

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 specimens¹. 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 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.

Table 1. RNA fusions in Seraseq Myeloid Fusion RNA Mix

Gene ID	HGVS	5' fusion partner	3' fusion partner
BCR-ABL1	BCR{NM_004327.3}:r.1_2782_ABL{NM_005157.3}:r.c.80_3393	NC_000022.11:23290413	NC_000009.12:130854064
ETV6-ABL1 (transcript 1)	ETV6{NM_001987.4}:r.1_463_ABL1{NM_007313.2}:r.137-3450	NC_000012.12:11869969	NC_000009.12:130854064
ETV6-ABL1 (transcript 2)	ETV6{NM_001987.4}:r.1_1009_ABL1{NM_007313.2}:r.137-3450	NC_000012.12:11853561	NC_000009.12:130854064
FIPL1-PDGRFA	FIP1L1{NM_030917.3}:r.1_923_PDGFRA{NM_006206.5}:r.1698_3270	NC_000004.12:53414722	NC_000004.12:54274885
MYST3-CREBBP	MYST3{NM_006766.4}:r.1_3352_CREBBP{NM_004380.2}:r.86_7329	NC_000008.11:41937256	NC_000016.10:3851009
PCM1-JAK2	PCM1{NM_006197.3}:r.1_3943_JAK2{NM_004972.3}:r.1514_3399	NC_000008.11:17972687	NC_000009.12:5069925
PML-RAR α	PML{NM_033238.2}:r.1_1646_ins134bp_RARA{NM_000964.3}:r.179_1389	NC_000015.10:74033403	NC_000017.11:40348316
RUNX1-RUNX1T1	RUNX1 {NM_001754.4}: r.1-613_RUNX1T1 {NM_004349.3}:r.419-2145	NC_000021.9:34859474	NC_000008.11:92017363
TCF3-PBX1	TCF3{NM_003200.3}:r.1_1450_PBX1{NM_002585.3}:r.266_1293	NC_000019.10:1619111	NC_000001.11:164792494