Seraseq®
20 Variant Tumor DNA Mix

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® 20 Variant Tumor DNA Mix is intended for use with Next Generation Sequencing (NGS) assays that identify DNA variants present in cancer which may aid in treatment decisions and confirm an NGS assay is functioning as intended. The Seraseq 20 Variant Tumor DNA Mix is intended as a quality reference material for translational and disease research testing and monitors 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 can provide added confidence in the reliability of results obtained for unknown specimens. The use of independent reference products may provide valuable information concerning assay accuracy and bioinformatics pipeline analysis.

PRINCIPLES OF THE PROCEDURE

Seraseq 20 Variant Tumor DNA Mix is ready-to-use in Next Generation Sequencing (NGS) assays in steps that follow DNA isolation; no further purification or DNA isolation is needed. The reference materials should follow the same workflow as unknown samples. The product contains DNA at a concentration of 20 ng/µL. The Reference Material is formulated in 1 mM Tris / 0.1 mM EDTA pH 8.0, which is a buffer that is compatible with both PCR-based target amplification and hybridization-based target selection methods.

Seraseq 20 Variant Tumor DNA Mix contains 20 mutations (not including those present in the GM24385 background) that are associated with cancer. The product is formulated to simulate DNA isolated from a tumor. The variant allele frequency is confirmed by digital PCR and reported in the batch-specific technical product report.

REAGENTS

Table 1. Seraseq 20 Variant Tumor DNA Mix

Material No.	Product
0710-4383	Seraseq® 20 Variant Tumor DNA Mix

WARNINGS AND PRECAUTIONS

For Research Use Only. Not for use in diagnostic procedures.
CAUTION: Handle Seraseq 20 Variant Tumor DNA Mix and all materials derived from human blood products as though it is capable of transmitting infectious agents. Seraseq 20 Variant Tumor DNA Mix is manufactured using genomic DNA extracted from the human cell line GM24385, which is a B-lymphocytic, male cell line from the Personal Genome Project offered by the NIGMS Human Genetic Cell Repository (https://catalog.coriell.org/1/NIGMS). Purified genomic DNA is formulated in a 1 mM Tris / 0.1 mM EDTA pH 8.0 aqueous buffer.

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
Avoid contamination of the product when opening and closing the vials.

STORAGE INSTRUCTIONS

Store Seraseq 20 Variant Tumor DNA Mix frozen at -20 °C or colder. Once opened, a vial can be thawed and re-frozen up to five (5) times. Sub-aliquoting of the product into low DNA binding tubes may be advisable to limit the number of freeze/thaw cycles to five (5) or less.

INDICATIONS OF REAGENT INSTABILITY OR DETERIORATION

Seraseq 20 Variant Tumor DNA Mix 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 20 Variant Tumor DNA Mix is a mixture of human genomic DNA and synthetic DNA constructs in a 1 mM Tris / 0.1 mM EDTA pH 8.0 buffer. Fifty (50) µL is provided per tube and the concentration is 20 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 20 Variant Tumor DNA Mix should be integrated into library preparation after the DNA isolation step. If a DNA shearing step is part of the workflow, Seraseq 20 Variant Tumor DNA Mix should be sheared and go through the target selection and library preparation in parallel with test specimens. Refer to standard assay procedures in order to determine the amount of material to use.

Quality Control
Although Seraseq 20 Variant Tumor DNA Mix is designed to simulate a tumor sample with multiple variant allele frequencies, the product does not have assigned values for mutation frequencies. There are many reasons why assays may observe deviation from the representative data which may or may not be of significance. It is therefore recommended that each laboratory qualify the use of Seraseq 20 Variant Tumor DNA Mix with each assay system prior to its routine use.

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15394-01 October 2026
OIT-000008 Rev. 1

INTERPRETATION OF RESULTS
Detection of the variants within Seraseq 20 Variant Tumor DNA Mix may vary with different types of tests and different test kit lots. Since the reference material does not have an assigned value, the laboratory must establish a range for each lot of Seraseq 20 Variant Tumor DNA Mix. 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.

LIMITATIONS OF THE PROCEDURE
Seraseq 20 Variant Tumor DNA Mix MUST NOT BE SUBSTITUTED FOR THE CONTROL REAGENTS PROVIDED WITH MANUFACTURED TEST KITS.

TEST PROCEDURES and *INTERPRETATION OF RESULTS* provided by manufacturers of test kits must be followed closely. Deviations from procedures recommended by test kit manufacturers may produce unreliable results. Seraseq 20 Variant Tumor DNA Mix is not a calibrator and should not be used for assay calibration. Adverse shipping and storage conditions or use of outdated product may produce erroneous results.

EXPECTED RESULTS
Specific detection of variants and variant allele frequencies will vary among different assays, different procedures, different lot numbers, and different laboratories. Each laboratory should establish its own acceptance criteria. 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 the variants in the product and their target allele frequencies (verified by digital PCR).

SPECIFIC PERFORMANCE CHARACTERISTICS
Seraseq 20 Variant Tumor DNA Mix has been designed for use with NGS sequencing procedures for the purposes of evaluating assay performance. Seraseq 20 Variant Tumor DNA Mix 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– Fourth Edition. CLSI document C24, 2016.

Table 2: List of Mutations Incorporated

Gene	Transcript	Nucleotide change	Protein change	Type of Nucleotide Alteration
BRAF	NM_004333.6	c.1799T>A	p.V600E	SNV
EGFR	NM_005228.5	c.2303G>T	p.S768I	SNV
EGFR	NM_005228.5	c.2310_2311insGGT	p.D770_N771insG	Insertion
EGFR	NM_005228.5	c.2369C>T	p.T790M	SNV
EGFR	NM_005228.5	c.2389T>A	p.C797S	SNV
FGFR3	NM_000142.5	c.746C>G	p.S249C	SNV
KRAS	NM_004985.5	c.34G>T	p.G12C	SNV
MET	NM_001127500.3	c.3082+1del	Exon 14 skipping	Deletion
NRAS	NM_002524.5	c.182A>G	p.Q61R	SNV
NTRK1	NM_002529.4	c.1783G>A	p.G595R	SNV
NTRK2	NM_006180.6	c.1915G>A	p.G639R	SNV
NTRK3	NM_001012338.3	c.1867G>A	p.G623R	SNV
PIK3CA	NM_006218.4	c.3140A>G	p.H1047R	SNV
PIK3CA	NM_006218.4	c.3203dup	p.N1068Kfs*5	Insertion
PTCH1	NM_000264.5	c.2307_2308delinsTT	p.R770*	INDEL
PTEN	NM_000314.8	c.741dup	p.P248Tfs*5	Insertion
PTEN	NM_000314.8	c.800del	p.K267Rfs*9	Deletion

Translocation	5' Transcript	3' Transcript
CD74::ROS1	NM_001025159.3	NM_001378902.1
FGFR2::BICC1	NM_000141.5	NM_001080512.3
NCOA4::RET	NM_001145263.2	NM_020975.6

CNV	GRCh37 Amplified Region
ERBB2	17:37838724_37957722
MYC	8:128666784_128811899

NOTE: Above list does not include variants present in the GM24385 background. Substitution refers to single nucleotide variant; Indels are defined as deletion/insertions less than 10 base pairs, and large deletions or insertions are larger than 10 base pairs.