Seraseq®

FFPE Tumor Fusion RNA Reference Material v2 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® FFPE Tumor Fusion RNA Reference Material v2 is a full-process reference material 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 nucleic acid extraction, 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. 0710-0129. One 10-micron FFPE curl per vial.

WARNINGS AND PRECAUTIONS

For Research Use Only. Not for use in diagnostic procedures.
CAUTION: Handle Seraseq FFPE Tumor Fusion RNA Reference Material v2 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). The FFPE-treated curls are lightly fixed with HistoGel then fixed with 10% Formalin and washed prior to embedding.

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 FFPE Tumor Fusion RNA Reference Material v2 beyond the expiration date. Avoid contamination of the product when opening and closing the vial.

STORAGE INSTRUCTIONS

Store Seraseq FFPE Tumor Fusion RNA Reference Material v2 at 2-8°C. Shelf life when stored under these conditions is one year from date of manufacture.

PROCEDURE

Materials Provided

Seraseq FFPE Tumor Fusion RNA Reference Material v2 consists of engineered cells which have been FFPE treated to create an FFPE block, which is then sliced into 10-micron sections. One 10-micron FFPE curl is proved per vial.

Materials Required but not Provided

Refer to instructions supplied by manufacturers of the test kits to be used.

Instructions for Use

Allow the product vial to come to room temperature before use. Seraseq FFPE Tumor Fusion RNA Reference Material v2 must go through an extraction process. Refer to your usual assay procedures in order to determine the amount of extracted material to use in library preparation.

EXPECTED RESULTS & INTERPRETATION OF RESULTS

RNA Yield and Quality

Seraseq FFPE Tumor Fusion RNA Reference Material v2 is compatible with different commercially available nucleic acid extraction methods commonly used for FFPE specimens. Table 1 shows observed average RNA yields across 10-micron FFPE curls for several different extraction methods, as measured via Qubit quantitation.

Table 1. Average RNA yield for commonly used FFPE RNA extraction methods.

Extraction Method	Average RNA Yield (ng)
Agencourt® Formapure	587.3
QIAGEN RNeasy FFPE Kit	383.5
Promega Maxwell® RSC	490.7

The quality of RNA obtained from Seraseq FFPE Tumor Fusion RNA Reference Material v2 is approximately consistent with an average FFPE tissue specimen. Representative data are shown in Figure 1.

Fusion RNAs Present in the Product

Table 2 indicates each of the fusion RNAs represented in Seraseq FFPE Tumor Fusion RNA Reference Material v2. The fusion RNA species in this product are NOT present at the DNA level. Detection of fusion RNAs may differ across different NGS panels and different test reagent lots. While the presence of each fusion RNA in this product is confirmed during manufacturing using functional NGS and/or digital PCR-based fusion RNA assays, there may be apparent differences in observed fusion levels due to assay characteristics. Seraseq FFPE Tumor Fusion RNA Reference Material v2 does not have assigned values for the ratios of fusion transcripts to wild-type transcripts for the same genes, or for the overall quantity of fusion transcripts. Each laboratory must establish an assay-specific expected value for each fusion and each lot of Seraseq FFPE Tumor Fusion RNA Reference Material v2. 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 changes in bioinformatics pipeline parameters. Additional support documents are available online at www.seracare.com/oncology.

LIMITATIONS OF THE PROCEDURE

Seraseq FFPE Tumor Fusion RNA Reference Material v2 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 FFPE Tumor Fusion RNA Reference Material v2 is not a calibrator and should not be used for assay calibration. 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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Figure 1. Representative RNA quality data for Seraseq FFPE Tumor Fusion RNA Reference Material v2 compared with FFPE tissue specimens

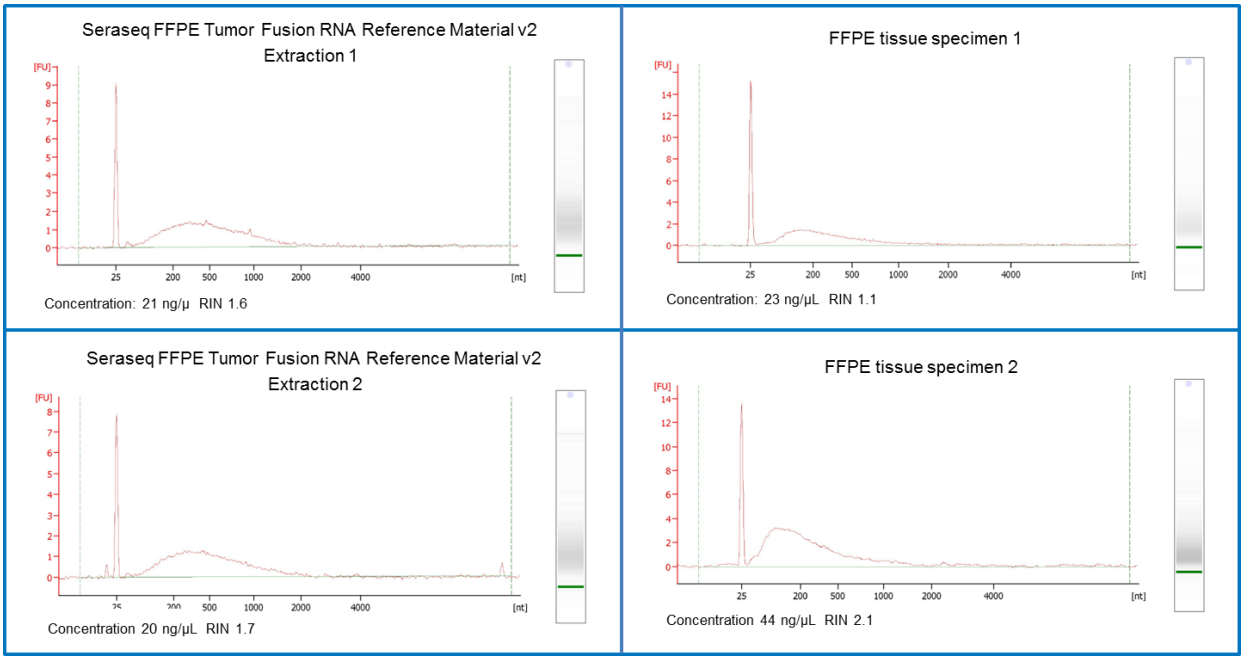

Table 2. Fusion RNAs present in Seraseq FFPE Tumor Fusion RNA Reference Material v2

	RNA Fusion	5' Partner	3' Partner	HGVS Name
1	EML4-ALK	EML4 exon 13	ALK exon 20	EML4{NM_019063.4}:r.1_1763_ALK{NM_004304.4}:r.4125_6265
2	KIF5B-RET	KIF5B exon 24	RET exon 11	KIF5B{NM_004521.2}:r.1_3231_RET{NM_020975.4}:r.2070_5617
3	NCOA4-RET	NCOA4 exon 8	RET exon 12	NCOA4{NM_001145260.1}:r.1_1014_RET{NM_020975.4}:r.2327_5617
4	CD74-ROS1	CD74 exon 6	ROS1 exon 34	CD74{NM_001025159.2}:r.1_812_ROS1{NM_002944.2}r.5757_7368
5	SLC34A2-ROS1	SLC34A2 exon 4	ROS1 exon 34	SLC34A2{NM_006424.2}:r.1_460_ROS1{NM_002944.2}:r.5757_7368
6	TPM3-NTRK1	TPM3 exon 7	NTRK1 exon 9	TPM3{NM_153649.3}:r.1_794_NTRK1{NM_001012331.1}:r.1234_2637
7	FGFR3-BAIAP2L1	FGFR3 exon 17	BAIAP2L1 exon 2	FGFR3{NM_001163213.1}:r.1_2530_BAIAP2L1{NM_018842.4}:r.315_3682
8	PAX8-PPARG1	PAX8 exon 9	PPARG1 exon 3	PAX8{NM_003466.3}:r.1_1253_PPARG{NM_138712.3}:r.246_1892
9	FGFR3-TACC3	FGFR3 exon 17	TACC3 exon 11	FGFR3{NM_000142.4}:r.1_2530_TACC3{NM_006342.2}:r.2097_2847
10	ETV6-NTRK3	ETV6 exon 5	NTRK3 exon 15	ETV6{NM_001987.4}:r.1_1283_NTRK3{NM_001012338.2}:r.1892_3004
11	LMNA-NTRK1	LMNA exon 2	NTRK1 exon 10	LMNA{NM_170707.3}:r.1_762_NTRK1{NM_001012331.1}:r.1290_2647
12	SLC45A3-BRAF	SLC45A3 exon 1	BRAF exon 8	SLC45A3{NM_033102.2}:r.1_109_BRAF{NM_004333.4}:r.1042_2949
13	TMPRSS2-ERG	TMPRSS2 exon 1 (5' UTR)	ERG exon 2	TMPRSS2{NM_005656.3}:r.1_78_ERG{NM_004449.4}:r.124_5042
14	EGFR-SEPT14	EGFR exon 24	SEPT14 exon 10	EGFR{NM_005228.3}:r.1_3192_SEPT14{NM_207366.2}:r.1237_3785
15	MET exon 14 skipping	MET exon 13	MET exon 15	MET{NM_001127500.2}:r.3144_3284del
16	EGFR Variant III	EGFR exon 1	EGFR exon 8	EGFR{NM_005228.3}:r.335_1135del