Seraseq®

ctDNA Myeloid Mix AF1%, AF0.5%, AF0.1%, WT

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

Seraseq® ctDNA Myeloid Mix AF1%, AF0.5%, AF0.1% & WT are formulated for use with targeted Next Generation Sequencing (NGS) assays that detect myeloid cancer-relevant somatic mutations present in the blood stream as circulating cell-free tumor DNA. These products are intended as quality reference materials 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

Table 1. Variant allele frequencies (AF) for Seraseq ctDNA Myeloid Mix AF1%, AF0.5%, AF0.1% & WT. Each Item No. is available as an individual product. Information in this Package Insert applies to all four products.

Item No.	Product
0710-2646	Seraseq ctDNA Myeloid Mix, 0% (WT)
0710-2647	Seraseq ctDNA Myeloid Mix, AF0.1%
0710-2648	Seraseq ctDNA Myeloid Mix, AF0.5%
0710-2649	Seraseq ctDNA Myeloid Mix, AF1%

Each product contains one (1) vial: 25 µL volume, 15 ng/µL concentration, 375 ng total mass.

WARNINGS AND PRECAUTIONS

For Research Use Only. Not for use in diagnostic procedures.
CAUTION: Handle Seraseq Myeloid Mutation DNA Mix AF1%, AF0.5%, AF0.1% & WT as though they are capable of transmitting infectious agents. These products are 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 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 ctDNA Myeloid Mix AF1%, AF0.5%, AF0.1% & WT beyond expiration date. Avoid contamination of the product when opening and closing the vials.

STORAGE INSTRUCTIONS

Store Seraseq ctDNA Myeloid Mix AF1%, AF0.5%, AF0.1% & WT frozen at -20 °C or colder. Aliquoting product into low DNA binding tubes may be advisable to limit the number of freeze-thaw cycles.

INDICATIONS OF REAGENT INSTABILITY OR DETERIORATION

Seraseq ctDNA Myeloid Mix AF1%, AF0.5%, AF0.1% & WT are mixtures of human genomic DNA and synthetic DNA constructs. When thawed, 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 ctDNA Myeloid Mix AF1%, AF0.5%, AF0.1% & WT are derived from DNA purified from a reference cell line, GM24385, plus constructs containing variants mixed at defined allele frequencies. Purified DNA is present in a 1 mM Tris, 0.1 mM EDTA, 10 mM KCl, pH 8.0 aqueous buffer. Material is ready to use in NGS assays in steps that follow circulating cell-free DNA isolation. No further purification or DNA isolation is needed if assays are compatible with this buffer.

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 ctDNA Myeloid Mix AF1%, AF0.5%, AF0.1% & WT may generally be input directly into library preparation following procedures used for clinical specimens. Refer to your usual assay procedures to determine the amount of material to use.

EXPECTED RESULTS & INTERPRETATION OF RESULTS

Table 2 indicates each of the somatic mutations represented in Seraseq ctDNA Myeloid Mix AF1%, AF0.5%, AF0.1% & WT. Detection of mutations may differ across different NGS panels and different test reagent lots. While the presence and frequency of each mutation in these products is evaluated during manufacture using functional NGS and/or digital PCR assays, there may be differences in observed allele frequencies due to assay characteristics. Seraseq ctDNA Myeloid Mix AF1%, AF0.5%, AF0.1% & WT does not have assigned values for allele frequencies of the mutations present in the product. Each laboratory must establish assay-specific expected values for each lot of Seraseq ctDNA Myeloid Mix AF1%, AF0.5%, AF0.1% & WT. 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/oncology.

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LIMITATIONS OF THE PROCEDURE

Seraseq ctDNA Myeloid Mix AF1%, AF0.5%, AF0.1% & WT MUST NOT BE SUBSTITUTED FOR THE CONTROL REAGENTS PROVIDED WITH MANUFACTURED TEST KITS.

TEST PROCEDURES and *INTERPRETATION OF RESULTS* provided by manufacturers must be followed closely. Deviations from procedures recommended by test kit manufacturers may produce unreliable results. These products are 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. Note that based on your particular assay protocol and regions interrogated, variants other than the 25 annotated in these products may be detected at varying allele frequencies. Seraseq ctDNA Myeloid Mix AF1%, AF0.5%, AF0.1% & WT are not calibrators 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.

Table 2. Somatic mutations[+] present in Seraseq® ctDNA Myeloid Mix AF1%, AF0.5%, AF0.1% & WT

#	Gene ID	HGVS	Protein Variant	Variant Type
1	ABL1	c.944C>T	p.T315I	SNV
2	ASXL1	c.1900_1922del	p.E635Rfs*15	Deletion
3	ASXL1	c.1934dup	p.G646Wfs*12	Insertion
4	BRAF	c.1799T>A	p.V600E	SNV
5	CALR	c.1099_1150del	p.L367Tfs*46	Deletion
6	CBL	c.1139T>C	p.L380P	SNV
7	CBL	c.1259G>A	p.R420Q	SNV
8	CEBPA	c.68dup	p.H24Afs*84	Insertion
9	CEBPA	c.937_939dup	p.K313dup	Insertion
10	CSF3R	c.1853C>T	p.T618I	SNV
11	EZH2	c.1937A>T	p.Y646F	SNV
12	FLT3	c.1759_1800dup	p.N587_D600dup	Insertion
13	FLT3	c.1806_1807insGGGGCTTTCAGAGAATATGAATATGATCTCAAA	p.K602_W603_insGAFREYEYDLK	Insertion
14	FLT3	c.2503G>T	p.D835Y	SNV
15	IDH1	c.394C>T	p.R132C	SNV
16	IDH2	c.419G>A	p.R140Q	SNV
17	IDH2	c.515G>A	p.R172K	SNV
18	JAK2	c.1624_1629del	p.N542_E543del	Deletion
19	JAK2	c.1849G>T	p.V617F	SNV
20	MPL	c.1544G>T	p.W515L	SNV
21	MYD88	c.755T>C	p.L252P	SNV
22	NPM1	c.860_863dup	p.W288Cfs*12	Insertion
23	SF3B1	c.1998G>T	p.K666N	SNV
24	SF3B1	c.2098A>G	p.K700E	SNV
25	SRSF2	c.284_307del	p.P95_R102del	Deletion

[+] For additional variant information, refer to the Technical Spreadsheet (document number MKT-00806).

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

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