

California Device Recall Information Sheet

Food and Drug Branch – Device Recalls

Healgen Scientific Llc Recalls Healgen Series Reagent Strips For Urinalysis

Recall Date	Product Description	Recalling Firm	Recall Reason
9/27/2024	Healgen Series Reagent strips for Urinalysis are composed of several color pads aligned on a test strip. Each pad is employed for testing one assay item by visually or instrumentally reading the color change of the pad and comparing with the corresponding blocks on a color chart. The Healgen Series Reagent Strips for Urinalysis provides tests for Glucose, Bilirubin, Ketone, Specific Gravity, Blood, pH, Protein, Urobilinogen, Nitrite, Ascorbic Acid and Leukocytes in Urine.	Healgen Scientific Llc	The reason for this recall is Healgen Scientific Ltd. has determined that their Urinary Reagent Strip products have shown reduced sensitivity, or potential false negative results for the detection of urinary protein by way of uneven color fading on the total protein test pad. This could lead to a delay in the identification of potential kidney diseases, their evaluation, and/or other conditions associated with elevated protein levels in urine and subsequently a delay in patient treatment.

Recall Class	Product Identification	Distribution	Affected Dates
II	Product Item Code: Urinox-P30 UDI-DI code: 196852593453 Lot Number: N2310003 N2310012 N2305013 N2308006 N2209013 N2302034 N2303002 Product Item Code: URS-11T UDI-DI code: 00816490024347 Lot Number: N2311002 N2306012 Product Item Code: Urinox10-30 UDI-DI code: 099654011043 Lot Numbers: N2311004 N2305015 N2305025 N2308011 N2309011 N2302027 N2302032 Product Item Code: URS-10T UDI-DI code: 00816490024323 Lot Numbers: N2311007 N2306001 N2306013 N2308004 N2309002 N2211004 Product Item Code: Urinox10-20 UDI-DI code: 707486987534 Lot Numbers: N2305014 N2305024 N2308010 N2309010 N2302031 Product Item Code: Urinox-10-60 UDI-DI code: 707486987053 Lot Numbers: N2305026 N2306006 N2308012 N2302028 N2302033 Product Item Code: URS-4T UDI-DI code: 00816490024330 Lot Number: N2306014	215 Units in California	September 2024 and prior.

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