

Medical Device & Diagnostics Symposium 2011

美中生物医药协会二〇一一医疗器械和诊断技术研讨会



Presented by
Chinese-American BioMedical Association (CABA)
美中生物医药协会

New England Chinese Information and Networking
Association (NECINA)
紐英倫中華資訊網路協會

American Chinese Medical Association (ACMA)
北美中华医学会

Harvard Medical School- Chinese Scholars and
Scientists Association
哈佛大学医学院中国专家学者联合会

Embracing Innovation in Medical Device and Diagnostics

This 2011 Medical Device & Diagnostics Symposium is aimed to enhance interactions of biomedical professionals, embrace innovation and entrepreneurship, identify the technical and market trends in medical device & diagnostics business in the US and China.

Highlights

- Cutting-edge innovation in Medical Device & Diagnostics Industry.
- Industry Strategy and Market Perspectives.
- Panel discussion on Medical Device & Diagnostics in the US and China.

Confirmed Speakers:

- Sridhar Iyengar, CTO, Agamatrix
- Martin Bakal, WW Market Manager, IBM
- Sam Chang, Director, Delsys Inc
- Sheila Hemeon-Heyer, President, Heyer Regulatory Solutions, LLC
- Liying Yan, CEO, EpigenDx
- Karl Ruping, President, INCTANK
- William Lee, Director, AST Products
- Shen Luan, Co-Founder, COO, Berg Diagnostics

Time: December 3rd 2011, 1:00 PM to 5:30 PM

Venue : IBM Innovation Center, 404 Wyman Street, North Entrance, Waltham, MA

Contact: Dr. Wei Zhang, Email: zhangwei999@hotmail.com

Admission: Free to CABA, NECINA and ACMA members, \$20 for nonmembers, \$10 for students. On site registration to become member is available. Because of space limitation, online registration is required. For more information, please visit www.cabaweb.org

www.cabaweb.org

www.necina.net

www.acma.org

www.hms-cssa.org



Time: 12:00-6:00 pm
Date: Saturday, December 3, 2011
Venue: IBM Innovation Center
Address: 404 Wyman Street, North Entrance
Waltham, MA 02454-1280

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Chinese-American Biomedical Association (CABA)
New England Chinese Information and Networking Association (NECINA)
American Chinese Medical Association (ACMA)
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Confirmed speakers/panelists

- Sridhar Iyengar, CTO, AgaMatrix
- Sam Chang, Director, Delsys
- Sheila Hemeon-Heyer, President, Heyer Regulatory Solutions
- William Lee, R&D Director, AST Products
- Martin Bakal, Marketing Manager, IBM
- Shen Luan, COO, Berg Diagnostics
- Minzi Ruan, CEO, VigeneTech
- Karl Ruping, President, IncTANK
- Liying Yan, Founder and CEO, EpigenDx

Admission: CABA, NECINA, ACMA and HMS-CSSA members: FREE; Non-members: \$20, Student: \$10. Seats are limited.

Symposium Steering Committee: *Symposium Chair:* Dr. Wei Zhang; *Symposium Co-Chairs:* Ji Shi, Dr. Sean Shen, Dr. John Xiaofeng Zhu, Ru Zheng, Dr. Zhenglun Zhu, Dr. Wenyu Song.

Symposium Program

12:00-1:00 Registration, Vendor Show and Networking

SESSION I: MARKETING/BUSINESS PERSPECTIVES, CO-CHAIR: MR. JI SHI AND MS. RU ZHENG

1:00-1:05 Opening Remark

1:05-1:35 Investment/Strategy on Medical Device Business

Karl Ruping
President, incTANK

1:35-2:05 How to Achieve Compliance with IEC 62304 for Medical Device Software Development

Martin Bakal
WW Market Manager - IBM

2:05-2:35 The US FDA 510(k) Program: Current Requirements and Potential Changes

Sheila Hemeon-Heyer
President, Heyer Regulatory Solutions

2:35-2:50 Coffee Break and Vendor Show

SESSION II: INNOVATIVE TECHNOLOGY, CHAIR: DR. WEI ZHANG

2:50-3:20 Building a Biosensor Company from the Kitchen to the World

Sridhar Iyengar, Ph.D. CTO, Agamatrix

3:20-3:50 Multiplexing of Genetic and Epigenetic Biomarkers For Clinical Diagnostics

Liyang, Yan, Ph.D.
Founder and CEO, EpigenDx Inc.

3:50-4:20 Technological Advances in Detection of Surface Electromyography

Sam Chang, Ph.D. Director, Delsys Inc.

4:20-4:50 Growth Opportunities in Biosensors

William Lee, Ph.D.
Director of R&D, AST Products Inc.

SESSION III: PANEL DISCUSSION, CHAIR: DR. ZHIHONG CHEN

4:50-5:30 Application on MDDI

Panelists:
Shen Luan, Co-Founder, COO, Berg Diagnostics
William Lee, Ph.D., Director of R&D, AST Products Inc.
Minzi Ruan, Ph.D. CEO, VigeneTech

5:30-6:00 Cocktail, Vendor Show and Networking

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NECINA 紐英倫中華資訊網路協會

ACMA 北美中华医学会

HMS-CSSA 哈佛大学医学院中国学者专家协会



2011 MDDI Symposium Committee

Wei Zhang (CABA)

Zhihong Chen (CABA)

Ji Shi (CABA)

Sean Shen (NECINA)

John Xiaofeng Zhu (NECINA)

Ru Zheng (NECINA)

Jerry Zhu (ACMA)

Wenyu Song (HMS-CSSA)

Chaoshe Guo (HMS-CSSA)

Acknowledgement

We sincerely thank IBM Innovation Center for providing event venue and facility.

SPONSORS



Biosketches of Speakers and Program Summary

VigeneTech Inc., is a multinational company offering world-class image analysis software solutions and a full complement of custom software development services. Our MicroVigene™ software for nucleic acid, DNA/RNA and protein microarray has been adopted by industry leaders and has quickly become the gold standard for automated microarray image analysis. Building on our expertise, we have recently introduced CellVigene™ for analysis of cell and Tissue images. Our software platforms offer a flexible design and can be scaled to accommodate a variety of applications including high-content screening and histopathology.

Minzi Ruan, Ph.D. CEO

VigeneTech Inc.

Tel: 978-371-5959

Email: minzi@vigenetech.com

Karl Ruping, President, incTANK

Karl Ruping is Founder and Managing Partner of incTANK Ventures, a venture capital fund investing in early stage, university-sourced technology companies. (www.inctank.com) He led the investment in AgaMatrix, a medical device company focused on diabetes care (www.agamatrix.com), and Agrivida, an agricultural biotechnology venture developing renewable fuels and chemicals from non-food cellulosic biomass. (www.agrivida.com) Other investments include Ligon Discovery a small molecule microarray company for high-throughput drug screening (www.ligondiscovery.com) and Emergent Analytics a quantitative hedge fund based on scientific modeling techniques. (www.emergenta.com)

Karl is at the crossroads of technology development, intellectual property rights, and venture funding. He is a US attorney and patent lawyer with a technical background in computational sciences. He holds a B.A. in economics from Colby College, a J.D. from Boston University, was a Fellow at MIT's School of Engineering and finally a post-doctoral student at the University of Tokyo. He has published numerous articles and book chapters on innovation and intellectual property rights, including Risk Management in Incubators in MANAGEMENT OF TECHNOLOGY: GROWTH THROUGH BUSINESS INNOVATION AND ENTREPRENEURSHIP and Management of Intellectual Property Rights: Challenges and Best Practices for New Technology Companies in IAMOT PROCEEDINGS (2004) and Intellectual Property Protection in University Startups, ANNUAL MEETINGS OF AICHE (2005).



Martin Bakal, WW Market Manager – IBM

Marty Bakal has over a decade of experience working in various capacities in the embedded systems and software industry with extensive customer experience worldwide in multiple industries including medical devices manufacturers. He is currently the electronics industry lead at IBM Rational and in that role leads the initiative around medical device lifecycle support. He holds a BS in Electrical Engineering and a Master of Science degree in Engineering Management, both from Tufts University.

Presentation Title: How to Achieve Compliance with IEC 62304 for Medical Device Software Development

Presentation Summary: Complying with the IEC 62304 standard for medical device software requires an established software lifecycle process that includes strong support for risk management, change management, and safety assessment. However, IEC 62304 compliance does not need to slow down your medical device software development. By applying best practices guidance and process automation, medical device companies can reap the benefits:

- Get through regulatory approvals faster
- Lower costs
- Deliver safer devices



Sheila Hemeon-Heyer, President, Heyer Regulatory Solutions

Sheila Hemeon-Heyer is the Founder and President of Heyer Regulatory Solutions LLC, providing global regulatory submission and compliance consulting services to the medical device industry. Ms Heyer has 25 years of experience in Regulatory Affairs, beginning at FDA where she was a Scientific Reviewer in the CDRH Office of Device Evaluation and was responsible for reviewing 510(k), IDE and PMA applications for orthopedic, physical medicine, and surgical devices. After leaving FDA, Ms. Heyer was Director of Regulatory Services for Medical Device Consultants, Inc. (MDCI), managing regulatory, clinical and compliance projects for a wide variety of medical device and combination products. Ms. Heyer joined Boston Scientific Corporation (BSC) in April, 2005 as Vice President, Global Regulatory Affairs, where she was responsible for worldwide regulatory strategies, operations and intelligence. She holds a B.S. in Biomedical Engineering from Boston University, an M.S. in Biomechanics from the University of Massachusetts at Amherst, a J.D. from Western New England College School of Law, is Regulatory Affairs Certified and a Fellow of the Regulatory Affairs Professional Society, and serves on the Board of Directors for the Food and Drug Law Institute (FDLI).

Presentation Title: The US FDA 510(k) Program: Current Requirements and Potential Changes

Presentation Summary: 510(k) Premarket Notification has been the pathway to market for the majority of medical devices sold in the United States since 1976. The 510(k) program has been criticized in recent years by industry, consumer groups, and FDA, but for different reasons. This session will provide an overview of the 510(k) program, the recommendations from the internal FDA and external IOM 510(k) task forces, and the impact of program changes to the medical device industry.

Sridhar Iyengar, Ph.D. CTO, Agamatrix

Sridhar Iyengar is the co-founder and CTO of AgaMatrix, a rapidly growing medical device company that invents, designs, and manufactures blood glucose meters and biosensors for people with diabetes. AgaMatrix products are sold worldwide by Sanofi, Medco, Walmart, Target, and are used by millions of patients across the globe. AgaMatrix recently released the first medical device capable of analyzing blood that works with the iPhone and is helping shape the future of mobile health.

AgaMatrix's core technology "WaveSense" combines Sridhar's background in electrical engineering and biological sciences into the concept of Dynamic Electrochemistry which couples an advanced DSP approach to enhance biosensor performance. Sridhar has several patents granted under his name and received his Ph.D. from Cambridge University as a Marshall Scholar.

Presentation Title: Building a Biosensor Company from the Kitchen to the World

Presentation Summary: This talk will be a historical account of how AgaMatrix's technology grew out of experiments performed in a kitchen "lab" into globally-distributed products that are used by millions of patients around the world. This is a story of how a startup company evolved from a technology company to a product-based organization with distribution and manufacturing, and how it evolved from a traditional biosensor company into one of the leading mobile health companies in the consumer space.

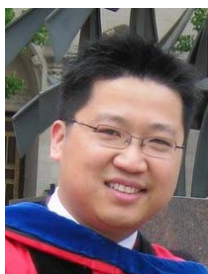
Liyang Yan, CEO, EpigenDx

With more than 15 years experiences in molecular diagnosis, Liyang Yan has a strong background, knowledge, and skill sets for developing a marketable molecular testing kit. She earned a Bachelor of Medicine in Shanghai University of Chinese Medicine and Pharmacy, a Master of Sciences in Organic Chemistry at University of Alabama in Huntsville, and a Master of Sciences in Molecular Biology at University of Oklahoma Health Science Center. In early years of her career, she worked as a process development scientist involving DNA Pap testing kit validation and production scale up at Digene Corporation. Later, she worked at Apogee Discoveries as a scientist involved in an entire process of developing a diagnostic kit for bacterial screening in platelets. In 2001, she joined Pyrosequencing, Inc, where she developed the expertise in Pyrosequencing technology. As a key member of the team, she was directly involved the development, validation, and final market launch of PyroMark RUO kits.

Presentation Title: Multiplexing of Genetic and Epigenetic Biomarkers For Clinical Diagnostics

Presentation Summary: Genetic changes such as BRAF and Kras mutations have been widely accepted as biomarkers for many types of cancer. There is also growing evidence that aberrant DNA methylation of CpG islands plays important role in carcinogenesis. Techniques for early detection and cancer diagnosis with high sensitivity and specificity for different tumor types are limited so far. We believe a combination of genetic and epigenetic biomarkers will fill the gap.

EpigenDx is focused on genetic and epigenetic biomarker assessment in easily accessible biological materials, mainly on circulated fluid (serum or plasmid). The goal is to develop a multiplex of clinically validated markers to be used in early screening and diagnosis to predict the treatment efficacy or clinical outcome of different human malignancies.



Sam Chang, Ph.D, Director, Delsys Inc.

Dr. Shey-Sheen Chang is a Signal Processing Scientist of Delsys Inc., an engineering firm specialized in devices that can be used to measure surface electromyographic (EMG) signal. His primary responsibility includes algorithm conceptualization and implementation as well as product commercialization. Prior to joining Delsys, Dr. Chang was a research associate of NeuroMuscular Research Center at Boston University where he completed training under Professors Carlo J. De Luca and S. Hamid Nawab. During the course of doctoral research, he participated in various NIH/SBIR funded projects focusing on the development of signal processing algorithms which can be utilized to separate surface EMG signal into its constituent motor unit action potential trains (MUAPTs). The successful algorithmic solution to resolving complex sEMG signal was built upon the Integrated Processing and Understanding of Signals (IPUS) architecture which provides the joint platform to signal processing algorithms and artificial intelligence (AI) for addressing real-world signal processing challenges. Dr. Chang is member of IEEE. He received the B.S. degree from Chang Gang University, Taiwan in 1998, and the M.S. and Ph.D. degrees from Boston University in 2003 and 2009, respectively.

Presentation Title: Technological Advances in Detection of Surface Electromyography

Presentation Summary: This presentation explores innovative wireless sensors that can be used to acquire surface electromyography (sEMG) and various physiological signals from the human body. As the wireless sensor technology becomes more accessible, many new applications, such as training of professional athletes, robotic control, and monitoring the physical capabilities of patients with movement disorders, are broadening the field of sEMG. During the discussion, a demonstration of data collection tools will be given, showing how real-time data display and processing can be used to optimize the quality of sEMG data collection. Novel technology for suppressing the movement artifact and reducing cross-talk detected during dynamic activities will also be discussed.



William Lee, Ph.D., Director, R&D, AST Products

Dr. Lee is a leading surface chemist in the field of nano/biotechnology who received his Ph.D. in Chemistry and Biotechnology from the University of Tokyo, Tokyo, Japan. Dr. Lee developed membranes for peritoneal dialysis, polymeric electrolyte fuel cells, microbial cell removal and immobilization, protein separation, and recovery of lithium and rare metals. Prior to AST Products, Dr. Lee founded eMembrane, Inc., a company that develops and commercializes multifunctional polymeric materials and membranes for chemical and biological applications. Prior to eMembrane, Dr. Lee worked for JAFCO, Japan's largest venture capital firm, Harvard Medical School/Massachusetts General Hospital, Japan Society for the Promotion of Science and Japan Atomic Energy Research Institute. Dr. Lee has won numerous awards and is fluent in 7 languages including English, Mandarin, Cantonese and Japanese.

Presentation Title: Growth Opportunities in Biosensors

Presentation Summary: Recent technological advances in the field of biosensors are allowing this technology to cater to an extensive range of applications. Beside home diagnostics, medical and bio-defense, fire and environmental applications hold immense potential for biosensors. In order to make the most of these emerging applications, researchers worldwide are hiking up investment in research and development activities. Biosensors are moving beyond detection of biological threats such as anthrax and are finding use in a number of non-biological applications. Emerging biosensor technologies that can sense toxic agents and avert related illnesses in a timelier manner, especially during wars, hold huge growth

potential. This presentation will focus on the world biosensors market and its growth opportunities as well as the high costs of development that challenge biosensor developers.



Shen Luan, Co-Founder, COO, Berg Diagnostics

Shen joined Cytotech Labs in 2009 as Director of Bioanalytical and Diagnostics. He was named as Vice President of Bioanalytical and Diagnostics in 2010. He was appointed as President and Chief Technology Officer in 2010 for the newly formed Berg Diagnostics. He leads the development and implementation of Berg Diagnostics' technology platforms, directs business development efforts, as well as provides corporate strategy.

Shen Luan was Technical Product Manager of Waters Corporation responsible for LC/MS and LC/MS/MS system solutions and laboratory informatics from 2004 to 2009. Prior to joining Waters Corporation in 2004, he was with Thermo Fisher Scientific for 9 years and has held various management positions including Engineering Manager, Research Manager, and Product Manager. He has solid business experience across the product lifecycle including design, development, project management, commercialization, manufacturing, supply chain, quality assurance, and regulatory compliance.

Shen received a Ph.D. in Analytical Chemistry from Iowa State University and a B.S. in Analytical Chemistry from Peking University. He authored and co-authored 10 peer-reviewed publications and 25 scientific meeting presentations. He holds a Lean - Six Sigma Black Belt certificate.

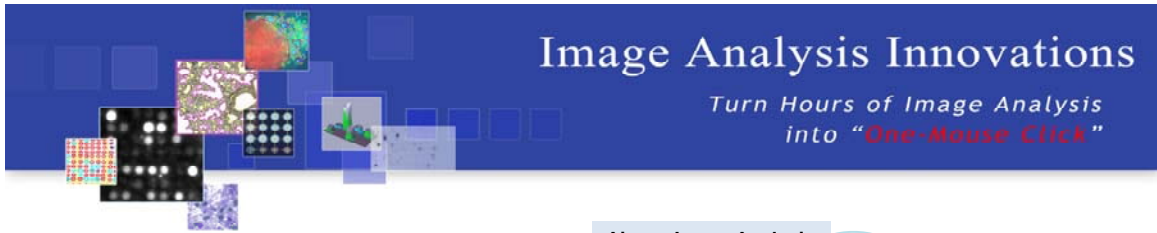


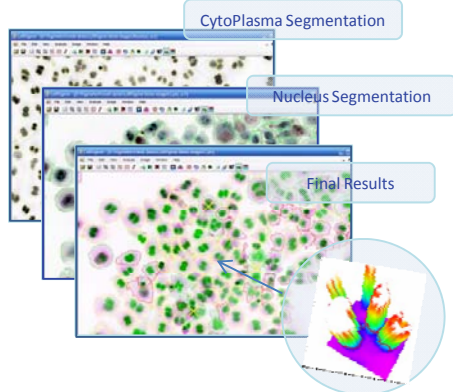
Image Analysis Innovations

Turn Hours of Image Analysis into "One-Mouse Click"

CellVigene™

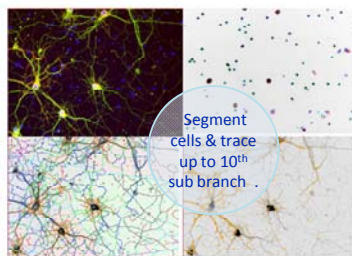
High automated image analysis software for cell based image analysis supports multiple signal segmentation. Clinical diagnosis cell and tissue image analysis software that provides accuracy, sensitivity, reliable results, unprecedented level of automation and high performance.

MicroNuclei Image Analysis



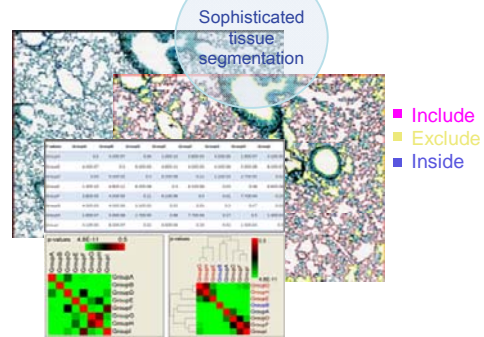
Cell based Micronuclei assay: able to detect tiny/weak micronuclei next to big/strong nuclei

Neurite Outgrowth Image Analysis



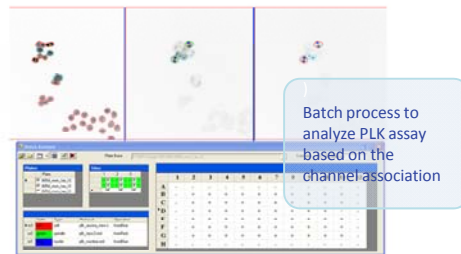
Segment cells & trace up to 10th sub branch

Airway Image Analysis

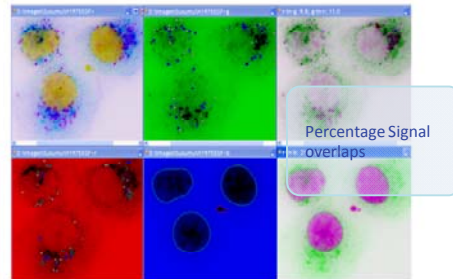


(A)Original lung image, (B) Classified and segmented image highlighting the alveolar walls. (C) The Average mean chord length was determined for 8 groups of animals (table) using CellVigene.

PLK Assay Image Analysis



Colocalization Tools



VigeneTech Inc.

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Tissue Microarray Analysis (TMA)

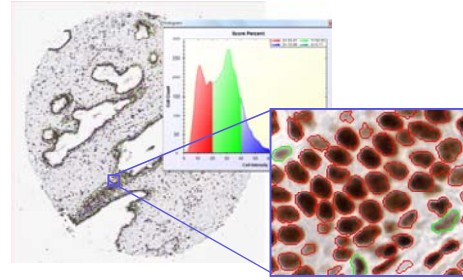
A classic issue in biology is validation of a new concept on actual human tissue. The difficulty of working with human tissue is further complicated by increasingly stringent guidelines regarding obtaining informed consent for its use. Thus, when tissue is obtained, it should be optimally managed to maximize its value. Tissue microarray represents a mechanism for highly effective use of this scarce resource.

Advantage:

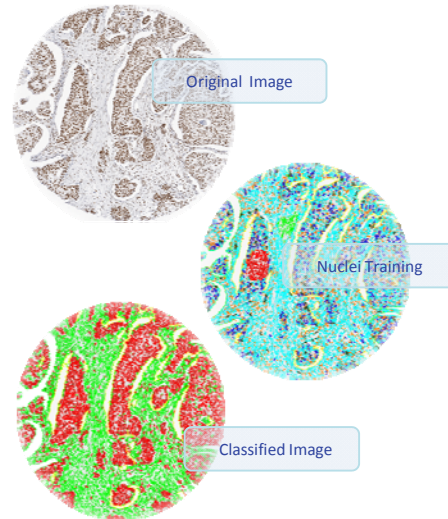
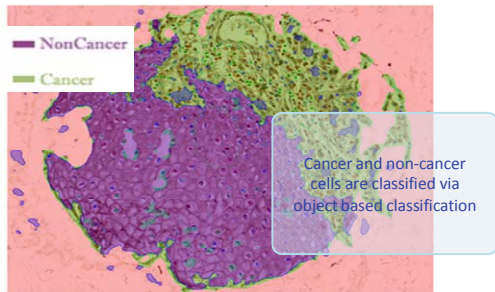
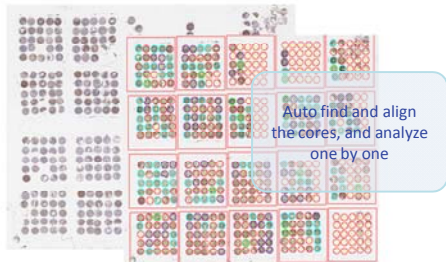
- Accurately measures nuclei, cytoplasm and Classify the different cells
- Provides multiple quantity parameters about Tissue , cell ,nuclei and cytoplasm
- Support all tissue format including slides and TMAs
- Enable to simply analyze whole TMA slides
- Verify the analyzed TMA slide through one core by one core

Automation:

- Tissue microarray core finding and grid definition
- Artificial intelligence for cancer tissue classification
- Signal segmentations of cell, nuclear, cytoplasm and staining of IHC, FISH, Antibody ...



Cancer cells are classified and scored based on the intensities. The histogram shows percent of cell of negative(0), low(1+), medium(2+), and high(3+) intensity



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