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FSN-FA-2019-22 December 2019

Field Safety Notification

### 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 As a result, the CE marks for these products are no longer valid and our product labeling is not compliant with the IVDD.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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FSN-FA-2019-22 December 2019

**Field Safety Notification** 

## All FTD CE-IVD kits

## **Unsupported Performance Claims for FTD CE-IVD kits.**

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

FTD Cat		FTD liquid		FTIyo	
FTD-2   (32) 10921702; (64) 10921703   FTIyo-2   (32H) 10734543; (32L) 11373557   Sepiratory pathogens 21   FTIy-2+1   (32) 10921704; (64) 10921705   FTIyo-3   (32H) 11373545; (32L) 11373545   Sepiratory pathogens 21   FTIy-2-1   (32H) 11373545; (32L) 11373545   Sepiratory pathogens 21   FTIy-2-1   (32H) 11373545; (32L) 11373545   Puls   Puls   Sepiratory pathogens 21   Puls	n°	SMN n°		SMN n°	Name of the kit
FTD-21	FTD-1.1	(32) 10921700; (64) 10921701	-	-	
FTD-2P.3   (32) 10921706; (64) 10921707   FTIyo-3   (32) 119736546; (64) 11973555; (32) 11373555   (32) 11973555   (32) 11973555   (32) 11973555   (32) 11973555   (32) 11973555   (32) 11973555   (32) 11973555   (32) 11973555   (32) 11973555   (32) 11973555   (32) 11973556   (32) 11973556   (32) 10921714; (64) 10921715   FTIyo-7   (32) 10921714; (64) 10921717   FTIyo-7   (32) 10921716; (64) 10921717   (64) 10921717   (64) 10921717   (64) 10921719   Dermatophytes   FTD-10.3   (32) 10921726; (64) 10921729   Dermatophytes   FTD-10.3   (32) 10921726; (64) 10921723   FTIyo-13   (32) 10921724; (64) 10921725   FTIyo-13   (32) 10921724; (64) 10921725   FTIyo-14.1   (32) 10921726; (64) 10921727   FTIyo-14.1   (32) 10921726; (64) 10921727   FTIyo-14.1   (32) 10921728; (64) 10921731   Dermatophytes   FTD-16   (32) 10921730; (64) 10921731   Dermatophytes   FTD-17   (32) 10921732; (64) 10921733   Dermatophytes   FTD-18   (32) 10921732; (64) 10921733   Dermatophytes   FTD-19   (32) 10921732; (64) 10921733   Dermatophytes   FTD-19   (32) 10921732; (64) 10921733   Dermatophytes   FTD-19   (32) 10921733; (64) 10921733   Dermatophytes   FTD-19   (32) 10921732; (64) 10921733   Dermatophytes   FTD-19   (32) 10921733; (64) 10921733   Dermatophytes   FTD-19   (32) 10921734; (64) 10921735   Dermatophytes   FTD-20.1   (32) 10921738; (64) 10921735   Dermatophytes   FTD-20.1   (32) 10921738; (64) 10921735   Dermatophytes   FTD-21   (32) 10921738; (64) 10921735   Dermatophytes   FTD-22   (32) 10921738; (64) 10921735   Dermatophytes   FTD-23   (32) 10921740; (64) 10921743   Dermatophytes   FTD-24   (32) 10921746; (64) 10921745   Dermatophytes   FTD-25   (32) 10921746; (64) 10921745   Dermatophytes   Dermatop		(32) 10921702; (64) 10921703	FTlyo-2		Respiratory pathogens 21
FTD-2P.3   (32) 10921706; (64) 10921707   FTIyo-3P.3   (32H) 11373551; (32L) 11373551   (32L) 11373554   FTD-3   (32) 10921718; (64) 10921715   FTIyo-7   (32H) 10734545; (32L) 11373576   (32H) 10734545; (32L) 11373577   Vesicular rash   (32L) 10921716; (64) 10921717	FTD-2+.1		FTlyo-2+.1		
FTD-3	FTD-2P.3	(32) 10921706; (64) 10921707	FTlyo- 2P.3	(32H) 11373551; (32L) 11373553	Respiratory pathogens 33
FTD-7	FTD-3	(32) 10921708; (64) 10921709		(32H) 10734547; (32L) 11373561	Viral gastroenteritis
FTD-9.1	FTD-7	(32) 10921714; (64) 10921715	FTlyo-7	(32H) 10734545; (32L) 11373577	Vesicular rash
FTD-10.3   (32) 10921720; (64) 10921725   -	FTD-8.1	(32) 10921716; (64) 10921717	-	-	Cytomegalovirus
FTD-12.1   (32) 10921722; (64) 10921725   FTIyo-13   (32H) 10734549; (32L) 11373605   FTD-14.1   (32) 10921726; (64) 10921727   FTIyo-14.1   (32H) 10734531; (32L) 11373609   Exterial gastroenteritis   FTD-15.1   (32) 10921730; (64) 10921729   FTD-16.1   (32) 10921730; (64) 10921731   -			-	-	
FTD-13	FTD-10.3	(32) 10921720; (64) 10921721	-	-	
FTD-14.1 (32) 10921726; (64) 10921727 FTlyo-14.1 (32) 10734531; (32L) 11373608 (64H) 10734531; (32L) 11373609 Bacterial gastroenteritis (64H) 10734532; (64L) 11373610 Eye FTD-15.1 (32) 10921732; (64) 10921733			-	-	
FTD-15.1 (32) 10921728; (64) 10921729 -			,	(64H) 10734550; (64L) 11373606	-
FTD-16   (32) 10921730; (64) 10921731   -	FTD-14.1	(32) 10921726; (64) 10921727	FTlyo-14.1		Bacterial gastroenteritis
FTD-17	FTD-15.1	(32) 10921728; (64) 10921729	-	-	Eye
FTD-19 (32) 10921736; (64) 10921737 FTIyo-20.1 (32H) 11373637; (32L) 11374053 Stool parasites  FTD-20.1 (32) 10921736; (64) 10921739 FTIyo-20.1 (32H) 11373638; (64L) 11374054  FTD-21.1 (32) 10921740; (64) 10921741 FTIyo-21.1 (32H) 11374058; (64L) 11374050  FTD-23 (32) 10921742; (64) 10921741 FTIyo-23 (32H) 10734535; (32L) 11373649 EPA  FTD-24 (32) 10921742; (64) 10921747 - Pneumocystis jirovecii  FTD-27 (32) 10921748; (64) 10921747 - Pneumocystis jirovecii  FTD-29.1 (32) 10921750; (64) 10921751 - Bacterial pneumonia_ CAP  FTD-30 (32) 10921752; (64) 10921753 - Bacterial pneumonia_ HAP  FTD-31.1 (32) 10921756; (64) 10921757 - Bacterial pneumonia_ HAP  FTD-33.1 (32) 10921756; (64) 10921757 - Neonatal sepsis  FTD-34.1 (32) 10921766; (64) 10921761 - Neonatal sepsis  FTD-34.1 (32) 10921766; (64) 10921765 - Priyo-33.1 (32H) 11373695 (64H) 11373695 (64H) 11373696 (64H) 113737696 (64H) 113737695 (64H) 11373695 (64H) 11373695 (64H) 113737695 (64H) 113737695 (64H) 11373769 (64H) 11373709 (64H) 11373730 (64L) 11373730 (64L) 11373730 (64L) 11373730 (64L) 11373730 (64L) 11373730 (732) 10921766; (64) 10921765 - Tropical fever core FTD-39 (32) 10921766; (64) 10921765 - Tropical fever Asia FTD-39 (32) 10921766; (64) 10921767 - Tropical fever Asia FTD-40 (32) 10921766; (64) 10921767 - Tropical fever Asia FTD-42 (32) 10921766; (64) 10921777 - HIYO-42 (32) 10921776; (64) 10921777 - HIYO-43 (32) 10921776; (64) 10921777 - HIYO-45 (32) 1093474; (64) 10921779 - HIYO-45 (32) 10934780; (64) 10921779 -	FTD-16	(32) 10921730; (64) 10921731	-	-	Mumps
FTD-20.1   (32) 10921736; (64) 10921737   FTIyo-20.1   (32H) 11373637; (32L) 11374053   Stool parasites		(32) 10921732; (64) 10921733	-	-	Gonorrhoea confirmation
FTD-21.1 (32) 10921738; (64) 10921739   FTIyo-21.1 (32H) 11374054   FTD-23 (32) 10921740; (64) 10921741   FTIyo-23 (32H) 10734535; (32L) 11373649   EPA (64H) 10734536; (64H) 10734536; (64H) 11373650   EPA (64H) 10734536; (64L) 11373650   EPA (64H) 10734536; (64L) 11373650   C. difficile   FTD-24 (32) 10921742; (64) 10921747   Pneumocystis jirovecii   FTD-28 (32) 10921748; (64) 10921749   FTIyo-28 (32H) 10734533; (32L) 11373665   Bacterial meningitis   Bacterial pneumonia_ (64H) 10734534; (64L) 11373666   Bacterial pneumonia_ (CAP   FTD-30 (32) 10921750; (64) 10921753   Bacterial pneumonia_ (64H) 10734534; (64L) 11373666   Bacterial pneumonia_ (64H) 10734534; (64L) 11373666   Bacterial pneumonia_ (64H) 10734534; (64L) 11373695   CaP (64H) 10734534; (64L) 11373695   CaP (64H) 10734534; (64L) 11373696   CaP (64H) 11373709   CaP (64H) 11373730   CaP (64H) 11373730   CaP (64H) 11373734   CaP (64H) 11373745   CaP (64H) 11373746   CaP (64H) 11373745   CaP (64H) 11373745   CaP (64H) 11373746   CaP (64H) 1137	FTD-19	(32) 10921734; (64) 10921735	-	-	
FTD-23	FTD-20.1	(32) 10921736; (64) 10921737	FTlyo-20.1		Stool parasites
FTD-23 (32) 10921740; (64) 10921741 FTIyo-23 (32H) 10734535; (32L) 11373649 (64H) 10734536; (64L) 11373650 FTD-24 (32) 10921742; (64) 10921747 - C. difficile FTD-27 (32) 10921748; (64) 10921749 FTIyo-28 (32H) 10734533; (32L) 11373665 FTD-28 (32) 10921750; (64) 10921751 - Bacterial meningitis FTD-30 (32) 10921752; (64) 10921753 - Bacterial pneumonia_ HAP FTD-31.1 (32) 10921754; (64) 10921755 - Bordetella FTD-31.1 (32) 10921756; (64) 10921757 - Bordetella FTD-31.1 (32) 10921758; (64) 10921757 - Neonatal sepsis FTD-33.1 (32) 10921758; (64) 10921759 FTIyo-33.1 (32H) 11373693; (32L) 11373695 FTD-34.1 (32) 10921760; (64) 10921761 - FTD-36 (32) 10921760; (64) 10921761 - FTD-37 (32) 10921760; (64) 10921765 - FTD-38 (32) 10921766; (64) 10921765 - Tropical fever Africa FTD-38 (32) 10921768; (64) 10921767 - Tropical fever Africa FTD-39 (32) 10921768; (64) 10921767 - Tropical fever Africa FTD-39 (32) 10921768; (64) 10921771 - Tropical fever Africa FTD-40 (32) 10921776; (64) 10921771 - Malaria differentiation FTD-42.1 (32) 10921776; (64) 10921771 - Malaria differentiation FTD-42 (32) 10921776; (64) 10921777 FTIyo-42.1 (32H) 11373743; (32L) 11373751 Dengue / Chik FTD-44 (32) 10921776; (64) 10921777 FTIyo-42.1 (32H) 11373743; (32L) 11373751 Dengue / Chik (32H) 11373750; (64L) 11373752 FTD-44 (32) 10921778; (64) 10921777 FTIyo-42.1 (32H) 11373745; (32L) 11373751 Dengue / Chik (32H) 11373750; (64L) 11373750 Noro	FTD-21.1	(32) 10921738; (64) 10921739	FTlyo-21.1		FLU
FTD-24 (32) 10921742; (64) 10921747 - C. difficile FTD-27 (32) 10921746; (64) 10921747 - Pneumocystis jirovecii FTD-28 (32) 10921748; (64) 10921749 FTIyo-28 (32H) 10734533; (32L) 11373665 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 - Bordetella FTD-33.1 (32) 10921758; (64) 10921757 - Neonatal sepsis  FTD-34.1 (32) 10921758; (64) 10921757 - Neonatal sepsis  FTD-34.1 (32) 10921760; (64) 10921761 - Neonatal meningitis  FTD-35 (32) 10921760; (64) 10921761 - Neonatal meningitis  FTD-36 (32) 10921762; (64) 10921763 - Neonatal meningitis  FTD-37 (32) 10921764; (64) 10921765 - Tropical fever Asia  FTD-38 (32) 10921766; (64) 10921767 - Tropical fever Asia  FTD-39 (32) 10921768; (64) 10921767 - Tropical fever Asia  FTD-39 (32) 10921768; (64) 10921770 - Malaria differentiation  FTD-40 (32) 10921770; (64) 10921771 - Malaria differentiation  FTD-41 (32) 10921776; (64) 10921777 - FTIyo-42.1 (32H) 11373749; (32L) 11373745 (32L) 11373751 Dengue / Chik  FTD-44 (32) 10921778; (64) 10921779 - Dengue differentiation  FTD-45 (32) 10921778; (64) 10921779 - Dengue differentiation  FTD-47 (32) 10921778; (64) 10921779 - Dengue differentiation  FTD-48 (32) 10921778; (64) 10921779 - Dengue differentiation  FTD-49 (32) 10921778; (64) 10921779 - Dengue differentiation  FTD-40 (32) 10921778; (64) 10921779 - Dengue differentiation  FTD-41 (32) 10921778; (64) 10921779 - Dengue differentiation  FTD-42 (32) 10921778; (64) 10921779 - Dengue differentiation  FTD-45 (32) 10921778; (64) 10921779 - Dengue differentiation	FTD-23	(32) 10921740; (64) 10921741	FTlyo-23	(32H) 10734535; (32L) 11373649	EPA
FTD-28 (32) 10921748; (64) 10921749 FTlyo-28 (32H) 10734533; (32L) 11373665 (64H) 10734534; (64L) 11373666 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 FTlyo-33.1 (32H) 11373693; (32L) 11373695 (G4H) 11373696 (G4H) 11373696 (G4H) 11373696 (G4H) 11373709; (32L) 11373709 (G4H) 11373709; (32L) 11373730; (32L) 11373730; (32L) 11373730; (32L) 11373730; (32L) 11373733; (32L) 11373733; (32L) 11373733; (32L) 11373733; (32L) 11373733; (32L) 11373734; (32L) 11373734; (32L) 11373734; (32L) 11373734; (32L) 11373745; (32L) 11373751; (32L) 11373751; (32L) 11373761;	FTD-24	(32) 10921742; (64) 10921743	-	-	C. difficile
FTD-29.1 (32) 10921750; (64) 10921751 - Bacterial pneumonia_ CAP   FTD-30 (32) 10921752; (64) 10921753 - Bacterial pneumonia_ HAP   Bordetella   FTD-31.1 (32) 10921754; (64) 10921755 - Neonatal sepsis   FTD-32,1 (32) 10921756; (64) 10921757 - Neonatal sepsis   FTD-33.1 (32) 10921758; (64) 10921759   FTIyo-33.1 (32) 10921758; (64) 10921759   FTIyo-33.1 (32) 10921760; (64) 10921761 - Neonatal meningitis   FTD-34.1 (32) 10921760; (64) 10921761 - Neonatal meningitis   FTD-36 (32) 10921762; (64) 10921763 - FTD-37 (32) 10921764; (64) 10921765 - Tropical fever core   FTD-38 (32) 10921766; (64) 10921765 - Tropical fever Africa   FTD-39 (32) 10921766; (64) 10921767 - Tropical fever Asia   FTD-40 (32) 10921770; (64) 10921771 - Tropical fever Asia   FTD-40 (32) 10921770; (64) 10921771   FTD-42.1 (32) 10921776; (64) 10921775   Tropical fever Asia   FTD-42 (32) 10921776; (64) 10921777   FTIyo-42 (32) 1137374; (64) 11373745   Urethritis plus   FTD-43 (32) 10921776; (64) 10921777   FTIyo-42 (32) 1137374; (64) 11373751   Dengue / Chik   FTD-45 (32) 10921778; (64) 10921779   Dengue differentiation   FTD-45 (32) 10921778; (64) 10921779   FTIyo-45 (32H) 1073454; (32L) 11373761   Dengue differentiation   FTD-45 (32) 10921780; (64) 10921771   Dengue differentiation   FTD-45 (32) 10921778; (64) 10921779   Dengue differentiation   FTD-45 (32) 10921778; (64) 10921779   Dengue differentiation   FTD-45 (32) 10921780; (64) 10921781   FTIyo-45 (32H) 10734541; (32L) 11373761   Noro	FTD-27	(32) 10921746; (64) 10921747	-	-	
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 FTlyo-33.1 (32H) 11373693; (32L) 11373695 Urethritis basic  FTD-34.1 (32) 10921760; (64) 10921761 - Neonatal meningitis  FTD-34.1 (32) 10921762; (64) 10921763 - Neonatal meningitis  FTD-36 (32) 10921762; (64) 10921763 - Tropical fever core  FTD-37 (32) 10921764; (64) 10921765 - Tropical fever Asia  FTD-38 (32) 10921766; (64) 10921767 - Tropical fever Asia  FTD-39 (32) 10921768; (64) 10921769 FTlyo-39 (32H) 11373731; (32L) 11373733 Malaria  FTD-40 (32) 10921770; (64) 10921771 Tropical fever Asia  FTD-42.1 (32) 10921774; (64) 10921775 FTlyo-42.1 (32H) 11373743; (32L) 11373746 Urethritis plus  FTD-43 (32) 10921776; (64) 10921777 FTlyo-42.1 (32H) 11373749; (32L) 11373751 Dengue / Chik  FTD-44 (32) 10921778; (64) 10921779 - Dengue differentiation  FTD-45 (32) 10921778; (64) 10921779 - Dengue differentiation  FTD-45 (32) 10921778; (64) 10921778 FTlyo-45 (32H) 10734541; (32L) 11373761 Noro	FTD-28		FTlyo-28		Bacterial meningitis
FTD-31.1 (32) 10921754; (64) 10921755 - Bordetella FTD-32,1 (32) 10921756; (64) 10921757 - Neonatal sepsis FTD-33.1 (32) 10921758; (64) 10921759 FTlyo-33.1 (32H) 11373693; (32L) 11373695 (11373695) FTD-34.1 (32) 10921760; (64) 10921761 - Neonatal meningitis FTD-34.1 (32) 10921760; (64) 10921761 - Neonatal meningitis 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 FTlyo-39 (32H) 11373731; (32L) 11373733 Malaria FTD-40 (32) 10921770; (64) 10921771 - Malaria differentiation FTD-42.1 (32) 10921776; (64) 10921775 FTlyo-42.1 (32H) 11373745; (32L) 11373745 FTD-43 (32) 10921776; (64) 10921777 FTlyo-42.1 (32H) 11373749; (32L) 11373751 Dengue / Chik FTD-44 (32) 10921778; (64) 10921779 - Dengue differentiation FTD-45 (32) 10921780; (64) 10921779 - Dengue differentiation FTD-45 (32) 10921780; (64) 10921781 FTlyo-45 (32H) 10734541; (32L) 11373761 Noro	FTD-29.1	(32) 10921750; (64) 10921751	-	-	CAP
FTD-32,1 (32) 10921756; (64) 10921757 Neonatal sepsis FTD-33.1 (32) 10921758; (64) 10921759 FTlyo-33.1 (32H) 11373693; (32L) 11373695 Urethritis basic  FTD-34.1 (32) 10921760; (64) 10921761 - Neonatal meningitis  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 FTlyo-39 (32H) 11373731; (32L) 11373733 Malaria  FTD-40 (32) 10921770; (64) 10921771 - Malaria differentiation  FTD-42.1 (32) 10921774; (64) 10921775 FTlyo-42.1 (32H) 11373745; (32L) 11373745  FTD-43 (32) 10921776; (64) 10921777 FTlyo-43 (32H) 11373749; (32L) 11373751 Dengue / Chik  FTD-44 (32) 10921778; (64) 10921779 - Dengue differentiation  FTD-45 (32) 10921778; (64) 10921779 - Dengue differentiation  FTD-45 (32) 10921780; (64) 10921781 FTlyo-45 (32H) 10734541; (32L) 11373761 Noro	FTD-30	(32) 10921752; (64) 10921753	-	-	
FTD-33.1 (32) 10921758; (64) 10921759 FTIyo-33.1 (32H) 11373693; (32L) 11373695 (64H) 11373696 FTD-34.1 (32) 10921760; (64) 10921761		(32) 10921754; (64) 10921755	-	-	
FTD-34.1   (32) 10921760; (64) 10921761   -			-	-	
- 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 Malaria  FTD-40 (32) 10921770; (64) 10921771 - Malaria differentiation FTD-42.1 (32) 10921774; (64) 10921775 FTIyo-42.1 (32H) 11373745 (32L) 11373745 FTD-43 (32) 10921776; (64) 10921777 FTIyo-43 (32H) 11373749; (32L) 11373751 Dengue / Chik  FTD-44 (32) 10921778; (64) 10921779 - Dengue differentiation  FTD-45 (32) 10921780; (64) 10921781 FTIyo-45 (32H) 10734541; (32L) 11373761 Noro	FTD-33.1	(32) 10921758; (64) 10921759	FTlyo-33.1		
FTD-36   (32) 10921762; (64) 10921763   -	FTD-34.1	(32) 10921760; (64) 10921761	-	-	
FTD-37         (32) 10921764; (64) 10921765         -         Tropical fever Africa           FTD-38         (32) 10921766; (64) 10921767         -         -         Tropical fever Asia           FTD-39         (32) 10921768; (64) 10921769         FTlyo-39         (32H) 11373731; (32L) 11373733         Malaria           FTD-40         (32) 10921770; (64) 10921771         -         -         Malaria differentiation           FTD-42.1         (32) 10921774; (64) 10921775         FTlyo-42.1         (32H) 11373743; (32L) 11373745         Urethritis plus           FTD-43         (32) 10921776; (64) 10921777         FTlyo-43         (32H) 11373749; (32L) 11373751         Dengue / Chik           FTD-44         (32) 10921778; (64) 10921779         -         Dengue differentiation           FTD-45         (32) 10921780; (64) 10921781         FTlyo-45         (32H) 10734541; (32L) 11373761         Noro	-	-	FTlyo-35	(32H) 11373707; (32L) 11373709 (64H) 11373708; (64L) 11373710	
FTD-38 (32) 10921766; (64) 10921767 - Tropical fever Asia FTD-39 (32) 10921768; (64) 10921769 FTlyo-39 (32H) 11373731; (32L) 11373733 Malaria  FTD-40 (32) 10921770; (64) 10921771 - Malaria differentiation FTD-42.1 (32) 10921774; (64) 10921775 FTlyo-42.1 (32H) 11373743; (32L) 11373745 Urethritis plus  FTD-43 (32) 10921776; (64) 10921777 FTlyo-43 (32H) 11373749; (32L) 11373751 Dengue / Chik  FTD-44 (32) 10921778; (64) 10921779 - Dengue differentiation  FTD-45 (32) 10921780; (64) 10921781 FTlyo-45 (32H) 10734541; (32L) 11373761 Noro			-	-	Tropical fever core
FTD-39 (32) 10921768; (64) 10921769 FTlyo-39 (32H) 11373731; (32L) 11373733 Malaria  FTD-40 (32) 10921770; (64) 10921771 - Malaria differentiation  FTD-42.1 (32) 10921774; (64) 10921775 FTlyo-42.1 (32H) 11373743; (32L) 11373745 Urethritis plus  FTD-43 (32) 10921776; (64) 10921777 FTlyo-43 (32H) 11373749; (32L) 11373751 Dengue / Chik  FTD-44 (32) 10921778; (64) 10921779 - Dengue differentiation  FTD-45 (32) 10921780; (64) 10921781 FTlyo-45 (32H) 10734541; (32L) 11373761 Noro			-	-	Tropical fever Africa
FTD-40   (32) 10921770; (64) 10921771   -			-	-	
FTD-42.1 (32) 10921774; (64) 10921775 FTlyo-42.1 (32H) 11373743; (32L) 11373745 Urethritis plus (64H) 11373744; (64L) 11373746  FTD-43 (32) 10921776; (64) 10921777 FTlyo-43 (32H) 11373749; (32L) 11373751 Dengue / Chik (64H) 11373750; (64L) 11373752  FTD-44 (32) 10921778; (64) 10921779 - Dengue differentiation FTD-45 (32) 10921780; (64) 10921781 FTlyo-45 (32H) 10734541; (32L) 11373761 Noro	FTD-39	(32) 10921768; (64) 10921769	FTlyo-39	, , , , ,	Malaria
FTD-42.1 (32) 10921774; (64) 10921775 FTlyo-42.1 (32H) 11373743; (32L) 11373745 Urethritis plus (64H) 11373744; (64L) 11373746  FTD-43 (32) 10921776; (64) 10921777 FTlyo-43 (32H) 11373749; (32L) 11373751 Dengue / Chik (64H) 11373750; (64L) 11373752  FTD-44 (32) 10921778; (64) 10921779 - Dengue differentiation FTD-45 (32) 10921780; (64) 10921781 FTlyo-45 (32H) 10734541; (32L) 11373761 Noro	FTD-40	(32) 10921770; (64) 10921771	-	-	Malaria differentiation
FTD-43 (32) 10921776; (64) 10921777 FTlyo-43 (32H) 11373749; (32L) 11373751 Dengue / Chik (64H) 11373750; (64L) 11373752 FTD-44 (32) 10921778; (64) 10921779 - Dengue differentiation FTD-45 (32) 10921780; (64) 10921781 FTlyo-45 (32H) 10734541; (32L) 11373761 Noro (64H) 10734542; (64L) 11373762	FTD-42.1	(32) 10921774; (64) 10921775	FTlyo-42.1		Urethritis plus
FTD-44 (32) 10921778; (64) 10921779 Dengue differentiation  FTD-45 (32) 10921780; (64) 10921781 FTlyo-45 (32H) 10734541; (32L) 11373761 Noro (64H) 10734542; (64L) 11373762	FTD-43	(32) 10921776; (64) 10921777	FTlyo-43	(32H) 11373749; (32L) 11373751	Dengue / Chik
FTD-45 (32) 10921780; (64) 10921781 FTlyo-45 (32H) 10734541; (32L) 11373761 Noro (64H) 10734542; (64L) 11373762	FTD-44	(32) 10921778; (64) 10921779	-	-	Dengue differentiation
			FTlyo-45		
	FTD-46	(32) 10921782; (64) 10921783	-	· · · · · · · · · · · · · · · · · · ·	Measles

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# Field Safety Notification

FSN-FA-2019-22 December 2019

Respiratory pathogens 16

HPV High Risk

#### All FTD CE-IVD kits

### **Unsupported Performance Claims for FTD CE-IVD kits.**

(32) 10921784; (64) 10921785 FTD-48.1 FTlyo-48.1 (32H) 10734537; (32L) 11373771 FLU/HRSV (64H) 10734538; (64L) 11373772 FTD-50.1 (32) 10921786; (64) 10921787 FTlyo-50.1 (32H) 10734539; (32L) 11373775 MERS-CoV (64H) 10734540; (64L) 11373776 FTD-52.1 (32) 10921788; (64) 10921789 STD9 (32) 10921790; (64) 10921791 Atypical CAP FTD-53.1 BKV FTD-55.1 (32) 10921794; (64) 10921795 FTD-56.1 (32) 10921796; (64) 10921797 FTlyo-56.1 (32H) 11373803; (32L) 11373805 **HCoV** (64H) 11373804; (64L) 11373806 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 (32) 10921804; (64) 10921805 HAdV/HMPV/HBoV FTD-63.1 FTD-65.2 (32H) 11373833; (32L) 11373835 (32) 10921806; (64) 10921807 FTlyo-65.2 HPIV (64H) 11373834; (64L) 11373836 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 (32) 10921815; (64) 10921816 FTD-73 Endogenous control (32) 11373875; (64) 11373876 FTD-74 Epstein-Barr virus FTD-75 (32) 11306496; (64) 11306497 Herpes simplex virus (32) 11306498; (64) 11306499 FTD-77 Zika virus FTD-78 (32) 11306500; (64) 11306501 Legionella (32) 11306502; (64) 11306503 FTD-82 West Nile virus FTD-84 (32) 10734553; (64) 10734554 Zika/Dengue/Chik

### Action to be taken by distributors

(32) 11382055; (64) 11382056

1. Quarantine the kits remaining in your stock and immediately stop shipment of FTD products to your end-users.

(32H) 11373915; (32L) 11373917

(64H) 11373916; (64L) 11373918

2. Forward this Field Safety Notification to all your customers who may be impacted.

FTIyo-86

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
- 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.

FTD-90 (3

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# Field Safety Notification

FSN-FA-2019-22 December 2019

### All FTD CE-IVD kits

Unsupported Performance Claims for FTD CE-IVD kits.

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: <a href="mailto:vigilance-ftd.team@siemens-healthineers.com">vigilance-ftd.team@siemens-healthineers.com</a>

### 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 le	tter.		
2.I am a distributor of the affected customers received one of the		Yes □	No 🗆
<ol><li>The 2 answers above are yes, stopped distributing FTD CE- forwarded this FSN to all my in</li></ol>	IVD products, and	Yes □	No □
	Quarantine attestation	า	
Product Description, Lot	number	Number o	of kits quarantined
Name of person completing questio	nnaire:		
Title:			
Institution:			
Street:			
City:	State:		
Phone:	Country:		
	Signatu	re and date	

Yes □

No □

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-2019-22, EFFECTIVENESS CHECK\_END-USERS

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 **20**<sup>th</sup> **of January 2020.** 

No □

1. I confirm that I have read and understood the content Yes

	of the FSN-FA-2019-22							
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					
	ne of person completing questionnaire:		-					
Title	):		-					
Inst	itution:		_					
Stre	eet:		-					
City	: State:		_					
Pho	ne: Country:		_					
	2.	المحلوب مراجع والمراجع						
	SIQ	gnature 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.