

FIELD NOTICE

July 19, 2024

Product: NOD[®] FREND VERIFICATION Kits

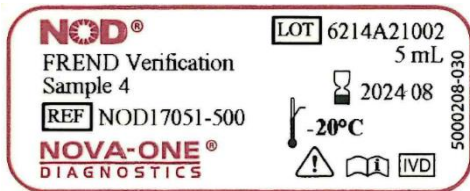
Part Numbers: NOD17051-500
NOD17151-500

Lots: 6214A21002 – Sample 4
6215A21002 – Sample 5

Expiration Date: August 2024

Shipping Dates: Orders shipped July 1, 2024 through July 16, 2024

During a manual relabeling event for the last 30 kits of the 500-kit lot, Sample 4 and Sample 5 vials were mislabeled. The Sample 4 vials were incorrectly labeled with the Sample 5 labels, as a result, the Sample 5 vials were incorrectly labeled with the Sample 4 labels. The need for relabeling arose from improved stability and extended shelf-life date.



The analytical properties of the products have not been compromised. Verification testing has been conducted. The mislabeled Sample 4 vials result within the acceptable ranges for Sample 5 and the mislabeled Sample 5 vials yield results within the acceptable ranges for Sample 4.

We apologize for the confusion. The date of the mislabeling event has been identified and corrective actions are being implemented to prevent recurrence. Other vials that may have been affected by this mislabeling, have been isolated.

A new FRENDA Verification lot is scheduled for production. These kits will be replaced, free of charge, in mid-August.