Urgent Field Safety Notice

2024-002

18 December 2024

PS-10: False results because of carry-over

Product Name	PS-10
Product Description	Sample Preparation System
Device Identifier	UDI-DI: 04987562501908 REF: BQ716341 Serial numbers affected: 2112005475 2111005547 2202005014 2201005948
Type of Action	IVD modification

Dear valued customer,

This Field Safety Notice (FSN) is intended to provide information about a potential risk of incorrect result measurement that could lead to incorrect treatment decision.

To date, Sysmex has not received any reports of misdiagnosis and mistreatment as a result of the malfunction described below.

Description of the situation:

Sysmex was made aware of a report of false results because of carry-over issue by omission of the probe wash step during antibody pipetting on sample preparation unit PS-10. The lack of probe washing may cause carry-over of small portion of antibody reagent to another reagent, a primary sample or secondary/daughter tubes.

This may cause incorrect sample preparation in the secondary/daughter tubes and incorrect results when the sample is analyzed on a flow cytometer. We would like to emphasize that there is only potential carry-over of antibody reagent and no sample carry-over.

The investigation reproduced the failure and confirmed the lack of necessary washing process during antibody pipetting. This omission of the probe wash step could occur when the number of potential dispenses per antibody in a run exceeds two. This software failure was introduced into PS-10 software Ver 1.5 and affects Ver 1.5 and 1.6 only.

Risk to health:

The PS-10 is an open system where a variety of antibody reagent vials may be used for sample preparation. There are no cleared IVD assays for the PS-10.

Omission of the probe wash step and potential antibody carry-over may lead to possible erroneous representation of antigen markers in a sample and thus generate erroneous results in subsequent flow cytometry analysis.

The risk to health is determined by the user's application in flow cytometry analysis, the intended purpose of the clinical test.

No misdiagnosis and/or incorrect treatment have been reported.

Actions to be taken by the customer:

1. Until a Sysmex representative visits you, please do not use the instrument running PS-10 software Ver 1.5 or 1.6.
2. Review the content of this communication with your facility's physician and/or pathologist and retain this letter for any future reference.
3. Sysmex advises you to consult your facility's physician and/or pathologist to determine any implications (including retrospective review and/or re-testing) specific to your patients.

Actions to be taken by Sysmex:

A Sysmex representative will contact you for the suggested immediate action.

Communication of this Field Safety Notice:

Distribute this FSN to all responsible persons within your organization and return the Acknowledgement of Receipt (AoR) with your signature by the end of January 2025 to your authorized local Sysmex representative.

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

Sincerely yours

Sysmex Corporation

Yoshiro Ueda

Safety Officer and

Vice President of Post-marketing Quality Assurance/ Regulatory Affairs & Quality Assurance