



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

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

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

Customer Reply

Immediate Action Required

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

Product	Product Description			List Number			Lot Number			UDI		
	Product Description	List Number	Lot Number	Product Description	List Number	Lot Number	Product Description	List Number	Lot Number	Product Description	List Number	Lot Number
Product	Multichem S Plus Level 1	08P88-10	0108032101	Multichem S Plus Level 1	08P88-10	0110072101	Multichem S Plus Level 1	08P88-10	0119112101	Multichem S Plus Level 1	08P88-10	0126052201
	Multichem S Plus Level 2	08P88-11	0108032102	Multichem S Plus Level 2	08P88-11	0119112102	Multichem S Plus Level 2	08P88-11	0126052202	Multichem S Plus Level 2	08P88-11	0130112201
	Multichem S Plus Level 3	08P88-12	0108032103	Multichem S Plus Level 3	08P88-12	0119112103	Multichem S Plus Level 3	08P88-12	0126052203	Multichem S Plus Level 3	08P88-12	0130112202
	Multichem S Plus Level 1	08P88-10	0110072101	Multichem S Plus Level 1	08P88-10	0130112203	Multichem S Plus Level 1	08P88-10	0131112201	Multichem S Plus Level 1	08P88-10	032004230
	Multichem S Plus Level 2	08P88-11	0110072102	Multichem S Plus Level 2	08P88-11	0131112202	Multichem S Plus Level 2	08P88-11	0131112202	Multichem S Plus Level 2	08P88-11	035106210
	Multichem S Plus Level 3	08P88-12	0110072103	Multichem S Plus Level 3	08P88-12	0131112203	Multichem S Plus Level 3	08P88-12	0131112203	Multichem S Plus Level 3	08P88-12	035810210
	Multichem S Plus Level 1	08P88-10	0119112101	Multichem S Plus Level 1	08P88-10	0131112201	Multichem S Plus Level 1	08P88-10	0131112201	Multichem S Plus Level 1	08P88-10	035810210
	Multichem S Plus Level 2	08P88-11	0119112102	Multichem S Plus Level 2	08P88-11	0131112202	Multichem S Plus Level 2	08P88-11	0131112202	Multichem S Plus Level 2	08P88-11	035810210
	Multichem S Plus Level 3	08P88-12	0119112103	Multichem S Plus Level 3	08P88-12	0131112203	Multichem S Plus Level 3	08P88-12	0131112203	Multichem S Plus Level 3	08P88-12	035810210
	Multichem S Plus Level 1	08P88-10	0126052201	Multichem S Plus Level 1	08P88-10	0131112201	Multichem S Plus Level 1	08P88-10	0131112201	Multichem S Plus Level 1	08P88-10	035810210
	Multichem S Plus Level 2	08P88-11	0126052202	Multichem S Plus Level 2	08P88-11	0131112202	Multichem S Plus Level 2	08P88-11	0131112202	Multichem S Plus Level 2	08P88-11	035810210
	Multichem S Plus Level 3	08P88-12	0126052203	Multichem S Plus Level 3	08P88-12	0131112203	Multichem S Plus Level 3	08P88-12	0131112203	Multichem S Plus Level 3	08P88-12	035810210
	Multichem S Plus Level 1	08P88-10	0130112201	Multichem S Plus Level 1	08P88-10	0131112201	Multichem S Plus Level 1	08P88-10	0131112201	Multichem S Plus Level 1	08P88-10	035810210
	Multichem S Plus Level 2	08P88-11	0130112202	Multichem S Plus Level 2	08P88-11	0131112202	Multichem S Plus Level 2	08P88-11	0131112202	Multichem S Plus Level 2	08P88-11	035810210
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	Multichem S Plus Level 1	08P88-10	0131112201	Multichem S Plus Level 1	08P88-10	0131112201	Multichem S Plus Level 1	08P88-10	0131112201	Multichem S Plus Level 1	08P88-10	035810210
	Multichem S Plus Level 2	08P88-11	0131112202	Multichem S Plus Level 2	08P88-11	0131112202	Multichem S Plus Level 2	08P88-11	0131112202	Multichem S Plus Level 2	08P88-11	035810210
	Multichem S Plus Level 3	08P88-12	0131112203	Multichem S Plus Level 3	08P88-12	0131112203	Multichem S Plus Level 3	08P88-12	0131112203	Multichem S Plus Level 3	08P88-12	035810210
	Multichem IA Plus	08P86-10	032004230	Multichem IA Plus	08P86-10	035106210	Multichem IA Plus	08P86-10	035810210	Multichem IA Plus	08P86-10	035810210
	Multichem IA Plus	08P86-10	035106210	Multichem IA Plus	08P86-10	035810210	Multichem IA Plus	08P86-10	035810210	Multichem IA Plus	08P86-10	035810210
Multichem IA Plus	08P86-10	035810210	Multichem IA Plus	08P86-10	035810210	Multichem IA Plus	08P86-10	035810210	Multichem IA Plus	08P86-10	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
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	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
Instructions	<ol style="list-style-type: none"> Please provide a copy of the accompanying Product Correction letter to the laboratory manager, supervisor or health professional responsible for the impacted product. Please complete all sections and return this Customer Reply Form to the Abbott contact prior to DDMMYY. Even if you no longer have the instrument(s)/reagent(s), this form is required for the reconciliation of our records. 			
Abbott contact	<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) 			
Acknowledgement	<p>By completing and signing this document I confirm that the Product Correction Letter was understood and that the necessary actions for the customer were completed. 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. <input type="checkbox"/> Not Applicable, Please Explain (e.g. no longer have the instrument): _____ </p>			
Customer number		Serial Number(s)		
Facility Name(s)				
Address				
City		State		
Phone Number		E-mail		
Name (print)		Title/Position		
Signature				