Abbott GmbH & Co. KG
Max-Planck-Ring 2
65205 Wiesbaden, Germany

Urgent Field Safety Notice
Product Correction

Urgent - Immediate Action Required

Date Issued April 15, 2019

Product

Product Name	List Number	Serial Number	UDI
Alinity c Cuvette Segment	04S47-01	All	Not applicable

Explanation

Individual cuvettes within the Alinity c Cuvette Segment may become seated lower than the designed height. This may result in inadequate dispense into specific cuvettes due to the sample probe being unable to make efficient contact with the cuvette bottom.

A cuvette may become seated lower than the designed height due to excessive force that causes damage to the sealant around the cuvette segment top or causes the cuvette segment base to detach. Excessive force is any force greater than normal operational forces exerted by the instrument, such as during manual cleaning of cuvettes or cuvette washer movement errors.

Based on post-market surveillance and internal data, Abbott is recommending the actions below to further reduce incidences associated with cuvette segments seated lower than designed height.

Patient Impact

Any assay run on the Alinity c processing module may be impacted if the cuvette is seated lower than the designed height.

If a cuvette is lower than the designed height, there is a potential to generate falsely depressed patient results in that cuvette for any assay run on the Alinity c processing module. The impact on the test result varies depending on the extent of the lowering observed. These falsely lowered patient results may be accompanied by “<” or “LOW” result flags, indicating that the result is below the linear range or the defined normal range of the assay, respectively. See the Alinity ci-series Operations Manual Section 5: Operating Instructions for more information on patient result flags. This failure mode will not cause falsely elevated results.

Necessary Actions

Abbott recommends customers inspect all cuvette segments per procedure contained in Appendix A upon receipt of this letter. Replace damaged cuvette segments before performing additional testing on your Alinity c processing module.

Abbott recommends customers adhere to the new instructions listed in Appendix A to avoid damaging the cuvette segments.

Necessary Actions continued

The procedures listed in Appendix A provide additional guidance for operators to avoid damaging the cuvette segments. The procedures will be updated in a future version of software and the Alinity ci-series Operations Manual.

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

If you or any of the health care providers you serve have any 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.

Appendix A: Updated Alinity ci-series Operations Manual and Procedures

1. Diagnostic procedure 5003 Clean cuvettes – Manually (c-series):

   Perform this Reaction Mechanisms diagnostic procedure to clean the cuvettes manually as per instructions in Alinity ci-series Operations Manual Section 9: Service, maintenance and diagnostics and the system software.
   Additional notes:
   a. Gently clean the cuvettes and do not apply significant downward pressure on the cuvette segment base.
   b. After the manual cleaning of the cuvettes within a cuvette segment, and before placement back into Alinity c processing module, inspect the cuvette segment following the "**Cuvette Segment Inspection Procedure**" below.

2. As-Needed maintenance procedure 5908 Clean Cuvette Washer Nozzles (c-series):
   Perform this as-needed procedure to clean the cuvette washer nozzles as per Alinity ci-series Operations Manual Section 9: Service, maintenance and diagnostics and the system software.
   Additional notes:
   Reposition the cuvette washer on the alignment pins. Ensure that the cuvette washer is completely seated so there is no space between the cuvette washer and the cuvette washer platform.
   IMPORTANT: Incorrect positioning of the cuvette washer on the alignment pins could result in misalignment of the cuvette washer. A misalignment can potentially cause cuvette damage or cause the cuvette segment base to detach.

3. Addition of a recommended inspection of the cuvette segments to all cuvette washer movement errors. See recommended "**Cuvette Segment Inspection Procedure**" below. The list of the message codes are as follows:

Message Code	Description
5111	Cuvette washer upper limit not found
5112	Cuvette washer lower limit not found
5651	Cuvette washer movement restricted at position (0) step number (1). 0 = Position 1 = Step number

4. Replace the cuvette dry tip (c‑series)

   Follow the procedure in Alinity ci-series Operations Manual Section 9: Service, maintenance and diagnostics: Component replacement, Replace the cuvette dry tip (c-series)

   Verify that the cuvette dry tip is correctly aligned and that it moves smoothly into the cuvette.

   Note: If the cuvette dry tip contacts the top of the cuvette segment when the cuvette washer moves down, inspect the cuvette segment following the "**Cuvette Segment Inspection Procedure**" below.

5. Observed problem: Erratic results, poor precision: Photometric results (c-series)

   If the cuvette or the cuvette segment is damaged, erratic results and poor precision may be observed. If the cuvette or cuvette segments appear damaged, replace the cuvette segment following the procedure in Alinity ci-series Operations Manual Section 9: Service, maintenance and diagnostics: Component replacement, Replace the cuvette segments (c-series). Inspect the cuvette segment following the "**Cuvette Segment Inspection Procedure**" below.

6. Cuvette Segment Inspection Procedure

To remove the cuvette segments from the Alinity c processing module for inspection, follow the procedure in Alinity ci-series Operations Manual Section 9: Service, maintenance and diagnostics: Component replacement, Replace the cuvette segments (c-series).

To inspect the cuvette segment, gently pull the segment base downward at several locations along the segment. Replace the cuvette segment if any of the following issues are identified:

- The cuvette segment base is detached.
- One or more cuvettes are seated lower than the other cuvettes in the segment.
- One or more cuvettes are damaged.

IMPORTANT: Wear gloves to perform the inspection. Residual oil from an ungloved hand can cause imprecise optical readings. Do not apply significant downward pressure on the cuvette segment base.

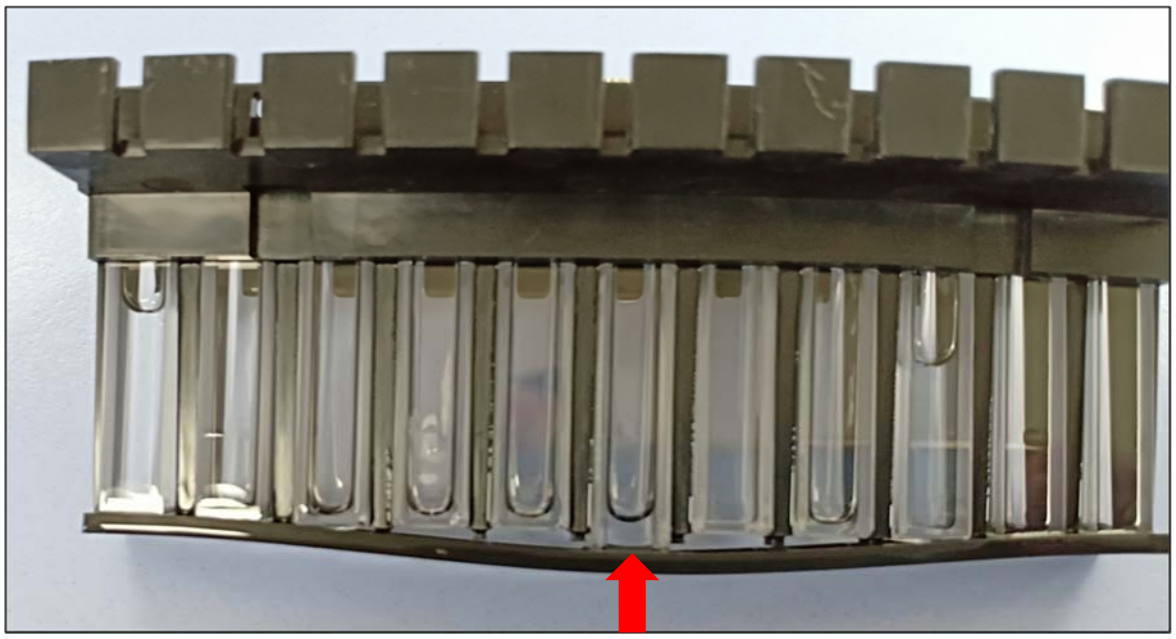
If damage is discovered, replace the damaged cuvette segments in the reaction carousel. Verify proper installation as instructed in Alinity ci-series Operations Manual 9: Service, maintenance and diagnostics: Component replacement, Replace the cuvette segments (c-series).

Repeat the inspection until all cuvette segments to inspect and replace are removed.

The following picture shows normal, undamaged cuvette segment:

Alinity c Cuvette Segment

The following pictures show examples of Alinity c cuvette segments where cuvettes are seated lower than designed height:



The red arrow indicates where a cuvette is seated lower than it's designed height