Seraseq®
Myeloid Fusion RNA 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 Fusion RNA Mix is formulated for use with targeted Next Generation Sequencing (NGS) assays that detect RNA expressed from gene fusions common in 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 fusion RNA detection under a given set of bioinformatics pipeline parameters. *For Research Use Only. Not for use in diagnostic procedures.*

REAGENTS

Item No. 0710-0407. 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 Fusion RNA Mix as though it is capable of transmitting infectious agents. This product is formulated using an engineered human cell line derived from 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 Fusion RNA Mix beyond the expiration date. Avoid contamination of the product when opening and closing the vial.

STORAGE INSTRUCTIONS

Store Seraseq Myeloid Fusion RNA Mix at -70 °C or colder. Limit the number of freeze thaws this product is exposed to by creating single-use aliquots, if necessary. Shelf life when stored under these conditions is two years from date of manufacture.

INDICATIONS OF REAGENT INSTABILITY OR DETERIORATION

Seraseq Myeloid Fusion RNA Mix is a mixture of biosynthetic RNA and total RNA purified from human cells. It should appear as a clear liquid. Alterations in this appearance may indicate instability or deterioration of the product and the vial should be discarded.

PROCEDURE

Materials Provided

Seraseq Myeloid Fusion RNA Mix consists of total cellular RNA purified from a reference cell line, plus biosynthetic RNA blended at characterized levels. The purified RNA is present in a 1 mM Tris, pH 8.0, aqueous buffer. Material is ready to use in NGS assays in steps that follow RNA isolation. No further purification or DNAse treatment 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 Fusion RNA Mix may be input directly into a reverse transcription assay step 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 RNA fusions represented in Seraseq Myeloid Fusion RNA Mix. Detection of fusion RNA may differ across different NGS panels and different test reagent lots. While the presence and relative abundance of each fusion RNA is confirmed during manufacture using functional NGS and/or digital PCR assays, there may be differences is observed transcript levels due to assay characteristics. Seraseq Myeloid Fusion RNA Mix does not have assigned values for transcript levels for the fusion transcripts present in the product. The fusion RNA species in this product are NOT present at the DNA level. Each laboratory must establish an assay-specific expected value for each fusion and each lot of Seraseq Myeloid Fusion RNA 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. Additional support documents are available online at www.seracare.com/cancer.

LIMITATIONS OF THE PROCEDURE

Seraseq Myeloid Fusion RNA 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 Fusion RNA 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 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. RNA fusions in Seraseq Myeloid Fusion RNA Mix

Fusion	HGVS	5' exon number	5' gene junction Hg19	3' exon number	3' gene junction Hg19
BCR-ABL1	BCR{NM_004327.3}:r.1_3378_ABL{NM_005157.3}:r.83_5384	BCR exon 14	23632600	ABL exon 2	133729451
ETV6-ABL1 (transcript 1)	ETV6{NM_001987.4}:r.1_737_ABL1{NM_007313.2}:r.576-5881	ETV6 exon 4	12006495	ABL exon 2	133729451
ETV6-ABL1 (transcript 2)	ETV6{NM_001987.4}:r.1_1283_ABL1{NM_007313.2}:r.576-5881	ETV6 exon 5	12022903	ABL exon 2	133729451
FIPIL1-PDGRFA	FIP1L1{NM_030917.3}:r.1_1109_PDGFRA{NM_006206.5}:r.2037_6590	FIP1L1 exon 11	54280889	PDGFRA exon 12	55141052
MYST3-CREBBP	MYST3{NM_006766.4}:r.1_3803_CREBBP{NM_004380.2}:r.290_10197	MYST3 exon 16	41794774	CREBBP exon 2	3901010
PCM1-JAK2	PCM1{NM_006197.3}:r.1_4365_JAK2{NM_004972.3}:r.2008_5285	PCM1 exon 23	17830196	JAK2 exon 12	5069925
PML-RARα	PML{NM_033238.2}:r.1_1786_ins134bp_RARA{NM_000964.3}:r.657_3301	PML exon 6	74325744	RARα intron 2	38499690
RUNX1-RUNX1T1	RUNX1 {NM_001754.4}: r.1-803_RUNX1T1 {NM_004349.3}:r.419-7420	RUNX1 exon 6	36231771	RUNX1T1 exon 2	93029591
TCF3-PBX1	TCF3{NM_003200.3}:r.1_1519_PBX1{NM_002585.3}:r.729_6918	TCF3 exon 16	1619110	PBX1 exon 3	164761731