BioVendor Group®



Advancing Molecular Diagnostics

Product overview

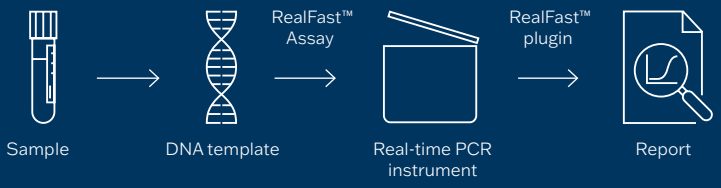
PCR Assays

Sample preparation kits

Area	REF	Product Name	Unit Size	Application	Regulatory Status
StripAssays® RealFast™ Assays	2-014	GEN^XTRACT™ Blood DNA Extraction System	100 Rxn	DNA extraction from fresh, frozen and dried blood	CE IVDR Class A
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 Class A
NEW SMN1 RealFast™ Assays SCID-XLA mpx RealFast™ Assays HbS-HbC mpx RealFast™ Assays	2-050 2-052	quickDBS	100 Rxn 500 Rxn	DNA extraction from DBS (Dried Blood Spots) for immediate use in PCR with SMN1 RealFast™Assays, SCID-XLA mpx RealFast™Assays and HbS-HbC mpx RealFast™Assays	RUO

RealFast™ Assay





Single marker detection

Category	Clinical Topic	REF 100 / 32 Rxn	Product Name	Detail	Regulatory Status
NEW	Spinal Muscular Atrophy (SMA)	7-700 / --- 7-702 (500 Rxn)	SMN1 RealFast™ Assay	Detects *SMN1* 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 *CFTR* gene	CE IVDD
	Carbamazepine Hypersensitivity	7-640 / 7-643	HLA-A3101 RealFast™ Assay	Detects the human leukocyte antigen (HLA) *HLA-A*31:01* 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) *HLA-B*15:02* 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 *lactase (LCT)* 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 *fibrinogen beta-chain (FGB)* 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 *Factor V (F5)* gene	CE IVDR
	CVD	7-240 / 7-243	FXII 46C>T RealFast™ Assay	Identifies patients with the unfavorable TT genotype for *Factor XII (F12)*, 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 Factor XIII (F13A) among at-risk patients of hereditary thrombophilia	CE IVDD
	CVD	7-160 / 7-163	MTHFR 677C>T RealFast™ Assay	Detects common mutation in the *methylenetetrahydrofolate reductase (MTHFR)* gene causing hyperhomocysteinemia, which is a risk factor for cardiovascular disease	CE IVDD

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Category	Clinical Topic	REF 100 / 32 Rxn	Product Name	Detail	Regulatory Status
	CVD	7-170 / 7-173	MTHFR 1298A>C RealFast™ Assay	Detects common mutation in the *methylenetetrahydrofolate reductase (MTHFR)* gene causing hyperhomocysteinemia, which is a risk factor for cardiovascular disease	CE IVDD
	CVD	7-180 / 7-183	PAI-1 4G/5G RealFast™ Assay	Detects the 4G risk allele in the *SERPINE1* 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 *Factor II* 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 *CYP21A2* 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) *HLA-B*27* 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 *HFE* 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 *HFE* 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 *CYP2D6* 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) *HLA-B*57:01* 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 *solute carrier organic anion transporter family member 1B1 (SLCO1B1)* 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 *Vitamin K Epoxide Reductase Complex 1 (VKORC1)* gene associated with interindividual dose requirements for oral anticoagulants	CE IVDD

Multiplex testing

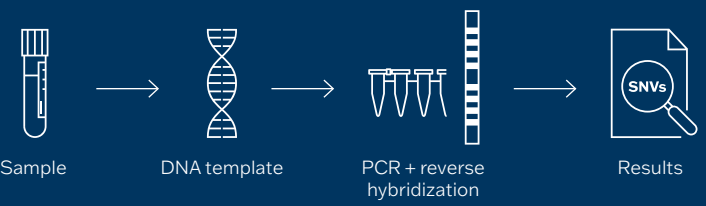
Category	Clinical Topic	REF 100 / 32 Rxn	Product Name	Detail	Regulatory Status
NEW	Severe Combined Immunodeficiency (SCID)	7-710 / --- 7-712 (500 Rxn)	SCID-XLA mpx RealFast™ Assay	Allows for the simultaneous analysis of the copy number of T-cell receptor excision circles (TRECs) and kappa-deleting recombination excision circles (KRECs)	RUO
NEW	Sickle Cell Disease (SCD)	7-280	HbS-HbC mpx RealFast™ Assay	Allows for the simultaneous analysis of c.20A>T (HbS) and c.19G>A (HbC*)* mutation in the β-globin *(HBB)* gene	RUO
	CVD	7-115 / 7-118	FV-PTH mpx RealFast™ Assay	Simultaneous detection of the most important thrombophilic mutations 1691G>A in the *Factor V* gene and 20210G>A in the *Factor II* 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 *MTHFR* 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 *SERPINA1* 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 *HFE* gene: H63D and C282Y	CE IVDR
	Pharmacogenetics	7-225 / 7-228	CYP2C9 mpx RealFast™ Assay	Simultaneous detection of *CYP2C9 *2* (c.430C>T) and *CYP2C9 *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: CE-marked under Regulation (EU) 2017/746. Notified Body 0123. IVDD products remain under legacy status until December 2028.

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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 *BRAF* mutations in codons 600 and 601	CE IVDD
	Cancer	5-630	EGFR XL StripAssay®	20 tests	Ultra-sensitive detection of 30 *EGFR* mutations in exons 18/19/20/21	CE IVDD
	Cancer	5-680	KRAS XL StripAssay®	20 tests	Ultra-sensitive detection of 29 *KRAS* 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 *NRAS* mutations in codons 12/13/59/60/61/146	CE IVDD
	Carbohydrate Intolerance	4-300	Lactose Intolerance StripAssay®	20 tests	Detection of two *lactase* gene polymorphisms -13910T>C and -22018A>G	CE IVDR
	Carbohydrate Intolerance	4-310	Sugar Intolerance StripAssay®	20 tests	Detection of two *lactase* gene polymorphisms and four *aldolase B* 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 *Factor V* Leiden and *Factor II*, encoding prothrombin (PTH), gene mutations	CE IVDD
	CVD	4-260	FV-PTH-MTHFR StripAssay®	20 tests	Detection of the *Factor V* Leiden, *Factor II*, encoding prothrombin (PTH), and *MTHFR* gene mutations	CE IVDD
	Congenital Adrenal Hyperplasia (CAH)	4-380	CAH StripAssay®	20 tests	Testing for 11 most prevalent *CYP21A2* 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 *CFTR* mutations and the IVS8 variants 5T/7T/9T	CE IVDR
	CF	4-430	CF StripAssay® GER	10 tests	Detection of 31 common *CFTR* mutations	CE IVDR
	CF	4-420	CF StripAssay® TUR	10 tests	Detection of 24 common *CFTR* mutations and the IVS8 variants 5T/7T/9T	CE IVDR
	CF	4-440	CF StripAssay® EXT	10 tests	Detection of 38 common *CFTR* mutations and the IVS8 variants 5T/7T/9T	CE IVDR
	Familial Mediterranean Fever (FMF)	4-230	FMF StripAssay®	20 tests	Detection of 12 *MEFV* gene mutations	CE IVDR
	FMF	4-390	FMF-SAA1 StripAssay®	20 tests	Detection of 12 *MEFV* gene mutations and *SAA1* genotypes 1.1, 1.3 and 1.5	CE IVDR

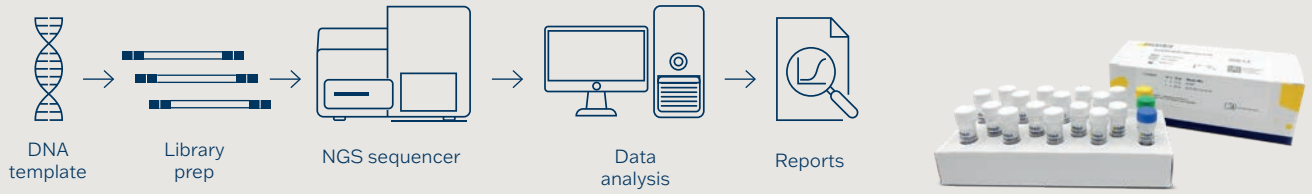
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Category	Clinical Topic	REF	Product Name	Unit Size	Detail	Regulatory Status
	Genetic Predisposition	4-320	HLA-B27 StripAssay®	20 tests	Detection of all disease-relevant *HLA-B*27* subtypes	CE IVDD
	Haemochromatosis	4-220	Haemochromatosis StripAssay® A	20 tests	Detection of 18 mutations: twelve *HFE* mutations, four *TFR2* mutations and two *FPN1* mutations	CE IVDR
	Haemochromatosis	4-210	Haemochromatosis StripAssay® B	20 tests	Detection of 3 *HFE* gene mutations: C282Y, H63D, S65C	CE IVDD
	Pharmacogenetics	4-780	PGX-5FU XL StripAssay®	20 tests	Detection of *DPYD* genetic variants HapB3, DPYD*13, DPYD*2A, 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 *TPMT* 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

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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	*NRAS, KRAS*: codons 12, 13, 59, 60, 61, 117 and 146 *BRAF*: codon 600	CE IVDD
	RDNGS0002	fastGEN LUNG Cancer Kit	16 Rxn	*EGFR*: exons 18, 19, 20 and 21	CE IVDD
	RDNGS0007	fastGEN PIK3CA Cancer Kit	16 Rxn	*PIK3CA*: exons 2, 3, 5, 7, 8, 10, 14 and 21	RUO
	RDNGS0008	fastGEN TERT Cancer Kit	16 Rxn	*TERT*: promotor and mutations C228T and C250T	RUO
	RDNGS0009 RDNGS0009-32	fastGEN TP53 Cancer Kit	16 Rxn 32 Rxn	*TP53:* 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	*POLE*: exons 9, 11, 13 and 14 *CTNNB1*: exons 3, 7 and 8	RUO

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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
	RDNGS0024	fastGEN EGFR/HER2 II Cancer Kit	16 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
	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

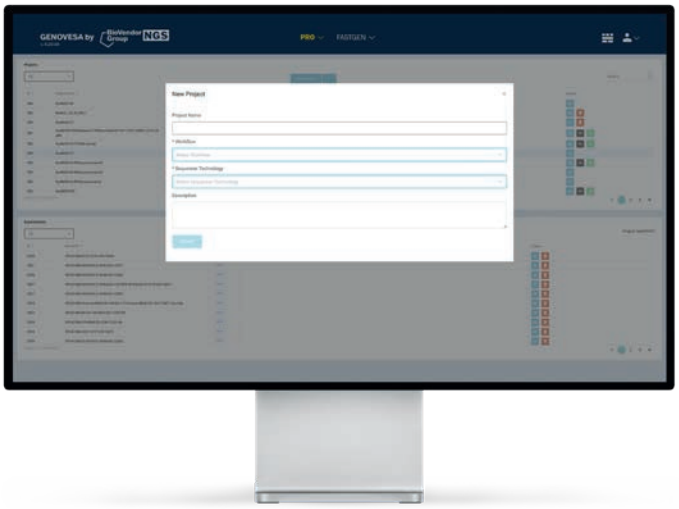
Hybrid capture-based assays

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 analysis of SNVs, InDels, and CNVs of the covered genes (e.g. *BRCA1, BRCA2, CDH1,...*).	RUO
	9-231	Somatic Mutations NGS Assay	16 Rxn	Targeting the whole CDS of genes covered. Analysis of SNVs and InDels in 10 genes (e.g. *BRAF, EGFR, KRAS*, ...) and fusions in 3 genes (i.e. *ALK, RET, ROS1*).	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 knowlege accumulation
- Research use only

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

For more information, please contact us at productsupport.moldx@biovendor.com

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