Abbott Laboratories
Diagnostics Division
Abbott Park, IL 60064, USA

DIAGNOSTICS

Product Correction

Urgent - Immediate Action Required

CC Chairman Medical Board and relevant Head-of-Department

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.

SEKISUI MEDICAL CO., LTD.
1-3, Nihonbashi 2-chome,
Chuo-ku, Tokyo 103-0027 Japan

June 17, 2019

Dear CP3000 Customer

This letter is to inform you that SEKISUI MEDICAL CO., LTD. (SEKISUI) has become aware of an issue with the CP3000 Automated Coagulation System, software version 1.11 that may result in incorrect patient results. Section 1 of this memo, entitled "Additional rinsing operations not performed in specific situations," provides details of the issue, along with the potential impact and instructions for actions that should be taken when using the CP3000 system.

Please note that a new version of the software, software version 1.22, addresses this issue and will be available beginning in July 2019. Software version 1.22 also includes fixes to issues described in previous Customer Notifications as well as several improvements to the CP3000. Details regarding software version 1.22 are provided in Section 2 of this memo, entitled "Release of software version 1.22."

Section 1: Additional rinsing operations not performed in specific situations

Description: The CP3000 system with software version 1.11 may miss required additional rinsing steps between reagent aspirations when there is a failure in the transmission between the System A PC and the Main Analyzer Unit while reagent information is being updated. This failure may occur during the following specific situations:

- Manual registration of reagents (when the Reagent Code Scanning function is disabled).
    - Manual registration is not routinely used as SEKISUI reagents are usually registered by automatic reading of the reagent Datamatrix code.
    - Manual registration may be used when loading reagents without a SEKISUI barcode, or in the event of a barcode reader failure.
- When unmasking a specific reagent position on the reagent carousel that was previously masked manually. Reagents that are automatically masked by the CP3000 and reagents in positions other than the specific masked position are not impacted.

Impact: There is a risk of incorrect patient results if there is reagent carryover due to the additional rinse being missed in the specific conditions described. No error message or flag is generated if this situation occurs, however, QC results may be out of range.

Immediate actions to be taken: Do not use the functions that could result in the issue.

- Do not use manual reagent registration.
- Do not manually mask individual positions on the reagent carousel.
- If these functions are used, then exit and restart the CP3000 PC software each time to prevent any impacted results.

Section 2: Release of software version 1.22

In addition to addressing rinse skip performance, the version 1.22 software update addresses issues described in Customer Notifications dated May 21, 2018 and October 31, 2018. The tables below provide a brief description of each issue. It is no longer necessary to carry out the actions described in these Customer Notifications for the items marked as "resolved" after your CP3000 system has been updated to software version 1.22.

Customer Notification dated May 21, 2018

Item number	Description	Status with software version 1.22 update
6	Reagent carryover when the lid is left on detergent bottle on the CP3000 reagent carousel	Resolved
7	Insufficient deficient plasma may cause incorrect results	Resolved

Customer Notification dated October 31, 2018

Item number	Description	Status with software version 1.22 update
1	Cap piercing liquid level detection issues with Becton Dickinson Vacutainer 1.8mL blood collection tubes	Resolved
2	Precautions when using the bottle changeover function with a new lot of reagent	Resolved

Updating the CP3000 software to version 1.22 does not change the performance characteristics of any SEKISUI assays available on the CP3000. As such, we do not believe additional validation will be required. However, consult your internal quality procedures to ensure compliance with internal procedures.

While software version 1.22 addresses the issues above, we are also informing you of three new behaviors, detailed below, related to this software version. Please note that these

issues have no impact on patient results; however, we would like you to take the following actions when using the CP3000 until the future release of software updates that will resolve these issues.

1 - E-STOP occurs when the start button is pressed two or more times consecutively

Description: E-STOP occurs and error comment "(AU-Main) PC Software Stopped. E-STOP" will be displayed if the start button on the unit or on the touch screen is pressed two or more times consecutively before the status shown on the upper right of the screen is transitioned from "Ready" to "PC: Analyzing; UNIT: Normal operation."

Impact: Delay in starting the CP3000 for testing. This issue has no impact on patient results.

Immediate actions to be taken: Press the start button on either unit or touch screen once and wait for change in activity message. If the error comment "(AU-Main) PC Software Stopped. E-STOP" is displayed due to the start button pressed two or more times consecutively, press the E-STOP button on the unit for reset. Once the reset operation is completed and the status "Ready" is shown on the upper right of the screen, resume analysis.

2 – Incorrect error comment of "The Lot Number of Reagent May Mismatched" is displayed when reagent is insufficient

Description: An error comment alerting the user that the reagent is insufficient will normally be displayed when reagents (including buffer, diluent and deficiency plasma) in use are insufficient and the instrument goes into S-STOP mode. With software version 1.22, an additional error comment, "(PC) The Lot Number of Reagent May Mismatched (No.XX-X*)," will also be displayed under error log. This error comment is incorrect for the action.

Impact: User may be troubleshooting an incorrect error comment. This error has no impact on patient results.

Immediate actions to be taken: Ensure there is sufficient reagent volume, taking dead volume into consideration, before running an analysis. If the volume is insufficient, the analysis will not be completed.

Note: If the single error comment of "(PC) The Lot Number of Reagent May Mismatched (No.XX-X*)" is displayed, please follow 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.

3 – Abnormal profile is shown on the Profile List screen in case of analysis failure

Description: When the error "SampSH" or "R1 SH" is detected and analysis fails, no result is obtained and no profile (reaction monitor) will appear. However, with software version 1.22, the abnormal profile which was generated with data alarm is shown on the Profile List screen.

Impact: No impact to patient results as an error and alarm occurs, and profile data is not transmitted to LIS. Although an abnormal profile is displayed, the analysis does not complete and there is no value provided in the results column.

Immediate actions to be taken: Do not refer to the profile (reaction monitor) of failed analysis. Run the analysis again after addressing the error.

An updated User Manual has also been released to accompany the launch of this software version and an electronic copy will be available on your CP3000 instrument following installation of software version 1.22.

If you have questions about any of the changes included with software version 1.22, please contact your local technical service team.

Yours sincerely,

[redacted]

Hiroshi Ogura
Division Director
Coagulation Division, Diagnostics Business Unit
SEKISUI MEDICAL CO., LTD.