Fast Track DIAGNOSTICS
A Siemens Healthineers Company

Urgent Field Safety Notice

FSN-FA-2019-04
04th of June 2019

Adaptation of FTD Lyophilized products shelf life after first opening

Details on affected product:
Our records indicate that your facility may have received one of the products mentioned in Table 1.

Table 1: List of products affected by FSN-FA-2019-04

Catalogue number	Product name
FTlyo-2	FTlyo Respiratory pathogens 21
FTlyo-2+.1	FTlyo Respiratory pathogens 21 plus
FTlyo-2P.3	FTlyo Respiratory pathogens 33
FTlyo-13	FTlyo Viral meningitis
FTlyo-21.1	FTlyo FLU
FTlyo-23	FTlyo EPA
FTlyo-43	FTlyo Dengue/Chik
FTlyo-48.1	FTlyo FLU/HRSV
FTlyo-56.1	FTlyo HCoV
FTlyo-65.2	FTlyo HPIV
FTlyo-86	FTlyo Respiratory pathogens 16

Reason for the Field Safety Notification:
The purpose of this communication is to provide you with updated information regarding performance of these kits after first opening of the lyophilized pouches. Please note that closed pouches are not impacted.

As outcomes of newly performed stability studies, FTD has determined the shelf life after the first opening of pouches containing lyophilised mastermix. The current FTlyo manuals contain incorrect information about the shelf life after the first opening. The concerned products and individual shelf life after first opening are listed in the Table 2 below.

Table 2: Shelf life of pouches once opened

Catalogue number	Product name	Shelf life after first opening of pouches
FTlyo-2	FTlyo Respiratory pathogens 21	9 months
FTlyo-2+.1	FTlyo Respiratory pathogens 21 plus	9 months
FTlyo-2P.3	FTlyo Respiratory pathogens 33	9 months
FTlyo-13	FTlyo Viral meningitis	9 months
FTlyo-21.1	FTlyo FLU	3 months
FTlyo-23	FTlyo EPA	9 months
FTlyo-43	FTlyo Dengue/Chik	3 months
FTlyo-48.1	FTlyo FLU/HRSV	3 months
FTlyo-56.1	FTlyo HCoV	9 months
FTlyo-65.2	FTlyo HPIV	3 months
FTlyo-86	FTlyo Respiratory pathogens 16	3 months

Other lyophilized products are not affected and can be used until the expiration date after the first opening of the pouches.

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Risk to Health:
Use of the affected FTlyo products beyond the duration indicated above may impact the stability of the product, possibly leading to a loss of sensitivity for the detection of RNA pathogens (see Table 3 for affected pathogens. As a consequence, the product might not detect low positive samples.

Table 3: List of potentially non-detected pathogens per kit

Catalogue number	Product name	Detection of following pathogens affected
FTlyo-2, FTlyo-2+.1, FTlyo-2P.3	FTlyo Respiratory pathogens 21, FTlyo Respiratory pathogens 21 plus, FTlyo Respiratory pathogens 33	Influenza A virus, Influenza B virus, Influenza A (H1N1) virus (swine lineage), human rhinovirus, human respiratory syncytial viruses (HRSVA and HRSVB), human coronaviruses (HCoV 229E, HCoV HKU1, HCoV OC43 and HCoV NL63), human parainfluenza viruses (HPIV1-4) human metapneumoviruses (HMPVA and B), enteroviruses and human parechoviruses.
FTlyo-13	FTlyo Viral meningitis	Mumps virus, enteroviruses and human parechoviruses.
FTlyo-21.1	FTlyo FLU	All pathogens detected by the product.
FTlyo-23	FTlyo EPA	Enteroviruses and human parechoviruses.
FTlyo-43	FTlyo Dengue/Chik	All pathogens detected by the product.
FTlyo-48.1	FTlyo FLU/HRSV	All pathogens detected by the product.
FTlyo-56.1	FTlyo HCoV	All pathogens detected by the product.
FTlyo-65.2	FTlyo HPIV	All pathogens detected by the product.
FTlyo-86	FTlyo Respiratory pathogens 16	Influenza A virus, Influenza B virus, human rhinovirus, human respiratory syncytial viruses (HRSVA and HRSV B), human coronaviruses (HCoV 229E, HCoV HKU1, HCoV OC43 and HCoV NL63), human parainfluenza viruses (HPIV1-4) and human metapneumoviruses (HMPVA and B).

Actions to be taken by distributors:
Please forward relevant information to your impacted end-users and send us back the annex #1 "Field Correction Effectiveness Check" of this FSN to support@fast-trackdiagnostics.com for the **11th of June 2019.** Please note that closed pouches are not impacted, and no replacement is needed for non-opened kits remaining in your facilities.

Actions to be taken by the user:
For any customers who are using these products, please perform the following steps:

- Please review your inventory for open pouches and refer to the Table 2 above to determine if the kit should be discarded. Should you require replacement kits, please complete the annex #2 below "Product replacement form" and send it back to: support@fast-trackdiagnostics.com for the 18th of June 2019.
- If you suspect that you conducted tests using pouches after the timeline described in Table 2 or see irregularities in your internal QC tests for the pathogens listed in Table 3, please review potentially affected results.

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

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

Fast Track Diagnostics assays are manufactured by Fast Track Diagnostics S.à.r.l. and Fast Track Diagnostics is a registered trademark of Fast Track Diagnostics Ltd.

Given the nature of this urgent safety notice, this notice is being provided in English immediately. Please note that further localization will follow without undue delay.

Annex 1 FSN-FA-2019-04, FIELD CORRECTION EFFECTIVENESS CHECK,

TO BE FILLED BY DISTRIBUTOR

Adaptation of FTD Lyophilized products shelf life after first opening

This response form is to confirm receipt of the enclosed Fast Track Diagnostics Urgent Field Safety Notification FSN-FA-2019-04, dated of 4th of June 2019, regarding "Adaptation of FTD Lyophilized products shelf life after first opening". 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, for the **11th of June 2019**.

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 ☐

If the answer to statement 2 above is yes, please complete the table below.

Communication of FSN-FA-2019-04 to end-users		
Product Name(s)	**Customer(s) Notified**	**Notification Date(s)**

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 support@fast-trackdiagnostics.com. If you have any questions, contact a Fast Track Diagnostics technical support representative.

Annex 2 FSN-FA-2019-04, PRODUCT REPLACEMENT FORM,

TO BE FILLED BY END-USER

Adaptation of FTD Lyophilized products shelf life after first opening

This form is to be used to request no-charge replacement product for the enclosed Fast Track Diagnostics FSN-FA-2019-04, dated of 4th of June 2019, regarding "Adaptation of FTD Lyophilized products shelf life after first opening". 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 for the **18th of June 2019.**

1. Do you currently have any of the noted product(s) on hand? Please check inventories before answering — Yes ☐ No ☐
2. Do you need replacement for expired products or retesting activities — Yes ☐ No ☐

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

Replacement needs	
Product Description, Lot number	**Replacement Quantity required**

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 support@fast-trackdiagnostics.com. If you have any questions, contact a Fast Track Diagnostics technical support representative.