

## Customer Notification

CN-2017-13  
08-Sep-2017

### Notification on Fluorocell PLT

Dear Customers, Healthcare Professional;

Cc : Chairman Medical Board and relevant Head of Department

This letter is to inform you concerning issue found on Fluorocell PLT on the below-mentioned lots. All products are not affected, however a part of products affected lots are susceptible to external environmental factors and tend to decrease their dye concentration over time.

It was reported that FLUOROCCELL PLT reagent revealed in-correct results of diagnostic parameter PLT-F. There is a high discrepancy between the correct PLT-I value and a false low PLT-F value.

Detailed investigation was conducted by S-Corp, it was confirmed that most of the measurements PLT-F values for degranulated specimen were associated with the flag "PLT Abn Scattergram". 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.

The affected lots are listed as follows:-

| Product Code | Product Name               | Lot No.        |
|--------------|----------------------------|----------------|
| CD994563     | FLUOROCCELL PLT (PLT-800A) | A6051 to A6090 |

#### Possible Cause

Tendency of reagent to deteriorate by external environmental factors such as oxidation by air, storage temperature of product.

#### Immediate Action

1. Discard any cartridges of Fluorocell PLT 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 judgment of affected samples.
6. Destroy or dispose the remaining affected lot of Fluorocell PLT which you have and fill in the detail and quantity in the attached "Replacement of Fluorocell PLT" Form
7. Kindly send the form for back to us for the necessary replacement.

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,



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