



Abbott

CORE DIAGNOSTICS
Abbott Laboratories
Diagnostics Division
Abbott Park, IL, 60064 USA

Single Registration Number (SRN):
IE-MF-000001822

Urgent Product Correction

Immediate Action Required

Date Issued August xx, 2023

Product

Product Description	List Number	Lot Number	UDI
Multichem S Plus Level 1	08P88-10	0108032101	(01)05391523440776 (17)230930 (10)0108032101
Multichem S Plus Level 2	08P88-11	0108032102	(01)05391523440783(17)230930 (10)0108032102
Multichem S Plus Level 3	08P88-12	0108032103	(01)05391523440790 (17) 230930(10)0108032103
Multichem S Plus Level 1	08P88-10	0110072101	(01)05391523440776(17)231231 (10)0110072101
Multichem S Plus Level 2	08P88-11	0110072102	(01)05391523440783(17)231231 (10)0110072102
Multichem S Plus Level 3	08P88-12	0110072103	(01)05391523440790(17)231231 (10)0110072103
Multichem S Plus Level 1	08P88-10	0119112101	(01)05391523440776(17)240531 (10)0119112101
Multichem S Plus Level 2	08P88-11	0119112102	(01)05391523440783(17)240531 (10)0119112102
Multichem S Plus Level 3	08P88-12	0119112103	(01)05391523440790(17)240531 (10)0119112103
Multichem S Plus Level 1	08P88-10	0126052201	(01)05391523440776(17)241031 (10)0126052201
Multichem S Plus Level 2	08P88-11	0126052202	(01)05391523440783(17)241031 (10)0126052202
Multichem S Plus Level 3	08P88-12	0126052203	(01)05391523440790(17)241031 (10)0126052203
Multichem S Plus Level 1	08P88-10	0130112201	(01)05391523440776(17)250531 (10)0130112201
Multichem S Plus Level 2	08P88-11	0130112202	(01)05391523440783(17)250531 (10)0130112202
Multichem S Plus Level 3	08P88-12	0130112203	(01)05391523440790(17)250531 (10)0130112203
Multichem S Plus Level 1	08P88-10	0131112201	(01)05391523440776(17)250531 (10)0131112201
Multichem S Plus Level 2	08P88-11	0131112202	(01)05391523440783(17)250531 (10)0131112202

Multichem S Plus Level 3	08P88-12	0131112203	(01)05391523440790(17)250531 (10)0131112203
Multichem IA Plus	08P86-10	032004230	(01)05391523440745(17)250731 (10)032004230
Multichem IA Plus	08P86-10	035106210	(01)05391523440745(17)230930 (10)035106210
Multichem IA Plus	08P86-10	035810210	(01)05391523440745(17)240131 (10)035810210
Multichem IA Plus	08P86-10	036404220	(01)05391523440745 (17)240731 (10)036404220
Multichem IA Plus	08P86-10	037209220	(01)05391523440745 (17)241231 (10)037209220
Multichem IA Plus	08P86-19	035506210	(01)05391523441636 (17)240531 (10)035506210
Multichem IA Plus	08P86-19	036010210	(01)05391523441636 (17)240930 (10)036010210
Multichem IA Plus	08P86-19	036604220	(01)05391523441636 (17)250331 (10)036604220
Multichem IA Plus	08P86-19	037409220	(01)0539152344163(17)250831 (10)037409220
Multichem P	08P90-10	04530621P	(01)05391523440769 (17)231130 (10)04530621P
Multichem P	08P90-10	04561021P	(01)05391523440769 (17)240430 (10)04561021P
Multichem P	08P90-10	04610523P	(01)05391523440769 (17)251130 (10)04610523P

Explanation

The purpose of this letter is to inform you that Technopath Manufacturing Ltd, the manufacturer of Multichem IA Plus controls and Multichem S Plus (Assayed) controls, has identified an issue with the 8mL Alinity glass vial commodity used to fill the products listed above. Some customers have experienced broken vials when receiving or thawing Technopath Multichem IA Plus controls, LN 08P86 or Multichem S Plus (Assayed) controls, LN 08P88.

**Impact on
Patient Results/
User Safety**

Please refer to the attached Technopath Urgent Field Safety Notice.

**Necessary
Actions to be
Taken by
Customer**

- Please review the attached Technopath Urgent Field Safety Notice and follow the required actions.
- Complete and return the Customer Reply Form.
- Contact Abbott Customer Service for assistance if needed.
- 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 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 online (<http://www.fda.gov/MedWatch/report.htm>), by phone (1-800-332-1088), or by fax (1-800-FDA0178).

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.

URGENT FIELD SAFETY NOTICE – FSN-RE23001
 For attention of: Healthcare Professionals

Date Issued: 31/08/2023

Type of Action: Field Safety Corrective Action

Products:

Product	Part Code	Lot Number	Expiry Date	UDI
Multichem S Plus Level 1	08P88-10	0108032101	30/09/2023	(01)05391523440776 (17)230930(10)0108032101
Multichem S Plus Level 2	08P88-11	0108032102	30/09/2023	(01)05391523440783 (17)230930(10)0108032102
Multichem S Plus Level 3	08P88-12	0108032103	30/09/2023	(01)05391523440790 (17)230930(10)0108032103
Multichem S Plus Level 1	08P88-10	0110072101	31/12/2023	(01)05391523440776 (17)231231(10)0110072101
Multichem S Plus Level 2	08P88-11	0110072102	31/12/2023	(01)05391523440783 (17)231231(10)0110072102
Multichem S Plus Level 3	08P88-12	0110072103	31/12/2023	(01)05391523440790 (17)231231(10)0110072103
Multichem S Plus Level 1	08P88-10	0119112101	31/05/2024	(01)05391523440776 (17)240531(10)0119112101
Multichem S Plus Level 2	08P88-11	0119112102	31/05/2024	(01)05391523440783 (17)240531(10)0119112102
Multichem S Plus Level 3	08P88-12	0119112103	31/05/2024	(01)05391523440790 (17)240531(10)0119112103
Multichem S Plus Level 1	08P88-10	0126052201	31/10/2024	(01)05391523440776 (17)241031(10)0126052201
Multichem S Plus Level 2	08P88-11	0126052202	31/10/2024	(01)05391523440783 (17)241031(10)0126052202
Multichem S Plus Level 3	08P88-12	0126052203	31/10/2024	(01)05391523440790 (17)241031(10)0126052203
Multichem S Plus Level 1	08P88-10	0130112201	31/05/2025	(01)05391523440776 (17)250531(10)0130112201
Multichem S Plus Level 2	08P88-11	0130112202	31/05/2025	(01)05391523440783 (17)250531(10)0130112202
Multichem S Plus Level 3	08P88-12	0130112203	31/05/2025	(01)05391523440790 (17)250531(10)0130112203



Product	Part Code	Lot Number	Expiry Date	UDI
Multichem S Plus Level 1	08P88-10	0131112201	31/05/2025	(01)05391523440776 (17)250531(10)0131112201
Multichem S Plus Level 2	08P88-11	0131112202	31/05/2025	(01)05391523440783 (17)250531(10)0131112202
Multichem S Plus Level 3	08P88-12	0131112203	31/05/2025	(01)05391523440790 (17)250531(10)0131112203
Multichem IA Plus	08P86-10	032004230	31/07/2025	(01)05391523440745 (17)250731(10)032004230
Multichem IA Plus	08P86-10	035106210	30/09/2023	(01)05391523440745 (17)230930(10)035106210
Multichem IA Plus	08P86-10	035810210	31/01/2024	(01)05391523440745 (17)240131(10)035810210
Multichem IA Plus	08P86-10	036404220	31/07/2024	(01)05391523440745 (17)240731(10)036404220
Multichem IA Plus	08P86-10	037209220	31/12/2024	(01)05391523440745 (17)241231(10)037209220
Multichem IA Plus	08P86-19	035506210	31/05/2024	(01)05391523441636 (17)240531(10)035506210
Multichem IA Plus	08P86-19	036010210	30/09/2024	(01)05391523441636 (17)240930(10)036010210
Multichem IA Plus	08P86-19	036604220	31/03/2025	(01)05391523441636 (17)250331(10)036604220
Multichem IA Plus	08P86-19	037409220	31/08/2025	(01)05391523441636 (17)250831(10)037409220
Multichem P	08P90-10	04530621P	30/11/2023	(01)05391523440769 (17)231130(10)04530621P
Multichem P	08P90-10	04561021P	30/04/2024	(01)05391523440769 (17)240430(10)04561021P
Multichem P	08P90-10	04610523P	30/11/2025	(01)05391523440769 (17)251130(10)04610523P



Technopath is part of LGC Clinical Diagnostics

Technopath Life Sciences Park, Fort Henry, Ballina, Co. Tipperary, Ireland. t: +353 61 525 700 | e: technopath.info@lgcgroup.com | w: www.technopathcd.com

Reason for Notice:

Dear Valued Customer,

Technopath Manufacturing Ltd. is initiating a field action for the products listed above.
 This letter contains important information that needs your immediate attention.

<p>ISSUE:</p>	<p>Technopath Manufacturing Ltd. has identified an issue with the glass vial commodity used to fill the products as listed above. Some customers have experienced broken vials when receiving or thawing Technopath Multichem IA Plus controls, LN 08P86 or Multichem S Plus (Assayed) controls, LN 08P88.</p> <p>Breakage has been observed upon delivery, while thawing, or while opening the vial.</p> <p>The breakage can result in the bottom of the vial breaking off, breakage in the neck thread area, or cracking on the sides of the vial.</p> <p>Technopath, Abbott and the vial supplier evaluated the vial manufacturing process for potential enhancements. Extensive investigation and verification studies were performed, and a strengthened glass vial design has now been qualified for use.</p> <p>Therefore, all future lots will be manufactured at Technopath Manufacturing Ltd. using the strengthened vials and will become available through the course of 2024.</p>
<p>IMPACT ON PATIENT RESULTS / USER SAFETY:</p>	<p>No patient results are impacted by this issue as there is no change to the product formulation.</p> <p>There is the potential for minor injuries or biohazardous exposure due to the possibility of vials breaking during thawing or handling.</p>
<p>NECESSARY ACTION TO BE TAKEN BY CUSTOMER:</p>	<p>Continue to adhere to the following points from the Procedures for Use in the respective Instructions for Use:</p> <ul style="list-style-type: none"> ➤ Allow the control vial to stand at room temperature (18 to 25°C) for 30 minutes or until completely thawed. The control must be completely solubilized before continuing to the next step. ➤ Place the thawed control vial on a suitable mixing device, e.g. roller mixer for 15 minutes, to achieve a homogenous solution.



	<p>If you identify that a vial has broken or cracks are visible, safely dispose of the vial in line with Safety Data Sheet (SDS).</p> <p>Continue to use caution to prevent operator exposure and wear gloves when handling the control, as it contains material of human and animal origin. In addition, refer to the respective Safety Data Sheet (SDS) for more information regarding exposure controls and personal protection.</p> <p>Please share this information with your laboratory staff who need to be aware of this safety notice and retain this notification as part of your laboratory Quality System documentation. If you have forwarded any of the impacted product(s) listed above to another laboratory, please provide them a copy of this letter.</p>
CONTACT	<p>If you or any of the health care providers you serve have questions regarding this notice, 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.</p>

We sincerely apologize for any inconvenience this may cause your laboratory and hope for your understanding and cooperation.

Yours Sincerely

Bernd Hass
Senior Vice President, Quality and Regulatory Affairs
LGC Clinical Diagnostics
Tel +353 (061) 525700



Technopath is part of LGC Clinical Diagnostics

Technopath Life Sciences Park, Fort Henry, Ballina, Co. Tipperary, Ireland. t: +353 61 525 700 | e: technopath.info@lgcgroup.com | w: www.technopathcd.com



CORE DIAGNOSTICS
 Abbott Laboratories
 Diagnostics Division
 Abbott Park, IL, 60064 USA

Single Registration Number (SRN):
 IE-MF-000001822

Distributor Reply

Immediate Action Required

Core Diagnostics Product Correction letter dated **Month/Day/Year** - FADDMMMMYYYY

Product	Product Description	List Number	Lot Number	UDI
		Multichem S Plus Level 1	08P88-10	0108032101
	Multichem S Plus Level 2	08P88-11	0108032102	(01)05391523440783(17)230930 (10)0108032102
	Multichem S Plus Level 3	08P88-12	0108032103	(01)05391523440790 (17)230930 10)0108032103
	Multichem S Plus Level 1	08P88-10	0110072101	(01)05391523440776(17)231231 (10)0110072101
	Multichem S Plus Level 2	08P88-11	0110072102	(01)05391523440783(17)231231 (10)0110072102
	Multichem S Plus Level 3	08P88-12	0110072103	(01)05391523440790(17)231231 (10)0110072103
	Multichem S Plus Level 1	08P88-10	0119112101	(01)05391523440776(17)240531 (10)0119112101
	Multichem S Plus Level 2	08P88-11	0119112102	(01)05391523440783(17)240531 (10)0119112102
	Multichem S Plus Level 3	08P88-12	0119112103	(01)05391523440790(17)240531 (10)0119112103
	Multichem S Plus Level 1	08P88-10	0126052201	(01)05391523440776(17)241031 (10)0126052201
	Multichem S Plus Level 2	08P88-11	0126052202	(01)05391523440783(17)241031 (10)0126052202
	Multichem S Plus Level 3	08P88-12	0126052203	(01)05391523440790(17)241031 (10)0126052203
	Multichem S Plus Level 1	08P88-10	0130112201	(01)05391523440776(17)250531 (10)0130112201
	Multichem S Plus Level 2	08P88-11	0130112202	(01)05391523440783(17)250531 (10)0130112202
	Multichem S Plus Level 3	08P88-12	0130112203	(01)05391523440790(17)250531 (10)0130112203
	Multichem S Plus Level 1	08P88-10	0131112201	(01)05391523440776(17)250531 (10)0131112201
	Multichem S Plus Level 2	08P88-11	0131112202	(01)05391523440783(17)250531 (10)0131112202
	Multichem S Plus Level 3	08P88-12	0131112203	(01)05391523440790(17)250531 (10)0131112203
	Multichem IA Plus	08P86-10	032004230	(01)05391523440745(17)250731 (10)032004230
	Multichem IA Plus	08P86-10	035106210	(01)05391523440745(17)230930 (10)035106210
	Multichem IA Plus	08P86-10	035810210	(01)05391523440745(17)240131 (10)035810210
	Multichem IA Plus	08P86-10	036404220	(01)05391523440745 (17)240731 (10)036404220

	Multichem IA Plus	08P86-10	037209220	(01)05391523440745 (17)241231 (10)037209220
	Multichem IA Plus	08P86-19	035506210	(01)05391523441636 (17)240531 (10)035506210
	Multichem IA Plus	08P86-19	036010210	(01)05391523441636 (17)240930 (10)036010210
	Multichem IA Plus	08P86-19	036604220	(01)05391523441636 (17)250331 (10)036604220
	Multichem IA Plus	08P86-19	037409220	(01)0539152344163(17)250831 (10)037409220
	Multichem P	08P90-10	04530621P	(01)05391523440769 (17)231130 (10)04530621P
	Multichem P	08P90-10	04561021P	(01)05391523440769 (17)240430 (10)04561021P
	Multichem P	08P90-10	04610523P	(01)05391523440769 (17)251130 (10)04610523P

Date range the affected product was distributed	Start Date: __12 APR 2021_____ End Date: __N/A_____
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Distributor Instructions	<p>Please ensure that all your affected customers are sent the attached Product Correction letter.</p> <p>The distributor responsible for the further distribution of the above product should complete the information below acknowledging receipt of notification and attesting that all their affected customers who were shipped the above product were informed of the Product Correction Letter.</p>
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Acknowledgement	<p>By completing and signing this document, I confirm that all affected customers were informed of the attached Product Correction letter. If not, please choose one of the options below.</p> <p><input type="checkbox"/> No, I would like to be contacted by an Abbott Representative.</p> <p><input type="checkbox"/> Not Applicable (product was not further distributed)</p>		
Abbott Contact	<p>Please return the completed Distributor Reply Form, prior to DDMMMYYYY via:</p> <ul style="list-style-type: none"> E-mail: PMS@abbott.com (insert local e-mail address here) Fax: 1-800-777-0051 (insert local number here) 		
Name of Distributor			
Address			
City		State	
Phone Number		Country	
Name (print)		Email	
Signature		Date	