



## California Device Recall Information Sheet

### Abbott Laboratories Recalls Architect Stat Myoglobin Reagent Kit For Manufacturing Issue Of Non-Conforming Microparticles Resulting in Affected Device Calibration

Recall Date	Product Description	Recalling Firm	Recall Reason
4/10/2024	<b>Architect Stat Myoglobin Reagent Kit</b> LN 2K43-25 and 2K43-20.	<b>ABBOTT LABORATORIES</b> Abbott Park, Illinois	The reason for the recall is the failure of calibration and quality controls due to a manufacturing issue of microparticles not meeting labeled claim. This may lead to incorrect myoglobin results and delayed diagnosis of myocardial infarction.

Recall Class	Product Identification	Distribution	Affected Dates
II	<b>Architect Stat Myoglobin Reagent Kit</b> LN 2K43-25 - Lot number 50808UN23, exp. 11/30/2024, UDI (01)00380740003302 (17)241130(10)50808UN23; LN 2K43-20 - Lot number 60104UN23, exp. 11/30/2024, UDI (01)00380740003296 (17)241130(10)60104UN23.	43 Units in California	Expires November, 2024

For additional information, please visit the [FDA website](https://www.fda.gov)

