



Advancing Molecular Diagnostics

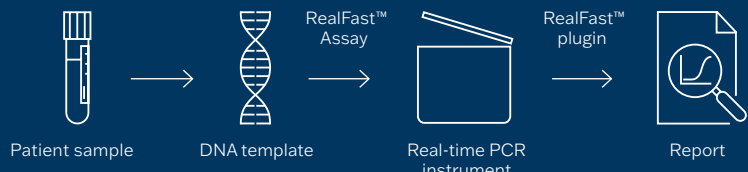
Product overview

PCR Assays

Sample preparation kits

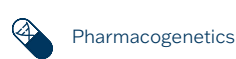
Area	REF	Product Name	Unit Size	Application	Regulatory Status
StripAssays® RealFast™ Assays	2-014	GEN ^x TRACT™ Blood DNA Extraction System	100 Rxn	DNA extraction from fresh, frozen and dried blood	CE IVDR
StripAssays® RealFast™ Assays	2-020	Spin Micro DNA Extraction Kit	20 Rxn	DNA extraction and purification from whole blood and buccal swabs	RUO
RealFast™ Assays	2-030	D2PCR™ Buffer	100 Rxn	For direct-to-PCR applications	CE IVDR











RealFast™ Assay










Single marker detection

Category	Clinical Topic	REF 100 / 32 Rxn	Product Name	Detail	Regulatory Status
NEW	Spinal Muscular Atrophy (SMA)	7-700	SMN1 RealFast™ Assay	Detects <i>SMN1</i> c.840C which is used for SMA analysis	RUO
NEW	Cystic Fibrosis (CF)	7-260 / 7-263	CF F508del RealFast™ Assay	Detects the most common clinically relevant mutation (F508del) in the <i>CFTR</i> gene	CE IVDD
	Carbamazepine Hypersensitivity	7-640 / 7-643	HLA-A3101 RealFast™ Assay	Detects the human leukocyte antigen (HLA) <i>HLA-A*31:01</i> allele, which is strongly associated with carbamazepine hypersensitivity reactions in Europeans and Japanese	CE IVDD
	Carbamazepine Hypersensitivity	7-630 / 7-633	HLA-B1502 RealFast™ Assay	Detects the human leukocyte antigen (HLA) <i>HLA-B*15:02</i> allele, which is strongly associated with carbamazepine hypersensitivity reactions in Asian populations	CE IVDD
	Carbohydrate Intolerance	7-150 / 7-153	LCT -13910C>T RealFast™ Assay	Detects the most common polymorphism in the <i>lactase (LCT)</i> gene causing lactase non-persistence	CE IVDD
	Cardiovascular Diseases (CVD)	7-230 / 7-233	FGB -455G>A RealFast™ Assay	Identifies homozygosity for the -455G>A <i>fibrinogen beta-chain (FGB)</i> allele which may increase susceptibility to atherothrombosis in at-risk patients	CE IVDD
	CVD	7-110 / 7-113	FV Leiden RealFast™ Assay	Detects the most common genetic risk factor associated with venous thromboembolism, the 1691G>A mutation in the <i>Factor V (F5)</i> gene	CE IVDR
	CVD	7-240 / 7-243	FXII 46C>T RealFast™ Assay	Identifies patients with the unfavorable TT genotype for <i>Factor XII (F12)</i> , who may have an increased susceptibility to thrombotic disorders	CE IVDD
	CVD	7-250 / 7-253	FXIII V34L RealFast™ Assay	Identifies carriers of the protective 34L variant of <i>Factor XIII (F13A)</i> among at-risk patients of hereditary thrombophilia	CE IVDD
	CVD	7-160 / 7-163	MTHFR 677C>T RealFast™ Assay	Detects common mutation in the <i>methylenetetrahydrofolate reductase (MTHFR)</i> gene causing hyperhomocysteinemia, which is a risk factor for cardiovascular disease	CE IVDD
	CVD	7-170 / 7-173	MTHFR 1298A>C RealFast™ Assay	Detects common mutation in the <i>methylenetetrahydrofolate reductase (MTHFR)</i> gene causing hyperhomocysteinemia, which is a risk factor for cardiovascular disease	CE IVDD

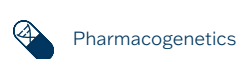


Category	Clinical Topic	REF 100 / 32 Rxn	Product Name	Detail	Regulatory Status
	CVD	7-180 / 7-183	PAI-1 4G/5G RealFast™ Assay	Detects the 4G risk allele in the <i>SERPINE1</i> gene, encoding plasminogen activator inhibitor-1 (PAI-1), and is associated with cardiovascular disease and pregnancy complications	CE IVDD
	CVD	7-120 / 7-123	PTH 20210G>A RealFast™ Assay	Detects the second most important genetic risk factor for venous thromboembolism in the <i>Factor II</i> gene, encoding prothrombin (PTH)	CE IVDR
	Congenital Adrenal Hyperplasia (CAH)	7-410 / ---	CAH RealFast™ CNV Assay	Discriminates between deletions, duplications and normal copy number status of the <i>CYP21A2</i> gene in patients with CAH. Recommended to be used in combination with CAH StripAssay® [REF 4-380]	CE IVDR
	Genetic Predisposition	7-620 / 7-623	HLA-B27 RealFast™ Assay	Detects the human leukocyte antigen (HLA) <i>HLA-B*27</i> allele, which is associated with ankylosing spondylitis	CE IVDR
	Haemochromatosis	7-130 / 7-133	HFE C282Y RealFast™ Assay	Detects the common C282Y variant in the <i>HFE</i> gene causing hereditary haemochromatosis (HH) type 1	CE IVDR
	Haemochromatosis	7-140 / 7-143	HFE H63D RealFast™ Assay	Detects the common H63D variant in the <i>HFE</i> gene causing hereditary haemochromatosis (HH) type 1	CE IVDR
	Pharmacogenetics	7-420 / ---	CYP2D6 RealFast™ CNV Assay	Discriminates between deletions, duplications and normal copy number status of the <i>CYP2D6</i> gene. Recommended to be used in combination with PGX-CYP2D6 XL StripAssay® [REF 4-770]	CE IVDR
	Pharmacogenetics	7-610 / 7-613	HLA-B5701 RealFast™ Assay	Detects the human leukocyte antigen (HLA) <i>HLA-B*57:01</i> allele, which is associated with hypersensitivity to the anti-HIV drug abacavir	CE IVDD
	Pharmacogenetics	7-210 / 7-213	SLCO1B1 c.521T>C RealFast™ Assay	Detects a variant in human <i>solute carrier organic anion transporter family member 1B1</i> (<i>SLCO1B1</i>) gene in patients who are at higher risk for developing statin-induced myopathy	CE IVDD
	Pharmacogenetics	7-190 / 7-193	VKORC1 -1639G>A RealFast™ Assay	Detects the most important polymorphism in the <i>Vitamin K Epoxide Reductase Complex 1</i> (<i>VKORC1</i>) gene associated with interindividual dose requirements for oral anticoagulants	CE IVDD

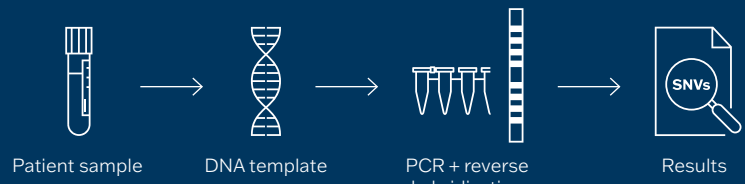
Multiplex testing

Category	Clinical Topic	REF 100 / 32 Rxn	Product Name	Detail	Regulatory Status
 NEW	Severe Combined Immunodeficiency (SCID)	7-710	SCID-XLA mpx RealFast™ Assay	Allows for the simultaneous determination of the copy number of T-cell receptor excision circles (TRECs) and kappa-deleting recombination excision circles (KRECs)	RUO
 NEW	Sickle Cell Disease (SCD)	7-280	HbS-HbC mpx RealFast™ Assay	Allows for the simultaneous detection of c.20A>T (HbS) and c.19G>A (HbC) mutation in the β -globin (<i>HBB</i>) gene	RUO
	CVD	7-115 / 7-118	FV-PTH mpx RealFast™ Assay	Simultaneous detection of the most important thrombophilic mutations 1691G>A in the <i>Factor V</i> gene and 20210G>A in the <i>Factor II</i> gene, encoding prothrombin (PTH)	CE IVDR
	CVD	7-165 / 7-168	MTHFR mpx RealFast™ Assay	Simultaneous detection of the two most common mutations in the <i>MTHFR</i> gene: 677C>T and 1298A>C	CE IVDD
	AAT deficiency/ COPD	7-265 / 7-268	AAT mpx RealFast™ Assay	Detects *S and *Z variants of the <i>SERPINA1</i> gene predisposing individuals to chronic obstructive pulmonary disease (COPD) and liver disease due to deficiency of alpha-1 antitrypsin (AAT)	CE IVDD
	Haemochromatosis	7-135 / 7-138	HFE mpx RealFast™ Assay	Simultaneous detection of the two most common mutations in the <i>HFE</i> gene: H63D and C282Y	CE IVDR
	Pharmacogenetics	7-225 / 7-228	CYP2C9 mpx RealFast™ Assay	Simultaneous detection of <i>CYP2C9</i> *2 (c.430C>T) and <i>CYP2C9</i> *3 (c.1075A>C) polymorphisms to determine the drug response of known targets, like S-warfarin or phenytoin	CE IVDD
	Service	CS-045	RealFast™ Confirmation Service	Service to assist in establishing RealFast™ Assays as well as for performance monitoring	













CE IVDR: Products marked with this symbol comply to the Regulation (EU) 2017/746 on *in vitro* diagnostic devices.



StripAssays®

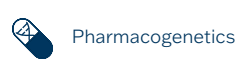
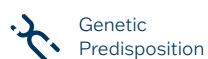


Category	Clinical Topic	REF	Product Name	Unit Size	Detail	Regulatory Status
	Alzheimer Disease	4-280	Apo E StripAssay®	20 tests	Detection of isoforms Apo E2, E3 and E4	CE IVDD
	Cancer	5-560	BRAF 600/601 StripAssay®	20 tests	Ultra-sensitive detection of 9 <i>BRAF</i> mutations in codons 600 and 601	CE IVDD
	Cancer	5-630	EGFR XL StripAssay®	20 tests	Ultra-sensitive detection of 30 <i>EGFR</i> mutations in exons 18/19/20/21	CE IVDD
	Cancer	5-680	KRAS XL StripAssay®	20 tests	Ultra-sensitive detection of 29 <i>KRAS</i> mutations in codons 12/13/59/60/61/117/146	CE IVDD
	Cancer	5-620	NRAS XL StripAssay®	20 tests	Ultra-sensitive detection of 22 <i>NRAS</i> mutations in codons 12/13/59/60/61/146	CE IVDD
	Carbohydrate Intolerance	4-300	Lactose Intolerance StripAssay®	20 tests	Detection of two <i>lactase</i> gene polymorphisms -13910T>C and -22018A>G	CE IVDR
	Carbohydrate Intolerance	4-310	Sugar Intolerance StripAssay®	20 tests	Detection of two <i>lactase</i> gene polymorphisms and four <i>aldolase B</i> gene mutations	CE IVDR
	Cardiovascular Diseases (CVD)	4-240	CVD StripAssay®	20 tests	Testing for 12 genetic variants associated with cardiovascular diseases	CE IVDD
	CVD	4-370	CVD StripAssay® A	20 tests	Testing for 8 genetic variants predisposing to atherosclerosis	CE IVDD
	CVD	4-360	CVD StripAssay® T	20 tests	Testing for 9 genetic variants predisposing to venous thromboembolism	CE IVDR
	CVD	4-290	FV-PTH StripAssay®	20 tests	Detection of the <i>Factor V</i> Leiden and <i>Factor II</i> , encoding prothrombin (PTH), gene mutations	CE IVDD
	CVD	4-260	FV-PTH-MTHFR StripAssay®	20 tests	Detection of the <i>Factor V</i> Leiden, <i>Factor II</i> , encoding prothrombin (PTH), and <i>MTHFR</i> gene mutations	CE IVDD
	Congenital Adrenal Hyperplasia (CAH)	4-380	CAH StripAssay®	20 tests	Testing for 11 most prevalent <i>CYP21A2</i> mutations. Recommended to be used in combination with CAH RealFast™ CNV Assay [REF 7-410]	CE IVDR
	Cystic Fibrosis (CF)	4-410	CF StripAssay®	10 tests	Detection of 34 common <i>CFTR</i> mutations and the IVS8 variants 5T/7T/9T	CE IVDR
	CF	4-430	CF StripAssay® GER	10 tests	Detection of 31 common <i>CFTR</i> mutations	CE IVDR
	CF	4-420	CF StripAssay® TUR	10 tests	Detection of 24 common <i>CFTR</i> mutations and the IVS8 variants 5T/7T/9T	CE IVDR
	CF	4-440	CF StripAssay® EXT	10 tests	Detection of 38 common <i>CFTR</i> mutations and the IVS8 variants 5T/7T/9T	CE IVDR
	Familial Mediterranean Fever (FMF)	4-230	FMF StripAssay®	20 tests	Detection of 12 <i>MEFV</i> gene mutations	CE IVDR
	FMF	4-390	FMF-SAA1 StripAssay®	20 tests	Detection of 12 <i>MEFV</i> gene mutations and <i>SAA1</i> genotypes 1.1, 1.3 and 1.5	CE IVDR

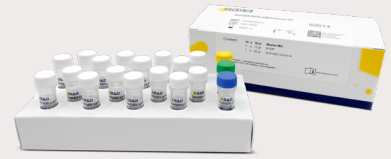
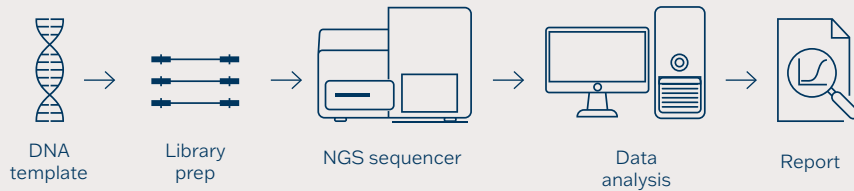
Category	Clinical Topic	REF	Product Name	Unit Size	Detail	Regulatory Status
	Genetic Predisposition	4-320	HLA-B27 StripAssay®	20 tests	Detection of all disease-relevant <i>HLA-B*27</i> subtypes	CE IVDD
	Haemochromatosis	4-220	Haemochromatosis StripAssay® A	20 tests	Detection of 18 mutations: twelve <i>HFE</i> mutations, four <i>TFR2</i> mutations and two <i>FPN1</i> mutations	CE IVDR
	Haemochromatosis	4-210	Haemochromatosis StripAssay® B	20 tests	Detection of 3 <i>HFE</i> gene mutations: C282Y, H63D, S65C	CE IVDD
	Pharmacogenetics	4-780	PGX-5FU XL StripAssay®	20 tests	Detection of <i>DPYD</i> genetic variants HapB3, <i>DPYD*13</i> , <i>DPYD*2A</i> , p.D949V associated with toxicity of 5-fluorouracil therapy	CE IVDD
	Pharmacogenetics	4-750	PGX-CYP2C19 StripAssay®	20 tests	Testing for CYP2C19 variants *1, *2, *3, *4, *5, *6, *7, *8 and *17	CE IVDR
	Pharmacogenetics	4-770	PGX-CYP2D6 XL StripAssay®	20 tests	Testing for CYP2D6 variants *1 - *12, *14, *15*, *17, *29, *35, *39, *40, *41, *58, *114. Recommended to be used in combination with CYP2D6 RealFast™ CNV Assay [REF 7-420].	CE IVDR
	Pharmacogenetics	4-740	PGX-TPMT StripAssay®	20 tests	Testing for <i>TPMT</i> variants *1, *2, *3A, *3B and *3C associated with response to thiopurine therapy	CE IVDD
	Thalassemia	4-160	α -Globin StripAssay®	10 tests	Detection of 21 common α -Globin gene mutations	CE IVDR
	Thalassemia	4-130	β -Globin StripAssay® MED	20 tests	Detection of 22 mutations covering >90% of β -Globin defects found in Mediterranean countries	CE IVDR
	Thalassemia	4-140	β -Globin StripAssay® IME	20 tests	Detection of 22 mutations covering >90% of β -Globin defects found in the Middle East and India	CE IVDR
	Thalassemia	4-150	β -Globin StripAssay® SEA	20 tests	Detection of 22 mutations covering >90% of β -Globin defects found in Southeast Asia	CE IVDR
	Thalassemia	4-170	β -Thal Modifier StripAssay®	20 tests	Testing for 5 polymorphisms associated with severity of β -Thalassemia	CE IVDD
	Service	CS-042	StripAssay® Confirmation Service		Service to assist in establishing StripAssays® as well as for performance monitoring	
	StripAssays®	6-100	StripAssay® Evaluator		Software for automated scanning of teststrips, interpretation, and archiving of results	RUO

StripAssay® and RealFast™ Assays are now presented within BioVendor Group's molecular diagnostics portfolio. The products themselves remain unchanged and continue to be developed and manufactured by ViennaLab Diagnostics, ensuring the same quality, performance, and reliability customers trust.

CE IVDR: Products marked with this symbol comply to the Regulation (EU) 2017/746 on *in vitro* diagnostic devices.







NGS Assays

















Amplicon-based assays

Microbiome

Category	REF	Product Name	Unit Size	Detail	Regulatory Status
	9-131-16	16S Microbiome + ITS NGS Assay [16 rxn]	16 Rxn	Targeted amplification of the bacterial V3-V4 variable regions of the 16S rRNA gene and the fungal ITS2 region. Includes bioinformatic analysis and report generation for species-level classification of the human gut microbiome.	RUO
	9-131	16S Microbiome + ITS NGS Assay [Set A]	96 Rxn	Differs from [Set B] and [Set C] in indexing primers only. Multiplexing up to 288 samples.	RUO
	9-132	16S Microbiome + ITS NGS Assay [Set B]	96 Rxn	Differs from [Set A] and [Set C] in indexing primers only. Multiplexing up to 288 samples.	RUO
	9-133	16S Microbiome + ITS NGS Assay [Set C]	96 Rxn	Differs from [Set A] and [Set B] in indexing primers only. Multiplexing up to 288 samples.	RUO




fastGEN

Category	REF	Product Name	Unit Size	Detail	Regulatory status
	RDNGS0001	fastGEN SOLID Cancer Kit	16 Rxn	<i>NRAS</i> , <i>KRAS</i> : codons 12, 13, 59, 60, 61, 117 and 146 <i>BRAF</i> : codon 600	CE IVDD
	RDNGS0002	fastGEN LUNG Cancer Kit	16 Rxn	<i>EGFR</i> : exons 18, 19, 20 and 21	CE IVDD
	RDNGS0007	fastGEN PIK3CA Cancer Kit	16 Rxn	<i>PIK3CA</i> : exons 2, 3, 5, 7, 8, 10, 14 and 21	RUO
	RDNGS0008	fastGEN TERT Cancer Kit	16 Rxn	<i>TERT</i> : promotor and mutations C228T and C250T	RUO
	RDNGS0009 RDNGS0009-32	fastGEN TP53 Cancer Kit	16 Rxn 32 Rxn	<i>TP53</i> : exons 2-11, 2 non-canonical exons (between exon 9 and 10) and adjacent introns (min 6nt)	RUO
	RDNGS0010	fastGEN POLE/CTNNB1 Cancer Kit	16 Rxn	<i>POLE</i> : exons 9, 11, 13 and 14 <i>CTNNB1</i> : exons 3, 7 and 8	RUO

Category	REF	Product Name	Unit Size	Detail	Regulatory Status
	RDNGS0011	fastGEN BCR::ABL1 Cancer Kit	16 Rxn	BCR::ABL1: major and minor breakpoint	RUO
	RDNGS0016	fastGEN H3F3A/IDH1/2 Cancer Kit	16 Rxn	IDH1: codon 132 IDH2: codons 140 and 172 H3F3A: codons 28 and 35	RUO
	RDNGS0018	fastGEN Food Intolerance Kit	16 Rxn	ALDOB1: rs118204429, rs387906225, rs1800546, rs76917243, rs78340951, rs77718928, rs370793608, rs764826805 AOC1: rs10156191, rs1049742, rs2268999, rs1049793, rs2052129 MCM6: rs4988235, rs182549	RUO
	RDNGS0019	fastGEN MSI Kit	16 Rxn	12 relevant loci for MSI status evaluation	RUO
	RDNGS0020-32	fastGEN EGFR/HER2 Cancer Kit	32 Rxn	EGFR: exons 18, 19, 20 and 21 HER2: exons 7, 8, 17, 19, 20 and 21	RUO
	RDNGS0021	fastGEN MPN Cancer Kit	16 Rxn	CALR: exon 9 JAK2: exons 12, 13, 14, 16 MPL: exons 4, 10, 12	RUO
	RDNGS1001	fastGEN SOLID II Cancer Kit	16 Rxn	NRAS, KRAS: codons 12, 13, 59, 60, 61, 117 and 146 BRAF: codons 594-609	RUO
NEW 	RDNGS0022	fastGEN Crohn's & Celiac Disease Kit	16 Rxn	NOD2: rs2066844, rs2066845, rs5743293 IL23R: rs1004819 and rs10889677 HLA-DQ2.2: rs2395182, rs7775228, rs4713586 HLA-DQ2.5: rs2187668 HLA-DQ8: rs7454108	RUO

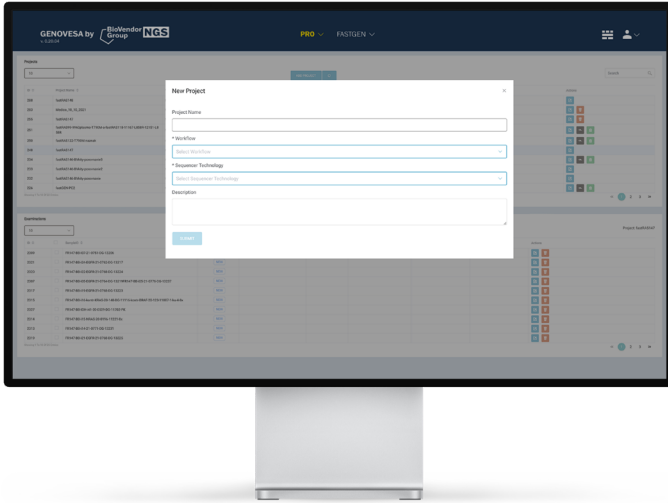
Hybrid capture-based assays

epicGEN

Category	REF	Product Name	Unit Size	Detail	Regulatory Status
	RDEG0001-32	epicGEN Solid Cancer & MSI Kit	32 Rxn (4x8 Rxn)	All relevant regions of 44 genes and 13 MSI loci	RUO
	9-221	Hereditary Cancer NGS Assay	16 Rxn	Targeting the whole CDS of 31 genes. Allows detection of SNVs, InDels, and CNVs of the covered genes (e.g. <i>BRCA1</i> , <i>BRCA2</i> , <i>CDH1</i> ,...).	RUO
	9-231	Somatic Mutations NGS Assay	16 Rxn	Targeting the whole CDS of genes covered. Detects SNVs and InDels in 10 genes (e.g. <i>BRAF</i> , <i>EGFR</i> , <i>KRAS</i> , ...) and fusions in 3 genes (i.e. <i>ALK</i> , <i>RET</i> , <i>ROS1</i>).	RUO

GENOVESA

Cloud-based platform for NGS analysis and interpretation



- Comprehensive variant detection workflows (CNV, MSI, TMB, HRD)
- Automated bioinformatics pipelines from FASTQ to report
- Advanced QC metrics
- Integrated somatic and germline workflows
- Customizable analysis settings for targeted panels (hybridization and amplicon), CES, WES, WGS
- Built-in annotation databases
- Easy variant filtering and prioritization
- Local variant database enabling internal knowledge accumulation

<u>REF</u>	<u>Product Name</u>	<u>Detail</u>	<u>Regulatory Status</u>
PLC1_Genovesa	GENOVESA software	Analysis of amplicons, panels, CES, WES, and WGS	RUO

For more information, please contact us at marketing@viennalab.com

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MANUFACTURER

ViennaLab Diagnostics GmbH
Gaudenzdorfer Guertel 43-45
A-1120 Vienna, Austria
+43 1 812 0156
marketing@viennalab.com
www.viennalab.com

BioVendor – Laboratorní medicína s.r.o.
Karásek 1767/1
621 00 Brno
Czech Republic
www.biovendor.com