

FTD-10.2 Fever and rash

**Potentially non-detected measles B3 variant
Recall and replacement of FTD-10.2**

Details on affected product:

Our records indicate that your facility may have received the following products:
FTD Fever and rash, CE IVD (catalogue number FTD-10.2-32 or FTD-10.2-64).

Reason for the Field Safety Notification:

This is a follow-up notification to FSN-FA-2019-01, issued on 22/02/2019. The purpose of this communication is to provide further instructions on actions that customers (both distributors and end users) must take to ensure proper handling of the FTD-10.2 CE IVD kit.

At Fast Track Diagnostics (FTD), a Siemens Healthineers company, we rely on Post Market Surveillance to continuously monitor the safety and effectiveness of our kits, including learning about product performance in the context of new viral strains. On the 06 February 2019, FTD became aware that a new variant of B3 measles virus has been reported in French overseas territories. Subsequent testing revealed that the FTD-10.2 CE IVD kit does not detect this new measles virus B3 variant. In response to this information, FTD issued FSN-FA-2019-01 to immediately inform you about this issue.

Further testing confirmed that FTD-46 CE IVD Measles kit is able to detect the identified new measles virus B3 variant.

Given these results, FTD will be taking the following action to address this issue within the FTD-10.2 CE IVD kit:

- Replace the current FTD-10.2 CE IVD kit with a new version FTD-10.3 CE IVD, which offers detection of all pathogens in current FTD-10.2 CE IVD kits (except for Measles) and combine this kit with a free of charge FTD-46 CE IVD kit.

Please follow the directions below to ensure a prompt replacement of FTD-10.2 CE IVD kits you may have in your possession.

Risk to Health:

False negative results may be reported when using the FTD-10.2 CE IVD for the detection of measles virus, for patients infected with the B3 variant. This may lead to delay diagnosis and treatment for patients infected with measles, False-negative measles results can lead to potential serious, life-threatening effects due to complications of infection and the threat of viral transmission.

Actions to be taken:

I. Destruction of the kits held in inventory

It is **mandatory** to discard all FTD-10.2 CE IVD kits still within your facilities, according to your local regulation. Use the provided Product Replacement Form, see Annex 1 of this FSN, to document the destruction of the FTD-10.2 CE IVD kits. Please note that replacement will only be sent after receiving proof attesting that the FTD-10.2 CE IVD kits held at your facilities have been discarded.

Once completed, please sign the form and send it back to FTD via one of the following channels:

- a. to the following email address: support@fast-trackdiagnostics.com (Preferred option)
- b. via post to the address: Fast Track Diagnostics, Technical Support, 29, rue Henri Koch, L-4354 Esch-sur-Alzette, G.-D de Luxembourg, Europe.
- c. via fax to the following number: +352281098214

II. Replacement of the kit(s)

FTD will replace destroyed products with the following kits:

- FTD-10.3 Fever and rash CE IVD kit
and
- FTD-46 Measles CE IVD kit

This complementary pair of kits is intended to support detection of the same array of analytes originally addressed by the FTD-10.2 Fever and rash CE IVD kit. Please refer to Table 1 for the detailed content of those kits.

Table 1: List of Pathogens Detected by FTD-10.3 CE IVD kit and FTD-46 Measles CE IVD kit

Kit #	Kit name	PPmix	Pathogens	Channel
FTD-10.3	Fever and rash	HHV/B19	HHV6	1 FAM
			B19	3 ROX
			HHV7	4 CY5
		Mea/EV	EV	1 FAM
			IC	4 CY5
FTD-46	Measles	ME	MeV	2 VIC
			IC	3 ROX

Please review your current inventory of the FTD-10.2 CE IVD product to determine your replacement needs and provide this information to Fast Track Diagnostics by 15th March 2019, according to Annex 1, "Product Replacement Form".

Please note that replacement will only be sent after receiving proof attesting that the FTD-10.2 CE IVD kits held in your facilities have been discarded.

If you are a distributor of the affected products, please share this information with your customers as soon as possible, and either consolidate all replacement requirements within your request, or have your customers contact Fast Track Diagnostics directly regarding replacements. This replacement will be free of charge and available for shipment starting on the week of March 18th 2019.

If you have received any complaint or report of illness or adverse events associated with FTD-10.2 CE IVD, immediately contact your FTD Technical support at: support@fast-trackdiagnostics.com.

Please retain this letter with your records and forward the relevant information to those who may have received this product.

If you have any questions, please contact your FTD technical support at: support@fast-trackdiagnostics.com.

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Annex 1, PRODUCT REPLACEMENT FORM

Potentially non-detected measles B3 strains Recall and replacement of FTD-10.2

This form is to be used to attest the destruction of FTD-10.2 CE IVD kits, and request no-charge replacement product for the enclosed Fast Track Diagnostics FSN-FA-2019-01.1, date of 8th March 2019, regarding "Potentially non-detected measles B3 strains, Recall and replacement of FTD-10.2". Please read each statement and indicate the appropriate answer.

Send back this completed and signed form by **15th of March 2019** via one of the channels listed below.

1. Do you currently have any of the noted product(s) on hand? Please check inventories before answering Yes No

2. Can you attest that the FTD-10.2 kits still in your facilities have been destroyed according to the instructions from the FSN-FA-2019-01.1 Yes No

3. Do you need replacement of the destroyed kits (via FTD-10.3 + FTD-46 CE IVD kits) Yes No

If the answer to statement 1 and 2 above is yes, please complete the table A below to indicate the quantity of affected product in your stock and replacement product required.

Table A: FTD-10.2 CE IVD kits discarded	
Product Description, Lot number	Replacement Quantity required

Name of person completing questionnaire: _____

Title: _____

Institution: _____

Street: _____

City: _____ State: _____

Phone: _____ Country: _____

Signature and date

Once completed and signed, please sent this form back to FTD via one of the following channels:

- a. to the following email address: support@fast-trackdiagnostics.com (Preferred option)
- b. via post to the address: Fast Track Diagnostics, Technical Support, 29, rue Henri Koch, L-4354 Esch-sur-Alzette, G.-D de Luxembourg, Europe.
- c. via fax to the following number: +352281098214

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