



Sysmex Europe GmbH
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Norderstedt, 27.05.2016/TKR

FIELD SAFETY NOTICE (FSN)

Dear Sysmex **XN-Series** customers,

It has come to our attention that Sysmex hematology reagent

FLUOROCELL PLT LOT A5053

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". However, in rare cases no flag was set.

IPF% is also affected by this phenomenon.

This may lead to wrong diagnostics decisions and serious outcome for patients.

Immediate Correction (FSN):

- 1) Distribute this FSN to the appropriate persons in your organisation
- 2) Discard any cartridges of Fluorocell PLT- **Lot A5053** you might have on stock.
- 3) Insert cartridges of another lot of Fluorocell PLT, if available.
- 4) Please make sure that you perform reagent replenishment for Fluorocell PLT (Maintenance Menu) to ensure that reagent was completely replenished.
- 5) 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.
- 6) 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 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,

Sysmex Europe GmbH

Thomas Kröger

Safety Officer



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Customer's Acknowledgment of Receipt (AoR)

We hereby confirm the receipt of Field Safety Notice (FSN) issued 27th May, 2016 concerning the corrective action on the IVD-Medical Device

**Sysmex reagent FLUROCELL PLT
- Lot A 5053**

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 have been discarded by us.

Place.....

Date.....

Responsible & authorized Person.....

Position.....

Signature.....