ICCVAM Recommendations and Limitations of the BG1Luc ER TA Test Method for Identifying Estrogen Receptor Agonists and Antagonists

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ICCVAM recently evaluated the BG1Luc estrogen receptor (ER) transactivation (TA) test method. An international interlaboratory validation study was conducted to determine the usefulness and limitations of the BG1Luc ER TA test method as a screening tool to identify substances with *in vitro* ER agonist and antagonist activity. Three laboratories (one each from the United States, Europe, and Japan) tested coded reference chemicals up to three times each. Results were similar across the three participating laboratories. For the agonist protocol, only one of the 35 reference substances that produced a definitive result was discordant (false negative) with existing reference data from other *in vitro* ER TA assays. For the antagonist protocol, all 25 reference substances that produced a definitive result were concordant with existing reference data from other *in vitro* ER TA assays. ICCVAM compared the BG1Luc ER TA test method results with results from the only *in vitro* ER TA test method currently included in national and international regulatory testing guidelines (i.e., U.S. EPA OPPTS 890.1300/OECD Test Guideline 455), resulting in identical accuracy statistics when each method tested the same agonist reference chemicals. ICCVAM concluded that the accuracy of this assay is at least equivalent to that of U.S. EPA OPPTS 890.1300/OECD Test Guideline 455 test method. Thus, the BG1Luc ER TA may be applicable to the U.S. EPA Endocrine Disruptor Screening Program. ICCVAM considered the peer review panel report, public comments, and the comments of the Scientific Advisory Committee on Alternative Toxicological Methods in preparing the ICCVAM final test method recommendations. ICCVAM recommends that the BG1Luc ER TA test method can be used as a screening assay to identify substances with *in vitro* ER agonist and antagonist activity.