Abbott GmbH
Max-Planck-Ring 2
65205 Wiesbaden, Germany

DIAGNOSTICS

Single Registration Number (SRN): N/A

Urgent Field Safety Notice
Product Correction

Urgent - Immediate Action Required

Date Issued June 10, 2021

Product

Product Description	List Number (LN)	Lot Number	US UDI	EU UDI
Activated Alanine Aminotransferase (A-ALT)	8L92-22	02954UN20	(01)00380740161859 (17)210829(10)02954UN20	N/A
		37921UN20	(01)00380740161859 (17)211201(10)37921UN20	
		81823UN21	(01)00380740161859 (17)220216(10)81823UN21	
	8L92-42	84126UN20	(01)00380740161866 (17)210709(10)84126UN20	
		03676UN20	(01)00380740161866 (17)210825(10)03676UN20	
		10597UN20	(01)00380740161866 (17)210829(10)10597UN20	
		26275UN20	(01)00380740161866 (17)211020(10)26275UN20	
		77748UN20	(01)00380740161866 (17)211208(10)77748UN20	
		65958UN20	(01)00380740161866 (17)211208(10)65958UN20	
		81824UN21	(01)00380740161866 (17)220216(10)81824UN21	

Explanation

This letter is to inform you that the Activated Alanine Aminotransferase assay (LN 8L92-22 and LN 8L92-42) linearity specification may not be met when using A-ALT reagent as it nears the lot expiration. Internal testing demonstrated a potential for > 10% under-recovery on A-ALT samples greater than 1,200 U/L. To address this issue, the High-Linearity assay parameter has been reduced from 4,772 U/L to 1,200 U/L to prevent the potential for incorrect results.

A-ALT assay file version 10 includes the following updates:

- Updated High-Linearity value
- Flex Rate read times have been removed

Explanation continued

The Automated Dilution Protocol (1:5) is not impacted by this change and is included in A-ALT assay file version 10, allowing testing to extend the reportable range to 6,000 U/L. Configuring retest rules can enable Automated Dilution without user intervention.

In addition, internal interference testing demonstrated a > 10% shift in patient results with samples containing bilirubin concentrations greater than 31 mg/dL. Updated interference data is provided in the table below.

Interfering Substance	Interferent Concentration	Target (U/L)	Observed (% of Target)
Bilirubin	31 mg/dL (530 µmol/L)	59.7	91
	46 mg/dL (787 µmol/L)	59.7	86
	61 mg/dL (1,043 µmol/L)	59.7	117

The Activated Alanine Aminotransferase reagent Instructions for Use (IFU) will be updated with the linearity range reduction and the new bilirubin interference information. Until the IFU is updated, all A-ALT reagent kits will include labeling with this revised information.

Impact on Patient Results

There is a potential for incorrect patient results:

- There is a potential for > 10% under-recovery on A-ALT samples greater than 1,200 U/L.
- There is a potential for a > 10% shift in patient results with samples containing bilirubin concentrations greater than 31 mg/dL.

Necessary Actions

- **Immediately** install A-ALT assay file, version 10, obtained from www.corelaboratory.abbott
- Manually configure the High-Linearity assay parameter to 1,200 U/L. For detailed information, refer to Changing assay configuration settings, *Change a linearity range* in the ARCHITECT System Operations Manual, Section 2.
- Complete and return the Customer Reply Form.
- If you have forwarded the products 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 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.

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Product

Product Description	List Number (LN)	Lot Number	US UDI	EU UDI
Alinity c Activated Alanine Aminotransferase Reagent Kit (A-ALT)	08P1820	83459UN20	(01)00380740132569 (17)210709(10)83459UN20	N/A
		03168UN20	(01)00380740132569 (17)210925(10)03168UN20	
		09787UN20	(01)00380740132569 (17)211024(10)09787UN20	
		37977UN20	(01)00380740132569 (17)220101(10)37977UN20	
		63000UN20	(01)00380740132569 (17)220101(10)63000UN20	
		77745UN20	(01)00380740132569 (17)220108(10)77745UN20	
		77743UN21	(01)00380740132569 (17)220302(10)77743UN21	
		09237UN21	(01)00380740132569 (17)220409(10)09237UN21	

Explanation

This letter is to inform you that the Alinity c Activated Alanine Aminotransferase Reagent Kit (LN 08P1820) linearity specification may not be met when using A-ALT reagent as it nears the lot expiration. Internal testing demonstrated a potential for > 10% under-recovery on A-ALT samples greater than 1200 U/L. To address this issue, the High Linearity assay parameter has been reduced from 4772 U/L to 1200 U/L to prevent the potential for incorrect results.

A-ALT assay file version 7 includes the following updates:

- Updated High-Linearity value
- Flex Rate read times have been removed

The Automated Dilution Protocol (1:5) is not impacted by this change and is included in A-ALT assay file version 7, allowing testing to extend the reportable range to 6000 U/L. Configuring retest rules can enable Automated Dilution without user intervention.

In addition, internal interference testing demonstrated a > 10% shift in patient results with samples containing bilirubin concentrations greater than 31 mg/dL. Updated interference data is provided in the table below.

Explanation continued

Interfering Substance	Interferent Level		Target (U/L)	Recovery (% of Target)
	Default Units	Alternate Units		
Bilirubin	31 mg/dL	530 µmol/L	59.7	91
	46 mg/dL	787 µmol/L	59.7	86
	61 mg/dL	1043 µmol/L	59.7	117

The Alinity c Activated Alanine Aminotransferase Reagent Kit Instructions for Use (IFU) will be updated with the linearity range reduction and the new bilirubin interference information. Until the IFU is updated, all A-ALT reagent kits will include labeling with this revised information.

Impact on Patient Results

There is a potential for incorrect patient results:

- There is a potential for > 10% under-recovery on A-ALT samples greater than 1,200 U/L.
- There is a potential for a > 10% shift in patient results with samples containing bilirubin concentrations greater than 31 mg/dL.

Necessary Actions

- **Immediately** install A-ALT assay file, version 7, obtained from www.corelaboratory.abbott
- Manually configure the High Linearity assay parameter to 1200 U/L.
    - For systems with Alinity ci-series System software V3.2.0 or higher, install the updated assay file, then change the current High Linearity value from 4772 to 1200 U/L. For detailed information, refer to *Edit result settings of assay parameters* in Section 2 of the Alinity ci-series Operations Manual.
    - For systems that have not upgraded to Alinity ci-series System software V3.2.0 or higher, install the updated assay file, then change the current High Linearity value from 4772 to 1200 U/L. When installing this assay file as an update to a previous version, the assay must be removed and re-added to all control configurations containing the assay. For single constituent controls, add a temporary assay, then remove and re-add the updated assay. 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.
- Complete and return the Customer Reply Form.
- If you have forwarded the products 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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