

Single Registration Number (SRN): US-MF-000023583



Urgent Field Safety Notice
Urgent Product Correction
Immediate Action Required

Date Issued September 9, 2022

Product

Product Description	List Number	Control Number	UDI
Alinity hq Analyzer	09P68-01	See Attachment 1	
Alinity hs Slide Maker Stainer Module	09P69-01		

Explanation

The Alinity h-series System Control Center (SCC) Application Software Version 4.3 (and below) and the Local User Interface (LUI) Embedded Analyzer Engine (EAE) contain a cybersecurity certificate that expired on 08SEP2022. Whenever the software checks for the cybersecurity certificate expiration date and it detects that it has expired, the SCC and/or LUI becomes nonfunctional. This renders the Alinity h-series unable to process samples.

There is no impact to cybersecurity or results integrity on the Alinity h-series with this issue.

Impact on Patient Results

As the SCC and/or LUI is down, the instrument is unavailable to process patient samples leading to a potential delay of patient results.

Necessary Actions to be Taken by Customer

Your Abbott representative will contact you for the correction of this issue.

Please retain this letter for your laboratory records.

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.

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.