Seraseq®

Myeloid Mutation 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® Myeloid Mutation DNA Mix is a reference material formulated for use with targeted Next Generation Sequencing (NGS) assays that detect somatic mutations that are associated with various types of myeloid cancers. This product is intended as a quality reference material for translational and disease research testing to monitor library preparation, sequencing, and variant detection under a given set of bioinformatics pipeline parameters. *For Research Use Only. Not for use in diagnostic procedures.*

REAGENTS

Item No. 0710-0408. 1 vial, 25 µL per vial, 15 ng/µL concentration.

WARNINGS AND PRECAUTIONS

For Research Use Only. Not for use in diagnostic procedures.
CAUTION: Handle Seraseq Myeloid Mutation DNA Mix as though it is capable of transmitting infectious agents. This product is formulated using a reference 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).

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 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 Myeloid Mutation DNA Mix beyond the expiration date. Avoid contamination of the product when opening and closing the vial.

STORAGE INSTRUCTIONS

Store Seraseq Myeloid Mutation DNA Mix frozen at -20°C or colder. Aliquoting of the product into low DNA binding tubes may be advisable to limit the number of freeze-thaw cycles..

INDICATIONS OF REAGENT INSTABILITY OR DETERIORATION

Seraseq Myeloid Mutation 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 Myeloid Mutation DNA Mix consists of DNA purified from a reference cell line, GM24385, plus constructs containing variants mixed at defined allele frequencies. The purified DNA is present in a 1 mM Tris, 0.1 mM EDTA, pH 8.0 aqueous buffer. Material is ready to use in NGS assays in steps that follow DNA isolation. No further purification or DNA isolation is needed.

Materials Required but not Provided

Refer to instructions supplied by manufacturers of the test kits to be used.

Instructions for Use

Thaw the product vial on ice. Mix by vortexing to ensure a homogenous solution and spin briefly. Seraseq Myeloid Mutation DNA Mix may be input directly into library preparation following procedures used for clinical specimens. Refer to your usual assay procedures in order to determine the amount of material to use.

EXPECTED RESULTS & INTERPRETATION OF RESULTS

Table 1 indicates each of the somatic mutations represented in Seraseq Myeloid Mutation DNA Mix, as well as the variant allele frequency targeted for each during manufacture of the product. Detection of mutations may differ across different NGS panels and different test reagent lots. While the presence and frequency of each mutation in this product is confirmed during manufacture using functional NGS and/or digital PCR assays, there may be differences in observed allele frequencies due to assay characteristics. Seraseq Myeloid Mutation DNA Mix does not have assigned values for allele frequencies of the mutations present in the product. Each laboratory must establish an assay-specific expected value for each mutation and each lot of Seraseq Myeloid Mutation 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 changes in bioinformatics pipeline parameters. Additional support documents are available online at www.seracare.com/cancer.

LIMITATIONS OF THE PROCEDURE

Seraseq Myeloid Mutation DNA Mix MUST NOT BE SUBSTITUTED FOR THE CONTROL REAGENTS PROVIDED WITH MANUFACTURED TEST KITS. *TEST PROCEDURES* provided by manufacturers must be followed closely. Deviations from procedures recommended by test kit manufacturers may produce unreliable results. This product is offered for Research Use Only. Not for use in diagnostic procedures. Data are provided for informational purposes. SeraCare Life Sciences does not claim that others can duplicate test results exactly. Seraseq Myeloid Mutation DNA Mix is not a calibrator and should not be used for assay calibration. These materials are not whole-process controls and do not evaluate the methods used for specimen extraction. Adverse shipping and/or storage conditions or use of outdated product may produce erroneous results.

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.

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Table 1. Somatic mutations present in Seraseq Myeloid Mutation DNA Mix

Gene ID	HGVS	Prot	VAF	Mutation type
ABL1	c.944C>T	p.T315I	10%	SNV
ASXL1	c.1900_1922del	p.E635fs*15	10%	Deletion
ASXL1	c.1934dup	p.G646fs*12	10%	Insertion
BRAF	c.1799T>A	p.V600E	10%	SNV
CALR	c.1099_1150del	p.L367fs*46	5%	Deletion
CBL	c.1259G>A	p.R420Q	10%	SNV
CBL	c.1139T>C	p.L380P	10%	SNV
CEBPA	c.68dup	p.H24fs*84	15%	Insertion
CEBPA	c.937_939dup	p.K313_V314insK	15%	Insertion
CSF3R	c.1853C>T	p.T618I	5%	SNV
FLT3	c.1759_1800dup	p.N600_L601_insNEYVDFREYEYD	5%	Internal tandem duplication
FLT3	c.1806_1807insGGGGCTTTCAGA GAATATGAATATGATCTCAAA	K602_W603insGAFREYEYDLK	10%	Internal tandem duplication + 5 bp foreign sequence
FLT3	c.2503G>T	p.D835Y	10%	SNV
IDH1	c.394C>T	p.R132C	5%	SNV
JAK2	c.1849G>T	p.V617F	5%	SNV
JAK2	c.1624_1629del	p.N542_E543del	10%	Deletion
MPL	c.1544G>T	p.W515L	5%	SNV
MYD88	c.794T>C	p.L265P	10%	SNV
NPM1	c.860_863dup	p.W288fs*12	5%	Insertion
SF3B1	c.2098A>G	p.K700E	5%	SNV
SF3B1	c.1998G>T	p.K666N	5%	SNV
SRSF2	c.284_307del	p.P95_R102del	5%	Deletion
U2AF1	c.101C>T	p.S34F	10%	SNV