



Biokit

A Werfen Company

Field Safety Notice

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Edition 2

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FIELD SAFETY NOTICE
QUANTIA RF
PART NUMBER: 6K44-01
Calibration issues - Error codes 1353 and/or 1455

Date: April 5th, 2019

Dear Valued Customer:

Our records indicate that your laboratory may have used or currently has in inventory one or more kits of:

Product	Code	Lot Number	Expiration Date
QUANTIA RF	6K4401	01518H000	2019-09-08

• Issue Description and Patient Impact:

The purpose of this letter is to inform you of a product recall for QUANTIA RF Reagent Kit PN 6K44-01, lot 01518H000 and to provide instructions on what actions your laboratory must take.

Biokit has confirmed calibration failures with the indicated product and lot. Upon trying to calibrate the lot 01518H000, the calibration cannot be achieved and the instrument will generate error codes 1353 and/or 1455. There has been a high frequency in error code generation, resulting in the instrument not being able to calibrate.

Patient impact includes a potential delay in patient results. However, if no error codes are generated, there is no impact to patient results.

Biokit tested all other available lots of QUANTIA RF and confirmed these lots do not exhibit the same calibration failure shown in lot 01518H000.

The root cause for this issue is under investigation.

• Mandatory Customer Action:

Please stop using the affected lot and discard any remaining kits of the QUANTIA RF 6K44-01 lot 01518H000 from your inventory and analyzers.

Please forward this notice to all organizations / individuals who are impacted by this action and retain this notice for your laboratory records.

We ask our customers to inform your local Abbott representatives of the current number of kits in their inventory in order to be able to provide you with the new material as soon as it becomes available.

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.

Sincerely,

BIOKIT, S.A.