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DIAGNOSTICS

Urgent Field Safety Notice
Product Correction

Urgent - Immediate Action Required

Date Issued June 19, 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 two issues with Quality Control (QC) functionality, after an assay file update, that impacts all Alinity ci-series software versions.

Issue 1: After an assay file is updated, subsequently generated QC results are not evaluated for Westgard failures when the system is configured for Westgard rule assessment. QC results are correctly evaluated when the system is configured to assess a QC range. This issue does not exist when an assay file is originally installed on a system. New controls and new control lot numbers configured after an assay file is updated are not impacted.

When a control is configured for Westgard rule evaluation (mean/SD), the following quality control features are impacted after an assay file is updated:

- The Levey-Jennings Graph screen incorrectly displays points that have a Westgard failure as a black dot instead of a red dot.
- QC results that fail Westgard rules are not flagged with CNTL.
- Red badges associated with Westgard rule failures are not displayed on the QC icon on the Home screen.
- Alert notifications associated with Westgard rule failures are not present in the Alert Center.
- Reagents are not disabled due to a Westgard rule failure.

When a control is configured with a QC range (with or without Westgard rules enabled), the following quality control features are correctly evaluated against the QC range after an assay file is updated:

- Out of range QC results are flagged with CNTL.
- Red badges associated with QC range failures are displayed on the QC icon on the Home screen.
- Alert notifications associated with QC range failures are present in the Alert Center.
- Reagents are disabled due to QC range failures.

Explanation continued	**Issue 2:** After an assay file update, specimen results generated after a QC failure are not marked with a CNTL flag. This issue occurs regardless of the control configuration (QC range, Westgard mean/SD). This issue does not exist when an assay file is originally installed on a system. New controls and new control lot numbers configured after an assay file is updated are not impacted. Both issues will be resolved in Alinity ci-series software version 3.2.0. Abbott has reviewed your system's logs via AbbottLink and found your Alinity ci-series is impacted as there is evidence of assay file upgrades. Your Abbott representative can provide you additional information on the upgrades identified within the logs.
Patient Impact	The failure to notify users of failed QC results could lead to reporting of incorrect patient results.
Necessary Actions	Your Abbott representative will schedule a mandatory upgrade of your Alinity ci-series to software version 3.2.0. Until software version 3.2.0 is installed on your Alinity ci-series, Abbott recommends the following workarounds for issues 1 and 2: In order to restore the QC analysis function for all assay files that have been previously updated and for all future assay file revisions until software 3.2.0 is installed on your system, it will be necessary to remove and then re-add the assay to all control configurations containing the assay. ▪ See **Appendix A** for instructions to remove and re-add an assay from a control that contains more than one assay. ▪ See **Appendix B** for instructions to remove and re-add an assay from a control that contains only one assay. ▪ These procedures will delete historical QC data from the Quality Control Summary screen and Levey-Jennings (Graph) screen. You may choose to print the QC Levey-Jennings Report, the QC Summary Report and to archive control results before performing this option. QC results will remain on the Control tab of the Results screen. Assay calibration data, calibrator configuration data and assay parameter configuration data are retained. Please complete the included Abbott 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	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.

Contact Information continued

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: Instructions to remove and re-add an assay from a control that contains more than one assay

Prerequisite: Ensure that no control orders are pending for the control to be edited.
Required instrument status: Stopped, Warming, or Idle
Operator access level: Supervisor

1. On the Configure screen, tap the **Assay** tab.
2. On the **Assay** tab of the Configure screen, tap **Quality Control**.
3. Under **Control Count** on the Quality Control screen, tap the control name.
4. Tap the updated assay to be removed from the configured control.
5. Tap **View/Edit**.
6. When a confirmation message is displayed, tap **Yes** to remove the assay from the control configuration.
7. Tap **Save** and then **Done**.
8. Under **Control Count** on the Quality Control screen, tap the control name.
9. Tap the updated assay to add back to the configured control.
10. Tap **View/Edit**.
11. Enter the control specifications and tap **Save**.
12. Repeat step 11 for each control level.
13. Tap **Done**.

For detailed information refer to *Delete an assay from a quality control* and *Add an assay to a quality control* in Section 2 of the Alinity ci-series Operations Manual.

Appendix B: Instructions to remove and re-add an assay from a control that contains only one assay

Prerequisite: Ensure that no control orders are pending for the control to be edited.
Required instrument status: Stopped, Warming, or Idle
Operator access level: Supervisor

1. On the Configure screen, tap the **Assay** tab.
2. On the **Assay** tab of the Configure screen, tap **Quality Control**.
3. Under **Control Count** on the Quality Control screen, tap the control name.
4. Tap the updated assay to remove from the configured control and add a temporary assay to add to the configured control.
   NOTE: At least one assay must be configured to maintain the control configuration.
5. Tap **View/Edit**.
6. When a confirmation message is displayed, tap **Yes** to remove the assay from the control configuration.
7. Tap **Save** and then **Done**.
8. Under **Control Count** on the Quality Control screen, tap the control name.
9. Tap the temporary assay to remove it from the control and tap the updated assay to add it back to the configured control.
10. Tap **View/Edit**.
11. Enter the control specifications and tap **Save**.
12. Repeat step 11 for each control level.
13. Tap **Done**.

For detailed information refer to *Delete an assay from a quality control* and *Add an assay to a quality control* in Section 2 of the Alinity ci-series Operations Manual.