



[Food and Drug Branch – Device Recalls](#)

California Device Recall Information Sheet

Drg International Inc. Recalls Salivary Testosterone Elisa Model

Recall Date	Product Description	Recalling Firm	Recall Reason
8/21/2024	<p>Salivary Testosterone Elisa Model Catalog Number: SLV-3013 An enzyme immunoassay for the quantitative in vitro diagnostic measurement of free active testosterone in saliva.</p>	<p>DRG INTERNATIONAL INC. Springfield, Nj</p>	<p>Invalid Controls. The Low Control is out of range; too high which causes invalid runs that would result in repeating the runs and delays for reporting results to patients.</p>

Recall Class	Product Identification	Distribution	Affected Dates
III	<p>Salivary Testosterone Elisa Model UDI-DI/Lot: 04048474030136/66K014, 66K123</p>	<p>5 Units in California</p>	<p>August 2024 and prior</p>

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