PRODUCT SHEET

Seraseq® MSI Reference Panel Mix AF5% and AF20%

PLASMID-BASED MICROSATELLITE INSTABILITY REFERENCE MATERIAL FOR VALIDATION OF MSI BIOMARKERS

HIGHLIGHTS

VALIDATE LOD OF MICROSATELLITE INSTABILITY (MSI) ASSAYS WITH GROUND-TRUTH MSI BIOMARKERS AT TWO AF LEVELS

APPLY PCR AND NGS TO QUANTITATE CANCER-ASSOCIATED MICROSATELLITES IN PATIENT SAMPLES

HIGH-QUALITY MANUFACTURED REFERENCE MATERIAL; PROVIDES CONSISTENT GROUND TRUTH

INTRODUCTION

Microsatellites are regions of DNA repeats with different lengths, i.e., instability, highlighting DNA mismatch repair gene deficiencies. Typical repeat units are between 1-6 base pairs and the number of repeats vary from person to person such that each person has a set length of these microsatellites in their genome. Measurements of MSI have traditionally been performed using capillary electrophoresis (CE) fragment length analysis methods, but new methodologies are now available that includes digital droplet PCR (ddPCR) as well as Next Generation Sequencing (NGS). Microsatellite instability status has been linked to favorable outcomes in immuno-oncology (I-O) treatment response by patients with diseases such as Lynch Syndrome and colorectal cancer. Hence MSI measurements have become an important biomarker in I-O therapeutics.

LGC SeraCare has developed microsatellite instability (MSI) reference materials that target the lengths of the regions commonly referred to as BAT-25, BAT-26, NR-21, NR-24, and MONO-27. These markers are blended at two different allele frequency (AF) levels – 5% and 20% - to support MSI assay limit of detection (LoD) determinations and accurate MSI detection. These products are offered as tumor-normal matched pairs, with variants precisely quantitated by digital PCR against a highly characterized genomic DNA from a background WT cell line (GM24385) determined as microsatellite stable (MSS).

MICROSATELLITE BIOMARKERS AND GENOMIC LOCATIONS IN THE SERASEQ® MSI REFERENCE PANEL MIX AF5% AND AF20%

Marker	Gene	Chromosome	Position (hg19 based)	Comment
BAT-25	KIT (intron16)	chr4	55598211	25T -> 19T
BAT-26	MSH2 (intron5)	chr2	47641559	27A -> 17A
NR-21	SLC7A8 (5'UTR)	chr14	23652346	21A -> 13A
NR-24	ZNF2 (3'UTR)	chr2	95849361	23T -> 17T
MONO-27[1]	MAP4K3 (intron 3)	chr2	39573062	27A -> 21A
	MAP4K3 (intron13)		39536689	

[1] There is ambiguity in the literature on the MONO-27 locus so two constructs are included in the product to ensure compatibility (see, Bacher J, Halberg R, Kent-First M, Wood KV. "Methods and kits for detecting mutations" US Patent US20090068646A1 issued March 12, 2009; and Pino MS, Chung DC. "Application of molecular diagnostics for the detection of Lynch syndrome." Expert review of molecular diagnostics vol. 10,5 (2010): 651-65. doi:10.1586/erm.10.45).

FEATURES AND BENEFITS

- Plasmid-based spike-in of 5 key MSI biomarkers typically analyzed in molecular assays
- Offered as tumor-normal matched pairs per AF level
- Each biomarker blended at two AF levels – 5% and 20% - to support assay LoD determinations and accurate MSI detection
- Variant AFs quantitated by ddPCR and CE fragment length analysis assays
- Normal background DNA is a highly characterized GM24385 human genomic DNA known to be microsatellite stable (MSS)
- Manufactured within cGMP compliant and ISO 13485 certified facilities

ORDERING INFORMATION

Product Description	Kit Composition	Material No	Concentration	Volume	Total Mass (DNA)
Seraseq MSI Reference Panel Mix AF5%	gDNA – Tumor gDNA - Normal	0710-1675	2 x 20 ng/ µl	2x 15 µl	2 x 300 ng
Seraseq MSI Reference Panel Mix AF20%	gDNA – Tumor gDNA - Normal	0710-1676	2 x 20 ng/ µl	2x 15 µl	2 x 300 ng

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

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