Seraseq®

FFPE Fusion RNA v4 Reference Material

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 Fusion RNA v4 Reference Material is a full-process reference material formulated for use with targeted Next Generation Sequencing (NGS) assays that detect RNA expressed from gene fusions in a wide range of cancer genes. This product is intended as a quality reference material for translational and disease research testing to monitor nucleic acid extraction, library preparation, RNA sequencing and fusion detection under a given set of bioinformatics pipeline parameters. *For Research Use Only. Not for use in diagnostic procedures.*

REAGENTS

Item No. 0710-0496. One 10 µm FFPE curl per vial.

WARNINGS AND PRECAUTIONS

For Research Use Only. Not for use in diagnostic procedures.
CAUTION: Handle Seraseq FFPE Fusion RNA v4 Reference Material 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 Genome in a Bottle (GIAB) Project. The FFPE-treated curls are made by treating cells with HistoGel, then fixing them with 10% Formalin, and washing prior to embedding and sectioning.

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 Fusion RNA v4 Reference Material beyond the expiration date. Avoid contamination of the product when opening and closing the vial.

STORAGE INSTRUCTIONS

Store Seraseq FFPE Fusion RNA v4 Reference Material at 2-8°C. Shelf life when stored under these conditions is two years from date of manufacture.

PROCEDURE

Materials Provided

Seraseq FFPE Fusion RNA v4 Reference Material consists of engineered cells which have been formalin treated and embedded in paraffin to create an FFPE block, which is then sliced into 10 µm sections. One 10 µm FFPE curl is provided 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 Fusion RNA v4 Reference Material 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 Fusion RNA v4 Reference Material is compatible with different commercially available nucleic acid extraction methods commonly used for FFPE specimens. RNA extraction yields per FFPE curl (10 µm) when using Agencourt® Formapure® Kit, Qiagen AllPrep DNA/RNA FFPE Kit, and Promega Maxwell® RSC RNA FFPE Kit, quantitated by Thermo Fisher's Qubit RNA HS assay, are as provided in Table 1 below.

Table 1: Representative RNA extraction yields per 10 µm FFPE curl.

	Yield per 10 µm curl (ng)		
FFPE Block	Agencourt Formapure Kit	Qiagen AllPrep DNA/RNA FFPE Kit	Promega Maxwell RSC RNA FFPE Kit
1	1146	1077	170
2	1156	857	177
3	1338	1128	163
Average	1213 ng	1021 ng	170 ng

Fusion RNAs Present in the Product

Table 2 indicates each of the fusion RNAs represented in Seraseq FFPE Fusion RNA v4 Reference Material. 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 digital PCR-based fusion RNA assays, there may be apparent differences in observed fusion levels due to assay characteristics. Seraseq FFPE Fusion RNA v4 Reference Material 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 Fusion RNA v4 Reference Material. 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 Fusion RNA v4 Reference Material 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 Fusion RNA v4 Reference Material 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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Table 2. Fusion RNAs present in Seraseq FFPE Fusion RNA v4 Reference Material

RNA Fusion	5' Partner	3' Partner	HGVS Name
CCDC6-RET	CCDC6 ex 1	RET ex 12	CCDC6{NM_005436.5}:r.1_435_RET{NM_020975.6}:r.2327_5617
CD74-ROS1	CD74 ex 6	ROS1 ex 34	CD74{NM_001025159.2}:r.1_812_ROS1{NM_002944.2}r.5757_7368
EGFR Variant III	EGFR ex 1	EGFR ex 8	EGFR{NM_005228.5}:r.350_1150del
EGFR-SEPT14	EGFR ex 24	SEPT14 ex 10	EGFR{NM_005228.5}:r.1_3207_SEPT14{NM_207366.3}:r.1200_3752
EML4-ALK	EML4 ex 13	ALK ex 20	EML4{NM_019063.4}:r.1_1763_ALK{NM_004304.4}:r.4125_6265
ETV6-NTRK3	ETV6 ex 5	NTRK3 ex 15	ETV6{NM_001987.4}:r.1_1283_NTRK3{NM_001012338.2}:r.1892_3004
FGFR3-BAIAP2L1	FGFR3 ex 17	BAIAP2L1 ex 2	FGFR3{NM_000142.4}:r.1_2530_BAIAP2L1{NM_018842.4}:r.315_3682
FGFR3-TACC3	FGFR3 ex 17	TACC3 ex 11	FGFR3{NM_000142.4}:r.1_2530_TACC3{NM_006342.3}:r.2066_2799
KIF5B-RET	KIF5B ex 24	RET ex 11	KIF5B{NM_004521.2}:r.1_3231_RET{NM_020975.6}:r.2070_5617
LMNA-NTRK1	LMNA ex 2	NTRK1 ex 10	LMNA{NM_170707.3}:r.1_762_NTRK1{NM_001012331.1}:r.1290_2647
MET ex 14 Skipping	MET ex 13	MET ex 15	MET{NM_001127500.3}:r.3338_3478del
NCOA4-RET	NCOA4 ex 8	RET ex 12	NCOA4{NM_001145260.1}:r.1_1014_RET{NM_020975.6}:r.2327_5617
PAX8-PPARG1	PAX8 ex 9	PPARG1 ex 3	PAX8{NM_003466.4}:r.1_1253_PPARG{NM_138712.3}:r.246_1892
SLC34A2-ROS1	SLC34A2 ex 4	ROS1 ex 34	SLC34A2{NM_006424.2}:r.1_460_ROS1{NM_002944.2}:r.5757_7368
SLC45A3-BRAF	SLC45A3 ex 1	BRAF ex 8	SLC45A3{NM_033102.3}:r.1_109_BRAF{NM_004333.5}:r.1206_4560
TFG-NTRK1	TFG ex 5	NTRK1 ex 9	TFG{NM_006070.5}:r.1_851_NTRK1{NM_001012331.1}:r.1234_2647
TMPRSS2-ERG	TMPRSS2 ex 1 (5' UTR)	ERG ex 2	TMPRSS2{NM_005656.3}:r.1_78_ERG{NM_004449.4}:r.124_5042
TPM3-NTRK1	TPM3 ex 7	NTRK1 ex 9	TPM3{NM_153649.3}:r.1_794_NTRK1{NM_001012331.1}:r.1234_2647