Session: **Alternate Tests and Models II**
1:00 - 4:30 PM, Wednesday, March 18
Exhibit Hall

Establishing a Historical Database for a Multi-phased International Validation Study of a Stably Transfected Estrogen Receptor (ER) Transcriptional Activation (TA) Test Method

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The LUMI-CELL® ER assay is a stably transfected ER TA method developed for the detection of ER agonists and antagonists. Based on an ICCVAM recommendation, NICEATM, ECVAM, and JaCVAM initiated a validation study, using three laboratories (one each in the United States, Japan, and Europe), to evaluate the reproducibility and accuracy of the LUMI-CELL® ER assay. This four-phased study will ultimately evaluate all of the 78 reference substances recommended by ICCVAM for validation of *in vitro* ER test methods (http://iccvam.niehs.nih.gov/methods/endocrine/endocrine.htm). During Phase I, multiple testing of reference standards and controls was conducted using standardized LUMI-CELL® agonist and antagonist protocols to demonstrate proficiency, establish historical databases to be used as quality controls for subsequent testing, and provide measured or calculated reference standard and control data for an evaluation of intra- and inter-laboratory reproducibility. Phase I also included an evaluation at the U.S. laboratory for "edge" effects on the 96-well plate used for testing, which resulted in a redesign of the plate layout to include all 96 wells. Additional testing was also conducted at the European and Japanese laboratories to demonstrate proficiency with a visual observation method of assessing cell viability. Results of Phase I testing demonstrated the ability of the three laboratories to conduct the assay in a reproducible manner and supported modifications made to the protocols to increase testing efficiency. The three laboratories also established a historical database to use as quality controls when testing coded reference substances in the subsequent phases of the validation study.
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Keywords: validation, endocrine disruptors, estrogen receptor