



Urgent Field Safety Notice Product Recall Immediate Action Required

Date Issued

April 11, 2012

Product

ARCHITECT STAT Troponin-I, List Number 2K41-28, Lot 74264UN11

Explanation

- The purpose of this communication is to provide instructions on actions your laboratory must take regarding a single lot of ARCHITECT STAT Troponin-I reagent.
- This issue is specific for lot 74264UN11.
- Abbott has confirmed that ARCHITECT STAT Troponin-I, lot 74264UN11 is demonstrating a shift in expected results in some cases. This effect can vary from kit to kit.
- All levels of Abbott Controls will detect the shift. If controls are out of range, performing a recalibration will restore the controls in range and accurate results would be generated. As described in the ARCHITECT STAT Troponin-I package insert, it is recommended that each control level be tested once every 24 hours each day of use.
- An investigation is in process. Initial indications suggest that the issue is caused by depressed Relative Light Unit (RLU) values.

Patient Impact

- Through our investigation we assessed the magnitude of the shift. A concentration change of up to +/- 55% could occur when switching kits without re-calibrating.

**Necessary
Actions**

- Determine if you are currently using and/or have inventory of lot 74264UN11.
- Discontinue use of and destroy any remaining inventory of this lot according to your laboratory procedures.
- If lot 74264UN11 is the only lot available in your laboratory, immediately order a new lot.
 - Recalibrate and run controls every 24 hours and whenever switching to a new kit of the same lot
 - Once a replacement reagent lot has been received, discontinue use and destroy any remaining inventory of lot 74264UN11
- If you have forwarded any kits of this lot to other laboratories, please inform them of this Product Recall and provide a copy of this letter to them.
- Follow your laboratory procedure in discussing previously reported results with your physicians.

**Contact
Information**

We sincerely apologize for any inconvenience this may cause. Abbott is committed to providing you with the highest quality diagnostic products and support services to meet the needs of your laboratory and the providers and patients you serve.

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