



Urgent Field Safety Notice
Product Recall
Immediate Action Required

Date Issued

July 18, 2018

Product

Product Name	List Number	Lot Number	Expiration Date	UDI Number
Alinity c Creatine Kinase	08P4220	99634UN18	02JAN2019	(01)00380740132590 (17)190102(10)99634UN18

Explanation

The purpose of this letter is to inform you of a product recall for the Alinity c Creatine Kinase (CK) reagent lot number listed above and to provide instructions on what actions your laboratory must take.

Abbott has identified a product stability issue that may lead to the following:

- Message code 1041 "Unable to calculate result. Reaction check failure."
- Quality Control (QC) results out of range low

Patient Impact

A potential delay may exist in the reporting of patient results due to Quality Control values falling outside of expected ranges and the generation of Message code 1041. Internal testing on patient samples showed no atypical bias for the impacted reagent lots, therefore if Quality Controls are in range, patient results are not impacted.

Necessary Actions

If...	Then...
You HAVE an alternate reagent lot available in inventory	Immediately discontinue use of the reagent lot number listed above and switch to the alternate reagent lot. Destroy any remaining inventory of impacted material according to your laboratory procedures.
You do NOT have an alternate reagent lot available in inventory and the current lot continues to generate valid QC results	Immediately order a replacement reagent lot. You may continue to use the reagent lot number listed above while following your current laboratory QC procedures. Once you receive the replacement reagent lot, destroy any remaining inventory of impacted material according to your laboratory procedures.

- Complete and return the Customer Reply Form. Your local Abbott representative can help provide you with replacement product.
- Please retain this letter for your laboratory records.

**Necessary
Actions
Continued**

Abbott has not yet identified a root cause and corrective action for this issue.

To prevent reoccurrence:

- New Creatine Kinase reagent lots will have shortened expiration (exp) dating.

**Contact
Information**

We sincerely regret any inconvenience this may have caused your laboratory. If you or any of the health care providers you serve have any questions regarding this information, please contact your local area Customer Service.
