



Urgent Field Safety Notice Product Correction

Urgent - Immediate Action Required

Date Issued

March 29, 2019

Product

Product Name: Alinity hq Analyzer

List Number: 09P68-01

UDI Number: Not applicable

Serial Numbers: All

Explanation

This letter is to inform you of the following potential issues with the Alinity hq Analyzer incubation paddles.

- Increase in “step loss on axis” errors (error code 5874)
- Foaming of the reagent in the incubation cup

You may have received an initial communication dated 11 October 2018 associated with seizing of the incubation paddle, which will cause the system to halt.

Patient Impact

There is a potential for delay in the generation of patient results due to the increase in step loss on axis errors and seizing of the incubation paddle. There is a potential of impact to patient results due to the foaming of the reagent in the incubation cup.

Necessary Actions

This will require monitoring and/or replacement of the incubation paddles installed on your Alinity hq analyzer. This replacement may occur more than once.

If you recently had your incubation paddles replaced due to FA11OCT2018, an Abbott representative will contact you to schedule a replacement. Additionally, Abbott will monitor all paddles and replace as needed until new design paddles are available.

Once the new design paddles are available, an Abbott representative will contact you to schedule the replacement anticipated to start in September 2019.

Ensure that you have a backup instrument or an alternate method of generating hematology patient results should the system become inoperable.

No changes are required to the recommended maintenance schedule.

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.

If you have experienced any patient or user injury associated with this Field Action, please immediately report the even to your local area Customer Service.
