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Product Correction

Urgent - Immediate Action Required

CC Chairman Medical Board and relevant Head-of-Department

Date Issued May 21, 2019

Product

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

*Only includes Alinity ci-series System Control Modules which are configured with Alinity c Processing Modules

Explanation

Abbott has identified an issue with all on-market versions of Alinity ci-series software where the software may not detect an issue on the Alinity c Integrated Chip Technology (ICT) assays, sodium (Na^+), potassium (K^+), and chloride (Cl^-).

The software contains a specification for ICT Reference Solution voltage drift. This specification defines the drift threshold for the ICT Reference Solution voltage before and after ICT sample aspiration. An elevated ICT Reference Solution voltage drift can be a result of multiple causes. For additional information on probable causes and corrective actions related to this issue, refer to message code: 1042 “Unable to calculate result. ICT reference solution voltage drift error.” or message code: 1075 “ICT measurement error for (Na).” in Section 10 of the Alinity ci-series Operations Manual and Appendix A of this letter.

The current specification for ICT Reference Solution voltage drift is 10 mV. Samples with an ICT Reference Solution voltage drift above 10 mV generate message code: 1042 “Unable to calculate result. ICT reference solution voltage drift error.” or message code: 1075 “ICT measurement error for (Na).”

Reference solution voltage drift values between 3 mV and 10 mV may indicate an issue that potentially impacts ICT results (specimens, calibrators, and controls). The range of the bias on ICT results from the expected value is estimated to be between -34% and +51%. The ICT Reference Solution voltage drift values are not visible to the user.

Abbott will be releasing Alinity ci-series Software version 2.6.1 to change the ICT Reference Solution voltage drift threshold from 10mV to 3mV to improve the ability of the system to detect ICT Reference Solution voltage drift.

Patient Impact

ICT issues may cause incorrect patient results for the Na^+, K^+, and Cl^- assays for all specimen types (serum, plasma, and urine).

Necessary Actions

To mitigate the issue until software version 2.6.1 are available, customers should

1. Run all ICT patient specimens in duplicate. For information on ordering replicates, refer to *Create a single specimen order* in the Alinity ci-series Operations Manual, Section 5.
2. Verify that the difference in recovery between the sample replicates is no greater than the thresholds listed below:

ICT Assay	Threshold (Serum/Plasma)	Threshold (Urine)
Na	+/- 4 mmol/L*	+/- 10%
K	+/- 0.5 mmol/L*	+/- 10% for results ≥ 20.0 mmol/L* +/- 2.0 mmol/L for results < 20.0 mmol/L*
Cl	+/- 5%	+/- 10%

*Results expressed in mmol/L are equivalent to mEq/L.

3. If the difference in recovery between the sample replicates exceeds the threshold, refer to *Erratic results, poor precision: ICT results (c‑series)* in the Alinity ci-series Operations Manual, Section 10 for recommended troubleshooting.
4. After troubleshooting, rerun the specimen in duplicate.
5. If three or more discrepant ICT samples, without an assignable cause, are identified within a 24-hour period:
    a. Stop ICT testing and disable all ICT assays via the software user interface until the issue is resolved.
        i. On the **General** tab of the Assay Parameters screen, tap **Patient Disabled** in the **Assay Availability** drop-down list.
    b. Contact Customer Service to resolve any hardware failures.

Your Abbott representative will schedule a mandatory upgrade of your Alinity ci-series Software to version 2.6.1 to resolve this issue. Reminder: Alinity ci-series Software version 2.6.0 must be installed prior to installation of version 2.6.1.

Appendix A contains additional probable causes for message codes 1042 and 1075. Please retain a copy of Appendix A until the next revision of the Alinity ci Operations Manual is released.

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, 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

Additional probable causes and corrective actions associated with message code: 1042 “Unable to calculate result. ICT reference solution voltage drift error.” or message code: 1075 “ICT measurement error for (Na).”

Probable cause	**Corrective action**
A temporary fluidic disturbance occurred within the ICT module (air bubbles, fluid blockage, etc.) during the ICT measurement.	Rerun the sample. If this error occurs several times a day, see other probable causes and corrective actions.
The ICT sample concentration is outside the linear range as defined in the assay insert.	1. Ensure the specimen type is appropriate for the ICT application tested. For example, ensure a urine sample was not run as a serum sample. 2. Rerun the sample.
The sample contains elevated concentrations of a substance that interferes with ICT electrode performance. For example, chloride is impacted by samples with elevated bromide or iodide concentrations. Sodium and potassium are impacted by samples with elevated concentrations of cationic surfactants such as benzalkonium chloride.	Test the sample using an alternative methodology. Although it may be possible to generate error-free results by running two or more sample replicates, the results will be elevated due to the presence of the interfering substances.

For additional information on probable causes and corrective actions related to this issue, refer to message code: 1042 “Unable to calculate result. ICT reference solution voltage drift error.” or message code: 1075 “ICT measurement error for (Na).” in Section 10 of the Alinity ci-series Operations Manual.