Seraseq®
Endometrial Cancer 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® Endometrial Cancer DNA Mix is a reference material formulated for use with targeted Next Generation Sequencing (NGS) assays that detect somatic mutations associated with endometrial cancer. This product 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 Endometrial Cancer 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 15 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 Endometrial Cancer DNA Mix contains 32 mutations (not including those present in the GM24385 background) that are associated with endometrial cancer (see Table 2). Variant allele frequency (VAF) and copy gain are confirmed by digital PCR. VAF is also measured by NGS as reported in the batch-specific Technical Product Report (TPR).

REAGENTS

Table 1. Seraseq Endometrial Cancer DNA Mix

Material No.	Product
0710-4125	Seraseq® Endometrial Cancer DNA Mix

1 vial, 20 µL per vial, 15 ng/µL concentration.

WARNINGS AND PRECAUTIONS
For Research Use Only. Not for use in diagnostic procedures.
CAUTION: Handle Seraseq Endometrial Cancer DNA Mix and all materials derived from human blood products as though it is capable of transmitting infectious agents. Seraseq Endometrial Cancer 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 Endometrial Cancer DNA Mix frozen between - 30 °C to -10 °C. 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 Endometrial Cancer 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 Endometrial Cancer 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. 20 µL is provided per tube, and the concentration is 15 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 Endometrial Cancer DNA Mix should be integrated into library preparation after the DNA isolation step. Refer to standard assay procedures in order to determine the amount of material to use.

Quality Control
Although Seraseq Endometrial Cancer DNA Mix is designed to assess DNA present at the indicated target VAF, 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 Endometrial Cancer DNA Mix with each assay system prior to its routine use.

INTERPRETATION OF RESULTS
Detection of the variants within Seraseq Endometrial Cancer 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 Endometrial Cancer 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.

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LIMITATIONS OF THE PROCEDURE

Seraseq Endometrial Cancer 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 Endometrial Cancer 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 Endometrial Cancer DNA Mix has been designed for use with NGS sequencing procedures for the purpose of evaluating assay performance. Seraseq Endometrial Cancer 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 ID	Nucleotide Change	Transcript	Variant Type	Target VAF and Amplification
POLE	c.857C>G	NM_006231.4	SNV	10%
POLE	c.1231G>C	NM_006231.4	SNV	10%
POLE	c.890C>T	NM_006231.4	SNV	10%
POLE	c.1366G>C	NM_006231.4	SNV	10%
POLE	c.1376C>T	NM_006231.4	SNV	10%
POLE	c.1100T>C	NM_006231.4	SNV	10%
POLE	c.1270C>A	NM_006231.4	SNV	10%
POLE	c.884T>G	NM_006231.4	SNV	10%
POLE	c.1102G>T	NM_006231.4	SNV	10%
POLE	c.1307C>G	NM_006231.4	SNV	10%
POLE	c.1331T>A	NM_006231.4	SNV	10%
MSH2	c.942+20_942+29delAAAAAAAAAA	NM_000251.3	Deletion	10%
MLH1	c.1852_1854del	NM_000249.4	Deletion	10%
MSH2	c.942+3A>T	NM_000251.3	SNV	10%
MSH6	c.3261dup	NM_000179.3	Duplication	10%
PMS2	c.861_864del	NM_000535.7	Deletion	10%
TP53	c.743G > A	NM_000546.6	SNV	10%
TP53	c.524G>A	NM_000546.6	SNV	10%
TP53	c.818G>A	NM_000546.6	SNV	10%
TP53	c.723del	NM_000546.6	Deletion	10%
PTEN	c.389G>A	NM_000314.8	SNV	10%
PIK3CA	c.3140A>G	NM_006218.4	SNV	10%
PIK3CA	c.3203dup	NM_006218.4	Insertion	10%
KRAS	c.35G>A	NM_004985.5	SNV	10%
CTNNB1	c.98C>T	NM_001904.4	SNV	10%
CTNNB1	c.121A>G	NM_001904.4	SNV	10%
AKT1	c.49G>A	NM_005163.2	SNV	10%
POLD	c.1433G>A	NM_002691.4	SNV	10%
FBXW7	c.1513C>T	NM_001349798.2	SNV	10%
PPP2R1A	c.536C>G	NM_014225.6	SNV	10%
ERBB2	Amplification	NM_004448.4	CNV	+3 copies

NOTE: Above list does not include variants present in the GM24385 background.

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