

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 v1 contains 10 micron sections of FFPE material made using engineered cells that express twelve fusion RNA species. Seraseq FFPE Tumor Fusion RNA Reference Material v1 is intended for use with targeted NGS assays that detect RNA expressed from gene fusions common in cancer. The Seraseq FFPE Tumor Fusion RNA Reference Material v1 monitors RNA purification, library preparation, sequencing, and fusion gene detection under a given set of bioinformatics pipeline parameters. *For Research Use only. Not for use in diagnostic procedures.*

PRODUCT DESCRIPTION

Seraseq FFPE Tumor Fusion RNA Reference Material v1 is a single tube that contains a single 10 micron-thick section of formalin-fixed, paraffin-embedded cells. One tube is provided per kit.

REAGENTS

Item No. 0710-0010. 1 vial, 1 FFPE-treated 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 v1 as though it is capable of transmitting infectious agents. Seraseq FFPE Tumor Fusion RNA Reference Material v1 is 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>).

Safety Precautions

Use Center for Disease Control and Prevention (CDC) recommended universal precautions for handling reference materials and human specimens. 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 v1 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 v1 at 2-8 °C. Shelf life when stored under these conditions is one year from date of manufacture.

PROCEDURE

Materials Provided

1 vial, 1 curl per vial, of Seraseq FFPE Tumor Fusion RNA Reference Material v1.

Materials Required but not Provided

Refer to instructions supplied by manufacturers of the test kits to be used, including extraction of RNA or total nucleic acid from FFPE-treated material.

Instructions for Use

Allow the product vial to come to room temperature before use. Seraseq FFPE Tumor Fusion RNA Reference Material v1 needs to go through an extraction process. Each FFPE section or curl contains approximately 50,000 cells; a yield of 100 ng of RNA per vial is typical, but can vary significantly based on the extraction method used. Refer to your usual assay procedures in order to determine the amount of extracted material to use in library preparation.

EXPECTED RESULTS AND INTERPRETATION

Detection of fusion variants may vary with different NGS fusion RNA detection panels and different test reagent lots. While each fusion RNA is expressed at similar levels, there may be apparent differences between observed fusions due to multiplex assay characteristics. Each manufactured batch is tested using functional NGS-based and/or digital PCR-based fusion RNA assays to ensure presence of all 12 fusion RNA species.

Table 1 indicates each of the fusion genes represented.

LIMITATIONS OF THE PROCEDURE

Seraseq FFPE Tumor Fusion RNA Reference Material v1 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.

SPECIFIC PERFORMANCE CHARACTERISTICS

Seraseq FFPE Tumor Fusion RNA Reference Material v1 has been designed for use with targeted NGS fusion RNA panels for the purposes of assessing assay characteristics and lower limits of detection. The product is manufactured from an engineered human cell line. Although the product is manufactured to contain each fusion RNA gene listed in Table 1, Seraseq FFPE Tumor Fusion RNA Reference Material v1 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 1: Fusion RNA Genes in the Seraseq™ FFPE Tumor Fusion RNA Reference Material v1

	RNA Fusion	Primary Cancer Tissue	5' Partner- Exon #	3' Partner- Exon #	GenBank Reference and positions included
1	EML4-ALK	Lung	EML4 Exon 13	ALK Exon 20	AB274722.1 position 1510- 2009
2	NPM1-ALK	Lymphoid	NPM1 exon 5	ALK Exon 20	U04946.1 position 106- 605
3	KIF5B-RET	Lung	KIF5B Exon 24	Ret Exon 11	AB795257.1 position 2721- 3220
4	NCOA4-RET	Thyroid	NCOA4 Exon 8	RET exon 12	S71225.1 position 531- 900*
5	CD74-ROS1	Lung	CD74 Exon 6	Ros 1 Exon 34	EU236945.1 position 374- 873
6	SLC34A-ROS1	Lung, Stomach	SLC34A Exon 4	Ros 1 Exon 34	EU236947.1 position 123- 622
7	TPM3-NTRK1	Lung, Large Intestine	TPM3 Exon 8	NTRK1 Exon 10	X03541.1 position 648- 1147
8	TFG-NTRK1	Thyroid (rare)	TFG Exon 5	NTRK1 Exon 10	X85960.1 position 348- 847
9	FGFR3-BAIAP2L1	Urinary tract (rare)	FGFR3 Exon 18	BAIAP2L1 Exon 2	NA- contains XM_011513422.1 positions 2297- 2546 joined to NM_018842.4 positions 315- 564
10	FGFR3-TACC3	Urinary tract, CNS	FGFR3 Exon 18	TACC3 Exon 11	NA- contains XM_011513422.1 positions 2297- 2546 joined to XM_005247930 positions 1022- 1271
11	PAX-PPARG	Thyroid	Pax8 Exon 8	PPARG Exon 1	AR526805.1 position 835 - 1334
12	ETV6-NTRK3	Kidney, Breast, Soft Tissue	ETV6 Exon 5	NTRK3 Exon 13	AF041811.2 position 88- 587

*Includes additional sequence in exons 12 and 13 of RET.