

Field Corrective Action

Jun. 2024

FCA2309/2315

CN-6000/3000 Program Update and Distribution of corrected barcode labels for platelet aggregation reagents

Attention

Operators and Users of Sysmex CN-6000 and CN-3000 analyzers

<Affected products (software)>

Product code and name	Affected product range
CV339763 CN-6000	All instruments with software version 00-25 and less
CL971029 CN-3000	

<Affected products (accessory)>

Supply parts code and name	Affected SN range
BR317748 CN-6000 Supply Parts (EXP)	A3000 and before
CC839163 CN-3000 Supply Parts (EXP)	A1532 and before

Introduction

(1) Vacuum sensor (PCB#30027) malfunction

With software versions below 00-26 it is found out during the measurement that bubbles in the waste chamber are travelled back along the vacuum fluid line and reached to the vacuum sensor equipped in the PCB#30027 and eventually may lead to the PCB breakdown and the system down.

(2) Overflow from sample arm B washing station

The problem is found out at the software version 00-23 to 00-25 that there is a potential risk to have overflow of the wash solution from the sample arm B washing station under a certain condition below. No incorrect result due to carryover nor customer property damage like firing or so, just a small amount wash solution is overflowed without any errors, however, it is very rare to occur under the limited hazardous condition below.

1. The "reagent and/or dilute solution is run out" error is displayed.
2. The new fresh reagent and/or dilute solution is replaced.
3. During the error recovery, the remaining reagent volume measurement is performed.

(3) Failure to read barcode for platelet aggregation reagent with software version 00-26

The problem is found out at the software version 00-26 which adds the function to read the GS1-Datamatrix reagent barcode, that the following 6 types of barcode label attached to the reagent cup holder used for platelet aggregation measurement cannot be read. However, the manual entry for reagent information is to be a workaround.

Item number	Item name	Reagent name
AA381097	Label No. 8465	Base(Reagent stock solution)
AD219819	Label No. 8469	Arachidonic
AE990981	Label No. 8466	Adp
AJ361781	Label No. 8470	Ristocetin
AK234054	Label No. 8468	Epinephrine
BX979799	Label No. 8467	Collagen

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Cause and Sysmex Action

- (1) (2) are all related to instrument sequence program issue, then the program is updated to version 00-26 and after. As for the problem (2), if the liquid in the vacuum fluid line is confirmed near the PCB, the related tubing and PCB would be replaced as necessary.
- (3) The original design of the current reagent barcode was code128, but the GS1 identifier was inadvertently added to the barcode by mistake, therefore, the corrected label kit is distributed and placed in the affected supply parts at the customer visit for the version up activity above.

Action to be taken by the customer

Please distribute this notice to your associates and allow our local Field Service Representative (FSR) visit onsite to take this measure for about 1 hour 30 mins.

We deeply apologize for any inconvenience that this situation has caused and thank you for your patience and continued support.

Sincerely yours

Sysmex Corporation

A handwritten signature in black ink, appearing to read "Y. Ueda".

Yoshiro Ueda

Vice President at Sysmex Corporation
Quality Assurance