

Field Corrective Action

July-2024

FCA2201-2: XN-31- Change to titanium alloy nozzle Preventive action to decrease in fluorescence intensity of Fluorocell M stain solution

Dear Valued Customer

Introduction:

Systemex has aware of the risk of decrease in fluorescence intensity of Fluorocell M stain solution which is used on XN-31 Automated Hematology Analyzer, and the expiration date after opening of Fluorocell M solution had to be change from 90 days to 45 days.

Affected Products

Product Code	Name of Product
AX137775	Fluorocell M
BU351757	XN-31

Problem Description:

In past problem, the stability after opening was evaluated by the newly requested CLSI#EP25-A compliant test, and the specifications of the expiration date after opening of the following products had to be change from 90 days to 45 days.

In this new change, nozzle of XN-31 is changed to titanium alloy nozzle in order to make the reagent more stable after opening.

Actions to be taken:

1. Systemex released Engineering change record ECR323D025 including the change for this issue. Please change current nozzle with titanium alloy nozzle in accordance with the ECR323D025.
2. Please distribute this FCA notification to all applicable person in your organization.

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

Sincerely yours
Systemex Corporation



Yoshiro Ueda
Vice President at Systemex Corporation
Post-marketing Quality Assurance