December 8 2017

To: Whom It May Concern

ARKRAY Factory, Inc.

Recall for SPOTCHEM II Glucose, SPOTCHEM II PANEL-1, SPOTCHEM II PANEL-V and SPOTCHEM II PANEL-V2 (Field Safety Notice)

We thank you for choosing the SPOTCHEM series.

It was found that a lower reading may be given with SPOTCHEM II Glucose, SPOTCHEM II PANEL-1, SPOTCHEM II PANEL-V and SPOTCHEM II PANEL-V2.

Therefore, we have decided to notify the regulatory authorities and initiate voluntary recall.

We are very sorry for any inconvenience this issue may cause. We appreciate your understanding and cooperation with the recall.

1. Products and Lots Subject to Recall

SPOTCHEMII Glucose (MEN) (Code 33905)
Lot : EA7C14,EA7D15,EA7E16,EA7F17,EA7J21

SPOTCHEM II PANEL-1 (MEN) (Code 33927)
Lot : QC7B70,QC7C71,QC7D72,QC7G76

SPOTCHEM II PANEL-V (MEN) (Code 32138)
Lot : PL7B27,PL7C29,PL7D31,PL7E32,PL7G36,PL7H37

SPOTCHEM II PANEL-V2 (MEN) (Code 48492)
Lot : QR7B13,QR7C14

2. Details of Defect

It was found that a lower reading may be given for the glucose item when the blood glucose concentration of a sample exceeds approximately 300mg/dL. More specifically, when the blood glucose concentration exceeds the upper limit of the measurement range (450mg/dL), the message "OVER", indicating that the reading is outside the measurement range, was not displayed and readings of approximately 300~400mg/dL may be given.

In addition, when within the measurement range, for high glucose concentrations (approximately 350~450mg/dL), there is a possibility that the reading may be around -20~ -30% of the known concentration.

3. Estimated Impact

It cannot be denied that there is a possibility that the onset of diabetes may be overlooked when the diagnosis criteria is high glucose concentration exceeding 300mg/dL. Up until now there have been no reports of damage to health.

4. Cause

The main causes of the lowered reactivity in the high glucose concentration are estimated that in-process products (a roll of material with reagent applied to the pet film, which is ultimately cut and used for the reagent pad for GLU item) meeting the following two conditions have been used for finished products, resulting in relatively lowered amount of enzyme and the enzyme was further deactivated due to the change with time after shipment, affecting the reactivity in the high glucose concentration.

<Condition1>

In-process products with the thickness of liquid film adjusted to be thinner than the center value when applying the reagent solution including enzyme during manufacturing of in-process products

<Condition2>

In process products which were stored at room temperature for a long time before they were used for finished products

In addition to the above-mentioned causes, a deficiency of the spreadsheet used for a determination of shipping inspection for SPOTCHEM II PANEL-1 (IVD) was found in the process of cause investigation. However, it has been confirmed that the affected three lots (Lot: QC7E73, QC7F74, and QC7G75) are all included in the lots affected by the main causes and the affected range is limited.

5. Action

Only in-process products satisfying the stricter conditions (storage conditions, etc) are currently being used for manufacturing and the spreadsheet with the deficiency has been corrected and used for shipment approvals.

6. Requests

Please don't use any relevant lots in your possession, which will be replaced. We sincerely appreciate your understanding and cooperation.

Ryuichi Sasaki

Ryuichi Sasaki
Manager, Quality Assurance Team,
Quality Division