
Urgent Field Safety Notice

FSN-20181109

November 2018

FTIyo 2+.1 Respiratory pathogens 21 plus
FTIyo 2P.3 Respiratory pathogens 33
FTIyo 48.1 FLU/HRSV v.2
FTIyo 56.1 HCoV v.1

Incorrect FastFinder™ Suffix in User Manuals

Details on affected devices:

FTIyo 2+.1 Respiratory pathogens 21 plus, user manual “FTIyo 2+.1-32_64-MANUAL-v2-2018_02”

FTIyo 2P.3 Respiratory pathogens 33, user manual “FTIyo 2P.3-32_64-MANUAL-v3-2018_10”

FTIyo 48.1 FLU/HRSV v.2, user manual “FTIyo 48.1 - 32_64 - MANUAL - v2 - 2018_05 EN”

FTIyo 56.1 HCoV v.1, user manual “FTIyo 56.1 - 32_64 - MANUAL - v1 - 2018_01 EN”

Description of the problem:

FTD has become aware that the information contained in the user manuals listed above contains incorrect information regarding the use of FastFinder™. Specifically, the tables entitled “Setting sample, control and detector programming” contained incorrect information regarding the suffixes and final programming of the samples and control for FastFinder™.

If the incorrect suffix appearing in the user manuals is entered into the FastFinder™ software, a partial analysis or no analysis of the plate would be completed by the software, leading to no analysis of the Primer Probe mixes of affected wells. Table 1 summarizes the pathogens that may be absent from analysis when the incorrect suffix is used.

Table 1: Pathogens with Potentially Absent Analysis

Kit Name	Potentially Absent Pathogens
FTIyo 2+.1 Respiratory pathogens 21 plus	Chlamydomphila pneumoniae; Streptococcus pneumoniae, Haemophilus influenzae B and Staphylococcus aureus
FTIyo 2P.3 Respiratory pathogens 33	influenza C virus, Chlamydomphila pneumoniae; Streptococcus pneumoniae; Haemophilus influenzae type B; Staphylococcus aureus; Pneumocystis jirovecii; Moraxella catarrhalis; Bordetella spp.; Klebsiella pneumoniae; Legionella pneumophila/Legionella longbeachae; Salmonella spp. and Haemophilus influenzae.
FTIyo 48.1 FLU/HRSV	All Pathogens
FTIyo 56.1 HCoV	All Pathogens

These instructions were available during the timelines as outlined in Table 2.

Table 2: Timeframe for Incorrect Information

Manual File Name	Timeframe of Availability
FTIyo 2+.1-32_64-MANUAL-v2-2018_02	16.02.2018 to 08.11.2018
FTIyo 2P.3-32_64-MANUAL-v3-2018_10	16.02.2018 to 08.11.2018
FTIyo 48.1 - 32_64 - MANUAL - v2 - 2018_05 EN	28.05.2018 to 08.11.2018
FTIyo 56.1 - 32_64 - MANUAL - v1 - 2018_01 EN	02.01.2018 to 08.11.2018

Risk to Health:

For the kits listed above, pathogens may have been missed in the analysis of a run using FastFinder™ software. In the event that a partial analysis or no analysis occurred, results for pathogens listed in Table 1 would not be reported.

Actions to be taken by the user:

For any customers who are using these products with the FastFinder™ software, please perform the following steps:

- Review results of the affected products that were generated during the respective timeframes listed in Table 2 above. Ensure that analysis was performed on all necessary pathogens, including those listed in Table 1.
For any results where necessary pathogens were missed, run files will need to be re-analysed, either manually or using the correct FastFinder™ suffix. Manual interpretation can be performed using the updated manuals now appearing on the FTD website: <http://www.fast-trackdiagnostics.com/human-line/resources/product-manuals/>. To find the correct suffixes open the Assays page of FastFinder™ by selecting the Assays button on the top left of the screen and go to the Mix Definition nametags section.
- Review any internal procedures where lab technicians are instructed to enter a specific suffix, and ensure they are consistent with FastFinder™ instructions. Update procedures and train personnel, as necessary. Please refer to table 3 for the correct information about the FastFinder™ suffixes. For future determination of those suffixes, please do always refer to the assay definition on FastFinder™ software.

Table 3: Summary of the Fast Finder suffixes for the involved kits:

Kit number	Mastermix denomination	Suffix to insert on FastFinder software
FTIyo 2+.1 Respiratory pathogens 21 plus	RE1	-RE+1
	RE2	-RE+2
	RE3	-RE+3
	RE4	-RE+4
	RE5	-RE+5
	RE6	-RE+6
FTIyo 2P.3 Respiratory pathogens 33	RE1	-RE33.1
	RE2	-RE33.2
	RE3	-RE33.3
	RE4	-RE33.4
	RE5	-RE33.5
	RE6	-RE33.6
	RE7	-RE33.7
	RE8	-RE33.8
FTIyo 48.1 FLU/HRSV	RS1	-FR
FTIyo 56.1 HCoV	COR	-COR

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

We apologize for the inconvenience this situation may cause. If you have any questions, please contact your FTD technical support at: support@fast-trackdiagnostics.com.

FastFinder™ is a registered trademark of UgenTec NV.

Fast Track Diagnostics assays are manufactured by Fast Track Diagnostics Ltd. and Fast Track Diagnostics is a registered trademark of Fast Track Diagnostics Ltd.

FIELD CORRECTION EFFECTIVENESS CHECK

Incorrect FastFinder™ Suffix in User Manuals

This response form is to confirm receipt of the enclosed Fast Track Diagnostics Urgent Field Safety Notification FSN-20181109, dated November 2018 regarding “Incorrect FastFinder™ Suffix in User Manuals”. 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.

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 use FastFinder™ with these products. Yes No

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

Product Name(s)	Customer(s) Notified	Notification Date(s)

Name of person completing questionnaire: _____

Title: _____

Institution: _____

Street: _____

City: _____ State: _____

Phone: _____ Country: _____

Please send a scanned copy of the completed form via email to support@fasttrack-diagnostics.com. If you have any questions, contact a Fast Track Diagnostics technical support representative.