



Urgent Field Safety Notice Product Correction

Urgent - Immediate Action Required

Date Issued

February 28, 2019

Product

Product Name	List Number	Serial Number	UDI
Alinity hq Analyzer	09P68-01	ALL	Not Applicable
Alinity hs Slide Maker Stainer Module	09P69-01	ALL	

Explanation

Abbott has identified the safety interlock covering the septum piercing probes may not deploy when the bulk solution 1 Liter bottle is removed on the Alinity h-series: Alinity hq Analyzer & the Alinity hs Slide Maker Stainer Module.

The Alinity hq Analyzer and the Alinity hs Slide Maker Stainer Module use bottles for the required bulk solutions (Alinity hq: WBC, HGB, RETIC reagents, Autoclean Alinity hs: Smear Fix solutions and May-Grunwald & Wright Griemsa Stain). The bottles are loaded into the bulk solution drawers. To load a bottle, the bottle is inverted into the appropriate bottle holder. A septum ensures the bulk solution does not spill as the bottle is inverted. As the bottle is placed into the bottle holder, a safety interlock is pushed back exposing the septum piercing probes to puncture the septum. When the bottle release button is depressed and the bottle is removed, the safety interlock should cover the septum piercing probes. If the safety interlock does not cover the septum piercing probes, the probes represent a probe stick hazard if the user were to place their hand in this area.



Drawings of Alinity hq Autoclean Solution bottle holder showing detail when the safety interlock covers the piercing probes and when the safety interlock does not deploy showing the exposed piercing probes. All bottle holders have identical piercing probes.

Safety Impact

The septum piercing probes could cut or puncture the user's hand.

As there may be residual bulk solution in the area, this could also expose the user's unprotected skin to the bulk solution. The specific hazards associated with the bulk solutions that may cause skin irritation are:

WBC Reagent (LN 07P79): Contains methylisothiazolinone that may cause an allergic skin reaction.

AutoClean Reagent (LN 01R51): Contains sodium hypochlorite that may cause skin irritation.

Smear Fix (LN 08P79): Contains methanol that may be toxic when in contact with skin.

May-Grunwald Stain (LN 08P81): Contains methanol and polyethylene glycol octylphenyl ether that may be toxic when in contact with skin.

Wright-Griesma Stain (LN 08P80): Contains methanol and polyethylene glycol octylphenyl ether that may be toxic when in contact with skin.

The HGB reagent (LN 07P81) and RETIC reagent (LN 07P80) do not present a chemical exposure hazard to unprotected skin.

Necessary Actions

Please continue to follow the instructions provided in the Alinity h-series Operations Manual when replacing the bulk solutions. As indicated in the Operations Manual, use caution when accessing bulk solution bottle holders or replacing bulk solution bottles as you may be exposed to a sharp hazard.

If the safety interlock or bottle release does not function correctly, please contact your area customer support for assistance.

Your Abbott representative will be contacting you to schedule the placement of a new safety hazard labeling for CAUTION: Sharp Element in the bulk solution drawer to increase the user awareness of this hazard.



CAUTION: Sharp Element. This activity or area may expose you to sharp elements.

The sharp elements safety symbol will be used on the Alinity hq Analyzer & the Alinity hs Slide Maker Stainer Module to identify potentially dangerous conditions. The safety symbol and definition will be included in a future version of the Alinity h-series Operations Manual.

Please complete and return the attached Customer Reply form.

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 have caused 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 event to your local area Customer Service.
