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

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

Urgent Field Safety Notice

Urgent Product Correction

Immediate Action Required

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

Date Issued August 20, 2024

Product

Product Description	List Number	Lot Number	UDI
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	036404220	(01)05391523440745 (17)240731(10)036404220
Multichem IA Plus	08P86-10	037209220	(01)05391523440745 (17)241231(10)037209220
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)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.

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.

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.