

Field Safety Notice

15-Jun-2016

Dear Sysmex **XN-Series** customers,

It has come to our attention that Sysmex hematology reagent

FLUOROCCELL PLT LOT A5053, 5054

revealed incorrect results of diagnostic parameter PLT-F. There is a high discrepancy between the correct PLT-I value and a false low PLT-F value. For most of the measurements PLT-F values were associated with the flag "PLT Abn Scattergram". This "PLT Abn Scattergram" was flagged in every circumstances when there is wrong value. However, there is one feedback from customer in Europe on the flag was not activated.

With that, evaluation was done on the sample of the affected lot. The result showed that the flag was activated for all cases where there is a wrong value. And there is no single case which the flag was not activated. As such, it was suspected that the case which customer's feedback about no flagging is most likely related to calibration issue of the equipment.

Based on the abovementioned evaluation and result, it was concluded the risk associated to this failure is relatively low.

Immediate Correction (FSN):

- 1) Discard any cartridges of Fluorocell PLT- **Lot A5053, 5054** you might have on stock.
- 2) Insert cartridges of another lot of Fluorocell PLT, if available.
- 3) Please make sure that you perform reagent replenishment for Fluorocell PLT (Maintenance Menu) to ensure that reagent was completely replenished.
- 4) If no other lot of Fluorocell PLT is available, please check PLT-F results for plausibility. In case of implausible results, please refer to the PLT-I results from the impedance channel.
- 5) Please follow your internal SOPs regarding retrospective judgement of affected samples.

Permanent Field Safety Corrective Action (FSCA):

Currently the root cause is under investigation, therefore, we exchange the lot A5053, 5054 with a new lot of Fluorocell PLT as a first step. After final root cause is known, we might implement additional measures.

We very much apologize for any inconvenience this may cause on your side and thank you for your kind understanding and continued support of Sysmex and our products.

Yours sincerely,



Shingo Maeda
Safety Officer
Sysmex Asia Pacific Pte Ltd.

Customer's
Acknowledgment of Receipt (AoR)

We hereby confirm the receipt of Field Safety Notice (FSN) issued 13th June 2016 concerning the corrective action on the IVD-Medical Device

Sysmex reagent FLUOROCCELL PLT
- Lot A 5053, 5054

with regards to a **false low measurement result of PLT-F# or false high measurement of IPF%.**

We hereby also confirm, that all affected cartridges of Fluorocell PLT Lot A5053, 5054 have been discarded by us.

Place

Date

Responsible & authorized Person

Position

Signature