



Urgent Field Safety Notice Product Recall

Immediate Action Required

Date Issued

January 21, 2016

Product

- ARCHITECT STAT High Sensitive Troponin-I Reagent Kit
- List Number 3P25-26
- Lot Number 56940UI00

Explanation

The purpose of this letter is to inform you of a product recall for ARCHITECT STAT High Sensitive Troponin-I Reagent, LN 3P25-26, lot number 56940UI00 and to provide instructions on what actions your laboratory must take.

Abbott has confirmed an increase in calibration failures when using lot 56940UI00. Replacement material is available.

Patient Impact

There is no impact to generated patient results. There is a potential for delay in results due to calibration errors and failure to calibrate.

Necessary Actions

We recommend that you follow the necessary actions below:

If....	Then...
You do NOT have an alternate reagent lot available in inventory and you have generated a valid calibration curve using lot 56940UI00	Immediately order a replacement reagent lot. Continue to use lot 56940UI00 and follow the recommended QC procedures in the Package Insert. Once you receive the replacement reagent lot , destroy any remaining inventory of reagent lot 56940UI00 according to your laboratory procedures.
You HAVE an alternate reagent lot available in inventory	Discontinue use of lot 56940UI00 immediately and switch to the alternate reagent lot. Destroy any remaining inventory of reagent lot 56940UI00 according to your laboratory procedures.

- Your local Customer Support will provide you with replacement product and/or credit.
- Complete and return the Customer Reply Form.
- If you have forwarded the product listed above to other laboratories, please inform them of this Product Recall and provide to them a copy of this letter.
- Please retain this letter for your laboratory records.

**Contact
Information**

We sincerely regret any inconvenience this issue may cause. An investigation is underway to determine the cause of this issue.

If you or any of the health care providers you serve have any questions regarding this information, please contact your local area Customer Service.
