

**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

| <b>Product Name</b> | <b>Catalogue Number</b> | <b>Lot Number</b> | <b>1<sup>st</sup> Distribution Date (DD/MM/YYYY)</b> |
|---------------------|-------------------------|-------------------|--|
| 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 As a result, the CE marks for these products are no longer valid and our product labeling is not compliant with the IVDD.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<br>(64H) 10734544; (64L) 11373558 | Respiratory pathogens 21      |
| FTD-2+.1   | (32) 10921704; (64) 10921705 | FTIyo-2+.1  | (32H) 11373545; (32L) 11373547<br>(64H) 11373546; (64L) 11373548 | Respiratory pathogens 21 plus |
| FTD-2P.3   | (32) 10921706; (64) 10921707 | FTIyo-2P.3  | (32H) 11373551; (32L) 11373553<br>(64H) 11373552; (64L) 11373554 | Respiratory pathogens 33      |
| FTD-3      | (32) 10921708; (64) 10921709 | FTIyo-3s    | (32H) 10734547; (32L) 11373561<br>(64H) 10734548; (64L) 11373562 | Viral gastroenteritis         |
| FTD-7      | (32) 10921714; (64) 10921715 | FTIyo-7     | (32H) 10734545; (32L) 11373577<br>(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<br>(64H) 10734550; (64L) 11373606 | Viral meningitis              |
| FTD-14.1   | (32) 10921726; (64) 10921727 | FTIyo-14.1  | (32H) 10734531; (32L) 11373609<br>(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<br>(64H) 11373638; (64L) 11374054 | Stool parasites               |
| FTD-21.1   | (32) 10921738; (64) 10921739 | FTIyo-21.1  | (32H) 11374057; (32L) 11374059<br>(64H) 11374058; (64L) 11374060 | FLU                           |
| FTD-23     | (32) 10921740; (64) 10921741 | FTIyo-23    | (32H) 10734535; (32L) 11373649<br>(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<br>(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<br>(64H) 11373694; (64L) 11373696 | Urethritis basic              |
| FTD-34.1   | (32) 10921760; (64) 10921761 | -           | -  | Neonatal meningitis           |
| -          | -                            | FTIyo-35    | (32H) 11373707; (32L) 11373709<br>(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<br>(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<br>(64H) 11373744; (64L) 11373746 | Urethritis plus               |
| FTD-43     | (32) 10921776; (64) 10921777 | FTIyo-43    | (32H) 11373749; (32L) 11373751<br>(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<br>(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<br>(64H) 10734538; (64L) 11373772 | FLU/HRSV                 |
| FTD-50.1 | (32) 10921786; (64) 10921787 | FTIyo-50.1 | (32H) 10734539; (32L) 11373775<br>(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<br>(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<br>(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<br>(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 **6<sup>th</sup> 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](mailto:support-ftd.team@siemens-healthineers.com)
4. Complete and return Annex 2, "EFFECTIVENESS CHECK\_END-USERS", no later than the **20<sup>th</sup> 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](mailto: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 **6<sup>th</sup> 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](mailto:vigilance-ftd.team@siemens-healthineers.com)  
 If you have any questions, contact a Fast Track Diagnostics support representative.

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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 **20<sup>th</sup> 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.