

Product Notification

Platelet (PLT) Recovery and Imprecision on Sysmex® Quality Control and Calibrator Products Field Correction

Attention

Hematology Lab Manager

Issue

Sysmex has become aware of some instances where platelet related parameter results have recovered outside expected ranges on calibrator and quality control (QC) products, resulting in imprecision.

The imprecision may be related to inadequate mixing of the calibrator or QC material prior to analysis. This issue may impact any of the products and lot numbers beginning with the lot numbers listed below.

Quality Control Products	Beginning Lot Number
<i>e</i> -CHECK™	7305
<i>e</i> -CHECK™ (XS)	7269
<i>e</i> -CHECK™ (XE)	7277
XN-L CHECK™	7300
XN CHECK™	7261
EIGHTCHECK™- 3WP X-TRA	7255

Calibrator Products	Beginning Lot Number
X-CAL™	7283
SCS-1000™	7283
XN CAL™	7282
XN CAL™ PF	7282

When performing QC analysis, platelet (PLT) and platelet related parameter results (mean platelet volume [MPV], immature platelet fraction [IPF]) recovering outside expected ranges may indicate inadequate mixing of the material. An increase in the coefficient of variation (CV%) of these parameters may also be an indicator of inadequate mixing.

Inadequate mixing of calibrator product during analyzer calibration may result in PLT calibration failures or post-calibration bias in QC data for PLT and platelet related parameters. Other parameters on the assay sheet are not affected.

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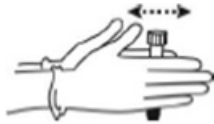
NOTE: Patient results are unaffected if QC results are within expected ranges for PLT and platelet related parameters.

Action

1. Until further notice, the instructions in this Product Notification supersede all other instructions for mixing of QC and calibrator material. All package inserts for QC and calibrator material are being revised to include the instructions below.
2. Ensure that the product has equilibrated to room temperature prior to mixing.
3. Mix the Sysmex control and calibrator products as described below:

NOTE: Do NOT mix mechanically or vortex

- a. Hold the vial vertically and roll each vial between the palms of the hands for 15-20 seconds.



- b. Continue to mix by holding the vial by the ends between the thumb and finger, rapidly inverting the vial 20 times end-over-end using a very quick turning motion of the wrist.



- c. Analyze immediately after mixing. Subsequent analyses during this test period may be performed by inverting the vial 5 times prior to instrument analysis.
- d. Steps a-c 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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4. After analysis, confirm PLT and platelet related parameters are within expected ranges.
 - a. If in range, accumulate sufficient data points to determine if updating target(s) is necessary. Ensure new targets are within the expected ranges on the published assay sheet.
5. If PLT and platelet related parameter results are recovering out of range, repeat the mixing procedure outlined above and repeat the QC analysis or calibration process.
6. **If results remain out of range**, contact the Technical Assistance Center at 1-888-879-7639 in the U.S., or at 1-888-679-7639 in Canada.
7. Please distribute this Product Notification as appropriate to your laboratory staff.
8. File this Product Notification as required by your laboratory's policy and procedures.

Questions

This Product Notification is posted on the Sysmex Customer Resource Center (CRC). If you have any questions concerning this information, please email the Sysmex Technical Assistance Center (TAC). Simply click on the email TAC button on the home page of the CRC, complete the form that appears and then click submit to send your question to TAC. Sending an email to TAC is recommended for non-urgent requests. For Canadian customers, please note emails to TAC are currently only processed in English.

For urgent requests, we recommend that you call the Technical Assistance Center at 1-888-879-7639 in the U.S., or at 1-888-679-7639 in Canada.

This notification applies to the instruments listed in the table below.

KX-21 & KX-21N	XN-330	XN-2000RL App	XN-9100RL App
pocH-100i	XN-350	XN-2000V	XS-1000i
XP-300	XN-430	XN-3000	XS-1000i RL App
XE-2100	XN-450	XN-3000 RL App	XS-1000i-AL
XE-2100C	XN-550	XN-3100	XS-1000i -AL RL App
XE-2100D	XN-1000 & XN-1000R	XN-3100RL App	XT-1800i
XE-2100DC	XN-1000RL App	XN-9000	XT-2000iV
XE-2100L	XN-1000V	XN-9000RL App	XT-2000i
XE-5000	XN-2000	XN-9100	XT-4000i