

**FTD-8.1, Cytomegalovirus, FTD-74 Epstein-Barr virus**

**Potential inaccurate quantification when using the FTD-8.1 Cytomegalovirus and FTD-74 Epstein-Barr virus quantitative kits**

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	1 <sup>st</sup> Distribution Date (DD/MM/YYYY)
FTD Cytomegalovirus	FTD-8.1-32, FTD-8.1-64	(32) 10921716 (64) 10921717	All lots	01/12/2016
FTD Epstein-Barr virus	FTD-74-32, FTD-74-64	(32) 11373875 (64) 11373876	All lots	29/03/2017

**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 generating potentially erroneous viral load quantification results when using the kits indicated 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 CMV or EBV 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 with an alternate clinically validated viral load test and correlation with clinical presentation.

**Actions to be taken by the user:**

**FTD-8.1, Cytomegalovirus, FTD-74 Epstein-Barr virus**

**Potential inaccurate quantification when using the FTD-8.1 Cytomegalovirus and FTD-74 Epstein-Barr virus quantitative kits**

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1. Immediately cease the use of the above-mentioned kits for quantitative purposes until further notice.
2. Fast Track Diagnostics recommends use of alternate validated viral load test for any patients that are currently undergoing viral load monitoring using FTD CMV or EBV 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](mailto:support-ftd.team@siemens-healthineers.com)
4. The Field Correction Effectiveness Check , as attached, should be returned no later than the 25<sup>th</sup> of October 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](mailto:support-ftd.team@siemens-healthineers.com)

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