

The Board of Pharmacy has received notice of the following product recall. The Board strongly encourages pharmacies to immediately review their quality assurance and recall policies and procedures to determine if any corrective action is required.

This is to inform you of a product recall by Immunocore Commercial LLC involving KIMMTRAK lot numbers filled from drug product batch 3D009A. The KIMMTRAK lot numbers listed below are affected. Immediately examine your inventory and quarantine product subject to recall.

This recall is being made with the knowledge of the Food and Drug Administration and has been initiated due to an unexpected decrease in potency identified through routine stability testing at the 18-month timepoint. All other attributes were within FDA approved specifications at the 18-month timepoint and the potency was within specifications at the 12-month and earlier timepoints. To date, no patient safety issue has been identified.

TRADE Product (NDC 80446-0401-**01**) was available for purchase by hospital and infusion centers between September 2024 and April 2025. PAP / Free Good product (NDC 80446-0401-**99**) was available for shipping to hospital and infusion centers between February 2024 and March 2025.

	NDC	Lot #s	Expiry
TRADE Product	80446-0401-01	3D009AA09	31 MAR 2026
		3D009AA10	
		3D009AA25	
	This NDC is only available through approved specialty distributors.		
PAP / Free Goods (labelled “NOT FOR SALE”)	80446-0401-99	3D009AA02	31 MAR 2026
		This NDC is only available for eligible patients through KIMMTRAK Connect (www.kimmtrakconnect.com) and provided on a named patient basis.	