

Discontinuation of FTD Urethritis basic (FTD-33.1), FTD Viral gastroenteritis (FTD-3) and FTD Bacterial gastroenteritis (FTD-14.1) CE-IVD

Dear customers,

Our records indicate that your facility may have received one of these products.

Table 1. List of affected products.

Product Name	FTD Catalogue Number [Siemens Material Number (SMN)]	Lot Number	1st Distribution Date (MM/YYYY)
FTD Urethritis basic	FTD-33.1-32 [10921758] FTD-33.1-64 [10921759]	All lots	02/2012
FTD Viral gastroenteritis	FTD-3-32 [10921708] FTD-3-64 [10921709]	All lots	02/2007
FTD Bacterial gastroenteritis	FTD-14.1-32 [10921726] FTD-14.1-64 [10921727]	All lots	02/2012

If so, we kindly ask you to review the following communication.

Reason for this Field Safety Notice

This notice follows the implementation of the Field Safety Corrective Action FA-2019-22, concerning "Unsupported Performance Claims for FTD CE-IVD kits":

- An initial FSN FA-2019-22 December 2019 was issued to inform that various performance claims listed in the current Instructions for Use will not be met (i.e. sensitivity, specificity, etc.).
- A first follow-up FSN FA-2019-22 January 2020 pointed out a potential for increased instances of erroneous results (false positives, false negatives) and provided information regarding discontinuation of some FTD products and update of performance claims for other FTD products to be re-introduced.

This second follow-up FSN FA-2019-22 October 2020 is meant to inform you that for strategic reasons, FTD is permanently discontinuing the products listed in Table 1. Please refer to the information below for further instructions on these kits.

We apologize for the inconvenience this situation may cause.

Risk to Health

This risk to health statement applies to all patient results that were generated using one of the products listed in Table 1.

Due to the inadequacy of validation and verification data for all lots manufactured since product launch, there is a possibility that erroneous results (false positive and false negative) were generated with these kits. Depending on the pathogen, these erroneous results may have impacted patient diagnosis and/or management plan.

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Actions to be taken by distributors:

1. Please destroy remaining stock of products listed in Table 1. Note: It is expected that expired products were already destroyed as per instructions for use.
2. Forward this Field Safety Notification to all your customers who may be impacted.
3. If you have received any complaints, reports of illness or adverse events associated with FTD kits, immediately contact FTD at: support-ftd.team@siemens-healthineers.com
4. Complete Annex 1 "FIELD CORRECTION EFFECTIVENESS CHECK" and return it to the address vigilance-ftd.team@siemens-healthineers.com by the **16th of November 2020** to confirm that you have cascaded the FSN to your impacted end-users.

Actions to be taken by the users:

1. Please review this letter with your medical advisor.
2. FTD reiterates the following actions, if not already taken per our earlier communication (Re: Follow-up FSN FA-2019-22 January 2020):
 - a. FTD recommends consultation with your medical advisor to evaluate the need for reassessment of any results previously generated with these kits, starting with the date when they first became available.
 - b. For patients who are currently under medical care and may benefit from confirmation of diagnosis, FTD strongly recommends discussions with your medical advisor regarding a review of the results generated with kits listed in Table 1. Results may be confirmed with an alternative validated test.
3. Please destroy remaining stock of products listed in Table 1. Note: It is expected that expired products were already destroyed as per instructions for use.
4. If you have received any complaints, reports of illness or adverse events associated with FTD kits, immediately contact FTD at: support-ftd.team@siemens-healthineers.com
5. Complete Annex 1 "FIELD CORRECTION EFFECTIVENESS CHECK", as attached, and return it to your local distributor or FTD representative no later than the **23rd of November 2020**.

This will serve as your final instruction for all products affected by the FA-2019-22.

Please retain this letter with your records and forward this letter to those who may have received this product.

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

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Annex 1 Follow-up FSN-FA-2019-22 October 2020, FIELD CORRECTION EFFECTIVENESS CHECK

This response form is to confirm receipt of the enclosed Fast Track Diagnostics Urgent Field Safety Notice Follow-up FSN-FA-2019-22, October 2020, regarding “Discontinuation of FTD Urethritis basic (FTD-33.1), FTD Viral gastroenteritis (FTD-3) and FTD Bacterial gastroenteritis (FTD-14.1) CE-IVD”. Please read each statement and indicate the appropriate answer.

I confirm that I have read and understood the content of Yes No
 the Follow-up FSN-FA-2019-22, October 2020

Destruction attestation	
Product Description, Lot number	Number of kits destroyed

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 e-mail to our Vigilance team using this e-mail address: vigilance-ftd.team@siemens-healthineers.com or to your local Siemens Healthineers FTD representative.