

Revised Technical Product Report

For Research Use Only; Not for use in Diagnostic Procedures

Product:

Seraseg® MSI Reference Panel Mix AF5%

Product Description:

Product	Material Code	10517733	
Seraseq [®] MSI Reference Panel Mix AF5%	0710-1675		
Kit Components			
Seraseg [®] MSI Panel Mix AF5% (Tumor)	0710-1862	10512056	
Seraseq [®] MSI Matched WT gDNA (Normal)	0710-1864 10512058		

The Seraseq MSI Panel Mix AF5% (Tumor) vial contains biosynthetic DNAs with altered lengths of five MSI mononucleotide markers blended with genomic DNA from GM24385 WT reference cell line at 5% allelic frequency. Seraseg® MSI Matched WT gDNA (Normal) is genomic DNA from GM24385 WT cell line.

Concentration:

Seraseg® MSI Panel Mix AF5% (Tumor): 27.5 Seraseg® MSI Matched WT gDNA (Normal): 25.7

Fill Volume:

Date of Manufacture:

(Qubit dsDNA BR Assay)

17 AUG 2020

Expiration Date:

05 AUG 2024

Test Method:

MSI status determined using Promega MSI Analysis System, v1.2.

Allele frequency determined using laboratory developed digital PCR assays and

BioRad QX200™ Droplet Digital™ PCR System.

MSI Status:

MSI-High

Target Allele Frequency:

5%

Marker	Gene	Chromosome	Position (hg19 based)	Comment	Measured Allele Frequency (dPCR)
BAT-25	KIT (intron16)	chr4	55598211	25T -> 19T	4.7
BAT-26	MSH2 (intron5)	chr2	47641559	27A -> 17A	4.6
NR-21	SLC7A8 (5'UTR)	chr14	23652346	21A -> 13A	4.9
NR-24	ZNF2 (3'UTR)	chr2	95849361	23T -> 17T	4.8
$MONO-27^1$	MAP4K3 (intron 3)	chr2	39573062	27A -> 21A	4.8
	MAP4K3 (intron13)		39536689		4.8

There is ambiguity in the literature on the MONO-27 locus so two constructs are included in the product to ensure compatibility. See J Bacher, R Halberg, M Kent-First, and KV Wood. "Methods and kits for detecting mutations" US Patent US20090068646A1 issued March 12, 2009. See also Pino, Maria S, and Daniel C Chung. "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

Approval:

m 11-4 10 AUG 2023

Date Prepared By