

4.0 REFERENCE DATA

AR TA assays measure the ability of a test substance to initiate or block transcription of a reporter gene or cell proliferation in an appropriate cell line. The ability of a test substance to activate or inhibit androgen-induced TA *in vitro* suggests, but does not demonstrate, the ability of the substance to act as an androgen agonist or antagonist *in vivo*.

The purpose of this BRD is to assess the performance of various *in vitro* AR TA assays with regard to their sensitivity for detecting weak AR agonists and antagonists and their reliability within and among laboratories and across procedures. No attempt is made to evaluate their performance with respect to other biological effects *in vivo*, such as growth promotion of male reproductive tissues. Such comparisons will be addressed elsewhere. Therefore, no reference data are included for measuring the biological relevance of AR TA assays.

[This page intentionally left blank]