



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
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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
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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
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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
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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

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	0126052201	Multichem S Plus Level 1	08P88-10	0130112201
	Multichem S Plus Level 2	08P88-11	0108032102	Multichem S Plus Level 2	08P88-11	0110072102	Multichem S Plus Level 2	08P88-11	0126052202	Multichem S Plus Level 2	08P88-11	0130112202
	Multichem S Plus Level 3	08P88-12	0108032103	Multichem S Plus Level 3	08P88-12	0110072103	Multichem S Plus Level 3	08P88-12	0126052203	Multichem S Plus Level 3	08P88-12	0130112203
	Multichem S Plus Level 1	08P88-10	0119112101	Multichem S Plus Level 1	08P88-10	0119112102	Multichem S Plus Level 1	08P88-10	0131112201	Multichem S Plus Level 1	08P88-10	0135106210
	Multichem S Plus Level 2	08P88-11	0119112102	Multichem S Plus Level 2	08P88-11	0119112103	Multichem S Plus Level 2	08P88-11	0135106210	Multichem IA Plus	08P86-10	032004230
	Multichem S Plus Level 3	08P88-12	0119112103	Multichem S Plus Level 3	08P88-12	0119112104	Multichem S Plus Level 3	08P88-12	0135106210	Multichem IA Plus	08P86-10	035106210
	Multichem S Plus Level 1	08P88-10	01240531	Multichem S Plus Level 1	08P88-10	01240531	Multichem S Plus Level 1	08P88-10	0135810210	Multichem IA Plus	08P86-10	035810210
	Multichem S Plus Level 2	08P88-11	01240531	Multichem S Plus Level 2	08P88-11	01240531	Multichem S Plus Level 2	08P88-11				
	Multichem S Plus Level 3	08P88-12	01240531	Multichem S Plus Level 3	08P88-12	01240531	Multichem S Plus Level 3	08P88-12				
	Multichem S Plus Level 1	08P88-10	01241031	Multichem S Plus Level 1	08P88-10	01241031	Multichem S Plus Level 1	08P88-10				
	Multichem S Plus Level 2	08P88-11	01241031	Multichem S Plus Level 2	08P88-11	01241031	Multichem S Plus Level 2	08P88-11				
	Multichem S Plus Level 3	08P88-12	01241031	Multichem S Plus Level 3	08P88-12	01241031	Multichem S Plus Level 3	08P88-12				
	Multichem S Plus Level 1	08P88-10	01250531	Multichem S Plus Level 1	08P88-10	01250531	Multichem S Plus Level 1	08P88-10				
	Multichem S Plus Level 2	08P88-11	01250531	Multichem S Plus Level 2	08P88-11	01250531	Multichem S Plus Level 2	08P88-11				
	Multichem S Plus Level 3	08P88-12	01250531	Multichem S Plus Level 3	08P88-12	01250531	Multichem S Plus Level 3	08P88-12				
	Multichem S Plus Level 1	08P88-10	01250531	Multichem S Plus Level 1	08P88-10	01250531	Multichem S Plus Level 1	08P88-10				
	Multichem S Plus Level 2	08P88-11	01250531	Multichem S Plus Level 2	08P88-11	01250531	Multichem S Plus Level 2	08P88-11				
	Multichem S Plus Level 3	08P88-12	01250531	Multichem S Plus Level 3	08P88-12	01250531	Multichem S Plus Level 3	08P88-12				

	Multichem IA Plus	08P86-10	036404220	(01)05391523440745 (17)240731 (10)036404220
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	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.</p> <p><input type="checkbox"/> Not Applicable, Please Explain (e.g. no longer have the instrument):</p> <p>_____</p>			
Customer number		Serial Number(s)		
Facility Name(s)				
Address				
City		State		
Phone Number		E-mail		
Name (print)		Title/Position		
Signature				



Abbott

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

Single Registration Number (SRN):
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Urgent Product Correction

Immediate Action Required

Date Issued August xx, 2023

Product

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**Contact
Information**

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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.

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 For attention of: Healthcare Professionals

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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	

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 No	Expiry Data	UDI from Kit Label
Multichem IA Plus	IA321A	0354062101	31.05.2024	(01)05391523442145(240)IA321A(17)230930(10)0354062101
Multichem IA Plus	IA322A	0354062102	31.05.2024	(01)05391523442152(240)IA322A(17)230930(10)0354062102
Multichem IA Plus	IA323A	0354062103	31.05.2024	(01)05391523442169(240)IA323A(17)230930(10)0354062103
Multichem IA Plus	IA321A	0368042201	31.03.2025	(01)05391523442145(240)IA321A(17)240731(10)0368042201
Multichem IA Plus	IA322A	0368042202	31.03.2025	(01)05391523442152(240)IA322A(17)240731(10)0368042202
Multichem IA Plus	IA323A	0368042203	31.03.2025	(01)05391523442169(240)IA323A(17)240731(10)0368042203
Multichem S Plus	CH114A.05	0116072101	31.12.2023	(01)05391523442107(240)CH114A.05(17)231231(10)0116072101
Multichem S Plus	CH115A.05	0116072102	31.12.2023	(01)05391523442114(240)CH115A.05(17)231231(10)0116072102
Multichem S Plus	CH116A.05	0116072103	31.12.2023	(01)08391523442138(240)CH116A.05(17)231231(10)0116072103
Multichem S Plus	CH114A.05	0123032201	28.02.2025	(01)05391523442107(240)CH114A.05(17)240831(10)0123032201
Multichem S Plus	CH115A.05	0123032202	28.02.2025	(01)05391523442114(240)CH115A.05(17)240831(10)0123032202
Multichem S Plus	CH116A.05	0123032203	28.02.2025	(01)05391523442138(240)CH116A.05(17)240831(10)0123032203

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 IA321A, IA322A and IA323A) or Multichem S Plus controls (LN CH114A.05, CH115A.05 and CH116A.05).</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.



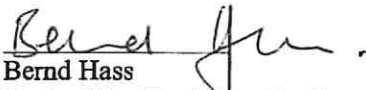
**CLINICAL
DIAGNOSTICS**

Technopath Manufacturing Ltd
Fort Henry Business Park
Ballina Co. Tipperary
Ireland
SRN: IE-MF-000001822
Ref: CC0159 Rev 01

	<p>➤ Place the thawed control vial on a suitable mixing device, e.g. roller mixer for 15 minutes, to achieve a homogenous solution.</p> <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, customers please contact fieldaction@lgcgroup.com</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

ACKNOWLEDGEMENT

URGENT FIELD SAFETY NOTICE – FSN-RE23001 - Action Required

Field Safety Notice Ref #RE23001

Date: 31st Aug 2023

Type of Action: Field Safety Corrective Action (FSCA)

Kindly complete and return this form to fieldaction@lgcgroup.com before **21st September 2023**.

Product Catalogue Number:

Customer Name and Dept:

Address:

Are the above contact details correct? Yes No

(If no please insert correct details below)

Contact Name:

Department:

Address:

Telephone Number:

Email:

Please acknowledge receipt of information and awareness of any required actions described within the accompanying Field Safety Notice. Please bring this notice to the attention of all personnel in your hospital or healthcare facility who need to be aware of this safety issue. If you have forwarded the affected product(s) listed above to another laboratory, please provide a copy of this notice to them.

I acknowledge receipt of this Field Safety Notice and have read, understood, and implemented its contents.

Name:

Signed: _____

Date: _____

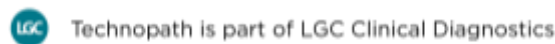
FSCA Attachment 1 – FSN-RE23001

Brand Name	Part Code	IVDD Classification	Lot number	Manufacture Date	Expiry Date
Multichem S Plus Level 1	08P88-10	IVD General	0108032101	30/03/2021	30/09/2023
Multichem S Plus Level 2	08P88-11	IVD General	0108032102	31/03/2021	30/09/2023
Multichem S Plus Level 3	08P88-12	IVD General	0108032103	01/04/2021	30/09/2023
Multichem S Plus Level 1	08P88-10	IVD General	0110072101	02/07/2021	31/12/2023
Multichem S Plus Level 2	08P88-11	IVD General	0110072102	09/04/2021	31/12/2023
Multichem S Plus Level 3	08P88-12	IVD General	0110072103	15/04/2021	31/12/2023
Multichem S Plus Level 1	08P88-10	IVD General	0119112101	18/11/2021	31/05/2024
Multichem S Plus Level 2	08P88-11	IVD General	0119112102	23/11/2021	31/05/2024
Multichem S Plus Level 3	08P88-12	IVD General	0119112103	25/11/2021	31/05/2024
Multichem S Plus Level 1	08P88-10	IVD General	0126052201	11/05/2022	31/10/2024
Multichem S Plus Level 2	08P88-11	IVD General	0126052202	18/05/2022	31/10/2024
Multichem S Plus Level 3	08P88-12	IVD General	0126052203	25/05/2022	31/10/2024
Multichem S Plus Level 1	08P88-10	IVD General	0130112201	16/11/2022	31/05/2025
Multichem S Plus Level 2	08P88-11	IVD General	0130112202	24/11/2022	31/05/2025
Multichem S Plus Level 3	08P88-12	IVD General	0130112203	30/11/2022	31/05/2025
Multichem S Plus Level 1	08P88-10	IVD General	0131112201	17/11/2022	31/05/2025
Multichem S Plus Level 2	08P88-11	IVD General	0131112202	24/11/2022	31/05/2025
Multichem S Plus Level 3	08P88-12	IVD General	0131112203	01/12/2022	31/05/2025
Multichem S Plus Level 1	CH114A.05	IVD General	0116072101	02/07/2021	31/12/2023
Multichem S Plus Level 2	CH115A.05	IVD General	0116072102	08/07/2021	31/12/2023
Multichem S Plus Level 3	CH116A.05	IVD General	0116072103	15/07/2021	31/12/2023



Technopath Manufacturing Ltd
 Fort Henry Business Park
 Ballina Co. Tipperary
 Ireland
 SRN: IE-MF-000001822
 Ref: CC0159 Rev 01

Brand Name	Part Code	IVDD Classification	Lot number	Manufacture Date	Expiry Date
Multichem S Plus Level 1	CH114A.05	IVD General	0123032201	08/03/2022	28/02/2025
Multichem S Plus Level 2	CH115A.05	IVD General	0123032202	11/03/2022	28/02/2025
Multichem S Plus Level 3	CH116A.05	IVD General	0123032203	15/03/2022	28/02/2025
Multichem IA Plus	08P86-10	IVD Annex II List B	032004230	05/04/2023	31/07/2025
Multichem IA Plus	08P86-10	IVD Annex II List B	035106210	29/06/2021	30/09/2023
Multichem IA Plus	08P86-10	IVD Annex II List B	035810210	12/10/2021	31/01/2024
Multichem IA Plus	08P86-10	IVD Annex II List B	036404220	14/04/2022	31/07/2024
Multichem IA Plus	08P86-10	IVD Annex II List B	037209220	05/10/2022	31/12/2024
Multichem IA Plus	08P86-19	IVD Annex II List B	035506210	29/06/2021	31/05/2024
Multichem IA Plus	08P86-19	IVD Annex II List B	036010210	12/10/2021	30/09/2024
Multichem IA Plus	08P86-19	IVD Annex II List B	036604220	13/04/2022	31/03/2025
Multichem IA Plus	08P86-19	IVD Annex II List B	037409220	05/10/2022	31/08/2025
Multichem IA Plus	IA321A	IVD Annex II List B	0354062101	29/06/2021	31/05/2024
Multichem IA Plus	IA322A	IVD Annex II List B	0354062102	22/06/2021	31/05/2024
Multichem IA Plus	IA323A	IVD Annex II List B	0354062103	24/06/2021	31/05/2024
Multichem IA Plus	IA321A	IVD Annex II List B	0368042201	13/04/2023	31/03/2025
Multichem IA Plus	IA322A	IVD Annex II List B	0368042202	21/04/2022	31/03/2025
Multichem IA Plus	IA323A	IVD Annex II List B	0368042203	27/04/2022	31/03/2025
Multichem P	08P90-10	IVD General	04530621P	10/06/2021	30/11/2023
Multichem P	08P90-10	IVD General	04561021P	21/10/2021	30/04/2024
Multichem P	08P90-10	IVD General	04610523P	26/05/2022	30/11/2025



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