



Urgent Field Safety Notice Product Correction

Urgent - Immediate Action Required

Date Issued	October 26, 2018
Product	Product Name: Alinity hq Analyzer and Alinity hs Slide Maker Stainer Module List Number: 09P68-01 and 09P69-01 UDI Number: Not applicable Serial Numbers: See Attachment 1
Explanation	<p>This letter is an extension to Product Correction FA11OCT2018 dated 11-Oct-2018.</p> <p>When the IAS3 channel of the RBC optical tracking goes out of specification, this results in an increase in RBC fragment flags. RBC fragment flags indicate the presence of RBC fragments or schistocytes. RBC fragments can make RBC results suspect or invalid based on the degree of fragmentation.</p>
Patient Impact	There is a potential for delay in generation of patient results due to the need for unplanned service.
Necessary Actions	<ul style="list-style-type: none">• Ensure the laboratory has a back-up instrument or an alternative method of generating hematology patient results.• When Software Version 3.0 is installed, optical Moving Averages will be enabled allowing detection of the issue prior to system being inoperable. User should contact local area customer service if optical Moving Average alert limit (Message Code 1801) is triggered.• Your Abbott representative will begin scheduling mandatory software, hardware, and Operations Manual upgrades starting in November 2018.• When you receive the mandatory software upgrade, it may be necessary to download the Alinity h-series Operations Manual (80000023-106) for Software Version 3.0 onto a USB drive for use until the upgraded on-line help is installed. The Operations Manual is available by accessing the Technical Library through the Abbott Customer Portal.• 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.• Please retain this letter for your laboratory records.
Contact Information	We sincerely regret any inconvenience this may cause your laboratory. If you or any of the health care providers you serve have any questions regarding this information, please contact your local area Customer Service.