



March 1, 2016

URGENT FIELD SAFETY NOTICE

Notification of market withdrawal of QuantiFERON®-TB Gold (QFT®) TB-Antigen blood collection tubes – LOT A150135A (as part of below mentioned LOT Number)

Dear Valued Customer;

QIAGEN wishes to advise you of a voluntary market withdrawal of QuantiFERON-TB Gold TB-Antigen tubes which were packaged in the following tube kit configuration:

Cat. No. (REF)	Product Name	LOT Number
0590-0201	QFT Tubes (100xNil,100xTBAg)	059061291

During production of this lot of TB antigen tubes, a portion did not meet endotoxin specification and was scrapped. The remaining portion was released upon additional testing and packaged in the above mentioned kit configurations.

To date, there has been no evidence of product performance being impacted for this lot. However we cannot dismiss the potential for an elevated rate of positivity due to increased endotoxin. In an abundance of caution the remainder of this lot is being withdrawn. No other lots are impacted.

Actions to be taken by the customer:

- Immediately discontinue use of this lot and discard any remaining inventory.
- Forward this information to all individuals and departments within your organization that have received or used this product. If you are not the end user, please forward the notice to the product end user.
- Please acknowledge receipt of this notification and the actions taken



Completion of the Acknowledgement of Receipt

Due to regulatory reasons, the completion of the Acknowledgement of Receipt is required. Please complete, sign and send back the attached "Acknowledgement of Receipt" by March 31, 2016 by email to TechService-AP@qiagen.com or fax to +65 6854 8184.

QIAGEN apologizes for any inconvenience this market withdrawal has caused, and continues to take every effort possible to ensure the highest quality of product is always available to our valued customers around the globe. Please do not hesitate to contact your local QuantiFERON sales representative or customer service representative should you have any questions or concerns.

QIAGEN Subsidiaries

<https://www.qiagen.com/about-us/contact/global-contacts/subsidiaries/>

Sincerely,

Your QIAGEN Team



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Notification of market withdrawal of QuantiFERON®-TB Gold (QFT®) TB-Antigen blood collection tubes – LOT: A150135A

Acknowledgement of Receipt

(Please use block letters)

I hereby acknowledge that I have received, read and understood the included Urgent Field Safety Notice dated March 1, 2016. We have taken the necessary actions as suggested by this notice:

- (1) We have immediately discontinued the use of this lot and discarded any remaining inventory.
- (2) We have forwarded this information to all individuals and departments within our organization that have received or used this product.

Please complete, sign and send back the attached "Acknowledgement of Receipt" by March 31, 2016 by email to TechService-AP@qiagen.com or fax to +65 6854 8184.

Laboratory name:			
Laboratory address:			
Name and title of contact:			
Phone:			
Email address:			
Quantity of kits discarded:	Cat. No. (REF)	LOT	Quantity
<hr/>			
<i>Signature</i>		<i>Date</i>	