PRODUCT SHEET

VariantFlex™ Custom Platform

EASILY BUILD CUSTOM REFERENCE MATERIALS TO FIT YOUR ASSAY AND BUDGET WITHIN WEEKS

INTRODUCTION

Next-generation sequencing (NGS) has revolutionized the genomics field and how IVD developers, laboratories, and clinicians are diagnosing, treating, and monitoring disease and genetic conditions. With NGS-based assays displacing older methodologies worldwide, it is extremely important that they are proven to be robust, accurate, consistent, and cost-effective in delivering timely results to improve patient care.

As NGS panels grow to include an ever increasing number of important biomarkers, so too must the reference materials used for development, validation, and routine QC. But sourcing sufficient quantities of remnant patient specimens or cell lines bearing all of the necessary variants is expensive, time consuming, and can leave you short of rare or challenging mutations.

With SeraCare's VariantFlex platform, you can easily get the variants you need at your desired allele frequencies in the format that fits your assay. Your custom reference material will arrive in weeks, starting at less than $10,000 thanks to our streamlined process and flexible biosynthetic technology.

FEATURES AND BENEFITS

- Easily select variants from a library or made to order, and configure to your specific assay
- Over 180 clinically relevant variants across 45 genes in our constantly growing library
- Range of variant types – SNVs, INDELs, RNA gene fusions, CNVs, trisomies
- Patient-like profile, complexity, and sequencing performance attributes
- Scale easily from development to validation and post-launch run monitoring
- Targets precisely quantitated with digital PCR
- Manufactured in GMP-compliant and ISO 13485-certified facilities

VARIANTFLEX OPTIONS BY APPLICATION*

	Tumor Profiling	Liquid Biopsy	Myeloid Cancer	Inherited Disease	NIPT	Infectious Disease
Variant Types	• SNV • INDELs • CNV				• Euploid • Trisomy	• HIV-1 • HCV • Other
Target Regions	Cancer hotspots (EGFR, JAK2, TP53, PIK3CA, etc.)		FLT3, JAK2, NPM1, ASXL1, etc.	BRCA1, MSH2 BRCA2, PMS2 MYBPC3, etc.	• T21 • T18 • T13	Any
Frequency	4 - 40%	0.125 - 10%	5 - 15%	50%	1 - 12% (fetal fraction)	• 1 - 20% NGS • 30 - 40% Sanger
Format	• DNA mix • GM24385 wild-type	• DNA mix or in plasma • 170 bp size • GM24385 wild-type	• DNA mix • GM24385 wild-type	• DNA mix • GM24385 wild-type	• In plasma or DNA Mix • 170 bp size	• Recombinant virus • Full-process

* Actual selection of variants, frequencies, and format combinations may vary based on specific project and type of application.

FEATURED PROJECTS

- **NIPT assay development** – Customized trisomy 21, 18, 13, and euploid materials across a range of fetal fractions to support a ground-breaking new platform and consumable launch
- **Cancer assay development** – Custom cancer panel with over 60 variants at 10% allele frequency to support a platform and system for targeted cancer applications
- **Liquid biopsy validation** – Custom ctDNA panel with key therapeutic variants as low as 1.25% to help identify patients for targeted drug therapy
- **HIV-1 assay validation** – Custom HIV-1 and HCV-positive run controls covering specific variants at 5,000 copies per sample and specific mutation frequency (recombinant virus design)
- **Tumor profiling routine QC** – Custom version of existing Seraseq™ tumor DNA reference materials to monitor daily run performance of a tumor profiling assay

ORDERING INFORMATION

Pricing – As low as $9,995, and available in as few as six weeks

Based on:

- Number and type of variants
- Availability from existing library or custom configuration
- Amount required (in µg)
- Fragment size - standard or cfDNA-like profile (170 bp average)
- Format required

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