

**CORE DIAGNOSTICS**

Abbott Ireland Diagnostics Division,
Finiskin Business Park,
Sligo, Ireland

Single Registration Number (SRN):
IE-MF-000009849

Urgent Field Safety Notice

Urgent Product Correction

Immediate Action Required

Date Issued April 24, 2023

Product

Product Description	List Number (LN)	Lot Number	UDI
Alinity i Anti-TPO Reagent Kit	09P3522	50321FN00	(01)00380740150617 (17)240720(10)50321FN00
Alinity i CMV IgM Reagent Kit	07P4432	49341FN00	(01)00380740129880 (17)240117(10)49341FN00

Explanation

Abbott has confirmed that due to a manufacturing fill volume error, the Alinity i reagents below, contain a marginal lower fill volume than detailed in the Kit Contents section of the Instructions For Use (IFU):

Alinity i Anti-TPO Reagent Kit, Lot 50321FN00.

Although the volume in the impacted lot is below the defined volume in the IFU, adequate reagent exists to provide the defined number of tests in the kit.

Alinity i CMV IgM Reagent Kit, Lot 49341FN00.

Due to the reduced reagent volume, there may not be adequate volume to achieve the defined number of tests in the IFU. There is the potential to generate Liquid Level Sense (LLS) message codes. For example, message code "3424 – (0) pipettor aspiration error" followed by "3048 - Maximum number of LLS errors exceeded in reagent cartridge (0) position located in reagent carousel position (1), 0 = Bottle, 1 = Reagent carousel position".

Abbott has confirmed there is no impact to assay performance for the affected lots.

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

**Impact on
Patient Results**

There is no impact to patient results.

We recommend that you follow the necessary actions below:

**Necessary
Actions to be
Taken by
Customer**

Alinity i Anti-TPO Reagent Kit (2x100T), Lot 50321FN00

No action is required. You may continue to use the lot as adequate volume exists to provide the defined number of tests in the kit.

Alinity i CMV IgM Reagent Kit (2x500T), Lot 49341FN00

You may continue to use LN 07P4432, lot 49341FN00, however these kits may not contain sufficient reagent volume to complete 500 tests. These kits will provide approximately 475 tests.

If liquid level sense message codes such as 3424 followed by 3048 are generated after approximately 475 tests, replace the reagent cartridge to continue testing. If you receive a message code before achieving 475 tests, please perform troubleshooting per the Alinity ci-series Operations Manual.

If you have forwarded the product listed above to other laboratories, please inform them of this Product Correction 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.
