



Urgent Field Safety Notice Product Correction

Urgent - Immediate Action Required

Date Issued September 2, 2020

Product

Product Description	List Number	Lot Number	US UDI	EU UDI
Alinity s Anti-HBc Reagent Kit	06P0655	All	N/A	N/A

Explanation

When the Alinity s Anti-HBc Reagent Kit (List Number 06P0655) and the Alinity s Syphilis Reagent Kit (List Number 06P0955) are calibrated and run on the same processing lane, false reactive Anti-HBc test results may occur.

Abbott is releasing Alinity s System software version 2.7.0 (List Number 04U76-13), which includes a new feature to separate assays to run on different processing lanes when prescribed by the associated assay file. In addition, the Alinity s Syphilis assay file will be updated to activate this new feature. The combination of Alinity s System software version 2.7.0 and the updated Alinity s Syphilis assay file (100_004) will separate the Alinity s Anti-HBc and Alinity s Syphilis assays when run on the same Alinity s System.

The updated, revised Alinity s Syphilis assay file (100_004) is expected to be available during October – November 2020.

**Donor /
Patient
Impact**

There is potential for incorrect Anti-HBc test results should the initial and retest results be falsely reactive.

**Necessary
Actions**

Installation of Alinity s System software version 2.7.0, in conjunction with installation of the updated Alinity s Syphilis assay file (100_004), will activate the new feature for assays requiring lane separation. Until your Alinity s System(s) is updated with the new system software and Alinity s Syphilis assay file, please perform the necessary actions associated with your current Alinity s assay file / lane configuration to mitigate potential impact:

**Necessary
Actions
continued**

If...	Then...
The Alinity s Anti-HBc and Alinity s Syphilis assays are not installed or do not run on the same Alinity s System.	No immediate action is required.
The Alinity s Syphilis assay is not calibrated and run on the same processing lane as the Alinity s Anti-HBc assay.	Maintain the current assay configuration and ensure Alinity s Anti-HBc is not run on the same processing lane as the Alinity s Syphilis assay.
The Alinity s Syphilis assay and the Alinity s Anti-HBc assay are calibrated on the same processing lane.	Contact your local area customer service representative to uninstall and reinstall the assays to run on separate processing lanes.

- Please review this letter with your Medical Director or Laboratory Management and follow your laboratory protocol regarding the need for reviewing previously reported test results.
- If you have forwarded the Alinity s Anti-HBc product to other laboratories, please inform them of this Product Correction and provide them a copy of this letter.
- Complete and return the Customer Reply Form.
- Please retain this letter for your laboratory records.

Your Abbott representative will be scheduling a mandatory upgrade of your Alinity s System to install Alinity s System software version 2.7.0.

Abbott will notify you when the updated Alinity s Syphilis assay file (100_004) is available for installation.

**Contact
Information**

If you or any of the health care providers you serve have any 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.