



Product Correction

Urgent - Immediate Action Required

Date Issued December 6, 2018

Product

Product Name	Product List Number	Lot or Control Number	UDI
CP3000 w/ CTS 230V	02R73-02	CP3490245, CP3490246, CP3490254, CP3490322, CP3490323, CP3490369, CP3490370, CP3490396, CP3490397, CP3490398, CP3490399, CP3490400, CP3490401	N/A
CP3000 w/o CTS 230V	02R74-02	CP3480243	N/A

Explanation

Abbott Diagnostics has received the attached letter from Sekisui Medical CO., LTD, the manufacturer of the CP3000 System. Sekisui has identified an issue with the current software V1.11 and below on the CP3000 System that could potentially impact patient results and usability. In addition, the letter from Sekisui includes precautions when using the bottle changeover function with a new lot of reagent if the instructions in the User Manual are not followed.

Patient Impact

Please refer to the attached letter from Sekisui Medical for information regarding potential patient impact.

Necessary Actions

The attached letter from Sekisui Medical provides information on immediate actions to be taken when using Becton Dickinson Vacutainer 1.8mL blood collection tubes.

Additionally, the Sekisui Customer Notification also includes clarification to the instructions in chapter 6.6.2.2 of the CP3000 User Manual (version UME-CP3K-R400) when loading more than one lot number of the same reagent onto the reagent carousel and immediate actions to be taken should the instructions not be followed.

Complete the included Abbott Customer Reply Form.

Please retain this letter for your laboratory records.

Contact Information

We sincerely regret any inconvenience this may have caused your laboratory. If you or any of the health care providers you serve have any questions regarding this information, please contact your local area Customer Service.