibit Hall with Poster Viewing

16:30 Panel Discussion with Cell-Free DNA Assay Providers

Michael Lutz, CEO, Life Codexx AG, Germany
Samantha Leonard, International Medical Director, Natera, France
Stephen Little, Ph.D., Chief Executive Officer, Premaitha Health, United Kingdom
Daniel Grosu, M.D., MBA, Consultant, Integrated Genetics, United States
Gautam Kollu, Head of Market Development, RGH Market, Illumina Inc., United States
Maximilian Schmid, M.D., Senior Director of Medical Affairs, Medical Affairs, Roche Sequencing Solutions, United States

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

19:00 Close of Day Two

WEDNESDAY, 12 APRIL

08:00 Registration and Morning Coffee

ISOLATION AND ANALYSIS OF FETAL CELLS FROM MATERNAL BLOOD

08:30 Chairperson's Remarks

Patrizia Paterlini-Brechot, Ph.D., Cellular & Molecular Biology, University of Paris Descartes, France

08:35 The Case for Cell-Based NIPT Using DNA from Fetal Cells

Ripudaman Singh, Ph.D., COO, ARCEDI Biotech Aps, Denmark

In our previous studies we have shown that extravillous trophoblasts enriched from maternal blood using specific markers can be used to detect chromosomal and sub-chromosomal variations in the fetal genome. We present data from our clinical validation study which brings us a step closer to pursuing cell-based NIPT on all pregnancies, avoiding the use of invasive procedures.

09:05 Updated Results for Isolation and Genetic Characterization of Trophoblastic Cells for Prenatal Diagnosis of Genetic Diseases

Patrizia Paterlini-Brechot, Ph.D., Cellular & Molecular Biology, University of Paris Descartes, France

The development of a non-invasive alternative to the invasive approaches for prenatal diagnosis of genetic diseases requires the use of fetal DNA non-mixed with maternal DNA, thus the availability of cells carrying the fetal DNA. We have developed ISET, allowing the consistent recovery of trophoblastic cells from blood and cervical samples, and have developed methods for the extensive genetic analyses of the collected cells. We will present results of the use of trophoblastic cells isolated by ISET for non-invasive prenatal diagnosis of trisomy 21 and monogenic disorders and discuss the technical issues involved in bringing to the market this new approach.

09:35 Advances in the Isolation of Fetal Cells from Maternal Blood

Leonard Kellner, President, KellBenx, United States

The isolation of fetal nucleated red blood cells (fnRBC) in maternal blood allows for a non-invasive diagnostic test of the fetal genome. Methods to analyze these cells will be presented and discussed.

10:05 Sponsored Presentation *(Opportunity Available)*

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

11:05 Closing Panel Discussion: Predicting the Landscape for Prenatal Molecular Diagnostics over the Next Few Years

Panelists to be Announced

12:05 Close of Advances in Prenatal Molecular Diagnostics Conference

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Inaugural 12 - 13 APRIL

Biomarkers for Immunotherapy

Integrating Immunotherapies into the Precision Medicine Model

WEDNESDAY, 12 APRIL

12:30 Registration

EMERGING IMMUNO-ONCOLOGY BIOMARKERS AND APPROACHES

13:30 Chairperson's Opening Remarks

Shao-An Xue, Ph.D., Genetic Engineering Laboratory, School of Biological & Environmental Engineering, Xi'an University, Institute of Immunity & Transplantation, University College London Medical School, United Kingdom

13:35 Cytomegalovirus and Epstein-Barr Virus, Two Unique Biomarkers for Immunotherapy of the Virally Associated Malignancies

Shao-An Xue, Ph.D., Genetic Engineering Laboratory, School of Biological & Environmental Engineering, Xi'an University, Institute of Immunity & Transplantation, University College London Medical School, United Kingdom

Using CMV and EBV as biomarkers, we isolated HLA-A2-restricted TCR genes specific for CMV and EBV, and retrovirally transduced them into human T cells, thus generated MHC class I-restricted both CD8+ and CD4+ T cells specific for these viruses. This talk will describe a robust approach for generating CD8+ CTL and CD4+ Th cells capable of providing MHC class I-restricted antitumor immunity by targeting CMV and EBV as biomarkers.

14:05 Biomarkers for Early Phase Immune-Oncology Trials

Sid Katugampola, Ph.D., Biomarker & Translational Scientist, Centre for Drug Development, Cancer Research UK, United Kingdom

Numbers of immunotherapeutic anti-cancer therapies are on the rise and these are showing promising anti-tumour efficacy. Successful translation of these agents and understanding if and how these would work clinically, particularly for first in class (FIC), are of great importance. The use of pharmacodynamic biomarkers in early phase clinical development for such FIC agents provide exciting opportunities but also significant challenges in trials done on late stage cancer patients.

14:35 PD-L1 Expression in HPV Related Cancer: A Multiparameter Biomarker Approach

Ekaterina S. Jordanova, Ph.D., Principle Investigator, Obstetrics and Gynaecology, Centre for Gynaecological Oncology Amsterdam, The Netherlands

Expression of PD-L1 is still a controversial biomarker for selecting patients for PD1/PD-L1 checkpoint inhibitor immunotherapy. In virally induced tumours such as cervical-, penile-, vulvar-, and head-and-neck cancer various immunotherapy clinical trials are being currently planned or performed. We have recently reported on the link between PD-L1 expression in cervical-, penile- and head-and-neck cancer with poor prognosis. We have developed a multiparameter immunofluorescent technique allowing the analysis of PD-L1 expression in combination with other crucial immune-microenvironment markers. Conceivably, in the near future patients might be easily stratified for particular personalized immunotherapies based on comparable approaches.

15:15 Refreshment Break in the Exhibit Hall with Poster Viewing

16:15 KEYNOTE PRESENTATION: Precision Immunotherapy: The Challenge of Converting Complex Predictive Biomarkers into Practical Companion Diagnostics

Kenneth Emancipator M.D., Executive Medical Director, Translational Medicine, Companion Diagnostics, Merck & Co., United States

Early immunotherapies have produced dramatic results for some patients, but future immunotherapies likely need to be guided by diagnostics to benefit more patients. Properly targeting immunotherapy requires incorporating into clinical practice complex diagnostics which can assess host immune response in addition to cancer biology itself. "Precision Immunotherapy" requires discovery of appropriate predictive biomarkers and incorporating them into practical companion diagnostics which will be adopted by practitioners.

DRUG RESISTANCE

16:45 Immunostimulatory and Oncolytic Properties of Rotavirus Can Overcome Resistance to Immune Checkpoint Blockade Therapy.

Tala Shekarian, Targeting of Tumor and It's Immune Environments, Lyon Cancer Center, France

Oncolytic properties of viruses can be exploited for the priming of anti-tumor immune responses. We have found that commercially available rotavirus vaccines do have oncolytic properties. This attenuated virus can directly kill cancer cells. They have pro-inflammatory properties and activate the NF-Kb pathway in a toll-like receptor and IRF3 independent manner. Interestingly, in immunocompetent murine tumor models, intra-tumoral rotavirus overcome resistance and synergize with immune checkpoint targeted therapy.

17:15 Engineering 2nd Generation SPEAR™-T Cells to Overcome TGF-β-Mediated Immunosuppression for Adoptive Cell Therapy

Jonathan Silk, Ph.D., Group Leader, Cellular Biology, Adaptimmune Ltd

Adoptive Cell therapy with NY-ESO SPEAR-T cells, is showing promising initial clinical responses in clinical trials for solid and liquid tumors. However, the depth and durability of responses may be affected by inhibitory cytokines such as Transforming Growth Factor-β (TGF-β). We investigated whether SPEAR-T cells engineered to express a dominant negative TGF-β receptor (dnTGFβRII) were resistant to the inhibitory effects of TGF-β *in vitro*.

17:45 Close of Day

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Inaugural **12 - 13 APRIL**

Biomarkers for Immunotherapy

Integrating Immunotherapies into the Precision Medicine Model

THURSDAY, 13 APRIL

BIOMARKERS FOR MONITORING PATIENTS

08:30 Registration and Morning Coffee

09:00 Chairperson's Remarks
Thomas O. Kleen, Ph.D., Executive Vice President, Immune Monitoring, Epiontis GmbH, Germany

09:05 Next-Generation Immune Monitoring Tools for Immuno-Oncology Trials and Biomarker Discovery- Reducing Sample Amounts and Simplifying Logistics
Thomas O. Kleen, Ph.D., Executive Vice President, Immune Monitoring, Epiontis GmbH, Germany
Current and next generation Immunotherapy trials now can be monitored with epigenetic-based, quantitative real-time PCR assisted cell counting (qPACC). Samples can be simply frozen and easily shipped without burden on clinical sites, allowing precise and robust quantification of immune cells in all human samples from only 75ul-250ul of whole blood or small amounts of tissue. Regulatory T cells (Tregs), Th17, Tfh, CD3+, CD4+, CD8+, B, NK and PD-1 positive cells are the first examples of a next generation tools for immune monitoring immuno-oncology trials and biomarker discovery.

09:35 Profiling of Immunity Biomarkers in Whole Blood
Alex Chenchik, Ph.D., Scientific Director, Cellecta, Inc., United States
For unbiased discovery of predictive and prognostic biomarkers, we have developed a targeted RNA expression assay that profiles 19,000 genes based on multiplex RT-PCR followed by NGS in whole blood samples stabilized in PAXgene. In this study, we present the performance of the assay for immunophenotyping of immune cells in blood samples from TNBC and sepsis patients and assess the immune responses to complex immunomodulatory stimuli in *ex vivo* model system.

10:05 Post Translationally Modified Auto-Antigens a Biomarker For Early Diagnosis of Autoimmune Disease
Ahuva Nissim, Reader, Antibody and Therapeutic Engineering, Biochemical Pharmacology, Queen Mary University
Oxidative stress might be a critical player in the parthenogenesis of inflammatory autoimmune diseases. This include Rheumatoid arthritis and type 1 diabetes. Our data shows that in both disease the tissue specific auto-antigens are infect auto-antigens that have been post-translationally modified by oxidants present in the diseased tissue. We have shown specific reactivity to oxidated collagen type II and insulin in rheumatoid arthritis and type 1 autoimmune diabetes, respectively.

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

11:20 Loss of Immune Recognition by Aberrant Expression of HLA Class I Antigens in Tumors
Barbara Seliger, Ph.D., Professor and Director, Medical Immunology, Martin Luther University Halle-Wittenberg, Germany
MHC class I abnormalities occur in a high frequency of tumors of distinct origin and are often associated with worse prognosis and reduced patients' survival. The underlying molecular mechanism of these deficiencies are diverse and include total, haplotype, allelic loss or downregulation of HLA class surface antigens, or deregulation of major components of component of the MHC class I antigen processing machinery mediated by either transcriptional, epigenetic or posttranscriptional control.

11:50 Monitoring Immune Dysfunction in the Leukemia Microenvironment
Sergio Rutella, M.D., Ph.D., Professor, Cancer Immunotherapy, John van Geest Cancer Research Centre, College of Science and Technology, Nottingham Trent University, United Kingdom
Escape from immune surveillance is a hallmark of cancer. The dysfunction of T cells, NK cells and dendritic cells (DC) contribute to defective anti-leukemia responses. IFN-γ-inducible targets expressed by tumor and/or microenvironmental cells, such as indoleamine 2,3-dioxygenase-1, arginase-II, HLA-G and PD-L1, favour T-cell suppression, inhibition of NK-cell function and DC maturation arrest. Strategies are being developed to tackle the above immune suppressive circuits with the aim to improve clinical outcome.

12:20 Sponsored Presentation *(Opportunity Available)*

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

13:20 Session Break

BIOMARKERS FOR COMBINATION THERAPIES

14:20 Chairperson's Remarks
Dirk Brockstedt, Ph.D., Senior Vice President, R&D, Aduro BioTech Inc., United States

14:25 Anticipating, Detecting and Treating Immune-Related Toxicity: A Challenge for Combinatorial Immunotherapy
Ioannis Karydis, Ph.D, Associate Professor, Oncology, Cancer Sciences, University of Southampton, United Kingdom
Tumour immunotherapy is coming of age, with a rising number of agents gaining regulatory approval. However, in most cases single agent response rates remain typically well below 40%. Combinatorial immunotherapy offers a chance to dramatically improve on this, at the cost of significant multi-system toxicity. This talk will discuss the issues involved in anticipating, detecting and managing immune-related side effects and outline possible mitigation strategies.

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Inaugural 12 - 13 APRIL

Biomarkers for Immunotherapy

Integrating Immunotherapies into the Precision Medicine Model

14:55 Novel Immune Monitoring and Biomarker Technologies to Support the Development of Combination Immunotherapies for the Treatment of Cancer.

Dirk Brockstedt, Ph.D., Senior Vice President, R&D, Aduro BioTech Inc., United States

The approval of several immunotherapies including cancer vaccines and immune checkpoint inhibitors has not only transformed patient's lives but also brought challenges to the conventional drug development paradigm and the use of typical PK/PD markers to identify optimal patient populations as well as dose level and schedule. This talk will discuss novel immune monitoring and biomarker technologies that were applied for the development of Aduro's Listeria-based cancer immunotherapy for pancreatic cancer and mesothelioma.

CLINICAL CASE STUDY

15:25 Hormone-Immunotherapy in Endocrine-Dependent Metastatic Breast Cancer: Laboratory and Clinical Data

Andrea Nicolini, M.D., Clinical Researcher, Internal Medicine, University of Pisa, Italy

Hormone therapy is currently advised for ER+ metastatic breast cancer patients however in most of them the arising of resistance is a not yet well understood hurdle to overcome. We hypothesized that in these patients during clinical benefit from antiestrogen therapy the addition of cycles of sequential immunotherapy could prolong the benefit and delay the occurrence of acquired hormone resistance. In order to validate this hypothesis, in 1992 we started an open, prospective exploratory clinical trial. Here we summarize and update the clinical data and focus on the main serum biomarkers that proved helpful to monitor the efficacy of hormone immune therapy

15:55 Sponsored Presentation *(Opportunity Available)*

16:25 Refreshment Break

CHALLENGES FOR FUTURE BIOMARKER DISCOVERY

16:45 CLOSING PANEL: Strategies for Practical Application of Biomarker Research

Moderator: Dirk Brockstedt, Ph.D., Senior Vice President, R&D, Aduro BioTech Inc., United States

Shao-An Xue, Ph.D., Genetic Engineering Laboratory, School of Biological & Environmental Engineering, Xi'an University, Institute of Immunity & Transplantation, University College London Medical School, United Kingdom

Ekaterina S. Jordanova, Ph.D., Principle Investigator, Obstetrics and Gynaecology, Centre for Gynaecological Oncology Amsterdam, The Netherlands

Kenneth Emancipator M.D., Executive Medical Director, Translational Medicine, Companion Diagnostics, Merck & Co., United States

- Sample quality, quantity, and type
- Standardizing procedures and assay validation
- Funding, resources, and collaboration

17:45 Close of Conference

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Third Annual **11 - 12 APRIL**

Advanced Diagnostics for Infectious Disease

A Revolution in Testing

Recommended Short Course*
SC2: Technologies, Applications and Commercialization of Point-of-Care Diagnostics
**Separate registration required. See page 2 for details*

TUESDAY, 11 APRIL

THE INFECTIOUS DISEASE DIAGNOSTIC REVOLUTION

08:00 Registration and Morning Coffee

09:00 Chairperson's Remarks
François Jean, Ph.D., Scientific Director, UBC Facility for Infectious Disease and Epidemic Research (FINDER); 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, Canada

09:10 OPENING KEYNOTE PRESENTATION: Public Health Emergencies: The Interplay Between Lab, Surveillance and Public Health Response
Francesco Vairo, M.D., Emerging and Reemerging Infectious Disease Unit, National Institute for Infectious Diseases (INMI) "L.Spallanzani"

10:05 Circulating MicroRNAs and their Targets as Potential Biomarkers of Treatment-Based Viral Cure of Chronic Infection with Hepatitis C Virus
François Jean, Ph.D., Scientific Director, UBC Facility for Infectious Disease and Epidemic Research (FINDER); Associate Professor, Microbiology and Immunology, University of British Columbia Team Leader, NCE IC-IMPACTS Grant in Next Generation Molecular Diagnostics for Emerging Viral Diseases, Canada

In this study we provide the first insights into a novel coordinated interplay between three important molecular players in lipid homeostasis— circulating microRNA (miR)-24 and miR-223 and PCSK9 — whose regulation are affected by hepatitis C virus (HCV) infection and treatment-based viral cure. In addition to represent potential biomarkers for treatment-based viral cure of chronic hepatitis C infection, circulating miR-24, miR-223 and PCSK9, may represent novel potential therapeutic targets to prevent HCV-associated liver disease progression.

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

11:15 Matrix-Assisted Laser Desorption/Ionization Time-of-Flight (MALDI-TOF) Mass Spectrometry Applied to Virus Identification
Adriana Calderaro, M.D., Ph.D., Associate Professor, Clinical Microbiology, Unit of Microbiology and Virology, Clinical and Experimental Medicine, University Hospital of Parma, Italy

MALDI-TOF mass spectrometry, a reliable identification method for the diagnosis of bacterial and fungal infections, was developed in this study as an innovative tool to identify human polioviruses and their specific protein to be used as biomarkers for serotyping; moreover, we created a protein profile library of cell cultures infected by the most common viruses causing infections of the respiratory tract in humans.

11:45 Circulating and Tissue Levels of miRNA in Infectious Diseases: Special Emphasis on HIV-Infection
Raphael Mohr, Ph.D., Medizinische Klinik und Poliklinik I, Bonn University Hospital, Germany

MicroRNAs (miRNAs) are small non-coding RNAs, which regulate the function of single genes and gene clusters. miRNA play a role in different cells and tissues. But they are also released passively though death damage and organ injury or even actively in specific conditions into the blood stream. Therefore, miRNA might serve as biomarkers for different conditions. We have analyzed several specific miRNA which play a role in the pathogenesis of liver injury associated with different viruses, not only in the tissue but also in the circulation.

12:15 Detection Methods of Infectious Diseases Based on Innovative Biochip Technology
Sponsored by CapitalBio Technology
Junquan Xu, MS, MBA, CEO, CapitalBio Technology, China

Precision Medicine is considered as a tendency for medicine in the future. It requires the more rapid and accurate detection than the traditional ones. CapitalBio developed a series of kits based on biochip technology for rapid detection of TB, respiratory tract, Zika, HPV and help to make precision medicine possible.

12:45 Luncheon Presentation *(Sponsorship Opportunity Available)* **or Enjoy Lunch on Your Own**

13:15 Session Break

RAPID DIAGNOSTICS FOR ANTIMICROBIAL DRUG RESISTANCE DETECTION (AMR)

14:15 Chairperson's Remarks
Till T. Bachmann, Ph.D., Reader, Personalised Medicine in Infectious Disease; Deputy Head, Division of Infection and Pathway Medicine, College of Medicine and Veterinary Medicine, University of Edinburgh, United Kingdom

Third Annual **11 - 12 APRIL**

Advanced Diagnostics for Infectious Disease

A Revolution in Testing

14:20 The Development of a Point-of-Care Assay for HNL (Human Neutrophil Lipocalin) to be Used in the Specific and Rapid Distinction between Bacterial and Viral Infections

Per Venge, Ph.D., Professor, Medical Sciences, University of Uppsala Hospital, Sweden

The distinction between bacterial and viral causes of acute infections is a major clinical challenge. Previous reports showed the superior diagnostic performance in this regard of serum measurements of HNL (Human Neutrophil Lipocalin). Serum measurement, however, is slow and we have therefore invented an alternative procedure suitable for the development of a rapid point-of-care application and show that this procedure has similar diagnostic performances and superior to any other biomarker such as CRP, procalcitonin and CD64.

14:50 ArcDia's Groundbreaking Technology Enables World's Fastest Phenotypic Antibiotic Resistance Testing

Janne O. Koskinen, Ph.D., R&D Director, ArcDia International Oy Ltd, Finland

ArcDia's proprietary technology allows sensitive immunoassays from miniature reaction volumes without separation steps. The binding reaction takes place on microparticles, which are detected by two-photon excitation fluorometry (TPX). In mariAST®, suspension culture is performed in the presence and absence of antimicrobials. Bacterial growth is monitored in real-time using pathogen-specific TPX detection. mariAST® allows phenotypic antimicrobial susceptibility testing of bacteria without pure culture directly from clinical samples in 3–6 hours.

15:20 "The Power within Me": Redefining the Set of Solutions for Antibiotics Misuse Using Host Response-Based Diagnostics

Kfir Oved, Ph.D., Co-Founder & CTO, R&D, MeMed, Israel

A major driver of antibiotic misuse is the difficulty to clinically discriminate bacterial from viral infections. Antibiotics misuse leads to ineffective treatment, emergence of antibiotics resistance, and costs tens of billions of dollars annually. ImmunoXpert™ is a novel IVD that leverages the most accurate diagnostic system known to man, our immune system. The ImmunoXpert™ measures three immune biomarkers and integrates them using a proprietary software to accurately distinguish bacterial from viral infections, thus empowering physicians to reduce antibiotics misuse and improve patient management.

15:50 Refreshment Break in the Exhibit Hall with Poster Viewing

APPLYING NEW TECHNOLOGIES TO CLINICAL CARE: WHAT IS NEEDED TO MAKE THEM USEFUL TOOLS FOR THE VIROLOGIST

16:30 Chairperson's Remarks

My VT Phan, Ph.D., Postdoctoral Research Fellow, Viroscience, Erasmus Medical Center

16:35 The Power of Molecular Viral Diagnostics in Clinical Medicine

Suzan Pas, Ph.D., Team Lead, Molecular Diagnostics, Viroscience Department, Clinical Virology, Erasmus Medical Center, The Netherlands

Molecular diagnostics is one of the major techniques used in clinical virology nowadays. This lecture will focus on the challenges and power of this technique used in the past two decades in a reference laboratory during peace time and outbreaks like Ebola and Zika virus.

17:05 Congenital Tremor in Piglets and the Threat to Human Health

Lia van der Hoek, Ph.D., Associate Professor, Laboratory of Experimental Virology, Microbiology, Center for Infection and Immunity Amsterdam (CINIMA), Academic Medical Center (AMC), University of Amsterdam, The Netherlands

Congenital tremor type A-II is a shaking disease in newborn pigs, possibly caused by a very recently-described virus: atypical porcine pestivirus (APPV). We detected the virus by VIDISCA in several outbreaks in the Netherlands. To demonstrate a causal relationship between APPV and disease, gilts were experimentally infected during pregnancy and the litter inspected for disease. We investigated whether infections can give a risk to human health.

17:35 The Utility of Next-Generation Sequencing and Viral Phylogenetics for Outbreak Control

My VT Phan, Ph.D., Postdoctoral Research Fellow, Viroscience, Erasmus Medical Center

Next-Generation Sequencing (NGS) provides great sensitivity to detect and identify viral pathogens. We are working to develop open-access infrastructure and analytical tools to implement NGS in clinical and public health laboratories for virus discovery, virus transmission and outbreak investigations. I will provide examples of the utility of these methods for tracking viruses through populations.

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

19:00 Close of Day

Third Annual **11 - 12 APRIL**

Advanced Diagnostics for Infectious Disease

A Revolution in Testing

WEDNESDAY, 12 APRIL

BRINGING POC FOR EARLY DIAGNOSIS TO AFRICA

08:30 Registration and Morning Coffee

09:00 Chairperson's Remarks

Debrah Boeras, Ph.D., Scientist and Consultant, The Global Health Impact Group, LLC, United States

09:05 Developing Technologies in Resource-Limited Settings: Bringing a Rapid Response to Africa

Adriana Goncalves, Ph.D., Research Fellow, London School of Hygiene & Tropical Medicine

A range of molecular assays that are highly sensitive and specific and can be performed at the point-of-care are now available for both HIV and TB. Further investments in technological innovation are being driven by successive global health emergencies including SARS, flu, MERS coV, Ebola virus disease and Zika virus infection. The challenge is to create a cost-effective, accurate, rapid, and easy-to-use test to guide patient management. As laboratory capacity in resource-limited settings increases, manufacturers should consider how increasing manufacturing capacity can contribute to lowering barriers to product development and market entry for new devices.

09:35 Innovation in Diagnostics: An Opportunity to Strengthen Health Systems and Combat Global Health Security

Rosanna Peeling, Ph.D., Professor and Chair, Diagnostic Research, London School of Hygiene and Tropical Medicine, United Kingdom

Rapid advances in diagnostic innovation have been driven in recent years by the need for more accurate and accessible diagnostics for high burden diseases such as HIV and tuberculosis, global health emergencies such as Ebola and Zika, and the threat of antimicrobial resistance. Connectivity solutions linking data from diagnostic laboratories and POC test readers/devices provide opportunities for automated surveillance and quality assurance systems, increasing the efficiency of health care systems and improving patient outcomes.

10:05 Affordable HIV Drug-Resistance Testing for Monitoring of Antiretroviral Therapy in Sub-Saharan Africa

Wendy Stevens, MBBch, MMed, FCPath, Professor and Head, Molecular Medicine and Haematology; Head of National Priority Programs, National Health Laboratory Service, University of the Witwatersrand, South Africa

Increased provision of antiretroviral therapy in sub-Saharan Africa has led to a growing number of patients with therapy failure and acquired drug-resistant HIV, driving the demand for more costly further lines of antiretroviral therapy. In conjunction with accelerated access to viral load monitoring, feasible and affordable technologies to detect drug-resistant HIV could help maximise the durability and rational use of available drug regimens. Potential low-cost technologies include in-house Sanger and next-generation sequencing in centralised laboratories, and point mutation assays and genotype-free systems that predict response to antiretroviral therapy at point-of-care.

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

11:05 Methods, Metrics & Quality in Dx: Quoid Neuf?

Nitika Pant Pai, M.D., MPH., Ph.D., Associate Professor, Medicine, Divisions of Clinical Epidemiology & Infectious Diseases, McGill University, Canada

In this talk, I will discuss methods, metrics and quality, of studies reported in the HIV Dx space and review reporting key quality parameters in acute HIV infection. The talk is targeted to physicians, and public health care professionals who wish to design their studies, critique and review evidence, formulate guidelines so as to eventually impact the Dx and Rx care continuum.

11:35 Expert Panel with Speakers

12:05 Close of Advanced Diagnostics for Infectious Disease

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Second Annual **12 - 13 APRIL**

Point-of-Care Diagnostics

Rapid Detection to Ensure Better Care

Recommended Short Course*

SC2: Technologies, Applications and Commercialization of Point-of-Care Diagnostics

**Separate registration required. See page 2 for details*

WEDNESDAY, 12 APRIL

12:30 Registration

NEW TRENDS IN HEALTHCARE MANAGEMENT- THE ROLE OF POCT FOR BETTER DIAGNOSIS

13:30 Chairperson's Opening Remarks

Wilfried von Eiff, Ph.D., Academic Director, Center for Health Care Management and Regulation, HHL, Leipzig Graduate School of Management, Germany

13:35 Point-of-Impact Testing in the Emergency Department: Rapid Diagnostics for Respiratory Viral Infections

H.G.M. Niesters, Ph.D., Director, Laboratory of Clinical Virology, University Medical Center Groningen, The Netherlands

The ability to determine rapidly respiratory viruses for patients visiting the emergency room, has shown that the cost/benefit ratio is favorable for both the patient (better care) as well as for the hospital (reduced cost) and on infection control measurements. These advantages of point-of-impact testing also clearly show that the current pressure to reduce costs for diagnostics is completely unfavorable for the only client we have, i.e. the patient.

14:05 The Boundaryless Hospital Approach: Background, Aims and Elements

Wilfried von Eiff, Ph.D., 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 at University of Muenster, Germany

Luís Velez Lapão, Habil., Ph.D., MSc, Professor, International Public Health, Population Health, Policies and Services Group Leader, Global Health and Tropical Medicine, Instituto de Higiene e Medicina Tropical, Universidade Nova de Lisboa, Portugal

In this presentation the nature, aims and impacts of the "Boundaryless Hospital Management Approach" on the quality of medical services along the "continuum of care" are described. In addition, selected network concepts like the portal clinic approach, cross-sectoral contracting, managed care opportunities and emergency network design are depicted. Furthermore, process improvement opportunities by implementing POCT technology in an emergency department are reflected. To conclude, the role of Digital Transformation in Improving Boundaryless Hospital Management will be addressed.

14:35 KEYNOTE PRESENTATION: Novel Analytical Opportunities for Patient-Near Testing

Peter B. Luppa, Ph.D., Head, Central Laboratory, Institute for Clinical Chemistry, Technische Universität München, Germany

The presentation generally defines the application fields of POCT and portrays the different instrument categories and analytical principles. In the focus are the analytical challenges of future POCT diagnostics. A series of novel POCT devices, broadening the spectrum of POCT analytics, will be presented. Among them, molecular-biological methods for nucleic acid detection of infectious agents will be addressed. Innovative nanoparticle-based techniques and alternative biological recognition elements will be elucidated in detail.

15:15 Refreshment Break in the Exhibit Hall with Poster Viewing

ENABLING TECHNOLOGIES FOR POINT-OF-CARE DIAGNOSTICS

16:15 Chairperson's Remarks: Introduction to Status and Trends in Cartridge-Based POCD

Holger Becker, Ph.D., Founder & CSO, microfluidic ChipShop GmbH, Germany

16:30 Building Your Future Diagnostic Product with IMEC's Smart Silicon Chip Solutions

Liesbet Lagae, Ph.D., Program Director, Life Science Technologies, IMEC, Belgium

Multitarget biosensors hold great promise to improve point-of-care diagnostics as they enable simultaneous detection of different biomolecular markers. Multiplexed detection of different markers, like cells, genes, proteins, or a combination of both, propels advancement in numerous fields such as genomics, medical diagnosis and therapy monitoring. IMEC has developed the most powerful silicon platform for multiplexed and multitarget detection. We will give examples of projects in development with industrial partners.

17:00 Precision Diagnostics Based on Modular Capillary-Driven Elements and with Smartphone Connectivity

Emmanuel Delamarche, Ph.D., Manager, Precision Diagnostics, IBM Research, Switzerland

I will present how to program capillary flow and encode specific functions to form microfluidic elements that can easily be assembled into self-powered devices for immunoassays. Small peripherals can augment the functionality of microfluidic chips having electrodes for monitoring flow with sub-nanoliter precision and providing connectivity to smartphones. All together, these concepts may extend the performances of microfluidic devices for point-of-care diagnostics to a next level of precision.

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Second Annual 12 - 13 APRIL

Point-of-Care Diagnostics

Rapid Detection to Ensure Better Care

17:30 Rapid Diagnostic Tests to Tackle Antimicrobial Resistance

Till T. Bachmann, Ph.D., Reader, Personalised Medicine in Infectious Disease; Deputy Head, Division of Infection and Pathway Medicine, College of Medicine and Veterinary Medicine, University of Edinburgh, United Kingdom

Antimicrobial Resistance (AMR) has become a global threat and rapid diagnostics are urgently needed to tackle this challenge. Depending on the clinical scenario and use case, these rapid tests should be suitable for point-of-care testing and detect the right targets and biomarkers to provide information with high clinical utility fulfilling a desired target product profile. The presentation will cover our own research on multiparametric detection using point-of-care sensors in the context of global developments and strategic activities for development and implementation of rapid diagnostic tests to fight AMR.

18:00 Close of Day

THURSDAY, 13 APRIL

COMMERCIALIZATION OF POCT

08:30 Registration and Morning Coffee

09:00 Chairperson's Remarks

John C. Carrano, Ph.D., President & CEO, Paratus Diagnostics LLC, United States

09:05 Convergence of Microfluidics and Consumer Electronics towards Field-Deployable Point-of-Care Tests

Samuel K. Sia, Ph.D., Professor, Biomedical Engineering, Columbia University; Founder, Claros, United States

Lab-on-a-chip (LOC) devices have a tremendous potential for revolutionizing personal health. In the U.S., patients and consumers can have greater access to traditionally complex diagnostics, and in developing countries, mobile diagnostics provides immediate diagnosis in the field. We will discuss our lab's current efforts in these areas, in conjunction with partners in industry, public health, and local governments. Our tests span a variety of technologies, and target HIV, sexually transmitted diseases, and chronic diseases.

09:35 Digital Microfluidics: Sample Preparation to Detection

Irena Barbulovic-Nad, Ph.D., Co-Founder Kapplex, Canada

Microfluidic techniques provide means to miniaturize biochemical assays and to package clinical diagnostics into disposable, point-of-care test cartridges. However, there are only a few technologies that can miniaturize and integrate a complete assay – from sample preparation to multiplexed biomarker detection – at a low cost. Digital microfluidics is a leading lab-on-a-chip technology enabling integration of series of complex sample purification and preparation steps, into a simple, cost-effective, diagnostic device.

10:05 Striking a Balance: Developing Multiplexed POC Assays for Military and Civilian Use

Christian J. Whitchurch, Ph.D., Chief Scientist, Detection & Diagnostics, Defense Threat Reduction Agency, United States

The common need for robust point-of-care (POC) medical diagnostics in both the civilian and military realms can obscure the distinct challenges inherent in designing assays suitable for either use. Military requirements for rugged, portable platforms and the capability to identify biological or chemical weapons exposure may limit the commercial opportunities that are critical to developing successful clinical diagnostic devices. This talk will outline the attributes of DTRA's approach to develop multiplexed POC diagnostics that strike this balance between military and civilian utility.

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

11:15 Microfluidic Diagnostics without Sample Preparation: A New Reality?

Ana Isabel Ferreira-Barbosa, Ph.D., IVD Manufacture Scientist, Capillary Film Technology Ltd., United Kingdom

A big challenge in the performance of portable point-of-care (POC) diagnostic devices is the interference of biological sample components with the test results, something often called "matrix effect". Sample preparation increases complexity and cost of miniaturized POC tests, being a bottleneck in the development of affordable POC tests. Our research team has reported for the first time (to our knowledge) portable testing of protein biomarkers from whole blood and undiluted serum in a novel miniaturized platform, with performance matching that with buffer. This presentation will explain how assay miniaturization offers an opportunity to avoid complex sample preparation procedures.

11:45 Panel Discussion: Commercializing a POCT Product

12:20 Pathogen-specific Phenotypic Antibiotic Susceptibility Test Directly From Clinical Samples Using Digital LAMP Quantification

Travis Schlappi, Student, Chemical Engineering, California Institute of Technology

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

13:20 Session Break

MOLECULAR POCT

14:15 Chairperson's Remarks

Gyorgy Abel, M.D., Ph.D., Director, Molecular Diagnostics, Immunology & Clinical Chemistry, Pathology and Laboratory Medicine, Lahey Hospital & Medical Center, United States

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Rapid Detection to Ensure Better Care

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14:20 Rapid Molecular Diagnostic Testing: A Major Weapon in Fighting Viruses and Antimicrobial Resistance

Gyorgy Abel, M.D., Ph.D., Director, Molecular Diagnostics, Immunology & Clinical Chemistry, Pathology and Laboratory Medicine, Lahey Hospital & Medical Center, United States

Rapid point-of-care molecular infectious disease testing holds great promise in the fight against viral and bacterial infections and antimicrobial resistance. This presentation reviews state-of-art rapid technologies for respiratory pathogen and positive blood culture testing, and discusses the concerted multi-disciplinary effort required to make test results readily available and actionable to health care providers. Hurdles to broader use include cost, quality issues, regulation, and complexity of integration of the results into patient care.

14:50 Practical Implementation of POCT: Overcoming Challenges

James H. Nichols, Ph.D., DABCC, FACB, Professor, Pathology, Microbiology and Immunology; Medical Director, Clinical Chemistry; Medical Director, POCT, Vanderbilt University School of Medicine, United States

POCT is an increasingly popular means of delivering laboratory testing with faster turnaround of results. However, the apparent simplicity of the devices diminishes the underlying risk of errors and numerous ways that operators can perform the testing. This session will focus on the challenges of implementing and maintaining POCT and will provide tips for ensuring quality, reliable test results.

15:20 Do Regulations and Guidelines for POCT Guarantee Qualitative and Safe Diagnostic Testing?

Viviane Van Hoof, M.D., Ph.D., Vice-Head, Clinical Biology, Antwerp University Hospital, Belgium

Specific guidelines and regulations for point-of-care testing (POCT) should guarantee a qualitative and safe diagnostic care. An overview and a critical appraisal will be given of the POCT regulations and guidelines issued by FDA/CLIA, CLSI, JCI, CAP, EU and ISO22870. The Dutch guidelines and the Belgian legislation on POCT will be discussed. Serious consequences of loopholes in the current POCT regulation will be illustrated by means of recent events.

15:50 New POCT Technologies and Platforms

Günther Proll, Ph.D., Institute of Physical and Theoretical Chemistry, Eberhard Karls University Tübingen, Germany

The development of new POCT technologies and platforms has to take into account the complete analytical procedure from sampling to validated data generation in a regulated environment. Within this talk, results of several current research projects will highlight novel parameters in POCT, new analytical strategies as combinations of test format and transduction including use of nanotechnology, and cost effective production processes.

16:25 Refreshment Break

REVOLUTIONIZING DIAGNOSTICS

16:40 Chairperson's Remarks

James H. Nichols, Ph.D., DABCC, FACB, Professor, Pathology, Microbiology and Immunology; Medical Director, Clinical Chemistry; Medical Director, POCT, Vanderbilt University School of Medicine, United States

16:45 Feasibility for Implementation of an 'On-Line' Clinical Investigative Ambulance

Ashfaq Gilkar, Senior Clinical Analyst, Strategy and Engagement, Essentia Technology, Guy's and St Thomas' NHS Foundation Trust, United Kingdom

The aim of this proposal is to ascertain whether interfacing on-line POCT devices (Abbott ISTAT and Radiometer HaemaCue blood analysers) within an 'Ambulance' setting prior to entry to the hospital could help front line staff accelerate decision making, reduce congestion and most importantly, improve patient waiting times in a busy A&E department or contribute to increasing see, treat and discharge in the community thus reducing the burden on the hospital A&E department. This life saving project will directly address the major national problem of congestion in the A&E department for Ambulance derived patients and help reduce admissions into the acute hospital, improving Clinical outcomes while at the same time the need to improve the level of clinical data integrity.

17:15 Can Point-of-Care Testing Ever Be Truly Economic?

Andy Anderson, CEO, Oxford Impedance Diagnostics Ltd., United Kingdom

The take up of POCT has been far slower than anticipated over the past few years. This has been due to a combination of inappropriate technology approaches and economic models.

17:45 Close of Conference

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Enabling Technologies for Cell-Free DNA

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Third Annual **11 - 12 APRIL**

Cell-Free DNA in Clinical Oncology

Strategies for Bringing Liquid Biopsy to the Clinic

TUESDAY, 11 APRIL

ACHIEVING EARLY DETECTION

08:00 Registration and Morning Coffee

09:00 Chairperson's Remarks
Helen Winter, Ph.D., Medical Oncologist and Clinical Research Fellow, Oncology, Green Templeton College, University of Oxford, United Kingdom

09:05 KEYNOTE PRESENTATION: Early Detection Using cfDNA: Promise and Challenges

Abhijit Patel, M.D., Ph.D., Assistant Professor, Therapeutic Radiology, Yale University, United States
Because circulating tumor DNA can be identified on the basis of highly cancer-specific mutations, it holds great promise as a potential biomarker for the early detection of a variety of malignancies. However, there are several technical and biological challenges that must be overcome to realize this goal. This presentation will review these challenges and the approaches being taken to address them.

09:35 Microfluidic Isolation of Cancer Cells from Body Fluids for Early and Non-Invasive Diagnosis of Cancer: Towards the Realization of Point-of-Care Liquid Biopsy
Lorena Diéguez, Ph.D., Staff Researcher, Life Sciences, International Iberian Nanotechnology Laboratory, Portugal
Tumor cells escape the primary tumor and disseminate through the blood stream and lymphatic system, potentially invading other organs and causing metastasis. Cancer cells from primary tumors also shed into surrounding body fluids, thus the study of tumor cells contained in body fluids offers unique opportunities for low invasive sampling in cancer patients, either for early diagnosis or for accurate prognosis. Our goal is to provide efficient inexpensive microfluidic tools to isolate and molecularly characterize tumor cells from unprocessed samples, overall relevant for early cancer detection, better prognosis and personalized treatment.

10:05 Nu.Q Triage Colorectal Cancer Screening Test
Sponsored by Volition
Mark Eccleston, Business Development Director, Volition, Belgium
Individuals who screen +ve by faecal immunochemical test (FIT) are referred for colonoscopy. However, < 95% have colorectal cancer placing a severe burden on the patient and the healthcare system. Triaging FIT +ve patients using a blood-based Nu.Q Triage Colorectal Cancer Screening Test can reduce colonoscopy referrals by 25%.

10:20 Multiplex Assays on Liquid Biopsy: A Practical Approach for CDx by πCode Technology
Sponsored by PlexBio
Stuart Palmer, Ph.D., COO, PlexBio Co., Ltd., Taiwan
PlexBio has developed a multiplex detection platform based on the Precision Image Code (πCode) Technology which is applicable to high complexity mutation analysis. PlexBio's IntelliPlex Mutation Kits are designed to be used in combination with the SelectAmp PCR technology to assess the status of mutations in a number of key genes (e.g. EGFR, KRAS, BRAF, NRAS, PIK3CA, ALK and ROS1).

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

MONITORING TREATMENT RESPONSES

11:15 Clinical Impact of a High-Sensitivity ctDNA Assay and Analytics for Low Frequency Mutations for Patient Monitoring and Stratification
Vincent Plagnol, Ph.D., Vice President, Computational Biology, Inivata, United Kingdom
Inivata has developed a highly sensitive assay for the detection and quantification of circulating cancer mutations in plasma. This incorporates improved molecular and analytical processes. We will show how very accurate ctDNA measurements can impact the management of cancer patients, and can be used for longitudinal monitoring of resistance mutations and choice of treatment. We will also highlight the value of refined analytics for detection of these calls.

11:45 Monitoring and Sequencing Cell-Free DNA in Patients Receiving Selective Internal Radiation
Helen Winter, Ph.D., Medical Oncologist and Clinical Research Fellow, Oncology, Green Templeton College, University of Oxford, United Kingdom
Analysis of cell-free (cf)DNA to monitor response to treatment is an emerging research priority. The objective of this study was to sequence serial cfDNA from patients with metastatic liver disease receiving SIRT, exploring the feasibility of this method to detect the evolution of somatic mutations after high dose radiation. Results presented are from patients at 3 time points: baseline (before SIRT), 4 and 10 weeks after SIRT using Ion Torrent Amplicon sequencing.

12:15 Parsortix: Utilise Both cfDNA and CTCs from a Single Patient Sample
Sponsored by ANGLE
Michael O'Brien, MBA, Business Development Director, ANGLE plc, United Kingdom
Maximising the 'liquid biopsy' insight from each patient sample is important. The Parsortix system from ANGLE, allows collection of plasma for cfDNA analysis whilst isolating CTCs. It captures all subtypes of CTCs from blood, using an epitope independent isolation approach, and hence outperforms more widely available antibody based technologies. Here we share a range of studies and outputs using Parsortix to illustrate the opportunities it opens up for research……getting the most out of every sample.

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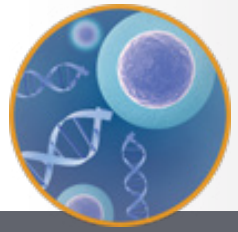


Third Annual **11 - 12 APRIL**

Cell-Free DNA in Clinical Oncology

Strategies for Bringing Liquid Biopsy to the Clinic

12:45 Luncheon Presentation *(Sponsorship Opportunity Available)*
or Enjoy Lunch on Your Own

13:15 Session Break

14:15 Chairperson's Remarks
Abhijit Patel, Ph.D., Assistant Professor, Therapeutic Radiology, Yale University, United States

14:20 Methylated Circulating DNA in Monitoring Cancer Treatment Response
Kristina Warton, Ph.D., Senior Research Officer, Garvan Institute of Medical Research, Australia
The levels of tumour-derived circulating DNA in blood are related to tumour burden, and fluctuations can reflect the response to clinical interventions such as surgery and chemotherapy, helping to guide treatment choices. Compared to DNA mutations, which are highly variable, DNA methylation is relatively consistent between individual tumours, and can also be measured by PCR. Measuring tumour-specific circulating DNA methylation offers a time-efficient, cost-efficient approach to monitoring tumour dynamics.

14:50 Cell-Free DNA: A Novel Gateway to the Genome of Hodgkin/Reed-Sternberg Cells in Hodgkin's Lymphoma?
Peter Vandenberghe, Ph.D., Head, Haematology, University Hospitals Leuven, Belgium
The rapid normalisation of circulating cell-free DNA profiles on therapy initiation suggests a potential role for circulating cell-free DNA profiling in early response monitoring. This finding creates several new possibilities for exploring the diversity of Hodgkin's lymphoma, and has potential implications for the future clinical development of biomarkers and precision therapy for this malignancy.

15:20 Could Circulating Tumor Cells (CTCs) Monitoring and Characterization, Reflect the Response to Treatment in NSCLC?
Elisabetta Rossi, Ph.D., Researcher, Surgical Oncology and Gastroenterology, University of Padova, Italy
Circulating tumour cells (CTCs) serve as valuable biomarkers. Recent experiences demonstrated that CTC detection could help improve diagnosis and predict prognosis in patients with non–small cell lung cancer (NSCLC). However, EpCAM positive CTCs are less frequently detected in NSCLC patients compared to other epithelial tumours. We questioned whether we could detect a higher number of CTCs by implementing the standard CellSearch® assay and if we could better monitor response to therapy.

15:50 Refreshment Break in the Exhibit Hall with Poster Viewing

ESTABLISHING STANDARDS FOR ctDNA

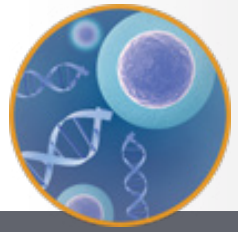
16:30 Role of dPCR in Supporting the Standardisation of Liquid Biopsy Measurements
Alison Devonshire, Ph.D., Science Leader, Molecular and Cellular Biology, LGC Ltd., United Kingdom
Molecular measurements of tumour associated mutations in cfDNA offer an increasingly popular option for cancer management; however mechanisms to ensure reproducible clinical analysis are yet to be established. Digital PCR (dPCR) has the potential to ensure greater confidence in measurement by acting as a reference method for reference material certification and clinical samples analysis. This talk will discuss dPCR performance when varying assays, reaction chemistries and platforms when measuring single nucleotide variants. An inter-laboratory study involving >20 laboratories was also performed to evaluate reproducibility when analysing a mutation commonly measured in liquid biopsies.

17:00 Standardization of Liquid Biopsies for Precision Medicine in Oncology – A Task for Clinical Biobanks?
Jens K. Habermann, Ph.D., Professor and Head, Surgery, Translational Surgical Oncology & Biobanking, University of Lübeck, Germany
Liquid biopsies 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 for standardized assessment of CTCs, cfDNA, RNA, and exosomes, (ii) how standardization can be facilitated, and (iii) how clinical biobanks can support liquid biopsies' use for research and precision medicine.

17:30 Standardization of Technologies for CTC, ctDNA and miRNA Enrichment, Isolation and Analysis
Thomas Schlange, Senior Biomarker Scientist, Global Biomarker Research, Bayer, Germany
The IMI CANCER-ID consortium with 36 partners from academia, clinic and industry collaborate on the evaluation of liquid biopsy technologies and development of corresponding workflows for the use of these technologies in the clinical setting. The focus in ctDNA analysis is directed at preanalytics, use of standards for NGS approaches on NSCLC and breast cancer plasma samples, detection limits, concordance between liquid and conventional biopsy and comparison of bioinformatics methods.

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

19:00 Close of Day



Third Annual **11 - 12 APRIL**

Cell-Free DNA in Clinical Oncology

Strategies for Bringing Liquid Biopsy to the Clinic

WEDNESDAY, 12 APRIL

MOVING INTO CLINICAL PRACTICE

08:30 Registration and Morning Coffee

09:00 Chairperson's Remarks

Kristina Warton, Ph.D., Senior Research Officer, Garvan Institute of Medical Research, Australia

09:05 Clinical Applications of Liquid Biopsy: Potential and Challenges

Klaus Pantel, M.D., Professor and Founding Director, Institute of Tumor Biology, University Medical Center Hamburg-Eppendorf, Germany

Clinical applications of liquid biopsies in precision medicine include early detection of cancer, surveillance of minimal residual disease and stratification of patients for targeted therapies based on the molecular analysis of genes such as EGFR or KRAS that encode therapeutic targets or confer resistance mechanisms. The potential and challenges of liquid biopsy analyses (cfDNA vs. CTCs) will be discussed in the context of specific therapies (e.g., drug-induced blockades of EGFR or immune checkpoint inhibitors) and tumor types.

09:35 Monitoring Treatment Response and Identification of Actionable Targets from Plasma DNA

Ellen Heitzer, Ph.D., Associate Professor, Institute of Human Genetics, Medical University Graz, Austria

Molecular stratification of patients to targeted therapies is currently based on a molecular characterization of tumors tissues. A liquid biopsy, i.e. the analysis of circulating tumour DNA (ctDNA), is a promising alternative to tissue biopsies since it is minimal-invasive, it can be immediately analyzed, and most likely provides a more complete molecular profile of tumor heterogeneity than a single biopsy achieves. Moreover, a continuous monitoring of tumor-specific changes during the entire course of the disease, can be achieved.

10:05 Improved Material for Developing, Validating and Monitoring Liquid Biopsy Assays

Sponsored by seracare

Dale Yuzuki, MA, Med, Director, Market Development - Oncology, SeraCare Life Sciences, United States

Random ultrasonication-based fragmentation methods have inherent weaknesses. Current liquid biopsy reference material needs include standards that are more commutable to native samples, and behave in NGS library preparation close to native DNA from plasma. SeraCare has highly multiplexed, human-like NIPT and ctDNA QC standards that are stabilized in plasma matrices.

10:20 Crystal Digital PCR for Detection and Quantification of Circulating EGFR Mutations in Advanced Non-Small Cell Lung Cancer

Sponsored by STILLA

Cécile Jovelet, Pharm.D., Ph.D., Postdoctoral Fellow, Translational Research Lab, Gustave Roussy Institute, France

Targeted therapies increase the progression-free survival for non-small cell lung cancer patients harboring specific mutations. Molecular monitoring of tumor is required to detect the resistance mutation EGFR T790M which requires alternative therapeutic approaches. This talk discusses the use of Crystal™ Digital™ PCR for monitoring the EGFR mutational status in ctDNA.

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

11:05 Establishment and Characterization of a Cell Line from Human Circulating Colon Cancer Cells

Catherine Alix-Panabières, Ph.D., Maître de Conférence, Praticien Hospitalier, Associate Professor, Director, Laboratory of Rare Human Circulating Cells, Institute of Research in Biotherapy, Saint-Eloi Hospital, University Medical Centre of Montpellier, France

The unique colon CTC-MCC-41 cell line displays a very specific transcription program. Interestingly, among the 1,624 transcripts exclusively upregulated in CTC-MCC-41 samples compared to other colon cancer cell lines obtained from primary tumors or from metastatic sites, key genes related to energy metabolism, DNA repair and stemness genes were observed. Such data may supply insights for the discovery of new biomarkers to identify the most aggressive CTC sub-populations and for the development of new drugs to inhibit metastasis-initiator CTCs in colon cancer.

11:35 Circulating Tumor DNA Clinical Application

Pierre Laurent-Puig, M.D., Ph.D., Professor, Paris Descartes University, France

The clinical implication of circulating tumor DNA will be discussed in different tumor locations (pancreas, colon and lung cancer).

12:05 Close of Cell-Free DNA in Clinical Oncology

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Third Annual **12 - 13 APRIL**

Enabling Technologies for Cell-Free DNA

Improving Assays for Clinical Use

WEDNESDAY, 12 APRIL

12:30 Registration

ADVANCES IN TECHNOLOGIES FOR cfDNA MUTATION TESTING AND ANALYSIS

13:30 Chairperson's Opening Remarks

Christa Noehammer, Ph.D., Senior Scientist, Molecular Diagnostics, Austrian Institute of Technology GmbH, Austria

13:35 KEYNOTE PRESENTATION: Quantitative Nuclease-Assisted Minor-Allele Enrichment Simplifies Circulating DNA Analysis

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

Circulating DNA analysis presents both opportunities and challenges in harnessing the potential of circulating tumor biomarkers. We present a powerful new development qNaME-PrO-NGS that combines mutation enrichment as well as strict quantification of original mutation abundance by use of molecular barcoding technology. qNaME-PrO enables 100-fold cheaper sequencing on existing sequencing platforms. We present applications in tracing circulating tumor DNA following sequencing of tumor and cfDNA in clinical cancer samples.

14:05 Circulating DNA Analysis as the Next-Generation Diagnostic in Oncology

Alain R. Thierry, Ph.D., Senior Investigator, Research Institute in Oncology of Montpellier, INSERM, France

Based upon observations on circulating cell-free DNA (cfDNA) structural and origin features, we developed an Allele Specific-qPCR-based method with blocker (termed Intplex) which is the first multiplexed test for cfDNA. The Intplex test can be adapted to all mutations, genes or cancers and enables rapid, highly sensitive, cost effective and repetitive analysis. It offers the opportunity in detecting quantitatively and dynamically mutation. We showed the first clinical validation and utility of the analysis of cfDNA in oncology and demonstrated efficient tracking of emergence of resistance clone under cancer treatment. Studies of the evaluation of the cfDNA analysis for following up sage 2-3 cancer patients are ongoing expanding the scope of personalized cancer medicine.

14:35 Simple, Multiplexed, PCR-Based Barcoding of DNA for Ultra-Sensitive Mutation Detection by NGS: SiMSen-Seq

Anders Ståhlberg, Associate Professor, Sahlgrenska Cancer Center, University of Gothenburg, Sweden

Several barcoding strategies have been reported but all require long and complex library preparation protocols. SiMSen-Seq was developed to generate barcoded libraries with minimal DNA input, flexible target selection and a very simple, short (~4 hour) library construction protocol. SiMSen-Seq allows detection of variant alleles at <0.1% frequency with easy customization of library content and a protocol that can be implemented in any molecular biology laboratory.

15:15 Refreshment Break in the Exhibit Hall with Poster Viewing

16:15 Screening for Circulating RAS/RAF Mutations by Multiplex Digital PCR

Rikke Fredslund Andersen, Ph.D., Molecular Biologist, Clinical Biochemistry, Vejle Hospital, Denmark

A multiplex digital PCR method of screening for 31 mutations in the KRAS, NRAS, BRAF, and PIK3CA genes in the plasma will be presented. The method combines a high sensitivity with the ability to analyze for several mutations at a time and could be a step towards routine clinical application of liquid biopsies.

16:45 Non-Invasive Prenatal Testing of Monogenic Disorders by Droplet Digital PCR Combined with Uniformly Most Powerful Likehood Ratio Test

Juilette Nectoux, Pharm.D., Ph.D., Molecular Geneticist, Molecular Genetics, Cochin Hospital, France

We propose a digital PCR approach based on the evaluation of the Uniformly Most Powerful Likehood Ratio Test (UMP LRT) that determines if the dosages of the mutant and wild-type alleles of a disease-causing gene are balanced or unbalanced in maternal plasma. When applied to the testing of women heterozygous for a disease causing mutation, digital UMP LRT allows the fetal genotype to be deduced. This proof-of-concept study of non-invasive droplet dPCR for the analysis of both paternally and maternally inherited fetal alleles demonstrates that NIPT for single-gene disorders is now becoming achievable.

17:15 Nucleic Acid Quantification Technologies and Software Tools

Stefan Rödiger, Ph.D., Group Leader, Institute of Biotechnology, Brandenburg University of Technology Cottbus, Germany

Nucleic acids such as cfDNA have huge potential for diagnose, treatment, and monitoring of patients. However, there is a need for improved assays for routine clinical use. The talk will examine the perspective of a researcher working towards clinical hard and software applications, address challenges we faced with the qPCR methodology and lessons we learned for novel technologies such as digital PCR. In particular, assays and data standardization are briefly addressed in the context of reproducible analysis.

17:45 Close of Day

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Third Annual **12 - 13 APRIL**

Enabling Technologies for Cell-Free DNA

Improving Assays for Clinical Use

THURSDAY, 13 APRIL

DETECTION, EXTRACTION, AND ISOLATION OF cfDNA

08:30 Registration and Morning Coffee

09:00 Chairperson's Remarks
Alain R. Thierry, Ph.D., Senior Investigator, Research Institute in Oncology of Montpellier, INSERM, France

09:05 Impact of Extraction on cfDNA Analysis: Considerations for Sample and Process QC
Alison Devonshire, Ph.D., Science Leader, Nucleic Acid Metrology, LGC, UK
Isolation of cfDNA from biological matrices can have a dramatic impact on the limit of detection and precision of analytical techniques to measure low concentration minority genetic targets such as somatic mutations. This talk will present how control materials have been developed and can be applied to monitoring the efficiency of cfDNA recovery in patient samples and for quality control of different workflows using alternative extraction methods and analytical techniques.

09:35 The Importance of Determining the Limit of Detection of Non-Invasive Prenatal Testing Methods
Francesco Fiorentino, Ph.D., CEO, GENOMA Group, Italy
Several non-invasive prenatal testing (NIPT) methods that rely on quantification of fetal cell-free DNA (cfDNA) suggest a fetal fraction (FF) of 4% or greater for a reportable result. In this study we demonstrated that the minimum FF level necessary for accurate aneuploidy assessment should be related to the actual limit of detection (LOD) of each specific NIPT approach used, and not necessarily fixed at 4% for all cfDNA testing methodologies. This study also underscores the importance of testing samples with low FF.

10:05 Active Extraction of NGS Grade Nucleic Acids from Challenging Clinical Sample Types
Sponsored by Covaris
Berwyn Clarke, Ph.D., Clinical Diagnostics and Pharmaceutical Industry Manager, Covaris, United Kingdom
Whilst there is great emphasis on NGS as tool for precision medicine and bioinformatic interpretation of NGS data to make it actionable, by comparison much less consideration is given to original sample processing to ensure results reflect the biological reality. Here we discuss a variety of methods to address this.

10:20 Circulating Cell-Free DNA Pre-Analytics: Importance of Standardized Workflow for Liquid Biopsy Applications
Sponsored by QIAGEN
Andrea Ullius, Scientist, PAXgene Product Development, QIAGEN GmbH
Proper, standardized preanalytical method is key to maximizing the accuracy of circulating cell-free DNA (ccfDNA) analysis by minimizing any negative effects on assays caused by the release of genomic DNA from blood cells, and providing reliable and reproducible extraction of the low abundance and short ccfDNA fragments.

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

11:20 Selected Poster Presentation: A Simple and Robust Real-Time qPCR Method for the Detection of PIK3CA H1047R Mutations
Nicholas R. Leslie, PhD, FRSB, Reader and Associate Professor, Institute of Biological Chemistry, Biophysics and Bioengineering,, Nasmyth Building, Heriot Watt University, United Kindgom
Somatic activating mutations in the phosphoinositide 3 kinase (PI3K) catalytic subunit alpha (PIK3CA) have been reported in many human cancers and several PI3K inhibitors are in late stage clinical oncology trials. In most tumour types PIK3CA mutations predominantly cluster within two major hotspot genomic regions: exon 9 (E542K, E545K) and exon 20 (H1047R). Assessing the PIK3CA H1047R status is of particular relevance in breast cancer patients where it represents the most frequently occurring single base mutation in this cancer. Here we describe a highly effective method for PIK3CA H1047R point mutation detection based on a simple SYBR green real-time PCR. This method can effectively detect PIK3CA H1047R mutation by using a set of allele-specific primers that target the mutant variant in combination with a non-productive primer blocking wild-type amplification and an internal control reaction running in parallel. It has been successfully validated using genomic DNA extracted from cancer cell lines and breast cancer tissue biopsies. Overall this approach could become a promising tool for the analysis of PIK3CA H1047R status in cancer patients and given the simplicity of the technique it could potentially be performed in any laboratory with real-time PCR capability.

11:50 Development and Optimization of a Microfluidic System for DNA Extraction and Purification
Joana Carvalho, Ph.D. Student, Environment Monitoring, Security and Food Quality Control, International Iberian Nanotechnology Laboratory, Portugal
The main goal of this work is the development of a portable and integrated DNA analysis device for *in situ* applications, where is intended to include all the steps of DNA analysis in a single device as a micro total analysis system (μTAS). With this in mind, a microfluidic device has been developed for DNA extraction and purification, which is a critical step for the success of the following DNA analysis stages. The miniaturization of this method brings several advantages compared with the traditional ones, such as portability, and it is possible to adapt this technology for different purposes.

12:20 Sponsored Presentation *(Opportunity Available)*

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

13:20 Session Break

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Third Annual **12 - 13 APRIL**

Enabling Technologies for Cell-Free DNA

Improving Assays for Clinical Use

CHARACTERIZATION OF cfDNA: ADVANCES IN PROFILING AND SAMPLE TYPES

14:20 Chairperson's Remarks

Stefan Rödiger, Ph.D., Group Leader, Institute of Biotechnology, Brandenburg University of Technology Cottbus, Germany

14:25 Identification of Biologics Treatment-Specific Changes in miRNA Expression in Exosomes of Patients with Chronic Inflammatory Diseases

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

Exosomes have raised recently considerable interest, but many researchers hesitate to move into the field due to insufficient information about the experimental procedures. We present a detailed experimental, bioinformatic, and statistical procedure to identify a treatment-specific small RNA-signature. While applied to a chronic inflammatory disease, the procedure could also be applied to samples taken non-invasively from cancer patients under a genotype-driven treatment.

14:55 Study of Spatial and Temporal Tumor Heterogeneity Using Copy Number Profiling and Whole Exome Sequencing on cfDNA in Neuroblastoma

Mathieu Chicard, Molecular Biology Engineer, Translational Research in Pediatric Oncology, Institut Curie, France

Neuroblastoma is a paediatric tumor with a very wide heterogeneity. Genetically, copy number alterations and some mutations are observed but no recurrent biomarker is present. To study this heterogeneity, we compared the genomic copy number of tumor and cfDNA using microarray for 70 patients and we also performed WES on cfDNA for 19 patients. For each technique, we observed more alterations in cfDNA than in tumor.

15:25 Next-Generation Sequencing to Detect Tumor Mutations in Circulating DNA: Base-Position Error Rate (BPER) Methodology and Clinical Application in Lung Cancer Patients

Nicolas Pecuchet, M.D., Engineer, R&D Biosphere Technology, Dassault Systemes, France

I will present our latest technical development for mutation detection in circulating DNA using targeted next-generation sequencing: the Base-Position Error Rate method. I will emphasize on the clinical perspectives of the BPER method by presenting the results of a prospective study of ctDNA in advanced Non-Small Cell Lung Cancer patients.

15:55 Detection of the Paternally Inherited Fetal Alleles in the Maternal Plasma using Fast Temperature-Tolerant COLD PCR for the Prenatal Diagnosis of β-Thalassemia

Stefania Byrou, Ph.D. Student, Molecular Genetics Thalassaemia, Cyprus Institute of Neurology and Genetics, Cyprus

Fast Temperature-Tolerant COLD PCR is a rapid and inexpensive technique which allows the enrichment of a minor allele over the overwhelming background of a major allele. A variation of this technique was attempted from our group aiming the detection of paternally inherited fetal alleles in the maternal plasma samples of pregnancies at risk for β-thalassemia. Seventeen maternal plasma samples were analyzed in at least triplicate reactions for two single nucleotide polymorphisms (SNPs) and the fetal paternally inherited allele was correctly detected in 92.96% of reactions tested (66/71) for SNP1 and in 97.34% (73/75) for SNP2. Our results demonstrate the efficiency and sensitivity of Fast Temperature-Tolerant-COLD-PCR in detecting the minor paternally inherited alleles in the maternal plasma.

16:25 Refreshment Break

16:45 Accuracy and Clinical Value of Maternal Incidental Findings During Noninvasive Prenatal Testing for Fetal Aneuploidies

Joris Vermeesch, Ph.D.Ir, Professor, Human Genetics, Laboratory of Cytogenetics and Genome Research, KU Leuven, Belgium

Genome-wide sequencing of cell-free (cf)DNA of pregnant women aims to detect fetal chromosomal imbalances. Because the largest fraction of cfDNA consists of maternal rather than fetal DNA fragments, maternally derived copy-number variants (CNVs) are also measured. Despite their potential clinical relevance, current analyses do not interpret maternal CNVs. We explored the accuracy and clinical value of maternal CNV analysis. We demonstrate that interrogating the maternal CNV landscape can improve overall pregnancy management.

17:15 Circulating Biomarkers and Exosomes in Salivary Diagnostics

Christa Noehammer, Ph.D., 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. Besides reporting on the evaluation of different exosome isolation approaches we will share results from genome-wide DNA-methylation analysis in serum - and saliva-derived exosomes from healthy individuals and present data obtained along genome-wide microRNA analysis from the same sample sources using both microarrays and microRNA sequencing.

17:45 Close of Conference

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SC2: Technologies, Applications and Commercialization of Point-of-Care Diagnostics
~~SC3: Liquid Biopsy as a Tool for Cancer Treatment~~

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

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