Sysmex Europe GmbH
Bornbarch 1,
D-22848 Norderstedt, Germany
Email: vigilance@sysmex-europe.com

Norderstedt, 31.01.2022

FSN 524700045

FIELD SAFETY NOTICE (FSN)

Dear Sysmex customer,

Unfortunately it has come to our attention that Sysmex haematology IVD reagent

Fluorocell PLT

might show a decrease of the side fluorescence (SFL) intensity that could potentially lead to false low measurement results in the PLT-F channel. This may lead to wrong diagnostic and patient treatment decisions.

All customers not using this reagent are not affected.

Herewith we request you:

1) Distribute this FSN to the responsible device operators in your organisation
2) Make sure that below described Immediate Action will be applied immediately
3) Please follow your internal SOPs regarding retrospective judgement of affected samples upon consideration of chapter 2.2
4) Confirming back to us that you have received this FSN by the Acknowledgement of Receipt (AoR) form attached hereby.

1. Detailed description of the problem

The observations described below are related to randomly affected cartridges of the following lots of Fluorocell PLT (displayed as REF: CD-994-563 on the reagent box), used with XN-Series haematology analysers:

Fluorocell PLT lot	Expiry date
A1003	2022-02-14
A1004	2022-02-16
A1006	2022-02-16

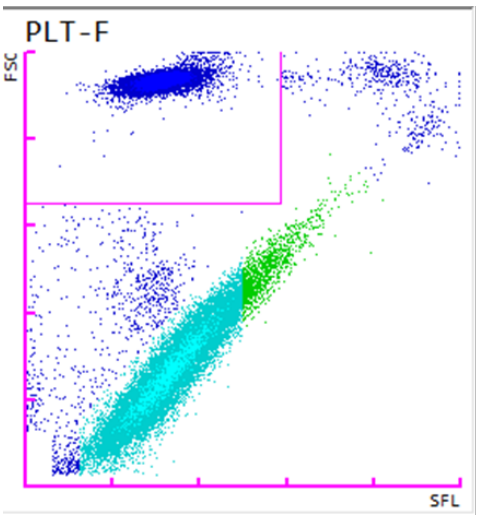
Due to decrease of the side fluorescence intensity caused by randomly affected cartridges per indicated lot listed above, Sysmex Europe GmbH has decided to recall the reagents as a measure to avoid reporting of false measurement results.

Isolated cartridges of the above mentioned lots show a decrease of fluorescence intensity in the sensitivity parameters PLTF-X and PLT-F-RBC-X.
In some cases, the observed decrease was associated with an underestimation of PLT-F and IPF. The false low PLT-F value was caused by a false classification of the PLT population in the PLT-F scattergram. In the majority of these underestimated samples the flag 'PLT Abn Scattergram' was triggered.

Measurements with fresh human blood samples showed a decrease of side fluorescence for samples measured in PLT-F channel when the affected lots of Fluorocell PLT were used.

In some cases the PLT-F population was classified as debris and thus the PLT-F results have been underestimated. This is recognisable by a dark blue coloured portion of the PLT population (please see Fig. 2). In addition, the diagnostic parameters IPF (IPF %) and IPF# (IPF count) were potentially affected as well.

Examples of human blood measurement:

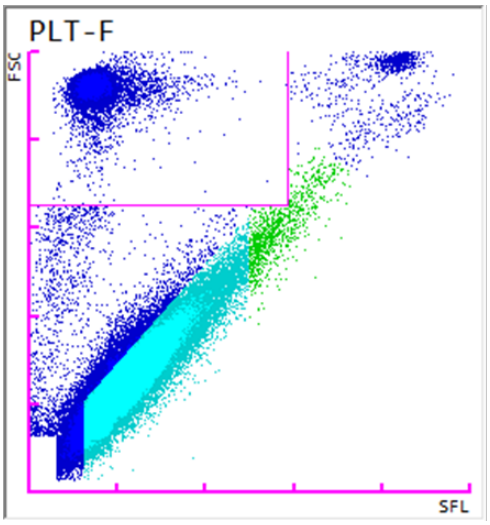


Item	Data	Unit
PLT-I	244	10^3/uL
PLT-F	244	10^3/uL
IPF	6.0	%
IPF#	14.6	10^3/uL

PLT-F-RBC-X	81.2	ch
PLT-F-X	85.2	ch

PLT Flag(s)

Fig. 1: Sample with a correct PLT-F classification and normal fluorescence intensity



Item	Data	Unit
PLT-I	1132 *	10^3/uL
PLT-F	1027 *	10^3/uL
IPF	1.2 *	%
IPF#	12.3 *	10^3/uL

PLT-F-RBC-X	38.2	ch
PLT-F-X	51.0	ch

PLT Flag(s)
Thrombocytosis
PLT Abn Scattergram

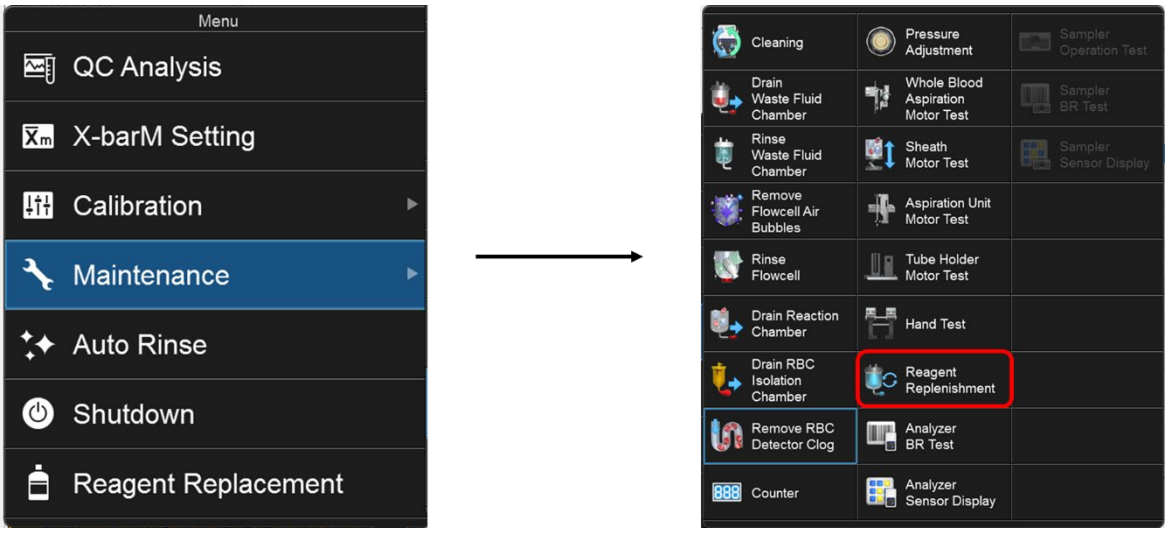
Fig. 2: Sample with a PLT-F misclassification and decreased fluorescence intensity

2. Immediate Action to avoid the risk of false measurement results

All Fluorocell PLT lots not listed in the table of chapter 1 can be used as a replacement of the 'affected' lots. They are named 'replacement lots' in this document.

2.1 If a replacement lot of Fluorocell PLT is available

- Kindly discard the Fluorocell PLT of the affected lots that you might have on stock as per your local guidelines.
- Stop using the affected lots of Fluorocell PLT that you might currently have connected to your XN-Series analyser.
- Upon receipt of replacement lots, **please ensure that the reagent replenishment for Fluorocell PLT is performed twice after executing reagent replacement**. This is to ensure that the reagent in the analysers' tubing and chambers is completely exchanged by the new reagent lot. The 'Reagent Replenishment' option can be found in the analyser maintenance submenu (see image below).



- After reagent replenishment, analyse at least five human blood samples and verify the PLT-F scattergram for abnormalities (review above Fig. 1 and Fig. 2) to ensure the reagent is correctly replenished.

2.2 If a replacement lot of Fluorocell PLT is NOT available

As the analyser cannot operate without a cartridge installed (if a PLT-F license is installed), some customers may have to continue using the affected lots of Fluorocell PLT until a replacement is available.

In such a case, it is **mandatory** to perform the following **'plausibility check' for every** PLT-F result:

1. Check whether the PLT-F value is below the clinical threshold applied in the respective lab, or whether the sample is flagged with 'PLT Abn Scattergram'.

   Samples can be easily filtered in the sample explorer to focus on measurements with PLT-F, and samples with 'affected reagent lots' can be identified by using the 'Reagent' tab (see Fig. 3).

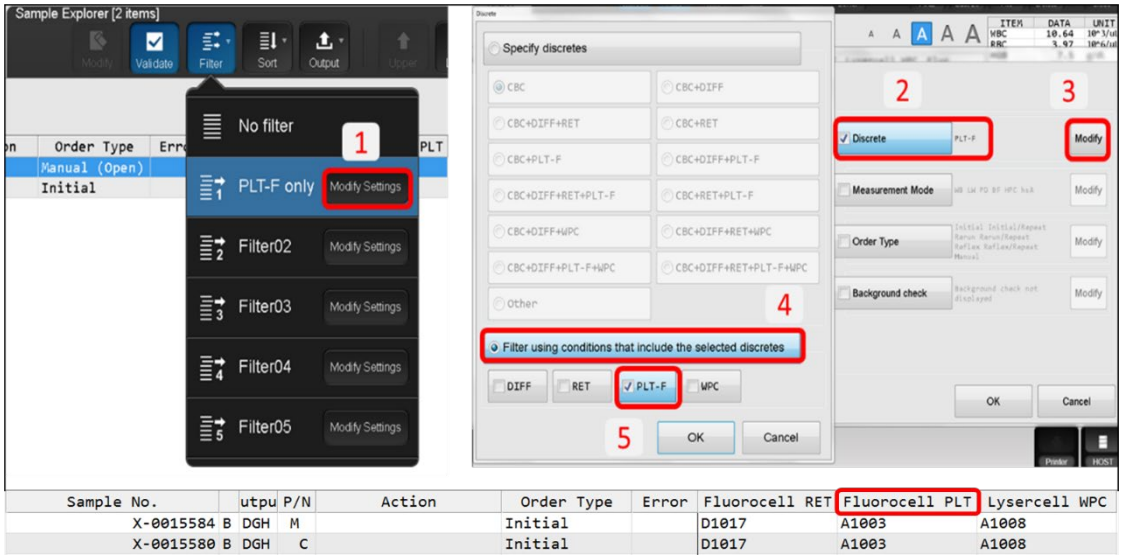


Fig. 3: Filtering of samples with PLT-F measurements. The Fluorocell PLT lot can be seen in the 'Reagent' tab for each measurement

Analyse the PLT-F scattergram for abnormalities in the classification of the PLT population, as illustrated in the example above (Fig. 2).

2. Check whether the PLT-F value is significantly lower than the PLT-I value, thereby potentially affecting clinical decisions.

3. If such a significant difference is observed causing a clinical impact, please consider whether the PLT-I value can be used, after verifying the PLT-I histogram. Alternatively, if PLT-O is calibrated, the PLT-O value can be used after verifying PLT-O scattergram (please verify with your local Sysmex representative if PLT-O has been calibrated on your analyser).

4. If during the plausibility check PLT-I, PLT-O and PLT-F values are questionable, perform a smear or measure PLT with the backup system available in your laboratory. For example if PLT-I and/or PLT-F are marked unreliable (*), and the PLT-I histogram and PLT-F scattergram are both abnormal, please verify results with the backup method defined in the laboratory's SOP.

For retrospective analysis, the same 'plausibility check' can be applied to samples that give justified reasons to believe they are affected.

3. Permanent Field Safety Corrective Action (FSCA)

Currently the root cause investigation is ongoing. After the final countermeasure for the product is known, we will inform you about the permanent corrective action.

We very much apologise 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