

# 2023 US SUMMIT OF LABORATORY MEDICINE INNOVATIONS



JANUARY 12TH-14TH, 2023

The Woodlands Resort, Curio Collection by Hilton  
Houston, TX

# HOSTING ASSOCIATIONS

Alliance for Laboratory Medicine Innovation (ALMI), *supported by Foundation for Laboratory Medicine Innovation (FLMI)*

North American Chinese Clinical Chemists Association (NACCCA);

Chinese American Pathologist Association-Clinical Pathology Education Division (CAPA-CP);

Sino-American Pharmaceutical Professionals Association-Medical Device & Diagnostic Community (SAPA-MDDC)

# INVITED PARTICIPANTS

\*This meeting is by invitation-only. More speakers and panelists information in the back.

**Invited speakers and participants are decision-makers and experts in the field of laboratory medicine and in vitro diagnosis, including:**

**Medical directors from laboratories of:**

- Chemistry & Immunology
- Molecular & HLA
- Microbiology & Infectious disease
- Transfusion & Coagulation
- Hematology & Hematopathology

AND from institutions, e.g.

- MD Anderson Cancer Center
- Memorial Sloan Kettering Cancer Center
- Tulane University Medical Center
- UTMB Health at Galveston
- Texas Children Hospital
- Weill Cornell Medicine
- University of Kentucky Healthcare
- Duke University Medical Center
- St. Jude Children's Research Hospital
- UT Southwestern Medical Center
- Houston Methodist Hospital
- Stanford University Medical Center
- Baylor College of Medicine
- Northwestern University

**Leaders from international laboratory medicine associations, e.g.**

- ALMI, NACCCA, CAPA-CP, SAPA-MDDC

**Representatives of IVD industry & legal and regulatory consultant, including CEO, CMO or founders from e.g.**

- Danaher & Cepheid China
- Wanda Henry
- Biotime Biotechnology
- AdvanBio & Autobio
- ET Healthcare
- XYZSure
- Intelligene Biosystems
- NanoBiotec
- EmerTher
- Protogo Biotechnologies
- ProCaliber
- Breiten Associates

# WELCOME ADDRESS

Dear Colleagues and Friends,

On behalf of the Organizing Committee, I cordially invite you to participate in the 2023 US Summit of Laboratory Medicine Innovations.

During the meeting, we will celebrate the establishment of a new non-profit organization: Alliance for Laboratory Medicine Innovation (ALMI) to promote communication among clinical pathologists and laboratory medicine professionals and to promote strategic cooperation between laboratory directors, in vitro diagnostics industry leaders, and regulatory experts.

At the beautiful and comfortable Woodlands Resort, Curio Collection by Hilton in Houston, Texas, the Organization Committee has arranged an attractive, two full-day conference program for you. In addition to academic programs covering different disciplines of laboratory medicine, several social programs are meticulously designed which include network reception, outdoor networking, and winery tour at the wild station vineyards. The Summit will also be an informal platform for exchange of information, experiences and innovations between pathologists and scientists, and academia and industry.

Let's get together to do something mutually beneficial. Have fun.



Yi-Wei Tang, MD, PhD  
CMO, Danaher & Cepheid China  
President, ALMI

## ORGANIZING COMMITTEE

Yi-Wei Tang, MD, PhD  
CMO, *Danaher & Cepheid China*  
President, ALMI

Jian Chen, MD, PhD  
Associate Professor, *Houston Methodist Hospital & Weill Cornell Medical Center*  
Vice President, ALMI  
Chair, CAPA-CP

Jing Cao, PhD  
Associate Professor, *University of Texas Southwestern Medical Center*  
Treasurer, ALMI

Xin Yi, PhD  
Associate Professor, *Houston Methodist Hospital & Weill Cornell Medical Center*  
Secretary, ALMI

Zhen Zhao, PhD  
Professor, *Weill Cornell Medicine & New York Presbyterian Hospital*  
Board of Director, ALMI

He Yang, PhD  
Associate Professor, *Weill Cornell Medicine & New York Presbyterian Hospital*  
President, NACCCA

Yongmei Li, PhD  
CEO, *EmerTher*  
President, SAPA

## MEETING SPONSORS



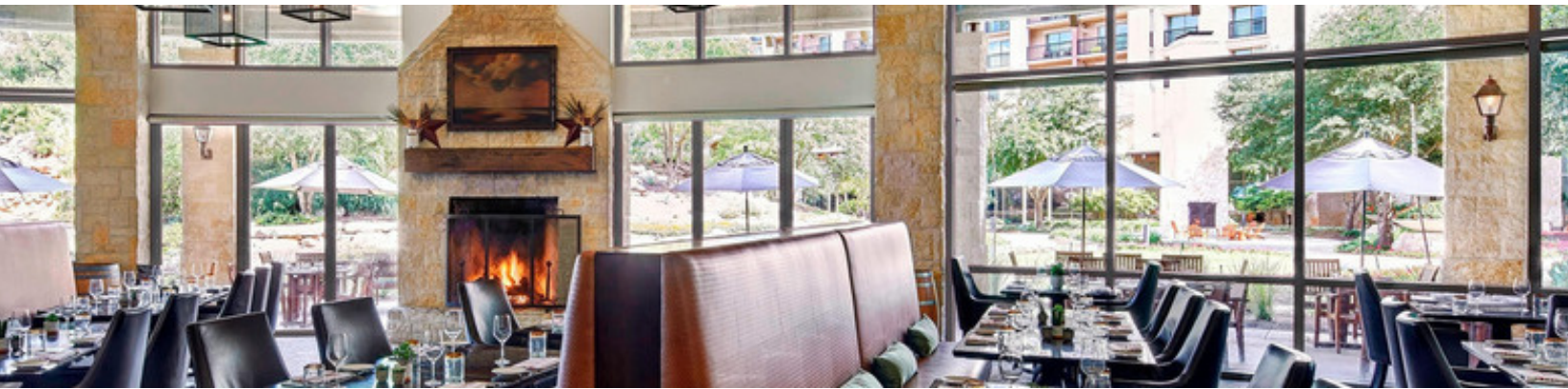
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# MEETING

## AIMS

- Promote communication among clinical pathologists and laboratory medicine professionals
- Promote strategic cooperation between laboratory directors, IVD industry leaders, and regulatory experts



## MEETING THEME

### Emerging Diagnostic Innovations in Laboratory Medicine

- Existing pain points that urgently need technological breakthroughs
- Technology innovation and emerging diagnostics
- Technology implementation in clinical settings
- Market opportunity and collaboration among key stakeholders
- Regulatory strategies in post-pandemic era
- Artificial intelligence and digital diagnostics
- Diagnostic topics, e.g. epigenetic markers in tumor diagnosis, infectious disease diagnostics, point-of-care, early diagnosis of high risk diseases, companion diagnostics, laboratory tools for immuno-&cell-therapy.

# CONFERENCE PROGRAM



**JAN 12 - PM**

Resort Conference Center - Glass Ballroom



7:00PM-9:00PM

Network Reception

**JAN 13 - AM**

Resort Conference Center - Spanish/Republic Room

7:00AM-8:00AM

Breakfast Buffet - All American Breakfast



## **KEYNOTE TALK**

8:00AM-8:30AM

***The Evolution of SARS-CoV-2 During the Pandemics and The Implication to Laboratory Innovation***

Xiao-Ming Yin, MD, PhD. Chair & Professor of Department of Pathology & Lab Medicine, Tulane University



## **CHEMISTRY/LAB GENERAL**

8:30AM-9:10AM Featured Talks

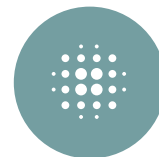
***Machine Learning in Clinical Laboratory Medicine: Challenges and Pitfalls***

He Sarina Yang, PhD, Associate Professor, Weill Cornell Medicine & New York Presbyterian Hospital

***Top-Down Mass Spectrometry Study of Proteoforms: A New Dimension in the Measurement of Protein Markers***

Yiqi Ruben Luo, PhD, Assistant Professor, Stanford Health Care

# CONFERENCE PROGRAM



**JAN 13 - AM**

Resort Conference Center - Spanish/Republic Room

## **CHEMISTRY/LAB GENERAL (Cont)**

9:10AM-9:55AM Panel Discussion

### ***Hot Topics in Clinical Chemistry: Emerging Technologies and Innovations***

Qing H. Meng, MD, PhD, Professor, UT MD Anderson Medical Center (Moderator)

Min Yu, MD, PhD, Assistant Professor, University of Kentucky Healthcare

Rongrong Huang, PhD, Assistant Professor, Ben Taub Hospital/Baylor College of Medicine

Yiqi Ruben Luo, PhD, Assistant Professor, Stanford Health Care

9:55AM-10:05AM Coffee Break

## **HEMATOLOGY/HEMATOPATHOLOGY/COAG**

10:05AM-10:45AM Featured Talks

### ***Aptamer-Mediated Molecular-Immunoassays for Disease Diagnosis***

Youli Zu, MD, PhD, Professor, Houston Methodist Hospital, Weill Cornell Medical College

### ***Digital Pathology and Artificial Intelligence as The Next Chapter In Diagnostic Hematopathology***

Mingyi Chen, MD, PhD, Professor, University of Texas Southwestern Medical Center

10:45AM-11:30 AM Panel Discussion

### ***Artificial Intelligence in Laboratory Diagnostics***

Youli Zu, MD, PhD, Professor, Houston Methodist Hospital, Weill Cornell Medical College (Moderator)

Mingyi Chen, MD, PhD, Professor, UT Southwestern Medical Center

He Sarina Yang, PhD, Associate Professor, Weill Cornell Medicine/NewYork Presbyterian

Kai Ying, PhD, Senior Director of Bioinformatics, Baylor Genetics

Jian Chen, MD, PhD, Associate Professor, Houston Methodist Hospital/Weill Cornell Medical College



# CONFERENCE PROGRAM



**JAN 13- AM**

Resort Conference Center - Spanish/Republic Room



## **IN VITRO DIAGNOSTIC ADVANCES**

11:30AM-12:15 PM Panel Discussion

### ***New Advancement and Trends in In Vitro Diagnostics and Laboratory Testing***

Yongmei Maggie Li, PhD, CEO&Founder, EmerTher; President, SAPA (Moderator)

Harris Zhang, PhD, CEO&Founder, NanoBiotec LLC (Picolmmune)

Joseph Zhou, PhD, CTO&Founder, Intelligene Biosystems

Hong Tan, PhD, CEO&Founder, ET Healthcare

12:15PM-2:00PM LUNCH

Featured Talk in IVD & Regulatory

### ***Compliance Concerns and Implementations of Biomarkers Testing and CDx Development in Clinical Trial***

Young Wang, MD, CEO&Founder, Wanda Henry

### ***Patents 101: Protecting Your Intellectual Assets***

Lukas W Pfannenstiel, PhD, Patent Agent, Saul Ewing Arnstein & Lehr LLP

**JAN 13 - PM**

Poolside/Resort Lobby/Golf



## **BIOTIME SOCIAL NETWORK ACTIVITY**

3:00PM-5:00PM

Outdoor network - co-host with Biotime



6:00PM-9:00PM - GROUP DINNER

Tommy Bahama Restaurant, The Woodlands Market Street  
Shuttle by Resort or Self-drive (5-7min)



# CONFERENCE PROGRAM

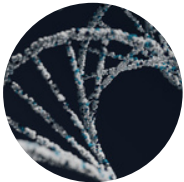


**JAN 14 - AM**

Resort Conference Center - Spanish/Republic Room

7:00AM-8:00AM

Breakfast buffet - Houston Breakfast



## **MOLECULAR**

8:00AM-8:40AM Featured Talks

### ***Advances in Molecular Diagnostics of Cancer***

Zejuan Li, MD, PhD, Associate Professor, Houston Methodist Hospital, Weill Cornell Medical College

### ***Integrating Whole-Genome and Whole-Transcriptome Sequencing for Molecular Diagnosis, Classification and Risk Stratification in Pediatric and Adolescent Leukemia***

Lu Wang, MD, PhD, Associate Professor, St. Jude Children's Research Hospital

8:40AM-9:25 AM Panel Discussion

### ***Implementing Novel Technologies into Clinical Molecular Diagnostics***

Zhenya Tang, MD, PhD, Associate Professor, UT MD Anderson Medical Center  
(Moderator)

Xinyan Lu, MD, PhD, Professor, Feinberg School of Medicine, Northwestern University

Hui Chen, MD, PhD, Associate Professor, UT MD Anderson Medical Center

Wenli Zhou, PhD, Co-founder, XYZ Laboratory/ XYZSure

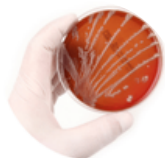
Yuxin Fan, MD, PhD, Associate Professor, Texas Children's Hospital/Baylor College of Medicine

9:25AM-9:35AM COFFEE BREAK

# CONFERENCE PROGRAM



**JAN 14 - AM** Resort Conference Center - Spanish/Republic Room



## **MICROBIOLOGY**

9:35AM-10:15AM Featured Talks

### ***Forty Years in Diagnostic Molecular Microbiology***

Yi-Wei Tang, MD, PhD, China Chief Medical Officer of Danaher Corporation & Cepheid

### ***Clinical Microbiology Testing - Transition from research to clinical during COVID pandemic***

Ping Ren, PhD, Professor, UT Medical Branch of Galveston

10:15AM-11:00 AM Panel Discussion

### ***Proteomics and Spatial Multi-omics for Precision Medicine***

Zhen Zhao, PhD, Professor, Weill Cornell Medicine/NewYork-Presbyterian (Moderator)

Ping Ren, PhD, Professor, UT Medical Branch of Galveston

Xin Yi, PhD, Associate Professor, Houston Methodist Hospital/Weill Cornell Medical College

Zhiyong Ding, PhD, Founder of Protogo Biotechnologies



## **HLA/TRANSFUSION**

11:00AM-12:10AM Featured Talks/Q&A

### ***Transplant tribulations: barriers and solutions***

Jian Chen, MD, PhD, Associate Professor, Houston Methodist Hospital/Weill Cornell Medical College

### ***HLA Antibody Detection For Solid Organ Transplantation and Its Challenges***

Dongfeng Chen, PhD, Associate Professor, Duke University Medical Center

# CONFERENCE PROGRAM



JAN 14 - PM

## **HLA/TRANSFUSION (CONT)**

### ***Effect of SIRP $\alpha$ Mismatch on the Outcome of Allogeneic Hematopoietic Stem Cell Transplantation from an HLA Matched Related Donor***

Jun Zou, MD, PhD, Associate Professor, UT MD Anderson Cancer Center

### ***Chimerism Testing in Post-Transplant Engraftment Monitoring***

Fei Ye, PhD, Director of Assay Development, Memorial Sloan Kettering Cancer Center



12:30 - 2:00PM - LUNCH

### ***Introduce the US R&D center of Autobio Diagnostics and possible collaborative opportunities in lab medicine***

Charles Lee, PhD/DVM/MBA, CEO, AdvanBio

### ***Innovative Use of Excel for Data Collection, Test Validation and Clinical Studies***

Paul Breitenbecher, MBA,SSGB(ASQ),SC,C(ASCP), CEO, Breiten Associates

## OPTIONAL

2:00-4:00 PM

WINERY TOUR - WILD STALLION VINEYARDS

Self-Drive from Resort, 6.8 mile - 15 min

BUSINESS MEETING - ORGANIZING COMMITTEE

# SPEAKERS & PANELISTS

## **Xiao-Ming Yin, MD, PhD**

Chair & Professor, Department of Pathology & Lab Medicine, Tulane University

Dr. Xiao-Ming Yin obtained his medical degree from Shanghai Medical School, Fudan University and his PhD from University of Texas Southwestern Medical Center at Dallas. He completed his post-doctoral fellow training and clinical pathology residency at Washington University School of Medicine at St. Louis. He was a faculty at the Department of Pathology at University of Pittsburgh SOM (1998-2010), and the Louis Y. Mazzini Professor and Vice Chair for Clinical Pathology of the Department of Pathology and Laboratory Medicine, Indiana University SOM (2010-2020). Since February 2020 Dr. Yin has been the Dr. Donald R. Pulitzer and Donna G. Pulitzer Professor and Chair of the Department of Pathology and Laboratory Medicine at Tulane University SOM. Dr. Yin is a fellow of College of American Pathologists, American Association for the Study of Liver Diseases and Southern Society for Clinical Investigation, and an elected member of American Association of University Pathologists. He was the recipient of 2017 Outstanding Investigator Award from American Society for Investigative Pathology, and the 2022 Distinguished Pathologist Award from Chinese American Pathologist Association.

## **He Sarina Yang, PhD, DABCC, FAACC**

Associate Professor, Weill Cornell Medicine & New York Presbyterian Hospital

Dr. He Sarina Yang obtained her Bachelor of Medicine degree from Peking University Health Science Center and her PhD in Neuroscience from Northwestern University. She was then trained as a Clinical Chemistry/Toxicology fellow at University of California, San Francisco. Dr. Yang is certified in both Clinical Chemistry (2015) and Toxicological Chemistry (2017) by the American Board of Clinical Chemistry. After the training, she served as the Scientific Director of Clinical Toxicology and Special Chemistry at Quest Diagnostics for 3.5 years. Currently, she is an Associate Professor in the Department of Pathology and Laboratory Medicine at Weill Cornell Medicine and New York Presbyterian Hospital where she oversees high-volume automated chemistry, immunology, serology, and toxicology testing. Dr. Yang's research interests involve: 1) evaluate and validate novel biosensor-based assays and other cutting-edge technologies in the clinical laboratory; 2) apply machine learning algorithms to the analysis of clinical laboratory big data; 3) develop new mass spectrometry assays to support drug analysis in biological specimens and metabolomic studies.

## **Yiqi Ruben Luo, PhD, DABCC, FAACC**

Assistant Professor, Stanford Health Care

Ruben Y. Luo, PhD, DABCC, FAACC is an Assistant Professor of Pathology at Stanford University and the Associate Director of Clinical Chemistry and Immunology Laboratory at Stanford Health Care. He received PhD in chemistry from Stanford University, and worked in the clinical diagnostic industry for several years. He completed clinical chemistry fellowship at the University of California San Francisco. He is dedicated to the innovation of clinical diagnostic technologies, and his research focuses on applying top-down mass spectrometry and label-free immunoassays to the characterization and precise measurement of clinical diagnostic markers.

## **Qing H. Meng, MD, PhD, DABCC, FAACC**

Professor, University of Texas MD Anderson Medical Center

Dr. Qing Meng is Professor and the Section Chief of Clinical Chemistry in the Department of Laboratory Medicine at The University of Texas MD Anderson Cancer Center. He also serves as Director of Clinical Chemistry Postdoctoral Training Program at MD Anderson Cancer Center. Dr. Meng has served various roles in national and international professional societies and committees. Currently he is the AACC Academy Council member, Chair of AACC Global Lab Quality Initiative (GLQI) Asia Pacific Working Group (APWG), and Co-Chair of The International Federation of Clinical Chemistry and Laboratory Medicine (IFCC) Task Force on Global Lab Quality. His research interest focuses on tumor biology, tumor biomarkers, liquid biopsy, and cancer diagnostics in addition to his service-related research in general chemistry, laboratory errors and quality improvement. Dr. Meng has published over 140 papers in peer-reviewed journals with H-index 37. He is an Associate Editor of Clinical Biochemistry and the Editor of Clinical Pathology Section of Annals of Medicine as well as on the Editorial Board of CCA, CRCLS, JALM.

## **Jing Cao, PhD, DABCC, FAACC**

Associate Professor, University of Texas Southwestern Medical Center

Dr. Jing Cao received her Ph.D. degree in Biochemistry, Molecular Biology and Biophysics from the University of Minnesota, Twin Cities, and is board certified in Clinical Chemistry after completion of fellowship training at the University of Minnesota Medical Center in 2015. She is currently an Associate Professor of Pathology at the University of Texas Southwestern Medical Center, Director of mass spectrometry and POCT. Her major clinical research focuses include application of advanced lipoprotein testing in cardiovascular disease management, as she has been an investigator of NIH-funded cohort study of MESA since 2013. Starting in 2022, she also leads NIH-funded translational research in extracellular vesicle-based diagnostic assay development.

## **Min Yu, MD, PhD, DABCC**

Assistant Professor, University of Kentucky Healthcare

Dr. Min Yu, MD, PhD, DABCC, is the assistant professor, director of clinical chemistry of the Department of Pathology and Laboratory medicine at the University of Kentucky. As a laboratory medicine practitioner, her professional area of interests includes laboratory tests utilization and harmonization, drug testing for pain management, laboratory automation and clinical and translational research on evaluation of biomarkers for diagnosis and prognosis of diseases. She is also interested in utilization of the open-source computational tools to gain new insights from the laboratory data. Her work has been published in peer-reviewed journals and has been presented to the national and international meetings. Her clinical chemistry fellowship training was completed at the University of Virginia and then became a Diplomate of the American Board of Clinical Chemistry. Prior to that, she earned her medical degree at the Nanjing Medical University in Nanjing, China, where she also completed her graduate education in pharmacology (MS). She received her PhD degree in Molecular and Environmental Toxicology from University of Wisconsin.

# SPEAKERS & PANELISTS

## Rongrong Huang, PhD, DABCC

Assistant Professor, Ben Taub Hospital/Baylor College of Medicine  
Dr. Rongrong Huang is a board-certified clinical chemist (DABCC), currently serving as a Medical Director at Harris Health Ben Taub Hospital for several clinical laboratory sections including Clinical Chemistry, Diagnostic Immunology, Point-of-Care and Lab Quality. Dr. Huang holds an academic appointment with Baylor College of Medicine as assistant professor at Department of Pathology and Immunology, upon finishing her two-year ComACC clinical chemistry fellowship training at Houston Methodist Hospital. After obtaining her Ph.D. degree in analytical chemistry from Complex Carbohydrate Research Center at University of Georgia, she worked three years as a clinical scientist dedicated in developing mass spectrometry-based diagnostic tests for inborn errors of metabolism. Dr. Huang's clinical research interests include laboratory regulations, data science for quality improvement and test utilization, applications of new technologies for advanced clinical diagnosis and improved patient care.

## Mingyi Chen, MD, PhD

Professor, University of Texas Southwestern Medical Center  
Dr. Mingyi Chen is a professor of Pathology at the University of Texas Southwestern Medical Center. He is board certified in pathology (anatomic and clinical pathology) with a subspecialty in hematology. He received MD from Peking University Health Science Center and PhD in Pharmacology from Kyoto University. He completed residency training at UCSD and Loma Linda University Medical Center and a Fellowship in Hematopathology at City of Hope National Medical Center. His clinical interests include hematopathology for the diagnosis of lymphoma, and leukemia, flow cytometry, bone marrow transplant pathology, and diagnostic molecular pathology. Dr. Chen's research interests include sickle cell disease, vascular biology, graft-vs-host disease (GVHD), molecular pathogenesis of lymphoma and leukemia, tumor immunology, and cancer stem cells. His current research focuses on the AI/ML approach in diagnostic hematology. The primary diseases against which advancements in his laboratory are targeted include malignant lymphoma, leukemia, and other hematological problems.

## Youli Zu, MD, PhD

Professor, Houston Methodist Hospital, Weill Cornell Medical College  
Dr. Youli Zu received his medical degrees from Jilin Medical College in China and PhD degree from Kyoto University School of Medicine in Japan. For clinical practice, Dr. Zu has completed pathology residence training at New York University and hematopathology fellowship at National Cancer Institute of NIH. In 2004, Dr. Zu joined the pathology faculty at Baylor College of Medicine (the former Houston Methodist Hospital pathology department). Currently, Dr. Zu is the Professor at Weill Cornell Medical College of Cornell University, and the Medical Director of the Hematopathology Section, the Director of the Cancer Pathology Research, and the Endowed Chair for translational research in Department of Pathology and Genomic Medicine, Houston Methodist Hospital, Houston, Texas. As a well-established physician-scientist, Dr. Zu is a pioneer in oligonucleotide aptamer research and the development of new technology for disease diagnosis and targeted cancer therapy. Dr. Zu has published more than 160 peer-reviewed articles, and his research is supported by multiple grants from CPRIT, NIH, and DOD.

## Lei Chen, MD, PhD

Professor, University of Texas MD Anderson Medical Center  
Dr. Qing Meng is Professor and the Section Chief of Clinical Chemistry in the Department of Laboratory Medicine at The University of Texas MD Anderson Cancer Center. He also serves as Director of Clinical Chemistry Postdoctoral Training Program at MD Anderson Cancer Center. Dr. Meng has served various roles in national and international professional societies and committees. Currently he is the AACC Academy Council member, Chair of AACC Global Lab Quality Initiative (GLQI) Asia Pacific Working Group (APWG), and Co-Chair of The International Federation of Clinical Chemistry and Laboratory Medicine (IFCC) Task Force on Global Lab Quality. His research interest focuses on tumor biology, tumor biomarkers, liquid biopsy, and cancer diagnostics in addition to his service-related research in general chemistry, laboratory errors and quality improvement. Dr. Meng has published over 140 papers in peer-reviewed journals with H-index 37. He is an Associate Editor of Clinical Biochemistry and the Editor of Clinical Pathology Section of Annals of Medicine as well as on the Editorial Board of CCA, CRCLS, JALM.

## Kai Ying, PhD

Senior Director of Bioinformatics, Baylor Genetics  
2006 - 2012, PhD in genomics and genetics, Iowa State University  
2013-2015, postdoctoral research fellow, NIH  
2016-2018, bioinformatics scientist at Ichan medical school of Mount Sinai hospital  
2019-2022, Director of bioinformatics of precision genetics lab at Columbia University medical center  
2022-present Senior Director of Bioinformatics, Baylor genetics

## Yongmei Maggie Li, PhD

CEO&Founder, EmerTher; President, SAPA  
Yongmei Li is the CEO of the Emerther Company, which focuses on the development of nano-scale superparamagnetic bead products and their applications in molecular diagnosis and protein analysis. Prior to her entrepreneurial journey, Yongmei had ten years of experience working at Boehringer Ingelheim Pharmaceuticals, Inc. As a Senior Principal Scientist, she led a group of scientists in drug metabolism and pharmacokinetics in support of new drug development and was heavily involved in global regulatory submissions. She also published more than 20 articles and two book chapters. Yongmei holds a Ph.D. degree in Pharmacognosy (Natural Product Chemistry) from School of Pharmacy at University of Illinois, a MS degree and a BS degree in Pharmacy from West China University of Medical Sciences. Yongmei is currently the President of SAPA. Previously, she also served as a BD (Board of Directors) member of SAPA from 2017 to 2021, the President of SAPA-Connecticut from 2015 to 2016, a Vice-principal of Huaxia Chinese School at Connecticut from 2012 to 2015, and the President of Western Connecticut Chinese Association from 2006 to 2007.

# SPEAKERS & PANELISTS

## Harris Zhang, PhD

CEO&Founder, NanoBiotec LLC (PicoImmune)

Harris Zhang is the co-founder of a NJ-based biotech company known as PicoImmune. He is trained as a cancer biologist and immunologist, and is leading the biology efforts for discovery and development of therapeutics and companion diagnostics for cancer, autoimmune and many other diseases with un-met needs. Harris is responsible for managing an innovative team to provide high-quality multidisciplinary services and products supporting various preclinical and clinical studies. Harris has accrued expertise in molecular pathways and assay development for discovery and translational medicine, while he worked at Celgene and BMS as a scientist, and the MIT Center for Cancer Research as a CRI postdoc fellow for cancer immunology. Dr. Zhang earned his Ph.D. in Pharmacology and Immunology from a joint program of Peking University Medical School and Peking Union Medical School. Currently, Harris is managing a group of PhD/MD/BSc biologists/immunologists dedicated to supporting drug discovery and translational development.

## Joseph Zhou, PhD

CTO&Founder, Intelligene Biosystems

Dr. Zhou has over 30 years of industrial and academia experiences in analytical instrumentation development for life sciences and clinical diagnostics in both the US and China. He is the founder and CTO of Intelligene Biosystems, a company developing and manufacturing cutting-edge analytical products and total solutions for biological and clinical applications. Prior establishing his own company, Dr. Zhou worked at Applied Biosystems, Inc. in the US as a senior manager of technology and engineering and Thermo Fisher Scientific as project leader for the development of various award-winning biological mass spectrometer products.

## Young Wang, MD

CEO&Founder, Wanda Henry

Dr. Young Wang is the past-president, North American Chinese Clinical Chemists Association (NACCCA) 2020 – 2021 and the Board Member of Industry Division, American Association for Clinical Chemistry (AACC). Dr. Wang has been working in the field of clinical laboratory testing, assay development, quality management system and regulatory registration over 20 years. He is proficient in regulations and industry standard, has successfully led the FDA submissions for many IVD products and obtained approval. He has established the clinical research laboratories of the Johns Hopkins Singapore and Fuji-USA. Dr. Wang was a postdoctoral fellow and faculty member in the Clinical Chemistry Division of the Department of Pathology at Johns Hopkins University School of Medicine.

## Lukas W Pfannenstiel, PhD

Patent Agent, Saul Ewing Arnstein & Lehr LLP

Dr. Lukas Pfannenstiel is a registered Patent Agent with Saul Ewing LLP and has a PhD in cellular and molecular medicine from Johns Hopkins School of Medicine as well as practical working experience as an academic scientist. Lukas's practice draws from his background in cancer biology and immunotherapy to advocate for academic and biotechnology industry clients in diverse aspects of intellectual property protection including patentability and inventorship determinations, freedom to operate and due diligence, and patent drafting and prosecution.

## Lu Wang, MD, PhD

Associate Professor, St. Jude Children's Research Hospital

Lu Wang, MD, PhD, is a molecular pathologist and an Associate Member in Pathology Department at St. Jude Children's Research Hospital. Dr. Wang serves as the Medical Director of Molecular Pathology at St. Jude, and oversees clinical genomics, conventional molecular diagnostics, and clinical cytogenetics. Dr. Wang received her MD and PhD degrees from Shandong University School of Medicine and Shanghai Jiao Tong University School of Medicine in China and completed her post-graduate training at Weill Medical College of Cornell University and Memorial Sloan Kettering Cancer Center (MSKCC) in New York City. Dr. Wang is board certified by the American Board of Medical Genetics and Genomics (ABMG). Before joining the faculty at SJCRH, Dr. Wang had been a faculty member in Molecular Diagnostics Service, Department of Pathology at MSKCC from 2010 to 2017. Dr. Wang's clinical research focuses on molecular profiling of rare tumors with an emphasis on clinical translation of potential diagnostic markers and therapeutic targets, as well as clinical tests development. Her research lab has focused on functional characterization of oncogenic gene fusions.

## Zejuan Li, MD, PhD

Associate Professor, Houston Methodist Hospital, Weill Cornell Medical College

Dr. Zejuan Li is a clinical molecular geneticist certified by the American Board of Medical Genetics and Genomics. Dr. Li currently is an Associate Professor of Pathology and Genomic Medicine at the Houston Methodist and Weill Cornell Medical College, and an Associate Medical Director of the Molecular Diagnostic Laboratory at the Houston Methodist Hospital. Before joining Houston Methodist in 2018, Dr. Li was an Assistant Professor of Human Genetics and an Assistant Director of Molecular Diagnostic Laboratory at the University of Chicago. Dr. Li's clinical interest is in developing and implementing cutting-edge technologies in cancer. Dr. Li's research interest is in identifying novel genetic and epigenetic biomarkers for diagnosis, prognosis, and therapeutic response in cancer. Her research has been published in high-impact journals, including Cancer Cell, Journal of Clinical Oncology, Nature Communications, Blood, Leukemia, Proceedings of the National Academy of Science, Genome Research, and Cancer Research. Dr. Li has received awards and funding from the American Cancer Society, Gabrielle's Angel Foundation for Cancer Research, and the Leukemia & Lymphoma Society.

## Zhenya Tang, MD, PhD

Associate Professor, UT MD Anderson Medical Center

Dr. Zhenya Tang is an Associate Professor at Department of Hematopathology, the University of Texas MD Anderson Cancer Center (UTMDACC) in Houston, TX. His research interests include but are not limited to genomic aberrations in hematologic malignancies, lung cancer and other solid tumors. Dr. Tang attended and obtained his MD and MS degrees from Tongji Medical University (now Tongji Medical College, Huazhong University of Science and Technology), Wuhan, China and PhD degree from Albert-Ludwigs University of Freiburg, Germany. In addition to his clinical services, he is also interested in translational research, mainly on biomarkers which are being applied and/or potentially applicable to diagnosis and clinical management of patients with hematologic malignancy, lung cancer and other solid tumor. More information about his research interests can be found through this link: <https://faculty.mdanderson.com>.

# SPEAKERS & PANELISTS

## **Xinyan Lu, MD, PhD**

Professor, Department of Pathology, Feinberg School of Medicine, Northwestern University

Dr. Lu received her MD degree in Clinical Medicine from Suzhou Medical College (now Soochow University) in 1990. From 1992 to 1996, she worked as a Pediatrician in the Second Affiliated Hospital of Suzhou Medical College. During 1998- 2003, Dr. Lu completed her postdoc training in the field of Molecular Cytogenetic Characterizations for pediatric cancers, at the Texas Children's Cancer Center, Department of Pediatrics, Baylor College of Medicine. From 2005 to 2007, she completed the designated fellowship training in Clinical Cytogenetics by the American Board of Medical Genetics and Genomics (ABMGG), in the Department of Molecular and Human Genetics, Baylor College of Medicine. In 2007, she was board certified by the ABMGG. From 2008 to 2012, she served as the Medical Director in the Clinical Molecular-Cytogenetics Laboratory at the Texas Children's Cancer Center. From 2013 to 2016, she served as the Medical Director and Section Chief of the Clinical Cytogenetics Laboratory, in the Department of Hematopathology, at the University of Texas MD Anderson Cancer Center.

## **Hui Chen, MD, PhD**

Associate Professor, University of Texas MD Anderson Medical Center

Dr. Chen is a board-certified pathologist specialized in solid tumor molecular diagnostics and breast pathology in MD Anderson Cancer Center. My research interest is to study actionable genetic alterations in advanced solid tumors and their predications for therapeutic intervention. I work with molecular diagnostic laboratory, breast pathology, and cytogenetics teams on various quality improvement projects to improve the overall performance of immunohistochemistry and genotype platforms including next-generation sequencing for clinical molecular diagnostics. I participate in multiple clinical test development/validations of biomarker testing for solid tumors. I am co-medical director of Clinical Trial Operation to oversee test validation and customized tests of novel biomarkers for clinical trials at MD Anderson and nationwide. The accurate interpretation of biomarkers in cases with borderline and conflicting results can be extremely challenging. I am interested in improving the interpretation accuracy of biomarkers i.e. ER, PR, HER2, PTEN and MET in cases with borderline and conflicting results using alternative test platform to guide treatment decision for personalized cancer therapy.

## **Wenli Zhou, PhD**

Co-founder, XYZ Laboratory/XYZSure

In her clinical laboratory career, Dr. Wenli Zhou has developed and consulted numerous LDTs including pharmacogenetics, inherited genetic conditions, somatic mutation analysis, prenatal genetic testing, CTC and ctDNA, etc. In 2016, Dr. Zhou co-founded XYZ molecular diagnostic lab consulting company (XYZ), providing services to various labs on LDT development and accreditation compliance. In 2020, XYZ established its own CLIA certified/CAP accredited laboratory which has been focusing on molecular testing of infectious diseases. In the past 10 year, Dr. Zhou and her team also had opportunities to participate in or lead various clinical trials and accumulated broad experience working with IVD developers and regulatory agencies. In 2022, Dr. Zhou co-founded XYZSure, a CRO company providing pre-market regulatory review consultation, and performance evaluations of IVD products. XYZ provided services to many IVD developers for the FDA EUA requests of their COVID-19 testing products in the past three years and is now working with various developers in gaining clearance or approval of their class II or class III IVD products by the FDA or other international regulatory agencies.

## **Yuxin Fan, MD, PhD**

Associate Professor, Texas Children's Hospital/Baylor College of Medicine

Dr. Yuxin Fan is a board certified clinical molecular geneticist by the American Board of Medical Genetics and Genomics and the medical director of John Welsh Genetics Laboratory, Division of Genomic Medicine, Department of Pathology, Texas Children's Hospital and Baylor College of Medicine. My clinical interests mainly involve in the development and implantation of molecular genetic diagnosis of inherited human diseases, especially cardiovascular disorders using Sanger sequencing, next generation sequencing and chromosomal microarray. My clinical oriented research has been focused on cardiovascular genetics, especially on the genetic screening for new genes related to cardiovascular diseases.

## **Yi-Wei Tang, MD, PhD**

China Chief Medical Officer of Danaher Corporation/Cepheid

Dr. Yi-Wei Tang obtained his medical training from Fudan University Shanghai School of Medicine and Ph.D. in microbiology and immunology from Vanderbilt University. He was a Lecturer and Clinical Fellow at the Mayo Clinic, a Professor at the Vanderbilt University School of Medicine, the Chief of the Clinical Microbiology Service at the Memorial Sloan-Kettering Cancer Center and a Professor of Pathology and Laboratory Medicine at the Weill Medical College of Cornell University. Dr. Tang is currently the China Chief Medical Officer of Danaher Corporation/Cepheid in Shanghai. Dr. Tang ranks among the top of the scientific field in clinical and molecular microbiology, as evidenced by his election as an Editor for the Journal of Clinical Microbiology, an Associate Editor for the Journal of Molecular Diagnostics, an Associate Editor for the Emerging Microbes and Infection, a Fellow of the American Academy for Microbiology and of the Infectious Disease Society of America. Dr. Tang has been recognized for his extraordinary expertise in the molecular microbiology diagnosis and monitoring with over 400 peer-reviewed articles book chapters in this field during the past 20 years.

## **Ping Ren, PhD, D(ABMM)**

Professor, University of Texas Medical Branch of Galveston

Dr. Ping Ren studied biology and received her Bachelor of Science degree from Nanjing Normal University in Nanjing, China. She received her Ph.D. from Georgia State University in Atlanta, Georgia, in 1996. Dr. Ren received her postdoc training in Epidemiology and Public Health at Yale University School of Public Health. After that, she worked at Wadsworth Center, New York State Department of Health, for 15 years. She is certified by the American Board of Medical Microbiology after joining the University of Texas Medical Branch in 2015. She is currently employed as a Professor at the Dept. of Pathology and Laboratory Services at UTMB and co-director of the Clinical Microbiology Laboratory. Dr. Ren's research interests include but are not limited to diagnostic methods development and evaluation, pre-clinical and clinical trials on infectious diseases; special investigations of infectious disease diagnoses such as bacterial, fungal, viral, and parasitic identifications using molecular methods & genotyping from formalin-fixed paraffin-embedded tissue blocks and other non-cultivable, non-viable specimens; drug combination susceptibility study on multi-drug resistant fungi, etc.

# SPEAKERS & PANELISTS

## Zhen Zhao, PhD, DABCC, FAACC

Professor, Weill Cornell Medicine/NewYork-Presbyterian

Dr. Zhao is a Professor of Clinical Pathology and Laboratory Medicine at Weill Cornell Medicine and Director of Central Laboratory and Clinical Chemistry Service at the NewYork-Presbyterian/Weill Cornell Medical Center. She received her BS in biology from Xiamen University and PhD from Northwestern University. She fulfilled clinical chemistry postdoctoral fellowship training at Washington University in St. Louis. She is board certified by the American Board of Clinical Chemistry. She is an Associate Editor of *Annals of Medicine*, Co-Chair of AACC COVID-19 Community Study, Chair of AACC Tumor Markers and Cancer Diagnostics Division, and Chair of IFCC Task Force on Outcome Studies in Laboratory Medicine.

## Xin Yi, PhD, DABCC, FAACC

Associate Professor, Houston Methodist Hospital/Weill Cornell Medical College

Dr. Yi is a board-certified clinical chemist, currently serving as the Co-director of Clinical Chemistry at Houston Methodist Hospital and Associate Professor of Clinical Pathology and Laboratory Medicine at Weill Cornell Medical College. She is also a fellow of the AACC Academy and the Co-director of the clinical chemistry fellowship program at Houston Methodist Hospital. Dr. Yi completed her clinical chemistry fellowship training at the University of Chicago after completing her PhD in clinical-bioanalytical chemistry at Cleveland State University/Cleveland Clinic. She is interested in the application of new technologies, especially mass spectrometry and genetic analysis, in broader clinical diagnostic use. Her work has been published frequently on influential journals and presented at national or international conferences. Dr. Yi served as the president of North American Chinese Clinical Chemists Association (NACCCA) in 2021-2022 and is currently the chair-elect of AACC personalized medicine division and Texas session. She is also on several editorial boards of international clinical laboratory journals, including *AJCP*, *Archives of Pathology & Lab Med*, *Encyclopedia of Analytical Chemistry*, as well as CLSI document development committees.

## Zhiyong Ding, PhD

Founder, Protogo Biotechnologies

Dr. Zhiyong Ding obtained his BS degree in Microbiology from Shandong University and MS/PhD in Molecular Cell Biology from Peking University. He started working at the University of Texas Medical School and MD Anderson Cancer Center from 2000 for 19 years. He then switched from academics to the Biotechnology Industry. In academics, Dr. Ding worked as a faculty member at MD Anderson for 13 years. As a Principal Investigator, he received research funds from NCI and multiple foundations. Dr. Ding has over 50 peer-reviewed publications in cancer research areas, with an H-Index of 29. In industry, Dr. Ding founded several biotechnology companies in the US and China, focusing on proteomics and spatial multi-omics technologies for cancer precision medicine. He has built R&D teams and implemented multiple advanced technology platforms, including Reverse Phase Protein Array (RPPA), GeoMx Digital Spatial Profiler (DSP), and single-cell spatial proteomics technologies, and employs these technologies in drug development and IVD development.

## Jian Chen, MD, PhD, CABP(AABB)

Associate Professor, Houston Methodist Hospital/Weill Cornell Medical College

Dr. Jian Chen received his medical degree from Shandong Medical University and a Ph.D. in Molecular and Cellular Pathology from the University of Alabama at Birmingham. After completion of his residency in clinical pathology and fellowship in transfusion medicine at Houston Methodist Hospital, he became an attending pathologist at the Ohio State University Wexner Medical Center in 2013. His primary clinical duties included apheresis service, immunohematology consultation, blood bank administration, coagulation consultation and clinical chemistry consultation. He was also the medical director of the Clinical Coagulation Laboratory and the Biomarker Reference Laboratory. In early 2018, Dr. Chen moved to New York and joined Memorial Sloan Kettering Cancer Center with a clinical focus on hematopoietic progenitor cell mobilization and collection as well as cellular therapy. In September 2019, he returned to Houston Methodist Hospital and became the medical director of Coagulation laboratory and Co-director of Transfusion medicine. Dr. Chen has a strong interest in pursuing clinical and translational research in the field of transfusion medicine and coagulation.

## Dongfeng Chen, PhD, D(ABHI)

Associate Professor, Duke University Medical Center

Dr. Dongfeng Chen received his PhD from Hannover Medical School in Germany in 1996 where he started his career in the field of Immunogenetics and Histocompatibility. In 1997, Dr. Chen was recruited by the Center for Blood Research, Harvard University Medical School in Boston, MA where he functioned as Technical Supervisor and Associate Director of the HLA lab for more than 5 years. After he worked as Associate Director of the HLA lab at UCSF for a short period of time in 2003, Dr. Chen joined the Clinical Transplantation Immunology Lab of Duke University Medical Center in 2004 where he was appointed as Assistant Professor and Assistant Director and has become the Director and Associate Professor since 2006. Dr. Chen is accredited by the American Board of Histocompatibility and Immunogenetics as HLA lab director D(ABHI) for HLA testing for related and unrelated BMT, living and deceased donor solid organ transplantations, and HLA testing for non-transplantation. Dr. Chen's clinical research interests include relevance of HLA and non-HLA antibodies in solid organ transplantations and Histocompatibility in stem cell transplantation.

## Jun Zou, MD, PhD

Associate Professor, UT MD Anderson Cancer Center

Dr. Jun Zou studied medicine and received his medical degree from Xian Medical University in China. He received his PhD degree in Biochemistry from the University of Missouri in 2005. Dr. Zou received a CP residency and a combined HLA and transfusion fellowship training at Washington University in St. Louis. He is currently an Associate Professor at MD Anderson and served as Medical Director for HLA Laboratories at MD Anderson and UTMB. Dr. Zou's research interests are transplant immunology and molecular mismatch.



# SPEAKERS & PANELISTS

## Fei Ye, PhD

Director of Assay Development, Memorial Sloan Kettering Cancer Center

Dr. Ye studied molecular biology and received her PhD from Norman Bethune University of Medical Sciences at Changchun in China in 1999. Dr. Ye received fellowship training for immunology from Tongji University at Wuhan in China in 2001. She is certified by New York State Department of Health Certificate of Qualification in Transplant Monitoring, HLA, Molecular Oncology, Molecular Virology, and Molecular Genetics. She served as Assistant Director and Associate Professor at Molecular Pathology Laboratory at Department of Pathology and Laboratory Medicine at Mount Sinai School of Medicine from 2001 to 2017 and at Westchester Medical Center from 2017 to 2019, before she joined as a clinical faculty at Department of Pathology and Laboratory Medicine at Memorial Sloan Kettering Cancer Center. She is currently employed as Attending Clinical Scientist and assistant director at HLA Lab and director of assay development. Dr. Ye's research has been mainly focused on therapeutic and diagnostic biomarker discovery for cancer diagnosis and treatment. Overall, more than 87 papers that were resulted from these studies have been published.

## Charles Lee, PhD/DVM/MBA

CEO, AdvanBio

Dr. Lee received his Veterinary & Master's degrees in Virology from the National Taiwan University in Taipei and Ph.D. in Immunology, Comparative Pathology Program from the University of California at Davis in 1999, and an MBA from the IPAG business school in Paris, France. Dr. Lee has served in multiple scientific and strategic leadership roles during his career including the Director, Head of Biomarker Research, APCOE, Janssen Pharmaceuticals, Director, China R&D Center for Abbott Diagnostics; the Executive VP, Global R&D for HOB Biotech Group in Suzhou, China; the Associate Director for Novartis Molecular Diagnostics in Cambridge, MA and the Assay Development & R&D Managers for Siemens Healthcare Diagnostics in Los Angeles, CA. Dr. Lee joined AdvanBio Inc with over 20 years of experience in IVD & biomarker research from genomics, transcriptomics, proteomics, and metabolomics companion diagnostics. Charles is specialized in delivering IVD products to the US, European and Chinese markets after leading assay development teams to launch various IVD assays on fully automated systems and companion diagnostics & clinical biomarkers in drug trials.

## Paul Breitenbecher, MBA,SSGB(ASQ),SC,C(ASCP)

CEO, Breiten Associates

Paul Breitenbecher received his BS from Providence College in Providence RI. He is both CC and SC ASCP certified. He graduated from Endicott College with his MBA in 2011. He is Six Sigma Green Belt company trained and certified. He has over 30 years of Lab experience. With at least 20 years of management and quality experience in small to large reference labs. He taught Clinical Chemistry at Northeastern University in Boston MA for 5 years and served as clinical lab instructor for 10 years for MT schools in the MA and RI area. He has 30 years of CLIA and CAP experience serving as a peer inspector with several inspection teams in the US, including the East Coast Commissioner inspection team. He has worked as a Quality Manager for Harvard Vanguard Medical Associates, Novartis Institute for Biological Research and Miraca Life Sciences (Currently Inform Diagnostics). In 2013 he was asked to set up two labs for Partners in Health in Haiti. In 2013 he started his consulting firm setting up CROs, preparing and obtaining CLIA and CAP certifications and NY state permits, designing electronic quality systems, and overseeing clinical trial testing as the Quality Manager for several labs.