



Urgent Field Safety Notice Product Correction

Immediate Action Required

Date Issued

August 30, 2018

Product

Product	List Number (LN)	UDI
Alinity s System	06P16-01	N/A

Explanation

This letter is to inform you of a Product Correction for Alinity s System software and provide instructions on the actions your laboratory must take.

Alinity s System software V2.1.0 is now available and will resolve the following issues that Abbott has identified.

1. When the Alinity s CMV IgG Qualitative assay is run as the last assay on a sample, the instrument may shut down. If the instrument does not shut down, the result is an insufficient wash of the probe. The insufficient wash may compromise the following sample aspirated with that probe, potentially causing a false reactive result for any of the assays run. All other assays, when run in any position in a profile, have sufficient probe washes. This does not impact software versions prior to Alinity s System software V2.0.0.
2. During sample processing, exceptions that have completed transmission to the Laboratory Information System (LIS) or middleware may continue to appear on the Alinity s Exception Details screen as Pending Transmission.

Patient/Donor Impact

1. If the Alinity s CMV IgG Qualitative assay is run as the last assay on a sample, a potential false reactive test result for any of the Alinity s assays may occur on the following sample aspirated with the impacted probe.
2. There is no Donor/Patient Safety Impact related to the Alinity s Exception Details screen incorrectly indicating completed transmissions are still pending.

Necessary Actions

1. If you are running an Alinity s System software version prior to V2.0.0, the only action required is to update to software V2.1.0. Your Abbott representative will be scheduling mandatory upgrades of your Alinity s System to install Alinity s System software V2.1.0.

If you are running Alinity s System software V2.0.0 or greater and are not yet running the Alinity s CMV IgG Qualitative assay, please install Alinity s System software V2.1.0 prior to using Alinity s CMV IgG Qualitative or follow the actions below.

**Necessary
Actions
continued**

If you are running Alinity s System software V2.0.0 or V2.0.1 and the Alinity s CMV IgG Qualitative assay:

- All supplemental testing for repeatedly reactive samples as indicated in the package inserts for Alinity s Anti-HCV, Alinity s Chagas, Alinity s HIV Ag/Ab, Alinity s HTLV, and Alinity s Syphilis, should be performed with a fresh sample.
 - For repeatedly reactive Alinity s HBsAg samples, if using Alinity s HBsAg Confirmatory, supplemental testing should be performed using a fresh sample and run without Alinity s CMV IgG Qualitative. If you are using an alternate supplemental method, testing should also be performed using a fresh sample.
 - For Alinity s CMV IgG Qualitative, it is recommended to perform supplemental testing of reactive samples using a fresh sample.
 - As there are no recommended supplemental tests for Alinity s Anti-HBc, if you have an initial reactive result for Alinity s Anti-HBc, it is recommended that those samples should be tested in duplicate using a fresh sample and run without Alinity s CMV IgG Qualitative.
2. Should your facility experience completed transmitted exceptions appearing as pending transmissions on the Alinity s Exception Details screen, you may set the Host to “off” and then back to “on” and manually re-transmit the exception to recover from this issue prior to Alinity s System software V2.1.0 being installed.

Please review this letter with your Medical Director and follow your laboratory protocol regarding the need for reviewing previously reported patient results.

Follow your laboratory procedures and please retain this letter for your laboratory records.

**Contact
Information**

We sincerely regret any inconvenience this may have caused your laboratory. If you or any of your customers or health care providers you serve have any questions regarding this information please contact your local area Customer Service.
