Customer
Hospital
City
Postal code
Country
Attn.: XXX

[ISSUE DATE]

Field Safety Notice: AQT90 FLEX TnI Test Kit Box

Priority Level: Urgent

Dear Customer

RADIOMETER has recently become aware of a potential risk of receiving false high results with the AQT90 FLEX TnI Test Kit Box, 942-903 of Lot 09619.

It has been reported that calibration adjustment cups may have been packed into the TnI Test Kit cartridges of Lot 09619. Thus, in some test cartridges one or more cups may be a calibration adjustment cup. As a result, when a patient sample is tested in a calibration adjustment cup, the result will always be above 2.5 ng/mL (the cut-off for AMI is 0.023 ng/mL).

Affected product:
AQT90 FLEX Test Kit Box, 942-903 Lot 09619

What you should do:

- Please check your inventory and remove any AQT90 FLEX TnI Test Kit Boxes from the affected lot.
- Please check the AQT90 FLEX TnI Test Kit Boxes distributed in your institution and collect any AQT90 FLEX TnI Test Kit Boxes from the affected lot.
- Please complete page 2 of this letter and return to your RADIOMETER representative.

RADIOMETER has informed your national competent authority of this Field Action as required.

Your RADIOMETER representative will replace the quantity of AQT90 FLEX TnI Test Kit Boxes discarded by you.

If you have any questions, please contact your RADIOMETER representative. RADIOMETER sincerely apologizes for the inconvenience this situation may cause you.

Best regards,
<Radiometer distributor>

Recall Response Fax Form no. 1

Fax No.:

Concerning:

AQT90 FLEX TnI Test Kit Box, 942-903 of Lot 09619

□ I have received the customer letter, and reviewed my current inventory of AQT90 FLEX TnI Test Kit Boxes, 942-903.
All boxes from lot 09619 have been removed and discarded.

I have discarded the following quantity: _____ boxes

□ I have none of the affected lot in stock.

Hospital Name:	
Your Name:	
Date:	
Signature:	
Email Address:	