Abbott Laboratories
Diagnostics Division
Abbott Park, IL 60064, USA

DIAGNOSTICS

Product Correction

Urgent - Immediate Action Required

Date Issued June 21, 2019

Product

Product Name	Product List Number	Lot or Control Number	UDI
CP3000 w/ CTS 120V	02R73-01	ALL	N/A
CP3000 w/ CTS 230V	02R73-02	ALL	N/A
CP3000 w/o CTS 120V	02R74-01	ALL	N/A
CP3000 w/o CTS 230V	02R74-02	ALL	N/A

Explanation

Abbott Diagnostics has received the attached letter from Sekisui Medical CO., LTD, the manufacturer of the CP3000 System. Sekisui will be releasing Software V1.22 to address the following:

- The CP3000 system may miss required additional rinsing steps between reagent aspirations.
- Reagent carryover when the lid is left on detergent bottle issue on the CP3000 reagent carousel and insufficient deficient plasma that may cause incorrect results as identified in the previous field action FA23MAR2018.
- Cap piercing liquid level detection issues with Becton Dickinson Vacutainer 1.8mL blood collection tubes and bottle change over as identified in the previous field action FA06DEC2018.

Additionally, three new software defects have been identified in Software V1.22, which will be addressed in a future software upgrade.

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 the CP3000 until software upgrade and the associated user manual updates are available.
- An Abbott representative will be contacting you to schedule the software upgrade which includes the associated user manual updates.
- Complete and return the included Abbott Customer Reply Form.

Necessary Actions continued	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. 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.