Seraseq®
Tumor Mutation DNA Mix v2 AF7

Package Insert

PLEASE NOTE:
THESE REAGENTS MUST NOT BE SUBSTITUTED FOR THE MANDATORY POSITIVE AND NEGATIVE CONTROL REAGENTS PROVIDED WITH MANUFACTURED TEST KITS.

NAME AND INTENDED USE
The Seraseq® Tumor Mutation DNA Mix v2 AF7 is formulated for use with targeted Next Generation Sequencing (NGS) assays that detect mutations in key oncogenes and tumor suppressor genes. The Seraseq Tumor Mutation DNA Mix v2 AF7 is intended as a quality reference material for translational and disease research testing to monitor library preparation, sequencing, and variant allele detection under a given set of bioinformatics pipeline parameters. *For Research Use only. Not for use in diagnostic procedures.*

SUMMARY
A well-designed quality control program provides added confidence in the reliability of results obtained for unknown specimens. The use of independent reference materials may provide valuable information concerning assay sensitivity and bioinformatics pipeline analysis.

PRINCIPLES OF THE PROCEDURE
Seraseq Tumor Mutation DNA Mix v2 AF7 is ready to use in NGS assays in steps that follow DNA isolation; no further purification or DNA isolation is needed. The product contains human genomic DNA at a concentration of 25 ng/µL. The reference material is formulated in a diluted 1 mM Tris / 0.1 mM EDTA, pH 8.0, aqueous buffer that is compatible with both PCR-based target amplification and hybridization-based target selection methods.

REAGENTS

Table 1. Seraseq Tumor Mutation DNA Mix v2 AF7

Material No.	Product
0710-0095	Seraseq® Tumor Mutation DNA Mix v2 AF7, RUO
Material No. (Kit Component)	
0710-0087	Vial

1 vial: 25 µL per vial, 25 ng/µL concentration and 625 ng total mass

WARNINGS AND PRECAUTIONS
For Research Use Only. Not for use in diagnostic procedures.
CAUTION: Handle Seraseq Tumor Mutation DNA Mix v2 AF7 and all materials derived from human blood products as though they are capable of transmitting infectious agents. Seraseq Tumor Mutation DNA Mix v2 AF7 is manufactured using processed human genomic DNA and biosynthetic mutant sequences.

Safety Precautions
Use Centers for Disease Control and Prevention (CDC) recommended universal precautions for handling reference materials and human specimens[1]. Do not pipette by mouth; do not smoke, eat, or drink in areas where specimens are being handled. Clean any spillage by immediately wiping up with 0.5% sodium hypochlorite solution. Dispose of all specimens and materials used in testing as though they contain infectious agents.

Handling Precautions
Do not use Seraseq Tumor Mutation DNA Mix v2 AF7 beyond the expiration date. Avoid contamination of the product when opening and closing the vials.

STORAGE INSTRUCTIONS
Store Seraseq Tumor Mutation DNA Mix v2 AF7 frozen at -20 °C or colder. Once opened, a vial can be thawed and re-frozen up to twelve (12) times. Sub-aliquoting of the product into low DNA binding tubes may be advisable to limit the number of freeze/thaw cycles to twelve (12) or less.

INDICATIONS OF REAGENT INSTABILITY OR DETERIORATION
Seraseq Tumor Mutation DNA Mix v2 AF7 is a mixture of human genomic DNA and synthetic DNA constructs. It should appear as a clear liquid. Alterations in this appearance may indicate instability or deterioration of the product and vials should be discarded.

PROCEDURE
Materials Provided
Seraseq Tumor Mutation DNA Mix v2 AF7 is a mixture of human genomic DNA and synthetic DNA constructs in a 1 mM Tris / 0.1 mM EDTA, pH 8.0, aqueous buffer. 25 µL is provided per tube and the concentration is 25 ng/µL.

Materials Required but not Provided
Refer to instructions supplied by manufacturers of the test kits to be used.

Instructions for Use
Allow the product vial to come to room temperature before use. Mix by vortexing to ensure a homogeneous solution and spin briefly. Seraseq Tumor Mutation DNA Mix v2 AF7 should be integrated into library preparation after the DNA isolation step. Seraseq Tumor Mutation DNA Mix v2 AF7 must go through target selection and library preparation in parallel with the test specimens. Refer to your usual assay procedures in order to determine the amount of material to use.

Quality Control
Seraseq Tumor Mutation DNA Mix v2 AF7 does not have assigned values for the variant allele frequencies. However, the product is formulated using digital PCR quantitation to target each variant listed in Table 2 to be present at 7%. There are many reasons why assay results may deviate from this target, which may or may not be of significance. It is therefore recommended that each laboratory qualify the use of each lot of Seraseq Tumor Mutation DNA Mix v2 AF7 with each assay system prior to its routine use.

INTERPRETATION OF RESULTS
Detection of variants and the variant allele frequency may vary with different NGS targeted sequencing-based cancer panels and different test reagent lots. Since the reference material does not have an assigned value, the laboratory must establish an acceptable range for each variant and each lot of Seraseq Tumor Mutation DNA Mix v2 AF7. When results for the product are outside of the established acceptance range, it may indicate unsatisfactory test performance. Possible sources of error include: deterioration of test kit reagents, operator error, faulty performance of equipment, contamination of reagents, or change in bioinformatics pipeline parameters. Support documents containing the target sequence coordinates are available online at http://www.seracare.com/oncology.html.

LIMITATIONS OF THE PROCEDURE
Seraseq Tumor Mutation DNA Mix v2 AF7 MUST NOT BE SUBSTITUTED FOR THE CONTROL REAGENTS PROVIDED WITH MANUFACTURED TEST KITS.

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13141-02 September 2025

TEST PROCEDURES provided by manufacturers must be followed closely. Deviations from procedures recommended by test kit manufacturers may produce unreliable results. Seraseq Tumor Mutation DNA Mix v2 AF7 is not a calibrator and should not be used for assay calibration. These materials are also not whole process controls and do not evaluate the methods used for specimen extraction.

Adverse shipping and storage conditions or use of outdated product may produce erroneous results.

EXPECTED RESULTS

Specific detection of cancer variants and variant allele frequencies will vary among different assays, different procedures, different lot numbers, and different laboratories. Each laboratory should establish its own range of acceptable values. For example, the acceptable range for each variant might include all values within two standard deviations of the mean of 20 data points obtained in 20 runs[2]. Table 2 lists mutations that are present in the product.

SPECIFIC PERFORMANCE CHARACTERISTICS

Seraseq Tumor Mutation DNA Mix v2 AF7 has been designed for use with targeted NGS Cancer hotspot panels for the purposes of assessing assay characteristics. The product is manufactured from purified human genomic DNA as well as biosynthetic DNA. Although the product is formulated with a 7% variant allele target for each mutation listed in Table 2 as determined by droplet digital PCR, Seraseq Tumor Mutation DNA Mix v2 AF7 does not have assigned values. Procedures for implementing a quality assurance program and monitoring test performance on a routine basis must be established by each individual laboratory.

REFERENCES

1. Siegel JD, Rhinehart E, Jackson M, Chiarello L, and the Healthcare Infection Control Practices Advisory Committee, 2007 Guideline for Isolation Precautions: Preventing Transmission of Infectious Agents in Healthcare Settings.
2. Statistical Quality Control for Quantitative Measurements: Principles and Definitions; Approved Guideline-Second Edition. NCCLS document C24-A2, 1999.

Table 2: Seraseq Tumor Mutation DNA Mix v2 AF7 mutations

Gene ID	Mutation Type	HGVS Nomenclature	Amino Acid Change
AKT1	Substitution	c.49G>A	p.E17K
APC	Substitution	c.4348C>T	p.R1450*
APC	Insertion in HP 7N	c.4666_4667insA	p.T1556fs*3
ATM	Deletion	c.1058_1059delGT	p.C353fs*5
BRAF	Substitution	c.1799T>A	p.V600E
CTNNB1	Substitution	c.121A>G	p.T41A
EGFR	Deletion	c.2236_2250del15	p.E746_A750delELREA
EGFR	Insertion	c.2310_2311insGGT	p.D770_N771insG
EGFR	SNV in 3N	c.2573T>G	p.L858R
EGFR	Substitution	c.2369C>T	p.T790M
ERBB2	Insertion	c.2313_2324dup	p.Y772_A775dup
FGFR3	Substitution	c.746C>G	p.S249C
FLT3	Substitution	c.2503G>T	p.D835Y
FOXL2	Substitution	c.402C>G	p.C134W
GNA11	Substitution	c.626A>T	p.Q209L
GNAQ	SNV in HP 3N	c.626A>C	p.Q209P
GNAS	Substitution	c.601C>T	p.R201C
IDH1	Substitution	c.394C>T	p.R132C
JAK2	SNV in HP 3N	c.1849G>T	p.V617F
KIT	Substitution	c.2447A>T	p.D816V
KRAS	Substitution	c.35G>A	p.G12D
MPL	Substitution	c.1544G>T	p.W515L
NCOA4-RET	Gene Fusion (DNA)	NCOA4{NC_000010.10}:r.1_1014+1312_RET {NC_000010.10}:r.2327-1437_5659	N.A.
NPM1	Insertion	c.863_864insTCTG	p.W288fs*12
NRAS/CSDE1	Substitution	c.182A>G	p.Q61R

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Gene ID	Mutation Type	HGVS Nomenclature	Amino Acid Change
PDGFRA	Insertion	c.1694_1695insA	p.S566fs*6
PDGFRA	Substitution	c.2525A>T	p.D842V
PIK3CA	Substitution	c.1633G>A	p.E545K
PIK3CA	Substitution	c.3140A>G	p.H1047R
PIK3CA	Insertion	c.3204_3205insA	p.N1068fs*4
PTEN	Insertion	c.741_742insA	p.P248fs*5
PTEN	Deletion 6N > 5N	c.800delA	p.K267fs*9
RET	Substitution	c.2753T>C	p.M918T
SMAD4	Insertion	c.1394_1395insT	p.A466fs*28
TP53	Substitution	c.818G>A	p.R273H
TP53	Substitution	c.743G>A	p.R248Q
TP53	Deletion	c.723delC	p.C242fs*5
TP53	Substitution	c.524G>A	p.R175H
TP53	Deletion 5N >4N	c.263delC	p.S90fs*33
TPR-ALK	Gene Fusion (DNA)	TPR{NC_000001.10}:r.1_2185+246_ALK {NC_000002.11}:r.4125-550_6265	N.A.

Note: List of mutations included in the Seraseq Tumor Mutation DNA Mix v2 AF7. The above list does not include variants present in the GM24385 background. The presence of the mutation in a particular assay depends upon the enrichment strategy and sequencing platform used. The mutation types are listed; HP = homopolymer, N = nucleotide. Because of ambiguity surrounding exact genomic coordinates for sequence deletions contained entirely within repetitive motifs such as homopolymers, analytic calls generated by certain analyses may differ relative to the mutation names presented in this table. In such cases, additional analysis would be required during concordance evaluation.