



# Urgent Product Correction

## Immediate Action Required

This letter is to be provided to all laboratory personnel with direct product handling responsibilities.

Date Issued December 17, 2024

### Product

Product Description	List Number	Lot Number	UDI
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	037209220	(01)05391523440745 (17)241231(10)037209220
Multichem IA Plus	08P86-19	036604220	(01)05391523441636 (17)250331(10)036604220
Multichem IA Plus	08P86-19	037409220	(01)05391523441636 (17)250831(10)037409220
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. The occurrence of broken product bottles has the potential to cause injury or biohazardous exposure.

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**Necessary  
Actions to be  
Taken by  
Customer**

- Please review the attached Technopath Urgent Field Safety Notice with all laboratory personnel with direct product handling responsibilities and follow the required actions, ensuring that necessary safety precautions outlined are taken when handling the glass bottles. These measures include:
  - Careful handling the packaged product when opening the outer bag and box.
  - Should any shards of broken glass or leaking product be present, please take the necessary precautions to safely dispose of the product per laboratory procedures.
  - Careful handling of the glass bottles during preparation and use per instructions for use and the respective Safety Data Sheet (SDS).
- 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.

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**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. 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.

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**URGENT FIELD SAFETY NOTICE – FSN-RE23001**

For attention of: Healthcare Professionals

**Date Issued:** 13/12/2024

**Type of Action:** Field Safety Corrective Action

**Products:**

Product	Part Code	Lot Number	Expiry Date	UDI
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
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	037209220	31/12/2024	(01)05391523440745 (17)241231(10)037209220
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	04610523P	30/11/2025	(01)05391523440769 (17)251130(10)04610523P



**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.

<b>ISSUE:</b>	<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>
<b>IMPACT ON PATIENT RESULTS / USER SAFETY:</b>	<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>
<b>NECESSARY ACTION TO BE TAKEN BY CUSTOMER:</b>	<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 adhere to the following points from the Procedures for Use in the respective Instructions for Use:</p> <ul style="list-style-type: none"> <li>➤ 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.</li> <li>➤ Place the thawed control vial on a suitable mixing device, e.g. roller mixer for 15 minutes, to achieve a homogenous solution.</li> </ul> <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>



Technopath is part of LGC Clinical Diagnostics

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	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.
<b>ACTIONS TO BE TAKEN BY TECHNOPATH</b>	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.  Therefore, all future lots will be manufactured at Technopath Manufacturing Ltd. using the strengthened vials and will become available through the course of 2024.
<b>CONTACT</b>	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. Customers outside the U.S., please contact your local area Customer Service.

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

Yours Sincerely

*PP C. Kiely 13 Dec 2024.*

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Technopath is part of LGC Clinical Diagnostics

**TECHNOPATH**  
CLINICAL DIAGNOSTICS

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