

## California Device Recall Information Sheet

### Food and Drug Branch – Device Recalls

Qualigen Inc The FastPack IP Sex Hormone Binding Globulin Immunoassay

Recall Date	Product Description	Recalling Firm	Recall Reason
01/03/2025	The FastPack IP Sex Hormone Binding Globulin Immunoassay, Part #25000081, is for the quantitative measurement of SHBG in human serum and plasma. For in vitro diagnostic Use and contains 30 FastPacks.	Qualigen Inc	Three lots of the FastPacks kitted into the FastPack SHBG Complete Kits were labeled with the incorrect expiration date. The following is a listing of affected lots: Lot Number: 2408018-1, 2409015-1, and 2409015-2. The likelihood of patient harm is expected to be low as routine Quality Control should detect kits that are impacted by signal deterioration due to age.

Recall Class	Product Identification	Distribution	Affected Dates
II	UDI-DI: 20816467020345  Lot numbers: 2408018-1 Exp: 2025-09-05 - 2409015-2, Exp: 2025-06-26	6 kits in California	December and prior

For additional information, please visit the [FDA Website](#).