

## DECLARATION OF CONFORMITY

### according to the directive 98/79/EC

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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) and the Austrian Medical Device Act (1996:657). According to this the products are classified as "Other IVD" (all devices other than those covered by IVDD Annex II and self-testing devices). Conformity assessment is performed according to IVDD Annex III. All products are marked with the **CE** - symbol.

#### Product details

REF	Product Name	Contents	Quantity	Classification	Conformity Assessment
4-130	$\beta$ -Globin StripAssay <sup>®</sup> MED	50 ml Lysis Solution, 5 ml Genextract Resin, 500 $\mu$ l Amplification Mix, 500 $\mu$ l Taq Dilution Buffer, 1.5 ml DNAT, 3 Typing Trays, 20 Teststrips, 25 ml Hybridization Buffer, 80 ml Wash Solution A, 25 ml Conjugate Solution, 80 ml Wash Solution B, 25 ml Color Developer	20 tests	Other IVD	Annex III IVDD
4-130-TRIAL	$\beta$ -Globin StripAssay <sup>®</sup> MED	50 ml Lysis Solution, 5 ml Genextract Resin, 500 $\mu$ l Amplification Mix, 500 $\mu$ l Taq Dilution Buffer, 75 U Taq DNA Polymerase, 1.5 ml DNAT, 1 Typing Tray, 5 Teststrips, 25 ml Hybridization Buffer, 80 ml Wash Solution A, 25 ml Conjugate Solution, 80 ml Wash Solution B, 25 ml Color Developer	5 tests	Other IVD	Annex III IVDD
4-140	$\beta$ -Globin StripAssay <sup>®</sup> IME	50 ml Lysis Solution, 5 ml Genextract Resin, 500 $\mu$ l Amplification Mix, 500 $\mu$ l Taq Dilution Buffer, 1.5 ml DNAT, 3 Typing Trays, 20 Teststrips, 25 ml Hybridization Buffer, 80 ml Wash Solution A, 25 ml Conjugate Solution, 80 ml Wash Solution B, 25 ml Color Developer	20 tests	Other IVD	Annex III IVDD
4-140-TRIAL	$\beta$ -Globin StripAssay <sup>®</sup> IME	50 ml Lysis Solution, 5 ml Genextract Resin, 500 $\mu$ l Amplification Mix, 500 $\mu$ l Taq Dilution Buffer, 75 U Taq DNA Polymerase, 1.5 ml DNAT, 1 Typing Tray, 5 Teststrips, 25 ml Hybridization Buffer, 80 ml Wash Solution A, 25 ml Conjugate Solution, 80 ml Wash Solution B, 25 ml Color Developer	5 tests	Other IVD	Annex III IVDD
4-150	$\beta$ -Globin StripAssay <sup>®</sup> SEA	50 ml Lysis Solution, 5 ml Genextract Resin, 500 $\mu$ l Amplification Mix, 500 $\mu$ l Taq Dilution Buffer, 1.5 ml DNAT, 3 Typing Trays, 20 Teststrips, 25 ml Hybridization Buffer, 80 ml Wash Solution A, 25 ml Conjugate Solution, 80 ml Wash Solution B, 25 ml Color Developer	20 tests	Other IVD	Annex III IVDD
4-150-TRIAL	$\beta$ -Globin StripAssay <sup>®</sup> SEA	50 ml Lysis Solution, 5 ml Genextract Resin, 500 $\mu$ l Amplification Mix, 500 $\mu$ l Taq Dilution Buffer, 75 U Taq DNA Polymerase, 1.5 ml DNAT, 1 Typing Tray, 5 Teststrips, 25 ml Hybridization Buffer, 80 ml Wash Solution A, 25 ml Conjugate Solution, 80 ml Wash Solution B, 25 ml Color Developer	5 tests	Other IVD	Annex III IVDD

REF	Product Name	Contents	Quantity	Classification	Conformity Assessment
4-150-TRIAL	$\beta$ -Globin StripAssay <sup>®</sup> SEA	50 ml Lysis Solution, 5 ml Genextract Resin, 500 $\mu$ l Amplification Mix, 500 $\mu$ l Taq Dilution Buffer, 75 U Taq DNA Polymerase, 1.5 ml DNAT, 1 Typing Tray, 5 Teststrips, 25 ml Hybridization Buffer, 80 ml Wash Solution A, 25 ml Conjugate Solution, 80 ml Wash Solution B, 25 ml Color Developer	5 tests	Other IVD	Annex III IVDD
4-160	$\alpha$ -Globin StripAssay <sup>®</sup>	250 $\mu$ l Amplification Mix A1, 250 $\mu$ l Amplification Mix A2, 250 $\mu$ l Amplification Mix B, 500 $\mu$ l Taq Dilution Buffer, 125 U HS-Taq DNA Polymerase, 1.5 ml DNAT, 3 Typing Trays, 10 Teststrips A, 10 Teststrips B, 25 ml Hybridization Buffer, 80 ml Wash Solution A, 25 ml Conjugate Solution, 80 ml Wash Solution B, 25 ml Color Developer	10 tests	Other IVD	Annex III IVDD
4-160-TRIAL	$\alpha$ -Globin StripAssay <sup>®</sup>	250 $\mu$ l Amplification Mix A1, 250 $\mu$ l Amplification Mix A2, 250 $\mu$ l Amplification Mix B, 500 $\mu$ l Taq Dilution Buffer, 125 U HS-Taq DNA Polymerase, 1.5 ml DNAT, 2 Typing Trays, 5 Teststrips A, 5 Teststrips B, 25 ml Hybridization Buffer, 80 ml Wash Solution A, 25 ml Conjugate Solution, 80 ml Wash Solution B, 25 ml Color Developer	5 tests	Other IVD	Annex III IVDD
4-170	$\beta$ -Thal Modifier StripAssay <sup>®</sup>	50 ml Lysis Solution, 5 ml Genextract Resin, 500 $\mu$ l Amplification Mix, 500 $\mu$ l Taq Dilution Buffer, 1.5 ml DNAT, 3 Typing Trays, 20 Teststrips, 25 ml Hybridization Buffer, 80 ml Wash Solution A, 25 ml Conjugate Solution, 80 ml Wash Solution B, 25 ml Color Developer	20 tests	Other IVD	Annex III IVDD
4-170-TRIAL	$\beta$ -Thal Modifier StripAssay <sup>®</sup>	50 ml Lysis Solution, 5 ml Genextract Resin, 500 $\mu$ l Amplification Mix, 500 $\mu$ l Taq Dilution Buffer, 75 U Taq DNA Polymerase, 1.5 ml DNAT, 1 Typing Tray, 5 Teststrips, 25 ml Hybridization Buffer, 80 ml Wash Solution A, 25 ml Conjugate Solution, 80 ml Wash Solution B, 25 ml Color Developer	5 tests	Other IVD	Annex III IVDD
4-210	Haemochromatosis StripAssay <sup>®</sup> B	50 ml Lysis Solution, 5 ml Genextract Resin, 500 $\mu$ l Amplification Mix, 500 $\mu$ l Taq Dilution Buffer, 1.5 ml DNAT, 3 Typing Trays, 20 Teststrips, 25 ml Hybridization Buffer, 80 ml Wash Solution A, 25 ml Conjugate Solution, 80 ml Wash Solution B, 25 ml Color Developer	20 tests	Other IVD	Annex III IVDD
4-210-TRIAL	Haemochromatosis StripAssay <sup>®</sup> B	50 ml Lysis Solution, 5 ml Genextract Resin, 500 $\mu$ l Amplification Mix, 500 $\mu$ l Taq Dilution Buffer, 75 U Taq DNA Polymerase, 1.5 ml DNAT, 1 Typing Tray, 5 Teststrips, 25 ml Hybridization Buffer, 80 ml Wash Solution A, 25 ml Conjugate Solution, 80 ml Wash Solution B, 25 ml Color Developer	5 tests	Other IVD	Annex III IVDD
4-220	Haemochromatosis StripAssay <sup>®</sup> A	50 ml Lysis Solution, 5 ml Genextract Resin, 500 $\mu$ l Amplification Mix, 500 $\mu$ l Taq Dilution Buffer, 1.5 ml DNAT, 3 Typing Trays, 20 Teststrips, 25 ml Hybridization Buffer, 80 ml Wash Solution A, 25 ml Conjugate Solution, 80 ml Wash Solution B, 25 ml Color Developer	20 tests	Other IVD	Annex III IVDD
4-220-TRIAL	Haemochromatosis StripAssay <sup>®</sup> A	50 ml Lysis Solution, 5 ml Genextract Resin, 500 $\mu$ l Amplification Mix, 500 $\mu$ l Taq Dilution Buffer, 75 U Taq DNA Polymerase, 1.5 ml DNAT, 1 Typing Tray, 5 Teststrips, 25 ml Hybridization Buffer, 80 ml Wash Solution A, 25 ml Conjugate Solution, 80 ml Wash Solution B, 25 ml Color Developer	5 tests	Other IVD	Annex III IVDD
4-230	FMF StripAssay <sup>®</sup>	50 ml Lysis Solution, 5 ml Genextract Resin, 500 $\mu$ l Amplification Mix, 500 $\mu$ l Taq Dilution Buffer, 1.5 ml DNAT, 3 Typing Trays, 20 Teststrips, 25 ml Hybridization Buffer, 80 ml Wash Solution A, 25 ml Conjugate Solution, 80 ml Wash Solution B, 25 ml Color Developer	20 tests	Other IVD	Annex III IVDD
4-230-TRIAL	FMF StripAssay <sup>®</sup>	50 ml Lysis Solution, 5 ml Genextract Resin, 500 $\mu$ l Amplification Mix, 500 $\mu$ l Taq Dilution Buffer, 75 U Taq DNA Polymerase, 1.5 ml DNAT, 1 Typing Tray, 5 Teststrips, 25 ml Hybridization Buffer, 80 ml Wash Solution A, 25 ml Conjugate Solution, 80 ml Wash Solution B, 25 ml Color Developer	5 tests	Other IVD	Annex III IVDD

REF	Product Name	Contents	Quantity	Classification	Conformity Assessment
4-240	CVD StripAssay®	50 ml Lysis Solution, 5 ml Genextract Resin, 500 µl Amplification Mix A, 500 µl Amplification Mix B, 500 µl Taq Dilution Buffer, 1.5 ml DNAT, 3 Typing Trays, 20 Teststrips, 25 ml Hybridization Buffer, 80 ml Wash Solution A, 25 ml Conjugate Solution, 80 ml Wash Solution B, 25 ml Color Developer	20 tests	Other IVD	Annex III IVDD
4-240-TRIAL	CVD StripAssay®	50 ml Lysis Solution, 5 ml Genextract Resin, 500 µl Amplification Mix A, 500 µl Amplification Mix B, 500 µl Taq Dilution Buffer, 75 U Taq DNA Polymerase, 1.5 ml DNAT, 1 Typing Tray, 5 Teststrips, 25 ml Hybridization Buffer, 80 ml Wash Solution A, 25 ml Conjugate Solution, 80 ml Wash Solution B, 25 ml Color Developer	5 tests	Other IVD	Annex III IVDD
4-250	Gaucher Disease StripAssay®	50 ml Lysis Solution, 5 ml Genextract Resin, 500 µl Amplification Mix A, 500 µl Amplification Mix B, 500 µl Taq Dilution Buffer, 1.5 ml DNAT, 3 Typing Trays, 20 Teststrips, 25 ml Hybridization Buffer, 80 ml Wash Solution A, 25 ml Conjugate Solution, 80 ml Wash Solution B, 25 ml Color Developer	20 tests	Other IVD	Annex III IVDD
4-250-TRIAL	Gaucher Disease StripAssay®	50 ml Lysis Solution, 5 ml Genextract Resin, 500 µl Amplification Mix A, 500 µl Amplification Mix B, 500 µl Taq Dilution Buffer, 75 U Taq DNA Polymerase, 1.5 ml DNAT, 1 Typing Tray, 5 Teststrips, 25 ml Hybridization Buffer, 80 ml Wash Solution A, 25 ml Conjugate Solution, 80 ml Wash Solution B, 25 ml Color Developer	5 tests	Other IVD	Annex III IVDD
4-260	FV-PTH-MTHFR StripAssay®	50 ml Lysis Solution, 5 ml Genextract Resin, 500 µl Amplification Mix, 500 µl Taq Dilution Buffer, 1.5 ml DNAT, 3 Typing Trays, 20 Teststrips, 25 ml Hybridization Buffer, 80 ml Wash Solution A, 25 ml Conjugate Solution, 80 ml Wash Solution B, 25 ml Color Developer	20 tests	Other IVD	Annex III IVDD
4-260-TRIAL	FV-PTH-MTHFR StripAssay®	50 ml Lysis Solution, 5 ml Genextract Resin, 500 µl Amplification Mix, 500 µl Taq Dilution Buffer, 75 U Taq DNA Polymerase, 1.5 ml DNAT, 1 Typing Tray, 5 Teststrips, 25 ml Hybridization Buffer, 80 ml Wash Solution A, 25 ml Conjugate Solution, 80 ml Wash Solution B, 25 ml Color Developer	5 tests	Other IVD	Annex III IVDD
4-280	Apo E StripAssay®	50 ml Lysis Solution, 5 ml Genextract Resin, 500 µl Amplification Mix, 500 µl Taq Dilution Buffer, 1.5 ml DNAT, 3 Typing Trays, 20 Teststrips, 25 ml Hybridization Buffer, 80 ml Wash Solution A, 25 ml Conjugate Solution, 80 ml Wash Solution B, 25 ml Color Developer	20 tests	Other IVD	Annex III IVDD
4-280-TRIAL	Apo E StripAssay®	50 ml Lysis Solution, 5 ml Genextract Resin, 500 µl Amplification Mix, 500 µl Taq Dilution Buffer, 75 U Taq DNA Polymerase, 1.5 ml DNAT, 1 Typing Tray, 5 Teststrips, 25 ml Hybridization Buffer, 80 ml Wash Solution A, 25 ml Conjugate Solution, 80 ml Wash Solution B, 25 ml Color Developer	5 tests	Other IVD	Annex III IVDD
4-290	FV-PTH StripAssay®	50 ml Lysis Solution, 5 ml Genextract Resin, 500 µl Amplification Mix, 500 µl Taq Dilution Buffer, 1.5 ml DNAT, 3 Typing Trays, 20 Teststrips, 25 ml Hybridization Buffer, 80 ml Wash Solution A, 25 ml Conjugate Solution, 80 ml Wash Solution B, 25 ml Color Developer	20 tests	Other IVD	Annex III IVDD
4-290-TRIAL	FV-PTH StripAssay®	50 ml Lysis Solution, 5 ml Genextract Resin, 500 µl Amplification Mix, 500 µl Taq Dilution Buffer, 75 U Taq DNA Polymerase, 1.5 ml DNAT, 1 Typing Tray, 5 Teststrips, 25 ml Hybridization Buffer, 80 ml Wash Solution A, 25 ml Conjugate Solution, 80 ml Wash Solution B, 25 ml Color Developer	5 tests	Other IVD	Annex III IVDD
4-300	Lactose Intolerance StripAssay®	50 ml Lysis Solution, 5 ml Genextract Resin, 500 µl Amplification Mix, 500 µl Taq Dilution Buffer, 1.5 ml DNAT, 3 Typing Trays, 20 Teststrips, 25 ml Hybridization Buffer, 80 ml Wash Solution A, 25 ml Conjugate Solution, 80 ml Wash Solution B, 25 ml Color Developer	20 tests	Other IVD	Annex III IVDD

REF	Product Name	Contents	Quantity	Classification	Conformity Assessment
4-300-TRIAL	Lactose Intolerance StripAssay®	50 ml Lysis Solution, 5 ml Genextract Resin, 500 µl Amplification Mix, 500 µl Taq Dilution Buffer, 75 U Taq DNA Polymerase, 1.5 ml DNAT, 1 Typing Tray, 5 Teststrips, 25 ml Hybridization Buffer, 80 ml Wash Solution A, 25 ml Conjugate Solution, 80 ml Wash Solution B, 25 ml Color Developer	5 tests	Other IVD	Annex III IVDD
4-310	Sugar Intolerance StripAssay®	50 ml Lysis Solution, 5 ml Genextract Resin, 500 µl Amplification Mix, 500 µl Taq Dilution Buffer, 1.5 ml DNAT, 3 Typing Trays, 20 Teststrips, 25 ml Hybridization Buffer, 80 ml Wash Solution A, 25 ml Conjugate Solution, 80 ml Wash Solution B, 25 ml Color Developer	20 tests	Other IVD	Annex III IVDD
4-310-TRIAL	Sugar Intolerance StripAssay®	50 ml Lysis Solution, 5 ml Genextract Resin, 500 µl Amplification Mix, 500 µl Taq Dilution Buffer, 75 U Taq DNA Polymerase, 1.5 ml DNAT, 1 Typing Tray, 5 Teststrips, 25 ml Hybridization Buffer, 80 ml Wash Solution A, 25 ml Conjugate Solution, 80 ml Wash Solution B, 25 ml Color Developer	5 tests	Other IVD	Annex III IVDD
4-320	HLA-B27 StripAssay®	50 ml Lysis Solution, 5 ml Genextract Resin, 500 µl Amplification Mix, 500 µl Taq Dilution Buffer, 1.5 ml DNAT, 3 Typing Trays, 20 Teststrips, 25 ml Hybridization Buffer, 80 ml Wash Solution A, 25 ml Conjugate Solution, 80 ml Wash Solution B, 25 ml Color Developer	20 tests	Other IVD	Annex III IVDD
4-320-TRIAL	HLA-B27 StripAssay®	50 ml Lysis Solution, 5 ml Genextract Resin, 500 µl Amplification Mix, 500 µl Taq Dilution Buffer, 75 U Taq DNA Polymerase, 1.5 ml DNAT, 1 Typing Tray, 5 Teststrips, 25 ml Hybridization Buffer, 80 ml Wash Solution A, 25 ml Conjugate Solution, 80 ml Wash Solution B, 25 ml Color Developer	5 tests	Other IVD	Annex III IVDD
4-360	CVD StripAssay® T	50 ml Lysis Solution, 5 ml Genextract Resin, 500 µl Amplification Mix, 500 µl Taq Dilution Buffer, 1.5 ml DNAT, 3 Typing Trays, 20 Teststrips, 25 ml Hybridization Buffer, 80 ml Wash Solution A, 25 ml Conjugate Solution, 80 ml Wash Solution B, 25 ml Color Developer	20 tests	Other IVD	Annex III IVDD
4-360-TRIAL	CVD StripAssay® T	50 ml Lysis Solution, 5 ml Genextract Resin, 500 µl Amplification Mix, 500 µl Taq Dilution Buffer, 75 U Taq DNA Polymerase, 1.5 ml DNAT, 1 Typing Tray, 5 Teststrips, 25 ml Hybridization Buffer, 80 ml Wash Solution A, 25 ml Conjugate Solution, 80 ml Wash Solution B, 25 ml Color Developer	5 tests	Other IVD	Annex III IVDD
4-370	CVD StripAssay® A	50 ml Lysis Solution, 5 ml Genextract Resin, 500 µl Amplification Mix, 500 µl Taq Dilution Buffer, 1.5 ml DNAT, 3 Typing Trays, 20 Teststrips, 25 ml Hybridization Buffer, 80 ml Wash Solution A, 25 ml Conjugate Solution, 80 ml Wash Solution B, 25 ml Color Developer	20 tests	Other IVD	Annex III IVDD
4-370-TRIAL	CVD StripAssay® A	50 ml Lysis Solution, 5 ml Genextract Resin, 500 µl Amplification Mix, 500 µl Taq Dilution Buffer, 75 U Taq DNA Polymerase, 1.5 ml DNAT, 1 Typing Tray, 5 Teststrips, 25 ml Hybridization Buffer, 80 ml Wash Solution A, 25 ml Conjugate Solution, 80 ml Wash Solution B, 25 ml Color Developer	5 tests	Other IVD	Annex III IVDD
4-380	CAH StripAssay®	50 ml Lysis Solution, 5 ml Genextract Resin, 500 µl Amplification Mix A, 500 µl Amplification Mix B, 500 µl Amplification Mix C, 500 µl Taq Dilution Buffer, 175 U HS-Taq DNA Polymerase, 1.5 ml DNAT, 3 Typing Trays, 20 Teststrips, 25 ml Hybridization Buffer, 80 ml Wash Solution A, 25 ml Conjugate Solution, 80 ml Wash Solution B, 25 ml Color Developer	20 tests	Other IVD	Annex III IVDD
4-380-TRIAL	CAH StripAssay®	50 ml Lysis Solution, 5 ml Genextract Resin, 500 µl Amplification Mix A, 500 µl Amplification Mix B, 500 µl Amplification Mix C, 500 µl Taq Dilution Buffer, 125 U HS-Taq DNA Polymerase, 1.5 ml DNAT, 1 Typing Tray, 5 Teststrips, 25 ml Hybridization Buffer, 80 ml Wash Solution A, 25 ml Conjugate Solution, 80 ml Wash Solution B, 25 ml Color Developer	5 tests	Other IVD	Annex III IVDD

REF	Product Name	Contents	Quantity	Classification	Conformity Assessment
4-390	FMF-SAA1 StripAssay®	50 ml Lysis Solution, 5 ml Genextract Resin, 500 µl Amplification Mix, 500 µl Taq Dilution Buffer, 1.5 ml DNAT, 3 Typing Trays, 20 Teststrips, 25 ml Hybridization Buffer, 80 ml Wash Solution A, 25 ml Conjugate Solution, 80 ml Wash Solution B, 25 ml Color Developer	20 tests	Other IVD	Annex III IVDD
4-390-TRIAL	FMF-SAA1 StripAssay®	50 ml Lysis Solution, 5 ml Genextract Resin, 500 µl Amplification Mix, 500 µl Taq Dilution Buffer, 75 U Taq DNA Polymerase, 1.5 ml DNAT, 1 Typing Tray, 5 Teststrips, 25 ml Hybridization Buffer, 80 ml Wash Solution A, 25 ml Conjugate Solution, 80 ml Wash Solution B, 25 ml Color Developer	5 tests	Other IVD	Annex III IVDD
4-410	CF StripAssay®	50 ml Lysis Solution, 5 ml Genextract Resin, 250 µl Amplification Mix A, 250 µl Amplification Mix B, 500 µl Taq Dilution Buffer, 125 U HS-TaQ DNA Polymerase, 1.5 ml DNAT, 3 Typing Trays, 10 Teststrips A, 10 Teststrips B, 25 ml Hybridization Buffer, 80 ml Wash Solution A, 25 ml Conjugate Solution, 80 ml Wash Solution B, 25 ml Color Developer	10 tests	Other IVD	Annex III IVDD
4-410-TRIAL	CF StripAssay®	50 ml Lysis Solution, 5 ml Genextract Resin, 250 µl Amplification Mix A, 250 µl Amplification Mix B, 500 µl Taq Dilution Buffer, 125 U HS-TaQ DNA Polymerase, 1.5 ml DNAT, 2 Typing Trays, 5 Teststrips A, 5 Teststrips B, 25 ml Hybridization Buffer, 80 ml Wash Solution A, 25 ml Conjugate Solution, 80 ml Wash Solution B, 25 ml Color Developer	5 tests	Other IVD	Annex III IVDD
4-420	CF StripAssay® TUR	50 ml Lysis Solution, 5 ml Genextract Resin, 250 µl Amplification Mix A, 250 µl Amplification Mix B, 500 µl Taq Dilution Buffer, 125 U HS-TaQ DNA Polymerase, 1.5 ml DNAT, 3 Typing Trays, 10 Teststrips A, 10 Teststrips B, 25 ml Hybridization Buffer, 80 ml Wash Solution A, 25 ml Conjugate Solution, 80 ml Wash Solution B, 25 ml Color Developer	10 tests	Other IVD	Annex III IVDD
4-420-TRIAL	CF StripAssay® TUR	50 ml Lysis Solution, 5 ml Genextract Resin, 250 µl Amplification Mix A, 250 µl Amplification Mix B, 500 µl Taq Dilution Buffer, 125 U HS-TaQ DNA Polymerase, 1.5 ml DNAT, 2 Typing Trays, 5 Teststrips A, 5 Teststrips B, 25 ml Hybridization Buffer, 80 ml Wash Solution A, 25 ml Conjugate Solution, 80 ml Wash Solution B, 25 ml Color Developer	5 tests	Other IVD	Annex III IVDD
4-430	CF StripAssay® GER	50 ml Lysis Solution, 5 ml Genextract Resin, 250 µl Amplification Mix A, 250 µl Amplification Mix B, 500 µl Taq Dilution Buffer, 125 U HS-TaQ DNA Polymerase, 1.5 ml DNAT, 3 Typing Trays, 10 Teststrips A, 10 Teststrips B, 25 ml Hybridization Buffer, 80 ml Wash Solution A, 25 ml Conjugate Solution, 80 ml Wash Solution B, 25 ml Color Developer	10 tests	Other IVD	Annex III IVDD
4-430-TRIAL	CF StripAssay® GER	50 ml Lysis Solution, 5 ml Genextract Resin, 250 µl Amplification Mix A, 250 µl Amplification Mix B, 500 µl Taq Dilution Buffer, 125 U HS-TaQ DNA Polymerase, 1.5 ml DNAT, 2 Typing Trays, 5 Teststrips A, 5 Teststrips B, 25 ml Hybridization Buffer, 80 ml Wash Solution A, 25 ml Conjugate Solution, 80 ml Wash Solution B, 25 ml Color Developer	5 tests	Other IVD	Annex III IVDD
4-710	PGX-HIV StripAssay®	50 ml Lysis Solution, 5 ml Genextract Resin, 500 µl Amplification Mix, 500 µl Taq Dilution Buffer, 1.5 ml DNAT, 3 Typing Trays, 20 Teststrips, 25 ml Hybridization Buffer, 80 ml Wash Solution A, 25 ml Conjugate Solution, 80 ml Wash Solution B, 25 ml Color Developer	20 tests	Other IVD	Annex III IVDD
4-710-TRIAL	PGX-HIV StripAssay®	50 ml Lysis Solution, 5 ml Genextract Resin, 500 µl Amplification Mix, 500 µl Taq Dilution Buffer, 75 U Taq DNA Polymerase, 1.5 ml DNAT, 1 Typing Tray, 5 Teststrips, 25 ml Hybridization Buffer, 80 ml Wash Solution A, 25 ml Conjugate Solution, 80 ml Wash Solution B, 25 ml Color Developer	5 tests	Other IVD	Annex III IVDD

REF	Product Name	Contents	Quantity	Classification	Conformity Assessment
4-720	PGX-5FU StripAssay®	50 ml Lysis Solution, 5 ml Genextract Resin, 500 µl Amplification Mix, 500 µl Taq Dilution Buffer, 1.5 ml DNAT, 3 Typing Trays, 20 Teststrips, 25 ml Hybridization Buffer, 80 ml Wash Solution A, 25 ml Conjugate Solution, 80 ml Wash Solution B, 25 ml Color Developer	20 tests	Other IVD	Annex III IVDD
4-720-TRIAL	PGX-5FU StripAssay®	50 ml Lysis Solution, 5 ml Genextract Resin, 500 µl Amplification Mix, 500 µl Taq Dilution Buffer, 75 U Taq DNA Polymerase, 1.5 ml DNAT, 1 Typing Tray, 5 Teststrips, 25 ml Hybridization Buffer, 80 ml Wash Solution A, 25 ml Conjugate Solution, 80 ml Wash Solution B, 25 ml Color Developer	5 tests	Other IVD	Annex III IVDD
4-730	PGX-Thrombo StripAssay®	50 ml Lysis Solution, 5 ml Genextract Resin, 500 µl Amplification Mix, 500 µl Taq Dilution Buffer, 1.5 ml DNAT, 3 Typing Trays, 20 Teststrips, 25 ml Hybridization Buffer, 80 ml Wash Solution A, 25 ml Conjugate Solution, 80 ml Wash Solution B, 25 ml Color Developer	20 tests	Other IVD	Annex III IVDD
4-730-TRIAL	PGX-Thrombo StripAssay®	50 ml Lysis Solution, 5 ml Genextract Resin, 500 µl Amplification Mix, 500 µl Taq Dilution Buffer, 75 U Taq DNA Polymerase, 1.5 ml DNAT, 1 Typing Tray, 5 Teststrips, 25 ml Hybridization Buffer, 80 ml Wash Solution A, 25 ml Conjugate Solution, 80 ml Wash Solution B, 25 ml Color Developer	5 tests	Other IVD	Annex III IVDD
4-740	PGX-TPMT StripAssay®	50 ml Lysis Solution, 5 ml Genextract Resin, 500 µl Amplification Mix, 500 µl Taq Dilution Buffer, 1.5 ml DNAT, 3 Typing Trays, 20 Teststrips, 25 ml Hybridization Buffer, 80 ml Wash Solution A, 25 ml Conjugate Solution, 80 ml Wash Solution B, 25 ml Color Developer	20 tests	Other IVD	Annex III IVDD
4-740-TRIAL	PGX-TPMT StripAssay®	50 ml Lysis Solution, 5 ml Genextract Resin, 500 µl Amplification Mix, 500 µl Taq Dilution Buffer, 75 U Taq DNA Polymerase, 1.5 ml DNAT, 1 Typing Tray, 5 Teststrips, 25 ml Hybridization Buffer, 80 ml Wash Solution A, 25 ml Conjugate Solution, 80 ml Wash Solution B, 25 ml Color Developer	5 tests	Other IVD	Annex III IVDD
4-750	PGX-CYP2C19 StripAssay®	50 ml Lysis Solution, 5 ml Genextract Resin, 500 µl Amplification Mix, 500 µl Taq Dilution Buffer, 1.5 ml DNAT, 3 Typing Trays, 20 Teststrips, 25 ml Hybridization Buffer, 80 ml Wash Solution A, 25 ml Conjugate Solution, 80 ml Wash Solution B, 25 ml Color Developer	20 tests	Other IVD	Annex III IVDD
4-750-TRIAL	PGX-CYP2C19 StripAssay®	50 ml Lysis Solution, 5 ml Genextract Resin, 500 µl Amplification Mix, 500 µl Taq Dilution Buffer, 75 U Taq DNA Polymerase, 1.5 ml DNAT, 1 Typing Tray, 5 Teststrips, 25 ml Hybridization Buffer, 80 ml Wash Solution A, 25 ml Conjugate Solution, 80 ml Wash Solution B, 25 ml Color Developer	5 tests	Other IVD	Annex III IVDD
4-760	PGX-CYP2D6 StripAssay®	50 ml Lysis Solution, 5 ml Genextract Resin, 500 µl Amplification Mix, 500 µl Taq Dilution Buffer, 1.5 ml DNAT, 3 Typing Trays, 20 Teststrips, 25 ml Hybridization Buffer, 80 ml Wash Solution A, 25 ml Conjugate Solution, 80 ml Wash Solution B, 25 ml Color Developer	20 tests	Other IVD	Annex III IVDD
4-760-TRIAL	PGX-CYP2D6 StripAssay®	50 ml Lysis Solution, 5 ml Genextract Resin, 500 µl Amplification Mix, 500 µl Taq Dilution Buffer, 75 U Taq DNA Polymerase, 1.5 ml DNAT, 1 Typing Tray, 5 Teststrips, 25 ml Hybridization Buffer, 80 ml Wash Solution A, 25 ml Conjugate Solution, 80 ml Wash Solution B, 25 ml Color Developer	5 tests	Other IVD	Annex III IVDD
4-770	PGX-CYP2D6 XL StripAssay®	500 µl Amplification Mix A, 500 µl Amplification Mix B, 500 µl Taq Dilution Buffer, 125 U HS-Taq DNA Polymerase 1.5 ml DNAT, 3 Typing Trays, 20 Teststrips, 25 ml Hybridization Buffer, 80 ml Wash Solution A, 25 ml Conjugate Solution, 80 ml Wash Solution B, 25 ml Color Developer	20 tests	Other IVD	Annex III IVDD

REF	Product Name	Contents	Quantity	Classification	Conformity Assessment
4-770-TRIAL	PGX-CYP2D6 XL StripAssay®	500 µl Amplification Mix A, 500 µl Amplification Mix B, 500 µl Taq Dilution Buffer, 125 U HS-Taq DNA Polymerase 1.5 ml DNAT, 1 Typing Tray, 5 Teststrips, 25 ml Hybridization Buffer, 80 ml Wash Solution A, 25 ml Conjugate Solution, 80 ml Wash Solution B, 25 ml Color Developer	5 tests	Other IVD	Annex III IVDD
4-780	PGX-5FU XL StripAssay®	50 ml Lysis Solution, 5 ml Genextract Resin, 500 µl Amplification Mix, 500 µl Taq Dilution Buffer, 75 U Taq DNA Polymerase, 1.5 ml DNAT, 3 Typing Trays, 20 Teststrips, 25 ml Hybridization Buffer, 80 ml Wash Solution A, 25 ml Conjugate Solution, 80 ml Wash Solution B, 25 ml Color Developer	20 tests	Other IVD	Annex III IVDD
4-780-TRIAL	PGX-5FU XL StripAssay®	50 ml Lysis Solution, 5 ml Genextract Resin, 500 µl Amplification Mix, 500 µl Taq Dilution Buffer, 75 U Taq DNA Polymerase, 1.5 ml DNAT, 1 Typing Tray, 5 Teststrips, 25 ml Hybridization Buffer, 80 ml Wash Solution A, 25 ml Conjugate Solution, 80 ml Wash Solution B, 25 ml Color Developer	5 tests	Other IVD	Annex III IVDD
5-560	BRAF 600/601 StripAssay®	500 µl Amplification Mix, 500 µl Taq Dilution Buffer, 75 U Taq DNA Polymerase, 1.5 ml DNAT, 3 Typing Trays, 20 Teststrips, 25 ml Hybridization Buffer, 80 ml Wash Solution A, 25 ml Conjugate Solution, 80 ml Wash Solution B, 25 ml Color Developer	20 tests	Other IVD	Annex III IVDD
5-560-TRIAL	BRAF 600/601 StripAssay®	500 µl Amplification Mix, 500 µl Taq Dilution Buffer, 75 U Taq DNA Polymerase, 1.5 ml DNAT, 1 Typing Tray, 5 Teststrips, 25 ml Hybridization Buffer, 80 ml Wash Solution A, 25 ml Conjugate Solution, 80 ml Wash Solution B, 25 ml Color Developer	5 tests	Other IVD	Annex III IVDD
5-620	NRAS XL StripAssay®	500 µl Amplification Mix, 500 µl Taq Dilution Buffer, 75 U Taq DNA Polymerase, 1.5 ml DNAT, 3 Typing Trays, 20 Teststrips, 25 ml Hybridization Buffer, 80 ml Wash Solution A, 25 ml Conjugate Solution, 80 ml Wash Solution B, 25 ml Color Developer	20 tests	Other IVD	Annex III IVDD
5-620-TRIAL	NRAS XL StripAssay®	500 µl Amplification Mix, 500 µl Taq Dilution Buffer, 75 U Taq DNA Polymerase, 1.5 ml DNAT, 1 Typing Tray, 5 Teststrips, 25 ml Hybridization Buffer, 80 ml Wash Solution A, 25 ml Conjugate Solution, 80 ml Wash Solution B, 25 ml Color Developer	5 tests	Other IVD	Annex III IVDD
5-630	EGFR XL StripAssay®	500 µl Amplification Mix A, 500 µl Amplification Mix B, 500 µl Taq Dilution Buffer, 125 U Taq DNA Polymerase, 1.5 ml DNAT, 3 Typing Trays, 20 Teststrips, 25 ml Hybridization Buffer, 80 ml Wash Solution A, 25 ml Conjugate Solution, 80 ml Wash Solution B, 25 ml Color Developer	20 tests	Other IVD	Annex III IVDD
5-630-TRIAL	EGFR XL StripAssay®	500 µl Amplification Mix A, 500 µl Amplification Mix B, 500 µl Taq Dilution Buffer, 75 U Taq DNA Polymerase, 1.5 ml DNAT, 1 Typing Tray, 5 Teststrips, 25 ml Hybridization Buffer, 80 ml Wash Solution A, 25 ml Conjugate Solution, 80 ml Wash Solution B, 25 ml Color Developer	5 tests	Other IVD	Annex III IVDD
5-680	KRAS XL StripAssay®	500 µl Amplification Mix, 500 µl Taq Dilution Buffer, 75 U Taq DNA Polymerase, 1.5 ml DNAT, 3 Typing Trays, 20 Teststrips, 25 ml Hybridization Buffer, 80 ml Wash Solution A, 25 ml Conjugate Solution, 80 ml Wash Solution B, 25 ml Color Developer	20 tests	Other IVD	Annex III IVDD
5-680-TRIAL	KRAS XL StripAssay®	500 µl Amplification Mix, 500 µl Taq Dilution Buffer, 75 U Taq DNA Polymerase, 1.5 ml DNAT, 1 Typing Tray, 5 Teststrips, 25 ml Hybridization Buffer, 80 ml Wash Solution A, 25 ml Conjugate Solution, 80 ml Wash Solution B, 25 ml Color Developer	5 tests	Other IVD	Annex III IVDD
CS-012	StripAssay® Detection Reagents	1.5 ml DNAT, 25 ml Hybridization Buffer, 80 ml Wash Solution A, 25 ml Conjugate Solution, 80 ml Wash Solution B, 25 ml Color Developer	20 tests	Other IVD	Annex III IVDD

REF	Product Name	Contents	Quantity	Classification	Conformity Assessment
2-014	GEN <sup>X</sup> TRACT™ Blood DNA Extraction System	4 x 50 ml Lysis Solution, 4 x 5 ml GEN <sup>X</sup> TRACT Resin	100 extr.	Other IVD	Annex III IVDD
2-030	D2PCR™ Buffer	3 x 1.75 ml D2PCR Buffer	100 extr.	Other IVD	Annex III IVDD
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
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
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
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
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
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
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




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
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
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
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
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
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
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
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

REF	Product Name	Contents	Quantity	Classification	Conformity Assessment
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
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
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
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
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
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
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
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
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

REF	Product Name	Contents	Quantity	Classification	Conformity Assessment
7-620	HLA-B27 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
7-620-TRIAL	HLA-B27 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
7-623	HLA-B27 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
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
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
8-110	EGFR T790M RealFast™ Assay	1000 µl RealFast™ 2x Probe Mix, 550 µl Assay Mix, 75 µl Positive Control	100 tests	Other IVD	Annex III IVDD
8-110-TRIAL	EGFR T790M RealFast™ Assay	200 µl RealFast™ 2x Probe Mix, 550 µl Assay Mix, 75 µl Positive Control	20 tests	Other IVD	Annex III IVDD
8-113	EGFR T790M RealFast™ Assay	320 µl RealFast™ 2x Probe Mix, 550 µl Assay Mix, 75 µl Positive Control	32 tests	Other IVD	Annex III IVDD
8-410	SARS-CoV-2 RealFast™ Assay	500 µl RealFast™ 4x RT-PCR Mix, 100 µl RTase, 400 µl Assay Mix, 500 µl Positive Control	100 tests	Other IVD	Annex III IVDD
8-410-TRIAL	SARS-CoV-2 RealFast™ Assay	100 µl RealFast™ 4x RT-PCR Mix, 30 µl RTase, 400 µl Assay Mix, 500 µl Positive Control	20 tests	Other IVD	Annex III IVDD
8-412	SARS-CoV-2 RealFast™ Assay	2x 1250 µl RealFast™ 4x RT-PCR Mix, 2x 250 µl RTase, 2x 1000 µl Assay Mix, 500 µl Positive Control	500 tests	Other IVD	Annex III IVDD

Vienna, January 19<sup>th</sup>, 2021

  
 Martin Zeppetzauer, MRes  
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