

Single Registration Number (SRN): N/A



Product Correction

Urgent - Immediate Action Required

Date Issued

July 12, 2021

Product

Product Description	List Number	Serial Number Range	US UDI	EU UDI
Alinity s System	06P16-01	AS1001 – AS1330	N/A	N/A

Explanation

Abbott has identified an issue with liquid waste pressure monitoring. This communication provides actions to be followed until your Alinity s System analyzer(s) is upgraded with a future system software version and a hardware component.

The liquid waste assembly is located within the liquid waste area of the Alinity s System. It directs all liquid waste to a common laboratory drain outlet or receptacle via the external waste tubing. Pressure buildup may occur within the external waste tubing if the tubing becomes obstructed or if using an external waste tank and the inlet valve is inadvertently closed during instrument operation.

Due to an issue with the associated pressure sensor, the Alinity s System will not detect pressure buildup within the external waste tubing and the Alinity s System software will not stop processing new test requests or generate message code 5101 *Liquid waste high pressure detected*.

Abbott will be implementing a software and hardware resolution that will enable the Alinity s System to detect external waste tubing line pressure buildup and generate the associated message code.

Impact on Donor/Patient Results

There is no impact to donor / patient results. Failure of the Alinity s System to detect pressure within the liquid waste tubing line can cause the potential for biohazardous exposure and / or operator injury (contact with liquid waste). Buildup of internal pressure creates the potential for liquid waste to spray from the waste tube should it become disconnected due to the pressure buildup or removal during troubleshooting.

**Necessary
Actions**

As stated in Section 8, Hazards, of the *Alinity s System Operations Manual*, follow all product labeling and safety instructions in the laboratory. Always wear personal protective equipment (PPE) when operating the Alinity s System, other laboratory instrumentation and equipment, and when using chemicals.

Adhere to the instructions listed in the *Alinity s System Operations Manual*, Section 10, to resolve message codes pertaining to waste overflow and contact Customer Service to resolve issues related to hardware failure.

Use caution when handling the Alinity s System external waste tubing. Avoid any configuration that could impact the free flow of the external waste and cause pressure buildup within the external waste tubing.

A future Alinity s System software update and associated hardware upgrade will be implemented to enable external liquid waste tubing pressure monitoring and the display of the expected message code 5101 *Liquid waste high pressure detected*.

- 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.
- Complete and return the Customer Reply form.
- Please retain this letter for your laboratory records.

**Contact
Information**

If you or any of the health care providers you serve have questions regarding this information, U.S. Customers please contact Customer Service at 1-877-4ABBOTT (available 24 hours a day, 7 days a week). Customers outside the U.S., please contact your local area Customer Service.

Adverse reactions or quality problems experienced with the use of this product may be reported to the FDA's MedWatch Adverse Event Reporting program either online (<http://www.fda.gov/MedWatch/report.htm>), by mail (<http://www.fda.gov/MedWatch/getforms.htm>), by phone (1-800-332-1088), or by fax (1-800-FDA-0178).

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.
