Seraseq®
NTRK 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® NTRK 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.*

REAGENTS

Table 1. Seraseq NTRK Fusion RNA Mix

Material No.	Product
0710-1696	Seraseq® NTRK Fusion RNA Mix

20 µL volume per vial

WARNINGS AND PRECAUTIONS
For Research Use Only. Not for use in diagnostic procedures.
CAUTION: Handle Seraseq NTRK Fusion RNA Mix 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 NTRK Fusion RNA Mix beyond the expiration date. Avoid contamination of the product when opening and closing the vial. Based on data, product is stable for up to five (5) freeze thaw cycles. Limit the number of freeze thaws this product is exposed to by creating single-use aliquots in low nucleic acid binding vials, if necessary.

STORAGE INSTRUCTIONS
Store Seraseq NTRK Fusion RNA Mix at -70°C.

INDICATIONS OF REAGENT INSTABILITY OR DETERIORATION
Seraseq NTRK Fusion RNA Mix is 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 the vial should be discarded.

PROCEDURE
Materials Provided
Seraseq NTRK Fusion RNA 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. No further purification or RNA isolation is needed.

Materials Required but not Provided
Seraseq NTRK Fusion RNA Mix is ready for use as direct input into a NGS library preparation step. Refer to instructions supplied by manufacturers of the extraction kit to be used.

Instructions for Use
Thaw the product vial on ice. Mix by vortexing to ensure a homogenous solution and spin briefly. Seraseq NTRK Fusion RNA 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
Detection of fusion RNA 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 15 NTRK 1/2/3 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 NTRK 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/oncology.

Table 2 provides a list of all 15 NTRK 1/2/3 fusions in the Seraseq NTRK Fusion RNA Mix product.

LIMITATIONS OF THE PROCEDURE
Seraseq NTRK 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 NTRK Fusion RNA Mix is not a calibrator and should not be used for assay calibration. This material is not whole-process control and does not evaluate the method 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.

LGC Clinical Diagnostics, Inc. | 37 Birch Street, Milford, MA 01757 USA
Phone: +1 508.244.6400 | Toll Free (US Only) 800.676.1818
CDx-info@LGCGroup.com | www.seracare.com

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Table 2: Fusion RNA variants in the Seraseq® NTRK Fusion RNA Mix.

	NTRK Fusion Gene	5' Partner	3' Partner	HGVS Name
1	TPM3-NTRK1	TPM3 exon 7	NTRK1 exon 10	TPM3{ENST00000368533}:r.1_717_NTRK1{ENST00000392302}:r.1262_2609
2	LMNA-NTRK1	LMNA exon 11	NTRK1 exon 11	LMNA {ENST00000368299}:r.1:2015_NTRK1{ENST00000392302}:r.1318_2609
3	IRF2BP2-NTRK1	IRF2BP2 exon 1	NTRK1 exon 10	IRF2BP2{ENST00000366609}:r.1_1079_NTRK1{ENST00000392302}:r.1262_2609
4	SQSTM1-NTRK1	SQSTM1 exon 5	NTRK1 exon 10	SQSTM1{ENST00000389805}:r.1_932_NTRK1{ENST00000392302}:r.1262_2609
5	TFG-NTRK1	TFG exon 5	NTRK1 exon 10	TFG{ENST00000240851}:r.1_920_NTRK1{ENST00000392302}:r.1262_2609
6	AFAP1-NTRK2	AFAP1 exon 14	NTRK2 exon 12	AFAP1{ENST00000420658.1}:r.1_2170_NTRK2{ENST00000376214}:r.2098_5608
7	NACC2-NTRK2	NACC2 exon 4	NTRK2 exon 13	NACC2{ENST00000371753}:r.1_1314_NTRK2{ENST00000376214}:r.2134_5608
8	QKI-NTRK2	QKI exon 6	NTRK2 exon 16	QKI{ENST00000361752}:r.1_1485_NTRK2{ENST00000376214}:r.2383_5608
9	TRIM24-NTRK2	TRIM24 exon 12	NTRK2 exon 15	TRIM24{ENST00000343526}:r.1_2229_NTRK2{ENST00000376214}:r.2335_5608
10	PAN3-NTRK2	PAN3 exon 1	NTRK2 exon 17	PAN3{ENST00000380958}:r.1_582_NTRK2{ENST00000376214}:r.2572_5608
11	ETV6-NTRK3	ETV6 exon 5	NTRK3 exon 14	ETV6{ENST00000396373}:r.1_1283_NTRK3{ENST00000394480}:r.1719_19984
12	ETV6-NTRK3	ETV6 exon 5	NTRK3 exon 15	ETV6{ENST00000396373}:r.1_1283_NTRK3{ENST00000394480}:r.1908_19984
13	ETV6-NTRK3	ETV6 exon 4	NTRK3 exon 15	ETV6{ENST00000396373}:r.1_737_NTRK3{ENST00000394480}:r.1908_19984
14	ETV6-NTRK3	ETV6 exon 4	NTRK3 exon 14	ETV6{ENST00000396373}:r.1_737_NTRK3{ENST00000394480}:r.1719_19984
15	BTBD1-NTRK3	BTBD1 exon 4	NTRK3 exon 14	BTBD1{ENST00000261721}:r.1_1065_NTRK3{ENST00000394480}:r.1719_19984

Exon numbers correspond to ENST00000392302.6 for NTRK1
Exon numbers correspond to ENST00000376214.5 for NTRK2
Exon numbers correspond to ENST00000394480.6 for NTRK3