

10 August 2016
CN-2016-023

Dear Valued Sysmex Customers,

CUSTOMER LETTER FOR FLUOROCCELL PLT

This letter is to inform you about false-low PLT-F value which has occurred recently concerning our products Sysmex hematology reagent FLUOROCCELL PLT LOT A5041, A5042, A5044, A5045, A5046, A5047, A5048, A5049, A5050 and A5055.

It was reported that FLUOROCCELL PLT reagent 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. As a result of our investigation the flag "PLT Abn Scattergram" was flagged in every circumstance when there is wrong value.

The evaluation was done on each of the affected lots. The result showed that the flag was activated for all cases where there was a wrong value and there was no single case in which the flag was not activated. A single case of no flagging was reported in Europe, but it is suspected that this case is most likely related to calibration issue of the equipment.

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

1. Affected Product

FLUOROCCELL PLT LOT A5041, A5042, A5044, A5045, A5046, A5047, A5048, A5049, A5050 and A5055.

2. Immediate Correction

- a. Distribute this Customer letter to the appropriate persons in your organization
- b. Discard any cartridges of Fluorocell PLT you might have in stock.
- c. Insert cartridges of another lot of Fluorocell PLT, if available.
- d. Please make sure that you perform reagent replenishment for Fluorocell PLT (Maintenance Menu) to ensure that reagent was completely replenished.
- e. 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.
- f. Please follow your internal SOPs regarding retrospective judgment of affected samples.

3. Action Taken

- a. Accelerated testing was performed on the sample for lot A5056 to A6028 and confirmed the reagent's performance was not degraded.
- b. From production lot A6029, accelerated testing is being performed to confirm the reagent's performance before shipment.

We deeply apologize for any inconvenience that this situation has caused and thank you for your patience and continued support.

Sincerely yours

Sysmex Asia Pacific Pte Ltd



Shingo Maeda
Safety Officer