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A new cGMP bioassay involving electrophysiological recordings of CFTR currents

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Since 2006, ChanTest has performed Ussing assay research for clients to assess compound effects on electrogenic transporter proteins, such as the Cystic Fibrosis Transmembrane Conductance Regulator (CFTR). CFTR currents are measured in the Ussing assay by voltage clamping epithelial cell layers grown on permeable support (typically human bronchial epithelia or HBE cells) and measuring the current that flows in response to ligands or changes in trans-epithelial potential. ChanTest employs three, 24 chamber Ussing systems for higher throughput testing of compounds. In 2013, our group set-up an even higher throughput robotic system for measuring transporter currents from up to five 24-well permeable support microplates. In the fall of 2012, ChanTest added another bank of 24 Ussing chambers for the purpose of establishing an FDA approved cGMP bioassay. A client requested a cGMP compliant stability-indicating release bioassay for functional analysis of a botanical medicine in which the active species inhibits CFTR. All experiments and cell culture activities occur in a single cGMP certified room. A 24 chamber experiment evaluates the concentration-response relationship of two test articles and includes a reference standard and appropriate controls. Each experiment continues for approximately 90 minutes. This unique cGMP bioassay was approved by the FDA in December 2012. Representative data from CFTR experiments will be presented.

Biography

Antonio E. Lacerda, Ph.D., is Director of Contract Research and Development Services at ChanTest Corporation. His areas of research interest include the pharmacology and physiology of ion channels and epithelial transport. He joined ChanTest in 1997 and developed ion channel and epithelial transport assays, analytical and GLP compliance software, and implemented several assay technologies. He held faculty positions at Case Western Reserve University and Baylor College of Medicine, has published 32 articles in peer-reviewed journals and was a member of the Circulation Research editorial board. He received a Ph.D. in Neurobiology from The University of Connecticut and was an NRSA postdoctoral fellow at the University of Texas Medical Branch, Galveston.

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