California Device Recall Information Sheet

Food and Drug Branch – Device Recalls

Beckman Coulter, Inc. Access Erythropoietin

Recall Date	Product Description	Recalling Firm	Recall Reason
02/28/2025	Access Erythropoietin (EPO) Catalog Number - A16364 a glycoprotein (~30,400 Daltons) produced primarily by the kidney, is the principal factor regulating red blood cell production (erythropoiesis) in mammals. Renal production of EPO is regulated by changes in oxygen availability. Under conditions of hypoxia, the level of EPO in the circulation increases and this leads to increased production of red blood cells.	Beckman Coulter, Inc.	Affected lot (439363) exhibited a negative dose drop of -22% with native patient samples compared to alternate reagent lots. Patient samples tested with the affected lot may demonstrate repeatable falsely decreased results, which may lead to improper diagnosis or repeat testing.

Recall Class	Product Identification	Distribution	Affected Dates
II	Catalog: A16364 UDI-DI: 15099590201838 Lot: 439363	26 units in California	February and prior

For additional information, please visit the FDA Website.