Fast Track DIAGNOSTICS
A Siemens Healthineers Company

Field Safety Notice

FSN-FA-2019-19
December 2019

FTD Respiratory pathogens 21 (FTD-2.1) CE-IVD

Update of Instructions for Use concerning the FTD Respiratory pathogens 21 kit

Dear Customers,

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

Table 1. Affected products

Product Name	Catalogue Number	Lot Number	1st Distribution Date (MM/YYYY)
Respiratory pathogens 21	FTD-2-32 (10921702) FTD-2-64 (10921703)	Refer to table 3, page 4	11/2015

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

Reason for the Field Safety Notification:

This notification follows Field Safety Notification FA-2019-22, "Unsupported Performance Claims for FTD CE-IVD kits" and provides product-specific information regarding the indicated assays.

The purpose of this communication is to inform you of performance issues related to absence of validation and verification records for the performance claims of the Respiratory pathogens 21 product after a design change in November 2015 affecting the products indicated above in Table 1 and to provide instructions on actions that your laboratory must take.

FTD has corrected the above described issue by performing validation and verification for the Respiratory pathogens 21 kit performance characteristics.

Based on the new validation and verification data, the Instructions for Use (IFU) has been updated. Please see updated claims and the verification and validation data in chapter "Performance Characteristics", pages 26 to 39, within Respiratory pathogens 21 IFU 11414180_en Rev. B.

Here on, Respiratory pathogens 21 IFU 11414180_en Rev. B will be referred to as "NEW IFU" in this letter.

Please also note that coinciding with the recent validation and verification activity for the FTD Respiratory pathogens 21 kit, the FTD catalogue numbers of this kit have been changed to FTD-2.1-32 (10921702) and FTD-2.1-64 (10921703).

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Information regarding updates in Instructions for Use for FTD-2.1-32 (10921702) and FTD-2.1-64 (10921703)

Please review NEW IFU Respiratory pathogens 21 11414180_en Rev. B 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 IFU, and download the new IFU from the FTD website at this address:

http://www.fast-trackdiagnostics.com/human-line/resources/instructions-for-use-(ifu)/respiratory-infections-ifu/ftd-respiratory-pathogens-21-ifu/.

Table 2. Instructions for Use Updates Related to 2019 Validation and Verification Data for FTD-2.1-32 (10921702) and FTD-2.1-64 (10921703)

IFU Section (Page # of Rev. B)	Updated Claim
Specimen Collection and Handling (Page 9)	Reduced validated sample type to only nasopharyngeal swab specimens of human origin
Assay Procedure (Page 14)	Warning message added for ensuring proper use of the Internal Control (IC)
Results (Pages 18 to 24)	Warning added regarding crosstalk and non-specific signals that may cause false positive results
Performance Characteristics - Analytical Sensitivity (Pages 26 to 28)	Limit of detection (LoD) for all pathogens has been updated
Performance Characteristics - Interfering Substances (Page 37)	New section added to the IFU - moderate interference for samples containing 10% v/v whole blood
Performance Characteristics - Clinical Performance (Pages 38 to 39)	Revision of this section with updated information on diagnostic sensitivity and diagnostic specificity

Risk to Health:
This risk to health statement applies to all the patient results that were generated with the kit lots listed in Table 3 in accordance with an IFU version other than the NEW IFU.
Due to absence of validation and verification data for the kit lots in Table 3, there is a possibility that erroneous results (false positive and false negative) may have been generated with these kits. Depending on the pathogen, these erroneous results may have impacted patient diagnosis and management plan.

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Actions to be taken by Distributors

1. For FTD Respiratory pathogens 21 FTD-2 kits remaining in your stock please advise your customers/ users to utilize the kit for patient testing in accordance with the NEW IFU (Respiratory pathogens 21 11414180_en Rev. B).
2. Relay this Field Safety Notification to all of your customers who may have received the affected products.
3. Complete Annex 1 "FIELD CORRECTION EFFECTIVENESS CHECK, TO BE COMPLETED BY DISTRIBUTOR" and send it back to the e-mail address on the bottom of the page for attesting this action, no later than the 6th of January 2020.

Actions to be taken by Users:

1. Please review this letter with your medical advisor.
2. For FTD Respiratory pathogens 21 FTD-2 kits remaining in your stock please follow the NEW IFU (Respiratory pathogens 21 11414180_en Rev. B) to generate patient results.
3. For patients who are currently under medical care and may benefit from confirmation of diagnosis, Siemens recommends a review of previously generated results [generated by FTD test kits (*released between November 2015 – 2019 as listed in Table 3*) in accordance with previous or old IFU versions]. Results may be confirmed with an alternative validated test.
4. Please discard any copies of the previous version of IFU and download the NEW IFU from the FTD website using this link: http://www.fast-trackdiagnostics.com/human-line/resources/instructions-for-use-(ifu)/respiratory-infections-ifu/ftd-respiratory-pathogens-21-ifu/
5. Assess your internal procedures according to the NEW IFU Instructions for Use Rev. B.
6. 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
7. Complete Annex 2 "FIELD CORRECTION EFFECTIVENESS CHECK, TO BE COMPLETED BY END USER", as attached, and return it to your local distributor or FTD representative no later than the 20th of January 2020.

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: support-ftd.team@siemens-healthineers.com

Fast Track Diagnostics assays are manufactured by Fast Track Diagnostics Luxembourg S.à r.l.

FTD Respiratory pathogens 21 (FTD-2.1) CE-IVD

Update of Instructions for Use concerning the FTD Respiratory pathogens 21 kit

Table 3: List of lots impacted by FA-2019-19

FTD-2-32 (10921702)			FTD-2-64 (10921703)			
RE15-32-80	RE17-32-34	RE18-32-66	RE15-64-103	RE17-64-30	RE18-64-118	RE18-64-87
RE16-32-04	RE17-32-36	RE19-32-02	RE15-64-104	RE17-64-32	RE18-64-119	RE18-64-89
RE16-32-11	RE17-32-40	RE19-32-06	RE15-64-108	RE17-64-36	RE18-64-12	RE18-64-92
RE16-32-12	RE17-32-42	RE19-32-09	RE16-64-01	RE17-64-38	RE18-64-16	RE18-64-96
RE16-32-16	RE17-32-44	RE19-32-12	RE16-64-03	RE17-64-40	RE18-64-17	RE18-64-98
RE16-32-18	RE17-32-48	RE19-32-13	RE16-64-06	RE17-64-43	RE18-64-18	RE18-64-99
RE16-32-24	RE17-32-51	RE19-32-16	RE16-64-22	RE17-64-45	RE18-64-24	RE19-64-01
RE16-32-28	RE17-32-52	RE19-32-20	RE16-64-31	RE17-64-46	RE18-64-25	RE19-64-05
RE16-32-31	RE18-32-03	RE19-32-23	RE16-64-34	RE17-64-47	RE18-64-28	RE19-64-06
RE16-32-34	RE18-32-06	RE19-32-24	RE16-64-37	RE17-64-49	RE18-64-29	RE19-64-07
RE16-32-37	RE18-32-07	RE19-32-25	RE16-64-41	RE17-64-52	RE18-64-31	RE19-64-11
RE16-32-40	RE18-32-09	RE19-32-31	RE16-64-42	RE17-64-56	RE18-64-34	RE19-64-12
RE16-32-43	RE18-32-10	RE19-32-33	RE16-64-43	RE17-64-57	RE18-64-35	RE19-64-13
RE16-32-46	RE18-32-12	RE19-32-36	RE16-64-48	RE17-64-59	RE18-64-36	RE19-64-15
RE16-32-54	RE18-32-13	RE19-32-37	RE16-64-53	RE17-64-61	RE18-64-40	RE19-64-20
RE16-32-55	RE18-32-17	RE19-32-42	RE16-64-55	RE17-64-62	RE18-64-45	RE19-64-23
RE16-32-56	RE18-32-19	RE19-32-43	RE16-64-56	RE17-64-63	RE18-64-46	RE19-64-25
RE16-32-62	RE18-32-20	RE19-32-44	RE16-64-57	RE17-64-65	RE18-64-47	RE19-64-27
RE16-32-65	RE18-32-25	RE19-32-45	RE16-64-58	RE17-64-68	RE18-64-50	RE19-64-28
RE16-32-67	RE18-32-26		RE16-64-59	RE18-64-01	RE18-64-52	RE19-64-29
RE16-32-69	RE18-32-28		RE16-64-64	RE18-64-02	RE18-64-53	RE19-64-32
RE16-32-71	RE18-32-29		RE16-64-68	RE18-64-03	RE18-64-56	RE19-64-33
RE17-32-02	RE18-32-31		RE16-64-75	RE18-64-04	RE18-64-57	RE19-64-35
RE17-32-04	RE18-32-33		RE16-64-80	RE18-64-07	RE18-64-61	RE19-64-40
RE17-32-06	RE18-32-38		RE16-64-84	RE18-64-09	RE18-64-63	RE19-64-43
RE17-32-07	RE18-32-39		RE16-64-88	RE18-64-10	RE18-64-64	RE19-64-44
RE17-32-08	RE18-32-42		RE16-64-90	RE18-64-102	RE18-64-65	RE19-64-45
RE17-32-09	RE18-32-46		RE16-64-92	RE18-64-104	RE18-64-69	RE19-64-46
RE17-32-12	RE18-32-48		RE17-64-03	RE18-64-107	RE18-64-72	RE19-64-47
RE17-32-14	RE18-32-52		RE17-64-06	RE18-64-108	RE18-64-74	RE19-64-48
RE17-32-16	RE18-32-54		RE17-64-15	RE18-64-11	RE18-64-76	RE19-64-49
RE17-32-17	RE18-32-56		RE17-64-20	RE18-64-110	RE18-64-77	RE19-64-50
RE17-32-25	RE18-32-58		RE17-64-21	RE18-64-111	RE18-64-81	RE19-64-51
RE17-32-27	RE18-32-60		RE17-64-24	RE18-64-112	RE18-64-82	RE19-64-52
RE17-32-30	RE18-32-63		RE17-64-25	RE18-64-115	RE18-64-83	
RE17-32-32	RE18-32-64		RE17-64-27	RE18-64-116	RE18-64-84	

Annex 1 FSN-FA-2019-19, FIELD CORRECTION EFFECTIVENESS CHECK,

TO BE COMPLETED BY DISTRIBUTOR

Update of Instruction for Use concerning the kit FTD Respiratory pathogens 21

This response form is to confirm receipt of the enclosed Fast Track Diagnostics Urgent Field Safety Notification FSN-FA-2019-19, dated of December 2019, regarding "Update of Instruction for Use concerning the kit FTD Respiratory pathogens 21". Please read each statement and indicate the appropriate answer.

Email this completed form to Fast Track Diagnostics at the email address provided at the bottom of this page, by the **6th of January, 2020**.

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 one of the impacted kits	Yes ☐	No ☐
3. The 2 answers above are yes, and I confirm that I have forwarded this FSN to all my impacted end-users	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.

Annex 2 FSN-FA-2019-19, FIELD CORRECTION EFFECTIVENESS CHECK,

TO BE COMPLETED BY END USER

Update of Instruction for Use concerning the kit FTD Respiratory pathogens 21

This response form is to confirm receipt of the enclosed Fast Track Diagnostics Urgent Field Safety Notification FSN-FA-2019-19, dated of December 2019, "Update of Instruction for Use concerning the kit FTD Respiratory pathogens 21". Please read each statement and indicate the appropriate answer.

Email this completed form to Fast Track Diagnostics at the email address provided at the bottom of this page by the **20th of January, 2020.**

1. I confirm that I have read and understood the content of the FSN-FA-2019-19 Yes ☐ No ☐
2. I confirm that I took appropriate action concerning the FSN-FA-2019-19 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.