

# Seraseq® Microsatellite Instability (MSI) Reference Materials

**MICROSATELLITE INSTABILITY REFERENCE MATERIALS FOR DETECTION AND VALIDATION OF MSI BIOMARKERS IN CANCER PATIENT SAMPLES MEASURED BY PCR OR NGS.**

## HIGHLIGHTS

VALIDATE LOD OF MICROSATELLITE INSTABILITY 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 qPCR/CE fragment length analysis methods, or immunohistochemistry (IHC), but new methodologies such as digital droplet PCR (ddPCR) and Next Generation Sequencing (NGS) are now being applied to determination of MSI status of cancer patients. High incidence of microsatellite instability (MSI) 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, determination of MSI status for cancer patients is important in I-O therapeutics management.

LGC SeraCare has developed microsatellite instability (MSI) reference materials that support qPCR and NGS assays that target a range of short tandem repeat regions commonly analyzed for microsatellite instabilities. For assays that target specific mono and dinucleotide repeats such as BAT-25, BAT-26, NR-21, NR-24, MONO-27, we have created MSI reference materials containing these markers blended at two different allele frequency (AF) levels – 5% and 20%. Additionally, for NGS MSI assays that analyze for a large number of microsatellite loci across the human genome, we have a human diseased cell line-based MSI-High reference material for such analysis. These products are quantitated by PCR (qPCR/CE and ddPCR) and by targeted NGS assays to support all product claims.

## 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 <sup>1</sup>	MAP4K3 (intron 3)	chr2	39573062	27A -> 21A
	MAP4K3 (intron13)		39536689	

<sup>1</sup> 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).

## ABOUT LGC 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  
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## TARGETED NGS ASSAY DETERMINATION OF MICROSATELLITE INSTABILITY STATUS OF THE SERASEQ® MSI-HIGH PRODUCTS

Product Name	NGS Assay	Av. MSI Sites Detected*	Av. Unstable MSI sites*	Av. MSI Score*	MSI Call
Seraseq® gDNA MSI-High Mix	TSO500	106	81	77.1	High
Seraseq® FFPE MSI-High RM	TSO500	119	90	75.6	High
		105	75	71.4	High

\*MSI measurements are from replicate runs on the TSO500. MSI score is the ratio of the unstable MSI sites to the total number of sites detected (expressed as a percentage). The value must be >20% for an MSI-High result.

## FEATURES AND BENEFITS

1. Cell line or plasmid-based MSI reference material mix for analysis in molecular assays or NGS
2. Offered as tumor-only (MSI-High) or tumor-normal (AF5% and AF20%) options
3. Support MSI assay validation, LoD determination, and routine detection of MSI markers in cancer patient samples
4. Variant AFs (AF5% and AF20% products) quantitated by ddPCR and qPCR/CE fragment length analysis assays
5. Normal background DNA is a highly characterized GM24385 human genomic DNA known to be microsatellite stable (MSS)
6. Manufactured within cGMP compliant and ISO 13485 certified facilities

## ORDERING INFORMATION

Product Description	Kit Composition	Material No.	Concentration	Fill Volume	Total Mass
Seraseq gDNA MSI-High Mix	gDNA - Tumor	0710-1670	25 ng/μl	20 μl	500 ng
Seraseq® FFPE MSI-High RM	FFPE - Tumor	0710-2236	1 FFPE curl	10 μm	>200 ng*
Seraseq MSI Reference Panel Mix AF5%	gDNA - Tumor	0710-1675	2 x 20 ng/μl	2x 15 μl	2 x 300 ng
	gDNA - Normal				
Seraseq MSI Reference Panel Mix AF20%	gDNA - Tumor	0710-1676	2 x 20 ng/μl	2x 15 μl	2 x 300 ng
	gDNA - Normal				

\*QIAamp DNA FFPE Tissue kit or Promega Maxwell RSC FFPE DNA kit and Qubit dsDNA HS kit.



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