



January 21, 2021

To: Whom It May Concern

ARKRAY Factory, Inc

Urgent Field Safety Notice for
SPOTCHEM D-Concept Operation Unit D-00 SD-9810/
D-00 QR SD-9811 FSCA

We thank you for your patronage of our products.

When selecting/measuring urine in sample type setting to measure a urine sample of approximately zero electrolyte concentration using SPOTCHEM D Concept Operation Unit D-00 or D-00 QR and Measurement Unit D-02 and electrolyte plate which is a dedicated reagent, "UNDER", which means less than the lower limit, should be displayed, however, it was found that a measurement result may be given instead of displaying "UNDER". 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 correction.

1. Subject Products

Distribution Name: SPOTCHEM D-00 SD-9810 (INT-IVD) (Code 17402)
SPOTCHEM D-00QR SD-9811 (INT-IVD) (Code 104933)

2. Detail of Defect

When selecting/measuring urine in sample type setting (hereinafter referred to as Urine Mode measurement) to measure a urine sample of approximately zero electrolyte concentration using SPOTCHEM D Concept Measurement Unit SPOTCHEM D-02 SD-4810 (Code 17603) and electrolyte plate SPOTCHEM D Electrolyte (Code 77963) which is a dedicated reagent, "UNDER", which means less than the lower limit, should be displayed for K and Cl, however, it was found that a measurement result may be given instead of displaying "UNDER". Specifically, "UNDER" is displayed when K is $<1.0\text{mmol/L}$ and Cl is $<3.0\text{mmol/L}$, however, when measuring water as a sample of approximately zero electrolyte concentration, measurement results of approximately 3mmol/L for K and 30mmol/L for Cl may be given if they're largely impacted. Also, there is no problem when measuring blood (whole blood, plasma, and serum) as a sample.

3. Possible impacts

For K, specific health hazard is unlikely to occur due to the above positive errors. On the other hand, for Cl, we can't deny the possibility that metabolic alkalosis is incorrectly distinguished due to the above positive error and an improvement of alkalosis symptoms may be delayed due to a delay of saline administration. However, diagnosis is comprehensively judged by a doctor 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

The correction factor which is stored in SPOTCHEM D Concept Operation Unit (SPOTCHEM D-00 or D-00 QR) used for the basic calibration curb on the Urine Mode measurement was not adequate.



5. Countermeasures

Since the correction factor used for the basic calibration curb on the Urine Mode measurement is stored in the Operation Unit (SPOTCHEM D-00 or D-00 QR), this correction factor will be corrected.

6. Points to note up to completion of countermeasure

Please restrain from measuring on the Urine Mode.

END

A handwritten signature in blue ink that reads "Ryuichi Sasaki".

Ryuichi Sasaki
Manager, Quality Assurance Team,
Quality Division