

REFERENCE RECHARACTERIZATION FOR POTENCY ASSAYS USING REPLICATE TESTING IN 4 PARAMETER LOGISTIC MODEL

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Abstract. Clinical laboratories utilize various reference standards during testing for potency assays. Two types of references are used: International reference standards or in-house standards. The international reference standards are bought from WHO, CBER, NIBSC, etc. Very often clinical laboratories prepare new in-house reference lot to be used for testing because the lot is depleted or reached the expiration date. In order to be used, the new in-house reference need to be re-characterized, i.e., the potency of the new lot shall be compared to the old lot, the reference standard to determine whether it is appropriate to switch the bioassay standard lot to the new lot. This paper describes reference recharacterization study design for potency assay using four-parameter logistic model.

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