Abbott GmbH
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DIAGNOSTICS

Urgent Field Safety Notice
Product Correction

Urgent - Immediate Action Required

Date Issued May 12, 2020

Product

Product Name	List Number	Serial Number	UDI
Alinity c Processing Module	03R67-01	All	N/A

Explanation

This Product Correction letter is to inform you of an issue with the Alinity c system Optics Assembly (part number C-35016278-01). Abbott has identified the potential for a nonlinear optics response due to an issue with the Alinity c optics. The issue is with the diffraction grating within the optics assembly and can result in a lower than expected absorbance value. The root cause of this issue is unknown and currently under investigation. This issue can be identified using an Optics diagnostic procedure. Instruments that pass this Optics diagnostic procedure do not exhibit and will not develop the nonlinear optics response.

Abbott has tested multiple representative assays with different calibration types and wavelengths to understand the impact of the nonlinear optics response on Abbott's clinical chemistry menu. The studies compared sample results obtained between an Alinity c with a confirmed normal optics to the results obtained from an Alinity c with confirmed defective optics. The studies show that four assays are impacted by the nonlinear optics response: Alkaline Phosphatase, Amylase, Creatine Kinase, and Gamma-Glutamyl Transferase.

The impact on the test result is a false decrease in results. See Appendix A for assay testing information.

Patient Impact

There is a potential to generate incorrect patient results for the following assays on your Alinity c system: Alkaline Phosphatase, Amylase, Creatine Kinase, and Gamma-Glutamyl Transferase.

Necessary Actions

Abbott recommends discontinuing testing on the impacted assays (Alkaline Phosphatase, Amylase, Creatine Kinase, and Gamma-Glutamyl Transferase) until an assessment of your optics can be completed. An Abbott representative will contact you to schedule this assessment to determine potential impact to your optics assembly.

Your Abbott representative will provide you with the outcome of the inspection.

If the inspection indicates…	Then…
Your optics was not impacted by this issue	No further action is required; patient results generated on your system were not impacted by this issue.
Your optics was potentially defective and required replacement	All previously generated patient results for the assays listed above may have been impacted by this issue. Please review this letter with your Medical Director and follow your laboratory protocol regarding the need for reviewing previously reported results.

- 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.
- Complete and return the Customer Reply Form.
- 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: Assay Testing Data

Assays demonstrating impact from optics issue

Assay	Level	Results with confirmed normal optics		Results with confirmed defective optics		%Bias between Systems
		Mean (U/L)	%CV	Mean (U/L)	%CV	
Alkaline Phosphatase[3] (LN 08P20)	1	10.7	6.84	9.9	1.70	-7.8
	2	572.7	0.50	518.5	0.24	-9.5
	3	1128.1	0.48	981.4	0.28	-13.0
	4	1673.9	0.12	1375.4	0.14	-17.8
	5	2213.2	0.13	1689.8	0.32	-23.6
	6	4432.0	0.28	N/A[1]		
Amylase[3] (LN 07P58)	1	6.6	3.40	5.1	6.40	-22.9
	2	725.6	0.22	684.8	0.35	-5.6
	3	1447.5	0.53	1341.7	0.26	-7.3
	4	2160.2	0.15	1961.0	0.15	-9.2
	5	2878.9	0.32	2530.0	0.12	-12.1
	6	6279.6	0.23	4378.9	0.19	-30.3
Creatine Kinase (LN 08P42)	1	9.4	2.56	9.6	4.0	1.8
	2	1063.2	0.06	1007.0	0.4	-5.3
	3	2102.3	0.02	1960.0	2.6	-6.8
	4	3121.0	0.04	2853.1	5.3	-8.6
	5	4134.0	0.27	3654.7	9.0	-11.6
Gamma-Glutamyl Transferase Conventional assay file (LN 07P73)	1	8.3	3.00	7.5	4.06	-10.0
	2	370.2	0.17	356.9	0.78	-3.6
	3	724.2	0.34	699.6	0.48	-3.4
	4	1077.3	0.07	1024.5	0.39	-4.9
	5	1421.2	0.16	1339.2	0.30	-5.8
	6	7719.2	0.49	6311.7	1.47	-18.2
Gamma-Glutamyl Transferase assay file (IFCC)[2] (LN 07P73)	1	7.6	3.00	6.9	4.06	-10.0
	2	340.0	0.17	327.8	0.78	-3.6
	3	665.1	0.34	642.5	0.48	-3.4
	4	989.4	0.07	940.9	0.39	-4.9
	5	1305.2	0.16	1229.9	0.30	-5.8
	6	7089.3	0.49	5796.7	1.47	-18.2

[1]All Alkaline Phosphatase sample replicates for this concentration level generated message code: 1037 Unable to calculate result. Rate reaction linearity failure.
[2]Values are calculated from Gamma-Glutamyl Transferase Conventional assay file results.
[3]Assay results are displayed in default units.