



# Advancing Molecular Diagnostics

Product catalog

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# About BioVendor

We are an international group of biotechnology companies with expertise in molecular diagnostics, immunodiagnosics, and radio-immunodiagnosics. Founded in 1992 in the Czech Republic, we have grown from a local company into a global innovator with in-house research, development, and production of in-vitro diagnostic (IVD) products, supported by an international distribution network.

Our strategy is anchored by three key projects – CLIA, MBA, and NGS – focusing our innovation and delivery across next-generation sequencing, chemiluminescent

immunoassays, and Microblot-Array. By combining scientific excellence, strong innovation capacity, and a presence in more than 100 markets worldwide, we deliver solutions that advance laboratory practice and patient care, making us one of the key players in clinical diagnostics.

Our molecular diagnostics portfolio covers RealFast™ Assays, StripAssays®, NGS assays based on fastGEN and epicGEN technologies, microbiome solution, and GENOVESA bioinformatics software for NGS data analysis and interpretation.

## Meet the Molecular diagnostics team



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# PCR Assays

## When focus beats volume

Real-time PCR remains a gold-standard technology for fast, targeted genetic analysis. It enables the amplification and simultaneous detection of specific DNA sequences in real time using fluorescent signals, delivering highly reliable results with minimal complexity.

Our PCR portfolio is designed for laboratories that require speed, precision, and ease of implementation, whether for routine testing or targeted mutation analysis.

### Key benefits

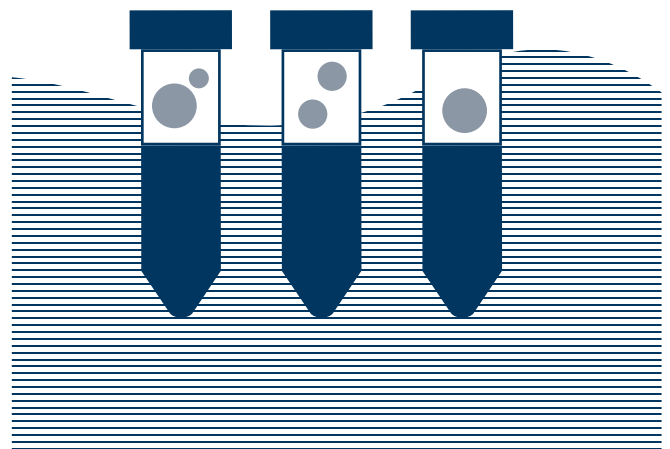
- Fast, accurate and easy-to-handle workflows
- Ready-to-use reagents
- Seamless integration into routine laboratory workflow
- Reliable detection of known variants
- Suitable for copy number variation (CNV) analysis

## Sample preparation

### What matters before you get started?

Reliable results begin long before amplification. High-quality DNA input is a critical factor influencing the accuracy, sensitivity, and reproducibility of any PCR-based assay.

To support every step of your workflow, we offer flexible sample preparation solutions, from standard DNA extraction to streamlined direct-to-PCR approaches, allowing you to choose the method that best fits your laboratory setup and sample type.



## Flexible solutions for every workflow

### DNA extraction kits

Designed to deliver high-quality DNA suitable for downstream PCR applications, including solutions with IVDR certification.

### Direct-to-PCR with D2PCR™ Buffer

An alternative approach that eliminates the need for DNA extraction from human peripheral whole blood anticoagulated with EDTA, significantly reducing hands-on time and turnaround time. Designed to be used in combination with RealFast™ Assays.

# Skip extraction. Save time.

Reduce workflow time and simplify your routine testing with direct-to-PCR, ideal for high-throughput or time-sensitive applications.

## Sample preparation kits

### Why choose our sample preparation solutions?

- Flexible workflows tailored to different laboratory needs
- Reduced hands-on time and operational complexity
- Reliable performance across various sample types

| Area                             | REF   | Product Name   | Unit Size | Application   | Regulatory Status |
|----------------------------------|-------|--|-----------|---|-------------------|
| StripAssays®<br>RealFast™ Assays | 2-014 | GEN <sup>x</sup> TRACT™<br>Blood DNA Extraction System | 100 Rxn   | DNA extraction from fresh, frozen and dried blood                 | CE IVDR           |
| StripAssays®<br>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™ Assays

## Ideal for targeted testing when speed and simplicity matter most.

RealFast™ Assays are designed for rapid and targeted detection of specific genetic markers using real-time PCR technology. Supporting both singleplex and multiplex formats, they provide a flexible solution for laboratories requiring fast, accurate, and cost-efficient analysis.

Whether you process a few samples or run high-throughput workflows, RealFast™ Assays delivers consistent performance with minimal complexity.

## Seamless workflow integration

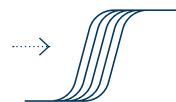
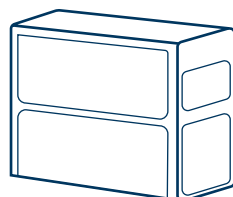
RealFast™ Assays are fully compatible with our sample preparation solutions, including direct-to-PCR using D2PCR™ Buffer, enabling laboratories to significantly reduce turnaround time and increase efficiency.

## Workflow

### 1 Patient sample



### 3 PCR amplification



RealFast™  
Plugins



### 2 DNA template

### 4 Report

## Key benefits

- High sensitivity and specificity
- From DNA to results in less than 90 minutes
- Ready-to-use reagents with minimal hands-on time
- Integrated controls for reliable performance
- Compatible with standard real-time PCR platforms

## Validated cyclers

- Applied Biosystems 7500 Fast
- Applied Biosystems StepOne™
- LightCycler® 480 II (Roche)
- CFX96 and CFX Opus 96 (Bio-Rad)
- Rotor-Gene 6000 (Qiagen)
- QuantStudio™ 5 (Thermo Fisher Scientific)
- MIC qPCR Cycler (Bio Molecular Systems)

## Sample requirements

- Low amount of starting DNA material
- Typically 2–10 ng/μl with adequate purity






## Applications

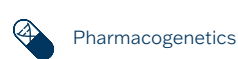
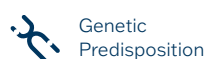
- Identification of disease-associated mutations
- Detection of genetic polymorphisms (SNPs, CNVs)
- Pharmacogenetics testing
- Screening and confirmatory testing




## Trial kit

An attractive trial option is available together with application support, enabling smooth and efficient implementation in your laboratory workflow.








## Single marker detection

| Category   | Clinical Topic   | REF 100 / 32 Rxn | Product Name                  | Detail  | Regulatory Status |
|------------|--|------------------|-------------------------------|---|-------------------|
| <b>NEW</b> |  Spinal Muscular Atrophy (SMA)          | 7-700            | SMN1 RealFast™ Assay          | Detects <i>SMN1</i> c.840C which is used for SMA analysis   | RUO               |
| <b>NEW</b> |  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           |
|            |  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           |



| Category  | Clinical Topic   | REF 100 / 32 Rxn | Product Name                     | Detail  | Regulatory Status |
|---|------------------|------------------|----------------------------------|---|-------------------|
|  | 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 (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 (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 |
|--|---|------------------|--------------------------------|--|-------------------|
| <b>NEW</b>  | 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               |
| <b>NEW</b>  | 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 $\beta$ -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*



Genetic Disorder



Genetic Predisposition



Cancer



Pharmacogenetics



Microbiology



## Smart qPCR Data Interpretation

RealFast™ Plugins, powered by FastFinder™ enables automated and standardized interpretation of RealFast™ Assay results, streamlining qPCR data analysis and reducing hands-on evaluation time. Assay-specific algorithms support reliable result interpretation, minimize manual evaluation errors, and generate standardized reports.

# StripAssays®

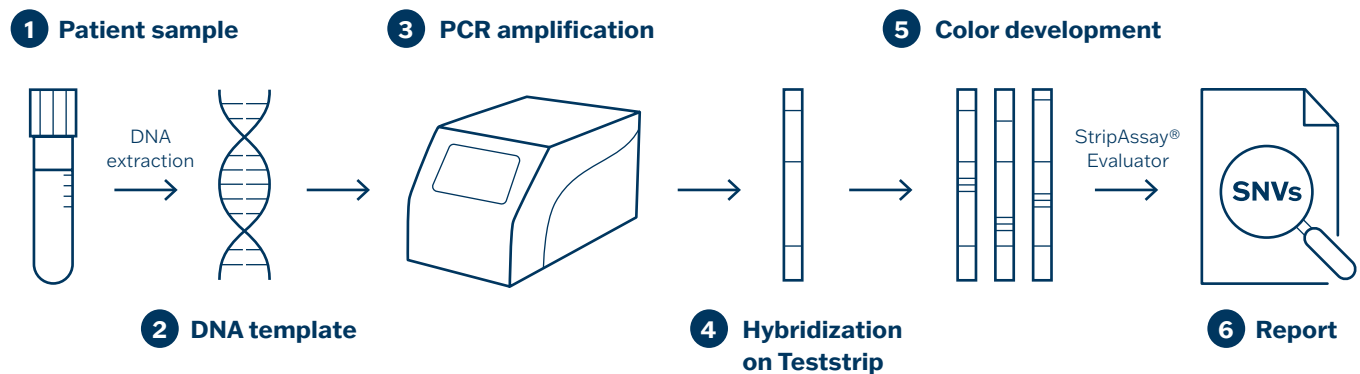
## Analyze multiple mutations in a single assay.

StripAssays® bridge the gap between targeted PCR testing and more complex NGS approaches. Based on reverse hybridization of biotinylated PCR products to mutation-specific probes immobilized on a Teststrip, they enable the simultaneous detection of multiple genetic variants in a single assay.

This makes them an ideal solution when single-marker testing is not sufficient, but full-scale sequencing is not required.



## Workflow



### Key benefits

- Detection of multiple mutations in a single test (up to 48 alleles)
- Robust and reproducible methodology
- From sample to result in less than 6 hours
- Low instrument complexity
- Clear and straightforward result interpretation

### Sample requirements

- Low amount of starting DNA material
- Typically 2-10 ng/μl with adequate purity



### Flexible workflow options

#### Manual workflow

- Thermocycler
- Water bath with shaking platform
- Shaker

#### Automated workflow



















- Automated instrument for Teststrip processing

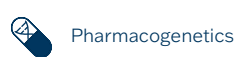
### Applications













- Detection of SNPs and InDels
- Pharmacogenetics markers
- Hereditary disorders testing
- Companion Diagnostics

## Trial kit

An attractive trial option is available together with application support, enabling smooth and efficient implementation in your laboratory workflow.

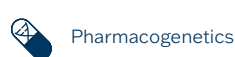
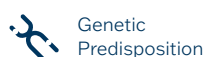
| Category  | Clinical Topic                       | REF   | Product Name                    | Unit Size | Detail   | Regulatory Status |
|---|--------------------------------------|-------|---------------------------------|-----------|--|-------------------|
|    | Alzheimer Disease                    | 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

## When insight goes further than single targets

Next-generation sequencing (NGS) is a powerful molecular technology that enables the simultaneous analysis of multiple genetic regions in a single run. By sequencing millions of DNA fragments in parallel, it provides comprehensive insights that go far beyond another approaches.

Our NGS portfolio is designed to support a wide range of applications from focused panels to more comprehensive genomic profiling while maintaining efficiency, flexibility, and ease of implementation.

## Amplicon-based assays

### Microbiome

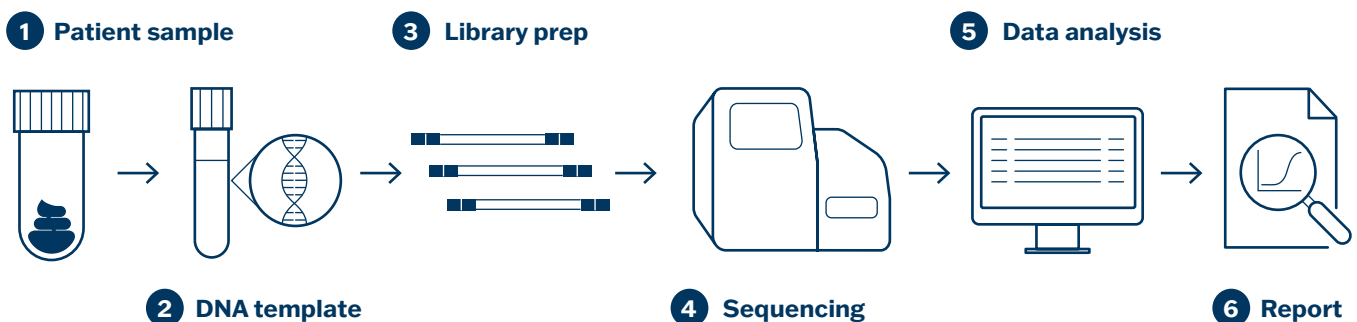
#### Key features

- Species-level identification of bacterial and fungal communities
- Input: 2.5–50 ng DNA
- No PhiX required
- Dedicated microbiome web tool (RUO) for data analysis

#### Sequencer compatibility





- Illumina
- Broader compatibility in development

#### Workflow



# Gut speaks. We translate!

Gain more comprehensive view of the human gut microbiome. Our solution analyzes both the 16S rRNA gene and the ITS region of fungal DNA, providing a more comprehensive view of the human gut microbiome.

| <u>Category</u>   | <u>REF</u> | <u>Product Name</u>                     | <u>Unit Size</u> | <u>Detail</u>  | <u>Regulatory Status</u> |
|---|------------|---|------------------|--|--------------------------|
|  | 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 bioinformatics 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                      |



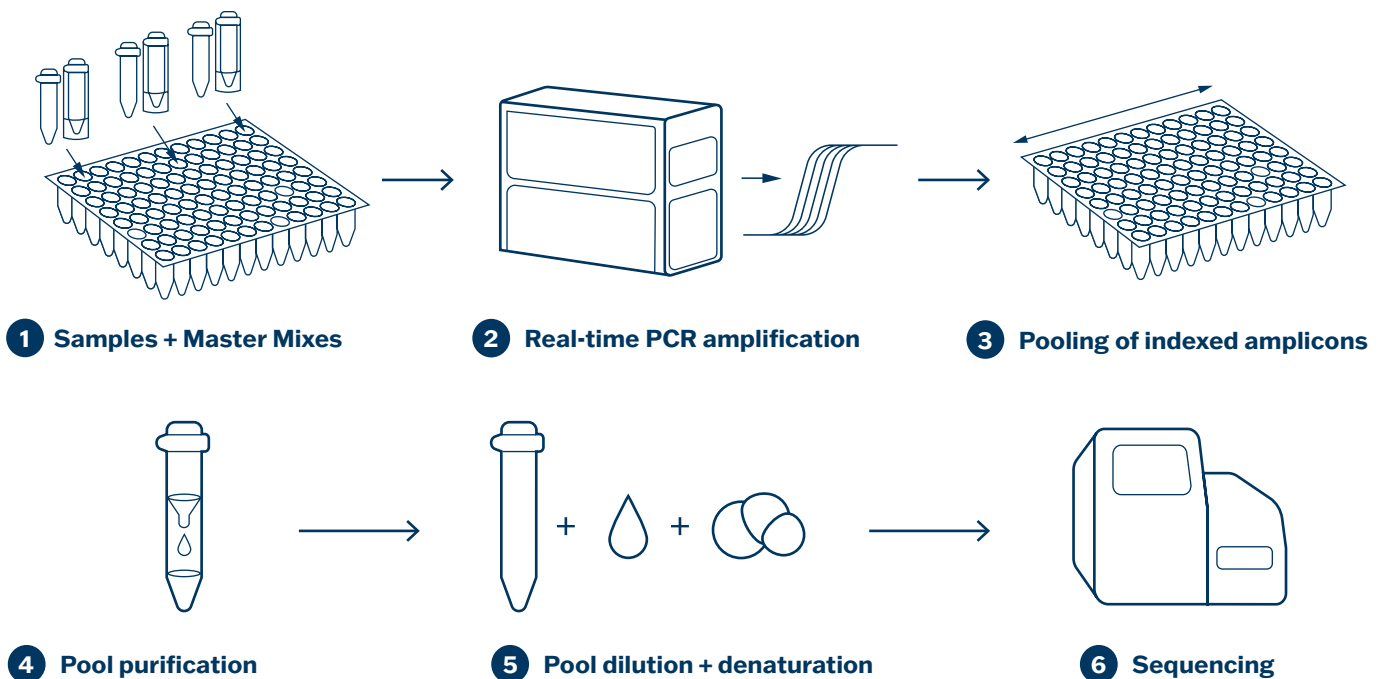
## Designed for targeted sequencing when sensitivity and confidence are critical.

fastGEN is an amplicon-based NGS solution designed for ultra-deep sequencing of clinically relevant targets. It enables reliable detection of low-frequency variants, even in challenging sample types, while maintaining a fast and streamlined workflow.

### Key features

- Ultra-deep sequencing for low-frequency variant detection
- High sensitivity and reproducibility
- Optimized for challenging samples, including FFPE and ctDNA
- Fast and efficient workflow
- Minimal input DNA requirements

### One-step PCR library preparation workflow



### Sample compatibility

- DNA isolated from tumor tissue
- DNA isolated from FFPE samples
- Circulating tumor DNA (ctDNA) from blood



### Applications













- Targeted oncology profiling
- Detection of low-frequency variants
- Hereditary predisposition analysis

## Sequencer compatibility

- Illumina
- Element Biosciences (AVITI)
- GeneMind
- MGI Tech (with conversion kit)

## Integrated data analysis

With every fastGEN kit, you have access to GENOVESA, our bioinformatics solution that streamlines data processing from raw sequencing data to clear and interpretable results.

| 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;<br><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<br>RDNGS0009-32 | fastGEN TP53 Cancer Kit              | 16 Rxn<br>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<br><i>CTNNB1</i> : exons 3, 7 and 8   | RUO               |
|             | RDNGS0011                 | fastGEN BCR::ABL1 Cancer Kit         | 16 Rxn           | <i>BCR::ABL1</i> : major and minor breakpoint  | RUO               |
|             | RDNGS0016                 | fastGEN H3F3A/IDH1/2 Cancer Kit      | 16 Rxn           | <i>IDH1</i> : codon 132<br><i>IDH2</i> : codons 140 and 172<br><i>H3F3A</i> : codons 28 and 35   | RUO               |
|             | RDNGS0018                 | fastGEN Food Intolerance Kit         | 16 Rxn           | <i>ALDOB1</i> : rs118204429, rs387906225, rs1800546, rs76917243, rs78340951, rs77718928, rs370793608, rs764826805<br><i>AOC1</i> : rs10156191, rs1049742, rs2268999, rs1049793, rs2052129<br><i>MCM6</i> : 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           | <i>EGFR</i> : exons 18, 19, 20 and 21<br><i>HER2</i> : exons 7, 8, 17, 19, 20 and 21   | RUO               |
|             | RDNGS0021                 | fastGEN MPN Cancer Kit               | 16 Rxn           | <i>CALR</i> : exon 9<br><i>JAK2</i> : exons 12, 13, 14, 16<br><i>MPL</i> : exons 4, 10, 12   | RUO               |
|             | RDNGS1001                 | fastGEN SOLID II Cancer Kit          | 16 Rxn           | <i>NRAS</i> , <i>KRAS</i> : codons 12, 13, 59, 60, 61, 117 and 146<br><i>BRAF</i> : codons 594-609   | RUO               |
| <b>NEW</b>  | RDNGS0022                 | fastGEN Crohn's & Celiac Disease Kit | 16 Rxn           | <i>NOD2</i> : rs2066844, rs2066845, rs5743293<br><i>IL23R</i> : rs1004819 and rs10889677<br>HLA-DQ2.2: rs2395182, rs7775228, rs4713586<br>HLA-DQ2.5: rs2187668<br>HLA-DQ8: rs7454108   | RUO               |

# Hybrid capture-based assays

## epicGEN

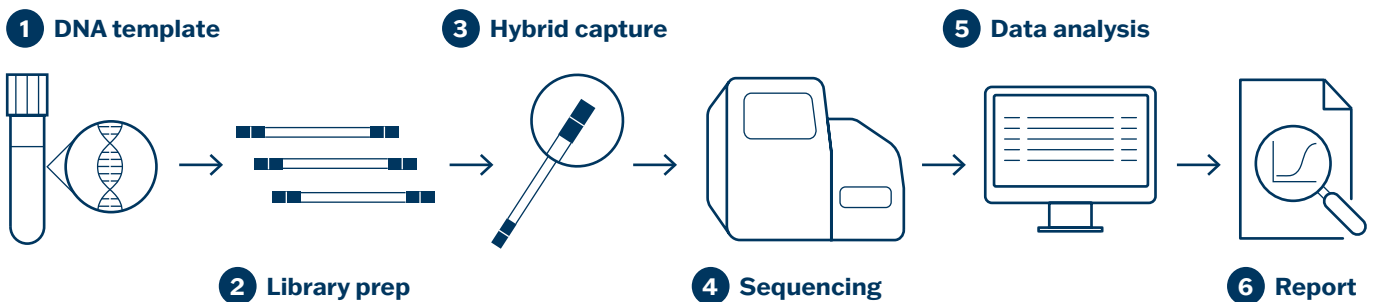
### Comprehensive genomic analysis made simple.

epicGEN is a hybrid capture-based NGS solution designed for comprehensive genomic profiling. It enables analysis beyond predefined hotspots, providing broader coverage and deeper insight into genetic alterations.

#### Key features

- Hybrid capture technology for extended genomic coverage
- MSI analysis included
- Flexible DNA input range (1-1000 ng)
- Suitable for challenging samples, including FFPE
- Tailored panel design

#### Workflow



#### Applications

- Comprehensive oncology profiling
- Detection of a wide range of variant types
- MSI status assessment

#### Sequencer compatibility

- Illumina
- Element Biosciences (AVITI)
- GeneMind
- MGI Tech

## 📌 Integrated data analysis

With every epicGEN kit, you have access to GENOVESA, our bioinformatics solution that streamlines data processing from raw sequencing data to clear and interpretable results.

| <u>Category</u> | <u>REF</u>  | <u>Product Name</u>            | <u>Unit Size</u> | <u>Detail</u>  | <u>Regulatory Status</u> |
|-----------------|-------------|--------------------------------|------------------|--|--------------------------|
| ☀️              | 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                      |



Genetic Disorder



Genetic Predisposition



Cancer



Pharmacogenetics



Microbiology

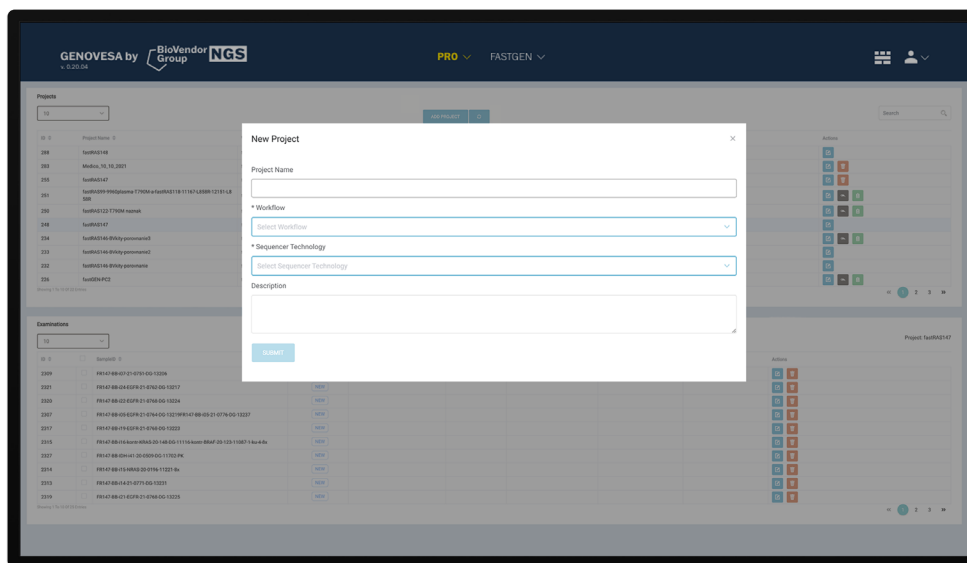


## From FASTQ to report. Simplified.

GENOVESA is our integrated bioinformatics solution designed to transform raw sequencing data into clear, actionable results. It streamlines the entire data analysis process, from primary data processing to variant interpretation, through an intuitive and user-friendly interface.

### Key features

- End-to-end analysis from FASTQ to final report
- Intuitive interface designed for routine laboratory use
- Predefined pipelines optimized for fastGEN and epicGEN kits
- Fast and reliable variant interpretation
- Secure data processing on dedicated in-house servers
- Supports analysis of third-party NGS data



# No bioinformatics expertise required.

Focus on results, not data processing.

## **i Why GENOVESA?**

- No need for complex bioinformatics infrastructure
- Reduced analysis time and hands-on effort
- Standardized and reproducible results
- Clear and actionable outputs for confident decision-making

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## **Functionalities**

- InDel detection
- CNV analysis
- RNA fusion and aberrant splicing isoform detection
- MSI, TMB and HRD analysis
- Integrated database
- Customizable filtering
- Automated reporting

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## **Applications**

- Somatic and germline variant analysis
- Genotyping
- RNA sequencing (RNA-seq)
- Metagenomics
- Whole exome sequencing (WES)
- Whole genome sequencing (WGS)
- Viral genomics

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

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