Fast Track DIAGNOSTICS
A Siemens Healthineers Company

Field Safety Notice

FSN-FA-2020-02
April 2020

FTD Vesicular rash (FTD-7) CE-IVD

Update of Instructions for Use for the FTD Vesicular rash kit

Dear Customers,

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

Table 1. Affected products

Product Name	Catalogue Number [FTD cat. Number /Siemens Material Number (SMN)]	Lot Number	1st Distribution Date (MM/YYYY)
FTD Vesicular rash	FTD-7-32 [10921714] FTD-7-64 [10921715]	All lots since kit launch	06/2008

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

Reason for the Field Safety Notice:

This notice follows the implementation of the Field Safety Corrective Action FA-2019-22 (issued December 2019), concerning "Unsupported Performance Claims for FTD CE-IVD kits" and provides product-specific information regarding the kits indicated in Table 1.

The purpose of this communication is to inform you of performance issues related to the inadequacy of validation and verification for the performance claims made about the FTD Vesicular rash kit since its launch date and to provide instructions on the actions that your laboratory must take.

FTD has corrected the above-described issue by performing complete validation and verification testing to establish new claims for the FTD Vesicular rash kit's performance characteristics.

Based on the new validation and verification data, the Instructions for Use (IFU) have been revised and are currently being translated in all required languages. Please see the updated claims and verification and validation data in chapter "Performance Characteristics" of FTD Vesicular rash IFU 11414195 Rev. B, 2020-03.

Please note, that in addition to the recent validation and verification activity and revision of the product performance claims for the FTD Vesicular rash kit, the respective FTD catalogue numbers have also been changed to FTD-7.1-32 [10921714] and FTD-7.1-64 [10921715].

Risk to Health:

This risk to health statement applies to all patient results that were generated using this product in accordance with an IFU version other than the FTD Vesicular rash IFU 11414195 Rev. B, 2020-03.
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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Information regarding updates in Instructions for Use for FTD-7.1-32 (10921714) and FTD-7.1-64 (10921715)

Please review the new FTD Vesicular rash IFU 11414195 Rev. B, 2020-03 Instructions for Use in its entirety to assess the impact of all changes on your own workflow. Table 2 provides a brief overview of the updates related to the recent validation and verification data.

Discard any copies of previous versions of the IFU and download the FTD Vesicular rash IFU 11414195 Rev. B, 2020-03 from the FTD website at the following address:

http://www.fast-trackdiagnostics.com/human-line/resources/instructions-for-use-(ifu)/fever,-rash,-childhood-infections-ifu/ftd-vesicular-rash-ifu/

Table 2. Updates to Instructions for FTD Vesicular rash IFU 11414195 Rev. B, 2020-03

IFU Section	Updated Claim
Specimen Collection and Handling	List of validated sample types reduced to vesicle swab specimens of human origin.
Assay Procedure	Warning message added to ensure proper use of the Internal Control (IC).
Criteria for a valid run	Caution section added regarding crosstalk signals in the Positive Control (PC).
Results	Important information added to ensure proper baseline settings
Performance Characteristics - Interfering Substances	New section added to the IFU – No interference observed with the substances tested.
Performance Characteristics - Clinical Performance	Revision of this section with updated information on diagnostic sensitivity and diagnostic specificity.

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Actions to be taken by Distributors

1. Please advise your customers/users to utilize the kit for patient testing only in accordance with the FTD Vesicular rash IFU 11414195 Rev. B, 2020-03 for any the FTD Vesicular rash (FTD-7) kits remaining in stock.
2. Forward this Field Safety Notice to all your customers who may have received the affected products.
3. Complete Annex 1 "FIELD CORRECTION EFFECTIVENESS CHECK", as attached, and return it to the email address vigilance-ftd.team@siemens-healthineers.com before the **17th of April 2020** to confirm that you have cascaded the FSN to your impacted end-users.

Actions to be taken by Users

1. Please review this letter with your medical advisor.
2. Effective immediately, please follow the FTD Vesicular rash IFU 11414195 Rev. B, 2020-03 to generate patient results. This includes testing performed using any FTD Vesicular rash (FTD-7) kits that you may have in stock.
3. Siemens 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.
4. For patients who are currently under medical care and may benefit from confirmation of diagnosis, Siemens recommends discussion with your medical advisor regarding a review of previously generated results. Results may be confirmed with an alternative validated test.
5. Please discard any copies of the previous version of the IFU and download the updated version FTD Vesicular rash IFU 11414195 Rev. B, 2020-03 in the language required by your local regulation from the FTD website using this link: http://www.fast-trackdiagnostics.com/human-line/resources/instructions-for-use-(ifu)/fever,-rash,-childhood-infections-ifu/ftd-vesicular-rash-ifu/
6. Assess your internal procedures according to the FTD Vesicular rash IFU 11414195 Rev. B, 2020-03.
7. If you have received any complaints or reports of illness or adverse events associated with a FTD product, immediately contact FTD at: support-ftd.team@siemens-healthineers.com
8. Complete Annex 1 "FIELD CORRECTION EFFECTIVENESS CHECK", as attached, and return it to your local distributor or FTD representative after you downloaded the FTD Vesicular rash IFU 11414195 Rev. B, 2020-03 in your required language from the website.

Please retain this letter with your laboratory records. This letter should also be forwarded to anyone else who may have received this product.

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

Fast Track Diagnostics assays are manufactured by Fast Track Diagnostics Luxembourg S.à r.l., A Siemens Healthineers Company.

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Annex 1 FSN-FA-2020-02, FIELD CORRECTION EFFECTIVENESS CHECK

This response form is to confirm receipt of the enclosed Fast Track Diagnostics Urgent Field Safety Notice FSN-FA-2020-02, dated of April 2020, regarding "Update of Instructions for Use for the FTD Vesicular rash kit". Please read each statement and indicate the appropriate answer.

I confirm that I have read and understood the content of the FSN-FA-2020-02	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 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.

If you have any questions, please contact a Fast Track Diagnostics support representative directly: support-ftd.team@siemens-healthineers.com.