
Fast Track DIAGNOSTICS
A Siemens Healthineers Company

Field Safety Notification

Follow-up FSN-FA-2019-22
January 2020

All Fast Track Diagnostics CE-IVD kits [excluding FTD-2.1] Unsupported Performance Claims

---

Dear customers,

This is a follow-up to the Field Safety Notification in relation to our Field Safety Corrective Action FA-2019-22, issued in December 2019 for Fast Track Diagnostics (FTD) CE labelled kits for In-Vitro Diagnostic (CE-IVD) use. In that Field Action, we had indicated that following an internal investigation, additional notifications would be issued to communicate important information regarding any confirmed product performance or patient safety issues.

For details of affected devices (Product Name/Catalogue No./Siemens Material Number), please see Table 1 and Table 2 in Annex 1 of this Notification.

Table Number	Content
Table 1	List of kits that will be permanently discontinued
Table 2	List of kits for which the Instruction for Use will be updated with new claims

We are writing to inform you that the initial investigation has confirmed that for identified products (see Table 1 and Table 2 in Annex 1 of this Notification), various performance claims listed in the current Instructions for Use will not be met (i.e. sensitivity, specificity, LoD, etc.). This creates the potential for increased instances of erroneous results (false positives, false negatives, etc.) and confirms a previously unidentified risk to patient health, starting with the date when these kits were first made available, as stated in Table 1 and Table 2 in Annex 1 of this Notification.

Given the above, FTD is permanently discontinuing the products listed in Table 1. Please refer to the information below for further instructions on these kits.

We are planning to update the performance claims and the instructions for use for kits listed in Table 2. You will receive individual Field Actions outlining the previous product performance discrepancies and instructions for accessing the updated Instructions for Use containing any revisions to the product's previous claims. Field Action FA-2019-19 dated December 2019 was issued in order to communicate the updated instructions for use and product performance claims for FTD Respiratory Pathogens 21.

Once again, we apologize for the inconvenience this situation may cause and kindly ask for your understanding and patience while we work to reintroduce the remaining seven (7) kits.

Risk to Health

Due to insufficient validation and verification data for all IVD kits mentioned in Table 1 and Table 2, there is a possibility that erroneous results (false positive and false negative) have been generated with these kits, starting with the date when they first became available. Depending on the pathogen, these erroneous results may have impacted patient diagnosis and/or management plan.

Fast Track DIAGNOSTICS
A Siemens Healthineers Company

Field Safety Notification

Follow-up FSN-FA-2019-22
January 2020

All Fast Track Diagnostics CE-IVD kits [excluding FTD-2.1] Unsupported Performance Claims

Actions to be taken by distributors

1. Please refer to Table 1 to have an overview of the kits for which the performance claims will not be updated. For those kits, please destroy remaining stock.
2. Please refer to Table 2 to have an overview of the kits for which the Instruction for Use will be updated. Please quarantine the stock of those kits you may have.
3. Forward this Field Safety Notification to all your customers who may be impacted.
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 2 "EFFECTIVENESS CHECK_DISTRIBUTOR" and return it to the address on the bottom of the page by the **5th of February 2020**.

Actions to be taken by the users:

1. For the kits listed in Table 1 and Table 2, 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.
2. 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 and Table 2. Results may be confirmed with an alternative validated test.
3. Discontinue the use of any IVD kits listed in Table 1 and Table 2 you may still have during the time of internal investigation.
4. Please refer to Table 1 to have an overview of the kits for which the performance claims will not be updated. For those kits, please destroy remaining stock.
5. Please refer to Table 2 to have an overview of the kits for which the Instruction for Use will be updated. Please quarantine the stock of those kits you may have until their claims are updated and a new IFU is available for further use.
6. 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
7. Complete and return Annex 3, "EFFECTIVENESS CHECK_END-USERS", no later than the **14th of February 2020** to your local distributor or FTD representative.

This will serve as your final instruction for all kits (listed in Table 1) that will not be reintroduced from the current ship-hold as IVD compliant.

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
or via the following telephone number: +352 281 098-215.

All Fast Track Diagnostics CE-IVD kits [excluding FTD-2.1] Unsupported Performance Claims

Annex 1: Tables of impacted kits

Table 1: List of kits that will be permanently discontinued

	FTD liquid			FTlyo		
Product Name	**FTD Cat n°**	**Siemens Material No.**	**Available since**	**FTD cat. n°**	**Siemens Material No.**	**Available since**
FTD ACE	FTD-1.1	(32) 10921700; (64) 10921701	12/2011	-	-	-
FTlyo Respiratory pathogens 21	N/A	See Table 2		FTlyo-2	(32H) 10734543; (32L) 11373557 (64H) 10734544; (64L) 11373558	01/2017
FTD Respiratory pathogens 21 plus	FTD-2+.1	(32) 10921704; (64) 10921705	12/2011	FTlyo-2+.1	(32H) 11373545; (32L) 11373547 (64H) 11373546; (64L) 11373548	03/2018
FTD Respiratory pathogens 33	FTD-2P.3	(32) 10921706; (64) 10921707	12/2011	FTlyo-2P.3	(32H) 11373551; (32L) 11373553 (64H) 11373552; (64L) 11373554	03/2018
FTlyo Viral gastroenteritis	N/A	See Table 2		FTlyo-3s	(32H) 10734547; (32L) 11373561 (64H) 10734548; (64L) 11373562	04/2016
FTlyo Vesicular rash	N/A	See Table 2		FTlyo-7	(32H) 10734545; (32L) 11373577 (64H) 10734546; (64L) 11373578	04/2016
FTD Cytomegalovirus	FTD-8.1	(32) 10921716; (64) 10921717	12/2011	-	-	-
FTD Dermatophytes	FTD-9.1	(32) 10921718; (64) 10921719	02/2011	-	-	-
FTD Fever and rash	FTD-10.3	(32) 10921720; (64) 10921721	02/2011	-	-	-
FTD Vaginal swab	FTD-12.1	(32) 10921722; (64) 10921723	11/2011	-	-	-
FTlyo Viral meningitis	N/A	See Table 2		FTlyo-13	(32H) 10734549; (32L) 11373605 (64H) 10734550; (64L) 11373606	03/2017
FTlyo Bacterial gastroenteritis	N/A	See Table 2		FTlyo-14.1	(32H) 10734531; (32L) 11373609 (64H) 10734532; (64L) 11373610	04/2017
FTD Eye	FTD-15.1	(32) 10921728; (64) 10921729	12/2011	-	-	-
FTD Mumps	FTD-16	(32) 10921730; (64) 10921731	02/2011	-	-	-
FTD Gonorrhoea confirmation	FTD-17	(32) 10921732; (64) 10921733	06/2008	-	-	-
FTD Genital ulcer	FTD-19	(32) 10921734; (64) 10921735	10/2010	-	-	-
FTlyo Stool parasites	N/A	See Table 2		FTlyo-20.1	(32H) 11373637; (32L) 11374053 (64H) 11373638; (64L) 11374054	06/2018
FTD FLU	FTD-21.1	(32) 10921738; (64) 10921739	08/2009	FTlyo-21.1	(32H) 11374057; (32L) 11374059 (64H) 11374058; (64L) 11374060	01/2018
FTD EPA	FTD-23	(32) 10921740; (64) 10921741	02/2011	FTlyo-23	(32H) 10734535; (32L) 11373649 (64H) 10734536; (64L) 11373650	03/2017
FTD C. difficile	FTD-24	(32) 10921742; (64) 10921743	12/2012	-	-	-
FTD Pneumocystis jirovecii	FTD-27	(32) 10921746; (64) 10921747	05/2013	-	-	-
FTD Bacterial meningitis	FTD-28	(32) 10921748; (64) 10921749	03/2012	FTlyo-28	(32H) 10734533; (32L) 11373665 (64H) 10734534; (64L) 11373666	04/2016
FTD Bacterial pneumonia_ CAP	FTD-29.1	(32) 10921750; (64) 10921751	01/2013	-	-	-
FTD Bacterial pneumonia_ HAP	FTD-30	(32) 10921752; (64) 10921753	09/2012	-	-	-
FTD Bordetella	FTD-31.1	(32) 10921754; (64) 10921755	09/2012	-	-	-
FTD Neonatal sepsis	FTD-32.1	(32) 10921756; (64) 10921757	04/2013	-	-	-

Fast Track DIAGNOSTICS
A Siemens Healthineers Company

Field Safety Notification

Follow-up FSN-FA-2019-22
January 2020

All Fast Track Diagnostics CE-IVD kits [excluding FTD-2.1] Unsupported Performance Claims

	FTD liquid			FTlyo		
Product Name	**FTD Cat n°**	**Siemens Material No.**	**Available since**	**FTD cat. n°**	**Siemens Material No.**	**Available since**
FTlyo Urethritis basic	N/A	See Table 2		FTlyo-33.1	(32H) 11373693; (32L) 11373695 (64H) 11373694; (64L) 11373696	03/2018
FTD Neonatal meningitis	FTD-34.1	(32) 10921760; (64) 10921761	09/2012	-	-	-
FTlyo Enteric fever	-	-	-	FTlyo-35	(32H) 11373707; (32L) 11373709 (64H) 11373708; (64L) 11373710	08/2017
FTD Tropical fever core	FTD-36	(32) 10921762; (64) 10921763	12/2012	-	-	-
FTD Tropical fever Africa	FTD-37	(32) 10921764; (64) 10921765	12/2012	-	-	-
FTD Tropical fever Asia	FTD-38	(32) 10921766; (64) 10921767	12/2012	-	-	-
FTD Malaria	FTD-39	(32) 10921768; (64) 10921769	10/2012	FTlyo-39	(32H) 11373731; (32L) 11373733 (64H) 11373732; (64L) 11373734	06/2018
FTD Malaria differentiation	FTD-40	(32) 10921770; (64) 10921771	09/2012	-	-	-
FTD Urethritis plus	FTD-42.1	(32) 10921774; (64) 10921775	03/2013	FTlyo-42.1	(32H) 11373743; (32L) 11373745 (64H) 11373744; (64L) 11373746	05/2018
FTD Dengue / Chik	FTD-43	(32) 10921776; (64) 10921777	10/2012	FTlyo-43	(32H) 11373749; (32L) 11373751 (64H) 11373750; (64L) 11373752	06/2018
FTD Dengue differentiation	FTD-44	(32) 10921778; (64) 10921779	10/2012	-	-	-
FTD Noro	FTD-45	(32) 10921780; (64) 10921781	09/2012	FTlyo-45	(32H) 10734541; (32L) 11373761 (64H) 10734542; (64L) 11373762	04/2016
FTD Measles	FTD-46	(32) 10921782; (64) 10921783	10/2012	-	-	-
FTlyo FLU/HRSV	N/A	See Table 2		FTlyo-48.1	(32H) 10734537; (32L) 11373771 (64H) 10734538; (64L) 11373772	03/2017
FTD MERS-CoV	FTD-50.1	(32) 10921786; (64) 10921787	05/2013	FTlyo-50.1	(32H) 10734539; (32L) 11373775 (64H) 10734540; (64L) 11373776	04/2016
FTD STD9	FTD-52.1	(32) 10921788; (64) 10921789	04/2013	-	-	-
FTD Atypical CAP	FTD-53.1	(32) 10921790; (64) 10921791	03/2013	-	-	-
FTD BKV	FTD-55.1	(32) 10921794; (64) 10921795	10/2013	-	-	-
FTD HCoV	FTD-56.1	(32) 10921796; (64) 10921797	03/2013	FTlyo-56.1	(32H) 11373803; (32L) 11373805 (64H) 11373804; (64L) 11373806	01/2018
FTD Internal Control EAV	FTD-57	(32) 10921798; (64) 10921799	03/2013	-	-	-
FTD Neuro 9	FTD-60.4	(32) 10921800; (64) 10921801	05/2013	-	-	-
FTD Flu differentiation	FTD-62	(32) 10921802; (64) 10921803	12/2013	-	-	-
FTD HAdV/HMPV/HBoV	FTD-63.1	(32) 10921804; (64) 10921805	08/2013	-	-	-
FTD HPIV	FTD-65.2	(32) 10921806; (64) 10921807	12/2014	FTlyo-65.2	(32H) 11373833; (32L) 11373835 (64H) 11373834; (64L) 11373836	01/2018

All Fast Track Diagnostics CE-IVD kits [excluding FTD-2.1] Unsupported Performance Claims

	FTD liquid			FTlyo		
Product Name	**FTD Cat n°**	**Siemens Material No.**	**Available since**	**FTD cat. n°**	**Siemens Material No.**	**Available since**
FTD SPn/Staph/MC/HI	FTD-66	(32) 10921808; (64) 10921809	10/2013	-	-	-
FTD Hepatitis E RNA	FTD-67.1	(32) 10734529; (64) 10734530	09/2015	-	-	-
FTD CCHFV	FTD-69	(32) 11306494; (64) 11306495	09/2015	-	-	-
FTD Ebola	FTD-71	(32) 10921811; (64) 10921812	12/2014	-	-	-
FTD Endogenous control	FTD-73	(32) 10921815; (64) 10921816	09/2016	-	-	-
FTD Epstein-Barr virus	FTD-74	(32) 11373875; (64) 11373876	04/2017	-	-	-
FTD Herpes simplex virus	FTD-75	(32) 11306496; (64) 11306497	09/2016	-	-	-
FTD Zika virus	FTD-77	(32) 11306498; (64) 11306499	06/2017	-	-	-
FTD Legionella	FTD-78	(32) 11306500; (64) 11306501	09/2016	-	-	-
FTD West Nile virus	FTD-82	(32) 11306502; (64) 11306503	09/2016	-	-	-
FTD Zika/Dengue/Chik	FTD-84	(32) 10734553; (64) 10734554	09/2016	-	-	-
FTlyo Respiratory pathogens 16	-	-	-	FTlyo-86	(32H) 11373915; (32L) 11373917 (64H) 11373916; (64L) 11373918	10/52017
FTD HPV High Risk	FTD-90	(32) 11382055; (64) 11382056	03/2018	-	-	-

'-': Not existing

Table 2: List of kits for which the Instruction for Use will be updated with new claims

Product name	FTD Cat n°	Siemens Material No.	Available since
FTD Respiratory pathogens 21*	FTD-2.1*	(32) 10921702*; (64) 10921703*	12/2019
FTD Viral gastroenteritis	FTD-3	(32) 10921708; (64) 10921709	02/2007
FTD Vesicular rash	FTD-7	(32) 10921714; (64) 10921715	02/2007
FTD Viral meningitis	FTD-13	(32) 10921724; (64) 10921725	04/2009
FTD Bacterial gastroenteritis	FTD-14.1	(32) 10921726; (64) 10921727	02/2012
FTD Stool parasites	FTD-20.1	(32) 10921736; (64) 10921737	02/2011
FTD Urethritis basic	FTD-33.1	(32) 10921758; (64) 10921759	02/2012
FTD FLU/HRSV	FTD-48.1	(32) 10921784; (64) 10921785	11/2012

*IFU already updated. Please refer to FSN-FA-2019-19.

Annex 2 Follow-up FSN-FA-2019-22, EFFECTIVENESS CHECK_DISTRIBUTOR

Unsupported Performance Claims

This response form is to confirm receipt of the enclosed Fast Track Diagnostics Urgent Field Safety Notification: Follow-up FSN-FA-2019-22, from January 2020, regarding "Unsupported Performance Claims". 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 **5th of February 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 taken appropriate actions and forwarded this FSN to all my impacted end-users	Yes ☐	No ☐

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

Annex 3 Follow-up FSN-FA-2019-22, EFFECTIVENESS CHECK_END-USERS

Unsupported Performance Claims

This response form is to confirm receipt of the enclosed Fast Track Diagnostics Urgent Field Safety Notification Follow-up FSN-FA-2019-22, from January 2020, regarding "Unsupported Performance Claims". Please read each statement and indicate the appropriate answer.

Email this completed form to Fast Track Diagnostics at the local distributor or FTD representative by the **14th of February 2020.**

1. I confirm that I have read and understood the content of the follow-up FSN-FA-2019-22. Yes ☐ No ☐
2. I confirm that I took appropriate action concerning all the CE-IVD kits in my stock Yes ☐ No ☐

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 email to your local distributor or FTD representative.

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