FOURTH INTERNATIONAL
Molecular Diagnostics EUROPE
4-7 APRIL 2016
SHERATON LISBOA HOTEL & SPA
LISBON, PORTUGAL

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CAMBRIDGE HEALTHTECH INSTITUTE'S FOURTH INTERNATIONAL

Molecular Diagnostics EUROPE

4-7 APRIL 2016 | SHERATON LISBOA HOTEL & SPA | LISBON, PORTUGAL

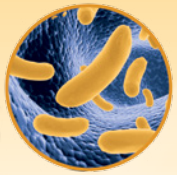
4-6 APRIL

Advances in Prenatal Molecular Diagnostics

6-7 APRIL

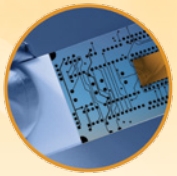
Reproductive Genetic Diagnostics

5-6 APRIL



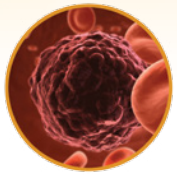
Advanced Diagnostics for Infectious Disease

6-7 APRIL



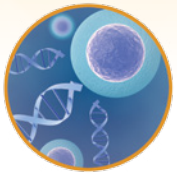
Point-of-Care Diagnostics

5-6 APRIL



Circulating Tumour Cells

6-7 APRIL



Circulating Cell-Free DNA

KEYNOTE PRESENTERS

Wybo Dondorp, Ph.D.
Associate Professor, Biomedical Ethics, Health, Ethics & Society, Maastricht University

Darren K. Griffin, Ph.D., D.Sc., FIBiol, FRCPath, FRSA
Professor, Genetics, School of Biosciences, University of Kent

Ulf B. Goebel, M.D., Ph.D.
Director, IMH Charité University Medicine Berlin; Director, Microbiology Labor Berlin Charité-Vivantes GmbH

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

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

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

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CONFERENCE AT-A-GLANCE

	Monday, 4 April	Tuesday, 5 April	Wednesday, 6 April	Thursday, 7 April
AM				
PM	Advances in Prenatal Molecular Diagnostics		Reproductive Genetic Diagnostics	
AM		Advanced Diagnostics for Infectious Disease		
PM			Point-of-Care Diagnostics	
AM		Circulating Tumour Cells		
PM			Circulating Cell-Free DNA	

About the Event

Novel molecular-based tools are rapidly entering the clinic and creating a new paradigm in healthcare. The **Fourth International Molecular Diagnostics Europe** event will return to Lisbon this spring and feature six tracks: *Prenatal Molecular Diagnostics*, *Reproductive Genetic Diagnostics*, *Circulating Tumour Cells*, *Circulating Cell-Free DNA*, *Advanced Diagnostics for Infectious Disease*, and *Point-of-Care Diagnostics*. As the prenatal diagnostics market has demonstrated, molecular diagnostics are being applied to the clinical setting for greater speed and accuracy of healthcare delivery, while paving the way for a new era in medicine.

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HOTEL & TRAVEL INFORMATION

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: €130 single/€150 double, includes breakfast
Discounted Room Rate Cut-off Date: 17 February 2016

Go to the travel page of www.MolecularDxEurope.com for additional info

Why Stay at the Sheraton Lisboa Hotel and Spa?

Be in the Heart of it All - The Sheraton Lisboa Hotel and Spa is located right in the heart of the city!

Get Here Quickly - Located just minutes from Lisbon Airport, it's a quick trip in and out.

Energize - Enjoy a complimentary delicious breakfast, visit the gym, or swim in the pool (weather permitting).

Be Productive - Complimentary wifi in all attendee guest rooms lets you get work done on YOUR time.

Relax and Enjoy - Restaurants, shops and the historic sites of the beautiful city of Lisbon are just a short walk away.

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- Focus group
- Reception style
- Plated dinner with specific conversation focus

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Exhibitors will enjoy facilitated networking opportunities with qualified delegates. Speak face-to-face with prospective clients and showcase your latest product, service, or solution.

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Select your top prospects from the pre-conference registration list. CHI will reach out to your prospects and arrange the meeting for you. A minimum number of meetings will be guaranteed, depending on your marketing objectives and needs. A very limited number of these packages will be sold.

Additional branding and promotional opportunities are available, including:

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Third Annual Advances in Prenatal Molecular Diagnostics

Trends, Advances & Prospects

MONDAY, 4 APRIL

12:00 – 13:00 Registration

13:00 Chairperson's Opening Remarks
Marta Rodriguez de Alba, Ph.D., Genetics, Fundación Jiménez Díaz, Spain

13:10 KEYNOTE PRESENTATION: AIM AND SCOPE OF PRENATAL SCREENING: THE AUTONOMY PARADIGM AND ITS LIMITS

Wybo Dondorp, Ph.D., Associate Professor, Biomedical Ethics, Health, Ethics & Society, Maastricht University, The Netherlands

In the light of the thrust of the dynamics in prenatal screening towards genome wide & non-invasive testing, the received ethical framework with its emphasis on facilitating autonomous reproductive choice is in need of qualification, taking account of a) the 'paradox of choice', b) the informational privacy interests of the future child and c) the fact that increasingly, prenatal screening will serve prevention-aimed outcomes in addition to reproductive choice.

INVASIVELY-OBTAINED SAMPLES

13:55 Molecular-Cytogenetic Analysis of Invasively-Obtained Samples, Are We Getting More Comfortable with It? The Lab-Side Point of View
Marta Rodriguez de Alba, Ph.D., Genetics, Fundación Jiménez Díaz, Spain

The incorporation of the different emerging technologies applied to the field of prenatal diagnosis has varied throughout Europe. It has been mainly dependent on economic issues but also on the expertise of providers. Since genetic analysis of prenatal samples is usually performed in Services also offering postnatal diagnosis, providers have acquired the expertise testing those samples and therefore started to feel more comfortable with the interpretation of results in prenatal samples. The reasons for referral vary and although many articles support the idea that array-CGH technology should only be applied in specific cases, in many occasions the sample is referred to the Genetic Department with a mild indication and therefore, many concerns arise.

14:25 Prenatal Array Testing – How Unexpected Is the Unexpected?
Margorzata Srebniak, Ph.D., Laboratory Specialist, Clinical Genetics, Erasmus Medical Center, The Netherlands

Microarray is still not widely used in diagnostic laboratories across Europe, although it is already recommended for fetuses with congenital anomalies and may also be done in other cases referred for invasive testing. Unexpected diagnoses and incidental findings (in parental samples) are arguments against microarray especially in pregnancies without ultrasound anomalies. We would like to show all unexpected diagnoses as well as incidental findings that we encountered since 2010, to show that whole genome analysis with array may be favorable in prenatal diagnosis and to answer the question how unexpected is the unexpected.

14:55 Refreshment Break

15:30 Why Should We Implement aCGH as the First-Tier Test in All Invasive Prenatal Samples?
Julian Nevado, Ph.D., MBA, Genetics, Hospital Universitario La Paz (IdiPAZ), Spain

We evaluated the effectiveness of whole-genome array comparative genomic hybridization (aCGH) in prenatal diagnosis in a routine genetic laboratory. Array CGH was performed on 315 samples recruited prospectively as the first-tier test study during the last 3 years. In addition, 77 prenatal samples with abnormal fetal ultrasound findings found to have normal karyotypes were analyzed as a retrospective study using a custom Agilent-based 60K oligonucleotide array. In both cases, aCGH offered higher yields than conventional karyotype. Thus, for cost-effectiveness reasons among others that we discussed, we proposed aCGH in all invasive prenatal diagnosis as a first-tier test in combination with QFPCR to exclude common aneuploidies, triploidies and maternal cell contamination.

16:00 Invasive Confirmatory Procedure after a High-Risk cfDNA Test Result: May the Type of Detected Chromosomal Abnormality Influence the Choice of Diagnostic Procedure?
Francesca Romana Grati, Ph.D., Director, R&D, TOMA Advanced Biomedical Assays SpA, Italy

Cell-free DNA (cfDNA) screening tests use cell-free fetal DNA sequences isolated from maternal blood samples to evaluate the presence of fetal chromosome anueploidies and microdeletions. Currently, there is debate about the most appropriate confirmatory invasive method. The present study is aimed to discuss about the criteria for choice of i) the diagnostic invasive procedure basing on the chromosome specific likelihood of fetoplacental mosaicism and of ii) the laboratory diagnostic test that should be applied on invasively collected sample/s basing on the type of chromosome abnormality for which the cfDNA testing provided a high risk result.

16:30 Roundtable Breakout Discussions
Topics to be covered:

- Challenges of Ethics and Genetic Counseling
  Moderator: Wybo Dondorp, Ph.D., Associate Professor, Biomedical Ethics, Health, Ethics & Society, Maastricht University, The Netherlands
- Trends with Analysis of Invasively-Obtained Samples
  Moderator: Marta Rodriguez de Alba, Ph.D., Genetics, Fundación Jiménez Díaz, Spain
- Clinical Implementation Issues with Cell-Free DNA Testing
  Moderator: Dick Oepkes, Professor, Obstetrics and Fetal Therapy, Obstetrics, Leiden University Medical Center, The Netherlands

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- Testing beyond Common Aneuploidies
  Moderator: Daniel Grosu, M.D., MBA, CMO, Sequenom, Inc., United States
- Commercialization Potential for Isolated Fetal Cells
  Moderator to be announced
- Biomarkers for Preeclampsia and Pre-Term Labor
  Moderator to be announced

17:30 Close of Day One

TUESDAY, 5 APRIL

NON-INVASIVE TESTING BASED ON CELL-FREE DNA

8:00 Registration and Morning Coffee

9:00 Chairperson's Remarks

9:05 Intellectual Property and NIPT: Controversies and Concerns
Naomi Hawkins, Ph.D., Senior Lecturer, School of Law, University of Exeter
As in other fields of medicine, and human genetics in particular, patents in NIPT generate controversy and concern. Anxieties surrounding the possibility for patents to result in increased costs, administrative burdens and ultimately, a negative effect on healthcare in this developing field of genetic medicine are voiced by many.

It is apparent that commercial interests are highly involved in the development and delivery of NIPT, and patents are an important means of leveraging competitive positions. At present, the patent landscape is contested, with various commercial parties in disputes about patents and the legitimacy of their various testing technologies. Such disputes have implications for commercial and public sector testing. In this presentation, I discuss the key patent issues relevant to NIPT and consider the potential impact of patents on the development of the field.

9:35 Cell-Free DNA as a First Line Test vs. Contingent Screening: Perspective from Patients
Dick Oepkes, Professor, Obstetrics and Fetal Therapy, Obstetrics, Leiden University Medical Center, The Netherlands
Screening for chromosomal abnormalities in the fetus is a service to (anxious) pregnant women. For professionals, optimal quality is often equal to highest test performance. For patients, or actually pregnant women since they are not ill themselves, safety, short waiting time and avoidance of living in uncertainty for weeks are equally important. Although on paper, contingent screening may have benefits in terms of reasonably high accuracy against reasonable costs, the prolonged waiting time and especially the 'intermediate' bad news message that further testing is needed before we can reassure her, is a very serious drawback for the pregnant woman. Complexity of counseling is another disadvantage. Working towards reducing the costs of a fast and reliable one-step screening appears preferable.

10:05 The Next Generation of Cell-Free DNA Analysis: a Visual Platform for Chromosomal Aneuploidy Research
Sponsored by Cartagenia, A part of Agilent Technologies
Steven Van Vooren, Ph.D., Product Marketing Manager, Cartagenia
As the demand for cfDNA testing grows, analytical methods for detecting chromosomal aneuploidies in NGS samples are in high demand. Cartagenia, a part of Agilent Technologies, has developed OneSight, a user friendly, state-of-the art bioinformatics solution for the visual analysis of chromosomal aneuploidies in NGS samples.

10:20 Implementation of Seraseq™ Aneuploidy Reference Materials for Non-Invasive Prenatal Screening
Sponsored by seracare
Laurence Lohmann, Ph.D., Medical Genetics Director, Laboratoire CERBA
As the market for NIPT expands from high-risk to general population, there is a greater need for patient-like reference materials to monitor the accuracy of assay results. In this presentation, we describe our NIPT assay development, including the importance of using robust and multiplexed reference materials.

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

11:15 VENDOR PANEL DISCUSSION: Cell-Free DNA
Maximillian Schmid, M.D., Associate Director, Medical Affairs, Ariosa, United States
Alex Helm, Product Manager, Illumina, United States
Michael Lutz, Ph.D., CEO, Life Codexx, Germany
Solomon Moshkevich, Vice President, Product & Strategy, Natera, United States
Hari Radhakrishnan, PhD, Commercialization Manager, NIPD Genetics, Cyprus
Stephen Little, Ph.D., CEO, Premaitha Health, United States
Daniel Grosu, M.D., MBA, CMO, Sequenom, Inc., United States

12:45 Luncheon Presentation: Non Invasive Prenatal Testing by Digital Counting of Fluorescently Labeled DNA Molecules
Sponsored by vanadis diagnostics, a PerkinElmer company
Olle Ericsson, Ph.D., CEO, Vanadis Diagnostics
Several countries have implemented Non Invasive Prenatal Testing (NIPT) to analyze chromosomal abnormalities in high-risk pregnancies. The majority of these tests are performed using next generation sequencing technologies that provide both superior specificity and sensitivity compared to traditional first trimester screening. However, in order to provide all women with high performance prenatal screening, the NIPT assay cost and complexity need to be dramatically reduced. We present a new Smart NIPT platform, that by by eliminating sequencing, PCR and complex data analysis enables cost effective automated high throughput NIPT screening.

13:15 Session Break

14:15 Chairperson's Remarks
Philippos Patsalis, Ph.D., Distinguished Professor, The Cyprus Institute of Neurology & Genetics and CEO, NIPD Genetics, Cyprus

14:20 Multiplexed Parallel Analysis of Targeted Genomic Regions for Non-Invasive Prenatal Testing
Philippos Patsalis, Ph.D., Distinguished Professor, The Cyprus Institute of Neurology & Genetics and CEO, NIPD Genetics, Cyprus
A novel targeted assay for the detection of fetal aneuploides of chromosomes 21, 18 and 13 has been developed by NIPD Genetics. It is based on the capture and analysis of selected genomic regions of interest. An advanced fetal fraction estimation and aneuploidy determination algorithm has also been developed. The analytical performance of this assay will be reviewed. The potential impact of this assay as an accurate and cost-effective option for non-invasive aneuplody detection will be discussed.

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14:50 The IONA Test: CE-IVD – Reliable, Simple, Standardised

Sponsored by premaithahealth

Mike Risley, Ph.D., Chief Development Officer, Premaitha

Focusing on the technical aspects of the IONA® test and the background to why the test has been developed using certain innovative methods. These include a dynamic fetal fraction assessment method and the result output of a likelihood ratio, ideal for prenatal screening as it can be combined with prior risks. Additional features include Premaitha Workflow Manager, world class Technical Support and bespoke analysis software.

15:20 Genome-Wide Prenatal Cell Free DNA Testing: Validation and Clinical Experience

Sponsored by sequenom

Daniel Grosu, M.D., MBA, CMO, Clinical and Medical Affairs, Sequenom, Inc., United States

A significant proportion of chromosomal and subchromosomal abnormalities in the prenatal setting are not detectable by conventional cfDNA testing. Most of this informational gap can be bridged through a genome-wide approach that reports on CNVs ≥7 Mb in size across the entire genome, in addition to select microdeletions <7 Mb.

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

16:30 Advances in the Non-Invasive Prenatal Diagnosis of Mendelian Disorders using Digital-PCR

Ana Bustamante Aragones, Ph.D., Assistant Head, Genetics, Fundación Jiménez Díaz, Spain

Non-invasive prenatal diagnosis (NIPD) based on the analysis of maternal blood is currently offered worldwide in prenatal diagnosis units. However, to date NIPD for Mendelian disorders is only being offered for paternal and *de novo* mutation exclusion and the study of the maternal inheritance remains challenging. This work shows a validation study of digital PCR (ddPCR) technology for the analysis of both paternally and maternally inherited fetal alleles.

17:00 Bringing NIPT to the Next Level: Detection of Fetal Trisomy based on Quantitative Real-Time PCR

Sponsored by lifecodexx

Michael Lutz, CEO, LifeCodexx, Germany

We will present data of the PrenaTest® based on a quantitative real-time PCR (qPCR) for the determination of fetal trisomy 21. From a total of 261 samples all 17 samples positive with trisomy 21 were correctly classified, resulting in a sensitivity and specificity of the new assay of 100%. While qPCR presents a more cost-efficient solution over NGS, the new assay will also be able to provide results in 72 hours or less.

17:30 Genomic Signatures Associated with Spontaneous Preterm Birth

Iya Khalil, Ph.D., Executive Vice President and Co-Founder, GNS Healthcare, United States

Molecular markers associated with spontaneous premature birth (<37 weeks gestation) have been difficult to identify owing to heterogeneous clinical presentations and a multiplicity of pathways that regulate parturition. We analyzed genetic, molecular, and clinical data of expectant families to identify markers for longitudinal prenatal analysis and risk prediction using a big data machine learning analytics approach. Preterm birth was found to be associated with multiple markers and risk factors, which are potentially useful to predict gestational duration.

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

19:00 Close of Day Two

WEDNESDAY, 6 APRIL

FETAL CELL ISOLATION AND ANALYSIS

8:00 Registration and Morning Coffee

8:40 Chairperson's Remarks

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

8:45 Advances in the Use of Trophoblastic Cells for Prenatal Non-Invasive Diagnostics of Genetic Disorders

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

Non-Invasive Prenatal Diagnosis is technically bound to the challenge of analyzing rare fetal DNA sequences, extracted from blood along with maternal DNA sequences, or rare trophoblastic cells, extracted from blood or cervical samples along with maternal cells. Our results show that ISET allows the consistent recovery of trophoblastic cells from blood and cervical samples and the feasibility of using the trophoblast-derived fetal DNA for noninvasive prenatal diagnosis (NIPND). The advantages and limitations of using fetal cells versus those of using cell-free DNA for developing non-invasive prenatal diagnostic tests will also be discussed.

9:15 Recent Advances in the Enrichment and Characterization of Fetal Cells in Maternal Blood

Steen Kolvraa, Ph.D., CSO, ARCEDI Biotech, Denmark

Using expression array data, we have previously indicated that a major fraction of the fetal cells circulating in the blood of pregnant women are endovascular trophoblasts. Based on this, we had developed a method for the isolation of these fetal cells with the aim of doing cell-based NIPT. We have since then refined our procedure resulting in both higher fetal cell yield and better fetal cell specificity. These new results will be presented and discussed. Fetal DNA from circulating fetal cells is most likely of higher quality than free circulating fetal DNA and may therefore enable detection of more sub-chromosomal aberrations than NIPT based on circulating free fetal DNA. Knowledge on the present status on cell-based NIPT will also be presented.

9:45 Progress in Isolation and Analysis of Fetal Nucleated Red Blood Cells

Leonard Kellner, M.S., President, KellBenx, Inc., United States

Prenatal screening and diagnostics have changed forever. Karyotype (55 years) and MSS (35 years), since they were introduced, are feeling the pressures of the introduction of microarrays, next-gen and newer sequencing. The performance and reduced risk from non-invasive tests account for a significant drop in the level of invasive diagnostics. NIPT alone or as a reflex test in combination with MSS are being accepted around the world. With techniques used in pre-implantation genetics, and the ability to isolate fNRBC; the elusive diagnostic test using fetal cells may soon be realized.

10:15 Coffee Break in the Exhibit Hall with Poster Viewing

10:45 Image-Based Single Cell Sorting to Identify and Recover Fetal Cells Using the Deparray Platform

Farideh Bishoff, Ph.D., Executive Director, Scientific Affairs, Silicon Biosystems, United States

DEPArray™ is an innovative technology platform capable of sorting and isolating 100% pure single or pooled cells through a digitally controlled Dielectrophoretic field using a semiconductor chip. Single target cells can be isolated from enriched

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blood while pools of tens to hundreds of pure cells can be recovered from fixed tissue blocks. Thus, the DEPArray offers the potential for pre-analytical cell-type purification for downstream molecular analysis, which is a major step forward for precision medicine in oncology and prenatal genetics. Applications for recovery of fetal cells from maternal blood, placental tissue (to address heterogeneity and confined mosaicism) and products of conception will be addressed.

11:15 PANEL DISCUSSION Predicting the Landscape for Prenatal Molecular Diagnostics in Europe

Marta Rodriguez de Alba, Ph.D., Genetics, Fundación Jiménez Díaz, Spain

Brigitte Faas, Ph.D., Human Genetics, Radbound University, The Netherlands

Wybo Dondorp, Ph.D., Associate Professor, Biomedical Ethics, Health, Ethics & Society, Maastricht University, The Netherlands

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

11:45 Close of Conference

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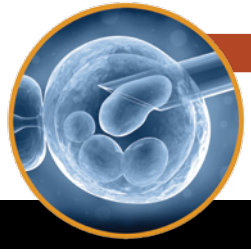

Inaugural

Reproductive Genetic Diagnostics

6-7 April 2016

Advances in Carrier Screening, Preimplantation Diagnostics, and POC Testing

WEDNESDAY, 6 APRIL

12:00 – 13:00 Registration

NEXT-GENERATION SEQUENCING FOR PGD AND PGS

13:00 Chairperson's Opening Remarks
Bert Smeets, Ph.D., Professor, Clinical Genomics, Mitochondrial Diseases, Maastricht University Medical Center, The Netherlands

» 13:05 KEYNOTE PRESENTATION: 25 YEARS OF CHROMOSOMAL PGD AND COUNTING

Darren K. Griffin, Ph.D., D.Sc., FIBiol, FRCPath, FRSA, Professor, Genetics, School of Biosciences, University of Kent, United Kingdom

The talk will chronicle the chromosomal aspects of PGS and its early beginnings, to clinical applications in the last 25+ years. The rise, fall, and rise again of PGS will be covered from a scientific perspective with many a cautionary tale along the way, and the presentation will conclude with the implementation of novel technologies (such as Karyomapping) for universal PGD.

13:35 Shallow Whole Genome Sequencing is Well Suited for the Detection of Chromosomal Aberrations in Human Blastocysts
Björn Menten, Ph.D., Center for Medical Genetics, Ghent University, Ghent University Hospital, Belgium

Recent advances in *in vitro* fertilization techniques such as vitrification and trophoblast biopsy, as well as the advent of massive parallel sequencing, open up new possibilities for better preimplantation genetic diagnosis and screening. I will discuss the benefits of day 5 biopsy combined with next-generation sequencing for the detection of aneuploidy and smaller copy number aberrations in human embryos.

14:05 Evaluating PGS in the Laboratory
Sebastiaan Mastenbroek, Center for Reproductive Medicine, Academic Medical Center, University of Amsterdam, The Netherlands

Rating quality of evidence and grading strength of recommendations are cornerstones of evidence-based medicine. Careful analysis of currently available trials on PGS shows that there is not enough evidence to justify the current use of PGS in routine clinical practice.

14:35 Refreshment Break in the Exhibit Hall with Poster Viewing

15:15 Genetic Counselling Challenges in a Rapidly Evolving Diagnostic Arena: Spotlight on Preimplantation Genetic Screening (PGS)
Karen A. Sage, MSc, GC, Genetic Service Manager, CARE Fertility; The Bridge Centre; The London Women's Clinic, United Kingdom

The transitions to Next-Generation Sequencing (NGS) and whole genome amplification (WGA) are leading to increased challenges for clinicians at the front line. How do we discuss these unknowns with the patient/couples undergoing this treatment? How do we counsel patients prior to embryo transfer and what are we offering patients post transfer? What is the consensus for PGS embryo transfer and follow up? What are the current guidelines and are they appropriate and current? This talk will illustrate some of the challenges faced by clinicians today offering PGS and PGD in practice.

NOVEL DIAGNOSTIC APPROACHES

15:45 Haplarithmis Enables Both Copy Number Profiling and Haplotyping of Single Cells and Improves Preimplantation Genetic Diagnosis
Joris Vermeesch, Ph.D.Ir, Professor, Molecular Cytogenetics and Genome Research, KU Leuven, Belgium

We developed a novel method, enabling concurrent copy number profiling and haplotyping, which improves preimplantation diagnosis. The approach and analysis pipeline, the validation and results from its clinical implementation will be presented.

16:15 Molecular Diagnostic and Reproductive Challenges in mtDNA Disease
Bert Smeets, Ph.D., Professor, Clinical Genomics, Mitochondrial Diseases, Maastricht University Medical Center, The Netherlands

The mitochondrial DNA (mtDNA) is a circular, maternally transmitted multicopy genome, located within the mitochondria Mutations in the mtDNA are a frequent cause of severe metabolic disorders. This presentation will focus on NGS protocols to identify mtDNA mutations, bioinformatics tools to classify the pathogenicity, and reproductive options, like PGD, to prevent the transmission of mtDNA diseases to future generations.

16:45 Close of Day One

THURSDAY, 7 APRIL

PROSPECTS FOR NON-INVASIVE DIAGNOSTIC METHODS

8:00 Registration

8:30 Breakfast Presentation *(Sponsorship Opportunity Available)* **or Morning Coffee**

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Molecular Diagnostics EUROPE
4-7 APRIL 2016
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9:00 Chairperson's Remarks
Darren K. Griffin, Ph.D., D.Sc., FIBiol, FRCPath, FRSA, Professor, Genetics, School of Biosciences, University of Kent, United Kingdom

9:05 Preimplantation Genetic Diagnosis and Screening: Now and the Future
Simone Palini, Ph.D., Senior Clinical Embryologist, Lab Director, IVF Unit, "Cervesi" Hospital Cattolica, Italy
Recent works describe the possibility of a non-invasive diagnosis on the blastocoele fluid and culture media, but its use has yet to be demonstrated in the clinic. This talk will discuss the use of PGS for the detection of aneuploid embryos, due to the presence of mosaicism in the embryo, and to discuss the limits that label an embryo as healthy. The future goal is to complement PGD and PGS with the analysis of other non-invasive matrices.

9:35 The Potential of Extracellular Embryo DNA for Preimplantation Genetic Testing
Luca Galluzzi, Ph.D., Research Fellow, Biomolecular Sciences, School of Biotechnology, University of Urbino, Italy
Preimplantation genetic diagnosis and screening currently rely on biopsy of one or few embryo cells. To avoid or limit this invasive procedure, the presence of embryo genomic DNA has been evaluated in extracellular matrices such as blastocoele fluid and embryo culture medium. The potential use of this extracellular DNA in genotyping applications has been then investigated.

10:05 Novel Correlates of Embryo Viability
Gabor L. Kovacs, M.D., Ph.D., DSc, Professor, Laboratory Medicine, Szentágothai Research Centre of the University of Pécs, Hungary
A novel polpeptide marker was found to differentiate between viable and nonviable embryos during *in vitro* fertilization. This molecule was identified with MS as the α-1 fragment of human haptoglobin. Further questions are if there is any correlation between the amount of the haptoglobin fragment in spent embryo culture medium with embryo morphology and cell free nucleic acid release into the medium.

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

11:15 FEATURED POSTER PRESENTATION: Molecular Analysis of Fetoplacental Discrepancies in Products of Conception (POCS) Obtained by Hysteroembryoscopy
Sandra García-Herrero, Senior Biologist, PGD Molecular Cytogenetics, Preimplantation Genetic Diagnosis Unit, IGENOMIX, Assistant Professor, Biotechnology of Assisted Human Reproduction Techniques, Valencia University
The analysis of the chromosomal status of POCs (Products of conception) is crucial to determine the cause of sporadic or recurrent pregnancy loss and allows the estimation of the of recurrence risk for future pregnancies. In some cases, chromosomal abnormalities are confined to the placenta, in rare instances, the placental karyotype can be normal, while fetal cells show an abnormal karyotype. To infer the real incidence of fetoplacental discrepancies, we retrospectively analyzed results from miscarriages where tissues from both, embryo and trophectoderm were obtained by hystroembryoscopy and analyzed by molecular genetic techniques.

EMBRYO PREPARATION, TREATMENT, AND ASSESSMENT

11:45 How the *in vitro* Environment Shapes Human Preimplantation Embryo Development
Sjoerd Repping, Head, Center for Reproductive Medicine, Academic Medical Center, University of Amsterdam, The Netherlands
During medically assisted reproduction, preimplantation embryos are exposed to an *in vitro* environment. This talk will shed light on how this environment affects the competence and development of human embryos, how these effects are mediated and what the potential consequences of these effects are for MAR success rates and health of offspring.

12:15 Sponsored Presentation *(Opportunity Available)*

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

13:15 Session Break

14:15 Dessert Break in the Exhibit Hall with Poster Viewing

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14:55 Chairperson's Remarks

Simone Palini, Ph.D., Senior Clinical Embryologist, Lab Director, IVF Unit, "Cervesi" Hospital Cattolica, Italy

15:00 Embryo Development with Regard to Its Chromosomal Status

Olga Chaplia, Embryologist, Cytogeneticist, IVF Laboratory, Medical Centre Reproductive Genetics Clinic Victoria, Ukraine

As genetic component of embryo significantly affects its implantation capacity, certain developmental patterns may reflect the chromosome status of embryo. The use of proper morphologic criteria indirectly advances selection of euploid embryos for transfer if genetic testing is not feasible.

15:30 Time-Lapse and PGS: Better Together?

Belén Ramos, Ph.D., Clinical Embryologist, IVF Spain – Alicante, Spain

Some groups suggest markers such as mitochondrial DNA levels in order to select the most viable embryo among the euploid ones. In our PGS program, we hypothesized that time-lapse could be as an additional viability marker to the euploidy in order to increase implantation. This talk will discuss our findings in a study focused on morphokinetic parameters, including P2 and P3, and how they correlate to blastocyst formation, euploidy, and implantation rates.

16:00 How Has Vitrification Changed Our Practice?

Amelia Rodríguez, MD, Obstetrics and Gynecologist specialized in ART, Medical Director, Eugin Clinic, Spain

Vitrification of oocytes and embryo has opened up new possibilities for assisted reproduction technology. Increased safety in ovarian stimulation, social and medical fertility preservation, improvement in oocyte donation efficiency, and the possibility of effectively perform preimplantation diagnosis at the blastocyst stage are some of its main consequences, which will be discussed in detail in this talk.

16:30 Sponsored Presentation *(Opportunity Available)*

17:00 Refreshment Break

ETHICAL IMPLICATIONS OF ADVANCED TESTING TECHNOLOGIES

17:15 Reproductive Genetic Testing: Dynamics and Ethics

Guido de Wert, Ph.D., Professor, Biomedical Ethics, Faculty of Health, Medicine and Life Sciences, Department of Health, Ethics & Society, Maastricht University, The Netherlands

Reproductive genetic testing, including both screening and diagnosis, and applied in the context of preconception care, medically assisted reproduction and during pregnancy, may help to avoid serious harms and contribute to human welfare. At the same time, such testing raises substantive and procedural normative questions. What are the proper aims of such testing in these different contexts? Which ethical principles and ethical frameworks should be guiding? And how to handle possible conflicts between different stakeholders?

17:45 Panel Discussion: The Future of Preimplantation Genetic Diagnostics and Screening: Ethical Implications and Future Prospects

Moderator: György Kosztolányi, Ph.D., President, Human Reproduction Committee of Scientific Health Council, Professor Emeritus, University of Pécs, Hungary

Panelists: Sjoerd Repping, Head, Center for Reproductive Medicine, Academic Medical Center, University of Amsterdam, The Netherlands

Juliet Tizzard, Director, Strategy and Corporate Affairs, Human Fertilisation & Embryology Authority, United Kingdom

Amelia Rodríguez, MD, Obstetrics and Gynecologist specialized in ART, Medical Director, Eugin Clinic, Spain

Diagnostic tools and technologies are rapidly evolving across the world, changing and challenging the way reproductive genetic diagnosis and screening are performed. We must continue to examine and debate the ethics, efficacy, and implications of preimplantation genetic diagnosis and screening across the world, as well as keep an eye toward regulatory challenges across Europe and the world.

18:30 Close of Conference

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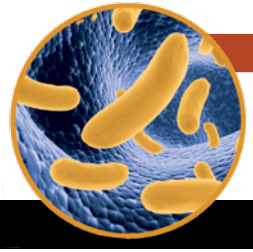

Second Annual

Advanced Diagnostics for Infectious Disease

5-6 April 2016

Latest Technologies and Impact on Clinical Outcome

TUESDAY, 5 APRIL

ANTIMICROBIAL RESISTANCE DIAGNOSTICS

8:00 Registration and Morning Coffee

9:00 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

» 9:05 KEYNOTE PRESENTATION: HURRICANE WATCH: USE OF NOVEL TECHNOLOGIES FOR EARLY DETECTION AND IDENTIFICATION OF MULTI-RESISTANT BACTERIA

Ulf B. Göbel, M.D., Ph.D., Director, IMH Charité University Medicine Berlin; Director, Microbiology Labor Berlin Charité-Vivantes GmbH, Germany

The rapid evolution of antimicrobial resistance and the alarming spread of multi-resistant bacteria represent a major challenge for health care systems worldwide. Early, rapid, accurate and cost-effective detection of phenotypic and/or genotypic resistance is therefore mandatory to prevent transmission and to initiate appropriate therapy. I am reviewing the latest developments and discussing pros and cons of their implementation from a large hospital laboratory's perspective.

9:35 Futuristic Antimicrobial Susceptibility Testing

Alex van Belkum, Ph.D., F(AAM), Corporate Vice President, Microbiology, bioMérieux, France

Antimicrobial susceptibility testing is a key technology in clinical microbiology. It helps identify drug resistance and directs patient treatment. Classical methods mostly rely on growth interruption. Many alternatives have been developed including several which utilize the detection and characterization of nucleic acid molecules. The presentation will review the current methodological state of affairs and will survey those molecular technologies which are considered candidates for ultimate replacement of the existing methods.

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10:05 New Technology and Workflow for Integrated Collection, Stabilization, and Purification of Circulating Cell-Free DNA

Phoebe Loh, Global Product Manager – PreAnalytiX, QIAGEN, Germany

Introducing the PAXgene® Blood ccfDNA System developed by PreAnalytiX (a joint venture between QIAGEN and BD), consisting of the PAXgene Blood ccfDNA Tube - a plastic blood collection tube with unique, non-crosslinking chemistry preserving extracellular levels of ccfDNA and preventing the release of intracellular DNA from cells into the plasma.

10:20 Sponsored Presentation *(Opportunity Available)*

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

11:15 AMR DxC Competition and the Longitude Prize

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

Worldwide efforts to develop rapid diagnostics to tackle antimicrobial resistance are facing substantial technical and non-technical barriers to innovation. As a consequence, international challenge prizes were launched. The Longitude Prize will reward a competitor that can develop a transformative point–of–care diagnostic test that will conserve antibiotics for future generations and revolutionise the delivery of global healthcare. AMR DxC, the Antimicrobial Resistance Challenge competition, will address AMR Diagnostics from an interdisciplinary perspective of the next generation of researchers.

11:45 The Impact of Sequencing as a Routine Clinical Diagnostic for Resistant Organisms

Samuel Reed, President, US Office, DNA Electronics, United States

The treatment of millions of critically-ill patients, and the appropriate use of antibiotics, is still often hampered by the bottleneck of the day(s)-long turnaround time of culture. There remains a need for a broad, versatile diagnostic, which is far more rapid. This talk will outline some additional solutions being developed to provide rapid, sample-to-result sequencing and highly-multiplexed molecular diagnostics, sensitive enough to operate directly from whole blood or other specimens, and easy enough to be used in a routine clinical testing environment.

12:15 Sponsored Presentation *(Opportunity Available)*

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

13:15 Session Break

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

14:15 Chairperson's Remarks

Matthew Cotten, Ph.D., Senior Staff Scientist, Virus Genomics, Wellcome Trust Sanger Institute, United Kingdom

14:20 Outbreak Sequencing of Ebola Virus: The Utility of Phylogenetics for Tracking Virus Transmission Chains

Matthew Cotten, Ph.D., Senior Staff Scientist, Virus Genomics, Wellcome Trust Sanger Institute, United Kingdom

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West Africa has experienced the largest known outbreak of Ebola virus disease (EVD) in history. The ability to rapidly identify virus sources and chains of transmission is essential for ending the epidemic. We show that local Ebola virus genome sequencing, (in as little as 24 hours from clinical sample to genome) combined with epidemiological data and a comprehensive database of virus sequences across the outbreak provide powerful tools for identifying sources of new infections and for interrupting Ebola virus transmission.

14:50 Virus Discovery in Diseases of Unknown Origin

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

Attributing the presence of a new virus to a disease can be a challenge since often the Koch's postulates cannot be fulfilled. Adding a selection for pathogenic viruses in next generation sequencing virus discovery via an antibody capture step enhances detection of those viruses to which a patient has developed an antibody response. This selection can justify further research to reveal the causative nature in disease.

15:20 From Months to Hours: Can Molecular TB Diagnostics Replace Phenotypic Tests?

Bouke de Jong, M.D., Ph.D., Head, Mycobacteriology Unit, Institute of Tropical Medicine, Belgium

Tuberculosis requires concurrent treatment with a minimum of three effective drugs. In the presence of drug resistance, the treatment duration increases from 6 months to 2 years, often with dismal outcome. Resistance testing can take up to 4 months. While molecular resistance tests have replaced the phenotypic gold standard for rifampicin, for other drugs the clinical relevance of discordant results remains unclear. Novel molecular tests need to resolve the interpretation for clinicians in order for these tests to impact on patient outcomes.

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

MOLECULAR DIAGNOSTICS TESTING OF INFECTIOUS DISEASE

16:25 Chairperson's Remarks

Matthew Cotten, Ph.D., Senior Staff Scientist, Virus Genomics, Wellcome Trust Sanger Institute, United Kingdom

16:30 Nanopore Sequencing for Microbial Diagnostics – The Perfect Fit?

Justin O'Grady, Ph.D., Lecturer in Medical Microbiology, Norwich Medical School, University of East Anglia, United Kingdom

We are developing unbiased metagenomic sequencing methods for diagnosing clinical syndromes such as sepsis and UTIs. The biggest challenges to successfully applying these approaches are (1) the presence of large amounts of host DNA and (2) turnaround-time to results. We are combining novel host depletion techniques with MinION sequencing to make this possible.

17:00 Resolving Molecular Diagnostics Need for Ebola, Advancing Point-of-Care Testing for the West

Sterghios Moschos, Ph.D., Reader and Associate Professor, Biomedical Sciences, University of Westminster, United Kingdom

The West African Ebola outbreak galvanized academics and biotech internationally to innovate solutions for mass point-of-need testing for category 4 biological agents. The international public-private EbolaCheck consortium has addressed this need by developing a 5-step, <30 min, portable system that can quantify Ebolavirus in as little as 5 ul of crude biofluids for under US$12 per test. Engineered for West Africa, the technology is now expanding to address differential diagnosis need for future infectious disease outbreaks and beyond.

17:30 Smear-Negative, Culture Positive TB: Diagnosis Improvement by Xpert MTB/RIF Assay: Evidences and Bologna University Hospital Experiences in Tuberculosis Patients Diagnostics and Follow-up

Valentina Di Gregori, M.D., Medical Epidemiologist Doctor, UO Microbiology, Sant'Orsola Malpighi University Hospital, Italy

Evidences on new diagnostics are upcoming in tubercolosis molecular characterisation. Xpert can induce an advantage in smear negative culture positive recognition of cases during ordinary practice. Even though, on small samples, our experience can be reported to be implemented on further hospital environment in high contingency and low expenditure conditions.

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

19:00 Close of Day One

WEDNESDAY, 6 APRIL

MASS SPEC

8:00 Registration and Morning Coffee

8:40 Chairperson's Remarks

François Jean, Ph.D., Associate Professor and Scientific Director (FINDER), University of British Columbia, Canada

8:45 Mass Spectrometry-Based Clinical Proteomics for Detection and Absolute Quantitation of Viral Proteins: A Tale of Two Fever-Associated Viruses, Dengue Virus and Ebola Virus

François Jean, Ph.D., Associate Professor and Scientific Director (FINDER), University of British Columbia, Canada

Dr. Jean's presentation focuses on the immense potential of multiple reaction monitoring mass spectrometry (MRM-MS) in clinical proteomics with the vision of developing a universal diagnostic test for emerging and re-emerging human viruses. Dr. Jean will discuss the development and potential downstream applications of his novel MRM-MS assays for early diagnosis of dengue hemorrhagic fever and Ebola viral disease. Dr. Jean's research program is funded by the Canadian Networks of Centres of Excellence (IC-IMPACTS) and the British Columbia Proteomics Network.

9:15 Mass Spectrometry for Microbial Identification: A Revolution in Your Laboratory

Victoria Girard, Ph.D., Head, Identification, R&D Microbiology, bioMerieux, France

Presentation of the principle of mass spectrometry, how the databases are built, what type of organisms can be identified and with which performance. Possibility of typing and other research activities using MALDI TOF MS.

9:45 Sponsored Presentation *(Opportunity Available)*

10:15 Coffee Break in the Exhibit Hall with Poster Viewing

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RAPID AND EARLY DETECTION

10:40 Chairperson's Remarks
François Jean, Ph.D., Associate Professor and Scientific Director (FINDER), University of British Columbia, Canada

10:45 The Pre-Symptomatic Diagnosis of Sepsis in Elective Surgery Patients: Finding Biomarker Signatures in the Transcriptomic Milieu
Roman A. Lukaszewski, Ph.D., DSTL Fellow, CBR Division, Defence Science & Technology Lab, United Kingdom
The early diagnosis of sepsis remains a challenge that, if overcome, will have considerable impact on patient management and outcome. In this study of the onset of sepsis in elective surgery patients, pre-symptomatic host biomarker signatures have been identified from patient blood samples that differentiate between those who go on to develop sepsis, SIRS or have an unremarkable recovery.

11:15 Twenty Minute Diagnosis of Infectious Diseases Using a Disposable Handheld Molecular Point-of-Care Test Device
James Mahony, Ph.D., Professor, Pathology & Molecular Medicine; Assistant Dean, Medical Sciences, McMaster University, Canada
Most point-of-care test (POCT) devices detect antigens or antibody; however, these assays are insensitive compared with nucleic acid detection methods. Therefore there is an urgent need for nucleic acid amplification-based POCT tests for the detection of infectious diseases. We describe here an instrument-free, hand-held, point-of-need test device that can detect viruses and bacteria on a swab providing an answer in 20 minutes.

11:45 Close of Conference

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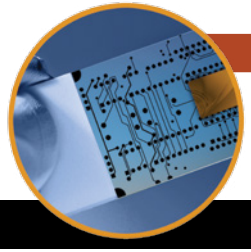

Inaugural

6-7 April 2016

Point-of-Care Diagnostics

Rapid Detection to Ensure Better Outcomes Globally

WEDNESDAY, 6 APRIL

12:00 – 13:00 Registration

POINT-OF-CARE TESTING AROUND THE GLOBE

13:00 Chairperson's Opening Remarks

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

» 13:05 KEYNOTE PRESENTATION: IMPACT OF POCT TECHNOLOGY ON EFFICIENCY AND EFFECTIVENESS OF CLINICAL PROCESSES

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

POCT technology enables us to leverage medical quality, patient outcome and economy of clinical processes. In two randomized single center trials the advantages of a POCT setting compared to a central lab test environment could be demonstrated. In an emergency department, POCT contributes to avoiding crowding effects and to reducing length-of-stay of patients suffering from non-specific thoracic pain. Furthermore, cost saving and efficiency effects were achieved using POCT for glucose monitoring onwards.

13:35 The Added Value POC Platforms for Pathogen Detection in Diagnostic Microbiology

Eric C.J. Claas, Ph.D., Associate Professor, Molecular Medical Microbiologist, Medical Microbiology, Leiden University Medical Center, The Netherlands

Over the last few decades nucleic acid amplification methods have revolutionized diagnostic microbiology. Initially, advanced laboratory skills were required for reliable implementation of these techniques but in recent years automated systems have become available for advanced processing of clinical samples. Different formats are available to accommodate specific laboratory requirements varying in the number of samples that can be processed, the number of pathogens that can be simultaneously detected, and time to result. An overview of the possibilities will be presented with a view on future diagnostic microbiology.

14:05 Point-of-Care Testing: A European Perspective

Anders Larsson, Ph.D., Professor, Medical Sciences, Uppsala University, Sweden

Over the past decades the availability and use of point-of-care testing (POCT) have steadily increased in Europe. Properly utilized, POCT has been shown to yield measurable improvements in patient care, workflow, and significant financial benefits in a number of different settings. It is important however that POCT is effectively integrated in the patient care including quality assurance systems and electronic handling of results.

14:35 Refreshment Break in the Exhibit Hall with Poster Viewing

NOVEL TECHNOLOGIES FOR POC DIAGNOSTICS

15:10 Chairperson's Remarks

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

15:15 Implementation of POCT Quality Standards to Optimize the Clinical Process Reliability

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

A POCT coordinator in a hospital has a pivotal role for quality assurance. He oversees all POCT processes and ensures that all necessary regulatory issues are met, establishing both quality and competence of testing. Implementation of POCT into clinical practice means: Assessing analytical reliability, evaluating clinical significance and establishing a comprehensive quality management system. Only when analytical performance characteristics and clinical limits are known, the POCT process reliability can be optimised.

15:45 A Universal POC Platform for Molecular, Immunological and Clinical Diagnostics

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

We have developed a universal diagnostic system which, as a platform, can handle molecular, immunological and clinical chemistry tests on a single instrument platform in a low resource setting. One example for a molecular diagnostic test on this platform is the fully automated sample-in answer-out cartridge for a rapid detection of mycobacterium tuberculosis (TB). This platform will be used in the future as an open platform to allow users a fast-track to bring their own assays onto a microfluidic cartridge format.

16:15 Emerging Technologies in Point-of-Care Diagnostics for Resource-Limited Settings

Ranald Sutherland, Ph.D., Head, Business Development, FIND Foundation for Innovative New Diagnostics

Diagnosing infectious diseases at the point at which care is delivered has the potential to save many lives, especially where access to laboratories is poor. Whether caring for an individual patient or responding to a worldwide pandemic, establishment of a microbial cause is fundamental to quality care. Emerging technologies enable this with new speed, sensitivity, and simplicity of use. However, there are significant challenges to the development and clinical integration of the new generation of diagnostic tests.

16:45 Close of Day One

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THURSDAY, 7 APRIL

NUCLEIC-ACID BASED TESTING AT THE POINT-OF-CARE

8:00 Registration

8:30 Breakfast Presentation *(Sponsorship Opportunity Available)* **or Morning Coffee**

9:00 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

9:05 A Handheld qPCR Device for Use in the Field

Jo-Ann Lee Stanton, Ph.D., Senior Research Fellow, Anatomy, University of Otago, New Zealand

Diagnosis of infectious disease at the initial point-of-care permits rapid infection containment, accurate diagnosis and the immediate implementation of appropriate treatment. qPCR is rapid, sensitive and accurate. We have invented a battery-powered, hand held qPCR device that can be used for point-of-care diagnostics. This talk will explore use of our handheld quantitative PCR device in non-laboratory environments.

9:35 Amplification Free Electrochemical Detection of Nucleic Acids for Rapid Antimicrobial Resistance Testing at Point-of-Care

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

Rapid diagnostics is of utmost importance to quickly initiate the correct antibiotic therapy and avoid the use of inappropriate antibiotics. Direct, amplification free detection of nucleic acids offers the possibility to shorten the time to result and specific sample preparation requirements need to be considered when setting up such assays. We have demonstrated the direct detection of nucleic acid antimicrobial resistance biomarkers from genomic and plasmid DNA from MRSA and CPE respectively. We used electrochemical impedance spectroscopy and disposable electrodes and will discuss their integration in sample to answer tests.

10:05 Sponsored Presentation *(Opportunity Available)*

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

11:15 Nucleic Acid-Based Diagnostics for Viral Lower Respiratory Tract Infections

Corné van den Kieboom, Ph.D., Postdoctoral Researcher, Laboratory of Pediatric Infectious Diseases, Radboud University Medical Center, The Netherlands

Respiratory syncytial virus is the most common cause of viral respiratory tract infections among hospitalized children. Symptoms range from common cold to severely compromised respiratory function. Accurate and fast diagnosis can substantially enhance the quality of care and lower the disease burden. Here utilization of nucleic acids offer tremendous possibilities, not only as target for detection or predicting the course of disease, but also as binding molecules for diagnostic devices.

11:45 A Rapid, Amplification-Free, and Sensitive Diagnostic Assay for Single-Step Multiplexed Fluorescence Detection of MicroRNA

Xue Qiu, Institut d'Electronique Fondamentale, Université Paris-Sud, France

I will present a fully homogeneous multiplexed microRNA FRET assay that combines careful biophotonic design with various RNA hybridization and ligation steps. The single-step and amplification-free assay provides a unique combination of performance parameters compared to state-of-the-art miRNA detection technologies. Precise quantification of miRNA-20a, -20b, and -21 with detection limits between 0.2 and 0.9 nM in 7.5 mL serum samples demonstrate the feasibility of both high throughput and point-of-care clinical diagnostics.

12:15 Sponsored Presentation *(Opportunity Available)*

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

13:15 Session Break

14:15 Dessert Break in the Exhibit Hall with Poster Viewing

NOVEL TECHNOLOGIES FOR POC DIAGNOSTICS (Cont.)

14:55 Chairperson's Remarks

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

15:00 Lab-on-DVD: Advanced Cellular and Molecular Diagnostics at Resource Limited Settings

Aman Russom, Ph.D., Associate Professor and Head, Clinical Microfluidics Lab, Division of Proteomics and Nanobiotechnology, Science for Life Laboratory, KTH Royal Institute of Technology, Sweden

Microfluidics and the concept of lab-on-a-chip continue to gain traction as a successful emerging field that aims to integrate complex biochemical analyses into automated systems. One of the most promising applications for these microfluidic systems is in point-of-care biological analysis. Here, I will describe and discuss a low-cost "Lab-on-DVD" platform capable of integrating sample handling and detection for POC blood diagnostics.

15:30 Global Health Diagnostics Demands

Francis Moussy, Ph.D., Lead, AMPR Diagnostics Innovation, Essential Medicines and Health Products Department, World Health Organization (WHO), Switzerland

Low-cost and robust POC diagnostics that are suitable for remote health care centers in low- and middle-income countries are needed to facilitate surveillance and identification of etiological agents (and/or biological responses) and thus guide decisions for timely and appropriate treatment and reporting in places where almost no tools are available. One approach towards such diagnostic tools is to facilitate the development of multipurpose POC diagnostic devices.

16:00 The Digital Revolution on a Disc for Next-Generation Point-of-Care Diagnostics

Jens Ducrée, Ph.D., Biomedical Diagnostics Institute, National Centre of Sensor Research, School of Physical Sciences, Dublin City University, Ireland

This talk will review significant advances on comprehensive process integration, automation and parallelization of bioanalytical assays on a compact and widely autonomous microfluidic platform. Similar to modern microelectronics, this next-generation Lab-on-a-Disc platform allows complex logical flow control architectures generated by strategic repetition of elementary building blocks such as transistors.

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Several applications in point-of-care diagnostics such as immunoassay, general chemistry, nucleic acid testing and cell counting will be demonstrated.

16:30 Sponsored Presentation *(Opportunity Available)*

17:00 Refreshment Break

17:15 Centrifugal Microfluidic Platform (LabDisk) as a Multi-Purpose, Multi-Target Diagnostic Tool for Patient Management at the Point-of-Care

Konstantinos Mitsakakis, Ph.D., Project Manager & International Business Development, Hahn-Schickard & IMTEK-University of Freiburg, Germany

The LabDisk is a CD-shaped microfluidic platform with all reagents integrated for on-site sample-to-answer diagnosis of single or multiple infectious diseases stemming from parasites, bacteria, viruses, or co-infections of theirs. By combining molecular diagnostics and protein biomarker detection, the LabDisk offers increased reliability in pathogen species identification. An overview of case-studies in infectious disease diagnostics will be presented, namely on neonatal sepsis, respiratory tract infections, antibiotic resistance, febrile tropical infections.

17:45 Integrated Sample-Prep and Immunoassay Array Platform for High-Sensitivity, Low-Complexity Multiplexed POC Diagnostics

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

Detection of infectious pathogens is critical to proper patient care and management of outbreaks, yet many existing diagnostic tests fail to provide adequate sensitivity and simplicity for use in an out-patient setting. Our solution resolves the problems associated with long delays in test results processed at a central laboratory thereby informing clinical decision-making during the normal course of the patient visit to the clinic. In this talk we will present a solution for a high-sensitivity, low-complexity multiplexed POC diagnostic test that addresses and resolves each of these challenges through the application or our unique and differentiated technologies.

18:15 Close of Conference

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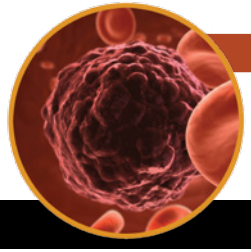

Inaugural

5-6 April 2016

Circulating Tumour Cells

Strategies for Bringing Liquid Biopsy to the Clinic

TUESDAY, 5 APRIL

CTC DETECTION, CHARACTERIZATION, AND ISOLATION

8:00 Registration and Morning Coffee

9:00 Chairperson's Remarks

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

» 9:05 KEYNOTE PRESENTATION: CLINICAL IMPLICATIONS OF CTCS ANALYSIS

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

Circulating tumor cells (CTCs), nucleic acids (ctDNA, cfmiRNA) and exosomes in the blood of cancer patients have received increasing attention as new diagnostic tools enabling "liquid biopsies". The perspective to avoid invasive tissue biopsies and obtain similar or even more information by a "simple" blood test has enormous implications in cancer diagnostics. Here the expectations and future steps required to bring liquid biopsies into clinical practice will be discussed.

9:35 Detection, Characterization, and *ex vivo* Expansion of Viable Circulating Tumour Cells

Catherine Alix-Panabières, Ph.D., Director, Laboratory Rare Human Circulating Cells, Cell and Tissue Biopathology of Tumors, University Medical Center of Montpellier, France

Circulating tumor cells (CTCs) in blood are promising new biomarkers potentially useful for prognostic prediction and monitoring of therapies in patients with solid tumors. We reported for the first time (1) the establishment of a permanent cell line from CTCs of one colon cancer patient & (2) that PDL1 is heterogeneously expressed on CTCs from metastatic breast cancer patients. CTC research opens a new avenue for understanding the biology of metastasis in cancer patients.

Sponsored by silicon biosystems

10:05 Presentation to be Announced

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

11:15 Quantification of Malignant Cells in CSF with Cellsearch VERIDEX Improves Diagnosis and Management of Carcinomatous Meningitis

Gilbert C. Faure, Ph.D., PU PH Consultant, Laboratoire d'Immunologie, Université Lorraine & CHU Nancy (Nancytomique), France

Diagnostic methods of leptomeningeal metastases (LM) in Cerebro-Spinal fluid (CSF), lack both specificity and sensitivity. We adapted the Veridex CellSearch® technology to detect Tumour Cells (CSFTCs) in CSF from breast, lung and melanoma cancer patients with LM. This method, established on a limited volume of CSF prove to be of great interest in diagnosis and follow-up of cancer patients with LM opening new fields for characterization of cells crossing the blood-brain-barrier and evaluation of efficiency of systemic or intrathecal therapies.

11:45 A Functionalized Medical Device for CTC Isolation *in vivo* and Single CTC Molecular Analysis

Shukun Chen, Research Assistant, Institute of Cell Biology, Histology & Embryology, Medical University of Graz, Austria

Using a *in vivo* isolation technique we currently immunocytochemically characterize CTCs in high-risk prostate cancer patients. However, CTC analysis needs to go beyond mere immunophenotyping which is why we test a new device allowing the recovery of isolated CTCs for the purpose of molecular analysis. Our *in vitro* study shows that cells captured by the new device, recovered and forwarded to whole genome amplification, array-CGH analysis and next generation sequencing at the single-cell level present with high-quality data, suggesting potential clinical application for personalized medicine.

12:15 Sponsored Presentation *(Opportunity Available)*

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

13:15 Session Break

EXISTING TECHNOLOGIES AND UNMET NEEDS

14:15 Chairperson's Remarks

Evi Lianidou, Ph.D., Professor, Analytical Chemistry – Clinical Chemistry, Analysis of Circulating Tumor Cells (ACTC) Lab, Laboratory of Analytical Chemistry, Department of Chemistry, University of Athens, Greece

14:20 Development, Validation, and Clinical Applications of Molecular Assays for the Molecular Characterization of CTCs

Evi Lianidou, Ph.D., Professor, Analytical Chemistry – Clinical Chemistry, Analysis of Circulating Tumor Cells (ACTC) Lab, Laboratory of Analytical Chemistry, Department of Chemistry, University of Athens, Greece

This lecture will be mainly focused on the analytical systems for CTC molecular characterization and its clinical applications in many types of solid cancer. We will also discuss the potential of the molecular characterization of CTC as a liquid biopsy in individualized therapy. This field has a tremendous potential towards the development of molecular assays with potential utility as companion diagnostics, in disease monitoring, or even for early cancer detection.

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14:50 3D Microdevice for the *in vivo* Trapping of Cancer-Associated Circulating Cells

Aline Cerf, Ph.D., CNRS Researcher, NanoBioSystems, LAAS-CNRS, France

We introduce a unique intravascular 3D micro-system for the selective capture of cancer-associated circulating cells directly from the bloodstream. Our methodology is intended to overcome sampling and selection biases of current circulating tumor cell (CTC) detection systems by placing the microdevice *in vivo*, and by performing CTC trapping based on their physical traits only. Using a fluidic platform reproducing *in vivo* conditions, we succeeded in capturing PC3 human prostate cancer cells from whole blood in just a few minutes, demonstrating our device's capability to capture CTCs in conditions close to those found *in vivo*.

15:20 Role of Epithelial-to-Mesenchymal Transition (EMT) on Circulating Tumor Cell Generation and Metastasis in Prostate Cancer

Alison Allan, Ph.D., Senior Oncology Scientist and Associate Professor, Oncology and Anatomy & Cell Biology, London Regional Cancer Program and Western University, Canada

The U.S. Food and Drug Administration (FDA)-approved CellSearch® system is the current gold standard for CTC enumeration. However, using the CellSearch® approximately 35% of metastatic prostate cancer patients have undetectable CTCs, which may result from the epithelial-to-mesenchymal transition (EMT) and subsequent loss of necessary CTC detection markers. We have developed two pre-clinical assays for assessing human CTCs in xenograft mouse models of metastasis; one that is comparable to the EpCAM-based CellSearch®

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

CTCs IN PATIENT STRATIFICATION AND THERAPY PREDICTION

16:30 Circulating Tumor Cells (CTC) and Pathological Complete Response (pCR) as Independent Prognostic Factors in Inflammatory Breast Cancer (IBC)

Jean-Yves Pierga, M.D., Ph.D., Circulating Cancer Biomarkers Lab, SiRIC, Translational Research and Medical Oncology, Institut Curie and University Paris Descartes, France

This talk will describe the largest prospective trial in non-metastatic IBC evaluating CTC detection. We observed a high CTC detection rate of 39%, with a strong and independent prognostic value for DFS and OS. Combination of pCR after neoadjuvant treatment, with CTC at baseline, isolates a subgroup of IBC with excellent survival. CTC count should be part of IBC stratification in prospective trials.

17:00 Expansion of Breast Circulating Cancer Cells Predicts Response to Anti-Cancer Therapy

Prashant Kumar, Ph.D., Faculty Scientist, Institute of Bioinformatics, India

This talk will present a new technique that provides an opportunity to analyse CTC clonal heterogeneity and adapt therapeutic modalities in refractory breast cancer patients which may help determine the efficacy of selected therapeutic regimes.

17:30 Clinical Significance of Bone Marrow DTC Detection in Cancer Patients

Nikolay Tupitsyn, M.D., Ph.D., Professor, Oncoimmunology, Haematopoiesis Immunology Lab, Federal State Budgetary Institute, N.N.Blokhin Cancer Research Center, Russia

CTC analysis in cancer patients is now proved to be of great clinical significance. However it cannot fully replace study of bone marrow (BM) DTC. Namely in the bone marrow tumor cells can survive in dormant state for years and decades, then giving rise to distant incurable metastases. We provide data on both detection and clinical significance of DTC in more than 200 patients (breast cancer, ovarian cancer, gastric cancer). While BM is studied excluding hemodilution with the use of modern methods allowing investigation of at least 20 x 106 cells by modern methods, the data received is of great prognostic significance allowing monitoring of treatment protocols efficacy.

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

19:00 Close of Day One

WEDNESDAY, 6 APRIL

CTCs IN PATIENT STRATIFICATION AND THERAPY PREDICTION (Cont.)

8:00 Registration and Morning Coffee

8:40 Chairperson's Remarks

Julie Lang, M.D., FACS, Associate Professor, Surgery, University of Southern California, United States

8:45 Gene Expression Profiling of Circulating Tumor Cells in Non-Metastatic Breast Cancer

Julie Lang, M.D., FACS, Associate Professor, Surgery, University of Southern California, United States

We hypothesized that transcriptional profiling of CTCs with RNA Seq prior to therapy may predict for pathologic complete response to neoadjuvant chemotherapy in Stage II-III breast cancer. RNA Seq of rare CTCs is feasible in Stage II-III breast cancer and shows evidence of oncogenes and tumor suppressor genes. RNA Seq of CTCs may be performed without background subtraction of leukocytes using our approach. Our preliminary analysis suggests that transcriptional profiling of CTCs may predict for a pathologic complete response to neoadjuvant chemotherapy.

9:15 Molecular Characterization and Genomic Sequencing of Circulating Tumor Cells in Breast Cancer

Aditya Bardia, M.D., Attending Physician, Medical Oncology, Massachusetts General Hospital Cancer Center, United States

Circulating tumor cells (CTCs) can serve as potential "liquid biopsies" offering a potential relatively non-invasive tool for monitoring of breast cancer. We have demonstrated that CTCs can potentially be utilized to monitor response to targeted therapies, to better understand tumor biology, and for the identification of novel actionable targets in breast cancer.

9:45 Sponsored Presentation *(Opportunity Available)*

10:15 Coffee Break in the Exhibit Hall with Poster Viewing

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10:45 How Clinical Biobanks Can Support Standardized CTC Assessment to Improve Individualized Medicine: A CTC Guide to Design and Report Trials

Jens K. Habermann, M.D., Ph.D., Professor & Head, Section of Translational Surgical Oncology and Biobanking; Scientific Director, Surgical Center for Translational Oncology-Lübeck (SCTO-L), University of Lübeck & University Medical Center Schleswig-Holstein (UKSH), Germany

Despite current interstudy heterogeneity, current data indicate that CTC detection is of clinical relevance, e.g., as a surrogate prognostic marker in colorectal cancer treatment. This talk will propose a standardized CTC guideline (CTC Guide) to prospectively design and report studies/trials in a harmonized form to overcome interstudy heterogeneity. This will be crucial before implementing CTC detection into clinical consensus guidelines. Hereby, hospital integrated biobanks can play a pivotal role by building the bridge between basic/translational research and clinical routine.

11:15 PANEL DISCUSSION Advancing Liquid Biopsy to Clinic

Moderator: Aditya Bardia, M.D., Attending Physician, Medical Oncology, Massachusetts General Hospital Cancer Center, United States

- What data/information is needed?
- What are the needs of clinicians?
- How should earlier stage patients be handled?
- How can the process be standardized?

Panelists: Ellen Heitzer, Ph.D., Assistant Professor, Institute of Human Genetics, Medical University Graz, Austria

Evi Lianidou, Ph.D., Professor, Analytical Chemistry – Clinical Chemistry, Analysis of Circulating Tumor Cells (ACTC) Lab, Laboratory of Analytical Chemistry, Department of Chemistry, University of Athens, Greece

Nikolay Tupitsyn, Oncoimmunology, Haematopoiesis Immunology Lab., Federal State Budgetary Institute, N.N.Blokhin Cancer Research Center, Russia

11:45 Close of Conference

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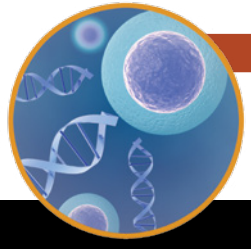

Second Annual

Circulating Cell-Free DNA

6-7 April 2016

Strategies for Bringing Liquid Biopsy to the Clinic

WEDNESDAY, 6 APRIL

12:00 – 13:00 Registration

EARLY STAGE DISEASE DETECTION

13:00 Chairperson's Opening Remarks
Daniel Grosu, M.D., MBA, CMO, Sequenom, Inc., United States

» 13:05 KEYNOTE PRESENTATION: NOVEL METHODS FOR ENRICHMENT OF MUTATIONS AND DIFFERENTIALLY METHYLATED SEQUENCES FROM LIQUID BIOPSY GENOMES

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

We present Nuclease-assisted-Mutation-Enrichment, NaME, a simple and powerful approach to remove wild-type DNA from large gene-pools simultaneously, in order to focus on clinically relevant DNA alterations. This single-step approach retains current sample preparation protocols almost unchanged and combines seamlessly with downstream technologies such as HRM, COLD-PCR, ddPCR and next-generation-sequencing. Application in clinical samples and liquid biopsies will be presented.

13:35 Enhanced Sensitivity for Cell-Free Tumour DNA Analysis Using Multiple Patient-Specific Assays
Charlie Massie, Ph.D., Senior Research Associate, Cancer Research UK Cambridge Institute, University of Cambridge, United Kingdom

Circulating cell-free tumour DNA (ctDNA) can be assayed using hotspot assays, gene panels, or genome-wide sequencing. However, in early cancers or post-therapy ctDNA levels can be very low. In late-stage disease, individual mutations may not represent dynamics of heterogeneous clones. We developed a combined workflow to measure multiple mutations in parallel. This provides greater sensitivity over single mutation assays, and can provide a detailed picture of clonal evolution.

14:05 Urine Cell-Free DNA Integrity Analysis for the Early Detection of Bladder and Prostate Cancer
Valentina Casadio, Ph.D., Researcher, IRCCS Istituto Scientifico Romagnolo per lo Studio e la Cura dei Tumori(I.R.S.T.) S.r.l., Italy

The presence of circulating cell-free DNA in plasma or serum has been reported to be a promising diagnostic marker for several tumor types but few studies have focused on the potential of urine cell-free (UCF) DNA to detect urological cancers. The objective of our research was to evaluate the potential role of UCF DNA integrity as a marker for the early diagnosis of prostate and bladder cancer. We highlighted the potential usefulness of UCF DNA to detect and characterize urologic malignancies.

14:35 Refreshment Break in the Exhibit Hall with Poster Viewing

ASSAY SENSITIVITY AND SPECIFICITY

15:15 Recent Technological Advances in the Analysis of ctDNA – Are We Ready for Clinical Use?
Ellen Heitzer, Ph.D., Assistant Professor, Institute of Human Genetics, Medical University Graz, Austria

The potential of the liquid biopsy in the field of clinical cancer research is being clearly recognized. However, cfDNA is a challenging analyte owing to the high degree of fragmentation and the highly variable allele frequencies of ctDNA in the circulation. Owing to technological advances, the analytical sensitivity and the specificity of detection improved dramatically in recent years and new technologies now allow the identification of mutant alleles at very low frequencies. Advantages and limitations of these technologies will be summarized and discussed.

15:45 Identification of Rare and Subclonal Mutations and Their Impact on Personalized Cancer Treatment Using Enhanced-ice-COLD-PCR
Jorg Tost, Ph.D., Director, Laboratory for Epigenetics & Environment, Centre National de Genotypage, CEA - Institut de Genomique, Evry, France

We developed a complete workflow for extraction, characterization and quality control of ccFDNA from small amounts of plasma. We have further 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 permitting the sensitive detection and sequence identification of mutations within three hours.

16:15 Clinical Validation of the Analysis of Circulating DNA for Theragnostics and Multiparametric Strategy for Cancer Patients Follow-Up
Alain R. Thierry, Ph.D., Senior Investigator, Research Institute in Oncology of Montpellier, INSERM, France

Circulating DNA and Cancer: Clinical validation of the detection of point mutations, and of the longitudinal metastatic colorectal patient follow-up for detecting emergence of resistance to targeted therapy. Data of two blinded clinical studies will be described highlighting the need of ultrasensitive assay and of a multi-parametric strategy for analyzing circulating DNA.

16:45 Close of Day One

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THURSDAY, 7 APRIL

WORKING WITH DIFFERENT SAMPLE TYPES

8:00 Registration

8:30 Breakfast Presentation *(Sponsorship Opportunity Available)* **or Morning Coffee**

9:00 Chairperson's Remarks

Hatim Husain, M.D., Physician, Medical Oncology, University of California, San Diego, United States

9:05 Epigenetic Biomarker Profiling in Serum- and Saliva-Derived Exosomes

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

Exosome-mediated cell-to-cell communication is of importance in both health and disease. Together with the finding that tumor-derived exosomes contain a specific RNA and protein cargo, this holds tremendous potential for exosomes as biomarkers for minimally invasive diagnostics. Along these lines we report on the evaluation of different strategies for exosome isolation and present data from genome-wide microRNA – and DNA-methylation microarrays, which showed a significant overlap of both microRNA- and DNA methylation profiles when comparing serum - with saliva-derived exosomes in healthy individuals.

9:35 Urine DNA Testing for Early and Non-Invasive Detection of Bladder Cancer

Per Guldberg, Ph.D., Group Leader, Danish Cancer Society, Denmark

The current gold standard for detecting bladder tumors is cystoscopy, an invasive and expensive method that requires dedicated hospital sites and well-trained operators. This paper discusses new developments that make urine DNA testing a powerful non-invasive tool for bladder cancer detection and surveillance. It also discusses the potential of urine DNA testing for preclinical detection of bladder cancer, to reduce mortality and economic cost.

10:05 Why is Circulating Tumor DNA (ctDNA) Reference Material needed for Oncology Precision Medicine?

Sponsored by seracare

Dale Yuzuki, M.A., M.Ed., Director, Market Development – Oncology, SeraCare Life Sciences, United States

There's understandable interest in the diagnostic and prognostic value of analyzing ctDNA from plasma of cancer patients. We'll report on the development and commercialization of biosynthetic mutation targets to as low as 0.1% allelic frequency in a commutable synthetic plasma matrix, suitable as reference material to accelerate oncology precision diagnostics.

10:20 Nucleosomics®-Revolutionising Cancer Diagnostics

Sponsored by VOLITION RX

Mark Eccleston, MBA, Business Development Director, Belgian Volition, A Volition Company, Belgium

Nucleosomics® is an immunoassay epigenetic profiling approach for novel blood-based biomarker development. Cell free nucleosomes include histone modifications and variants, DNA modifications and adducts between nucleosomes and non-histone proteins which can be correlated with clinical disease and overcomes a major limitation of simple nucleosome quantification for diagnostic and prognostic use.

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

11:15 Dynamic Changes in EGFR Mutation Circulating Tumor DNA in Urine on Anti-EGFR Therapy

Hatim Husain, M.D., Physician, Medical Oncology, University of California, San Diego, United States

We have been able to monitor early drug response to anti-EGFR therapy to model tumor lysis. We will be presenting data on pretreatment kinetics and dynamic changes in ctDNA for patients on therapies directed against KRAS. The data presented will be evaluating urine as a modality for monitoring ctDNA.

11:45 Epigenetically Altered Circulating Nucleosomes - Validation of a New Screening Paradigm for Cancer

Marielle Herzog, Ph.D., Lead Scientist, Nucleosomics, Belgian Volition, Belgium

Genome-wide epigenetic signals are altered in cancer cells. We have developed ELISA tests for circulating nucleosomes (NuQ®) and show that the profile of epigenetic features, including histone modifications and variants, DNA modifications can be correlated with clinical disease and overcomes a major limitation of simple nucleosome quantification for diagnostic and prognostic use. We present the results of a large clinical study using a cohort of several thousand subjects for a novel NuQ® based CRC diagnostic test.

12:15 Plasma DNA Sequencing Using a Comprehensive NGS Panel as a Tissue Biopsy Surrogate

Sponsored by sequenom

Daniel Grosu, M.D., MBA, CMO, Clinical and Medical Affairs, Sequenom, Inc., United States

The use of "liquid biopsies" for profiling potentially actionable genomic alterations, when biopsy material is not available, is a rapidly emerging application in Oncology. We review the performance of a comprehensive panel that interrogates several classes of genomic alterations in a large number of cancer-related genes across multiple tumor types.

12:30 Sponsored Presentation *(Opportunity Available)*

12:45 Application of Circulating Cell Free Tumor DNA

Sponsored by TECAN

Theresa Zhang, Ph.D., Vice President, Research Services, Personal Genome Diagnostics

Circulating cell-free tumor DNA (ctDNA) are small DNA fragments shed from tumors and carrying tumor-specific somatic alterations. Recent advances in digital PCR and Next Generation Sequencing technologies have made it feasible to detect and quantify ctDNA reliably, making the non-invasive ctDNA analysis an effective alternative to serial tumor biopsies. In this talk we will discuss applications of ctDNA for clinical uses and for drug development R&D, as well as the future of ctDNA as potential companion diagnostics.

13:15 Session Break

14:15 Dessert Break in the Exhibit Hall with Poster Viewing

ctDNA IN PATIENT STRATIFICATION AND THERAPY PREDICTION

14:55 Chairperson's Remarks

David I Smith, Ph.D., Professor, Laboratory Medicine and Pathology; Chairman, Technology Assessment Group, Center for Individualized Medicine, Mayo Clinic, United States

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15:00 Mate-Pair Sequencing of Oropharyngeal Squamous Cell Carcinoma Identifies Cancer-Specific Markers to Enable Liquid Biopsies to Monitor Patients

David I Smith, Ph.D., Professor, Laboratory Medicine and Pathology; Chairman, Technology Assessment Group, Center for Individualized Medicine, Mayo Clinic, United States

Mate-pair sequencing is a very powerful tool to characterize molecular alterations that occur during the development of cancer. We have been performing mate-pair sequencing of oropharyngeal squamous cell carcinomas, a cancer that has seen an epidemic increase due to human papillomavirus. The data provided by mate-pair sequencing can determine when and where HPV integrates into these cancers. We will describe how we plan to use mate-pair sequencing as a clinical test for these cancer patients.

15:30 Using Droplets to Highlight and Follow Cancer Genetic Markers

Valerie Taly, Ph.D., Group Leader, CNRS Researcher, UMR S1147, University of Paris Descartes, France

Droplet-based digital PCR allows the highlighting of rare genetic events with an unprecedented sensitivity. After a rapid technical presentation, application of this methods for cancer patient follow-up will be presented.

16:00 Tumor Genome Monitoring by Whole Genome Sequencing of Plasma DNA

Michael R. Speicher, M.D., Professor and Chairman, Institute of Human Genetics, Medical University of Graz, Austria

Liquid biopsies, i.e. the analyses of circulating tumor cells (CTCs) or circulating tumor DNA (ctDNA), are evolving to promising tools for monitoring changes in cancer genomes non-invasively. We establish genome-wide copy number profiles of the tumor by whole-genome sequencing from plasma of patients with cancer at a shallow sequencing depth and sequence high-interest genes with high coverage. Data of patients with breast, colon, lung, and prostate carcinoma will be presented.

16:30 Manual and Automated Cell-Free DNA from Plasma, Serum and Urine for Liquid Biopsy

Sponsored by ThermoFisher SCIENTIFIC

Susan Magdaleno, Ph.D., Senior Manager, Research & Development, Thermo Fisher Scientific

Critical to implementing a diagnostic biomarker for cell free DNA (cfDNA) is consistent and efficient isolation of nucleic acid from body fluids. The MagMAX™ Cell-Free DNA isolation kit is a new product that isolates cfDNA from liquid biopsy samples using a fast 35 minute workflow. We will discuss dPCR and NGS results generated by various customer test labs that used the MagMAX™ cfDNA isolation kit to isolate cfDNA from their plasma, serum and urine samples.

17:00 Refreshment Break

17:15 Monitoring Cell Free DNA in Patients Receiving Selective Internal Radiation for Liver Metastases and Intrahepatic Cholangiocarcinoma

Helen Winter, M.D., Clinical Research Fellow, Oncology, University of Oxford, United Kingdom

Preliminary results of cfDNA from PERFORM, a prospective imaging biomarker study in which 21 patients with liver malignancies have undergone selective internal radiation therapy (SIRT) as management for metastatic liver dominant disease are presented.

17:45 Circulating Free DNA in Metastatic Colorectal Cancer

Karen-Lise Garm Spindler, M.D., Ph.D., Specialist GI Oncologist, Aarhus University Hospital; Associate Professor, Oncology, Institute of Clinical Medicine, Aarhus University, Denmark

Colorectal tumors harbour a high frequency of clinically relevant genetic alteration, which are readily detected in the cfDNA, and suggested for tailoring palliative therapy, and monitoring during treatment. The total levels of cell free DNA in itself seems to hold strong prognostic value. This presentation will give an overview of both methodological, biological and clinical aspects of cfDNA and tumor specific mutations in metastatic colorectal cancer, based on the most current data.

18:15 Close of Conference

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(Includes access to one conference)

	Commercial	Academic, Government, Hospital-Affiliated
Registrations after 11 March 2016 and on-site	€1499	€699

CONFERENCE SELECTIONS

Monday-Wednesday, 4-6 April	Wednesday-Thursday, 6-7 April
Advances in Prenatal Molecular Diagnostics	Reproductive Genetic Diagnostics
Tuesday-Wednesday, 5-6 April	**Wednesday-Thursday, 6-7 April**
Advanced Diagnostics for Infectious Disease	Point-of-Care Diagnostics
Circulating Tumour Cells	Circulating Cell-Free DNA

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Poster Submission Discount (€45 Off) Poster abstracts are due by 4 March 2016. 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.

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Register 3 - 4th is Free! Individuals must register for the same conference or conference combination and submit completed registration form together for discount to apply.

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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.

To view our Substitutions/ Cancellations Policy, go to healthtech.com/regdetails

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