



Product Recall

Urgent - Immediate Action Required

Date Issued April 11, 2019

Product

Product Name	List Number (LN)	Lot Number	Expiration Date	UDI Number
Quantia RF	6K44-01	01518H000	08SEP2019	N/A

Explanation

Abbott received the attached Field Safety Notice from Biokit, the manufacturer of Quantia RF (Rheumatoid Factor) reagent (LN 6K44-01). Biokit has confirmed high frequency of calibration failures when using Quantia RF, lot number 01518H000 on ARCHITECT c Systems. The following error codes may be generated:

- Error Code 1353 "Assay (x) Number (y) calibration failure, calibration factor out of range."
- Error Code 1455 "Assay (x) Number (y) calibration failure, calibration out of order."

The root cause is still under investigation at Biokit.

Patient Impact

Please refer to the attached Biokit Field Safety Notice.

Necessary Actions

- **Immediately discontinue** use of LN 6K44-01, lot 01518H000 and **discard** any remaining inventory of the impacted material according to your laboratory procedures.
- Complete and return the Abbott Customer Reply Form. Please contact your local Abbott representative for assistance with replacement product.
- If you have forwarded the product listed above to other laboratories, please inform them of the Product Recall and provide 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 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.

If you have experienced any patient or user injury associated with this Field Action, please immediately report the event to your local area Customer Service.