

**Customer Notification
(Urgent Field Corrective Action Notice)**

CN-2017-11
16-AUG-2017

Important Information on Lysercell WDF

Dear Customers, Healthcare Professional;

Cc : Chairman Medical Board and relevant Head of Department

This letter is to inform you concerning Sysmex Hematology reagent Lysercell WDF.

It has been noticed that there is an increased frequency of false positive flags in the WDF channel.

Upon investigation, Sysmex notice there is a possibility that XN series generates the abovementioned problem due to certain lots of Lysercell WDF.

With that, the affected lots are listed as follows:-

Product Code	Product name	Affected lot
AW993605	Lysercell WDF 4Lx2 (WDF-200A)	A6027, A6028, A6029, A6030, A6031, A6032, A6033, A6034, A6035. A6037, A6039, A7001, A7002, A7004

Immediate Action

- a. Discards any of the Lysercell WDF lots mentioned in the above table which you might have on your stock.
- b. Perform reagent replenishment for Lysercell WDF (Maintenance Menu) to ensure that reagent is completely replenished.
- c. Insert new lot of Lysercell WDF if available
- d. Destroy the remaining affected lot of Lysercell WDF in your inventory and fill in the detail and quantity in the "Replacement of Lysercell WDF" form.
- e. Kindly send the form for back to us for the necessary replacement.

Root Cause

Currently, the investigation is still in progress.

The possible cause of this issue is likely related to one of the material used for Lysercell WDF.

We will update you the status once the detailed investigation is completed.



Contact Reference

If you have question concerning this information, please contact Sysmex Asia Pacific Customer Care team via AP GCD system or your local Sysmex Representative. We would be glad to assist you further.

We deeply apologize for any inconvenience caused, and we thank you for your kind patience and continued support.

Yours sincerely,



Shingo Maeda
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