Fast Track DIAGNOSTICS
A Siemens Healthineers Company

Field Safety Notice

FSN-FA-2020-01
February 2020

FTD FLU/HRSV (FTD-48.1) CE-IVD

Update of Instructions for Use for the FTD FLU/HRSV 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)
FLU/HRSV	FTD-48.1-32 / 10921784 FTD-48.1-64 / 10921785	All lots since kit launch	11/2012

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 indicated kits.

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 our FLU/HRSV product 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 FLU/HRSV kit's performance characteristics.

Based on the new validation and verification data, the Instructions for Use (IFU) have been revised accordingly and are currently being translated in all required languages. Please see the updated claims and verification and validation data in chapter "Performance Characteristics", within FLU/HRSV IFU 11414155 Rev. B, 2020-02.
Hereafter, the revised FLU/HRSV IFU 11414155 Rev. B, 2020-02 Instruction for Use will be referred to as "NEW IFU".

Please note, that in addition to the recent validation and verification activity and revision of the product performance claims for the FTD FLU/HRSV kit, the FTD catalogue numbers have also been changed to FTD-48.2-32 / 10921784 and FTD-48.2-64 / 10921785.

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 NEW IFU.
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-48.2-32 (10921784) and FTD-48.2-64 (10921785)

Please review the NEW IFU - FLU/HRSV IFU 11414155 Rev. B, 2020-02 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 NEW IFU updates related to the recent validation and verification data.

Discard any copies of previous versions of the IFU and download the NEW IFU from the FTD website at the following address:

http://www.fast-trackdiagnostics.com/human-line/resources/instructions-for-use-(ifu)/respiratory-infections-ifu/ftd-fluhrsv-ifu/

Table 2. Updates to Instructions for Use FLU/HRSV IFU 11414155 Rev. B, 2020-02 (NEW IFU)

NEW IFU Section	Updated Claim
Specimen Collection and Handling	List of validated sample types reduced to nasal and nasopharyngeal swab specimens of human origin
Assay Procedure	Warning message added for ensuring proper use of the Internal Control (IC)
Results	Warning added regarding crosstalk and non-specific signals that may cause false positive results
Performance Characteristics - Analytical Specificity	Details provided concerning appearance of non-specific signals (background or crosstalk)
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 NEW IFU (FLU/HRSV 11414155 Rev. B) for any FTD FLU/HRSV FTD-48.1 kits remaining in stock.
2. Relay 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 no later than the **02nd of March 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 NEW IFU (FLU/HRSV 11414155_en Rev. B) to generate patient results. This includes testing performed using any FTD FLU/HRSV FTD-48.1 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 NEW IFU 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)/respiratory-infections-ifu/ftd-fluhrsv-ifu/
6. Assess your internal procedures according to the NEW IFU (FLU/HRSV 11414155_en Rev. B).
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 **no later than 5 days after you downloaded the IFU** 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.

Annex 1 FSN-FA-2020-01, FIELD CORRECTION EFFECTIVENESS CHECK,

Update of Instructions for Use for the FTD FLU/HRSV kit

This response form is to confirm receipt of the enclosed Fast Track Diagnostics Urgent Field Safety Notice FSN-FA-2020-01, dated of February 2020, regarding "Update of Instructions for Use for the FTD FLU/HRSV kit". Please read each statement and indicate the appropriate answer.

Email this completed form to Fast Track Diagnostics at the contact provided at the bottom of this page.

1.	I confirm that I have read and understood the content of the FSN-FA-2020-01	Yes ☐	No ☐
2.	I confirm that I took appropriate action concerning the FSN-FA-2020-01	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 your local distributor or FTD representative.

If you have any questions, contact a Fast Track Diagnostics support representative.