# Seraseq®

## FFPE Tumor Fusion RNA Reference Material v1 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 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). 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 Center 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 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.

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**Table 1: RNA fusions included in the Seraseq® FFPE Tumor Fusion RNA Reference Material v1**

| Gene Fusion | 5' partner hg19 coordinate | 5' partner RefSeq accession | 5' exon names | 3' partner hg19 coordinate | 3' partner RefSeq accession | 3' exon names |
|---|---|---|---|---|---|---|
| CD74-ROS1 | chr5:149784241 | *NM_001025159.2* | *CD74e6* | chr6:117645580 | **NM_002944.2** | **ROS1e34** |
| EML4-ALK | chr2:42522655 | *NM_019063.4* | *EML4e13* | chr2:29446398 | **NM_004304.4** | **ALKe20** |
| ETV6-NTRK3 | chr12:12022903 | NM_001987.4 | ETV6e5 | chr15:88483990 | **NM_002530.3** | **NTRK3e15** |
| FGFR3-BAIAP2L1 | chr4:1808661 | **NM_000142.4** | **FGFR3e17** | chr7:97991744 | NM_018842.4 | BAIAP2L1e2 |
| FGFR3-TACC3 | chr4:1808661 | **NM_000142.4** | **FGFR3e17** | chr4:1741429 | NM_006342.2 | TACC3e11 |
| KIF5B-RET | chr10:32306071 | NM_004521.2 | KIF5Be24 | chr10:43609928 | **NM_020630.4** | **RETe11** |
| NCOA4-RET | chr10:51582939 | *NM_001145260.1* | *NCOA4e8* | chr10:43612032 | **NM_020630.4** | **RETe12** |
| NPMI-ALK | chr5:170818803 | *NM_002520.6* | *NPM1e4* | chr2:29446398 | **NM_004304.4** | **ALKe20** |
| PAX8-PPARG | chr2:113992973 | *NM_003466.3* | *PAX8e9* | chr3:12421205 | **NM_015869.4** | **PPARGe2** |
| SLC34A2-ROS1 | chr4:25665952 | *NM_001177999.1* | *SLC34A2e4* | chr6:117645582 | **NM_002944.2** | **ROS1e34** |
| TFG-NTRK1 | chr3:100451516 | *NM_006070.5* | *TFGe5* | chr1:156844363 | **NM_002529.3** | **NTRK1e10** |
| TPM3-NTRK1 | chr1:15412876 | *NM_152263.3* | *TPM3e8* | chr1:156844363 | **NM_002529.3** | **NTRK1e10** |

**TABLE 1.** RNA fusions present in Seraseq FFPE Tumor Fusion RNA Reference Material v1. Genomic coordinates (hg19) correspond to base-pairs directly up- (5') and downstream (3') of the breakpoint, and may vary slightly depending on breakpoint definitions. **Bold** indicates transcripts/ exons for drivers that match targets in the Archer™ FusionPlex™ manifest. *Italics* indicate accessions/ exon names for fusion partners that were selected based on longest confirmed mRNA in the NCBI database.