



March 10, 2021

To: Whom It May Concern

ARKRAY Factory, Inc

Urgent Field Safety Notice **SPOTCHEM CALIBRATOR KIT FSCA**

We thank you for your patronage of our products.

It was found that there is an error in the concentration value of CPK for SPOTCHEM CALIBRATOR KIT of the specific lot out of the concentration values of each analyte listed in the calibration card (magnetic card).

When calibration by calibrator is performed on SPOTCHEM EZ SP-4430 using the subject product, an inaccurate CPK result may be given. Accordingly, we have decided to notify to the regulatory authorities and conduct FSCA (voluntary correction).

We are very sorry for the inconvenience caused by this issue. We appreciate for your understanding and cooperation on the recall operations.

1. Subject Product and Subject Lot

Distribution Name: SPOTCHEM CALIBRATOR KIT (Code 77041I)

Lot: 06421

2. Detail of Defect

It was found that there is an error in the concentration value of CPK for SPOTCHEM CALIBRATOR KIT of the specific lot out of the concentration values of each analyte listed in the calibration card (magnetic card).

Therefore, when calibration by calibrator is performed on SPOTCHEM EZ SP-4430 using the subject product, an inaccurate CPK result may be given. An example of specific effect degree is shown below.

Measurement results using SPOTCHEM II CPK Lot: FF1B20 Unit :IU/L

Correct CPK result	50	150	250	300
CPK result when calibrating with the CALIBRATOR KIT of the subject lot	48	130	213	253
Divergence rate	-4%	-13%	-15%	-16%

3. Possible impacts

We can't deny the possibility that an abnormal CPK value may be overlooked in a screening test for CPK although it's limited to the case where the patient CPK value exceeds the upper limit of the normal range (cutoff value). However, a diagnosis is comprehensively judged including clinical conditions and other examination results, therefore, no critical health hazard is considered to occur. Also, there have been no reporting of health hazards.

4. Cause

Concentration value for CPK is determined per bulk lot of this product (master lot of each product lot). In the process of setting the concentration value for CPK, a correction is performed by referencing the concentration value of the previous bulk lot (one lot before). However, the correction was performed by referencing the concentration value of the further previous lot (lot some before) instead of the previous bulk lot (one lot before) this time.

5. Countermeasures

The system will be changed so that the concentration value of the previous bulk lot (one lot before) can be automatically read for correction in the spreadsheet which is used in the process of setting the concentration value to prevent a recurrence when newly setting the concentration value of the bulk lot.

6. Request

- Please don't use the subject lot you have. We will replace with a replacement product.
Your understanding and cooperation on the recall are appreciated.
 - Please be sure to perform calibration by calibrator using the replacement product again.
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