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.
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Product details

REF	Product Name	Contents	Quan-tity	Classifi-cation	Conformity Assessment
4-130	β-Globin StripAssay® MED	50 ml Lysis Solution, 5 ml Genxtract 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
4-130-TRIAL	β-Globin StripAssay® MED	50 ml Lysis Solution, 5 ml Genxtract 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

Vienna, May 25th, 2022

Martin Zeppetzauer, MRes
Chief Executive Officer
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Product details

REF	Product Name	Contents	Quan-tity	Classifi-cation	Conformity Assessment
4-140	β-Globin StripAssay® IME	50 ml Lysis Solution, 5 ml Genxtract 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
4-140-TRIAL	β-Globin StripAssay® IME	50 ml Lysis Solution, 5 ml Genxtract 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

Vienna, May 25th, 2022

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Product details

REF	Product Name	Contents	Quan-tity	Classifi-cation	Conformity Assessment
4-150	β-Globin StripAssay® SEA	50 ml Lysis Solution, 5 ml Genxtract 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
4-150-TRIAL	β-Globin StripAssay® SEA	50 ml Lysis Solution, 5 ml Genxtract 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

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Product details

REF	Product Name	Contents	Quantity	Classification	Conformity Assessment
4-170	β-Thal Modifier StripAssay®	50 ml Lysis Solution, 5 ml Genxtract 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
4-170-TRIAL	β-Thal Modifier StripAssay®	50 ml Lysis Solution, 5 ml Genxtract 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

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Product details

REF	Product Name	Contents	Quan-tity	Classifi-cation	Conformity Assessment
4-210	Haemochromatosis StripAssay® B	50 ml Lysis Solution, 5 ml Genxtract 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
4-210-TRIAL	Haemochromatosis StripAssay® B	50 ml Lysis Solution, 5 ml Genxtract 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

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Product details

REF	Product Name	Contents	Quan-tity	Classifi-cation	Conformity Assessment
4-220	Haemochromatosis StripAssay® A	50 ml Lysis Solution, 5 ml Genxtract 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
4-220-TRIAL	Haemochromatosis StripAssay® A	50 ml Lysis Solution, 5 ml Genxtract 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

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Product details

REF	Product Name	Contents	Quantity	Classification	Conformity Assessment
4-240	CVD StripAssay®	50 ml Lysis Solution, 5 ml Genxtract 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 Genxtract 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

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Product details

REF	Product Name	Contents	Quan-tity	Classifi-cation	Conformity Assessment
4-260	FV-PTH-MTHFR StripAssay®	50 ml Lysis Solution, 5 ml Genxtract 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 Genxtract 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

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Product details

REF	Product Name	Contents	Quantity	Classification	Conformity Assessment
4-280	Apo E StripAssay®	50 ml Lysis Solution, 5 ml Genxtract 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 Genxtract 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

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Product details

REF	Product Name	Contents	Quan-tity	Classifi-cation	Conformity Assessment
4-290	FV-PTH StripAssay®	50 ml Lysis Solution, 5 ml Genxtract 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 Genxtract 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

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Product details

REF	Product Name	Contents	Quan-tity	Classifi-cation	Conformity Assessment
4-300	Lactose Intolerance StripAssay®	50 ml Lysis Solution, 5 ml Genxtract 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
4-300-TRIAL	Lactose Intolerance StripAssay®	50 ml Lysis Solution, 5 ml Genxtract 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

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Product details

REF	Product Name	Contents	Quan-tity	Classifi-cation	Conformity Assessment
4-310	Sugar Intolerance StripAssay®	50 ml Lysis Solution, 5 ml Genxtract 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 Genxtract 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

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Product details

REF	Product Name	Contents	Quantity	Classification	Conformity Assessment
4-320	HLA-B27 StripAssay®	50 ml Lysis Solution, 5 ml Genxtract 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 Genxtract 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

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Product details

REF	Product Name	Contents	Quan-tity	Classifi-cation	Conformity Assessment
4-360	CVD StripAssay® T	50 ml Lysis Solution, 5 ml Genxtract 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 Genxtract 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

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REF	Product Name	Contents	Quantity	Classification	Conformity Assessment
4-370	CVD StripAssay® A	50 ml Lysis Solution, 5 ml Genxtract 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 Genxtract 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

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Product details

REF	Product Name	Contents	Quan-tity	Classifi-cation	Conformity Assessment
4-710	PGX-HIV StripAssay®	50 ml Lysis Solution, 5 ml Genxtract 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 Genxtract 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

Vienna, May 25th, 2022

Martin Zeppetzauer, MRes
Chief Executive Officer
ViennaLab Diagnostics GmbH

DECLARATION OF CONFORMITY

Manufacturer: ViennaLab Diagnostics GmbH
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Product details

REF	Product Name	Contents	Quantity	Classification	Conformity Assessment
4-730	PGX-Thrombo StripAssay®	50 ml Lysis Solution, 5 ml Genxtract 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 Genxtract 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

Vienna, May 25th, 2022

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Product details

REF	Product Name	Contents	Quan-tity	Classifi-cation	Conformity Assessment
4-740	PGX-TPMT StripAssay®	50 ml Lysis Solution, 5 ml Genxtract 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 Genxtract 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

Vienna, May 25th, 2022

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ESTABLISHED INNOVATIONS IN DIAGNOSTICS

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Product details

REF	Product Name	Contents	Quan-tity	Classifi-cation	Conformity Assessment
4-750	PGX-CYP2C19 StripAssay®	50 ml Lysis Solution, 5 ml Genxtract 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 Genxtract 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

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Product details

REF	Product Name	Contents	Quan-tity	Classifi-cation	Conformity Assessment
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
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

Vienna, May 25th, 2022

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Product details

REF	Product Name	Contents	Quan-tity	Classifi-cation	Conformity Assessment
4-780	PGX-5FU XL StripAssay®	50 ml Lysis Solution, 5 ml Genxtract 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 Genxtract 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

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REF	Product Name	Contents	Quan-tity	Classifi-cation	Conformity Assessment
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

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Product details

REF	Product Name	Contents	Quantity	Classification	Conformity Assessment
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

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Product details

REF	Product Name	Contents	Quantity	Classification	Conformity Assessment
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

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Product details

REF	Product Name	Contents	Quan-tity	Classifi-cation	Conformity Assessment
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

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