Product Notification

Aug-2025

PLT-I value, low recovery and high variability

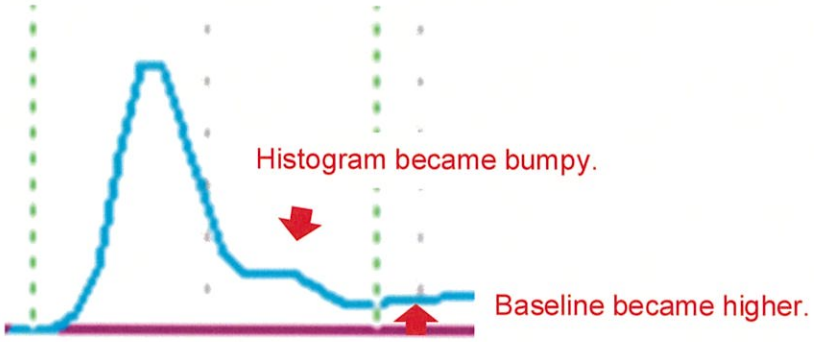
Dear Valued Customer

Introduction

Sysmex has identified low recovery and high variability in PLT-I values in XN Check, XN-L Check, XN Cal, Eightcheck-3WP and SCS-1000 with XN Check L1 being the most affected product. It was confirmed that the PLT-I values recovered low and became variable due to aggregation of platelet components, especially when not mixed sufficiently.
This phenomenon has been observed across all levels, with Level 1 being particularly affected. However, it does not impact specimen measurements.

Problem Description

Investigations confirmed that aggregation of platelet components may occur, leading to decreased PLT-I values in some runs. In such cases, the PLT-I histogram appears bumpy, and the baseline is not flat.
At the same time P-LCR, MPV and PDW recovered higher than expected. This issue has been observed in XN Check, XN-L Check, XN Cal, Eightcheck-3WP and SCS-1000 with XN Check L1 being the most affected product. Low cell counts amplify the effects of imprecision, resulting in run-to-run variability in quality control results and increased coefficients of variation (CV%) for PLT-I. This phenomenon is seen across all levels, but is most prominent in Level 1 of XN Check. Patient results remain unaffected.



Root Cause

It has been confirmed that the platelet components in the materials tend to aggregate. Histograms showing aggregation may result in low PLT-I counts.
The issue is currently under investigation at the manufacturing site. So far, no clear change points have been identified, and the issue was not observed at the time of release from the manufacturing site.
Storage conditions, transportation, sufficient time for temperature equilibration, and mixing procedures may influence the aggregation of platelet components.

Product Notification

Aug-2025

Action

1. Please mix the material thoroughly in accordance with the procedure described in Appendix 1 to help loosen the aggregated platelet components.
2. Especially for the first measurement after opening a new vial, please ensure that bubbles remain in the vial after mixing. Sysmex has confirmed that bubbles do not affect measurement results. Once the platelet components are loosened in a specific vial, they tend to loosen more easily on subsequent usage. Intense mixing does not harm stabilized cells.
3. If PLT-I recovers low and P-LCR, MPV and PDW recover higher than expected please repeat the mixing procedure.
4. If QC data is affected and your laboratory policy allows reporting patient results with two levels of control passing, you may conserve QC material by running Level 2 and Level 3 first, and evaluating the data for acceptability before deciding whether to run Level 1.
5. Replacement of the material is not recommended at this time.
6. Please distribute this Product Notification appropriately to your laboratory staff.
7. File this Product Notification as part of your laboratory's Quality System, as required.

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

Sincerely yours
Sysmex Corporation

Y. Ueda

Yoshiro Ueda
Vice President at Sysmex Corporation
Quality Assurance

Product Notification

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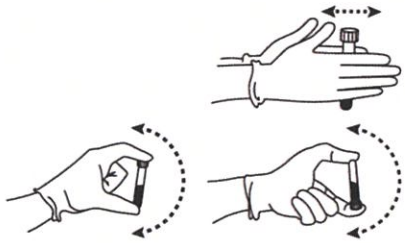
Appendix 1.

Mixing procedure



1. Remove the vial from the refrigerator and equilibrate to room temperature (15-30°C) for 15 minutes before use.
2. Roll each vial between the palms of your hands for 15 seconds.
3. Holding the vial by the ends between the thumb and finger, invert the vial 20 times end-to-end using a very quick motion of your wrist during mixing.
4. Analyze the QC reagent in the instrument according to the Instructions for Use. The pierceable septum in the vial cap allows sampler analysis.
5. Subsequent analyses during this test period may be performed by inverting the vial 5 times prior to instrument analysis.
6. Return to refrigerator (2-8°C) storage.

Steps 1-6 must be repeated upon removing the sample from the refrigerator for the entire open-vial time period regardless of the method of analysis (open tube, cap piercing, auto sample or manual sample).

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