Fast Track DIAGNOSTICS
A Siemens Healthineers Company

Field Safety Notice

FSN-FA-2019-13
October 2019

FTD-55.1 BKV

Potential inaccurate quantification when using the FTD-55.1 BKV quantitative kit

Dear Customers,

We kindly ask you to review the following communication.

Details on affected products:

Our records indicate that your facility may have received one or more of the following products:

Table 1 - Affected products:

Product Name	Catalogue Number	Siemens Material Number (SMN)	Lot Number	1st Distribution Date (DD/MM/YYYY)
FTD BKV	FTD-55.1-32 FTD-55.1-64	(32) 10921794 (64) 10921795	All lots	01/12/2016

Reason for the Field Safety Notification:

The purpose of this communication is to inform you of an issue affecting the products indicated above and to provide instructions on actions that your laboratory must take.

After internal investigation, Fast Track Diagnostics (FTD) has identified a risk of potentially generating erroneous viral load quantification results when using the kits listed above.
Internal investigation is currently ongoing to determine the magnitude and the likelihood of this issue.

The observed issue can affect results for both patient samples and quality control samples, and therefore, may not always be detectable by users of the product.

Risk to Health:

Erroneous quantification of BK polyomavirus (BKV) may lead to incorrect assessment of viral load, which may affect treatment decisions for patients undergoing viral load monitoring, including those who are immunocompromised. The risk is mitigated by serial monitoring of viral load and correlation with clinical presentation.

Actions to be taken by the user:

1. Immediately cease the use of the above-mentioned kits until further notice.

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2. Fast Track Diagnostics recommends use of alternate validated viral load test for any patients that are currently undergoing viral load monitoring using FTD BK polyomavirus (BKV) kits. The results of new viral load test should be used as a new baseline for patient management.

3. If you have received any complaint or report of illness or adverse events associated with one of the kits mentioned in Table 1, immediately contact FTD at: support-ftd.team@siemens-healthineers.com

4. The Field Correction Effectiveness Check , as attached, should be returned no later than the 4th of November 2019.

Currently, the issue remains under investigation at FTD. Additional information or updates will be provided as they become available.

Please review this letter with your medical advisor and retain this letter with your laboratory records. This letter should also be forwarded to those who may have received this product.

If you have any questions, please contact FTD at: support-ftd.team@siemens-healthineers.com

FIELD CORRECTION EFFECTIVENESS CHECK

Potential inaccurate quantification when using the FTD-55.1 BKV quantitative kit

This response form is to confirm receipt of the enclosed Fast Track Diagnostics Urgent Field Safety Notification FSN-FA-2019-013, dated October 2019 regarding "Potential inaccurate quantification when using the FTD-55.1 BKV quantitative kit". Please read each statement and indicate the appropriate answer.

Email this completed form to the email address provided at the bottom of this page, by the **4th of November 2019**.

1. I have read and understood the Field Safety Notice instructions provided in this letter.	Yes ☐	No ☐
2. I am a distributor of the affected products AND my customers received FTD-55.1	Yes ☐	No ☐
If yes has been selected within point 2, please confirm that you forward the relevant information to your impacted customers.	Yes ☐	No ☐

Name of person completing questionnaire:

Title:

Institution:

Street:

City: State:

Phone: Country:

Signature and date

Please send a scanned copy of the completed form via email to:
vigilance-ftd.team@siemens-healthineers.com
If you have any questions, contact a Fast Track Diagnostics support representative.