

State of California—Health and Human Services Agency

California Department of Public Health



Food and Drug Branch - Drug Recalls

CALIFORNIA DRUG RECALL INFORMATION SHEET

Biocheck Recalls T4 EIA Kit for Not Meeting Product Shelflife Standards

Recall Date	Product Description	Recalling Firm	Recall Reason
11/17/2021	T4 EIA Kit Cat No: BC-1007, Store at 2-8C, For in vitro diagnostic use only This products intended use is For the quantitative determination of total thyroxine (T4) concentration in human serum. The test is useful in the diagnosis and treatment of thyroid disorders	Biocheck Inc. South San Francisco, California	Immunoassay TEST Kit do not meet product shelf-life standards resulting in failed controls.

Recall Class	Product Identification	Distribution	Affected Dates
II	T4 EIA Kit Lot number: RN-60831	14 Kits in California	October 2021 and prior
II	T4 EIA Kit Lot numbers: RN-60923	8 Kits in California	October 2021 and prior

FOR ADDITIONAL INFORMATION, PLEASE VISIT THE FDA WEBSITE



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