

**Adaptation of FTD Lyophilized products shelf life after first opening- ADDENDUM**

**Dear customer,**

The purpose of this follow-up communication is to provide additional information related to FSN-FA-2019-04 issued earlier this month.

**Details on affected product:**

Please find here below, as per FSN-FA-2019-04, the list of affected products.

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

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

Please note that this FSN is not lot specific, but it applies to all produced batches for the above-mentioned kits.

**Update on the stability data:**

Please note that the stability of the lyophilized product depends on the storage condition of you lyophilised pouches. The Table 2 below contains stability data related to the temperature storage of the pouches.

Table 2: Shelf life of products after first opening, depending of storage conditions.

Catalogue number	Product name	Shelf life after first opening of pouches at 2 to 8°C	Shelf life after first opening of pouches at -30 to -10°C, as stated in manuals
FTIyo-2	FtIyo Respiratory pathogens 21	9 months	12 months
FTIyo-2+.1	FTIyo Respiratory pathogens 21 plus	9 months	12 months
FTIyo-2P.3	FTIyo Respiratory pathogens 33	9 months	12 months
FTIyo-13	FTIyo Viral meningitis	9 months	12 months
FTIyo-21.1	FTIyo FLU	3 months	12 months
FTIyo-23	FTIyo EPA	9 months	12 months
FTIyo-43	FTIyo Dengue/Chik	3 months	12 months
FTIyo-48.1	FTIyo FLU/HRSV	3 months	12 months
FTIyo-56.1	FTIyo HCoV	9 months	12 months
FTIyo-65.2	FTIyo HPIV	3 months	12 months
FTIyo-86	FTIyo Respiratory pathogens 16	3 months	12 months

NOTE: All open and closed pouches should not be used beyond the expiration date written on the kit box.

For the risk assessment, please refer to FSN-FA-2019-04.

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**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 [vigilance@fast-trackdiagnostics.com](mailto:vigilance@fast-trackdiagnostics.com) for the 15th of July 2019.

**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 FTD at: [support@fast-trackdiagnostics.com](mailto:support@fast-trackdiagnostics.com).

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**FIELD CORRECTION EFFECTIVENESS CHECK**

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This response form is to confirm receipt of the enclosed Fast Track Diagnostics Urgent Field Safety Notification FSN-FA-2019-04.1, dated June 2019 regarding “Adaptation of FTD Lyophilized products shelf life after first opening- ADDENDUM”. Please read each statement and indicate the appropriate answer.

Email this completed form to the email address provided at the bottom of this page, by the **15<sup>th</sup> of July 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 products impacted by this FSN Yes  No

If the answer to statement 2 above is yes, please confirm that you forward the relevant information to your impacted customers. Yes  No

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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@fast-trackdiagnostics.com](mailto:vigilance@fast-trackdiagnostics.com). If you have any questions, contact a Fast Track Diagnostics support representative.