



## Product Correction

Immediate Action Required

**Date Issued**

February 06, 2018

**Product**

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

**Explanation**

Abbott has identified the following issues with the Alinity ci-series:

1. After a failure of the Reagent 2 (R2) pipettor, the software fails to send scheduled tests that were aspirated after the failure to Exceptions.
2. Results, reported in alternate result units, that are greater than the linearity incorrectly displays the numerical result value in the default units, for assays using the spline or logit-4 data reduction method.
3. The host connection is disabled after 12 seconds when no order is received, even though the configured host query time-out has not been exceeded.
4. An unexpected software shutdown can occur when printing the Assay Parameter Report when the Thousand/Decimal Separator number format is set to the Period and Comma option.

**Patient Impact**

Refer to **Appendix A** for details concerning any patient or safety impact related to the issues identified in Alinity ci-series System Software version 2.00.

**Necessary Actions**

Your Abbott representative will be scheduling mandatory upgrade of your Alinity ci-series SCM to resolve each of these issues in the upcoming weeks.

Refer to **Appendix A** for necessary actions required until software version 2.10 can be installed. If you require additional information, please contact Abbott Customer Service.

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, please contact your local area Customer Service.

**Appendix A - Alinity ci-series software version 2.00 issues**

Issue	System/Assay Impacted	Patient or Safety Impact	Necessary Actions until mandatory upgrade is completed																																															
<p>After a failure of the Reagent 2 (R2) pipettor, the software fails to send scheduled tests that were aspirated after the failure to Exceptions.</p> <p>Tests that require the R2 pipettor that are in other statuses such as pending, running or in process will correctly generate an exception.</p>	Alinity i-series	Potential to generate incorrect patient results when tests continue processing without the R2 reagent.	<p>Troubleshoot and resolve the R2 pipettor failure. Refer to <i>Message codes</i> in Section 10, Troubleshooting.</p> <p>Rerun all exceptions and any scheduled tests requiring the R2 pipettor that were aspirated after the R2 pipettor failure. Refer to <i>Rerun a test or an exception for a specimen or control</i> in Section 5, Specimen, calibration, and control orders.</p>																																															
<p>Results, reported in alternate result units, that are greater than the linearity incorrectly displays the numerical result value in the default units, for clinical chemistry assays using the spline or logit-4 data reduction method. The greater than flag is only applied to results that exceed the default unit high linearity value.</p>	<p>The following clinical chemistry assays are impacted as follows when run using an alternate unit and the result produced is greater than the assay's linearity. Potential for patient result impact.</p> <table border="1" data-bbox="758 829 1535 1349"> <thead> <tr> <th>Assay</th> <th>LN</th> <th>Incorrectly Displayed Result</th> <th>Correct Result</th> </tr> </thead> <tbody> <tr> <td>Complement C3</td> <td>09P56</td> <td>&gt;385 g/L</td> <td>&gt;3.85 g/L</td> </tr> <tr> <td>Complement C4</td> <td>09P57</td> <td>&gt;720 g/L</td> <td>&gt;7.20 g/L</td> </tr> <tr> <td>CRP Vario</td> <td>07P56</td> <td>&gt;16.00 mg/L</td> <td>&gt;160 mg/L</td> </tr> <tr> <td>Digoxin</td> <td>08P37</td> <td>&gt;5.00 nmol/L</td> <td>&gt;6.40 nmol/L</td> </tr> <tr> <td>Gentamicin</td> <td>08P55</td> <td>&gt;10.0 umol/L</td> <td>&gt;20.90 umol/L</td> </tr> <tr> <td>Haptoglobin</td> <td>09P59</td> <td>&gt;300 g/L</td> <td>&gt;3.00 g/L</td> </tr> <tr> <td>Microalbumin</td> <td>08P04</td> <td colspan="2">n/a*</td> </tr> <tr> <td>Phenytoin</td> <td>08P54</td> <td>&gt;40.0 umol/L</td> <td>&gt;158.4 umol/L</td> </tr> <tr> <td>Transferrin</td> <td>08P38</td> <td>&gt; 536.00 g/L</td> <td>&gt;5.36 g/L</td> </tr> <tr> <td>Urine/CSF Protein</td> <td>07P59</td> <td>&gt;200.0 mg/L</td> <td>&gt;2000 mg/L</td> </tr> <tr> <td>Vancomycin</td> <td>08P52</td> <td>&gt;3.2 umol/L</td> <td>&gt;2.21 umol/L</td> </tr> </tbody> </table> <p>*This assay does not exhibit the problem because the two units supported (ug/mL and mg/L) have a unity (1.0) conversion factor and would not have discrepancy in values.</p>	Assay	LN	Incorrectly Displayed Result	Correct Result	Complement C3	09P56	>385 g/L	>3.85 g/L	Complement C4	09P57	>720 g/L	>7.20 g/L	CRP Vario	07P56	>16.00 mg/L	>160 mg/L	Digoxin	08P37	>5.00 nmol/L	>6.40 nmol/L	Gentamicin	08P55	>10.0 umol/L	>20.90 umol/L	Haptoglobin	09P59	>300 g/L	>3.00 g/L	Microalbumin	08P04	n/a*		Phenytoin	08P54	>40.0 umol/L	>158.4 umol/L	Transferrin	08P38	> 536.00 g/L	>5.36 g/L	Urine/CSF Protein	07P59	>200.0 mg/L	>2000 mg/L	Vancomycin	08P52	>3.2 umol/L	>2.21 umol/L	<p>Change the Results Units to report in the default unit. Refer to <i>Edit result settings of assay parameters</i> in Section 2, System configuration.</p>
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Issue	System/Assay Impacted	Patient or Safety Impact	Necessary Actions until mandatory upgrade is completed
The host connection is disabled after 12 seconds when no order is received, even though the configured host query time-out has not been exceeded.	Alinity ci-series	No patient or safety impact.	Enable the host and reintroduce the samples to the reagent and sample manager. Refer to <i>Enable or disable the host connection</i> in Section 5, Home screen.
An unexpected software shutdown can occur when printing the Assay Parameter Report when the Thousand/Decimal Separator number format is set to the Period and Comma option. The issue does not occur when the Thousand/Decimal Separator number format is set to the Comma and Period (default), None and Period, or None and Comma option.	Alinity ci-series	No patient or safety impact.	<p>Cycle power to the system. Refer to <i>Cycle power to the system</i> in Section 5, System cycle power, start, pause and stop.</p> <p>Change the Thousand/Decimal Separator option to Comma and Period, None and Period, or None and Comma. Refer to <i>Configure General Settings</i> in Section 2, System configuration.</p>