Seraseq®

Whole Transcriptome RNA Seq 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® Whole Transcriptome RNA Seq Mix product is a reference material formulated for use with Next Generation Sequencing (NGS) assays that detect somatic mutations in human cancer patient samples. 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. Product is *For Research Use Only. Not for use in diagnostic procedures.*

REAGENTS

Material Number	Product Name
0710-2129	Seraseq® Whole Transcriptome RNA Seq Mix

Product consist of 1 vial: 50 ng/µl concentration, 20 µl fill volume, and 1 µg total mass.

WARNINGS AND PRECAUTIONS

For Research Use Only. Not for use in diagnostic procedures.
CAUTION: Handle Seraseq Whole Transcriptome RNA Seq Mix product as though it is capable of transmitting infectious agents. This product is formulated using total RNA from 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).

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 Whole Transcriptome RNA Seq Mix product beyond the expiration date. Avoid contamination of the product when opening and closing the vial. Limit the number of freeze thaws this product is exposed to by creating single-use aliquots, if necessary.

STORAGE INSTRUCTIONS

Store Seraseq Whole Transcriptome RNA Seq Mix frozen at -70°C After opening, record the date opened and the expiration date on the vial. 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 Whole Transcriptome RNA Seq Mix is formulated from a mixture of human total RNA purified from GM24385 cell line and biosynthetic RNA. 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 Whole Transcriptome RNA Seq 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 50 ng/µL.

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 Whole Transcriptome RNA Seq 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.

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 22 fusion RNA variants (see Table 1), 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 Whole Transcriptome RNA Seq 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.

LIMITATIONS OF THE PROCEDURE

Seraseq Whole Transcriptome RNA Seq 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 Whole Transcriptome RNA Seq 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: List of 22 biosynthetic RNA plasmid spike-ins in the Seraseq Whole Transcriptome RNA Seq Mix product

RNA Fusion	5' Partner	3' Partner	Fusion Name (constructs contain only ~400 nt around break point)
BCR-ABL1	BCR exon 14	ABL1 exon 2	ENST00000305877.8:r.?_2782::ENST00000318560.5:r.80_?
CCDC6-RET	CCDC6 exon 1	RET exon 12	ENST00000263102.6:r.?_303::ENST00000355710.3:r.2137_?
CD74-ROS1	CD74 exon 6	ROS1 exon 34	ENST00000009530.7:r.?_625::ENST00000368508.3:r.5558_?
EML4-ALK	EML4 exon 14	ALK exon 20	ENST00000401738.3:r.?_1522::ENST00000389048.3:r.3173_?
ETV6-ABL1 (transcript 1)	ETV6 exon 4	ABL1 exon 2	ENST00000396373.4:r.?_463::ENST00000318560.5:r.80_?
ETV6-ABL1 (transcript 2)	ETV6 exon 5	ABL1 exon 2	ENST00000396373.4:r.?_1009::ENST00000318560.5:r.80_?
ETV6-NTRK3	ETV6 exon 5	NTRK3 exon 13	ENST00000396373.4:r.?_1009::ENST00000357724.2:r.1562_?
FGFR3-TACC3	FGFR3 exon 17	TACC3 exon 11	ENST00000340107.4:r.?_2280::ENST00000313288.4:r.1942_?
KIF5B-RET	KIF5B exon 24	RET exon 11	ENST00000302418.4:r.?_2761::ENST00000355710.3:r.1880_?
LMNA-NTRK1	LMNA exon 2	NTRK1 exon 10	ENST00000361308.4:r.?_513::ENST00000358660.3:r.1234_?
LMNA-NTRK1	LMNA exon 11	NTRK1 exon 10	ENST00000368299.3:r.?_1818::ENST00000358660.3:r.1234_?
MEF2D-CSF1R	MEF2D exon 7	CSF1R exon 12	ENST00000348159.4:r.?_855::ENST00000286301.3:r.1627_?
MET ex 14 Skipping	MET exon 13	MET exon 15	ENST00000318493.6:r.2942_3082del or ENST00000397752.3:r.2888_3028del
NACC2-NTRK2	NACC2 exon 5	NTRK2 exon 11	ENST00000277554.2:r.?_1255::ENST00000277120.3:r.1196_?
NCOA4-RET	NCOA4 exon 8	RET exon 12	ENST00000452682.1:r.?_762::ENST00000355710.3:r.2137_?
PML-RARA	PML exon 6	RARA intron 2	From PML exon 6 to 134 nt of RARA intron 2, then a new splice to exon 3
RUNX1-RUNX1T1	RUNX1 exon 5	RUNX1T1 exon 2	ENST00000300305.3:r.?_613::ENST00000265814.3:r.89_?
SLC34A2-ROS1	SLC34A2 exon 4	ROS1 exon 34	ENST00000382051.3:r.?_379::ENST00000368508.3:r.5558_?
SLC45A3-BRAF	SLC45A3 exon 1	BRAF exon 8	BRAF exon 8+ expression driven by SLC45A3
TCF3-PBX1	TCF3 exon 16	PBX1 exon 3	ENST00000344749.5:r.?_1450::ENST00000420696.2:r.266_?
TMPRSS2-ERG	TMPRSS2 exon 1 (5' UTR)	ERG exon 2	ERG expression driven by TMPRSS2
TPM3-NTRK1	TPM3 exon 8	NTRK1 exon 9	ENST00000271850.7:r.?_775::ENST00000358660.3:r.1178_?

Seraseq® Whole Transcriptome RNA Seq Mix

HIGHLIGHTS

INDUSTRY-FIRST TRANSCRIPTOME RNA SEQ REFERENCE MATERIAL FOR NOVEL FUSION RNA BIOMARKER ANALYSIS

22 PAN-CANCER FUSION GENES FOR TUMOR PROFILING NGS ASSAYS

HIGH-QUALITY MANUFACTURED REFERENCE MATERIAL SAVES TIME AND COST PROCURING SAMPLES OR PRODUCING HOMEBREW REAGENTS WITH SPECIFIC VARIANTS

Whole transcriptome RNA sequencing allows the analysis of fusion genes with (potential) clinical utility that currently cannot be detected using the limited genomic coverage of targeted NGS panels. Additionally, some clinical cancer testing labs are evaluating whole transcriptome panels for improved diagnostic yields and clinical utilization for NGS-based tumor profiling test reimbursements. Expanding fusion gene content and higher detection efficiencies will expand use of fusion analysis in clinical NGS applications. Maybe most importantly is that new therapies are targeting fusion genes as clinical biomarkers for treatments of various adult and pediatric cancers.

LGC SeraCare has developed an industry-first whole transcriptome RNA sequencing reference material for analysis of 22 fusion genes with clinical applications in oncology, when analyzed by RNA Seq NGS assays. Such assays provide a comprehensive view of the transcriptome with ability to detect known and novel fusions of clinical utility. This reference material is offered as a purified RNA mix with high titer concentration for all 22 RNA fusion constructs.

Fusion Genes in the Seraseq Whole Transcriptome RNA Seq Mix

BCR-ABL1	ETV6-NTRK3	MET ex 14 Skipping	SLC45A3-BRAF
CCDC6-RET	FGFR3-TACC3	NACC2-NTRK2	TCF3-PBX1
CD74-ROS1	KIF5B-RET	NCOA4-RET	TMPRSS2-ERG
EML4-ALK	LMNA-NTRK1 (transcript 1)	PML-RARα	TPM3-NTRK1
ETV6-ABL1 (transcript 1)	LMNA-NTRK1 (transcript 2)	RUNX1-RUNX1T1	
ETV6-ABL1 (transcript 2)	MEF2D-CSF1R	SLC34A2-ROS1	

FEATURES AND BENEFITS

- Single reference sample multiplexed at 22 clinically-relevant RNA gene fusions.
- Purified RNA format ready for RNA Seq transcriptome sequencing library prep.
- Fusion copies accurately quantitated using digital PCR.
- Fusion constructs blended into total RNA from well-characterized GM24385 cell line as background wild-type material.
- Manufactured in GMP-compliant and ISO 13485-certified facilities.

ORDERING INFORMATION

Product	Material No	Conc.	Fill Volume	Total RNA Size
Seraseq Whole Transcriptome RNA Seq Mix	0710-2129	50 ng/µl	20 µl	1 µg

ABOUT LGC SERACARE

TRUSTED SUPPLIER TO THE DIAGNOSTIC TESTING INDUSTRY FOR OVER 30 YEARS

FOR MORE INFORMATION, PLEASE VISIT OUR WEBSITE: WWW.SERACARE.COM

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