



# Urgent Field Safety Notice Urgent Product Recall

## Immediate Action Required

**Date Issued** January 24, 2024

**Product**

| Product Description            | List Number (LN) | Lot Number | UDI   |
|--------------------------------|------------------|------------|---|
| Alinity i Anti-HBs Reagent Kit | 07P8952          | 51441FN00  | (01)00380740138219 (17)240630 (10)51441FN00 |

**Explanation**

Abbott has identified that some cartridges within Alinity i Anti-HBs Reagent Kit, LN 07P8952, lot 51441FN00, have reduced volume in the microparticle bottle, which will result in aspiration error message codes.

We have received complaints associated with this issue due to aspiration errors related to the microparticle component of the reagent kit. Review of field data indicates that some cartridges are providing approximately 65 tests instead of 100 tests as indicated on the product labeling.

Abbott is investigating the root cause of this event and will take the necessary actions to prevent recurrence in the future.

**Impact on Donor/Patient Results**

There is no impact to patient results. The analyzer will generate an aspiration error and therefore no patient results will be generated.

**Necessary Actions to be Taken by Customer**

- Immediately discontinue use of Alinity i Anti-HBs Reagent Kit, lot number 51441FN00.
- Destroy all inventory of lot number 51441FN00 received according to your local procedures.
- Immediately contact Customer Support to order replacement material.
- If you have forwarded the product listed above to other laboratories, please inform them of this Product Recall and provide to them a copy of this letter.
- Complete and return the Customer Reply Form.
- Please retain this letter for your laboratory records.

**Contact Information**

If you or any of the health care providers you serve have questions regarding this information, please contact your local area Customer Service.

If you have experienced any patient or user injury associated with this Field Action, please immediately report the event to your local area Customer Service.