



Urgent Field Safety Notice Product Correction

Urgent - Immediate Action Required

Date Issued

January 24, 2020

Product

| Product Name | List Number | Serial Number | UDI |
|---|-------------|---------------|-----|
| Alinity ci-series System Control Module (SCM) | 03R70-01 | All | N/A |

Explanation

Abbott has identified potential performance issues for the Alinity ci-series Software version 2.6.2 and earlier. Abbott is releasing Alinity ci-series Software version 3.1.0 to correct these issues (see details in **Table 1** below).

Table 1 - Alinity ci-series software issues resolved in version 3.1.0

| Alinity i-series | | |
|---|---|--|
| Issue | Description | Necessary Actions required until Mandatory Upgrade to SW 3.1.0 is completed |
| <p>Re-use of RVs after diagnostic procedure <i>1525 Process Path Sensors Test</i>.</p> <p>Patient Results Impact There is the potential for incorrect results.</p> | <p>After performing diagnostic procedure <i>1525 Process Path Sensors Test</i>, there is the potential for up to 6 used RVs to be loaded on to the process path when the RV present sensor option is selected. The used RVs could potentially be re-used in processing samples.</p> | <p>Perform diagnostic procedure <i>1520 RV Load and Unload Test (i-series)</i> immediately after the completion of diagnostic procedure <i>1525 Process Path Sensors Test</i>.</p> |
| Alinity c-series | | |
| <p>Potential discrepant results after Alinity c R1 or R2 probe crash.</p> <p>Patient Results Impact There is the potential for incorrect results.</p> | <p>After an R1 or R2 probe crash occurs at the wash cup, tests in process continue to completion instead of going to exceptions, which may lead to discrepant results being generated.</p> | <p>If message codes 5744-C031 or 5745-C031 occur, stop the processing module by performing <i>Stop the processing module and the reagent and sample manager (RSM)</i>, as described in the Alinity ci-series Operations Manual.</p> <p>Results generated after the above message code(s) should not be reported and should be re-tested.</p> <p>Perform the troubleshooting steps as recommended in the Alinity ci-series Operations Manual to resolve the error.</p> <p>Perform As-Needed maintenance procedure <i>5910 Wash cuvettes (c-series)</i>, before resuming assay processing.</p> |

| | |
|------------------------------|---|
| Explanation continued | <p>Additional change included in Software 3.1.0:</p> <ul style="list-style-type: none"> Pressure monitoring algorithm reverted to previous version, due to increased reagent aspiration errors observed on the Alinity c after installation of the updated algorithm (CC PM Algorithm Improvement). |
| Patient Impact | <p>Refer to Table 1 for details concerning any patient results impacted due to the issues identified in Alinity ci-series System Software versions 2.6.2 and earlier.</p> |
| Necessary Actions | <p>Please follow the Necessary Actions required in Table 1 above until software version 3.1.0 is installed.</p> <p>Your Abbott representative will schedule a mandatory upgrade of your Alinity ci-series to software version 3.1.0.</p> <p>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.</p> <p>Please retain this letter for your laboratory records.</p> |
| Contact Information | <p>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.</p> <p>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).</p> <p>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.</p> |



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Table 1 - Alinity ci-series software issues resolved in version 3.1.0

| Alinity i-series | | |
|--|---|---|
| Issue | Description | Necessary Actions required until Mandatory Upgrade to SW 3.1.0 is completed |
| Re-use of RVs after diagnostic procedure <i>1525 Process Path Sensors Test</i> . Patient Results Impact There is the potential for incorrect results. | After performing diagnostic procedure <i>1525 Process Path Sensors Test</i> , there is the potential for up to 6 used RVs to be loaded on to the process path when the RV present sensor option is selected. The used RVs could potentially be re-used in processing samples. | Perform diagnostic procedure <i>1520 RV Load and Unload Test (i-series)</i> immediately after the completion of diagnostic procedure <i>1525 Process Path Sensors Test</i> . |
| Alinity c-series | | |
| Potential discrepant results after Alinity c R1 or R2 probe crash. Patient Results Impact There is the potential for incorrect results. | After an R1 or R2 probe crash occurs at the wash cup, tests in process continue to completion instead of going to exceptions, which may lead to discrepant results being generated. | If message codes 5744-C031 or 5745-C031 occur, stop the processing module by performing <i>Stop the processing module and the reagent and sample manager (RSM)</i> , as described in the Alinity ci-series Operations Manual. Results generated after the above message code(s) should not be reported and should be re-tested. Perform the troubleshooting steps as recommended in the Alinity ci-series Operations Manual to resolve the error. Perform As-Needed maintenance procedure <i>5910 Wash cuvettes (c-series)</i> , before resuming assay processing. |

Patient Impact

Refer to **Table 1** for details concerning any patient results impacted due to the issues identified in Alinity ci-series System Software versions 2.6.2 and earlier.

**Necessary
Actions**

Please follow the Necessary Actions required in **Table 1** above until software version 3.1.0 is installed.

Your Abbott representative will schedule a mandatory upgrade of your Alinity ci-series to software version 3.1.0.

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**

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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).

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