PRODUCT SHEET

Seraseq™ Copy Number Variation (CNV) Reference Materials

FIRST DISEASE-SPECIFIC CNV REFERENCE MATERIALS FOR NGS-BASED ASSAY DEVELOPMENT AND VALIDATION

HIGHLIGHTS

SINGLE-SAMPLE, MULTIPLEXED FORMAT; PATIENT-LIKE SAMPLE PERFORMANCE.

COPY NUMBER VARIANTS QUANTITATED WITH DIGITAL PCR; ASSURES ACCURATE AND CONSISTENT DETECTION OF CLINICALLY RELEVANT CNVs

HIGH-QUALITY MANUFACTURED REFERENCE MATERIAL; GUARANTEES CONSISTENT GROUND TRUTH

INTRODUCTION

Copy number variations (CNVs) are genomic changes that lead to higher (amplification) or lower (loss) gene copies in comparison to a reference genome. Cells that are affected by aberrant copy number changes for certain cancer-associated genes may experience disruption of normal cellular function and, ultimately, tumorigenesis. Next-generation sequencing (NGS) can be used to determine CNVs across multiple genes in a sequencing run. However, without a widely adopted standard for CNV profiling, NGS assays may evaluate dosage for different targets using different "wet" and "dry" methods. To ensure confidence in assay performance across relevant CNVs, clinical labs need to overcome the challenge of sourcing relevant variants and the high expense associated with singleplex samples such as residual patient specimens and cell lines.

SeraCare has developed the first disease-specific CNV reference materials — the Seraseq Breast CNV Mix and the Seraseq Lung & Brain Mix — to support clinical labs performing NGS-based tumor profiling of cancer patient samples. These first-of-their-kind products include varying copy numbers of relevant genes associated with cancers of the breast, lung, and brain. Amplifications in these target genes are precisely quantitated by digital PCR and blended with a single, well-characterized genomic background (GM24385).

GENES INCLUDED IN THE SERASEQ CNV MIXES

ERBB2	FGFR3	MYC
EGFR	MYCN	MET

FEATURES AND BENEFITS

- Develop, optimize, and validate your assay's ability to detect a range of copy numbers (amplifications) with confidence using industry's first disease-specific CNV reference materials
- Ensure robust sensitivity using a single sample with multiple clinically relevant CNVs
- Manufactured in GMP-compliant, ISO 13485-certified facilities

ABOUT SERACARE

TRUSTED SUPPLIER TO THE DIAGNOSTIC TESTING INDUSTRY FOR OVER 30 YEARS.

HIGH-QUALITY CONTROL PRODUCTS, RAW BIOLOGICAL MATERIALS, AND IMMUNOASSAY REAGENTS.

INNOVATIVE TOOLS AND TECHNOLOGIES TO PROVIDE ASSURANCE IN DIAGNOSTIC ASSAY PERFORMANCE AND TEST RESULTS.

FOR MORE INFORMATION, PLEASE VISIT OUR WEBSITE: WWW.SERACARE.COM.

CNVs INCLUDED

Product	Amplified Genes	Amplification Level	Primary Cancers
Seraseq Breast CNV Mix, +3 copies	ERBB2 FGFR3 MYC	Three extra copies (five total copies for each affected gene)	ERBB2: Breast FGFR3: Breast, lung, gastric (RARE) MYC: Breast
Seraseq Breast CNV Mix, +6 copies	ERBB2 FGFR3 MYC	Six extra copies (eight total copies for each affected gene)	
Seraseq Breast CNV Mix, +12 copies	ERBB2 FGFR3 MYC	12 extra copies (14 total copies for each affected gene)	
Seraseq Lung & Brain CNV Mix, +3 copies	EGFR MYCN MET	Three extra copies (five total copies for each affected gene)	EGFR: Glioblastoma, lung MYCN: Neuroblastoma MET: Lung
Seraseq Lung & Brain CNV Mix, +6 copies	EGFR MYCN MET	Six extra copies (eight total copies for each affected gene)	
Seraseq Lung & Brain CNV Mix, +12 copies	EGFR MYCN MET	12 extra copies (14 total copies for each affected gene)	

ORDERING INFORMATION

Each part code is available for individual purchase.

Product	Part Code	Format	Frequency	Concentration	Volume	Total Mass
Seraseq Breast CNV Mix, +3 copies	0710-0411	Purified DNA in buffer	Five total copies	10 ng/µL	20 µL	200 ng
Seraseq Breast CNV Mix, +6 copies	0710-0412	Purified DNA in buffer	Eight total copies	10 ng/µL	20 µL	200 ng
Seraseq Breast CNV Mix, +12 copies	0710-0413	Purified DNA in buffer	14 total copies	10 ng/µL	20 µL	200 ng
Seraseq Lung & Brain CNV Mix, +3 copies	0710-0414	Purified DNA in buffer	Five total copies	10 ng/µL	20 µL	200 ng
Seraseq Lung & Brain CNV Mix, +6 copies	0710-0415	Purified DNA in buffer	Eight total copies	10 ng/µL	20 µL	200 ng
Seraseq Lung & Brain CNV Mix, +12 copies	0710-0416	Purified DNA in buffer	14 total copies	10 ng/µL	20 µL	200 ng