Seraseq®
Sarcoma Plus RNA Fusion Mix

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® Sarcoma Plus Fusion RNA Mix is formulated for use with targeted Next Generation Sequencing (NGS) assays that detect RNA expressed from gene fusions common in cancer. 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.*

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 Sarcoma Plus RNA Fusion Mix is ready to use in NGS assays in steps that follow RNA isolation. No further purification or RNA isolation is needed.

REAGENTS

Table 1. Seraseq Sarcoma Plus RNA Fusion Mix

Material No.	Product
0710-3809	Seraseq Sarcoma Plus RNA Fusion Mix

Item No. 0710-3809. 1 vial, 20 µL per vial, 25 ng/µL. See Technical Product Report for lot specific information.

WARNINGS AND PRECAUTIONS
For Research Use Only. Not for use in diagnostic procedures.
CAUTION: Handle Seraseq Sarcoma Plus RNA Fusion Mix and all materials derived from human blood products as though it is capable of transmitting infectious agents. Seraseq Sarcoma Plus RNA Fusion Mix is manufactured using genomic RNA 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 RNA 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 Sarcoma Plus RNA Fusion Mix frozen at -70 °C or colder. Once opened, a vial can be thawed and re-frozen up to five (5) times. Sub-aliquoting of the product into low 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 Sarcoma Plus RNA Fusion Mix is a mixture of human total RNA and synthetic RNA transcripts. 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 Sarcoma Plus RNA Fusion Mix consists of total cellular RNA purified from GM24385 cell line and biosynthetic RNA. The RNA is in 1 mM Tris, pH 8.0, aqueous buffer. 20 µL is provided per vial and the concentration is 25 ng/µL. See Technical Product Report for lot specific information.

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 Sarcoma Plus RNA Fusion Mix may be input directly into a reverse transcription assay step in parallel with the test specimens prior to target selection and library preparation. Refer to your usual assay procedures in order to determine the amount of material to use.

Quality Control
Seraseq Sarcoma Plus RNA Fusion Mix does not have assigned values for the proportion of fusion transcripts relative to wild-type transcripts for the same genes, or the overall quantity of fusion transcripts. However, the product is tested using fusion-specific digital PCR quantitation to determine approximate transcript level for each fusion RNA listed in Table 2. There are many reasons why fusions contained in the product may not be positively detected, which may or may not be of significance. It is therefore recommended that each laboratory qualify the use of each lot of Seraseq Sarcoma Plus RNA Fusion Mix with each assay system prior to its routine use.

EXPECTED RESULTS & INTERPRETATION OF RESULTS
Detection of fusion RNA and exon skipping events may differ across different NGS fusion RNA panels and different test reagent lots. While each fusion RNA is present at a similar level as determined by fusion specific digital PCR-based assays, and functional NGS-based assays confirm the presence of all 30 fusion RNA variants, there may be apparent differences in observed fusion levels due to assay characteristics. 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 Sarcoma Plus RNA Fusion 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/oncology.

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Table 2 Indicates each of the fusion RNA variants and exon skipping events

LIMITATIONS OF THE PROCEDURE

Seraseq Sarcoma Plus RNA Fusion Mix 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. This product is offered for Research Use Only. Not for use in diagnostic procedures. Data are provided for informational purposes. LGC does not claim that others can duplicate test results exactly. Seraseq Sarcoma Plus RNA Fusion 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.

SPECIFIC PERFORMANCE CHARACTERISTICS

Seraseq Sarcoma Plus RNA Fusion Mix has been designed for use with NGS sequencing procedures for the purposes of evaluating assay performance. Seraseq Sarcoma Plus RNA Fusion 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.

Table 2: RNA Fusions Present

RNA Fusion	5' Partner Exon	3' Partner Exon
EWSR1::ERG	EWSR1 exon 10	ERG Exon 11
KIF5B::ALK	KIF5B exon 24	ALK exon 20
CD74::NRG1	CD74 exon 5	NRG1 Exon 6
EZR::ROS1	EZR exon 10	ROS1 exon 34
PRKAR1A::RET	PRKAR1A exon 7	RET exon 12
STRN::ALK	STRN exon 3	ALK exon 20
TPM3::ALK	TPM3 exon 7	ALK exon 20
AR-V7	AR Exon 3	AR cryptic exon 3
BRD4::NUTM1	BRD4 exon 11	NUTM1 exon 2
RANBP2::ALK	RANBP2 exon 18	ALK exon 20
TPM3::ROS1	TPM3 exon 8	ROS1 exon 35
EWSR1::FLI1	EWSR1 exon 7	FLI1 exon 6
EWSR1::ETV1	EWSR1 exon 10	ETV1 exon 14
PAX3::FOXO1	PAX3 exon 7	FOXO1 exon 2
SDC4::ROS1	SDC4 exon 2	ROS1 Exon 32
EWSR1::WT1	EWSR1 exon 10	WT1 Exon 6
FGFR1::TACC1	FGFR1 exon 17	TACC1 exon 7
FGFR2::CCDC6	FGFR2 exon 17	CCDC6 exon 2
SLC45A3::ERG	SLC45A3 exon 1	ERG Exon 4
SND1::BRAF	SND1 exon 10	BRAF exon 9
TMPRSS2::ETV1	TMPRSS2 exon 2	ETV1 exon 8
TRIM24::BRAF	TRIM24 exon 5	BRAF exon 8
TRIM24::RET	TRIM24 exon 9	RET exon 12
EWSR1::ATF1	EWSR1 exon 8	ATF1 exon 4
FGFR3::TACC3	FGFR3 exon 17	TACC3 exon 10
KIAA1549::BRAF	KIAA1549 exon 15	BRAF exon 9
PAX7::FOXO1	PAX7 exon 7	FOXO1 exon 2
SS18::SSX1	SS18 exon 10	SSX1 exon 6
SS18::SSX2	SS18 exon 10	SSX2 exon 6
COL1A1::PDGFB	COL1A1 exon 25	PDGFB exon 2

NOTE: Above list does not include variants present in the GM24385 background. For a more detailed description of positional information of the fusions, please see the technical spreadsheet posted on the product page.