9:00 Chairperson's Remarks
Art Beaudet, M.D., Department of Molecular & Human Genetics, Baylor College of Medicine

9:05 Prenatal DNA Sequencing: Clinical, Counseling, and Diagnostic Laboratory Considerations
Ahmad N. Abou Tayoun, Ph.D., Assistant Professor, Pathology and Laboratory Medicine, Children's Hospital of Philadelphia, University of Pennsylvania Perelman School of Medicine

Whole genome and exome sequencing on fetal is starting to be offered clinically in specialized centers, but it has not yet become routine practice. The technical, interpretation, and ethical challenges are greatest in the area of prenatal medicine because the fetus has a limited health history, and the physical examination is only indirectly available via prenatal sonography. This talk will describe an overview of these challenges and highlight the clinical utility, reporting, and counseling issues associated with prenatal DNA sequencing, as well as future considerations.

9:35 Prenatal Exome Sequencing in Anomalous Fetuses: New Opportunities and Challenges
Neeta Vora, M.D., Associate Professor, Department of OB GYN, Division of Maternal-Fetal Medicine, University of North Carolina Chapel Hill

Exome sequencing has utility in determining an underlying molecular etiology when performed on fetal specimens from pregnancies with structural abnormalities where standard genetic testing (karyotype and microarray) do not provide a diagnosis. Challenges related to genetics literacy and variant interpretation must be addressed by highly tailored pre- and post-test genetic counseling.

10:05 Implementation Considerations for Fetal Whole Exome Sequencing
Ignatia B. Van den Veyer, M.D., Professor, Obstetrics & Gynecology and Molecular Human Genetics, Baylor College of Medicine

Fetal diagnostic exome sequencing has the potential to significantly improve the identification of the genetic cause of fetal abnormalities detected on ultrasound imaging and in high-risk families. The responsible and effective implementation of fetal diagnostic exome sequencing into prenatal care is complex and still at early stages. Overview of current knowledge, research needs and case studies will be presented to highlight ethical, practical and counseling issues that must be considered.

10:35 Networking Coffee Break

10:55 WES for Recurrent Pregnancy Loss
Evica Rajcan-Separovic, Clinical Professor, University of British Columbia, Fellow Canadian College of Medical Genetics (Cytogenetics); Laboratory Scientist, Pathology and Laboratory Medicine, Children's and Women's Hospital of British Columbia

Epidemiological evidence suggests that genetic factors play a significant role in pathogenesis of miscarriage, and that both the fetal/placental and the parental genotypes are involved. The majority of miscarriages are sporadic; however, ~3-5% of couples trying to have children experience recurrent miscarriage. My talk will highlight advances in approaches to help diagnosis of recurrent miscarriage by identifying genetic abnormalities in miscarriages and couples using high resolution genomic technologies.

11:25 Effect of Maternal Cell Contamination on Prenatal NGS Testing
Heather Mason-Suares, Ph.D., FACMG, Associate Director, Pathology, Laboratory for Molecular Medicine and Brigham & Women's Hospital, Cytogenetics Laboratory

Maternal cell contamination (MCC) poses a significant risk for prenatal misdiagnosis in molecular diagnostics. However, the effect of MCC on the interpretation of NGS results is not well studied. Such characterization is extremely important as NGS is rapidly becoming the standard of care in prenatal molecular diagnostics for high risk pregnancies. This talk examines how MCC may confound NGS testing, causing erroneous interpretation of clinical results and affecting pregnancy management.

11:55 Introduction of Process Automation for the Quality Improvement of NIPT as Exemplified by the PrenaTest®
Wera Hofmann, CSO, LifeCodexx

The worldwide increasing use of non-invasive prenatal testing (NIPT) in clinical practice, the growing regulatory requirements and the national efforts for reimbursement are enforcing the need for further improvements of the applied methods. Pre-analytical laboratory processes such as automated solutions for cfDNA extraction to allow higher throughput and improved reproducibility of the method at lower cost are of high importance. The example of PrenaTest® describes such a successful development.

12:25 pm Luncheon Presentation (Sponsorship Opportunity Available) or Enjoy Lunch on Your Own

12:55 Session Break

1:55 Chairperson's Remarks
Patrizia Paterlini-Brechot, Ph.D., M.D., Cellular & Molecular Biology, University Paris Descartes
2:00 An Examination of PreSeek, a Non-Invasive Multi-Gene Sequencing Screen
Christine Eng, M.D., CMO, Chief Quality Officer, Baylor Genetics; Professor, Molecular and Human Genetics, Baylor College of Medicine
The PreSeek development team carefully selected genes for this non-invasive single gene detection platform by a thorough curation process focused on the detection of de novo variants in single gene disorders affecting the skeletal, cardiac, and neurological systems. Although traditional NIPT detects abnormalities that increase in risk with advanced maternal age, PreSeek is the first non-invasive test to detect disorders that may become more prevalent with advanced paternal age. Early clinical experience with this test demonstrates the use of this test in several different clinical situations including fetuses with ultrasound abnormalities.

2:30 (Mis)adventures in NIPT Confirmatory Testing
Stephen R. Moore, MBA, Ph.D., FACMG, Lab Director, Cytogenetics and Molecular Diagnostics; Assistant Professor, Molecular and Medical Genetics, Knight Diagnostics Labs, Oregon Health and Science University
Current recommendations are that all positive non-invasive prenatal testing (NIPT) be confirmed by one of two invasive tests, chorionic villi sampling or amniocentesis. There are many factors, technical and biological, that may lead to discordance between NIPT results and the result of the confirmatory test. This talk will outline such factors and provide examples from our own experience as a confirmatory testing center.

3:00 Extending the Scope of Prenatal Diagnosis for Monogenic Disorders: Non-Invasive Prenatal Diagnosis
Lyn Chitty, Ph.D., MBBS, MRCOG, Professor, Genetics and Genomic Medicine, UCL Great Ormond Street Institute of Child Health and North-East Thames Regional Genetics Service, Great Ormond Street Hospital for Children NHS Foundation Trust
We collaborated with the semiconductor and AI sectors to produce an automated system based on nanostructure, microfluidics, and user-friendly computer analysis software, of which the following steps are automatically processed: capturing both the fetal nucleated RBCs and cytotrophoblasts, machine learning identification, followed by the isolation of the captured cells. The isolated cells can then be subjected to WGA and the subsequent aCGH or NGS analyses. The in situ captured cells can be subjected to FISH analysis. We also compared the results of this cell-based system to our in-house devised cfDNA testing (the algorithm called "GWNS") in our CAP-certified core NIPT lab. The advantage of this "Cell Reveal" system is it may solve the problem of fetoplastic mosaicism, and can possibly revive the field of traditional cytogenetics.

3:30 Refreshment Break in Exhibit Hall with Poster Viewing

4:10 Cell-Based Non-Invasive Prenatal Diagnosis by Capturing Cytotrophoblasts and Fetal Nucleated RBC by Nanostructured Microfluidics and Its Comparison with In-House Developed cfDNA Testing
Ming Chen, M.D., Ph.D., CEO, Department of Genomic Science and Technology, Changhua Christian Hospital Healthcare System, Taiwan; Adjunct Associate Professor, Department of Obstetrics and Gynecology, National Taiwan University, Taiwan; Honorary Co-Founder, Cytoaurora Biotechnologies, Inc., Hsinchu Science Park, Taiwan; Honorary CSO, Golden Meditech Holdings Limited (HKSE)
We collaborated with the semiconductor and AI sectors to produce an automated system based on nanostructure, microfluidics, and user-friendly computer analysis software, of which the following steps are automatically processed: capturing both the fetal nucleated RBCs and cytotrophoblasts, machine learning identification, followed by the isolation of the captured cells. The isolated cells can then be subjected to WGA and the subsequent aCGH or NGS analyses. The in situ captured cells can be subjected to FISH analysis. We also compared the results of this cell-based system to our in-house devised cfDNA testing (the algorithm called "GWNS") in our CAP-certified core NIPT lab. The advantage of this "Cell Reveal" system is it may solve the problem of fetoplastic mosaicism, and can possibly revive the field of traditional cytogenetics.

4:40 Panel Discussion: Cell-Free vs. Cell-Based NIPT
Art Beaudet, M.D., Department of Molecular & Human Genetics, Baylor College of Medicine
Palle Schelde, CEO, ARCEDI Biotech Aps
Ming Chen, M.D., Ph.D., CEO, Department of Genomic Science and Technology, Changhua Christian Hospital Healthcare System, Taiwan; Adjunct Associate Professor, Department of Obstetrics and Gynecology, National Taiwan University, Taiwan; Honorary Co-Founder, Cytoaurora Biotechnologies, Inc., Hsinchu Science Park, Taiwan; Honorary CSO, Golden Meditech Holdings Limited (HKSE)
With cell-based noninvasive prenatal testing coming closer and closer to commercialization, those in industry and in the clinic need to consider how these tests differ, their advantages and limitations, and which is the best course to take for patients. Panellists will discuss scientific, insurance and reimbursement, and ethical considerations to take into account.

5:40 Networking Reception in Exhibit Hall with Poster Viewing
7:10 Close of Day
WEDNESDAY, NOVEMBER 29
8:00 am Breakfast Breakout Roundtable Discussions
ISOLATION AND ANALYSIS OF FETAL CELLS FROM MATERNAL BLOOD
9:00 Chairperson’s Remarks
Heather Mason-Suares, Ph.D., FACMG, Associate Director, Pathology, Laboratory for Molecular Medicine and Brigham & Women’s Hospital, Cytogenetics Laboratory
9:05 Reasons for the Elusiveness of Cell-Based NIPT
Art Beaudet, M.D., Department of Molecular & Human Genetics, Baylor College of Medicine
Researchers have struggled to develop clinical testing in the form of cell-based NIPT. The rarity of fetal cells in the mother's blood is perhaps the biggest challenge. At least three forms of testing are desirable: 1) detection of inherited Mendelian disorders, 2) genome-wide detection of copy number abnormalities at the highest possible resolution, and 3) genome-wide detection of de novo point mutations. Various combinations of methods will be required to achieve all of these goals.

9:35 Technical Advances for Isolation and Genetic Analysis of Circulating Trophoblastic Cells
Patrizia Paterlini-Brechot, Ph.D., M.D., Cellular & Molecular Biology, University Paris Descartes
Circulating fetal cells offer an interesting opportunity to analyze fetal DNA not mixed with maternal DNA aiming to develop a non-invasive approach for prenatal genetic diagnosis (NI-PND). Critical issues for this goal are the number of fetal cells which can be recovered from a blood sample, the purity of cell recovery, the quality of the recovered fetal cells DNA and the assay workflow allowing to develop a high-throughput analysis generating reliable results at a very affordable price. We will show results using the ISET patented method to isolate trophoblastic cells without the use of antibodies and analyze their DNA for non-invasive prenatal diagnosis. We will discuss the different critical issues and the possible solutions in order to bring to the market a new test for NI-PND.
10:05 Advances in Cell-Based Non-Invasive Prenatal Diagnosis
Ripudaman Singh, Ph.D., COO, ARCEDI Biotech Aps
In the last few years, advances in fetal cell enrichment and detection technologies have invigorated interest in using these rare cells for cell-based non-invasive prenatal diagnosis (cbNIPD). By using a proprietary technology, we have shown that we can isolate fetal cells from every pregnant sample and use the DNA from isolated fetal cells to detect chromosomal and sub-chromosomal changes in the fetal genome. The results from the cbNIPD were verified by the results from chorionic villi sampling. Having performed a preliminary study for implementing our method in a clinical setup, we are in the process of launching a cell-based clinical test in Denmark. In this test, results from the cell-based prenatal analyses on high risk pregnancies will be compared with cell-free non-invasive prenatal testing (cfNIPD). The aim of this clinical test will be to replace cfNIPD with a more superior alternative, based on fetal cells from maternal blood.

10:35 Coffee Break in Exhibit Hall with Poster Viewing

11:15 Imprinted NanoVelcro Microchips for Isolation and Characterization of Circulating Fetal Trophoblasts – Toward Noninvasive Prenatal Diagnostics
Shuang Hou, Ph.D., Senior Research Scientist, Department of Surgery, University of California, Los Angeles
Circulating fetal nucleated cells (CFNCs) in maternal blood offer an ideal source of fetal genomic DNA for noninvasive prenatal diagnostics (NIPT). We developed a new class of NanoVelcro Microchips to effectively enrich a subcategory of CFNCs, i.e., circulating trophoblasts (cTBs) from maternal blood. Our results support the use of NanoVelcro Microchips for cTB-based noninvasive prenatal genetic testing, which holds potential for further development toward future NIPT solution.

11:45 TRIC: Safe Prenatal Testing with Pap Smears to Interrogate the Fetal Genome and Pregnancy Health
D. Randall Armant, Ph.D., Professor, Obstetrics and Gynecology, Wayne State University School of Medicine
Trophoblast Retrieval and Isolation from the Cervix (TRIC) is a safe, noninvasive procedure that captures fetal cells migrating from the placenta as early as three weeks post-conception. TRIC holds promise for prenatal genetic testing and risk assessment of obstetrical complications. Isolated trophoblast cells provide fetal DNA for comprehensive analysis of the fetal genome. Additionally, their molecular profiles are associated with subsequent onset of preeclampsia, fetal growth restriction and miscarriage.

12:15 pm Expanded Carrier Screening: Diagnostic Yield and Unexpected Findings
Lisa Edelman, Ph.D., FACMG, Associate Professor, Department of Genetics and Genomic Sciences at the Icahn School of Medicine at Mount Sinai
Expanded carrier screening has the highest yield when a sequence-based approach is used to interrogate the coding regions of genes with supplementation by additional methodologies for regions of the genome in which sequencing is not adequate. The infrastructure necessary to build a high-throughput NGS-based carrier screen includes automation, extensive sequencing capacity and a multifaceted bioinformatics solution that allows for batch analysis, export and reporting. Data on over 150,000 individuals will be presented.

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

1:15 Session Break

2:15 Delivering a Prenatal Diagnosis of Down Syndrome: Lessons Learned from Evidence-Based Literature
Brian Skotko, M.D., Co-Director, Down Syndrome Program, Massachusetts General Hospital
In this presentation, Dr. Brian Skotko reviews the evidence-based research on how physicians can effectively deliver a prenatal diagnosis of Down syndrome. When should the diagnosis be given? How should the news be best delivered? Who should convey the information? What should be mentioned in that initial conversation? The presentation includes highlights from his publications in Pediatrics, American Journal of Obstetrics and Gynecology, and American Journal of Medical Genetics.

2:45 Meeting the Balance of Supply and Demand of Genetic Counselors
Katie Stoll, MS, LGC, Director, Clinical Services, Genetic Support Foundation
Genetic counselors are instrumental to the successful application of new genetic technologies into clinical practice. They help to ensure that genetic testing is used appropriately and also translate complex results into meaningful information for patients and other healthcare providers. The dramatic expansion of genetic testing technology has created many new opportunities for genetic counselors and has also created workforce challenges. In this presentation, we will consider the changing employment landscape of genetic counselors and the implications for genetic services. Alternative delivery models and innovative tools for supporting patient education and informed decision making will also be presented.

3:15 Integrative Omics in the Study of Preeclampsia
Rachel Kelly, BSc(Hons), MPH, Ph.D., Research Fellow, Channing Division of Network Medicine, Brigham and Women's Hospital Harvard Medical School
Omic technologies including metabolomics, transcriptomics and proteomics represent novel methods for the development of predictive, diagnostic and prognostic biomarkers of preeclampsia, as well as a means of identifying preeclampsia endotypes. Integration of multiple omic-based biomarkers representing different hierarchical stages of the central biological dogma, additionally provides a global systems biology view of the pathogenesis of this disorder. In this talk, we will demonstrate the utility of integrative omic analyses in the study of and management of preeclampsia.

3:45 Refreshment Break in Exhibit Hall with Poster Viewing

4:30 Closing Panel: Predicting the Landscape for Prenatal Molecular Diagnostics: The Next Few Years
There are a number of advancements that the prenatal field will pursue: cell-based NIPT, NIPT for microdeletions, biomarkers for preeclampsia and preterm birth, and ultimately patient and physician education. This panel will discuss future directions for the field and potential directions for these areas.

5:30 Close of Advances in Prenatal Molecular Diagnostics
Advances in Preimplantation and Infertility Diagnostics

November 30 – December 1, 2017 • Cambridge, MA • Hyatt Regency Cambridge

THURSDAY, NOVEMBER 30

7:30 am Registration

KEYNOTE SESSION

8:55 Chairperson’s Remarks
Mark Umbarger, Ph.D., Director, Research and Development, Good Start Genetics

9:00 KEYNOTE PRESENTATION: Single Cell Whole Genome Amplification Technologies and the Future of Chromosome Screening
Xiaoliang Sunney Xie, Ph.D., Mallinckrodt Professor, Chemistry and Chemical Biology, Harvard University

Preimplantation genetic screening (PGS) has been widely used to select in vitro fertilized embryos free of chromosomal abnormalities and to improve the clinical outcome of in vitro fertilization (IVF). A disadvantage of PGS is that it requires biopsy of the preimplantation human embryo, which can limit the clinical applicability of PGS due to the invasiveness and complexity of the process. We have developed a noninvasive chromosome screening (NICS) method based on sequencing the genomic DNA secreted into the culture medium from the human blastocyst. The NICS method offers the potential of much wider chromosome screening applicability in clinical IVF, due to its high accuracy and noninvasiveness.

PGD FOR MOSAICISM

9:30 Biopsy Techniques: How Do They Affect PGD Results and Where May We Be Going?
Catherine Racowsky, Professor, Department of Obstetrics, Gynecology & Reproductive Biology, Harvard Medical School; Director, IVF Laboratory, Brigham & Women’s Hospital

As methods for PGS testing have evolved, so has awareness of embryonic mosaicism. The clinical significance of mosaicism is not well understood, but mosaic embryos have resulted in healthy live births. Some mosaic embryos, however, may be diagnosed as aneuploid and potentially be discarded despite an unclear potential for healthy live birth. This talk will discuss our study which examined the rate of low-level mosaicism in blastocysts that were classified as euploid and the relative pregnancy rates compared with blastocysts in which no mosaicism was detected.

10:30 Coffee Break in the Exhibit Hall with Poster Viewing

10:40 Determination of the Karyotypic Concordance between Trophoderm and Inner Cell Mass
Andrea Victor, MS, Embryologist/Head of PGS Laboratory, Embryology and Human Molecular Genetics, Zouves Fertility Center

PGS on blastocysts is based on the premise that a TE biopsy is representative of the ICM. Previous studies testing the karyotypic concordance between TE and ICM have used small sample size and/or currently dated technologies. Here, we present data on a NGS-based analysis of concordance between TE and ICM in a large group of embryos, showing that a small but relevant percentage of blastocysts are discordant.

11:10 Low Level Mosaicism: Incidence and Implications on Clinical Pregnancies
Dawn Kelk, Ph.D., Director, IVF Laboratory, Yale University School of Medicine

As methods for PGS testing have evolved, so has awareness of embryonic mosaicism. The clinical significance of mosaicism is not well understood, but some mosaic embryos, however, may be diagnosed as aneuploid and potentially be discarded despite an unclear potential for healthy live birth. This talk will discuss our study which examined the rate of low-level mosaicism in blastocysts that were classified as euploid and the relative pregnancy rates compared with blastocysts in which no mosaicism was detected.

12:10 pm Sponsored Presentation (Opportunity Available)

12:40 Luncheon Presentation (Sponsorship Opportunity Available) or Enjoy Lunch on Your Own

1:10 Dessert Break in the Exhibit Hall with Poster Viewing

1:50 Chairperson’s Remarks
Tim Jenkins, Ph.D., Assistant Professor, Surgery (Division of Urology), University of Utah

1:55 Embryonic Mosaicism: Clinical Interpretation and Genetic Counseling
Andria G. Besser, MS, CGC, Genetic Counselor, NYU Fertility Center, NYU Langone Medical Center

Discussion of the clinical implications of a diagnosis of embryonic mosaicism, with particular emphasis on counseling patients about this type of result, both prior to and after preimplantation genetic screening, as well as during the prenatal period.
PGD and PGS can be performed concurrently using a small sample of biopsied trophectoderm cells, but despite the many advantages of PGS and ease of dual-screening, this has not yet become standard practice. Understanding the clinical advantages of combining PGD with PGS, measured against the potential downsides, is key to determining how the practice of PGD should evolve to improve clinical outcomes. Data will be discussed comparing outcomes of PGD with and without concurrent aneuploidy screening to explore the clinical value of dual-screening.

5:15 Close of Day

FRIDAY, DECEMBER 1

8:00 am Breakfast Breakout Roundtable Discussions

BIOMARKERS FOR INFERTILITY AND IMPLANTATION FAILURE

8:55 Chairperson's Remarks

Kara N. Goldman, M.D., FACOG, Assistant Professor, Obstetrics and Gynecology, Division of Reproductive Endocrinology and Infertility, New York University Langone Medical Center

9:00 Quantifying Mitochondrial DNA to Predict Implantation: Myth or Reality

Manuel Viotti, Ph.D., Senior Scientist, Embryology and Human Molecular Genetics, Zouves Fertility Center

The quantity of mitochondrial DNA in an embryo has been proposed as a biomarker of implantation, but recent studies have challenged this concept. Why is there discordance between different reports, and should it be used as a predictive tool in the clinic?

9:30 Immunologic Testing and Treatment Prior to IVF and for Recurrent Pregnancy Loss

Scott Morin, MD, FACOG, Fellow, Reproductive Endocrinology and Infertility, Reproductive Medicine Associates of New Jersey/Thomas Jefferson University

Amongst the factors which affect implantation failure of apparently reproductively competent embryos, the immune system has been perhaps both the most plausible and the most debated. Many investigators have developed and employed a wide range of immune tests and treatments aimed at manipulating the milieu to favor implantation. While the knowledge of the immune system's role in implantation is certain, our understanding of the physiology, let alone the pathophysiology, remains incomplete. It is imperative that we gain more clear evidence of cause and in order to test and implement treatment paradigms. In the meantime, immune testing or empiric treatment with immune modulators must be approached with caution.

10:00 Uncovering Novel Cytogenetic and Molecular Etiologies for Male Infertility

Samantha Schilit, MA, Ph.D. Candidate, Genetics, Harvard Medical School

Identifying genes involved in unexplained infertility not only informs an understanding of the mechanisms regulating fertility, but also provides information to support diagnosis, genetic counseling and eventual therapeutic intervention. In this study, we identified dysregulation of SYCP2 in a man with oligospermia and 46,XY(10;22)(q13.3;q11.2). Using patient LCL, budding yeast, and mammalian
models, we have dissected the molecular mechanisms underlying both SYCP2 misexpression as well as the resulting male infertility.

10:30 Sponsored Presentation (Opportunity Available)

11:00 Coffee Break

**DIAGNOSTIC POTENTIAL OF SPERM EPIGENETICS**

11:20 Chairperson's Remarks
Manuel Viotti, Ph.D., Senior Scientist, Embryology and Human Molecular Genetics, Zouves Fertility Center

11:25 Germline Epigenetics: Potential Diagnostic Utility for Fertility, Embryogenesis, and Offspring Health
Tim Jenkins, Ph.D., Assistant Professor, Surgery (Division of Urology), University of Utah

Sperm epigenetic patterns may offer clues to both spermatogenic abnormalities as well as reproductive potential and offspring health. We explore these important marks and their role in infertility, embryogenesis, and even offspring disease susceptibility. Further, we will discuss the efficacy of using epigenetic data in diagnostic testing.

11:55 Diagnostics for Male Infertility Foreshadowing the Future
Stephen Krawetz, Ph.D., Charlotte B. Failing Professor of Prenatal/Fetal Diagnosis

and Therapy, Ob/Gyn and Molecular Medicine & Genetics, Wayne State University School of Medicine

Next generation approaches are being developed to understand the information that Dad delivers upon fertilization. One example is sperm RNA elements that identify those males who are likely to father a child and that provide the opportunity to assess his current state of being and the possible state of the next generation. Interim analysis has also suggested their usefulness as surrogates of exposures.

12:25 pm Close of Reproductive Genetic Diagnostics
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