California Device Recall Information Sheet

Food and Drug Branch – Device Recalls

Immuno-Mycologics, Inc Recalls Candida ID Antigen, REAG, AG, REF C50110

Recall Date	Product Description	Recalling Firm	Recall Reason
03/18/2025	Candida ID Antigen, REAG, AG, REF C50110, Vol 1 mL REF ID1001, Immy Fungal Antigens, Positive Controls, & Immunodiffusion (ID) plates for use in the ID test, RX only, IVD, CE	Immuno-Mycologics, Inc	Candida Immunodiffusion Antigen may have reduced sensitivity which could result in false negative results.

Recall Class	Product Identification	Distribution	Affected Dates
II	Lot #: F4171005/UDI: 00816387020223	15 vials shipped Quest San Juan Capistrano in CA	February 2025 and Prior

For additional information, please visit the FDA Website.