



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
ARCHITECT Creatine Kinase	7D63-21	87697UN18	22OCT18	(01)00380740012878 (17)181022(10)87697UN18
		99632UN18	12NOV18	(01)00380740012878 (17)181112(10)99632UN18
		24358UN18	05DEC18	(01)00380740012878 (17)181205(10)24358UN18
	7D63-41	99633UN18	02JAN19	(01)00380740101176 (17)190102(10)99633UN18

Explanation

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

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

- Error Code 1054 “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 Error Code 1054. 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(s) 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(s) 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.

**Necessary
Actions
Continued**

- 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.

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, U.S. Customers please contact Customer Service at 1-877-4ABBOTT (available 24 hours a day, 7 days a week). Customers outside the U.S., please contact your local area Customer Service.
