

平成 30 年 7 月 吉日

製品内容変更のお知らせ

お客様各位

拝啓

平素より FastTrack Diagnostics 製品を御愛顧いただきまして、誠にありがとうございます。

このたび、一部の製品に仕様変更がございましたので、お知らせいたします。

変更内容の詳細につきましては、大変お手数をおかけいたしますが、添付の Modification List をご確認くださいますようお願い申し上げます。

なお、キット構成部品キャップの変更は、一時的なものとなります。

また、変更リストには以前の変更内容の記載も含まれております。前回のお知らせ（2018 年 2 月）から新たに追加されているものを「New」としております。

今後とも弊社製品をご愛顧賜りますようお願い申し上げます。

敬具

【お問合せ先】

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Modification list

FTD and FTlyo kits

Please be aware that some of the FTD and FTlyo kit's were recently modified. Check the overview below for detailed information (kit, changement, effective since date/lot). Each affected kit included in a shipment contains a individual insert notice to point out changes to the end-customers.

Cat n°	Name of the kit	Shortcut	Status	Comment	Effective since		
					Date	32rxn	64rxn
Modification Notice: Temporary replacement of yellow/red/purple cap tubes							
/	all kits	/	/	Due to a supply shortage beyond our control, certain yellow cap tubes containing PP mixes will temporarily be replaced by brown cap tubes.	23/01/2018	/	/
				Due to a supply shortage beyond our control, certain red cap tubes containing PC or PP mixes will temporarily be replaced by green cap tubes. Furthermore, purple cap tubes containing PP mixes will temporarily be replaced by brown cap tubes.	08/05/2018	/	/
Modification Notice: New kit version							
FTD CC.2-Bulk	LightCycler480® color compensation	CC	FRUO	new optimized PPMixes and positive controls as well as a new optimized PCR set-up on LC480	01/07/2017	CC17Bulk07	
FTD 31.1	Bordetella	BO	CE	new optimized Bord PP for detection of <i>B. pertussis</i> , <i>B. parapertussis</i> and IC (<i>S. equi</i>)	01/09/2017	BO17-32-04	BO17-64-08
FTD 32.1	Neonatal sepsis	NE	CE ₀₁₂₃	new optimized internal control (<i>S. equi</i>)	10/07/2017	NE17-32-04	NE17-64-07
FTD 34.1	Neonatal meningitis	NM	CE	new optimized internal control (<i>S. equi</i>)	10/07/2017	NM17-32-05	NM17-64-09
FTD 48.1	FLU/HRSV	FR	CE	new optimized FluRSV PPMix, including a new IC (<i>S. equi</i>)	01/07/2017	FR17-32-11	FR17-64-11
FTD 56.1	HCoV	COR	CE	new positive control Resp21 PC	01/07/2017	COR17-32-02	COR17-64-01
FTD 60.4	Neuro 9	NEU	CE ₀₁₂₃	1 new optimized PPMix: HHV/B19 PPMix and 1 new positive control NEU PC2. HPV-B19 is detected in ROX channel.	01/06/2017	NEU17-32-12	NEU17-64-17
FTD 63.1	HAdV/HMPV/HBoV	AMB	CE	new positive control Resp21 PC	01/11/2017	AMB17-32-02	AMB17-64-04
FTD 65.2	HPIV	PIV	CE	new optimized PIV PP to detect HPIV1-4 in one tube, new Resp16 PC, IC is not included	01/11/2017	PIV17-32-04	PIV17-64-04
Modification Notice: Change of NC/ Discontinuation of smartmix							
/	all kits	/	/	1. Negative control (NC) in all FTD/FTIyo kits has been changed from lysis buffer to nuclease free water. The hazard information for the internal control was revised and adapted. 2. Discontinuation of FTD smartmix. FTD kits can be used without FTD smartmix on the SmartCycler®. Therefore, FTD will discontinue FTD smartmix.	01/01/2018	/	/

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Cat n°	Name of the kit	Shortcut	Status	Comment	Effective since		
					Date	32rxn	64rxn
Modification Notice: Change from quantitative to qualitative							
FTD 14.1	Bacterial gastroenteritis	BG	CE	kit has changed from quantitative to qualitative	01/01/2018	BG18-32-01	BG18-64-01
FTD 28	Bacterial meningitis	BM	CE			BM18-32-01	BM18-64-01
FTD 30	Bacterial pneumonia_HAP	BPH	CE			BPH18-32-01	BPH18-64-01
FTD 32.1	Neonatal sepsis	NE	CE ₀₁₂₃			NE18-32-01	NE18-64-01
FTD 34.1	Neonatal meningitis	NM	CE			NM18-32-01	NM18-64-01
FTD 40	Malaria differentiation	MD	CE			MD18-32-01	MD18-64-01
FTD 66	SPn/Staph/MC/HI	SMH	CE			SMH18-32-01	SMH18-64-01
FTIyo							
Modification Notice: additional reagent included							
FTIyo 3s	Viral gastroenteritis	GAL	CE	kit includes additional Sapo mastermix and Sapo PC	10/07/2017	GAL17-32-13L/01H	GAL17-64-04L/03H
Modification Notice: New 8-well strips, sealing foil provided							
FTIyo 2	Respiratory pathogens 21	REL	CE	kit includes new 8-well strips, which needs to be sealed with an optical sealing foil, which is provide in each kit	24/11/2017	REL17-32-18H/07L	REL17-64-15H/05L
FTIyo 3s	Viral gastroenteritis	GAL	CE		08/02/2018	GAL18-32-12H/26L	GAL18-64-08H/12L
FTIyo 7	Vesicular rash	VEL	CE		15/02/2018	VEL18-32-07H/10L	VEL18-64-12H/11L
FTIyo 13	Viral meningitis	VML	CE		09/03/2018	VML18-32-13H/04L	VML18-64-10H/02L
FTIyo 14.1	Bacterial gastroenteritis	BGL	CE		01/03/2018	BGL18-32-19H/22L	BGL18-64-03H/11L
FTIyo 23	EPA	EPAL	CE		08/02/2018	EPAL18-32-08H/02L	EPAL18-64-05H/01L
FTIyo 28	Bacterial meningitis	BML	CE		08/02/2018	BML18-32-09H/10L	BML18-64-08H/03L
FTIyo 35	Enteric fever	ENFL	CE		30/10/2017	ENFL17-32-06L/01H	ENFL17-64-07L/02H
FTIyo 45	Noro	NOL	CE		08/02/2018	NOL18-32-05H/02L	NOL18-64-02H/01L

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Cat n°	Name of the kit	Shortcut	Status	Comment	Effective since		
					Date	32rxn	64rxn
Modification Notice: New 8-well strips, sealing foil provided							
FTIyo 50.1	MERS-CoV	COL	CE	kit includes new 8-well strips, which needs to be sealed with an optical sealing foil, which is provide in each kit	08/02/2018	COL18-32-06H/04L	COL18-64-03H/02L
Modification Notice: New kit version							
FTIyo 48.1	FLU/HRSV	FRL	CE	new optimized FluRSV PPMix, including a new IC (<i>S. equi</i>); kit includes new 8-well strips which needs to be sealed with a provided optical sealing foil	01/01/2018	FRL18-32-01L/01H	FRL18-64-01L/01H
Modification Notice: New vacuum blood collection tubes							
FTIyo 35-SEB	Enteric fever (SEB)	SEB	FRUO	The blood collection tubes (FTD VACulture Salmonella) provided with this kit now contain vacuum to facilitate the blood drawing procedure	26/02/2018	35SEB18-50-09	