



Urgent Field Safety Notice Product Correction

Urgent - Immediate Action Required

To Chairman Medical Board and relevant Head of Departments

Date Issued November 20, 2018

Product

Product Name	List Number	Lot Number	Expiration Date	UDI Number
Multichem IA Plus	05P76-10	37902180	30JUN2020	[REDACTED]

Explanation

Abbott received the attached letter from Technopath Clinical Diagnostics, the manufacturer of the Multichem IA Plus Controls. Technopath has identified an error was in the Multilingual Instructions for Use (IFU) for the Multichem IA Plus lot 37902180 (05P76) for the Chinese translation section. It was identified that the open vial stability claims were not populated in the Chinese translation. The exceptions to the standard stability claim for the products in relation to the length of time and analyte are missing from the Chinese translation. No other IFU translations for this lot are impacted.

Patient Impact

Please refer to the attached Product Correction letter from Technopath.

Necessary Actions

- Please review the attached Technopath letter carefully and follow the instructions.
- Complete and return the Abbott 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 any questions regarding this information, please contact your local area Customer Service.

Date Issued 23- October- 2018

Product Multichem IA + (05P76), Lot 37902180.

Multichem IA+ (05P76-10)		
Product Code	Size	Lot number
05P76-10	3 x 4 x 5mL	37902180
IA311 A	4 x 5mL	37902181
IA312 A	4 x 5mL	37902182
IA313 A	4 x 5mL	37902183

Reason During a review of the Instructions for Use (IFU) at Technopath Clinical Diagnostics (TCD) an error was observed in the Multilingual IFU for the Multichem IA+ lot 37902180 (05P76) for the Chinese translation section. It was identified that the open vial stability claims were not populated in the Chinese translation. The exceptions to the standard stability claim for the products in relation to the length of time and analyte are missing from the Chinese translation.

The IFU contained the following Chinese translation with XX replacing the length of time and the type of analyte:

XX在XX小时内保持稳定。
XX在XX天内保持稳定。
XX在XX天内保持稳定。
XX在XX天内保持稳定。

The IFU should have contained the following information:

BNP (1-32) will be stable for 1 hour.
Folate will be stable for 4 days.
PTH (1-84) will be stable for 4 days.
Troponin I will be stable for 7 days.

The populated Chinese translation is as follows:

B-型尿钠肽(1-32) (BNP)在1小时内保持稳定。

叶酸在4天内保持稳定。

甲状旁腺激素(PTH) (1-84)在4天内保持稳定。

肌钙蛋白-I在7天内保持稳定。

Current Status	There is no impact to product performance with no impact to patient results. If controls were used outside of the stability claims, controls may fail QC results; therefore, there is the potential for a delay in generation of patient results.
Action	Technopath Clinical Diagnostics advise that all impacted customers refer to the Monolingual IFU attached with this communication, whereby the open vial stability claims are available in the Chinese translation.
Contact	We sincerely regret any inconvenience this may cause your laboratory and are taking appropriate actions to ensure this issue will not occur in the future. If you have further questions, concerns, or need additional information, please contact gcsupport@technopathcd.com or your local Abbott customer service representative.

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