

PROCESS OF VALIDATION OF THE LUMI-CELL™ ER RECOMBINANT BIOASSAY
FOR RAPID EVALUATION OF POTENTIAL ESTROGENIC ENDOCRINE DISRUPTOR
CHEMICALS

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Endocrine disruptor chemicals (EDCs) are a class of compounds, which have tremendous adverse effects on human and wild life populations. The association between the exposure to, and bioaccumulation in the food chain, of EDCs has raised concern worldwide. Identification of EDCs requires a relevant bioassay, which can both detect these chemicals, as well as provide a relevant estimate of their endocrine disrupting potency. Xenobiotic Detection System (XDS) Inc. developed the LUMI-CELL™ ER bioassay in order to detect EDCs using a high-throughput bioassay system. To detect EDCs, BG-1 cells were stably transfected with an estrogen-responsive luciferase reporter gene plasmid (pGudLuc7ere). The resulting cell line responds to estrogenic chemicals in a time-, dose dependent- and chemical-specific manner with the induction of luciferase gene expression. XDS's LUMI-CELL™ ER bioassay system has tested over 110 chemicals, 53 of these chemicals were recommended by ICCVAM for validation of ER binding and transcriptional activation. Of the 53 chemicals tested, which were recommended by ICCVAM, all of the 28 compounds having historical data for a positive response demonstrated estrogenic activity. Out of the 110 chemicals tested by LUMI-CELL™ ER bioassay system, 69 demonstrated estrogenic activity, while 41 showed no activity. Of the 57 chemicals tested, which were not included in the ICCVAM requirements for validation, 30 were found to possess estrogenic activity, while 27 showed no activity. This data clearly demonstrates that XDS's LUMI-CELL™ ER high-throughput bioassay system is a fast, reliable, and relatively inexpensive method for detection of EDCs, meeting many of the requirements mandated by the EPA and ICCVAMs Tier I (screening) requirements for EDC detection assays. Supported by NIEHS SBIR grant ES10533-03, and Superfund Basic Research Grant ES04699.