

All FTD CE-IVD kits

Unsupported Performance Claims for FTD CE-IVD kits.

Dear customers,

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

Table 1: Affected Products

Product Name	Catalogue Number	Lot Number	1st Distribution Date (DD/MM/YYYY)
FTD CE-IVD Kits	All (See Table 2 below)	All lots	N/A

Reason for this Field Action:

The purpose of this communication is to instruct FTD customers to immediately stop distributing and using all FTD CE-IVD products that they may have in stock.

Internal investigation has revealed that, for the identified products, there is insufficient data to support the performance claims stated in the Instructions for Use. As a result, the CE marks for these products are no longer valid and our product labeling is not compliant with the IVDD.

Risk to Health:

The risk to health related to the use of each product cannot be determined at this time. For each CE IVD kit, FTD is currently reviewing all available information, to ensure that we have considered all the facts before communicating details regarding potential effects on patient safety.

Additional notifications will be issued to communicate information regarding any confirmed product performance or safety issues.

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Table 2: List of kits affected by this Field Action. Both liquid and lyophilized versions are impacted

FTD liquid		FTIyo		Name of the kit
FTD Cat n°	SMN n°	FTD cat. n°	SMN n°	
FTD-1.1	(32) 10921700; (64) 10921701	-	-	ACE
FTD-2	(32) 10921702; (64) 10921703	FTIyo-2	(32H) 10734543; (32L) 11373557 (64H) 10734544; (64L) 11373558	Respiratory pathogens 21
FTD-2+.1	(32) 10921704; (64) 10921705	FTIyo-2+.1	(32H) 11373545; (32L) 11373547 (64H) 11373546; (64L) 11373548	Respiratory pathogens 21 plus
FTD-2P.3	(32) 10921706; (64) 10921707	FTIyo-2P.3	(32H) 11373551; (32L) 11373553 (64H) 11373552; (64L) 11373554	Respiratory pathogens 33
FTD-3	(32) 10921708; (64) 10921709	FTIyo-3s	(32H) 10734547; (32L) 11373561 (64H) 10734548; (64L) 11373562	Viral gastroenteritis
FTD-7	(32) 10921714; (64) 10921715	FTIyo-7	(32H) 10734545; (32L) 11373577 (64H) 10734546; (64L) 11373578	Vesicular rash
FTD-8.1	(32) 10921716; (64) 10921717	-	-	Cytomegalovirus
FTD-9.1	(32) 10921718; (64) 10921719	-	-	Dermatophytes
FTD-10.3	(32) 10921720; (64) 10921721	-	-	Fever and rash
FTD-12.1	(32) 10921722; (64) 10921723	-	-	Vaginal swab
FTD-13	(32) 10921724; (64) 10921725	FTIyo-13	(32H) 10734549; (32L) 11373605 (64H) 10734550; (64L) 11373606	Viral meningitis
FTD-14.1	(32) 10921726; (64) 10921727	FTIyo-14.1	(32H) 10734531; (32L) 11373609 (64H) 10734532; (64L) 11373610	Bacterial gastroenteritis
FTD-15.1	(32) 10921728; (64) 10921729	-	-	Eye
FTD-16	(32) 10921730; (64) 10921731	-	-	Mumps
FTD-17	(32) 10921732; (64) 10921733	-	-	Gonorrhoea confirmation
FTD-19	(32) 10921734; (64) 10921735	-	-	Genital ulcer
FTD-20.1	(32) 10921736; (64) 10921737	FTIyo-20.1	(32H) 11373637; (32L) 11374053 (64H) 11373638; (64L) 11374054	Stool parasites
FTD-21.1	(32) 10921738; (64) 10921739	FTIyo-21.1	(32H) 11374057; (32L) 11374059 (64H) 11374058; (64L) 11374060	FLU
FTD-23	(32) 10921740; (64) 10921741	FTIyo-23	(32H) 10734535; (32L) 11373649 (64H) 10734536; (64L) 11373650	EPA
FTD-24	(32) 10921742; (64) 10921743	-	-	C. difficile
FTD-27	(32) 10921746; (64) 10921747	-	-	Pneumocystis jirovecii
FTD-28	(32) 10921748; (64) 10921749	FTIyo-28	(32H) 10734533; (32L) 11373665 (64H) 10734534; (64L) 11373666	Bacterial meningitis
FTD-29.1	(32) 10921750; (64) 10921751	-	-	Bacterial pneumonia_ CAP
FTD-30	(32) 10921752; (64) 10921753	-	-	Bacterial pneumonia_ HAP
FTD-31.1	(32) 10921754; (64) 10921755	-	-	Bordetella
FTD-32.1	(32) 10921756; (64) 10921757	-	-	Neonatal sepsis
FTD-33.1	(32) 10921758; (64) 10921759	FTIyo-33.1	(32H) 11373693; (32L) 11373695 (64H) 11373694; (64L) 11373696	Urethritis basic
FTD-34.1	(32) 10921760; (64) 10921761	-	-	Neonatal meningitis
-	-	FTIyo-35	(32H) 11373707; (32L) 11373709 (64H) 11373708; (64L) 11373710	Enteric fever
FTD-36	(32) 10921762; (64) 10921763	-	-	Tropical fever core
FTD-37	(32) 10921764; (64) 10921765	-	-	Tropical fever Africa
FTD-38	(32) 10921766; (64) 10921767	-	-	Tropical fever Asia
FTD-39	(32) 10921768; (64) 10921769	FTIyo-39	(32H) 11373731; (32L) 11373733 (64H) 11373732; (64L) 11373734	Malaria
FTD-40	(32) 10921770; (64) 10921771	-	-	Malaria differentiation
FTD-42.1	(32) 10921774; (64) 10921775	FTIyo-42.1	(32H) 11373743; (32L) 11373745 (64H) 11373744; (64L) 11373746	Urethritis plus
FTD-43	(32) 10921776; (64) 10921777	FTIyo-43	(32H) 11373749; (32L) 11373751 (64H) 11373750; (64L) 11373752	Dengue / Chik
FTD-44	(32) 10921778; (64) 10921779	-	-	Dengue differentiation
FTD-45	(32) 10921780; (64) 10921781	FTIyo-45	(32H) 10734541; (32L) 11373761 (64H) 10734542; (64L) 11373762	Noro
FTD-46	(32) 10921782; (64) 10921783	-	-	Measles

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FTD-48.1	(32) 10921784; (64) 10921785	FTIyo-48.1	(32H) 10734537; (32L) 11373771 (64H) 10734538; (64L) 11373772	FLU/HRSV
FTD-50.1	(32) 10921786; (64) 10921787	FTIyo-50.1	(32H) 10734539; (32L) 11373775 (64H) 10734540; (64L) 11373776	MERS-CoV
FTD-52.1	(32) 10921788; (64) 10921789	-	-	STD9
FTD-53.1	(32) 10921790; (64) 10921791	-	-	Atypical CAP
FTD-55.1	(32) 10921794; (64) 10921795	-	-	BKV
FTD-56.1	(32) 10921796; (64) 10921797	FTIyo-56.1	(32H) 11373803; (32L) 11373805 (64H) 11373804; (64L) 11373806	HCoV
FTD-57	(32) 10921798; (64) 10921799	-	-	Internal Control EAV
FTD-60.4	(32) 10921800; (64) 10921801	-	-	Neuro 9
FTD-62	(32) 10921802; (64) 10921803	-	-	Flu differentiation
FTD-63.1	(32) 10921804; (64) 10921805	-	-	HAdV/HMPV/HBoV
FTD-65.2	(32) 10921806; (64) 10921807	FTIyo-65.2	(32H) 11373833; (32L) 11373835 (64H) 11373834; (64L) 11373836	HPIV
FTD-66	(32) 10921808; (64) 10921809	-	-	SPn/Staph/MC/Hi
FTD-67.1	(32) 10734529; (64) 10734530	-	-	Hepatitis E RNA
FTD-69	(32) 11306494; (64) 11306495	-	-	CCHFV
FTD-71	(32) 10921811; (64) 10921812	-	-	Ebola
FTD-73	(32) 10921815; (64) 10921816	-	-	Endogenous control
FTD-74	(32) 11373875; (64) 11373876	-	-	Epstein-Barr virus
FTD-75	(32) 11306496; (64) 11306497	-	-	Herpes simplex virus
FTD-77	(32) 11306498; (64) 11306499	-	-	Zika virus
FTD-78	(32) 11306500; (64) 11306501	-	-	Legionella
FTD-82	(32) 11306502; (64) 11306503	-	-	West Nile virus
FTD-84	(32) 10734553; (64) 10734554	-	-	Zika/Dengue/Chik
-	-	FTIyo-86	(32H) 11373915; (32L) 11373917 (64H) 11373916; (64L) 11373918	Respiratory pathogens 16
FTD-90	(32) 11382055; (64) 11382056	-	-	HPV High Risk

- : Not existing

Action to be taken by distributors

1. Quarantine the kits remaining in your stock and immediately stop shipment of FTD products to your end-users.
2. Forward this Field Safety Notification to all your customers who may be impacted.
3. Complete Annex 1 "EFFECTIVENESS CHECK_DISTRIBUTOR" and return it to the address on the bottom of the page by the **6th of January, 2020**.

Actions to be taken by the user:

1. Discontinue the use of any kits you may still have during the time of internal investigation.
2. Quarantine the kits that you may have remaining in your stock.
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 and return Annex 2, "EFFECTIVENESS CHECK_END-USERS", no later than the **20th of January, 2020** to your local distributor or FTD representative.

Currently, the issue remains under investigation at FTD. Additional information or updates will be provided as they become available.

As an integral part of the Siemens Healthineers family, Fast Track Diagnostics is fully committed to compliance with all applicable laws and regulations.

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We apologize for the inconvenience and kindly ask for your understanding and patience while we work to resolve this issue.

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

Annex 1 FSN-FA-2019-22, EFFECTIVENESS CHECK_DISTRIBUTOR

Unsupported Performance Claims for FTD CE-IVD kits.

This response form is to confirm receipt of the enclosed Fast Track Diagnostics Urgent Field Safety Notification FSN-FA-2019-22, from December 2019, regarding “Unsupported Performance Claims for FTD CE-IVD kits.”. 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 stopped distributing FTD CE-IVD products, and forwarded this FSN to all my impacted end-users Yes No

Quarantine attestation	
Product Description, Lot number	Number of kits quarantined

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.

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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-2019-22 Yes No

2. I confirm that I took appropriate action concerning all the FTD CE-IVD kits in my stock Yes No

Quarantine attestation	
Product Description, Lot number	Number of kits quarantined

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.