

DECLARATION OF CONFORMITY

Manufacturer: ViennaLab Diagnostics GmbH
Address: Gaudenzdorfer Guertel 43-45
 A-1120 Vienna, Austria
Phone: (+43 1) 812 01 56-0
Web: www.viennalab.com

We declare under our sole responsibility that the products listed below are in compliance with the essential requirements of the "Directive 98/79/EC of the European parliament and of the council of 27 October 1998 on *in vitro* diagnostic medical devices (IVDD). According to the IVDD the products are classified as "Other IVD" (all devices other than those covered by Annex II and self-testing devices). Conformity assessment was performed according to Annex III.

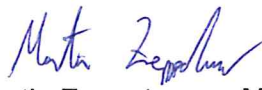
In addition, all products are in accordance with the requirements on post-market surveillance, vigilance and market surveillance of the Regulation (EU) 2017/746 of the European parliament and of the council of 5 April 2017 on *in vitro* diagnostic devices (IVDR).

All products are marked with the **CE** - symbol.

Product details

REF	Product Name	Contents	Quantity	Classification	Conformity Assessment
7-110	FV Leiden RealFast™ Assay	1000 µl RealFast™ 2x Genotyping Mix, 550 µl Assay Mix, 75 µl WT-Control, 75 µl MUT-Control	100 tests	Other IVD	Annex III IVDD
7-110-TRIAL	FV Leiden RealFast™ Assay	200 µl RealFast™ 2x Genotyping Mix, 550 µl Assay Mix, 75 µl WT-Control, 75 µl MUT-Control	20 tests	Other IVD	Annex III IVDD
7-113	FV Leiden RealFast™ Assay	320 µl RealFast™ 2x Genotyping Mix, 550 µl Assay Mix, 75 µl WT-Control, 75 µl MUT-Control	32 tests	Other IVD	Annex III IVDD

Vienna, May 25th, 2022


 Martin Zeppetbauer, MRes
 Chief Executive Officer
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Product details

REF	Product Name	Contents	Quantity	Classification	Conformity Assessment
7-115	FV-PTH mpx RealFast™ Assay	1000 µl RealFast™ 2x mpx Probe Mix, 550 µl Assay Mix, 75 µl WT-Control, 75 µl MUT-Control	100 tests	Other IVD	Annex III IVDD
7-115-TRIAL	FV-PTH mpx RealFast™ Assay	200 µl RealFast™ 2x mpx Probe Mix, 550 µl Assay Mix, 75 µl WT-Control, 75 µl MUT-Control	20 tests	Other IVD	Annex III IVDD
7-118	FV-PTH mpx RealFast™ Assay	320 µl RealFast™ 2x mpx Probe Mix, 550 µl Assay Mix, 75 µl WT-Control, 75 µl MUT-Control	32 tests	Other IVD	Annex III IVDD

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REF	Product Name	Contents	Quantity	Classification	Conformity Assessment
7-120	PTH 20210G>A RealFast™ Assay	1000 µl RealFast™ 2x Genotyping Mix, 550 µl Assay Mix, 75 µl WT-Control, 75 µl MUT-Control	100 tests	Other IVD	Annex III IVDD
7-120-TRIAL	PTH 20210G>A RealFast™ Assay	200 µl RealFast™ 2x Genotyping Mix, 550 µl Assay Mix, 75 µl WT-Control, 75 µl MUT-Control	20 tests	Other IVD	Annex III IVDD
7-123	PTH 20210G>A RealFast™ Assay	320 µl RealFast™ 2x Genotyping Mix, 550 µl Assay Mix, 75 µl WT-Control, 75 µl MUT-Control	32 tests	Other IVD	Annex III IVDD

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REF	Product Name	Contents	Quantity	Classification	Conformity Assessment
7-130	HFE C282Y RealFast™ Assay	1000 µl RealFast™ 2x Genotyping Mix, 550 µl Assay Mix, 75 µl WT-Control, 75 µl MUT-Control	100 tests	Other IVD	Annex III IVDD
7-130-TRIAL	HFE C282Y RealFast™ Assay	200 µl RealFast™ 2x Genotyping Mix, 550 µl Assay Mix, 75 µl WT-Control, 75 µl MUT-Control	20 tests	Other IVD	Annex III IVDD
7-133	HFE C282Y RealFast™ Assay	320 µl RealFast™ 2x Genotyping Mix, 550 µl Assay Mix, 75 µl WT-Control, 75 µl MUT-Control	32 tests	Other IVD	Annex III IVDD

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REF	Product Name	Contents	Quantity	Classification	Conformity Assessment
7-135	HFE mpx RealFast™ Assay	1000 µl RealFast™ 2x mpx Probe Mix, 550 µl Assay Mix, 75 µl WT-Control, 75 µl MUT-Control	100 tests	Other IVD	Annex III IVDD
7-135-TRIAL	HFE mpx RealFast™ Assay	200 µl RealFast™ 2x mpx Probe Mix, 550 µl Assay Mix, 75 µl WT-Control, 75 µl MUT-Control	20 tests	Other IVD	Annex III IVDD
7-138	HFE mpx RealFast™ Assay	320 µl RealFast™ 2x mpx Probe Mix, 550 µl Assay Mix, 75 µl WT-Control, 75 µl MUT-Control	32 tests	Other IVD	Annex III IVDD

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REF	Product Name	Contents	Quantity	Classification	Conformity Assessment
7-140	HFE H63D RealFast™ Assay	1000 µl RealFast™ 2x Genotyping Mix, 550 µl Assay Mix, 75 µl WT-Control, 75 µl MUT-Control	100 tests	Other IVD	Annex III IVDD
7-140-TRIAL	HFE H63D RealFast™ Assay	200 µl RealFast™ 2x Genotyping Mix, 550 µl Assay Mix, 75 µl WT-Control, 75 µl MUT-Control	20 tests	Other IVD	Annex III IVDD
7-143	HFE H63D RealFast™ Assay	320 µl RealFast™ 2x Genotyping Mix, 550 µl Assay Mix, 75 µl WT-Control, 75 µl MUT-Control	32 tests	Other IVD	Annex III IVDD

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REF	Product Name	Contents	Quantity	Classification	Conformity Assessment
7-150	LCT -13910C>T RealFast™ Assay	1000 µl RealFast™ 2x Genotyping Mix, 550 µl Assay Mix, 75 µl TT-Control, 75 µl CC-Control	100 tests	Other IVD	Annex III IVDD
7-150-TRIAL	LCT -13910C>T RealFast™ Assay	200 µl RealFast™ 2x Genotyping Mix, 550 µl Assay Mix, 75 µl TT-Control, 75 µl CC-Control	20 tests	Other IVD	Annex III IVDD
7-153	LCT -13910C>T RealFast™ Assay	320 µl RealFast™ 2x Genotyping Mix, 550 µl Assay Mix, 75 µl TT-Control, 75 µl CC-Control	32 tests	Other IVD	Annex III IVDD

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REF	Product Name	Contents	Quantity	Classification	Conformity Assessment
7-160	MTHFR 677C>T RealFast™ Assay	1000 µl RealFast™ 2x Genotyping Mix, 550 µl Assay Mix, 75 µl WT-Control, 75 µl MUT-Control	100 tests	Other IVD	Annex III IVDD
7-160-TRIAL	MTHFR 677C>T RealFast™ Assay	200 µl RealFast™ 2x Genotyping Mix, 550 µl Assay Mix, 75 µl WT-Control, 75 µl MUT-Control	20 tests	Other IVD	Annex III IVDD
7-163	MTHFR 677C>T RealFast™ Assay	320 µl RealFast™ 2x Genotyping Mix, 550 µl Assay Mix, 75 µl WT-Control, 75 µl MUT-Control	32 tests	Other IVD	Annex III IVDD

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REF	Product Name	Contents	Quantity	Classification	Conformity Assessment
7-165	MTHFR mpx RealFast™ Assay	1000 µl RealFast™ 2x mpx Probe Mix, 550 µl Assay Mix, 75 µl WT-Control, 75 µl MUT-Control	100 tests	Other IVD	Annex III IVDD
7-165-TRIAL	MTHFR mpx RealFast™ Assay	200 µl RealFast™ 2x mpx Probe Mix, 550 µl Assay Mix, 75 µl WT-Control, 75 µl MUT-Control	20 tests	Other IVD	Annex III IVDD
7-168	MTHFR mpx RealFast™ Assay	320 µl RealFast™ 2x mpx Probe Mix, 550 µl Assay Mix, 75 µl WT-Control, 75 µl MUT-Control	32 tests	Other IVD	Annex III IVDD

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REF	Product Name	Contents	Quantity	Classification	Conformity Assessment
7-170	MTHFR 1298A>C RealFast™ Assay	1000 µl RealFast™ 2x Genotyping Mix, 550 µl Assay Mix, 75 µl WT-Control, 75 µl MUT-Control	100 tests	Other IVD	Annex III IVDD
7-170-TRIAL	MTHFR 1298A>C RealFast™ Assay	200 µl RealFast™ 2x Genotyping Mix, 550 µl Assay Mix, 75 µl WT-Control, 75 µl MUT-Control	20 tests	Other IVD	Annex III IVDD
7-173	MTHFR 1298A>C RealFast™ Assay	320 µl RealFast™ 2x Genotyping Mix, 550 µl Assay Mix, 75 µl WT-Control, 75 µl MUT-Control	32 tests	Other IVD	Annex III IVDD

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REF	Product Name	Contents	Quantity	Classification	Conformity Assessment
7-180	PAI-1 4G/5G RealFast™ Assay	1000 µl RealFast™ 2x Genotyping Mix, 550 µl Assay Mix, 75 µl 4G/4G-Control, 75 µl 5G/5G-Control	100 tests	Other IVD	Annex III IVDD
7-180-TRIAL	PAI-1 4G/5G RealFast™ Assay	200 µl RealFast™ 2x Genotyping Mix, 550 µl Assay Mix, 75 µl 4G/4G-Control, 75 µl 5G/5G-Control	20 tests	Other IVD	Annex III IVDD
7-183	PAI-1 4G/5G RealFast™ Assay	320 µl RealFast™ 2x Genotyping Mix, 550 µl Assay Mix, 75 µl 4G/4G-Control, 75 µl 5G/5G-Control	32 tests	Other IVD	Annex III IVDD

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REF	Product Name	Contents	Quantity	Classification	Conformity Assessment
7-190	VKORC1 - 1639G>A RealFast™ Assay	1000 µl RealFast™ 2x Genotyping Mix, 550 µl Assay Mix, 75 µl GG-Control, 75 µl AA-Control	100 tests	Other IVD	Annex III IVDD
7-190-TRIAL	VKORC1 - 1639G>A RealFast™ Assay	200 µl RealFast™ 2x Genotyping Mix, 550 µl Assay Mix, 75 µl GG-Control, 75 µl AA-Control	20 tests	Other IVD	Annex III IVDD
7-193	VKORC1 - 1639G>A RealFast™ Assay	320 µl RealFast™ 2x Genotyping Mix, 550 µl Assay Mix, 75 µl GG-Control, 75 µl AA-Control	32 tests	Other IVD	Annex III IVDD

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REF	Product Name	Contents	Quantity	Classification	Conformity Assessment
7-200	IL28B RealFast™ Assay	1000 µl RealFast™ 2x Genotyping Mix, 550 µl Assay Mix, 75 µl TT/TT-Control, 75 µl ΔG/ΔG-Control	100 tests	Other IVD	Annex III IVDD
7-200-TRIAL	IL28B RealFast™ Assay	200 µl RealFast™ 2x Genotyping Mix, 550 µl Assay Mix, 75 µl TT/TT-Control, 75 µl ΔG/ΔG-Control	20 tests	Other IVD	Annex III IVDD
7-203	IL28B RealFast™ Assay	320 µl RealFast™ 2x Genotyping Mix, 550 µl Assay Mix, 75 µl TT/TT-Control, 75 µl ΔG/ΔG-Control	32 tests	Other IVD	Annex III IVDD

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REF	Product Name	Contents	Quantity	Classification	Conformity Assessment
7-210	SLCO1B1 c.521T>C RealFast™ Assay	1000 µl RealFast™ 2x Genotyping Mix, 550 µl Assay Mix, 75 µl TT-Control, 75 µl CC-Control	100 tests	Other IVD	Annex III IVDD
7-210-TRIAL	SLCO1B1 c.521T>C RealFast™ Assay	200 µl RealFast™ 2x Genotyping Mix, 550 µl Assay Mix, 75 µl TT-Control, 75 µl CC-Control	20 tests	Other IVD	Annex III IVDD
7-213	SLCO1B1 c.521T>C RealFast™ Assay	320 µl RealFast™ 2x Genotyping Mix, 550 µl Assay Mix, 75 µl TT-Control, 75 µl CC-Control	32 tests	Other IVD	Annex III IVDD

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7-225	CYP2C9 mpx RealFast™ Assay	1000 µl RealFast™ 2x mpx Probe Mix, 550 µl Assay Mix, 75 µl *1*1-Control, 75 µl *2*3-Control	100 tests	Other IVD	Annex III IVDD
7-225-TRIAL	CYP2C9 mpx RealFast™ Assay	200 µl RealFast™ 2x mpx Probe Mix, 550 µl Assay Mix, 75 µl *1*1-Control, 75 µl *2*3-Control	20 tests	Other IVD	Annex III IVDD
7-228	CYP2C9 mpx RealFast™ Assay	320 µl RealFast™ 2x mpx Probe Mix, 550 µl Assay Mix, 75 µl *1*1-Control, 75 µl *2*3-Control	32 tests	Other IVD	Annex III IVDD

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REF	Product Name	Contents	Quantity	Classification	Conformity Assessment
7-230	FGB -455G>A RealFast™ Assay	1000 µl RealFast™ 2x Genotyping Mix, 550 µl Assay Mix, 75 µl WT-Control, 75 µl MUT-Control	100 tests	Other IVD	Annex III IVDD
7-230-TRIAL	FGB -455G>A RealFast™ Assay	200 µl RealFast™ 2x Genotyping Mix, 550 µl Assay Mix, 75 µl WT-Control, 75 µl MUT-Control	20 tests	Other IVD	Annex III IVDD
7-233	FGB -455G>A RealFast™ Assay	320 µl RealFast™ 2x Genotyping Mix, 550 µl Assay Mix, 75 µl WT-Control, 75 µl MUT-Control	32 tests	Other IVD	Annex III IVDD

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REF	Product Name	Contents	Quantity	Classification	Conformity Assessment
7-240	FXII 46C>T RealFast™ Assay	1000 µl RealFast™ 2x Genotyping Mix, 550 µl Assay Mix, 75 µl WT-Control, 75 µl MUT-Control	100 tests	Other IVD	Annex III IVDD
7-240-TRIAL	FXII 46C>T RealFast™ Assay	200 µl RealFast™ 2x Genotyping Mix, 550 µl Assay Mix, 75 µl WT-Control, 75 µl MUT-Control	20 tests	Other IVD	Annex III IVDD
7-243	FXII 46C>T RealFast™ Assay	320 µl RealFast™ 2x Genotyping Mix, 550 µl Assay Mix, 75 µl WT-Control, 75 µl MUT-Control	32 tests	Other IVD	Annex III IVDD

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Manufacturer: ViennaLab Diagnostics GmbH
Address: Gaudenzdorfer Guertel 43-45
 A-1120 Vienna, Austria
Phone: (+43 1) 812 01 56-0
Web: www.viennalab.com

We declare under our sole responsibility that the products listed below are in compliance with the essential requirements of the “Directive 98/79/EC of the European parliament and of the council of 27 October 1998 on *in vitro* diagnostic medical devices (IVDD). According to the IVDD the products are classified as “Other IVD” (all devices other than those covered by Annex II and self-testing devices). Conformity assessment was performed according to Annex III.


In addition, all products are in accordance with the requirements on post-market surveillance, vigilance and market surveillance of the Regulation (EU) 2017/746 of the European parliament and of the council of 5 April 2017 on *in vitro* diagnostic devices (IVDR).

All products are marked with the **CE** - symbol.

Product details

REF	Product Name	Contents	Quantity	Classification	Conformity Assessment
7-250	FXIII V34L RealFast™ Assay	1000 µl RealFast™ 2x Genotyping Mix, 550 µl Assay Mix, 75 µl WT-Control, 75 µl MUT-Control	100 tests	Other IVD	Annex III IVDD
7-250-TRIAL	FXIII V34L RealFast™ Assay	200 µl RealFast™ 2x Genotyping Mix, 550 µl Assay Mix, 75 µl WT-Control, 75 µl MUT-Control	20 tests	Other IVD	Annex III IVDD
7-253	FXIII V34L RealFast™ Assay	320 µl RealFast™ 2x Genotyping Mix, 550 µl Assay Mix, 75 µl WT-Control, 75 µl MUT-Control	32 tests	Other IVD	Annex III IVDD

Vienna, May 25th, 2022


 Martin Zeppetbauer, MRes
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Product details

REF	Product Name	Contents	Quantity	Classification	Conformity Assessment
7-260	CF F508del RealFast™ Assay	1000 µl RealFast™ 2x Genotyping Mix, 550 µl Assay Mix, 75 µl WT-Control, 75 µl MUT-Control	100 tests	Other IVD	Annex III IVDD
7-260-TRIAL	CF F508del RealFast™ Assay	200 µl RealFast™ 2x Genotyping Mix, 550 µl Assay Mix, 75 µl WT-Control, 75 µl MUT-Control	20 tests	Other IVD	Annex III IVDD
7-263	CF F508del RealFast™ Assay	320 µl RealFast™ 2x Genotyping Mix, 550 µl Assay Mix, 75 µl WT-Control, 75 µl MUT-Control	32 tests	Other IVD	Annex III IVDD

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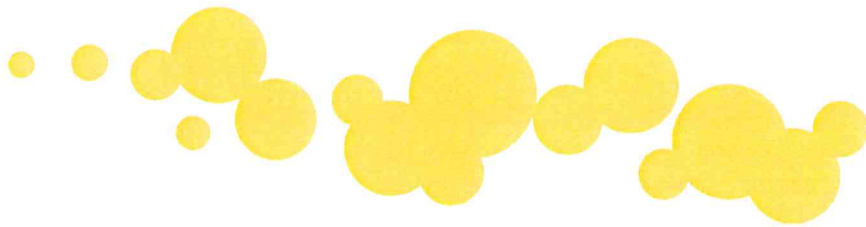
Product details

REF	Product Name	Contents	Quantity	Classification	Conformity Assessment
7-265	AAT mpx RealFast™ Assay	1000 µl RealFast™ 2x mpx Probe Mix, 550 µl Assay Mix, 75 µl WT-Control, 75 µl MUT-Control	100 tests	Other IVD	Annex III IVDD
7-265-TRIAL	AAT mpx RealFast™ Assay	200 µl RealFast™ 2x mpx Probe Mix, 550 µl Assay Mix, 75 µl WT-Control, 75 µl MUT-Control	20 tests	Other IVD	Annex III IVDD
7-268	AAT mpx RealFast™ Assay	320 µl RealFast™ 2x mpx Probe Mix, 550 µl Assay Mix, 75 µl WT-Control, 75 µl MUT-Control	32 tests	Other IVD	Annex III IVDD

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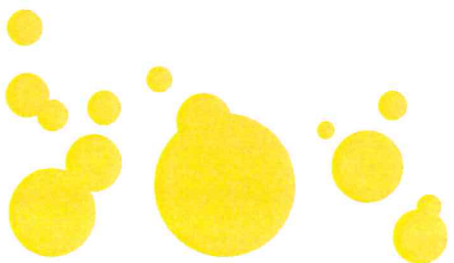
Product details

REF	Product Name	Contents	Quantity	Classification	Conformity Assessment
7-410	CAH RealFast™ CNV Assay	1000 µl RealFast™ 2x Probe Mix, 550 µl Assay Mix, 75 µl Calibrator	100 tests	Other IVD	Annex III IVDD
7-410-TRIAL	CAH RealFast™ CNV Assay	200 µl RealFast™ 2x Probe Mix, 550 µl Assay Mix, 75 µl Calibrator	20 tests	Other IVD	Annex III IVDD

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REF	Product Name	Contents	Quantity	Classification	Conformity Assessment
7-420	CYP2D6 RealFast™ CNV Assay	1000 µl RealFast™ 2x Probe Mix, 550 µl Assay Mix, 75 µl Calibrator	100 tests	Other IVD	Annex III IVDD
7-420-TRIAL	CYP2D6 RealFast™ CNV Assay	200 µl RealFast™ 2x Probe Mix, 550 µl Assay Mix, 75 µl Calibrator	20 tests	Other IVD	Annex III IVDD

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REF	Product Name	Contents	Quantity	Classification	Conformity Assessment
7-610	HLA-B5701 RealFast™ Assay	1000 µl RealFast™ 2x Genotyping Mix, 550 µl Assay Mix, 75 µl Positive Control, 75 µl Negative Control	100 tests	Other IVD	Annex III IVDD
7-610-TRIAL	HLA-B5701 RealFast™ Assay	200 µl RealFast™ 2x Genotyping Mix, 550 µl Assay Mix, 75 µl Positive Control, 75 µl Negative Control	20 tests	Other IVD	Annex III IVDD
7-613	HLA-B5701 RealFast™ Assay	320 µl RealFast™ 2x Genotyping Mix, 550 µl Assay Mix, 75 µl Positive Control, 75 µl Negative Control	32 tests	Other IVD	Annex III IVDD

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Product details

REF	Product Name	Contents	Quantity	Classification	Conformity Assessment
7-630	HLA-B1502 RealFast™ Assay	1000 µl RealFast™ 2x Genotyping Mix, 550 µl Assay Mix, 75 µl Positive Control, 75 µl Negative Control	100 tests	Other IVD	Annex III IVDD
7-630-TRIAL	HLA-B1502 RealFast™ Assay	200 µl RealFast™ 2x Genotyping Mix, 550 µl Assay Mix, 75 µl Positive Control, 75 µl Negative Control	20 tests	Other IVD	Annex III IVDD
7-633	HLA-B1502 RealFast™ Assay	350 µl RealFast™ 2x Genotyping Mix, 550 µl Assay Mix, 75 µl Positive Control, 75 µl Negative Control	32 tests	Other IVD	Annex III IVDD

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REF	Product Name	Contents	Quantity	Classification	Conformity Assessment
7-640	HLA-A3101 RealFast™ Assay	1000 µl RealFast™ 2x Genotyping Mix, 550 µl Assay Mix, 75 µl Positive Control, 75 µl Negative Control	100 tests	Other IVD	Annex III IVDD
7-640-TRIAL	HLA-A3101 RealFast™ Assay	200 µl RealFast™ 2x Genotyping Mix, 550 µl Assay Mix, 75 µl Positive Control, 75 µl Negative Control	20 tests	Other IVD	Annex III IVDD
7-643	HLA-A3101 RealFast™ Assay	320 µl RealFast™ 2x Genotyping Mix, 550 µl Assay Mix, 75 µl Positive Control, 75 µl Negative Control	32 tests	Other IVD	Annex III IVDD

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