Urgent Field Safety Notice

FCA2528

22 Dec 2025

XN Series BB mode False low Residual WBC count

Product Name	XN series Blood Bank mode
Product Description	Automated Hematology Analyzer
Device Identifier	XN-10 UDI-DI: 04987562424214 REF: AP795756 XN-20 UDI-DI: 04987562424221 REF: AE797961 Serial numbers affected: Blood bank mode activated with XN series software versions 22.15-00 22.16-00 22.17-00 22.18-00 22.19-00 22.22-00
Type of Action	IVD modification

Dear Valued Customer,

This Field Safety Notice (FSN) is intended to inform users about a potential risk of false low residual WBC count on Automated Hematology Analyzer XN series Blood bank mode activated with XN series software versions as above listed.

Description of the situation:

Sysmex has been made aware that in the above-mentioned software versions, when measuring XN CAL in Blood Bank (BB) mode, the WBC value was approximately 15% higher than expected. Furthermore, if calibration was performed using that XN CAL, subsequent measurements of residual leukocytes in actual blood products or samples would be erroneously underestimated by

about 15%. Our internal investigation revealed that an incorrect calculation had been incorporated into these software versions.

The false low result only occurs under specific conditions as below:

- ✓ Software Version: 22.15-00; 22.16-00; 22.17-00; 22.18-00; 22.19-00; 22.22-00
- ✓ BB mode is activated
- ✓ Calibration performed in BB mode with one of the affected aforementioned SW versions, i.e. if calibration of BB mode has been performed with any other software version, this issue does not affect your device.

Risk to health:

With respect to the potential health impact, depending on the clinical condition of the patient receiving the blood product, a risk of severe adverse consequences. exists.

Actions to be taken by the customer:

Please check the version of the BB mode currently in use. If it is version 22.20-00 or version 22.21-00, you may continue using it without any issues. If you are using an affected version, please contact your Sysmex representative.

Please confirm with your Sysmex representative whether calibration of the device has been performed in BB mode using one of the affected aforementioned software versions. If calibration was performed in BB mode, please either refrain from reporting WBC count from BB mode until the Sysmex representative completes the corrective action or continue while taking into account that the true residual white blood cell count may be approximately 15% higher than the reported value.

Sysmex advises you to consult your facility's physician and/or pathologist to determine any clinical implications (including retrospective review and/or re-testing).

Please ensure this notice is communicated to all relevant personnel and retained in a visible location until the software update is completed.

Actions to be taken by Sysmex:

The Sysmex representative will visit your site to perform immediate action, either by adjusting the relevant calibration factor to 15% higher or by changing the version to 22.20-00 or 22.21-00.

Sysmex will develop and will provide you the permanent corrective action as soon as possible.

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 to your authorized local Sysmex representative.

Manufacturer

Name: SYSMEX CORPORATION

Single Registration Number: JP-MF-000014037

Address: 4-4-4 Takatsukadai, Nishi-ku, Kobe 651-2271, Japan

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 Quality Assurance/ Regulatory Affairs & Quality Assurance