



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

Date Issued: 26/03/2024

Type of Action: Field Safety Corrective Action

Products:

Product	Part Code	Lot Number	Expiry Date	UDI
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
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



Technopath is part of LGC Clinical Diagnostics

TECHNOPATH
CLINICAL DIAGNOSTICS

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



**CLINICAL
DIAGNOSTICS**

Technopath Manufacturing Ltd
Fort Henry Business Park
Ballina Co. Tipperary
Ireland
SRN: IE-MF-000001822
Ref: CC0159 Rev 02

Product	Part Code	Lot Number	Expiry Date	UDI
Multichem IA Plus	08P86-10	032004230	31/07/2025	(01)05391523440745 (17)250731(10)032004230
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	04561021P	30/04/2024	(01)05391523440769 (17)240430(10)04561021P
Multichem P	08P90-10	04610523P	30/11/2025	(01)05391523440769 (17)251130(10)04610523P



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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.

ISSUE:	<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>
IMPACT ON PATIENT RESULTS / USER SAFETY:	<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>
NECESSARY ACTION TO BE TAKEN BY CUSTOMER:	<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"> ➤ 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>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>



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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.
ACTIONS TO BE TAKEN BY TECHNOPATH	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.
CONTACT	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.

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

Yours Sincerely

Bernd Hass 26-MARCH-2024.

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