May 10, 2023

Assure Prism Control Solution:
Labeling Notification

Dear Customer:

The purpose of this letter is to advise you that ARKRAY has become aware of a labeling issue with a very limited number (<100 bottles) of Assure Prism Control Solution sets, PN 530006, lot CSUB04AN/CSUB04AM.

Description of the Issue:

Fewer than 100 bottles for this lot may have an error in the label attached to the bottles.

Each Control Set should contain:

- One vial of Level 1 control solution with a blue cap, labeled “Level 1”, with printed lot (CSUB04AN)
- One vial of Level 2 control solution with a green cap, labeled “Level 2”, with printed lot (CSUB04AM)

A very limited number of Control Solution bottles within this specific lot (CSUB04AN/CSUB04AM) may include an incorrect Level number, as shown in the example below. **Note, however, that both the cap color and printed lot number are accurate and correctly identify the vial contents.**

Example:
**Impact of the Issue:**

- There is no health risk, as any mislabeled vial would result in a failed control solution test, which would require additional testing with a different bottle of controls or prompt a call to customer service. The issue has no impact on blood glucose measurement values.
- The vial contents can be correctly identified by the color of the bottle caps and the printed lot number.

**Actions to be taken:**

- If you become aware of a control solution set with this labeling issue, please instruct the end user to contact ARKRAY Customer Service at 800.818.8877 for return and replacement of product.

We are actively addressing this issue to prevent its reoccurrence and sincerely apologize for the inconvenience.